



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11, 16, and 112

[Docket No. FDA-2011-N-0921]

RIN 0910-AG35

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, the Food and Drug Administration (FDA or we) is establishing science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. FDA is establishing these standards as part of our implementation of the FDA Food Safety and Modernization Act. These standards do not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity. In addition, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance is eligible for exemption from the requirements of this rule. The rule sets forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of

such hazards. We expect the rule to reduce foodborne illness associated with the consumption of contaminated produce.

DATES: This rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The effective date of §§ 117.5(k)(2), 117.8, 117.405(c), 117.410(d)(2)(ii), 117.430(d), and 117.475(c)(13) published September 17, 2015 (80 FR 55908), is [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The effective date of §§ 507.12(a)(1)(ii), 507.105(c), 507.110(d)(2)(ii), 507.130(d), and 507.175(c)(13) published September 17, 2015 (80 FR 56170), is [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See section XXIV of this document for the compliance dates. The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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Executive Summary

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) requires FDA to conduct a rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities (RACs) for which we have determined such standards minimize the risk of serious adverse health consequences or death. Further, FSMA requires FDA to adopt a final regulation based on known safety risks, setting forth procedures, processes, and practices that we determine to minimize the risk of serious adverse health consequences or death, including those that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA published a proposed rule entitled, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” which would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human

consumption (78 FR 3504, January 16, 2013). The comment period for the proposed rule closed on November 22, 2013. In response to information we heard at public meetings, and based on a preliminary review of written comments submitted to the docket for the 2013 proposed rule, information available at that time, and our subsequent analysis of the proposed provisions in light of such information, FDA issued a supplemental notice of proposed rulemaking and reopened the comment period to seek public comment on specific issues and amended and new proposed provisions (79 FR 58434; September 29, 2014). The comment period for the supplemental notice of proposed rulemaking closed on December 15, 2014. We are now finalizing this rule entitled, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.”

The final rule focuses on biological hazards related to produce growing, harvesting, packing, and holding. We conducted a “Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce” and considered the findings of this assessment in finalizing this rule. While we acknowledge the potential for non-biological (physical or chemical (including radiological)) hazards in produce, we are not addressing such hazards in this rule.

Scope of Coverage of the Rule

The final rule applies to both domestic and imported produce. However, as explained in the remainder of this document, the rule contains several exemptions and limitations:

- The rule does not apply to certain specified produce commodities that are rarely consumed raw.
- The rule also does not apply to produce that is used for personal or on-farm consumption, or that is not a RAC.

- The rule provides an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g. via a “kill step”) as long as certain disclosures are made and written assurances are received, with appropriate documentation.
- The rule does not cover farms that have an average annual value of produce sold during the previous 3-year period of \$25,000 or less.
- The rule provides a qualified exemption and modified requirements for farms that meet two requirements: (1) the farm must have food sales averaging less than \$500,000 per year during the previous 3 years; and (2) the farm’s sales to qualified end-users must exceed sales to others. A qualified end-user is either: (1) the consumer of the food or (2) a restaurant or retail food establishment that is located in the same State or the same Indian reservation as the farm or not more than 275 miles away. Instead, these farms are required to include their name and complete business address either on the label of the produce that would otherwise be covered (if a label is required under the FD&C Act and its implementing regulations) or to display the same information at the point-of-purchase. These farms are also required to establish and keep certain documentation. This exemption may be withdrawn in the event of an active investigation of an outbreak that is directly linked to the farm, or if it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions on the farm that are material to the safety of the produce.

The rule also permits States, tribes, or foreign countries to submit a petition, along with supporting information, to FDA requesting a variance(s) from the requirements of this rule.

Summary of the Major Provisions of the Rule

The final rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. Based on the findings of the Qualitative Assessment of Risk, we are focusing the provisions of this rule on five major routes of contamination. We are finalizing requirements in the following major areas:

- Worker Training and Health and Hygiene
 - Establish qualification and training requirements for all personnel who handle (contact) covered produce or food-contact surfaces and their supervisors (§§ 112.21, 112.22, and 112.23);
 - Require documentation of required training and corrective actions (§ 112.30); and
 - Establish hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance (§§ 112.31, 112.32, and 112.33).

- Agricultural Water
 - Require that all agricultural water must be safe and of adequate sanitary quality for its intended use (§ 112.41). Agricultural water is defined in part as water that is intended to, or is likely to, contact the harvestable portion of covered produce or food-contact surfaces (§ 112.3(c));
 - Establish requirements for inspection, maintenance, and certain other actions related to the use of agricultural water, water sources, and water distribution systems associated with growing, harvesting, packing, and holding of covered produce (§§ 112.42 and 112.48);

- If a farm chooses to treat agricultural water to meet relevant requirements for its intended use, establish requirements related to methods of treatment and monitoring such treatment (§ 112.43);
 - Establish specific requirements for the microbial quality of agricultural water that is used for certain specified purposes, including provisions requiring periodic analytical testing of such water (with exemptions provided for use of public water supplies, under certain specified conditions, and treated water), and requiring certain actions to be taken when such water is not safe or of adequate sanitary quality for its intended use and/or does not meet the microbial quality requirements (§§ 112.44, 112.45, 112.46, and 112.47); and provide for the use of alternative requirements for certain provisions under certain conditions (§§ 112.12 and 112.49); and
 - Require certain records, including documentation of inspection findings, water testing results, scientific data or information relied on to support the adequacy of water treatment methods, treatment monitoring results, scientific data or information relied on to support microbial die-off or removal rates or any permitted alternatives to requirements, time intervals or log reductions applied, and corrective actions (§ 112.50).
- Biological Soil Amendments
 - Establish requirements for determining the status of a biological soil amendment of animal origin as treated or untreated, and for their handling, conveying, and storing (§§ 112.51 and 112.52);

- Prohibit the use of human waste for growing covered produce except in compliance with U.S. Environmental Protection Agency (EPA) regulations for such uses or equivalent regulatory requirements (§ 112.53);
 - Establish requirements for treatment of biological soil amendments of animal origin with scientifically valid, controlled, biological, physical and/or chemical processes that satisfy certain specific microbial standards (§§ 112.54 and 112.55), including examples of such processes;
 - Establish application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin (§ 112.56); and
 - Require certain records, including documentation from suppliers of treated biological soil amendments of animal origin, documentation that process controls were achieved, and corrective actions (§ 112.60).
- Domesticated and Wild Animals
 - If there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce, require measures to assess as needed relevant areas during growing and, if significant evidence of potential contamination is found, take measures reasonably necessary to assist later during harvest when the farm must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard (§§ 112.83 and 112.112).
- Equipment, Tools, and Buildings
 - Establish requirements related to equipment and tools that contact covered produce and instruments and controls (including equipment used in transport),

buildings, domesticated animals in and around fully-enclosed buildings, pest control, hand-washing and toilet facilities, sewage, trash, plumbing, and animal excreta (§§ 112.121-134); and

- Require certain records related to the date and method of cleaning or sanitizing equipment used in growing operations for sprouts, and in covered harvesting, packing, or holding activities, and corrective actions (§ 112.140).

- Sprouts

- Establish scope of applicability of sprout provisions (§ 112.141);
- Establish measures that must be taken related to seeds or beans for sprouting (§ 112.142);
- Establish measures that must be taken for the growing, harvesting, packing, and holding of sprouts (§ 112.143);
- Require testing the growing environment for Listeria species (Listeria spp.) or Listeria monocytogenes (L. monocytogenes) and testing each production batch of spent sprout irrigation water or sprouts for Escherichia coli (E. coli) O157:H7, Salmonella species (Salmonella spp.) and, under certain conditions, other pathogen(s), and taking appropriate follow-up actions (§§ 112.144-112.148); and
- Require certain records, including documentation of treatment of seeds or beans for sprouting, a written environmental monitoring plan and sampling plan, test results, certain test methods used, and corrective actions (§ 112.150).

The effective date of this rule is 60 days after its publication in the Federal Register. As shown in the following table, we are establishing three sets of compliance dates, all of which vary based on size of the farm: (1) for covered activities involving sprouts subject to subpart M,

which are also subject to all of part 112 as applicable; (2) for covered activities involving all other produce, which are subject to all of part 112 as applicable except subpart M; and (3) for farms eligible for a qualified exemption and related modified requirements. In the second set of compliance dates, we are also providing extended compliance dates for certain specified requirements related to agricultural water. In the compliance dates relating to the qualified exemption, the compliance date for the records that a farm is required by § 112.7(b) to maintain to support its eligibility for a qualified exemption is the effective date of this rule, i.e., [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER DATE].

Farms need not comply with the requirement for a written record reflecting that the farm has performed an annual review and verification of continued eligibility for the qualified exemption until the farm’s general compliance date, however. In addition, we are establishing January 1, 2020, as the compliance date for the modified requirement in § 112.6(b)(1).

Compliance Dates

Size of covered farm	Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of part 112)	Covered activities involving all other covered produce (i.e., subject to part 112, except subpart M)		Farms eligible for a qualified exemption (if applicable)		
		Compliance date for certain specified agricultural water requirements	Compliance date for all other requirements	Compliance date for retention of records supporting eligibility in § 112.7(b)	Compliance date for modified requirement in § 112.6(b)(1)	Compliance date for all other requirements in §§ 112.6 and 112.7
Time periods starting from the effective date of this rule						
Very small business	3 years	6 years	4 years	Effective date of rule	January 1, 2020	4 years
Small business	2 years	5 years	3 years			3 years
All other businesses	1 year	4 years	2 years			N/A

Costs and Benefits

The primary benefits of the provisions in this final rule are an expected decrease in the incidence of illnesses related to microbial contamination of produce. Annualizing benefits over the first ten years after the effective date of the rule at seven percent, benefits are expected to derive from averting approximately 331,964 illnesses per year (362,059 at 3 percent), valued at \$925 million annually (\$976 million at 3 percent). Similarly, annualized costs, estimated at 7 percent, are expected to be approximately \$366 million annually (\$387 million at 3 percent). Additionally, annualized costs for foreign farms are estimated to be approximately \$138 million annualized at 7 percent (\$146 million at 3 percent).

I. Background

A. FDA Food Safety Modernization Act

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), signed into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law contains important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal, and territorial authorities. A top priority for FDA are those FSMA-required regulations that provide the framework for industry's implementation of preventive controls and enhance our ability to oversee their implementation for both domestic and imported food. To that end, we proposed the

seven foundational rules listed in Table 1 and requested comments on all aspects of these proposed rules.

Table 1.-- Published Foundational Rules for Implementation of FSMA

Title	Abbreviation	Publication
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	2013 proposed produce safety rule or simply “2013 proposed rule”	78 FR 3504, January 16, 2013
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food	2013 proposed human preventive controls rule	78 FR 3646, January 16, 2013
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals	2013 proposed animal preventive controls rule	78 FR 64736, October 29, 2013
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals	2013 proposed FSVP rule	78 FR 45730, July 29, 2013
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications	2013 proposed third-party certification rule	78 FR 45782, July 29, 2013
Focused Mitigation Strategies To Protect Food Against Intentional Adulteration	2013 proposed intentional adulteration rule	78 FR 78014, December 24, 2013
Sanitary Transportation of Human and Animal Food	2014 proposed sanitary transportation rule	79 FR 7006, February 5, 2014

We also issued supplemental notices of proposed rulemaking for the rules listed in table 2 and requested comments on specific issues identified in each supplemental notice of proposed rulemaking.

Table 2.-- Published Supplemental Notices of Proposed Rulemaking for the Foundational Rules for Implementation of FSMA

Title	Abbreviation	Publication
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	2014 supplemental produce safety notice or simply “supplemental notice”	79 FR 58434, September 29, 2014
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food	2014 supplemental human preventive controls notice	79 FR 58524, September 29, 2014
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals	2014 supplemental animal preventive controls notice	79 FR 58476, September 29, 2014
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals	2014 supplemental FSVP notice	79 FR 58574, September 29, 2014

As FDA finalizes these seven foundational rulemakings, we are putting in place a framework for food safety that is modern and brings to bear the most recent science on provisions to enhance food safety, that is risk-based and focuses effort where the hazards are

reasonably likely to occur, and that is flexible and practical given our current knowledge of food safety practices. To achieve this, FDA has engaged in a great deal of outreach to the stakeholder community to find the right balance in these regulations of flexibility and accountability.

Since FSMA was enacted in 2011, we have been involved in approximately 600 engagements on FSMA and the proposed rules, including public meetings, webinars, listening sessions, farm tours, and extensive presentations and meetings with various stakeholder groups (Ref. 1). As a result of this stakeholder dialogue, FDA decided to issue the four supplemental notices of proposed rulemaking to share our current thinking on key issues and get additional stakeholder input on those issues. As we move forward into the next phase of FSMA implementation, we intend to continue this dialogue and collaboration with our stakeholders, through guidance, education, training, and assistance, to ensure that everyone understands and engages in their role in food safety. FDA believes these seven foundational final rules, when implemented, will fulfill the paradigm shift toward prevention that was envisioned in FSMA and be a major step forward for food safety that will protect consumers into the future.

B. 2013 Proposed Produce Safety Rule

Eating fruits and vegetables is an important part of a healthy diet. FDA is responsible for ensuring the safety of all domestic and imported fruits and vegetables. We place a high priority on identifying and implementing measures that can reduce the incidence of foodborne illness associated with produce and maintain a high level of consumer confidence in this important food category. Produce is vulnerable to contamination with microorganisms of public health significance (e.g., bacteria and viruses that can cause disease), as well as physical and chemical (including radiological) contaminants. Contamination of produce can occur on-farm during

growing (either in an open environment or in a fully- or partially-enclosed building), harvesting, packing, or holding; or elsewhere along the farm-to-table continuum.

Section 105 of FSMA adds section 419 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350h) requiring FDA to adopt a final regulation to provide for minimum science-based standards for fruits and vegetables that are RACs based on known safety risks, and directing FDA to set forth in the final regulation those procedures, processes, and practices that we determine to minimize the risk of serious adverse health consequences or death, including those that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. On January 16, 2013, FDA issued the produce safety proposed rule to propose such standards, as well as certain exemptions from the standards, consistent with section 419 of the FD&C Act (78 FR 3504; hereafter referred to as “the 2013 proposed produce safety rule” or simply “the 2013 proposed rule”). Specifically, we proposed, among other provisions, to:

- Establish, in 21 Code of Federal Regulations (CFR) proposed part 112, science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms, focusing on the areas of worker training and health and hygiene; agricultural water; biological soil amendments; domesticated and wild animals; equipment, tools, and buildings; and sprouts;
- Focus the rule on microbiological hazards related to produce growing, harvesting, packing, and holding;
- Apply proposed part 112 to both domestic and imported produce, with several exemptions, including that the rule would not apply to certain specified produce

commodities that are rarely consumed raw; produce that is used for personal or on-farm consumption; or produce that is not a RAC;

- Provide an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms (e.g., “kill step”) as long as certain documentation is kept;
- Not cover farms that have an average annual value of food sold during the previous 3-year period of \$25,000 or less;
- Provide a qualified exemption and modified requirements for farms that meet certain requirements, as well as establish circumstances and procedures under which this exemption may be withdrawn; and
- Require compliance within time periods ranging from 2 to 4 years based on the size of farm, with an additional 2 years to comply with some of the proposed water provisions.

We extended the comment period for the 2013 proposed produce safety rule in response to requests that we do so (78 FR 11611, February 19, 2013; and 78 FR 24692, April 26, 2013).

We later extended the comment period to allow interested persons an opportunity to consider the interrelationships between the 2013 proposed produce safety rule and the 2013 proposed FSVP and third-party certification rules (78 FR 48637, August 9, 2013). We also issued a notice correcting several typographical, stylistic, and reference numbering errors (78 FR 17155, March 20, 2013). At the time of that correction notice, we also made publicly available, in its entirety, the proposed produce safety rule with all errors corrected. The comment period for the 2013 proposed rule closed on November 22, 2013.

C. Draft Qualitative Assessment of Risk

We conducted a “Draft Qualitative Assessment of Risk to Public health from On-Farm Contamination of Produce” (hereafter referred to as “the draft QAR”) to evaluate hazards related to produce production and harvesting. We published the findings of our assessment, and asked for public comment on our assessment and findings (78 FR 3504, January 16, 2013). The tentative conclusions of this assessment informed our proposed science-based minimum standards for the safe production and harvesting of produce commodities.

D. Produce Safety Supplemental Notice

Taking into account information we heard at public meetings, and based on a preliminary review of written comments submitted to the docket, then-currently available information, and our subsequent analysis of the proposed provisions in light of this information, on September 29, 2014, we proposed certain new provisions and certain amendments to our provisions proposed in the 2013 proposed rule (79 FR 58434; hereafter referred to as “the 2014 supplemental produce safety notice” or simply “the supplemental notice”). Specifically, we proposed among other provisions:

- Amendment to not cover farms that have an average annual value of produce sold during the previous three year period of \$25,000 or less;
- Amendment to the definition of “farm” such that establishments that pack or hold produce that is grown or harvested on another farm would be subject to the produce safety standards of proposed part 112 regardless of whether or not that farm is under the same ownership;

- Amendments to update the microbial quality standard for water that is used during growing of produce (other than sprouts) using a direct application method; and to incorporate additional flexibility and provide means to achieve this standard, i.e., by applying a time interval between last irrigation and harvest and/or between harvest and end of storage to account for post-application microbial die-off or removal;
- Amendment to provide tiered-approaches for specific testing frequency requirements to test untreated surface water as well as untreated ground water, which would enable testing at a reduced frequency;
- Amendment to remove the 9-month minimum application interval for use of raw manure and other untreated biological soil amendments of animal origin, and defer FDA’s decision on an appropriate time interval until FDA takes certain specified actions;
- New provision to explicitly state that part 112 would not authorize or require covered farms to take actions that would constitute the “taking” of threatened or endangered species in violation of the Endangered Species Act (ESA), or require covered farms to take measures to exclude animals from outdoor growing areas, or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages; and
- New provisions to establish that, before FDA issues an order to withdraw a qualified exemption, FDA may consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak; and to list the circumstances under which FDA would reinstate a farm’s qualified exemption that is withdrawn.

In the 2014 supplemental produce safety notice, we reopened the comment period only with respect to the specific issues covered in the supplemental notice. In addition, we emphasized that the new and amended proposed provisions we included in the regulatory text

were based on a preliminary review of the comments. We also noted the 2013 proposed produce safety rule and the new and amended proposed provisions published in the 2014 supplemental produce safety notice, taken together, constitute the entirety of the proposed rule on “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.” The comment period for the supplemental notice closed on December 15, 2014.

In this document, we use the broad term “proposed produce safety rule” to refer to the complete proposed regulatory text, including both the proposed provisions we published in the 2013 proposed produce safety rule and the new and amended proposed provisions we published in the 2014 supplemental produce safety notice.

E. List of Federal Register Publications Regarding the Proposed Produce Safety Rule

Table 3 lists Federal Register publications regarding the proposed produce safety rule. This list does not include the Federal Register publications regarding the Environmental Impact Statement (EIS) related to this rule; the EIS and related publications are addressed in section XXVII of this document.

Table 3.-- List of Federal Register Publications Regarding the Proposed Produce Safety Rule

Description	Publication
2013 proposed produce safety rule, requesting comments by May 16, 2013	78 FR 3504, January 16, 2013
Notice of public meeting (held in Washington D.C. on February 28, 2013) on the 2013 proposed preventive controls rule and the 2013 proposed produce safety rule	78 FR 6762, January 31, 2013
Notice of public meetings (held in Chicago, IL on March 11, 2013 and in Portland, OR on March 27, 2013) on the 2013 proposed preventive controls rule and the 2013 proposed produce safety rule	78 FR 10107, February 13, 2013
Notice extending comment period, until May 16, 2013, for the information collection provisions of the 2013 proposed produce safety rule	78 FR 11611, February 19, 2013
Notice of correction for the 2013 proposed produce safety rule	78 FR 17155, March 20, 2013
Notice extending the comment period, until September 16, 2013, for the 2013 proposed produce safety rule and its information collection provisions	78 FR 24692, April 26, 2013
Notice extending the comment period, until November 15, 2013, for the 2013 proposed produce safety rule and its information collection provisions	78 FR 48637, August 9, 2013

Description	Publication
Notice extending the comment period, until November 22, 2013, for the 2013 proposed produce safety rule and its information collection provisions	78 FR 69605, November 20, 2013
Produce safety supplemental notice, requesting comments by December 15, 2014	79 FR 58434, September 29, 2014
Notice of public meeting (held in College Park, MD on November 13, 2014) on the human preventive controls supplemental notice, produce safety supplemental notice, animal preventive controls supplemental notice, and FSVP supplemental notice	79 FR 63346, October 23, 2014

F. Public Comments

Since issuing the 2013 proposed rule, we conducted numerous outreach activities. For example, we held four public meetings to solicit oral stakeholder and public comments on the 2013 proposed rule and the supplemental notice, inform the public about the rulemaking process (including how to submit comments, data, and other information to the rulemaking dockets), and respond to questions about the 2013 proposed rule and the supplemental notice (see Table 3) (Ref. 2) (Ref. 3) (Ref. 4) (Ref. 5) (Ref. 6) (Ref. 7). We also traveled across the country and around the world to discuss the 2013 proposed rule, as well as the other foundational FSMA proposed rules listed in section I.A of this document, with persons who would be affected by them (Ref. 8) (Ref. 9) (Ref. 10) .

We received a total of about 36,000 submissions (representing approximately 15,000 unique comments) on the proposed produce safety rule by the close of the comment period, each containing one or more comments. We received submissions from diverse members of the public, including produce farms; facilities co-located on a farm; cooperatives; coalitions; trade organizations; consulting firms; law firms; academia; public health organizations; public advocacy groups; consumers; consumer groups; Congress; federal, State, local, and tribal government agencies; and other organizations. Some submissions included signatures and

statements from multiple individuals. Comments addressed virtually every provision of the proposed produce safety rule, including our requests for comment on various topics.

In sections III through XXIV of this document, we describe these comments, respond to them, and explain any changes we made to the proposed produce safety rule. We discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. Our responses to the comments include our reasons for determining whether to modify any of the proposed requirements. The remainder of this document establishes a final rule (“the final rule,” “this final rule,” “the rule,” or “this rule”) based on the proposed produce safety rule.

Some comments address issues that are outside of the scope of this rule. We do not discuss such comments in this document. We also received comments that solely address topics, such as preventive controls applicable to food for humans or animals, traceability, foreign supplier verification programs, and third-party accreditation or certification, which are outside of the scope of this final produce safety rule, and will be appropriately addressed in other relevant FSMA rulemaking documents.

II. Legal Authority

The 2013 proposed rule contained an explanation of its legal basis under authorities in FSMA, the FD&C Act, and the Public Health Service Act (PHS Act). After considering comments received in response to the 2013 proposed rule and supplemental notice, FDA made changes in the final rule. The legal authorities relied on for the final rule are the same as in the 2013 proposed rule unless otherwise described in the paragraphs that follow.

A. Relevant Statutory Authorities Other Than Section 419 of the FD&C Act and Section

105 of FSMA

The final rule requires that, to rely on the exemption in § 112.2(b) for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health concern, a covered farm must disclose in documents accompanying the produce that the food is “not processed to adequately reduce the presence of microorganisms of public health significance” (§ 112.2(b)(2)). This requirement is authorized by sections 419 and 701(a) of the FD&C Act (21 U.S.C. 371(a)).

Section 112.2(b) exempts from most requirements in the rule produce that is low risk because it receives commercial processing that will adequately reduce the biological hazards that are the focus of this rule. It is important to ensure that such produce does indeed receive such commercial processing because such processing is the reason the produce is considered sufficiently low risk to be exempt from the other requirements in this rule. A food may pass through multiple entities in the distribution chain before the control is applied. Further, it may not be apparent from visual examination of the food whether a control has been applied. Consequently, without labeling, an entity in the distribution chain might not know whether a control has been applied. Therefore, FDA concludes that information that food has not been processed to adequately reduce the presence of microorganisms of public health significance must be provided in accompanying documentation when a farm is relying on this exemption from the rule. FDA also concludes that such labeling is necessary for the efficient enforcement of the FD&C Act to help ensure that food receives the required processing. Further, because the relevant hazards can cause communicable disease, FDA concludes that the requirement is necessary to prevent the spread of communicable disease from one State into another State and relies on sections 311, 361, and 368 of the PHS Act (42 U.S.C. 243, 264, and 271).

B. Legal Authority for Records Requirements

We are using our authority under the FD&C Act and the PHS Act to institute certain records requirements. In addition to those requirements we proposed in the 2013 proposed rule and the supplemental notice, we are adding the following new record requirement: For farms eligible for a qualified exemption and modified requirements, adequate records necessary to demonstrate that you satisfy the criteria for a qualified exemption, including a written record reflecting that you performed an annual review and verification of your farm's continued eligibility for the qualified exemption (§ 112.7).

We have also revised some of the records requirements in our 2013 proposed rule and the supplemental notice. We note in particular that the record requirement proposed as § 112.161(b) relating to documentation of corrective actions taken under subparts C, E, F, L, and M is now eliminated and, instead, we added specific provisions in two relevant subparts (E and M), at §§ 112.50(b)(6) and 112.150(b)(6). Moreover, in § 112.50(b)(6), we are also establishing specific requirements for documentation of any time interval or (calculated) log reduction applied in accordance with § 112.45(b)(1)(i) and/or (b)(1)(ii), including the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities such as the dates of last irrigation and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing.

In addition, we note that the revised records requirements in § 112.2(b) include: (1) For farms relying on the exemption in § 112.2(b), documentation of disclosures required under § 112.2(b)(2) and annual written assurances obtained from customers under § 112.2(b)(3) (§ 112.2(b)(4)); and (2) For entities that provide a written assurance under § 112.2(b)(3), documenting actions taken to satisfy the written assurance (§ 112.2(b)(6)).

As discussed further in the 2013 proposed rule and in sections XI, XIII, XIV, XVII, and XVIII of this document, these records requirements are necessary for regulated industry to ensure their own compliance with these aspects of the rule and for FDA to ensure that industry is complying with the same aspects of the rule. Therefore, these requirements are necessary for the efficient enforcement of the FD&C Act because they will aid both regulated industry and FDA in ensuring that food is not adulterated, and are necessary to prevent the spread of communicable disease because they will aid both regulated industry and FDA in ensuring that food does not become contaminated with human pathogens. In addition to having the authority under the FD&C Act and the PHS Act to require this recordkeeping, we also have the authority to require access to the records. Because the underlying requirements are necessary to minimize the likelihood of adulteration and the spread of communicable disease, access to records that demonstrate that regulated industry has followed those requirements is essential to confirm compliance and achieve the full benefits of the rule. We also have the authority to copy the records when necessary. We may consider it necessary to copy records when, for example, our investigator may need assistance in reviewing a certain record from relevant experts in headquarters. If we are unable to copy the records, we would have to rely solely on our investigators' notes and reports when drawing conclusions. In addition, copying records will facilitate follow up regulatory actions. Therefore, we conclude that the ability to access and copy records is necessary to enforce the rule and prevent adulteration and the spread of communicable disease. In other sections of this document, we explain in more detail the recordkeeping provisions that we believe are necessary, and because they are limited to what is necessary, that we believe do not create an unreasonable recordkeeping burden.

C. Intrastate Activities

(Comment 1) One comment argues that FDA should not apply this rule to activities that are intrastate in character, citing the lack of an explicit reference to intrastate activities in relevant sections of the FD&C Act, and asserting that the greatest risk of foodborne illness comes from food in interstate distribution networks. This comment argues that the rule as applied to intrastate commerce is beyond the federal government’s power under the commerce clause of the Constitution.

(Response) FDA disagrees. We conclude that the rule should be applicable to activities that are intrastate in character. The plain language of section 419 of the FD&C Act directs FDA to establish science-based minimum standards for the safe production and harvesting of fruit and vegetable RACs to minimize the risk of serious adverse health consequences or death. Section 419 does not include a limitation to interstate commerce. In addition, the exemption provided in section 419(f) of the FD&C Act, based in part on the proportion of a farm’s sales made to restaurants or retail food establishments intrastate or within 275 miles, suggests that Congress intended the rule issued under section 419 to apply to intrastate commerce because otherwise there would be no need to provide an exemption for farms whose sales are intrastate in character. In addition, section 301(vv) of the FD&C Act provides that “[t]he failure to comply with the requirements under section 419”, or the causing thereof, is a prohibited act. Section 301(vv) does not require an interstate commerce nexus. Notably, other subsections in section 301 of the FD&C Act, and section 304 of the FD&C Act (21 U.S.C. 334) demonstrate that Congress has included a specific interstate commerce nexus in the provisions of the FD&C Act when that is its intent. Accordingly, it is reasonable to interpret sections 419 and 301(vv) of the FD&C Act as not limiting the application of the rule only to those farms with a direct connection to interstate commerce.

FDA is mindful that its interpretation of FSMA and the FD&C Act should not cast doubt on their constitutionality. (See Solid Waste Agency of Northern Cook County v. U.S., 531 U.S. 159 (2001)). FDA has considered the relevant provisions of FSMA and the FD&C Act, FDA’s responsibilities in implementing those laws, and the law interpreting the commerce clause of the Constitution (Article I, section 8). Congress’s power to legislate under the commerce clause is very broad. However, such power is not without limits, see United States v. Lopez, 514 U.S. 549, 567 (1995); U.S. v. Morrison, 529 U.S. 598, 618 (2000), and these limits have been construed in light of relevant and enduring precedents. In particular, in Lopez, supra, the Supreme Court acknowledged the continuing vitality of Wickard v. Filburn, 317 U.S. 111 (1942), noting that “although Filburn’s own contribution to the demand for wheat may have been trivial by itself, that was not ‘enough to remove him from the scope of federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial.’” (514 U.S. at 556.) See also Gonzales v. Raich, 545 U.S. 1, 17–25 (2005). This principle applies to the application of sections 419 and 301(vv) of the FD&C Act, as added by section 105 of FSMA. Accordingly, given the collective impact on commerce of farms that grow, harvest, pack, or hold food that is sold in “intrastate” commerce, FDA concludes that such farms should be subject to the rule unless an exemption from the rule applies (for example, if the farm is eligible for the qualified exemption in § 112.5, or if the farm only grows produce exempt from the regulation under one of the exemptions in § 112.2). This outcome regarding intrastate commerce is consistent with section 709 of the FD&C Act (21 U.S.C. 379a), which states that in any action to enforce the FD&C Act’s requirements respecting foods, drugs, devices, and cosmetics, any necessary connection with interstate commerce is presumed. Likewise, this outcome is consistent

with FSMA's risk-based, preventive approach to food safety because the risk presented by unsafe food can be significant, whether or not the food moves from one state to another.

D. Application of Section 112.2(b)(6) to Entities Other Than Covered Farms

As discussed in IX.A.4 of this document, we are specifying in § 112.2(b)(6) that the entities that provide written assurances described in § 112.2(b)(3) must act consistently with the assurances and document the actions taken to satisfy the assurance. Section 112.2(b)(6) applies not just to covered farms, but to other entities that voluntarily agree to provide the written assurances described in § 112.2(b)(3). The application of this requirement to facilities subject to section 418 of the FD&C Act is consistent with section 419(h) of the FD&C Act. Providing, complying with, and documenting compliance with the written assurances described in § 112.2(b)(3) are not activities that are subject to section 418 of the FD&C Act. As discussed in section II.A of this document, in addition to sections 419 and 701(a) of the FD&C Act, this requirement is supported by sections 311, 361, and 368 of the PHS Act.

III. General Comments on the 2013 Proposed Rule

A. General Comments

(Comment 2) Some comments ask us to make the various rules we are establishing to implement FSMA consistent with each other.

(Response) We have aligned the provisions of the various rules to the extent practicable. For example, we use the same definitions of "farm" and the terms used in the definition of "farm" (i.e., harvesting, packing, holding, and manufacturing/processing) in this rule, the final human preventive controls rule (80 FR 55908; Ref. 11) that established part 117 (the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive

Controls for Human Food regulation; hereafter referred to as “the PCHF regulation”), and the final animal preventive controls rule (80 FR 56170) that established part 507 (the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals regulation; hereafter referred to as “the PCAF regulation”). However, the statutory requirements are not the same for all the rules, and the purposes and contents of the rules differ from each other. For example, section 419(f) of the FD&C Act (which relates to this rule) and section 418(l) of the FD&C Act (which relates to the final human preventive controls rule) both create qualified exemptions with modified requirements for certain entities based in part on business size and/or certain specific sales criteria. However, these two sections provide different criteria for eligibility for exemption from the two rules, and different modified requirements for farms and facilities eligible for the relevant exemptions.

(Comment 3) Several comments ask us to develop guidance to accompany this rule to help covered farms to understand and implement this rule, particularly in the areas of agricultural water, personnel training, domesticated and wild animals, sprout production, and biological soil amendments of animal origin. Some of these comments also ask that drafts of such guidance first be made available for public comment. Comments ask us to take into consideration existing public and private food safety programs as we develop our guidance. Comments also recommend that guidance documents should be easily understood, available in multiple formats (including simple checklists), and issued in a timely manner.

Other comments emphasize the importance of education and outreach and ask us to provide support for ongoing education and outreach, including taking an active role in providing needed instructional examples and lessons learned from current investigations and foodborne outbreaks.

(Response) We are developing guidance documents, including general guidance on the implementation of this rule, as well as a Small Entity Compliance Guide (SECG) in accordance with section 105(b) of FSMA (21 U.S.C. 350h note) and section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121). A SECG is a guidance that explains the actions a small entity must take to comply with a rule. We also intend to develop guidance specific to commodities, as needed. We agree that we should take into consideration existing public and private food safety programs as we develop our recommendations. We will develop and issue our guidances in accordance with our good guidance practices regulation, 21 CFR 10.115, which establishes criteria for when we issue a guidance document as an initial draft, invite public comment, and prepare a final version of the guidance document that incorporates suggested changes, when appropriate. The public may submit comments on any guidance document at any time (§ 10.115(g)(5)).

We agree with comments that stress the importance of education and outreach. Supporting efforts to help covered farms get the education and technical assistance they need to understand and implement the requirements is a central element of FDA's strategy to gain compliance with this rule (Ref. 12) (Ref. 13). Within FDA, we are establishing a Food Safety Technical Assistance Network and seeking funding to increase FDA staffing to provide a central source of information to support industry understanding and implementation of FSMA standards (Ref. 12). This will allow us to respond in a timely and consistent way to questions from covered farms related to this rule.

We continue to work with other government agencies, academia, and industry groups, as appropriate, to facilitate the successful implementation of this rule. For example, FDA, in collaboration with the Agricultural Marketing Service (AMS) of the United States Department of

Agriculture (USDA) and others, has established the Produce Safety Alliance (PSA). FDA and others also established the Sprouts Safety Alliance (SSA). Both PSA and SSA will develop and disseminate science- and risk-based training and education programs to provide produce farms with fundamental, on-farm food safety knowledge and equip them to comply with the produce safety regulation. FDA is working to ensure that the PSA and SSA training materials (which we refer to collectively as “the Alliance courses”) are consistent with the requirements of this rule.

We are also partnering with USDA’s National Institute of Food and Agriculture (NIFA). FDA and NIFA are funding a grant program that will provide funding for food safety training, education and technical assistance to small farm owners and food processors to help them comply with food safety standards to be established under FSMA. The purpose of the grant program is to train owners and operators of small businesses, including small- and medium-sized farms, beginning farmers, socially disadvantaged farmers, small processors, or small fresh fruit and vegetable merchant wholesalers, and farms that lack access to food safety training and other educational opportunities.

We also plan to work with cooperative extension units, land grant universities, trade associations, foreign partners, the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), and other stakeholders to develop a network of institutions that can provide technical assistance to the farming community, especially small and very small farms, as they endeavor to comply with the provisions of the final rule. FDA has entered into a cooperative agreement with National Association of State Departments of Agriculture (NASDA) to help with the implementation of the produce safety regulation. Such efforts will help ensure widespread compliance.

(Comment 4) Some comments ask us to establish and annually convene a scientific workgroup that includes experts in produce production, public health, and testing and laboratory science to advise us on pathogens that should be addressed in produce safety standards. Some other comments recommend that FDA establish a national advisory committee or a stakeholder advisory committee to provide ongoing input to FDA as FSMA implementation begins, and suggests that such committee include members from States, industry, and other stakeholders, as well as NASDA. These comments recommend that such advisory body should assist FDA in updating regulations or guidance as science evolves and new information becomes available. One commenter also believes such an established advisory body could function in a manner similar to the National Conference on Interstate Milk Shipments or the Interstate Shellfish Sanitation Conference and provide a formal and effective mechanism for dialogue between FDA, States, NASDA, and the regulated community.

(Response) We disagree with the suggestion to establish an advisory group for the purpose of assisting FDA in updating regulations or guidance as science evolves and new information becomes available. FDA's rulemaking and guidance development processes allow for future amendments, and also provide ample opportunity for public input when warranted. We will consider the need for such amendments in light of evolving scientific information and, as warranted, take appropriate actions.

(Comment 5) Some comments express the need for FDA to review and update the provisions in the produce safety regulation as new scientific information becomes available. One commenter requests that FDA establish a process for such review and update.

(Response) FDA may, on its own initiative or in response to a petition from an interested person, initiate administrative proceedings to amend existing regulations, including the produce safety regulation. See 21 CFR part 10 for our administrative practices and procedures.

(Comment 6) Some comments assert that the rule should be more concise, and that the average person without a team of experts should be able to understand the rule and manage the application of the rule.

(Response) We agree the rule needs to be understandable. We have incorporated plain language techniques – e.g., by framing the regulation in the form of questions and answers, and using active voice in the requirements. We also have established definitions that enable us to improve readability (e.g., “monitor,” “raw agricultural commodity,” and “you”). We have used examples in the codified, where appropriate, and provided examples throughout the preamble to assist with understanding the requirements. We will be issuing guidance documents that will be helpful in understanding the rule (See Comment 3). We anticipate that these various educational and outreach efforts will involve development of checklists, templates, protocols, and other tools that will facilitate compliance with the produce safety regulation.

(Comment 7) Some comments assert that the rule incorrectly assumes that all bacteria are harmful.

(Response) We have long recognized that some bacteria have a role in food production, such as the lactic-acid producing bacteria that our regulations explicitly acknowledge as being added to yogurt (see e.g., the standards of identity for yogurt, low fat yogurt, and nonfat yogurt, in 21 CFR 131.200, 131.203, and 131.206, respectively). This rule defines the term “microorganism,” which explains that the term “undesirable microorganism” includes those microorganisms that are of public health significance, that subject food to decomposition, that

indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated. The produce safety standards established in this rule focus on minimizing the risk of contamination of produce with microorganisms that can cause serious adverse health consequences or death, and are consistent with our “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” (the GAPs Guide) (Ref. 14).

(Comment 8) One comment suggests covering school-garden programs under the produce safety regulation. According to this comment, the current requirements for food safety assurance at these farms are variable, and practices such as improper manure or compost use could present a significant risk to high-risk consumers served by such farms.

(Response) We expect most school-garden programs would likely fall below the monetary threshold for coverage in § 112.4 and, therefore, would not be subject to this rule. We have determined the scope and coverage of this rule to establish only those requirements that are reasonably necessary to meet the public health objectives of the regulation. Note, however, that farms that are not subject to this rule are and will continue to be covered under the adulteration and other applicable provisions of the FD&C Act and applicable implementing regulations, irrespective of whether they are included within the scope of this rule. We recommend that farms that are not covered under part 112 follow good agricultural practices to ensure that the produce they grow, harvest, pack or hold does not serve as a vehicle for foodborne illness.

(Comment 9) Some comments express concern that current tests for pathogens such as E. coli and Salmonella are expensive and time-consuming, and could lead to holding up perishable produce in the food chain. Comments also highlight the need for affordable, on-site, and fast test methods, particularly for testing agricultural water.

(Response) We are not requiring final product testing of produce, except as in subpart M under certain circumstances for sprouts, for reasons explained in section III.F of this document. In prescribing certain analytical methods for testing the quality of agricultural water, for testing the growing environment of sprouts for Listeria spp. or L. monocytogenes, and for testing spent sprout irrigation water (or sprouts) for certain pathogens (in subpart N of part 112), we also provided flexibility for covered farms to use any other method that is at least equivalent to the prescribed analytical methods in accuracy, precision, and sensitivity in detecting the relevant organism. We are aware that there are numerous scientific testing and diagnostic development companies that have invented rapid tests and systems, and that many of these products undergo internal quality control and performance testing, as well as receive additional third-party approvals. In addition, we are aware of programs such as the AOAC International Research Institute's Performance Tested Methods Program that provides an independent third-party review of proprietary test method performance, and that test methods demonstrated to meet acceptable performance criteria are granted Performance Tested Methods (PTM) status. Such methods, including test kit methods, may be acceptable for testing for generic E. coli in agricultural water to satisfy the requirements of § 112.46, for testing for Listeria spp. or L. monocytogenes to satisfy the requirements of § 112.144(a), and for testing for certain pathogens to satisfy the requirements of § 112.144(b) and (c), provided they meet certain conditions in accordance with §§ 112.151(b), 112.152(b), and 112.153(a)(2) and (b), respectively. FDA will consider providing guidance on testing methods, specifically on rapid and low-cost test kits that might be useful for farms.

(Comment 10) Some comments ask us to address model laboratory standards and accreditation to ensure that laboratories are using sound and reliable test methods and practices

for detecting and identifying microorganisms of public health significance. These comments argue that if there are no criteria for training and appropriate use of testing devices or interpretation, test results may not be reliable. These comments also suggest posting a list of accredited laboratories on FDA's website for use by farms.

(Response) We are currently working on a proposed rule to implement section 202 of FSMA (section 422 of the FD&C Act), which addresses "Laboratory Accreditation for Analyses of Foods." Neither model laboratory standards nor laboratory accreditation are within the scope of the produce safety regulation in part 112.

(Comment 11) In the 2013 proposed rule, we requested comment on whether we should require, in a final rule, any or all covered farms that wash and pack produce, or that only pack produce, to perform environmental testing for L. monocytogenes or Listeria spp., and any criteria that should be employed to determine which farms should be subjected to such a requirement (78 FR 3504 at 3619). Some comments respond by noting that not all produce operations will be vulnerable to harborage and contamination by pathogens such as L. monocytogenes. These comments argue that mandatory environmental monitoring for such operations would not yield a food safety benefit and, instead, would impose a wasteful economic burden. These comments recommend that environmental monitoring or assessment for produce (other than sprouts) should be addressed in guidance and can be a part of food safety plans for operations vulnerable to relevant routes of contamination. On the other hand, some comments, suggest the environmental monitoring requirements we proposed for sprouts should be expanded to other high-risk produce.

(Response) We are not requiring environmental testing for L. monocytogenes or Listeria spp. for covered produce other than sprouts. See discussion in the 2013 proposed rule (78 FR 3504 at 3619). Farms may consider voluntarily performing environmental testing for L.

monocytogenes or Listeria spp. as appropriate for their operations. See also section VII of this document where we discuss farm-specific food safety plans.

B. Intentional Adulteration

(Comment 12) Several comments address intentional adulteration of produce. One comment contends that small farms are inherently more resilient to terrorism or other forms of intentionally introduced hazards than large farms due to their diversity, independence, and geographic decentralization. According to the comment, if the proposed produce safety rule negatively affects the viability of diverse small farms, in favor of large, centralized farms, then the net result may be an increase in the American food system's vulnerability to terrorism. With regards to economically motivated intentional adulteration, one comment states that this type of adulteration is difficult to prevent and should not be addressed in this rule.

(Response) FDA is implementing the intentional adulteration provisions in sections 418, 419, and 420 of the FD&C Act in a separate rulemaking. As such, neither intentional adulteration nor economically motivated adulteration in the context of fruits and vegetables that are RACs, during activities that occur on produce farms, are within the scope of the produce safety regulation in part 112. On December 24, 2013, FDA published a proposed rule to implement the intentional adulteration provisions for facilities that manufacture, process, pack, or hold food and are required to register under section 415 of the FD&C Act (per section 418 of the FD&C Act); for fruits and vegetables that are RACs (per section 419 of the FD&C Act); and for high risk foods, exempting farms except for farms that produce milk (per section 420 of the FD&C Act) (78 FR 78014).

C. Registration

In the 2013 proposed produce safety rule, we requested comment on whether we should require that covered farms, as described in proposed § 112.4(a), register with FDA. We acknowledged that we are not aware of a nationwide database of farms, nor an accumulation of statewide databases, that would enable us to identify the names and locations of all entities subject to the produce safety regulation, which, in turn, would enable us to better provide outreach and technical assistance to covered entities and to allocate our inspection resources. We also requested information about the existence of databases that could help us identify covered farms in the absence of a registration system, and the appropriate data elements that should be collected in a registration system, should we decide to set up such a system.

(Comment 13) Several comments support requiring registration of covered farms with FDA, and state that registration would be most helpful during response activities associated with illness outbreaks and recalls. These comments contend that any registration requirement should be kept simple, occur once annually, and apply to every farm no matter their size, sales volume, or method of trade. According to these comments, registration would provide FDA with key information to monitor each crop industry by knowing the size and scope of the regulated community, with a secondary advantage for that crop's association/board to be able to conduct industry outreach and education to assist with compliance with the final rule. Conversely, several other comments oppose a requirement for farms to register with FDA, stating that such a requirement would be unreasonable and inconsistent with FSMA. These comments argue that FSMA does not authorize FDA to require farms to register with FDA, and that FDA fails to establish how requiring farms to register would contribute to improved food safety outcomes in produce production. Other comments suggest that FDA has many State and federal partners to assist in reaching out to the produce production community, and that there are existing industry

resources, which include lists of producers. Some comments state that local and State agencies or extension agencies, not FDA, should maintain a database of farms. Still other comments argue that registration would be economically burdensome for farmers.

(Response) At this time, we are not establishing a requirement for farms to register with FDA. However, we believe that an inventory of farms would enable us to better provide outreach and technical assistance to covered farms and to allocate our inspection resources, so we intend to pursue other avenues for identifying farms. Historically, when we have needed a list of farms, such as for field assignments involving inspections, or for conducting education and outreach activities, FDA has worked with our district offices, State and local departments of health and agriculture, and local university extension services to identify farm operations. Doing this on an as needed, case-by-case basis can be resource intensive and may, or may not, result in a list of operations sufficient for our needs. FDA has entered into a cooperative agreement with NASDA to help with the implementation of the produce safety regulation, and will explore whether and how an inventory of farms located in the United States may be developed and may enhance these efforts.

D. Consistency With USDA's National Organic Program (NOP)

(Comment 14) Several comments state that the regulation may be interpreted to conflict with the requirements of the NOP. In this context, some comments specifically cited NOP's regulations in 7 CFR 205.200, 205.205, and 205.2. Another comment expresses concern that the regulation would discourage farms from becoming organic certified.

(Response) We disagree that the final produce safety regulation (or specifically any provisions in subparts E, F, or I) conflicts with, or discourages farms from following NOP standards, including the provisions in NOP's regulations at 7 CFR 205.200, 205.205, and 205.2.

The provisions in 7 CFR 205.200 require, in relevant part, that production practices implemented in accordance with the NOP must maintain or improve the natural resources of the operation, including soil and water quality. The provisions in 7 CFR 205.205 require an organic producer to implement a crop rotation including but not limited to sod, cover crops, green manure crops, and catch crops that provide the following functions that are applicable to the operation: (1) maintain or improve soil organic matter content; (2) provide for pest management in annual and perennial crops; (3) manage deficient or excess plant nutrients; and (4) provide erosion control. The provisions in 7 CFR 205.2 provide definitions of various terms for purposes of the NOP, including “crop rotation,” “natural resources of the operation,” and “organic production.”

Part 112, including subparts E, F, and I, does not establish any specific requirements that conflict with, or discourage compliance with, these or other NOP requirements. As noted in the 2013 proposed rule and the supplemental notice, consistent with sections 419(a)(1)(A), (a)(3)(E), and (a)(3)(D) of the FD&C Act, we consulted with the NOP, USDA's Natural Resources Conservation Service (NRCS), U.S. Fish and Wildlife Service (FWS), and the EPA to ensure that environmental and conservation standards and policies established by those agencies were appropriately considered in developing the requirements of this rule. See also sections XIII, XIV, and XV of this document where we discuss the requirements related to water, biological soil amendments of animal origin, and animals, respectively.

E. Consideration of Environmental Standards

(Comment 15) Several comments ask that FDA do more to support on-farm conservation efforts and ensure that farmers can continue to use sustainable practices that enhance conservation and food safety. Some comments request that FDA codify into the regulation specific conservation requirements, including requirements to train farm personnel in

conservation practices, not to destroy wild animal habitats, to promote natural barriers, to use sustainable conservation practices, and to use co-management of conservation and food safety. Some comments request that FDA recognize conservation practices intended to protect water quality; train enforcement officials on co-management principles; and/or define the term “co-management” in relation to such requirements.

(Response) As required by section 419 of the FD&C Act, the produce safety regulation establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of produce for human consumption, and sets forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. As discussed in the 2013 proposed rule and the supplemental notice, consistent with sections 419(a)(1)(A), (a)(3)(E), and (a)(3)(D) of the FD&C Act, we consulted with the NOP, NRCS, FWS, and EPA to ensure that environmental and conservation standards and policies established by those agencies are appropriately considered in developing the requirements established in this rule.

As discussed in the 2013 proposed rule and reiterated in the supplemental notice, we encourage the application of practices that can enhance food safety and that are also consistent with sustainable conservation. We believe that the provisions of part 112 are consistent with existing conservation and environmental practice standards and policies and are not in conflict with federal or State programs. In addition, by including § 112.84, as proposed in the supplemental notice, we are finalizing a codified statement in the produce safety regulation that the requirements of part 112 do not require or permit the use of practices in violation of the ESA,

and that the regulation does not require the use of practices that may adversely affect wildlife, such as removal of habitat or wild animals from land adjacent to produce fields.

We continue to encourage the co-management of food safety, conservation, and environmental protection. We consider it important to take into account the environmental practice standards and policies of other relevant agencies in the context of food safety. However, the commenters identified no reason that it would be necessary for FDA to go beyond the statements we have included in § 112.84 and create affirmative conservation-related requirements in this rule. Therefore, we are taking no further action in response to these comments.

F. Product Testing as a Strategy to Control Pathogens

(Comment 16) Some comments agree with FDA's tentative conclusion that product testing would be impracticable as a component of this rule, except as proposed in subpart M under certain circumstances for sprouts. One comment notes that sporadic contamination of produce cannot be detected reliably by product testing. One comment states that maintaining robust records of testing results will allow both farms and FDA to monitor for trends, correct imbalances or inaccuracies, and make adjustments to the system to best protect public health.

(Response) As discussed in section IV.I of the 2013 proposed rule, microbiological product testing for process control purposes presents several challenges that make it impracticable to be included within the framework of mandatory, science-based minimum standards established in part 112, with the exception of certain testing for sprouts described in subpart M (see section XVIII of this document). Among other issues, there are challenges associated with sampling plans, indicator organisms, and pathogen detection such that product testing is not appropriate as a generally applicable strategy to control pathogens across all

produce commodities. The final human preventive controls rule also notes that product testing and environmental monitoring are unlikely to be common in facilities complying with that rule that process, pack, or hold produce RACs. We agree that, when testing is conducted (either voluntarily or in compliance with this rule for sprouts), records are important and useful.

G. Aquaponic and Hydroponic Operations

(Comment 17) Several comments request that FDA exempt aquaponic farming (raising produce and fish together in an integrated system) from the produce safety regulation, including specifically from the standards directed to agricultural water in subpart E, the standards directed to biological soil amendments of animal origin and human waste in subpart F, and the standards directed to domesticated and wild animals in subpart I. These comments argue the proposed produce safety rule does not address the nature of aquaponic farming. Some other comments suggest making it clear that the produce safety regulation is not intended to prohibit aquaponic practices.

Some comments requested that the standards related to agricultural water not be applied to aquaponic water containing fish waste fertilizer that is not intended or likely to come into contact with the harvestable portion of the plants; aquaponic water that is drawn from potable sources; or to hydroponics using effluent from domestic fish or crustaceans that is kept under what commenters describe as closed, hygienic conditions (in accordance with the Aquaponic Association's GAPs). Other comments state that fish waste does not contain E. coli and, therefore, the water microbial quality and testing requirements in proposed §§ 112.44 and 112.45 should not apply to water used in aquaponic systems. With respect to subpart F, some comments suggest the water and fish waste used in aquaponic and hydroponic systems should not be considered a biological soil amendment of animal origin. With respect to subpart I, some

comments contend fish (including shellfish) are an inherently different reservoir for microorganisms than mammalian or avian species and, while fish may become temporary carriers of human pathogens, they do not act as hosts, and it is unlikely that they will come into contact with the harvestable portions of produce.

(Response) We acknowledge that aquaponic farming systems present a particular set of circumstances that differ in important ways from non-aquaponic farming. However, we do not agree that aquaponic farms should be excluded from the rule. We do not intend to prohibit using aquaponic farming systems to grow covered produce. The routes of contamination we considered for covered produce under this rule are applicable to aquaponic farming and covered produce grown in aquaponic systems is subject to the same potential for contamination from agricultural water, biological soil amendments of animal origin, and animals as covered produce grown using non-aquaponic systems.

With regard to subpart E of this rule, when covered produce is grown in an aquaponic system in which the water is not intended or likely to contact the harvestable portion of the produce, that water is not agricultural water for purposes of this rule. On the other hand, when covered produce is grown in an aquaponic system in which water is intended or likely to contact the harvestable portion of the produce, that water is agricultural water for purposes of this rule and must meet the applicable standards of subpart E, including the relevant microbial quality requirements in § 112.44 and the relevant water testing requirements in § 112.46. Also, as discussed further in Comment 222, the § 112.46(a) exception from water testing requirements applies only when water received from a public water system (as in § 112.46(a)(1)) or a public water supply (as in § 112.46(a)(2)) is not held under your control in a way that meets the definitions of “ground water” or “surface water” before you use it as agricultural water. For

example, where under the circumstances the water used in the aquaponic system is “agricultural water” (because it is intended to, or likely to, contact covered produce), if that water is from a surface water source (or held in a surface water capacity), it must meet the surface water testing requirements in § 112.46. For example, the testing requirements in § 112.46(b) for untreated surface water apply to an aquaponic system that is established in an outdoor stream or pond, if under the circumstances the water meets the definition of “agricultural water.” With regard to the comments that asserted that fish do not carry E. coli, we note that information submitted or otherwise available to us demonstrates that fish can become carriers of human pathogens, including E. coli and Salmonella, if they are exposed to contaminated feed (Ref. 15), waters or sediment (Ref. 16) (Ref. 17). Studies show that fish have natural defenses against bacterial colonization of human pathogens, but as the population of the pathogen is elevated the fish become stressed and are no longer able to mitigate harboring the pathogens, becoming more susceptible to carrying human pathogens and becoming infected with other fish pathogens (Ref. 18). Fish are also natural carriers of Vibrio spp. (Ref. 19), a zoonotic pathogen.

With regard to subpart F of this rule, we consider growth media to include solid or semi-solid matrices in which plants are grown; we do not consider liquid-only matrices to be growth media. If a liquid matrix in which covered produce is grown is intended to or is likely to contact the harvestable portion of the crop, the water is agricultural water subject to all applicable requirements in subpart E.

Subpart I of this rule applies only in outdoor areas and partially-enclosed buildings. As revised in this final rule, subpart I is not intended to address potential contamination from fish used as part of an aquaculturing system. We conclude that the risks presented by fish used in aquaculture are better suited to regulation via the requirements for agricultural water in subpart E

(when the water meets the definition of agricultural water) and the requirements related to harvesting in § 112.112 (for example, if covered produce is reasonably likely to have become contaminated by water containing fish waste that is not managed in compliance with subpart E's requirements for agricultural water). Thus, we are revising § 112.81 to specify that subpart I does not apply to fish used in aquaculture operations. We note that subpart I does apply to aquaculture operations conducted in outdoor areas or partially-enclosed buildings when, under the circumstances, there is a reasonable probability that animals other than the fish used in the aquaculture operation will contaminate covered produce. We will consider issuing additional guidance related to the application of this rule to aquaculture operations, as appropriate.

(Comment 18) One comment presents various arguments in support of a position that aquaponic or hydroponic farming of produce other than sprouts should not be subject to the proposed requirements in subpart M, including asserting that there are no documented instances of Salmonella or E. coli transmission via aquaponic or hydroponic produce (other than sprouts), and that the growth conditions in aquaponic or hydroponic systems for produce (other than sprouts) are different and safer than those used to germinate sprouts. This comment also requests that FDA clarify that “water used for growing sprouts” does not cover water used in aquaponic or hydroponic systems for produce (other than sprouts) and, likewise, that the definition of “spent sprout irrigation water,” does not include water used for irrigation in aquaponic or hydroponic systems for produce (other than sprouts).

(Response) We have added new § 112.141 to clarify the scope of subpart M. Therefore, an aquaponic or hydroponic system used to grow covered produce other than sprouts is not subject to the requirements in subpart M. Likewise, “spent sprout irrigation water” is defined as “water that has been used in the growing of sprouts”; thus, the term spent sprout irrigation

water, and the requirements for testing spent sprout irrigation water in subpart M, only apply to the water used for growing sprouts, and not to water used in an aquaponic or hydroponic operation growing produce other than sprouts. However, to the extent the specific aquaponic or hydroponic production systems used to grow produce other than sprouts may present risks similar to those associated with sprouts, we encourage aquaponic and hydroponic operations to consider voluntarily implementing the standards in subpart M.

(Comment 19) Some comments ask FDA to consider establishing additional regulations specifically applicable to aquaponics operations, as well as to hydroponic production of crops other than sprouts. According to one comment, this is especially important for high-risk crops such as leafy greens because the use of growth media in hydroponic production can increase the growth of pathogens.

(Response) At this time, we are not establishing additional standards specifically applicable to aquaponic or hydroponic production of crops other than sprouts. As noted in section V.M of the 2013 proposed rule, sprouts present a special concern with respect to human pathogens compared to other covered produce because of the warm, moist, and nutrient-rich conditions required to produce sprouts, the same conditions that are also ideal for the proliferation of pathogens if present (Ref. 20) (Ref. 21). Sprouts also have been frequently associated with foodborne illness outbreaks and, as a result, we issued our first commodity-specific guidance for sprouts. Likewise, the Codex Alimentarius Commission (or “the Codex”) supplemented the Codex Code of Practice for Fresh Fruits and Vegetables (the Codex Guide) (Ref. 22) with a Sprout Annex (Ref. 23). Therefore, we believe it is necessary to incorporate additional subpart M establishing standards specific to sprouts (including soil- or substrate-grown sprouts harvested with roots). Unlike sprouts, we believe that the production methods

and safety considerations associated with aquaponics, generally, as well as with hydroponic production of crops other than sprouts, are sufficiently addressed through the provisions of the rule that are generally applicable to covered produce, including the provisions for water in subpart E, for soil amendments of animal origin in subpart F (which include growth media that serve as the entire substrate during the growth of covered produce), and for harvesting in § 112.112. We will consider issuing guidance on these topics in the future, as appropriate. Aquaponic and/or hydroponic operations growing produce other than sprouts may also voluntarily choose to follow the standards in subpart M.

IV. Comments on the Regulatory Approach

In the 2013 proposed rule, in section IV of that document, we explained in detail our tentative conclusion that we should establish a regulatory framework based on practices, procedures, and processes associated with growing, harvesting, packing, and holding of all covered produce. We considered and rejected a framework that (based solely on a history of outbreaks or illnesses associated with the commodity) would be applicable to individual commodities or classes of commodities. As discussed in the 2013 proposed rule, foodborne illness outbreaks have regularly been associated with commodities that have previously not been linked to outbreaks. Moreover, as discussed in the QAR, some commodities (e.g., leafy greens) have been consistently associated with outbreaks while others (e.g., grapes, jalapeno peppers) have only rarely been associated with outbreaks. In addition, because only a small percentage of outbreaks are both reported and assigned to a food vehicle, outbreak data may not provide a complete picture of the commodities upon which we need to focus to minimize current and future risk of illness. See also discussion at 78 FR 3504 at 3524-3528. We proposed an integrated approach to prescribe standards for on-farm routes of contamination

that we tentatively determined are reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. Importantly, this integrated approach does take into account differences in commodities in that it takes into account differences in practices associated with the growing, harvesting, packing, and holding of produce commodities. We believe this integrated approach that focuses on the likelihood of contamination of produce posed by the agricultural practices applied to the crop, while exempting the lowest-risk produce, provides the most appropriate balance between public health protection, flexibility, and appropriate management of different levels of risk. The requirements of this regulation are based on identified routes of contamination and the associated practices that affect the likelihood that produce becomes contaminated.

Agricultural practices that are more likely to contaminate produce require more stringent measures to ensure that the likelihood of contamination is sufficiently minimized. For example, as discussed in section XIII of this document, we are establishing the most stringent microbial quality standard for water that is used in direct contact with the harvestable portion of covered produce during or after harvest activities (when there is little further opportunity for pathogen die-off) and in certain other uses that present significant safety risk for the safety of the produce (such as irrigation of sprouts); less stringent criteria for water that directly contacts the harvestable portion of covered produce (other than sprouts) during growing activities (when the opportunity for pathogen die-off is greater); and no requirements when water is used during growing, but does not contact the harvestable portion of covered produce (other than sprouts). In addition, we recognized the need for, and proposed, additional standards specifically tailored to the growing, harvesting, packing, and holding of sprouts.

We requested comment on our tentative conclusions related to our proposed regulatory approach. We asked for comment on various issues, as discussed in section IV.C of the 2013 proposed rule.

A. Commodity-Specific Versus Integrated Approach

(Comment 20) Several comments generally support our proposed integrated approach for various reasons, including that: (1) an integrated approach focuses on practices of highest risk and provides a whole farm approach rather than commodity-specific measures, which would be challenging for farms that grow multiple crops; (2) an approach that relies on outbreak data to make determinations about which produce should be covered would be inconsistent with the prevention-based approach mandated by FSMA; (3) relying on outbreak data would be insufficient to protect the public because many foodborne illnesses are not linked to an outbreak and the patterns of outbreaks associated with produce commodities change over time; (4) relying on pathogen surveillance data would not provide sufficient information to make risk determinations because FDA collects few data on produce and data collected are typically targeted to produce that is already known to be risky, which is not a preventive approach.

In contrast, several other comments request that we develop a commodity-specific approach, arguing that the proposed integrated approach is not sufficiently based on risk or science and does not sufficiently align with the intent of Congress that FDA establish a rule that considers differences in risk among various commodities. Several comments contend that, with the exception of exemptions for produce rarely consumed raw and produce that receives commercial processing, FDA has proposed a generic, one-size-fits-all approach. Some comments maintain that, by focusing on agricultural practices, FDA has ignored relevant commodity-specific factors, such as adhesion and infiltration. Some comments also express

concern that FDA did not consider past association with outbreaks a major determinant for coverage of produce commodities, contending that doing so would result in more cost-effective and targeted risk reduction. Still other comments state that there is a known and significant variation in risk profiles, practices, and regional differences across produce commodities, and ask FDA and USDA to fund research to determine the relative risk of microbial contamination.

Some comments suggest FDA should analyze each commodity separately and develop commodity-specific requirements, and establish a level of regulation commensurate to the level of risk of causing foodborne illness presented by a specific commodity, focusing on commodities presenting the highest risk. Some comments point to commodities such as tree fruits, produce with an inedible peel, and nuts as “low risk,” and argue that such commodities should not be regulated the same way as other commodities that present a greater risk profile. Some comments state that citrus fruit is grown off the ground, the peel is generally not consumed, the fruit is acidic, and irrigation water generally does not touch the fruit and, therefore, citrus fruits should be considered low risk. Other comments suggest FDA should start by regulating only commodities that have been associated with an outbreak and consider expanding to include other commodities only after evaluating the public health benefits of the initial rulemaking. Some comments also ask FDA to consider the crop grouping strategies employed by other organizations, such as the grouping used by Codex Alimentarius (in Codex classification of foods); the USDA (in IR-4 project); and the EPA (in EPA’s Crop Group listings).

(Response) We agree with comments that indicated the integrated approach proposed by FDA is appropriate for a variety of reasons. We recognize the diversity of produce operations and agree with comments that pointed out that multiple, crop-specific standards

could be confusing and burdensome both in their implementation and in assessing compliance, especially for diversified operations. As discussed in the 2013 proposed rule and the QAR, we agree that an approach that relies on outbreak data, or certain commodity characteristics, to make determinations about which produce should be covered would be inconsistent with the prevention-based approach mandated by FSMA and that relying on outbreak data would be insufficient to protect the public because many foodborne illnesses are not linked to an outbreak and the patterns of outbreaks associated with produce commodities change over time. For example, cucumbers are frequently (although not always) peeled prior to consumption and, until recently, did not have a history of association with outbreaks. In 2009, based on literature indicating the potential for cucumbers to be contaminated with Salmonella (Ref. 24) (Ref. 25), we added cucumbers to our routine surveillance sampling assignments and, in fact, detected an outbreak linked to cucumbers that year (Ref. 26) (Ref. 27). Between 2011 and 2014, we have identified cucumbers as the food vehicle in three additional outbreaks (Ref. 28).

FDA based its proposal of a practices-based approach in part on the results of our draft QAR. We received public comment on the QAR and also had it peer reviewed and have now issued a final QAR (or the QAR), which incorporates revisions based on public comments and the peer review (Ref. 29). While we have made some revisions, the conclusions of the QAR are unchanged. We conclude that, while different commodities may have different risk profiles at different stages of production, all commodities have the potential to become contaminated through one or more of the routes identified, especially if practices are poor and/or conditions are insanitary. Commenters did not provide information affecting this conclusion. We also conclude that commodity characteristics, such as an inedible peel or the fact that it is grown off the ground, may be relevant to relative likelihood of contamination during growing, but are not

good indicators of an association, or lack thereof, with outbreaks. Commenters also did not provide information affecting this conclusion. The QAR looked at likelihood of contamination during growing, harvest, and postharvest activities for 47 commodities and found that commodity characteristics, including microbial adhesion and infiltration considerations, were not reliably protective against contamination, as evidenced by past association with an outbreak for a range of commodities with variable characteristics. For example, if a pathogen is present on the surface of the peel or rind of a piece of fruit, cutting the fruit with a knife can carry the pathogen into the edible portion of the fruit (Ref. 30). Indeed, produce commodities with a peel or removable outer layer, such as honeydew, cantaloupe, papaya, and mango, have previously been associated with outbreaks of foodborne illness. From 1997 to 2014, there have been a total of 20 outbreaks in the United States associated with produce commodities sold whole (not fresh-cut) where the commodity has an outer peel that is removed prior to consumption, with a range of pathogens (Salmonella, Shigella, and Listeria) implicated in the outbreak (Ref. 28) (Ref. 29). The public health consequences of these outbreaks have been significant. For example, the 2011 L. monocytogenes outbreak in the United States associated with cantaloupe resulted in 147 reported cases of illness, 143 reported hospitalizations, and 33 reported deaths (Ref. 28).

With regard to comments asking that we start by regulating only commodities that have been associated with an outbreak, we note in the QAR that “new” commodities are associated with outbreaks on a regular basis, which means that a history of outbreaks is not appropriate as a basis for determining the regulatory status of various commodities. Many comments asked that we consider factors such as commodity characteristics or past association with an outbreak to define a subset of low risk commodities that would be exempt from the requirements of part

112. However, these comments did not provide data that affected the findings of the QAR, and in finalizing this rulemaking we continue to conclude that the integrated approach is the appropriate regulatory framework to ensure the safety of produce.

In considering options for the regulatory framework for the produce rule, we considered the crop groupings used by Codex Alimentarius, the IR-4 project, and EPA's crop grouping designations (Ref. 31) (Ref. 32) (Ref. 33), which were suggested by comments. These programs categorize commodities based on commodity characteristics, production practices, or pest pressures. They were not created for the purposes of characterizing relative risk of causing serious adverse health consequences or death, or to determine what procedures, processes, and practices should apply to such commodities to minimize the risk of serious adverse health consequences or death. Thus, we did not find these groupings appropriate for purposes of this regulation. As demonstrated by the QAR, even within a commodity group, physical characteristics (such as texture of the fruit) of the commodity that could alter the potential for contamination and, therefore, association with an outbreak, do not always appear to do so.

In the 2013 proposed rule, we specifically sought comment on various possible strategies for developing a commodity-specific approach, including covering only commodities/commodity groups that had been associated with outbreaks during a specified time period; covering only commodities/commodity groups that had ever been associated with an outbreak; and combining outbreak-based commodity classification with other information, such as commodity characteristics, or pathogen surveillance data. We noted specific problems with each of these approaches. In summary, commenters did not provide data or information suggesting that the problems we identified could be adequately addressed to allow development of a commodity-specific approach that would be sufficiently protective of public health. As a

result, we are finalizing our conclusion that the integrated approach is the most appropriate, risk-based, and scientifically sound approach, and we are adopting such an approach.

We also asked specific questions in the 2013 proposed rule regarding whether we might additionally exclude commodities beyond those we identified as the lowest risk (i.e., those that are rarely consumed raw and those that receive commercial processing that adequately reduces pathogens). We asked if produce, such as bananas and coconuts, that are peeled or shelled before consumption in a manner that can be expected not to transfer contamination onto the interior, edible portion of the commodity should be covered by the rule or subject to a less stringent set of requirements (78 FR 3504 at 3528). We received several comments indicating that bananas should not be covered because they have an inedible peel, which according to commenters means that it is unlikely that contamination will contact the edible portion. In response to our questions in the preamble, no comments identified any unique characteristics, in addition to the ones we identified, of bananas and coconuts that would justify their exemption. We indicated with our question a characteristic of bananas and coconuts that might put them in a lower risk category than other commodities. However, there is no evidence that bananas and coconuts are lower risk than other low-risk commodities or that the method of peeling or opening these commodities generally precludes transfer of contamination on the exterior to the edible portion. As noted in the QAR, there are limited data on the effect of cutting and peeling on the levels of pathogens across the range of produce commodities (Ref. 29). In addition, in the final QAR, while both bananas and coconuts have low ‘route scores’ in the assessment of potential routes of contamination and likelihood of contamination on-farm, other commodities have lower scores. As noted previously, we continue to conclude that commodity characteristics, such as an inedible peel or the fact that produce is grown off the

ground, may be relevant to relative likelihood of contamination during growing, but are not good indicators of an association, or lack thereof, with outbreaks. Therefore, we conclude that they should be subject to part 112.

We also asked about certain commodities that are ranked in the QAR as presenting a relatively lower likelihood of exposure, in part because they have fewer potential routes of contamination and/or lower potential for contamination and have not previously been associated with an outbreak. We asked if commodities that meet both these criteria should be subject to the rule or subject to a less stringent set of requirements (78 FR 3504 at 3528). We specifically mentioned pears, grapefruit, oranges and lemons as examples. As noted earlier, we received a comment arguing that citrus fruits should be considered low risk commodities due to the fact that they are acidic, have a rarely consumed peel, are grown in trees, irrigation water generally does not touch the fruit, and citrus fruits have not been associated with outbreaks. However, the comment did not ask for citrus to be exempt, but to be deemed in compliance with the rule if farms are in compliance with the Citrus industry's good agricultural practices (the Citrus GAPs) (Ref. 34). However, while different commodities may have different risk profiles at different stages of production, all commodities have the potential to become contaminated through one or more of the routes identified, especially if practices are poor and/or conditions are insanitary. In addition, commodity characteristics, such as an inedible peel or the fact that it is grown off the ground, may be relevant to relative likelihood of contamination during growing, but are not good indicators of an association, or lack thereof, with outbreaks. For these reasons, and because comments provided no other information to suggest that citrus fruits or pears should not be covered by the rule, we conclude that they should be subject to part 112. With regard to compliance with the Citrus GAPs, see Comment

143.

(Comment 21) One comment suggests that, as an alternative to developing a commodity-specific regulatory approach, FDA should provide for a notification process by which industry can voluntarily notify FDA about a particular commodity that should be characterized as low risk and, therefore, exempt from the produce safety regulation.

(Response) We believe the alternative and variance provisions, in subparts B and P, respectively, provide adequate flexibility to address particular situations, and the rule otherwise provides exemptions for certain types of low-risk produce (§§ 112.2(a)(1) and (b)). We are not establishing an additional process or exemptions.

(Comment 22) We received numerous comments stating that we have adopted a “one-size-fits-all,” rigid and prescriptive approach. These comments argue that our proposed approach is not flexible or scale appropriate.

(Response) Under our regulatory approach, the scope and stringency of the requirements are based on risk, and depend in several cases on the types of practices employed within operations, such that producers of different commodities who use different practices will not necessarily be subject to all of the same requirements. We note that § 112.4(a) requires that “[i]f you are a covered farm subject to this part, you must comply with all applicable requirements of this part when you conduct a covered activity on covered produce” (emphasis added). As discussed in the 2013 proposed rule, given various considerations, we proposed an integrated approach that draws on our past experiences and appropriately reflects the need to tailor requirements to specific on-farm routes of contamination. In some cases, our standards are similar to current good manufacturing practices-type provisions, especially where the routes of contamination are well-understood and appropriate measures are well-established and

generally applicable across covered produce commodities (e.g., personnel qualifications, training, health, and hygiene; harvesting, packing, and holding activities; equipment, tools, buildings, and sanitation). In other cases, our standards require the farm to inspect or monitor an on-farm route of contamination and take appropriate measures if conditions warrant. We rely on such a monitoring approach where the diversity of conditions that can be expected relative to an on-farm route of contamination is very high and it would be impractical and unduly restrictive to set out a standard that specifies the appropriate measures for each possible circumstance (e.g., requirements for visual assessment for working or grazing animals or animal intrusion in § 112.83 and inspection of agricultural water system in § 112.42). In still other cases (e.g., sprouts), our standards require the farm to develop a written plan, committing itself to specific measures (e.g., sprout environmental testing and spent sprout irrigation water testing). Finally, on a limited basis, we are establishing specific numerical standards against which the effectiveness of a farm's measures would be compared and actions that would be taken to bring the operation into conformance, as necessary (e.g., microbial quality criteria for agricultural water in subpart E). We rely on the numerical standards approach where our evaluation of current scientific information to determine reasonable measures allows us to establish numerical criteria that are broadly applicable across a wide range of conditions, while acknowledging that such criteria may be tailored, as appropriate, when applied specifically to a commodity (or group of commodities) or under a set of farm practices.

We incorporated flexibility into the standards, where appropriate, so covered farms are able to comply with the requirements while taking into account their specific commodities and conditions in their operations, and risk profile associated with them. For example, we define "agricultural water," in relevant part, to mean water that is intended to, or likely to, contact the

harvestable portion of the crop or food-contact surfaces, thus allowing consideration of commodity-specific characteristics and/or practices. For example, if irrigation water does not contact the produce (e.g., drip or furrow irrigation of tree fruit), the microbial quality criteria for agricultural water applied during growing using a direct water application method (for produce other than sprouts) do not apply because the water is not “agricultural water” as we have defined that term. We also incorporated additional flexibility to accommodate future changes in science and technology and the particularities of local growing conditions and commodities. Under § 112.12, we list the specific numerical standards established in this rule for which we allow alternatives to be established and used in appropriate circumstances. This provision provides significant flexibility by allowing individual farms to develop alternative standards suitable to their operations with appropriate scientific support (for example, under §§ 112.12(a) and 112.49(a), alternatives are permitted to the microbial quality criteria in § 112.44(b) related to agricultural water used in a direct application method during growing of produce (other than sprouts)). In addition, in subpart P, we provide for a mechanism by which a State, tribe, or a foreign country from which food is imported into the United States may request a variance from one or more requirements of part 112, where such variance, among other conditions, is demonstrated to provide the same level of public health protection as the relevant requirement(s) of part 112.

Taking into account comments in response to the 2013 proposed rule and as proposed in the supplemental notice, we incorporated further flexibility in certain key areas such as the standards for agricultural water. For example, § 112.45(b)(1) provides additional means by which to satisfy the microbial quality criteria for agricultural water that is used in a direct application method during the growing of produce (other than sprouts). Allowing for microbial

die-off between last irrigation and harvest and/or microbial reduction or removal resulting from postharvest practices provides covered farms viable options to meet the microbial quality criteria without needing to, for example, treat water or switch to a ground water source. This additional flexibility recognizes the diversity of commodities and production practices. It may also be useful for other postharvest activities, for example, commercial washing and controlled atmosphere storage of apples, with adequate supporting data and documentation.

We believe the coverage threshold, qualified exemption, and extended compliance periods adequately address concerns related to scale-appropriate regulation of farms. We have provided as much flexibility as is appropriate while maintaining the overall public health goal of this produce safety regulation. This regulation does not apply to those businesses with \$25,000 or less in sales of produce, as described in § 112.4(a), because such farms do not contribute significantly to the produce market and, therefore, to the volume of production that could become contaminated. In addition, for farms that fit our criteria for very small business or small business, we are providing extended compliance periods ranging from two to three years for covered activities involving sprouts; and ranging from three to four years for most provisions coupled with more time for certain water-related requirements for covered activities involving all other covered produce (see section XXIV of this document), so they are given sufficient time to make any necessary adjustments to their current practices. There are also provisions for qualified exemption for certain farms based on monetary value and direct-to-consumer sales, and associated modified requirements, as described in §§ 112.5, 112.6, and 112.7.

In addition, the provisions in subpart A provide risk-based exemptions for certain types of produce based on our determination that the manner in which the produce is consumed does

not require that produce to be subject to the requirements in part 112. We are exempting produce commodities that are rarely consumed raw (§ 112.2(a)(1)). Produce that receives commercial processing that adequately reduces the presence of pathogens is also eligible for exemption under certain conditions (§ 112.2(b)).

(Comment 23) One comment asks whether covering all commodities in the rule is compliant with the provisions of the WTO-SPS agreement about the appropriate level of protection. This commenter expresses concern specifically with respect to covering under this rule those fruits and vegetables that have an inedible peel and that are peeled before consumption.

(Response) We believe that the regulatory framework underlying the science-based minimum standards established in part 112 is supported by currently available scientific information, as explained throughout the 2013 proposed rule and in this rule and, as such, satisfies our obligations under the WTO-SPS agreement. We also note that not all produce commodities are subject to the rule. Section 112.2(a)(1) specifies certain commodities that are not covered based on our conclusion that they are rarely consumed raw. See Comment 20 for our consideration of produce with inedible peel.

B. Use of Quantitative Metrics

(Comment 24) Several comments express concern with the use of quantitative metrics in the rule. For example, one comment indicates the proposed requirements in subpart I to “monitor...for evidence of animal intrusion” and “evaluate whether the covered produce can be harvested”, allows for regional and commodity diversity and provides sufficient flexibility to be applicable to any operation, whereas the quantitative metrics, such as in proposed §§ 112.44, 112.45, 112.55 and 112.56, are too prescriptive and inflexible to be codified in the regulation.

Several comments argue the current status of produce safety research is inadequate to establish the quantitative metrics as applicable to all commodities and regions and all situations. Another comment asks us to limit the metrics to those for which sufficient scientific evidence exists that such standards will protect public health and reduce risk. Some comments argue that guidance would be a more appropriate vehicle to convey quantitative metrics, as recommendations rather than requirements, because there is such variation in region, operations, and commodities, and because guidance is easier to amend than a regulation.

(Response) The standards that FDA is issuing in part 112 are based in science. Taking into account comments received in response to the 2013 proposed rule we proposed revisions to some provisions in the supplemental notice and explained our rationale, including scientific support for those new and amended proposed provisions. Among proposed §§ 112.44, 112.45, 112.55, and 112.56, which included quantitative criteria, there was one, the minimum application interval for an untreated biological soil amendment of animal origin in proposed § 112.56, for which we indicated that we would conduct further research and a risk assessment. FDA has committed to pursuing this work before revisiting the interval. We conclude we have an adequate basis on which to finalize the metrics in this rule, including in final §§ 112.44, 112.45, 112.46, and 112.55. For a discussion of the final provisions, and comments received in response to the supplemental notice, we refer you to sections XIII and XIV of this document. We disagree with comments that suggest eliminating all quantitative metrics from this rule in favor of recommending such numerical criteria in guidance. We believe it is clearer to regulated industry to establish these metrics in the rule, and important for public health that these metrics be binding requirements rather than recommendations.

C. Scientific Support for the Rule

(Comment 25) Some comments state the record of proven on-farm causation of outbreaks is thin. One comment acknowledges our estimates of produce-related reported outbreaks, outbreak-related illnesses, hospitalizations, and deaths, and argues that, although these adverse impacts are regrettable, the number of deaths pale in comparison to the 2.5 million total deaths in the country, including about 35,000 caused by motor vehicle accidents.

(Response) In the 2013 proposed rule, FDA outlined the history of contamination associated with produce, predominantly during growing, harvesting, packing, and holding (78 FR 3504 at 3507), from 1996 to 2010. On-farm contamination of produce is well documented. We also developed and finalized the QAR which evaluates likely routes of contamination for 47 produce commodities, including pre-harvest and postharvest activities on farms. We have updated our outbreak data since the 2013 proposed rule issued, and between January 2011 and 2014, there were 44 outbreaks, 3120 illnesses, 735 hospitalizations, and 42 deaths associated with produce (including sprouts) (Ref. 28). We continue to conclude that there is an ample history of microbiological contamination of produce on farms to justify establishing the provisions of part 112 to help prevent contamination and illness. This rule is also consistent with our statutory mandate to develop standards for the safe production and harvesting of produce to minimize the risk of serious adverse health consequences or death.

(Comment 26) One comment questions FDA's interpretation of the term "scientifically valid," which, according to the commenter, relies too much on peer review for validation.

(Response) We use the term "scientifically valid" to mean an approach that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. Use of peer-reviewed literature is just one component of what we mean by the term "scientifically valid;" however, we continue to believe that peer-

reviewed literature may be an important source of validation of, for example, a procedure, process, or practice allowed as an alternative to a specific requirement of this rule under § 112.12.

(Comment 27) Some comments suggest we should revise the regulation to align with what the commenters identify as the modern microbial ecology paradigm, stating that achieving public health goals is more complex than eliminating pathogens and that exposure to diverse microbes may be necessary for health.

(Response) We do not expect or intend for this rule to bring about a “microbe-free” food production system. We acknowledge that eliminating all pathogens would not be a realistic expectation, especially in an open field environment. However, foodborne illness associated with consumption of contaminated produce can carry high public health and financial costs. Many produce contamination events are preventable, and we will work with industry and other stakeholders to achieve successful implementation of this rule and, ultimately, protect public health. This rule is also consistent with our statutory mandate to develop standards for the safe production and harvesting of produce to minimize the risk of serious adverse health consequences or death.

D. Market Channels

(Comment 28) We received several comments in response to our question about whether and how we could use market channels as a factor in the rule beyond inclusion of the qualified exemption that already takes market channels into account. One commenter states that local food is less risky because there is less time between harvest and consumption (and, therefore, less time for pathogen growth and multiplication) as well as less centralized processing with potential for cross contamination. This comment argues that FDA’s analysis confuses data on hazards that

occur on-farm, with hazards that occur off-farm, including hazards that occur later in the chain of production. In addition, one comment suggests that FDA should support research and data collection to compare the risks of different types of supply chains, including direct-to-consumer and multiple “touch-points” supply chains. One comment recommends establishing a three-tiered structure for the regulation of produce safety, reflecting current produce production and marketing systems. As recommended, the three tiers would be: (1) “farm-direct,” which would include farm stands, farmers’ markets, community supported agriculture (CSA) programs (e.g. subscription farms) and other strategies where the relationship between individual farmers and consumers is “immediate and understood;” (2) “identity-preserved,” which would include distribution on a regional scale where the farmer and consumer do not necessarily meet, but the identity of the farm is displayed or otherwise preserved on products all the way through the system; and (3) “commodity-stream,” which would include other distribution systems besides “farm-direct” and “identity-preserved.”

(Response) FDA disagrees with the commenter who argues that we are using off-farm food safety data to justify control of farming practices. We recognize that contamination can happen at any point in the supply chain. In a review of outbreaks in the United States attributed to fresh leafy vegetables between 1973 and 2012, Herman and colleagues noted that most (85 percent) fresh leafy vegetable outbreaks during the study period were attributed to food prepared in a restaurant or catering facility (Ref. 35). According to Herman et al., the large number of fresh leafy vegetable outbreaks in which the food was prepared in a restaurant and contaminated with norovirus, often by an ill food worker, underscores the need to enforce safe handling practices for food workers for these types of foods. The authors also noted, however, that contamination of leafy vegetables early in production by bacterial pathogens such as

Shiga-toxin producing E. coli (STEC) and Salmonella caused nearly all multistate outbreaks associated with those commodities, including some of the largest leafy vegetable outbreaks: Shigella and fresh parsley in 1998, Hepatitis A and green onions in 2003, E. coli O157:H7 and spinach in 2006. Furthermore, leafy green vegetables used in ready-to-eat pre-packaged salads retain much of their indigenous microflora after minimal processing, including pathogens, if present (Ref. 36).

The focus of the produce rule on contamination on-farm, the earliest point in the supply chain, is consistent with FSMA's focus on prevention of food safety problems. On-farm routes of contamination have been well documented. However, this does not mean that FDA is singling out farms as the only source of contamination for produce; other efforts are directed to potential contamination at later stages of manufacturing and processing. For example, the PCHF regulation addresses manufacturing/processing operations for food, including produce commodities; the FDA Model Food Code (Ref. 37) addresses practices at the retail level; and educational campaigns, such as consumer advice for safe handling of raw produce and juice (Ref. 38) (Ref. 39), are designed to enhance safe handling practices by consumers.

We decline to establish the three-tiered system advocated for by a comment. The comment described potential categorizations that relate to traceability of produce. Tracing may be easier when only selling through the types of arrangements described in the commenter's "farm-direct" category, or in a manner described in the commenter's "identity-preserved" category; however, the goal of this regulation is the prevention of foodborne illness. The commenter did not provide data or information from which we can conclude that the "farm-direct" or "identity-preserved" market channels described represent lower risk of foodborne illness, only that such market channels may better facilitate traceback after illness occurs.

As discussed in the 2013 proposed rule, we acknowledge that the number of opportunities for contamination during packing and holding may be greater for produce in market channels involving greater numbers of handlers and touch points. At the same time, we concluded that produce in both direct market channels and other commercial channels are subject to the same routes of contamination, and we indicated that we were not aware of any data that would allow us to compare the likelihood of contamination for produce in more or less direct market channels. This rule includes the statutory qualified exemption which addresses market channels (see section 419(f) of the FD&C Act, and § 112.5). We identified no data that would allow us to otherwise use market channels as a basis of risk categorization under this rule. Nor did commenters provide any data or factual information that would allow us to do so. We believe that the commenter who advocated the three tiered system described previously is arguing that it is most important from a public health standpoint to focus our efforts on large farms that sell produce through attenuated supply chains. We agree that we should prioritize our enforcement and compliance efforts in an efficient way that is based on risk. See our discussion in section XXII of this document. We also note that the proposed revised definition of “retail food establishment” (80 FR 19160; April 9, 2015) may affect the number of farms that are subject to the requirements of part 112.

E. Guidance in Lieu of the Produce Safety Regulation

(Comment 29) Several comments recommend that FDA consider issuing guidance, or otherwise providing information and advice to farms, in lieu of establishing the produce safety regulation. These comments note there is a tremendous amount of research being done to address known produce safety issues and enhance produce safety, and use of guidance rather than a regulation would allow FDA to readily and easily incorporate new science and preventive

controls as they become available. Some comments state FDA has not explained why we determined not to adopt a voluntary approach and request that any guidance documents consider industry-developed recommendations. Some commenters ask FDA to consider the number of other regulations with which farms must currently comply, suggesting that further regulation is unnecessary.

(Response) Under section 419 of the FD&C Act (created by section 105 of FSMA), Congress explicitly requires the issuance of regulations establishing science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are RACs for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death. Adopting a voluntary approach, in lieu of regulatory requirements, does not fulfill this statutory mandate nor does it achieve the public health objectives intended by the produce safety regulation. Rather, this rule implements the statutory mandate described in section 419 of the FD&C Act. We also recognize that there are many requirements with which produce farms must comply, including environmental and worker safety regulations. However, such regulations do not minimize the risk of severe adverse health consequences or death from produce for consumers, which is the goal of part 112.

FDA recognizes that there are many growing situations across the country and abroad, each of which is unique to a particular growing region and site location, and that there may be different measures a farmer can take to prevent and/or minimize food safety risks in compliance with the regulation. In this regard, we note that part 112 gives farm operators sufficient flexibility to tailor their practices as appropriate to achieve compliance with the applicable produce safety standards. Moreover, guidance will play an important role in

providing recommendations to assist farms in tailoring their activities to the conditions, practices and commodities specific to their farm. As discussed throughout this document, we intend to issue guidance to help covered farms comply with the requirements of this rule, including a SECG specifically intended for small and very small businesses.

F. Existing Industry Guidelines and Certification Programs

(Comment 30) Several comments request FDA approve or recognize existing industry voluntary programs, and accept participation in such programs as a means to meet the requirements of the produce safety rule. Some comments believe such programs are as protective, or more protective, of public health than the proposed produce safety rule. Some comments note that many farms currently use and understand voluntary auditing and other food safety programs such as the USDA Good Agricultural Practices (GAP) and Good Handling Practices (GHP) programs, the Global Food Safety Initiative's (GFSI) food safety program, the California Leafy Greens Marketing Agreement (CA LGMA) (Ref. 40), the California Cantaloupe Marketing Order, the Arizona Leafy Greens Products Shipper Marketing Agreement (AZ LGMA) (Ref. 41), the Florida Tomato Good Agricultural and Best Management Practices programs, the Citrus GAPs, and the Massachusetts GAP and Commonwealth Quality programs. Some comments argue that it would not be efficient to create a separate inspection framework under the produce safety regulation without taking steps to provide integration with such existing programs, and integrating inspections would allow FDA to focus its resources on operations that are not part of an existing system. Some comments state that the internal and external audit components of these programs would serve as an additional check to ensure food safety practices are being implemented effectively at farms. Some comments suggest that FDA should grant an

exemption or an alternative or variance for GAP-certified farms, those participating in the CA LGMA or AZ LGMA, or those complying with other certification programs.

(Response) FDA appreciates the efforts of commodity groups and industry segments that have proactively developed food safety programs. We also appreciate that farms currently implementing these programs may have developed an understanding and comfort level with the provisions in these programs. Such farms will likely be well-positioned to comply with this rule.

To the extent that certification schemes or food safety programs are consistent with the produce safety regulation, then compliance with those schemes or programs could be relevant to compliance with the requirements of part 112. We reviewed widely used food safety schemes and programs in developing this rule and note that there are consistencies with several of the provisions of this rule. We understand that, as of the publication of this document, many of the widely used food safety schemes and programs will be considering whether and how to revise their provisions in light of the requirements of FDA regulations, including this produce safety regulation and our other new FSMA regulations. Over time, we expect that certification programs and food safety programs will develop tools to demonstrate the alignment of their provisions with FDA requirements. FDA believes there is value in such efforts and will consider the possible implications for FDA's work if and when such information on alignment is available. With respect to the comment about alternatives or variances, see our response to Comment 143.

G. Reducing Burden on Small Farms

(Comment 31) Some comments request a range of options designed for small and mid-sized agricultural operations, and express concern about the burden of the rule on small farms

and their ability to stay in business. Some comments state the rule should be established in a manner that does not create a burden on new farm startup enterprises. Comments also request the rule minimize burden on smaller operations by streamlining and reducing unnecessary paperwork. Several comments agree problems with food safety need to be addressed, but request FDA's emphasis should be on "industrial agriculture," which they contend is the primary source of food safety problems, rather than on small farms. One comment suggests costs of compliance will be more burdensome to small farms than to large farms because certain costs, such as those associated with water testing, paperwork, and documentation, remain relatively constant regardless of the size of the operation.

(Response) FDA appreciates that this rule will establish, for the first time, regulatory requirements for on-farm growing, harvesting, packing, and holding of produce. We also appreciate that implementing the requirements of this rule will come with a cost, both in time and resources. As discussed in section IX of this document, we have incorporated a coverage threshold (§ 112.4(a)) and a qualified exemption and corresponding modified requirements (§§ 112.5, 112.6, and 112.7), as well as extended compliance periods (see section XXIV of this document) each based, in part, on the size of the farm. We conclude that these provisions adequately address the concerns of small farms and are in compliance with our statutory mandate under section 419 of the FD&C Act. This rule also provides sufficient flexibility to allow individual operations to tailor their practices as appropriate. Our recordkeeping requirements established in subpart O of part 112 allow farms to use existing records, and do not require duplication provided such records satisfy all of the applicable requirements of part 112. FDA agrees that education, training, and technical assistance to farmers is important. As mentioned throughout this document, FDA will be issuing guidance, including SECG,

specifically aimed at assisting small and very small farms to comply with the requirements of this rule. See also Comment 3 and sections XI and XXII of this document.

(Comment 32) Some comments assert the rule will disproportionately affect New England farmers, with negative impacts on New England's food supply because New England farms are small and production costs are higher compared to elsewhere in the country. Other comments assert this rule will force small farmers out of business, forcing the United States to rely on foreign suppliers who these commenters assert are under very little FDA oversight. These comments argue the requirements of this rule should be reduced in various ways as a means of supporting small, local farmers. Other comments express concern that this rule will discourage farmers from supplying the "Farm to School" market.

(Response) We believe that the "farm" definition that we have established in the PCHF regulation, and which we are adopting into part 112 through this rule, reduces the impact of the FSMA rulemakings on farms of all sizes, because several types of operations that were required to register as food facilities under the section 415 registration regulations as established in 2003 (68 FR 58894, October 10, 2003) will no longer be required to do so by virtue of the changes we are making to the definition of "farm." (See the discussion of the changes to the "farm" definition in section IV of the final human preventive controls rule (80 FR 55908).) In addition, a farm that has annual sales of produce below the monetary threshold in § 112.4(a) is not covered under this rule. Moreover, under § 112.5, a farm is eligible for a qualified exemption (and subject to certain modified requirements) if it satisfies certain criteria. We are also establishing delayed compliance dates for small and very small businesses as discussed in section XXIV of this document. All of these factors will reduce the burden of this rule on small

farms.

H. Estimated Produce Outbreaks and Associated Illnesses

(Comment 33) Several comments question our analysis and estimates of produce-related outbreak illnesses. According to these comments, the number of outbreaks and health consequences should be reduced by removing known foreign-sourced outbreaks. Some comments point out limitations of the CDC dataset, including that the data do not differentiate between illnesses caused by contamination in the production of produce and contamination due to improper handling by the consumer, and that the data do not include illnesses caused by “unspecified agents”. Finally, some comments contend that FDA should limit its consideration of past outbreak data on which it relies in the proposed regulation; for example, if previous outbreaks are related to activities that would be covered by the proposed Preventive Controls for Human Food rule, then these comments argue that FDA should not consider those outbreaks when determining the risk of activities covered by the produce safety regulation.

(Response) FDA acknowledges that there are a number of limitations associated with available outbreak data. For example, the data do not include illnesses that were not reported, sporadic cases of illness, or illnesses transmitted person-to-person (secondary transmission). The data also do not include a large number of reported illnesses/outbreaks where the contaminated food vehicle cannot be determined. The data do not include illnesses/outbreaks where the point of contamination is determined to be the home, retail, or institutional setting. We thus conclude that, if anything, our dataset likely undercounts the number of outbreaks associated with the production of produce. We disagree with comments that suggest illnesses and outbreaks attributed to foreign sources should be excluded from data considered in support

of this rule. Our goal is to minimize illnesses and deaths associated with the consumption of contaminated produce. Imported produce, like domestically-grown produce, contributes to the risk of foodborne illness from contaminated produce and is therefore relevant to this rulemaking.

Finally, while we are not counting these illnesses for purposes of the Regulatory Impact Analysis (RIA) for this rule, we are otherwise considering them in our assessment in the QAR and in establishing this rule. We have determined that it is most appropriate to attribute the benefits of avoiding fresh-cut produce related illnesses to the PCHF regulation for purpose of economic analysis to avoid double counting such benefits; however, we note that it appears that in several cases, the most likely point of original contamination for the fresh-cut-related outbreaks occurred on the farm rather than at the fresh-cut facility. Both farms and fresh-cut manufacturing/processing operations provide routes of contamination that may contribute to adulteration of fresh-cut produce, and the integrated system of preventive controls we are establishing under FSMA is intended to address these risks at multiple stages in the farm-to-table continuum. Thus, illnesses attributable to fresh-cut produce are relevant to both this rule and the PCHF regulation even though the economic benefits of avoiding illnesses attributable to such products are being estimated only in the RIA for the PCHF regulation.

I. Impact on Traditional Farming Methods

(Comment 34) Several comments express concern that the proposed produce safety rule would impose undue restrictions on traditional farming methods. Comments indicate concern with our proposed approach as applied to diversified livestock-crop farms, the use of working animals, and the use of biological soil amendments of animal origin. These comments urge FDA to remove restrictions applicable to these methods of farming, absent data showing an actual,

verified increased rate of foodborne illness associated with use of such. In addition, these comments argue that FDA is inappropriately placing the burden on farmers to prove that their methods are safe.

(Response) We disagree the produce safety regulation would impose undue restrictions on traditional farming methods, such as diversified livestock-crop farms, the use of working animals, or the use of biological soil amendments. These issues are further discussed in sections XIV (standards directed to biological soil amendments) and XV (standards directed to animals) of this document. We have made changes in those subparts that we expect will address at least some of these commenters' concerns. See also section III.E of this document. Farms have a responsibility to produce food that complies with the FD&C Act, and FDA disagrees that we are inappropriately placing burden on farmers to prove that their methods are safe. We are establishing requirements in this rule that will minimize the risk of serious adverse health consequences or death from produce. We are also establishing a rule with significant flexibility for farms to tailor their practices to their operations while remaining in compliance with the rule. We intend to commit significant resources to education, training, and technical assistance to help farms comply with the rule – see section XXII of this document. Also, as discussed in section X of this document, although we expect farms that establish and use an alternative approach (where permitted) to have the necessary scientific data or other information in support of that alternative, such data or information may be developed by you, available in the scientific literature, or available to you through a third party. We anticipate that the necessary scientific support for an alternative could be developed with broad efforts across the produce community, involving academia, extension services, industry associations, and federal, State, tribal, and local government agencies. FDA is collaborating with partners on

research that may provide scientific support for specific alternatives, and we intend to disseminate useful scientific information, when available, and issue commodity- and region-specific guidance as appropriate, such that farmers would be able to consider our recommendations and apply the new scientific information to their operations, as appropriate.

J. Other Comments

(Comment 35) Comments strongly encourage FDA to interact with the retail community to promote the adoption of the final produce rule as a uniform public/private standard. Citing concerns that farms are suffering from “audit fatigue” due to the multitude of requirements already in place from handlers, retailers, and state authorities, these comments urge FDA to facilitate standardization of produce safety requirements and third-party audits.

(Response) FDA is aware of the multitude of audit programs with varying requirements and the associated burden that this places on farms. The produce safety regulation represents science-based minimum standards for the safe production and harvesting of produce to minimize the risk of serious adverse health consequences or death. We understand that, as of the publication of this document, many of the widely used food safety schemes and programs will be considering whether and how to revise their provisions in light of the requirements of FDA regulations, including this produce safety regulation and our other new FSMA regulations. We expect to continue to work in collaboration with stakeholders, including the buyer community, as we move forward in implementing this rule.

(Comment 36) One comment requests FDA to provide a safe harbor exemption for contracts and from torts when produce is not delivered due to demonstrated food safety concerns.

(Response) We are not establishing requirements of the type suggested by this

commenter. We do not believe it would be appropriate for FDA to dictate, or to invalidate, the specific aspects of contract terms between private parties that the commenter asks us to regulate in this rule. We do not discourage private parties from including “safe harbor” provisions such as those described by the commenter in their agreements, but we decline to require or otherwise establish them. In addition, we note that section 301(a) of the FD&C Act already prohibits the introduction or delivery for introduction of adulterated food into interstate commerce. Tort law duties are outside the scope of this rulemaking.

V. Final Qualitative Assessment of Risk

In the 2013 proposed produce safety rule, we discussed the findings of a draft qualitative assessment of risk (“the draft QAR”) of hazards related to produce production and harvesting that we conducted to inform the development of our proposed regulatory approach. The draft QAR addressed various questions related to produce safety, including: (1) What are the biological hazards of concern in produce that can lead to serious adverse health consequences or death? (2) How does produce become contaminated (i.e., routes of contamination) during on-farm growth, harvesting, and postharvest operations? (3) Does the likelihood of contamination vary among produce commodity types? (4) Does the likelihood of illness attributable to produce consumption vary among produce commodity types? (5) What is the impact of postharvest practices on the level of contamination at consumption? (6) What on-farm interventions are available to reduce the likelihood of contamination?

As indicated in the 2013 proposed produce safety rule, the draft QAR was peer reviewed in April, 2013. We considered peer reviewers' comments as well as public comments received in response to the proposed produce safety rule, and finalized the QAR. We consider changes made from the draft QAR to the final QAR, such as adding a sensitivity analysis regarding the scoring

system used in the draft QAR and updating the datasets for outbreaks and farm investigations to include data through 2014, to have improved the robustness of the QAR. We provide a brief summary of conclusions of the QAR in the paragraphs that follow. For the complete QAR and our responses to comments received, see (Ref. 29) (Ref. 42), respectively. Key conclusions from this assessment are: (1) Produce can be contaminated with biological hazards, and the vast majority of produce-related illnesses are associated with biological hazards; (2) the known routes of contamination from growing, harvesting, and on-farm postharvest activities are associated with seed (for sprouts), water, soil amendments, animals, worker health and hygiene, and buildings/equipment; (3) although some types of produce have been repeatedly associated with outbreaks, all types of produce commodities have the potential to become contaminated through one or more of these potential routes of contamination; (4) the specific growing, harvesting, and on-farm postharvest conditions and practices associated with a produce commodity influence the potential routes of contamination and the likelihood that the given route could lead to contamination and illness. Use of poor agricultural practices could lead to contamination and illness, even where the potential for contamination is relatively low; and (5) postharvest practices such as cooking (and possibly certain peeling) before consumption may have an impact on the likelihood of contamination of the edible portion and, thus, may decrease the likelihood of exposure of consumers to contamination.

Hazards of concern in produce -- The scientific evidence from outbreaks, surveys and published literature establishes that human pathogens (e.g., Salmonella, pathogenic E.coli, Shigella, and Cyclospora) constitute a biological hazard with the potential to cause serious adverse health consequences or death and result in the vast majority of foodborne illness known to be associated with produce consumption.

Potential routes of contamination -- Based on our observations during inspections, investigations, and surveillance activities and other available information, we have grouped the possible routes of contamination into five major pathways: Water, Soil amendments, Animals, Worker health and hygiene, and Equipment and buildings. Seed is an additional route of contamination for sprouts.

Likelihood of contamination -- All produce commodities can be contaminated before, during, and/or after harvest through one or more of the potential routes of contamination. Although the likelihood of contamination varies by commodity, it appears to be dependent on the practices employed and, to a lesser extent, on the characteristics of the commodity. There appears to be greater variability in the likelihood of contamination among commodities during growing than during harvest or after harvest.

Likelihood of exposure -- Subsequent to any contamination on-farm, consumer and retail handling practices and produce consumption rates affect the likelihood that consumers will be exposed to contamination (see also section IX.A.3 of this document). Postharvest practices such as cooking (and possibly certain peeling) before consumption may have an impact on the likelihood of exposure if indeed the produce is contaminated.

Risk of illness – Contaminated produce has the potential to cause illness. However, there are differences among commodities in the risk of illness, primarily based on the routes of contamination associated with the commodity.

Produce commodities that are ranked as “higher” risk of illness and those ranked as “lower” risk of illness share some of the same characteristics. Both categories include:

- Crops where the harvestable portion grows in the ground;
- Row crops where the harvestable portion grows on or near the ground;

- Crops where the harvestable portion grows above the ground;
- Crops where the harvestable portion grows on trees, high above the ground; and
- Crops that are generally grown without soil.

Such diversity suggests that sorting commodities for risk based only on the manner in which commodities grow would be inappropriate. This diversity also characterizes commodities associated with outbreaks. Even within a commodity group, physical characteristics (such as texture of the fruit) of the commodity that could alter the potential for contamination and, therefore, association with an outbreak, do not always appear to do so.

In summary, some produce types are repeatedly associated with reported foodborne illness whereas other produce types are only intermittently associated with foodborne illness. Still other produce commodities have not been associated with reported foodborne illness. Likely factors contributing to the likelihood of contamination, exposure, and illness include: agricultural practices used during growing, harvesting, and postharvest; physical characteristics of the crop; consumer and retail handling practices (such as cooking and peeling); and rates of consumption. However, use of poor agricultural practices could lead to contamination and illness, even where the potential for contamination is relatively low.

The QAR also identifies certain data gaps and research needs that would reduce our uncertainty in understanding how produce becomes contaminated and how that contamination contributes to risk during growing, harvesting, and postharvest activities. Areas for research needs identified in the QAR are origins of pathogens in the farm environment; survival and distribution of pathogens in the farm environment, specifically in animals, soils, water; transfer of pathogens to produce; survival and growth of pathogens on produce; and prevalence and levels of pathogens in produce that cause illness.

We conclude the QAR advances our ability to describe, in a systematic manner, the current state of our knowledge about the likelihood of illness associated with produce and the likely routes of contamination from on-farm activities. It provides a framework for integrating and evaluating the scientific knowledge related to public health and can be used in support of regulatory decisions in the implementation of section 419 of the FD&C Act.

In the 2013 proposed rule, we also provided our tentative conclusions of a quantitative risk assessment to estimate the predicted effectiveness of our proposed requirements related to irrigation water with respect to one example commodity, i.e., fresh-cut lettuce, and one example pathogen, i.e., enterohemorrhagic E. coli (EHEC) (Ref. 43). We noted that the quantitative risk assessment document was being peer-reviewed, and we would consider peer reviewers' and public comments in finalizing the quantitative risk assessment and the 2013 proposed rule.

However, taking into account public comments received in response to the 2013 proposed rule, in the supplemental notice, we proposed revised requirements for agricultural water, including those for irrigation water. To inform our revised proposed requirements, we conducted two new separate analyses: (1) an analysis of existing recommendations and standards related to water quality to determine whether and how they may be used to develop appropriate microbial quality criteria for water used during growing of produce (other than sprouts) using a direct water application method (Ref. 44); and (2) an evaluation of decay rates of microorganisms on produce to determine whether a decay rate between irrigation and harvest could be identified and, if so, identify an appropriate decay rate (Ref. 45). We relied on the conclusions derived from these new analyses to support our revised proposed requirements for agricultural water quality in proposed § 112.44. In this rule, we are finalizing those proposed

requirements, with revisions, consistent with our updated supporting analyses (see section XIII of this document).

Because the quantitative risk assessment of fresh-cut lettuce cited in the 2013 proposed rule pre-dates our revised proposed requirements in the supplemental notice, and because we continue to rely on the new analyses to finalize our proposed requirements, we are not taking further action to finalize the quantitative risk assessment of fresh-cut lettuce cited in the 2013 proposed rule.

VI. Comments on Non-Biological Hazards

In the 2013 proposed rule, FDA tentatively concluded that the produce safety regulation should be limited in scope to biological hazards and science-based standards necessary to minimize the risk of serious adverse health consequences or death associated with biological hazards (78 FR 3504 at 3524). FDA noted that the frequency and nature of non-biological hazards in produce are such that promulgation of a new regulatory regime for their control does not, at this time, appear to be reasonably necessary to prevent their introduction into produce or to provide reasonable assurances that produce will not be adulterated under section 402 of the Act. We requested comment on this approach, and specifically, on whether there are procedures, practices or processes that are reasonably necessary to prevent the introduction of known or reasonably foreseeable non-biological hazards into produce or otherwise to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. After considering comments, we are finalizing this rule, as proposed, with its scope limited to biological hazards.

Although in the 2013 proposed rule, we referred to radiological hazards separately from chemical hazards, we believe that radiological hazards have been considered in the past as chemical hazards and, therefore, we use the phrase “chemical (including radiological)”

throughout this rule. This reference to radiological hazards as a subset of chemical hazards is consistent with how these hazards are considered in the PCHF regulation (see definition of “hazard” in § 117.3).

(Comment 37) Several comments generally agree with our proposed approach to focus on biological hazards, and state that food safety resources should be allocated where public health is best served by limiting the scope of the rule to biological hazards. These comments agree with FDA that there are already sufficient regulatory controls on the use of agricultural chemicals in the United States, as evidenced by FDA’s own historical data. One comment states that farms are already regulated at both the State and federal levels in their use of agricultural chemicals, and this should not be duplicated. Comments also maintain that most produce farms have already implemented sufficient controls to minimize the likelihood of physical hazards reaching consumers; e.g., washing, visual sorting, and mechanical separation devices (such as gaps in rollers) to remove potentially harmful objects from produce. In addition, comments note that physical hazards rarely, if ever, present a risk of severe adverse health consequences or death.

(Response) FDA is finalizing the produce safety regulation with the scope limited, as proposed, to biological hazards and science-based standards necessary to minimize the risk of serious adverse health consequences or death associated with biological hazards. As we noted in the 2013 proposed rule, although the potential for physical or chemical (including radiological) contamination of produce exists, we do not believe that a new regulatory regime is necessary to address those hazards. In a reference memorandum that accompanied the 2013 proposed rule (Ref. 46), FDA provided an overview of the non-biological agents that are reasonably likely to occur in produce at the farm and capable of causing adverse health effects.

FDA identified the hazards using relevant sources, such as scientific literature and recall data. Our analysis led us to conclude that non-biological hazards associated with produce rarely pose a risk of serious adverse health consequences or death for individuals that would consume the product. This is because physical or chemical (including radiological) hazards in produce either: 1) occur only rarely at levels that can pose a risk of serious adverse health consequences or death (e.g., radiological contamination as a result of a nuclear power plant accident); 2) occur with greater frequency, but rarely at levels that can pose a risk of serious adverse health consequences or death (e.g., pesticide or mycotoxin residues); or, 3) occur infrequently and usually do not pose a risk of serious adverse health consequences or death (e.g., physical hazards). We have also updated our analysis to consider hazards from food allergens associated with produce (Ref. 47). No comments included data or information suggesting that we should adjust these conclusions about hazard severity and frequency.

FDA continues to routinely monitor chemical and pesticide residues through its regulatory monitoring programs, with an emphasis on RACs and foods consumed by infants and children (Ref. 48). We continue to believe that current programs, such as FDA monitoring, EPA registration of pesticides, and State and industry efforts are sufficient to keep these hazards under control. In addition, our focus on biological hazards is consistent with the recommendations in the Codex Guide, which pay particular attention to minimizing microbial hazards and address physical and chemical hazards only in so far as these hazards relate to good agricultural and manufacturing practices (Ref. 22).

It is also important to note that potential contamination of produce from physical or chemical (including radiological) hazards will continue to be covered under the applicable provisions of the FD&C Act and implementing regulations. Under section 402(a)(1) of the

FD&C Act, a food is adulterated if it bears or contains any added poisonous or deleterious substance which may render it injurious to health, and such substances may include or otherwise result from physical and chemical (including radiological) contamination.

(Comment 38) One comment notes that food allergens, which are chemical hazards, are rarely introduced in the growing and handling of intact produce, except when the produce itself is a food allergen (i.e., tree nuts and peanuts). Another comment refers to the practice among some small farms of using milk to manage downy mildew, and expresses concern with the introduction of food allergens into produce. This commenter requests that FDA forbid the use of allergens in contact with produce, regardless of the size of the farm or the type of crop.

(Response) The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Pub. L. 108-282) addresses, among other issues, the labeling of foods that contain major food allergens. Raw agricultural commodities such as fruits and vegetables in their natural state are not within the scope of FALCPA. However, allergen hazards associated with the growing, harvesting, packing, or holding of produce rarely occur. A review of our recall data from 2004 to 2014 shows that there were no recalls associated with allergens and produce commodities in their RAC form (Ref. 47). As with other chemical hazards associated with produce, we do not believe that the incidence of food allergens as a hazard associated with growing, harvesting, packing, or holding of produce warrants adoption of a new regulatory scheme.

(Comment 39) Some comments argue that the language of FSMA means that the produce safety rule should cover physical and chemical (including radiological) hazards.

(Response) We disagree. Focusing the produce safety regulation on biological hazards is consistent with section 419(c)(1)(A) of the FD&C Act, which requires FDA to “set forth those procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards * * * and to provide reasonable assurances that the produce is not adulterated under section 402 [of the FD&C Act].” This language provides FDA with discretion to determine what procedures, processes, and practices are “reasonably necessary” for the purposes identified in the statute with respect to the identified types of hazards.

As discussed previously, we carefully considered different types of hazards, and determined that available data and information clearly establish that human pathogens constitute a biological hazard with the potential to cause serious adverse health consequences or death and result in the vast majority of foodborne illness known to be associated with produce consumption. There is also no pre-existing federal regulatory requirement directed at minimizing the risks presented by biological hazards in produce. Thus, we conclude it is reasonably necessary to set forth controls to prevent the introduction of biological hazards into produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act on account of biological hazards.

On the other hand, FDA’s analysis of the potential for physical and chemical (including radiological) hazards to contaminate produce and cause serious adverse health consequences or death, as well as the adequacy of existing regulatory programs to address such potential, did not demonstrate that additional regulation was reasonably necessary. We conclude that it is not

reasonably necessary to establish controls for physical or chemical (including radiological) hazards in this rulemaking in light of the severity and frequency of occurrence of these hazards in produce, and the existing regulatory structures that apply to these hazards.

(Comment 40) Several comments argue for an approach that includes a broader range of hazards, in light of local, regional or country-wide differences. A number of comments maintain that the rule should apply the principles of the Hazard Analysis and Critical Control Point (HACCP) to identify risks. One comment argues that the general requirement in § 112.11 should apply to all known or reasonably foreseeable hazards. Several comments provide example scenarios where they believe biological, chemical, or physical hazards could represent a significant food safety hazard on a farm. For example, one comment argues that water is a potential source of chemical contaminants so the requirements for water should cover these hazards. Other comments maintain that if a covered farm's land was previously used for another activity that may have contaminated the soil with chemical hazards, the covered farm should be required to take measures (such as collecting and analyzing soil samples for residues) to prevent the introduction of the chemical hazards into or onto produce. Other comments express concern about the use of sewage sludge that can carry a high load of heavy metals and other chemicals (such as drug residues).

(Response) While FDA recognizes that specific scenarios are likely to arise in which physical or chemical (including radiological) hazards present risks of contaminating produce on farms, we conclude that it is not reasonably necessary to establish required controls for such hazards in this rulemaking, in light of the severity and frequency of occurrence of these hazards in produce, and the existing regulatory structures that apply to these hazards. FDA agrees that it

is desirable for individual operations to consider their particular circumstances and address relevant hazards. As discussed in section VII of this document, we believe that one way to do this is through the voluntary use of farm-specific operational assessments and food safety plans. Although we are not requiring that covered farms conduct operational assessments or develop food safety plans, we continue to believe that such assessment can help farms identify and take measures that may be prudent for their individual operations to prevent the introduction of known or reasonably foreseeable hazards, including any non-biological hazards. Implementation of food safety plans that are developed based on operational assessments can help farms to be more proactive and effective in protecting the safety of their produce. We also acknowledge that existing guidances on produce safety, including the GAPs Guide, the Codex Guide, and Industry Harmonized GAPs (Ref. 49) (Ref. 50), all recommend that a farm tailor its food safety practices to the practices and conditions at its individual operation.

Even on a voluntary basis, FDA believes that a full-fledged HACCP approach would not necessarily be appropriate at the farm level because, although there are practices to reduce contamination of produce on the farm, there are typically few critical control points. However, many of the principles of HACCP can still be applied, such as an assessment of risk and the development of a food safety plan based on that assessment.

As discussed previously, we continue to believe that current programs are sufficient to keep these hazards under control. We also emphasize that contamination of produce with physical or chemical (including radiological) hazards will continue to be covered under applicable provisions of the FD&C Act and implementing regulations, and adulterated food may be subject to enforcement action by FDA, as appropriate.

(Comment 41) Citing the increased importance of urban agriculture and urban farming, one comment maintains that FDA failed to consider the contamination of urban properties in the United States with chemical (including radiological) hazards, as well as similar contamination of agricultural lands in other countries used for growing produce, and suggests addressing this issue, at a minimum in guidance.

(Response) We have and will continue to consider agency action, as appropriate, to address the issues associated with risks presented to produce by urban farming, heavy metals, and other non-biological hazards. For example, the GAPs Guide addresses previous land use including animal grazing, chemical application, and toxic spills. In addition, at the request of some foreign audiences, the JIFSAN International GAPs Train-the-Trainer program (Ref. 51) has been updated to include information about the importance of previous land use due to the potential for contamination with both biological and non-biological hazards and a section on EPA requirements for pesticide use.

(Comment 42) One comment notes that while other regulatory and non-regulatory control programs may indirectly control physical and chemical food safety hazards, the fact that those programs are not necessarily intended to deliver food safety outcomes means there may be gaps which a food safety focused regulation may need to address. Another comment states that even though pesticide use does not cause immediate adverse health consequences or death, food safety is still a concern. This comment urges FDA to consider certain research on the public health risk associated with widespread use of commercial pesticides and herbicides built up in our environment, watershed, and food supply. The comment mentions the 2010 report by the President's Cancer Panel and other bodies, which the commenter believes documents growing

evidence on the negative impacts of agricultural chemical use on public health. Other comments express concern over other chemical hazards, such as those used in fields, and state that these chemicals can have harmful effects on both health and the environment.

(Response) That physical or chemical (including radiological) hazards are not addressed in this regulation does not mean that these hazards do not exist or that there is no potential for contamination of produce from these hazards. It also does not mean that these hazards are not included in a comprehensive food safety regulatory strategy. Rather, we believe the frequency and nature of physical and chemical (including radiological) hazards occurring in produce and the existing regulatory programs are such that promulgation of a new regulatory regime is not reasonably necessary to minimize the risk of serious adverse health consequences or death associated with these hazards.

There are effective governmental control programs in place in the United States to assure generally that unlawful pesticide residues are unlikely to occur. For pesticides, these controls include pesticide registration, applicator licensure, and government sampling and enforcement programs. For example, the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136-136y) (FIFRA) authorizes EPA to regulate the use and sale of pesticide to protect human health and to preserve the environment. As part of this evaluation, EPA must ensure with a reasonable certainty that no harm will result from the legal uses of the pesticide. EPA's evaluation considers, among other things, the combined risk from that pesticide from all non-occupational sources (including uses on food), and whether there is an increased sensitivity from exposure of the pesticide to infants and children (Ref. 52). Pesticide tolerances set by EPA are enforced by FDA for most foods and by USDA's Food Safety and Inspection Service (FSIS) for meat, poultry, and some egg products. As mentioned previously, FDA also routinely

monitors for chemicals, pesticide residues, metals and radionuclides through its regulatory monitoring programs, with an emphasis on RACs and foods consumed by infants and children (Ref. 48). Other federal and state programs, too, monitor chemical hazards in food directed at food safety. For example, AMS operates the Pesticide Data Program, which collects and analyzes samples for pesticide residues in food, and data from this program is utilized by USDA, FDA, EPA, and other groups (Ref. 53). Individual States also have programs to routinely monitor for non-microbiological hazards in foods.

With respect to the 2008-2009 President's Cancer Panel "Reducing Environmental Cancer Risk" (Ref. 54), we note that, among other conclusions, the Panel recommends that consumers can reduce exposure to pesticides in food by selecting food grown without pesticides or chemical fertilizers and washing conventionally grown produce to remove residues. This recommendation is consistent with FDA and the Partnership for Food Safety Education advice to consumers that produce should be washed immediately before preparation and consumption (Ref. 38) (Ref. 55).

(Comment 43) One comment points out that a recent United States Government Accountability Office (GAO) report criticized FDA for its lack of pesticide residue testing on food. This commenter asks FDA to adopt better chemical safety standards for produce.

(Response) In October, 2014, the GAO released a report entitled "Food Safety – FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations" (GAO-15-38). In that report, GAO discusses its review of federal oversight of the foods regulated by FDA, FSIS, and AMS, and makes a number of recommendations to further enhance the pesticide monitoring programs of the two agencies. As

noted in that report, FDA has already undertaken certain actions to enhance its program. For example, FDA has increased its monitoring of pesticide residues by taking actions consistent with the GAO recommendations and increased the scope of its testing program. FDA uses AMS's Pesticide Data Program, which generates national statistically-valid data, to target commodities for testing. FDA also has an ongoing effort as part of its pesticide residue monitoring program to evaluate the effectiveness of regulatory actions in preventing violations.

(Comment 44) Some comments maintain certain biological soil amendments contain chemical hazards that FDA should address in this rule. For example, one comment states that animal manure from animal production facilities can contain heavy metals, such as arsenic, zinc, and copper; and animal drug residues, including antibiotics that raise human health concerns. Some comments point out that industry commodity-specific food safety guidelines and the NOP prohibit the use of both raw human waste and biosolids, as these materials present a risk of introducing pharmaceuticals and heavy metals. Some comments also state that research on the risks presented by pharmaceuticals present in produce-growing soils that have been treated with biosolids, and any subsequent uptake into plants, is in its infancy.

(Response) As discussed previously, FDA's analysis of the potential for chemical hazards (including heavy metals and drug residues) to contaminate produce and cause serious adverse health consequences or death, as well as the adequacy of existing regulatory programs to address such potential, did not demonstrate that additional regulation was reasonably necessary. We conclude that it is not reasonably necessary to establish controls for physical or chemical (including radiological) hazards in this rulemaking in light of the severity and frequency of

occurrence of these hazards in produce, and the existing regulatory structures that apply to these hazards. Therefore, we are limiting the scope of this rulemaking to biological hazards.

VII. Comments on Farm-Specific Food Safety Plans

We discussed farm-specific operational assessments and food safety plans in section IV.F of the 2013 proposed produce safety rule. We tentatively decided not to require farms to conduct operational assessments or to develop food safety plans. However, we explained that operational assessments and food safety plans have a prominent place in ensuring produce safety and recommended that farms do so, because this could help farms be more effective in protecting the safety of their produce. We requested comment on whether we should require that some or all covered farms perform operational assessments and/or develop a food safety plan, and any criteria that should be employed to determine which farms should be subjected to such a requirement. After considering comments, we are finalizing this rule as proposed, with no requirement for a covered farm to conduct an operational assessment or to develop a farm-specific food safety plan, although we recommend that farms do so.

(Comment 45) Several comments recommend that FDA require all covered farms to perform operational assessments and/or develop a written food safety plan. These comments state that conducting an assessment of likely hazards that could occur on the farm can help farmers identify potential situations which could lead to contaminated food, helping allocate resources efficiently. Some comments indicate that this requirement is appropriate regardless of the size of an operation or volume of sales and note that many farms already operate using well-developed, monitored, and maintained food safety plans. Some comments also state that operational assessments would also provide inspectors—whether State or federal—with a

mechanism for understanding the particular hazards the farm believes it is mitigating. In addition, some comments maintain that many farms currently develop and use food safety plans under certain industry programs. One comment supports a requirement for a food safety plan, but indicates that the food safety plan should be used as a tool to advance food safety practices rather than as an enforcement tool to determine if a farm is non-compliant.

Conversely, many comments oppose any FDA requirement for farms to develop food safety plans. Although acknowledging that some farms may perform operational assessments or develop food safety plans and farms may benefit from food safety plans, these comments argue that FSMA does not authorize FDA to require farms to perform operational assessments or develop food safety plans. These comments believe that such a requirement established in regulation would be unreasonable; overly burdensome, particularly for small farmers; would decrease the flexibility of the produce safety rule; and may affect current State requirements or industry recommendations. Other comments find a requirement for a farm-specific food safety plan unnecessary because, according to these commenters, FDA has already performed a hazard analysis for most operations by identifying in the produce safety proposed rule the hazards reasonably likely to occur, and communicated that future guidance will include additional information on control measures that operations can use to minimize the likelihood of those hazards affecting produce.

(Response) In our guidances to industry, FDA has previously recommended the use of farm-specific food safety plans. For example, in the GAPs Guide, we stated that the recommendations in that guide would be most effective if farms took them and tailored them to their individual operations (Ref. 14). Since publication of the GAPs Guide, the principle of tailoring practices to an individual operation has evolved into using an operational assessment

and developing an on-farm food safety plan that is specific to that operation, based on the assessment. Food safety plans have become an important component in a number of existing programs and guidances and, as several commenters noted, tools are currently available to fit a variety of operations. FDA's draft commodity-specific guidances, too, include draft recommendations to develop and maintain written food safety plans and standard operating procedures for areas such as handling and storage practices; field, building, and vehicle cleaning and sanitation; and employee training programs (Ref. 56) (Ref. 57) (Ref. 58).

FDA agrees that all farms, irrespective of the size of the operation, the commodities they grow, the practices they follow, or their status with respect to coverage under the produce safety rule, could benefit from performing an operational assessment and having a food safety plan, and we encourage all farms to do so. A site-specific assessment can help a farm tailor practices to their specific operation. We agree that assessments and plans should be commensurate with the size and scope of an operation and that different assessment tools may be best suited for different operations, e.g., by commodity, size, or region.

We continue to believe, however, that requiring covered farms to conduct an operational assessment and develop a food safety plan, particularly at the level required for hazard analysis and development of a food safety plan in our juice HACCP regulation (i.e., the Hazard Analysis and Critical Control Point Systems regulation in 21 CFR part 120) and our seafood HACCP regulation (i.e., the Fish and Fishery Products regulation in 21 CFR part 123), or prescribed by section 418 of FSMA for food facilities, is not warranted as a mandatory requirement for the safe production of covered produce. The statutory direction in section 419 is for FDA to establish science-based minimum standards, including procedures, processes, and practices that are reasonably necessary to prevent introduction of hazards and provide reasonable assurances

produce is not adulterated. As discussed in the 2013 proposed rule, relevant documents on produce safety, such as the GAPs Guide, industry commodity-specific guidelines for melons, tomatoes, leafy greens, and green onions (Ref. 40) (Ref. 59) (Ref. 60) (Ref. 61), the CA LGMA, the AZ LGMA, the Association of Food and Drug Officials' (AFDO) Model Code of Practice for the Production of Fresh Fruits and Vegetables (the AFDO Model Code) (Ref. 62), the Codex Guide, and Industry Harmonized GAPs, all recommend that a farm tailor its food safety practices to the practices and conditions at its individual operation. We believe the most appropriate approach for the produce safety regulation is to establish the standards that are described in part 112. While operational assessments and food safety plans are valuable tools, we believe they may be more than a minimum standard and more than what is reasonably necessary for us to require to achieve the statutory purposes. Therefore, we are not establishing a requirement for farms to conduct operational assessments or to develop food safety plans.

FDA agrees that, in issuing the produce safety regulation, FDA has essentially performed a hazard analysis and established what could be characterized as a baseline or minimum food safety plan for covered farms. We also agree the process of conducting an operational assessment and developing a plan could be a useful exercise to help many farms, whether they are subject to the rule or not, to more closely examine their operations and identify potential risks along with ways those risks might best be reduced. Therefore, we encourage farms to develop a food safety plan.

In response to comments urging education and outreach efforts, FDA notes that the PSA working groups identified operational assessments and food safety plans as being valuable components of an on-farm food safety system and have developed a food safety plan training module as part of their training curriculum. The PSA is also planning an optional 2-day

workshop that can be added to their basic training on the assessment and food safety plan development process. We also acknowledge the efforts of other non-governmental organizations, farm groups, and private businesses that are currently working with farmers on development of food safety plans.

Finally, in response to the comment suggesting that food safety plans should not be used in enforcement, we note that we are recommending, but not requiring, that farms have a food safety plan.

(Comment 46) Some comments suggest that FDA should provide in guidance documents model food safety plans for use by farms that are not covered by the rule or that are eligible for the qualified exemption. Some comments state that they expect the produce safety regulation to lead consumers and commercial buyers to demand that all produce farms are following practices that reduce food safety risks, such that farms that are not required to comply with the rule would be at a disadvantage in the market.

(Response) As discussed previously, FDA continues to recommend operational assessments and food safety plans for all farms, including those not required to comply with the rule, and we intend to address this further in guidance.

(Comment 47) Some comments suggest that FDA should stipulate that farms eligible for the qualified exemption that have food safety plans would have protection from having that exemption revoked. According to these commenters, if these farms receive additional incentives to develop food safety plans, it would help prevent them from creating conditions that could cause their exemption to be revoked, and assist them in defending themselves, should the FDA

determine that a food borne illness was caused by material conduct or conditions linked to their operation. Another comment states that FDA guidance and model food safety plans should encourage farms to record information that would be useful in the event of a challenge to their exemption.

(Response) We encourage the use of food safety plans by all farms, including those that are not covered by the produce safety regulation as well as those that are eligible for a qualified exemption and subject to certain modified requirements. We also refer you to the discussion in section XXIII.A of this document where we discuss the circumstances under which FDA may withdraw a qualified exemption, in accordance with § 112.201. As established in § 112.201(b)(1), before FDA issues an order to withdraw your qualified exemption, FDA may consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction. Although we are not providing any categorical limitation on withdrawal of qualified exemptions based on existence of a food safety plan, we believe that food safety problems are less likely to happen in an operation that has thoughtfully assessed its risks, identified potential hazards, and taken steps to mitigate the hazards identified.

(Comment 48) One comment suggests that the produce safety rule could be structured to allow farms to comply either by following the requirements as proposed or by developing, documenting, implementing, monitoring, and maintaining a food safety plan based on a comprehensive hazard analysis that utilizes the same principles as HACCP in the proposed human preventive controls rule. The commenter explains that, instead of following the prescribed standards, a covered farm would have the option to demonstrate and document the

identification of its risks through its unique hazard analysis, and maintain adequate scientific data or information to support its resultant approach and conclusion that its food safety plan would provide the same level of public health protection as following the set of prescribed rules, similar to the alternative provisions permitted under proposed § 112.12.

(Response) As noted in response to Comment 45, we do not believe requiring covered farms to conduct an operational assessment and develop a farm-specific food safety plan, particularly at the level required for hazard analysis and development of a food safety plan in our juice and seafood HACCP regulations, or prescribed by section 418 of FSMA for food facilities, is warranted to meet the statutory direction in section 419 to establish “minimum science-based standards” for produce safety and “procedures, processes, and practices that the Secretary determines to be reasonably necessary” to meet the statutory goals of preventing introduction of known or reasonably foreseeable hazards and providing reasonable assurances produce is not adulterated.

We agree that an operational assessment and written food safety plan could be useful to a farm to identify whether and how an alternative approach to an FDA-established requirement (as permitted under § 112.12) could be applied to the specific operations at the farm. Note, however, section § 112.12 provides for the use of alternatives for only certain specified requirements of part 112, and not for all of the requirements of part 112. FDA does not agree with the commenter’s suggestion that we should allow covered farms to choose between complying with the requirements of part 112 and conducting an operational assessment and developing a food safety plan based on such assessment. Such an approach would be akin to permitting the use of an alternative to every one of the provisions of part 112, which FDA has determined is not an appropriate approach (we refer you to the discussion in section X.C of this document). The

provisions FDA is establishing in this rule are those that FDA has determined are appropriate to require of all covered farms when they are applicable to the farms' operations. Where FDA believes that alternative approaches may reasonably provide the same level of public health protection, we have provided an option to use an alternative in § 112.12.

(Comment 49) One comment suggests that national and regional crop associations should have the flexibility to add commodity-specific and risk-based standards to FDA-prescribed standards to fit their own crop(s), as necessary. This comment maintains that such an approach would allow farms to continue using commonly accepted food safety practices that they have determined to be the best approach for their crop(s). This comment refers to mandatory food safety and recall plans within a food safety program as examples.

(Response) Part 112 does not prohibit or otherwise preclude covered farms from developing and implementing farm-specific food safety plans, including continued use of food safety plans that may be currently in place, as long as the farms also comply with the provisions of part 112. The provisions for use of alternatives (in accordance with § 112.12) and use of variances (in accordance with subpart P of part 112) provide flexibility for the use of measures that are tailored to specific commodities and conditions, either in addition to the FDA-established science-based minimum standards in part 112, or in lieu of them where allowed under the rule. FDA anticipates that its guidance may also contain additional commodity-, region- and practice-specific, risk-based recommendations, as needed and appropriate, to assist covered farms in following best practices appropriate to their crop(s), region and practices. In developing such guidance, we intend to take existing guidance and produce safety programs into

consideration, similar to our development of draft commodity-specific guidances for melons, tomatoes, and leafy greens.

VIII. Comments Related to Foreign Farms

In the 2013 proposed produce safety rule, we noted that proposed part 112 would apply to foreign farms that meet the criteria to be covered farms and that grow, harvest, pack, or hold covered produce for import into the United States. We also noted our intention to provide equal treatment for foreign and domestic farms and to identify areas for outreach and technical cooperation to help foreign farms understand the rule's applicability to them.

We received a number of comments regarding foreign farms from both domestic and foreign stakeholders that addressed various aspects of the produce safety regulation. For example, comments addressed issues related to coverage of farms (subpart A), personnel training (subpart C), variances (subpart P), and compliance and enforcement (subpart Q), which we considered in the sections of this document where the relevant subparts of part 112 are discussed. In this section, we summarize and respond to comments that address general and cross-cutting issues related to foreign farms.

(Comment 50) Several comments recognize the need to apply the rule equally to domestic and foreign farms that sell produce in the United States market, but believe that the rule may place domestic farmers at an economic disadvantage. These comments argue that enforcement of the regulation will inevitably be more stringent on United States farms than on foreign farms, citing limitations of FDA resources and FDA jurisdiction over foreign farms.

(Response) This rule applies equally to domestically-produced and imported produce. Covered entities in the United States and abroad must adhere to the same standards. As such, we do not agree that it will disadvantage United States farms as compared to foreign farms.

With respect to enforcement, FDA intends to use the resources at its disposal to ensure that both domestic and foreign producers are following the requirements of the rule. As discussed in section XXII of this document, our strategy to ensure the safety of produce, both domestically- produced and originating from foreign farms, will focus on education, training, and guidance to achieve compliance. This will include outreach to foreign governments. We will also work to provide education and assistance in local languages to reach farmers exporting covered produce into the United States, including by working with organizations and other sources of information that are familiar and accessible to the produce farming community (such as alliances, international organizations, universities, trade associations, foreign partners, JIFSAN, and federal agencies (such as USAID and USDA), among others).

Inspections will also play a key role. Under the FD&C Act, FDA has authority to inspect produce farms and can take enforcement action when needed, such as to prevent significant hazards from entering the food supply or in response to produce safety problems. While FDA is not in a position to inspect every foreign farm that produces food for consumption in the United States, the inspections FDA is able to conduct will be bolstered by other efforts, such as the final FSVP rule establishing subpart L of 21 CFR part 1 (hereafter referred to as “the FSVP regulation”) (published elsewhere in this issue of the Federal Register). The FSVP regulation establishes requirements for importers to verify that imported food (including produce) is produced in compliance with FDA food safety regulations (including the produce safety

regulation) or is produced in accordance with processes and procedures that ensure the same level of public health protection as is required in the United States.

(Comment 51) Several comments stress the importance of publishing the Produce Safety rule concurrently with the import-related FSMA rules, such as the FSVP and third-party certification rules, in order to ensure consistent regulation of domestic and imported produce.

(Response) In finalizing this rule, FDA has considered issues related to the FSVP and third-party certification rules. Section 301 of FSMA directs us to establish foreign supplier verification programs for importers of food. In addition, section 307 of FSMA directs us to establish a system for the recognition of accreditation bodies that accredit third-party auditors to certify that eligible entities meet certain requirements. In the rulemakings establishing the FSVP regulation and the third-party certification regulation, published elsewhere in this issue of the Federal Register, FDA explained how the supplier verification requirements and third-party certification requirements in those rules relate to farms that are subject to the produce safety regulation and those that are not subject to the produce safety regulation.

(Comment 52) Several comments argue that the requirements of the rule will disadvantage foreign farms as compared to domestic farms. Some of these comments argue that the rule is too prescriptive and suggest that greater flexibility could be achieved by allowing foreign farms to make their own choices about what methods and tools are necessary to ensure food safety. These comments also note that foreign authorities have a role in enforcing their own requirements regarding food safety practices. One comment recommends that FDA not establish any requirements related to foreign farms' production practices. Instead, the comment asserts

that FDA should only verify whether articles of produce themselves comply with the FD&C Act, and should only check the compliance of produce from farms with a history of non-compliance.

(Response) This rule applies equally to domestically-produced and imported produce. Covered entities in the United States and abroad must adhere to the same standards. As such, we do not agree that it will disadvantage foreign farms as compared to domestic farms. The risks from imported and domestic produce arise from the same or similar pathogens and routes of contamination. Therefore, the requirements that we are establishing in part 112 apply equally to these concerns wherever they arise.

We also disagree with comments that suggest that the rule is too prescriptive. We have incorporated significant flexibility into our requirements, wherever appropriate, by relying on an integrated approach that employs various mechanisms (for example, current good manufacturing practices, numerical criteria, and monitoring) as appropriate to the hazards. This provides sufficient flexibility to allow all covered farms, both foreign and domestic, to determine the methods and tools necessary to produce safe food as appropriate, taking into account the specific practices, procedures, and processes in their individual farm operations. We have also provided additional flexibility by permitting a foreign government to request from FDA a variance from any one or more of the requirements in part 112, under certain conditions as described in subpart P of part 112.

Neither FDA, generally, nor this rule, specifically, imposes any restrictions on foreign governments from establishing or enforcing their own requirements within their sovereign nations. This rule covers produce RACs that are grown domestically and produce RACs that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. This includes produce RACs that are grown

domestically for export to foreign countries. To the extent a foreign covered farm exports covered produce to the United States, such farm must ensure that its production of such produce complies with all applicable requirements of part 112. Conversely, the requirements of part 112 do not apply to produce that is grown, harvested, packed, or held on a foreign farm that is not exported to the United States.

Finally, with respect to the comment about focusing on the produce commodity, itself, rather than on production practices, we refer you to the discussion in section IV.I of the 2013 proposed rule and section III.F of this document, where we explain our conclusion that product testing requirements (except under certain circumstances for sprouts) would be impracticable. We also refer you to the discussion on commodity-specific approaches in section IV.A of this document.

(Comment 53) Several comments argue that requiring foreign farms to adhere to the rule will cause them to incur considerable costs and restrict farms from engaging in trade with the United States. Some of these comments specifically state that the rule should not impose requirements that would act as barriers to trade in conflict with United States trade obligations.

(Response) This rule is fully consistent with United States trade obligations. In developing the produce safety standards in part 112, and in formulating our implementation strategy (as described under subpart Q of part 112), we considered United States trade obligations to ensure that the final rule is based on risk and on science, and we are applying the same standards to imported and domestic food to ensure the safety of the United States food supply.

(Comment 54) Some comments argue that imported produce should be more closely monitored than domestically-grown produce. Some of these commenters believe that applying additional oversight to imported produce may decrease the number of contamination events and illnesses occurring in the United States.

(Response) This rule covers produce RACs that are grown domestically and produce RACs that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. This includes produce RACs that are grown domestically for export to foreign countries. We are not aware of evidence indicating that imported produce contributes a disproportionately higher risk of illness to United States consumers compared to domestically-grown produce. We expect that compliance with the standards in part 112 will reduce the risk of foodborne illness associated with the consumption of contaminated produce, whether domestic or imported.

(Comment 55) One comment asks FDA to clarify the applicability of the rule to a foreign farm that harvests produce and ships it to the United States in non-consumer containers, where the produce is subsequently packaged in retail containers sold to the public.

(Response) In this example, neither the foreign location of the farm nor the packaging/repackaging that occurs in the United States affects the status of the foreign farm or its produce under this rule. Assuming that the foreign farm is a covered farm, and the produce is covered produce, the farm and its produce are subject to this rule.

(Comment 56) Many comments express the need for FDA to engage foreign governments to help them understand what is expected of foreign farms under this rule. One comment states

that FDA should provide training and capacity building programs for foreign governments.

Another comment requests that FDA provide translations of the regulation as well as accompanying guidance documents in order to facilitate understanding by both foreign governments and foreign farms, and compliance by foreign farms.

(Response) As noted previously, education, training, and guidance will be key components of our strategy to achieve compliance with the produce safety regulation, both for domestic and imported produce. Specifically, we recognize that some foreign farms may have difficulty understanding the applicability of the rule to them, and we will work with new and existing partners to identify areas for international outreach and technical cooperation to achieve greater understanding. Moreover, section 305 of FSMA directs FDA to develop a plan to build the capacity of foreign governments with respect to food safety. Leveraging and partnerships are important in everything FDA does, and even more so with capacity building. FDA recognizes the importance of establishing strong relationships and mutual support among all stakeholders from farm to table. We will also work to provide education and assistance in local languages to reach farmers exporting covered produce into the United States, and will work with organizations and other sources of information that are familiar and accessible to the produce farming community (such the Alliances, international organizations, universities, trade associations, foreign partners, JIFSAN, and federal agencies (such as USAID and USDA), among others). We will work with partners to provide technical assistance to the farming community, especially small and very small farms, regarding compliance with this rule. We also intend to disseminate guidance documents in multiple languages.

IX. Subpart A – Comments on Definitions and General Provisions

In proposed subpart A of part 112, we proposed to establish provisions that establish the scope of, and definitions applicable to, this regulation, and which identify who and what is subject to the requirements of this part. As proposed, this subpart also described the criteria for eligibility for qualified exemptions, and modified requirements for those eligible for a qualified exemption from this rule. We asked for comment on all provisions in subpart A.

We are finalizing these provisions with revisions (see Table 4). We discuss these changes in this section.

Table 4.-- Description of Revisions to Subpart A

Final Provision	Description of Revisions
§ 112.1(b)(1)	- Revisions to the list of examples of fruits and vegetables
§ 112.2(a)(1) – exhaustive list of rarely consumed raw produce	- Revisions to the list of exempt commodities based on our updated robust analysis using more recent data and information, and considering public comments
§ 112.2(b) – produce that receives commercial processing	- Addition of wine and beer as examples in § 112.2(b)(1) - New provisions § 112.2(b)(2), (3), and (4) to require certain disclosure and documentation, and annually obtain certain written assurances - New provision § 112.2(b)(6) related to entities that provide the written assurances described in § 112.2(b)(3)(i) or (ii)
§ 112.3(b) – Definition of “small business” and “very small business”	- Revision to acknowledge that such businesses may be subject to only some requirements of part 112 if the farm is also eligible for qualified exemption.
§ 112.3(c) – Definition of “agricultural tea”	- Revision to add “Agricultural teas are soil amendments for purposes of this rule” - Revision to replace “humus” with “stabilized compost” - Revision to specify that agricultural teas are soil amendments for the purposes of this rule
§ 112.3(c) – Definition of “biological soil amendment”	- Revision to replace “humus” with “stabilized compost”
§ 112.3(c) – Definition of “biological soil amendment of animal origin”	- Revision to add animal mortalities as an example
§ 112.3(c) – Definition of “composting”	- Revision to replace “humus” with “stabilized compost”
§ 112.3(c) – Definition of “covered activity”	- Revision to reflect new § 112.2(b)(6) by adding “Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in section 112.2(b) of this part are also covered activities.”

§ 112.3(c) – Definition of “curing”	<ul style="list-style-type: none"> - Revision to replace “maturation” with “final” - Revision to add “Curing may or may not involve insulation, depending on environmental conditions.”
§ 112.3(c) – Definition of “farm”	<ul style="list-style-type: none"> - Revision consistent with changes made in PCHF regulation
§ 112.3(c) – Definition of “ground water”	<ul style="list-style-type: none"> - New definition of “ground water” added, with corresponding changes to definition of “surface water”
§ 112.3(c) – Definition of “growth media”	<ul style="list-style-type: none"> - Revision to replace “humus” with “stabilized compost”
§ 112.3(c) – Definition of “harvesting”	<ul style="list-style-type: none"> - Revision consistent with changes made in PCHF regulation
§ 112.3(c) – Definition of “hazard”	<ul style="list-style-type: none"> - Revision to more clearly distinguish “hazard” from “known or reasonably foreseeable hazard” by replacing “is reasonably likely to” with “has the potential to”
§ 112.3(c) – Definition of “holding”	<ul style="list-style-type: none"> - Revision consistent with changes made in PCHF regulation
§ 112.3(c) – Definition of “known or reasonably foreseeable hazard”	<ul style="list-style-type: none"> - Replacing the term “reasonably foreseeable hazard” with “known or reasonably foreseeable hazard” - Revision to more clearly distinguish this term from “hazard” - Revision to specify that for the purposes of this rule, such hazards are biological
§ 112.3(c) – Definition of “manufacturing/processing”	<ul style="list-style-type: none"> - Revision consistent with changes made in PCHF regulation
§ 112.3(c) – Definition of “mixed-type facility”	<ul style="list-style-type: none"> - Revision consistent with changes made in PCHF regulation
§ 112.3(c) – Definition of “monitor”	<ul style="list-style-type: none"> - Revision to replace the phrase “when applicable” with “when required”
§ 112.3(c) – Definition of “non-fecal animal byproduct”	<ul style="list-style-type: none"> - Revision to replace “other than excreta” with “other than manure”
§ 112.3(c) – Definition of “packaging” (when used as a verb)	<ul style="list-style-type: none"> - Deleted consistent with changes made in PCHF regulation
§ 112.3(c) – Definition of “packing”	<ul style="list-style-type: none"> - Revision consistent with changes made in PCHF regulation
§ 112.3(c) – Definition of “produce”	<ul style="list-style-type: none"> - Revision to add “primarily” before “grown and processed for use as meal, flour, baked goods, cereals and oils” in description of grains - Revision to replace “fresh consumption” in description of grains with “direct consumption as small, hard fruits or seeds” - Revision to include “oilseeds” as an example of grains, and to include flax seed, rapeseed, and sunflower seed as more specific examples - Revision to add commas
§ 112.3(c) – Definition of “qualified end-user”	<ul style="list-style-type: none"> - Revision to add “or the same Indian reservation” - Revision to move “The term ‘consumer’ does not include a business” from under (ii) into a parenthetical phrase within the definition
§ 112.3(c) – Definition of	<ul style="list-style-type: none"> - Revision to refer to adequately treating “surfaces”

“sanitize”	rather than “food-contact surfaces,” consistent with changes made in PCHF regulation
§ 112.3(c) – Definition of “stabilized compost”	- Revision to use the term “stabilized compost” rather than proposed term “humus” to better reflect the finished product of composting
§ 112.3(c) – Definition of “soil amendment”	- Revision to replace “humus” with “stabilized compost”
§ 112.3(c) – Definition of “static composting”	- Revision to replace “covered with at least 6 inches of insulating material” with “that may or may not be covered with insulating material” - Revision to replace “humus” with “stabilized compost”
§ 112.3(c) – Definition of “surface water”	- Revision corresponding to new definition of “ground water,” to clarify the differences between the two sources
§ 112.3(c) – Definition of “turned composting”	- Revision to replace “humus” with “stabilized compost”
§ 112.3(c) – Definition of “visitor”	- New definition of “visitor” added, with corresponding deletion of proposed definition that previously appeared in § 112.33(a) (content of final definition is unchanged)
§ 112.3(c) – Definition of “you”	- Revision to clarify that “you” as used in this part “means the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of part 112”
§ 112.4	- Revision to adjust the monetary threshold for inflation - Revision to reflect revised definition of “you”
§ 112.5	- Revision to reflect revised definition of “you”
§ 112.6	- Revision to add subpart O (Records) to the list of subparts applicable to farms eligible for the qualified exemption, corresponding to addition of new records provision in § 112.7 - Revision to clarify which other subparts of part 112 are applicable to farms eligible for the qualified exemption - Revision to reflect revised definition of “you”
§ 112.7	- New provision to establish certain recordkeeping requirements in relation to qualified exemption

A. Food That is Covered and That is Not Covered (§§ 112.1 and 112.2, and Definition of “Produce” in § 112.3(c))

1. Definition of “Produce” (§ 112.3(c)) and Food That is Covered (§ 112.1)

We are finalizing our definition of “produce” with certain changes discussed in the paragraphs that follow, and editorial changes (adding commas). We note that the definitions of “produce,” “fruit,” and “vegetable” in this rule are applicable for the purposes of this rule. FDA

has used different definitions of “fruit” and “vegetable” in certain other contexts and continues to do so. For example, see 65 FR 54686 at 54687 (September 8, 2000) (“Although seeds are clearly part of the plant kingdom, they are not ordinarily thought of as vegetables. Therefore, FDA is concerned that the term ‘vegetable oil sterol esters’ may not be understood to cover esterified sterols from sources like canola oil”); see also discussion of “vegetable” in Draft Guidance for Industry: Ingredients Declared as Evaporated Cane Juice (“the agency considers the term “vegetable” in the context of the juice definition to refer more narrowly to edible plant parts that consumers are accustomed to eating as vegetables in their diet”) (Ref. 63).

(Comment 57) Some comments state that we should not consider peanuts or tree nuts to be “produce” for the purposes of this regulation. In support of this argument, one comment states that there are controls in place to limit the level of aflatoxin in nuts.

(Response) These comments did not provide us with information from which to conclude that we should change our view of whether peanuts or tree nuts are “produce” within the definition in the rule. As explained in the 2013 proposed rule, the dictionary definitions of “peanut” and “nut” are consistent with our definition of “produce,” the industry appears to recognize peanuts and tree nuts as produce, and the biological hazards and controls relevant to minimizing serious adverse health consequences or death during the growing, harvesting, packing, and holding of peanuts and tree nuts are generally similar to those for other produce, including the shared hazard of pathogens. Aflatoxin, a mycotoxin, is a chemical hazard rather than a biological hazard. In section VI of this document, we discuss this rule’s focus on biological hazards. Because this rule focuses only on biological hazards and controls relevant to biological hazards, mycotoxin risk is not relevant to determining whether peanuts or tree nuts

should be considered to be “produce” for the purposes of this rule. Determining that peanuts and tree nuts are “produce” is only the first step in determining whether a particular type of nut, or a particular lot of nuts, is subject to the rule. Some types of nuts are not covered by the rule because they are rarely consumed raw. Cashews, hazelnuts, peanuts, and pecans are listed in § 112.2(a)(1) and are therefore not covered by this rule. We also expect that some nuts will be exempt from this rule (with appropriate documentation) because they receive commercial processing that adequately reduces the presence of microorganisms of public health significance under § 112.2(b).

(Comment 58) Some comments ask whether “produce” includes food grains, algae, dry legumes, and food crops used in the production of spices, dietary ingredients, or food additives. Some comments express diverse views and disagree on whether oilseeds (such as sunflower seeds) should be considered “covered produce”.

(Response) As explained in the 2013 proposed rule, for the purposes of part 112, the definition of “produce” does not include food grains. We explicitly excluded grains from our proposed definition of produce, which stated, “Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, and soybeans.” We are aware that there are some commodities, such as sunflower and flax seeds, soybeans, black-eyed peas, and chickpeas, that are both processed for use in other forms (such as oil or flour) and consumed

directly as small hard fruits or seeds. For example, sunflower seeds can be processed into oil or consumed directly as sunflower seeds. When used for direct consumption as hard fruits or seeds, these commodities typically receive some commercial processing that adequately reduces pathogens, such as roasting, before they are consumed and, therefore, these commodities are not likely to present the hazards or the level of risk that warrants applying the standards of this rule even though they may have some uses other than as grains. We are revising the grains definition to clarify that such commodities are grains if they are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption. In response to comments, and to provide clarity, we are revising the definition of “produce” to include “oilseeds” generally as an example, and to provide flaxseed, rapeseed, and sunflower seed as additional examples of grains. We are also replacing the term “fresh consumption” in this portion of the definition with “direct consumption as small, hard fruits or seeds” for clarity. As revised, this part of the definition states, “Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).”

As defined, the term “produce” includes fruits (the harvestable or harvested part of a plant developed from a flower) and vegetables (harvested part of any plant or fungus), which by definition does not include algae. Algae are organisms that were at one time classified as plants due to having chlorophyll and other pigments, but now, with the exception of blue-green

algae (which are considered to be bacteria, of the kingdom Monera), are regarded as belonging in the kingdom Protista for possessing cellular features not found among plants and animals and for their lack of true stems, roots, and leaves (Ref. 64). Algae do not form a distinct phylogenetic group, but include widely varying green, brown, and red organisms that grow mostly in water, and can range in size from single cells to large spreading masses. Algae are a major component of marine plankton and can also be seen as pond scum or as blooms in tidal pools (Ref. 65). In addition, algae are not all closely related, and do not form a single evolutionary lineage devoid of other organisms, which makes classification challenging. As an example, the blue-green algae, also known as cyanobacteria, are generally considered to be bacteria (Ref. 66) , but because blue-greens are aquatic and possess photosynthetic pigments like seaweeds, they are still called algae (Ref. 67). We do not consider algae to be “produce” within the scope of this rule. However, algae that are used as “food” will continue to be covered under the FD&C Act and applicable implementing regulations. As appropriate, we may consider issuing guidance on the topic of algae production for human food use in the future.

Legumes are a group of commodities rather than a single commodity. For example, peanuts, beans (such as lima beans, white pea beans, and great Northern beans) and lentils (such as green lentils, yellow lentils, and brown lentils) are all legumes. Many legumes fall within our definition of “produce” but also meet the criteria for produce that is rarely consumed raw, and are therefore not subject to this rule under § 112.2(a)(1).

For example, as discussed in the 2013 proposed rule, we consider that peanuts fit within the definition of produce (78 FR 3504 at 3536). However, peanuts are rarely consumed raw and are therefore not subject to this rule under § 112.2(a)(1).

As another example, we consider beans to fit within the definition of produce. Beans are typically sold in both a “fresh” and a dried form and the drying in these cases creates a distinct commodity. The fresh beans are produce RACs (rather than processed foods) and are subject to this rule except where an exemption applies. Some types of fresh beans are not subject to this rule because they fit the criteria for produce that is rarely consumed raw, and are therefore exempt under § 112.2(a)(1) (e.g., black beans, great Northern beans, and kidney beans are exempt). Other types of fresh beans (for example, broad beans, cowpea beans, and pink beans) do not meet the criteria for rarely consumed raw and therefore are covered produce except where another exemption applies. We understand that many beans receive commercial processing that adequately reduces the presence of microorganisms of public health significance, such that in many cases, beans that are not exempt from this rule as rarely consumed raw may be eligible for the exemption in § 112.2(b). In addition, dried beans are distinct commodities from fresh beans and are therefore processed foods. Processed foods are not subject to this rule (see § 112.2(a)(3)), such that once beans subject to this rule are dried/dehydrated, they are no longer subject to this rule.

We also consider that lentils fit within the definition of produce. Lentils are the edible part of an herbaceous plant grown for an edible part, and are the harvestable or harvested part of the plant. Lentils are “small, hard fruits or seeds of arable crops” (the first part of the definition of grains), but because they are not primarily grown and processed for use as “meal, flour, baked goods, cereals and oils” rather than for direct consumption (Ref. 68), they are not “grains” as we have defined that term, and therefore they are produce. However, lentils are rarely consumed raw and are therefore not subject to this rule under § 112.2(a)(1).

The definition of “produce” in § 112.3 and the provisions for produce that is not

covered under this rule in § 112.2(a) apply regardless of whether that produce is used in other finished foods. Produce that is covered under this rule is eligible for exemption if it receives commercial processing that adequately reduces the presence of microorganisms of public health significance (§ 112.2(b)). Produce that is used in the production of spices, ingredients of dietary supplements, or food additives, to the extent it is covered produce (i.e., it is not excluded under § 112.2(a)), may be eligible for exemption under § 112.2(b) if it meets the criteria set forth in that section. Such produce is not exempt by virtue of its use in spices, dietary supplements, or food additives; such produce may be exempt only if it meets the criteria in § 112.2(b) (i.e., it receives commercial processing that adequately reduces the presence of microorganisms of public health significance and the covered farm takes the required steps set forth in that section). As discussed previously, processed foods are not subject to this rule (see § 112.2(a)(3)), such that once produce RACs subject to this rule are made into processed foods, those processed foods are not subject to this rule.

(Comment 59) Some comments ask whether edible flowers that are consumed raw are considered “covered produce.”

(Response) Within the definition of produce, we define a “vegetable” as the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Edible flowers fit within our definition of “produce” and when reasonably expected to be directed to a food use, unless otherwise exempt under other

provisions of subpart A, they are covered produce subject to the requirements of this rule.

(Comment 60) One comment questions whether FDA intends to apply the rule to farms that export their produce to foreign countries.

(Response) Section 112.1(a) explains that the rule covers produce RACs that are grown domestically and produce RACs that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. This includes produce RACs that are grown domestically for export to foreign countries.

2. Produce That is Covered and Not Covered (§ 112.2)

(Comment 61) One comment states that the proposed produce safety rule should apply to all fruit and vegetable commodities, and opposes all of the exemptions we proposed in § 112.2. This comment argues that people are consuming more fruits and vegetables to maintain a healthier diet, and thus all fruit and vegetables should be subject to the same preventive safety requirements.

(Response) We disagree. FSMA mandates that FDA set risk-based standards to ensure the safety of produce. In §§ 112.2(a)(1) and 112.2(b), we exempt, or make eligible for exemption, produce that pose little to no risk of foodborne illness, either because it is rarely consumed raw (§ 112.2(a)(1)) (see section IX.A.3 of this document) or because it receives commercial processing that adequately reduces the presence of pathogens (§ 112.2(b)). We conclude that it is not reasonably necessary to apply the requirements of the rule to such produce to minimize the risk of serious adverse health consequences or death or to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. In

addition, we exempt produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management (§ 112.2(a)(2)), and produce that is not a raw agricultural commodity (§ 112.2(a)(3)). These exemptions are consistent with sections 419(g) and 419(a)(1)(A), respectively, of the FD&C Act. We note, however, that produce exempt from this rule under § 112.2 is and will continue to be covered under the adulteration provisions and other applicable provisions of the FD&C Act and applicable implementing regulations, irrespective of whether it is included within the scope of the produce safety regulation.

3. Produce That is Exempt Because It is Rarely Consumed Raw (§ 112.2(a)(1))

(Comment 62) Some comments oppose exempting produce commodities based on the produce being rarely consumed raw. One such comment argues that the public has an expectation that FDA will oversee and regulate all fruits and vegetables. This comment suggests that an appropriate approach would be to provide regulatory oversight combined with guidance documents addressing specific variability applicable to different fruits and vegetables, which in the view of this comment, would be similar to the seafood HACCP regulation. Other comments point out that rarely consumed raw produce may still cause food safety problems. One commenter explains that food safety begins with agricultural growing practices and continues through the supply chain to the consumer, and believes that exemption of produce rarely consumed raw would ignore the issue of potential cross-contamination at retail and during food preparation by consumers. Another commenter suggests that any produce exempt as rarely consumed raw should be required to undergo a processing step that adequately reduces the presence of microorganisms of public health concern.

(Response) As discussed in section IV.A.2.a of the 2013 proposed rule, we are exempting produce that is “rarely consumed raw” from the requirements of part 112 because such fruits and vegetables are almost always consumed only after being cooked, which is a kill-step that can be expected to adequately reduce the presence of microorganisms of public health significance in most cases. Studies have shown that the numbers of microorganisms of public health significance (such as L. monocytogenes, Salmonella, STEC) are significantly reduced in produce by a variety of relatively moderate heat treatments (Ref. 69) (Ref. 70) (Ref. 71) (Ref. 72). Therefore, cooking that produce receives before it is consumed, whether commercially or by the consumer, can be expected to reduce the risk of serious adverse health consequences or death associated with commodities that are rarely consumed raw. As a result, FDA concludes it is not reasonably necessary to subject such commodities to requirements under this rule, or in the alternative to require such commodities to undergo a processing step to adequately reduce pathogens.

We are not aware of any information or scientific data suggesting that cross-contamination at retail or during food preparation in the home represent a significant concern for any of the commodities that we are identifying as “rarely consumed raw” produce. The 2013 FDA Model Food Code includes provisions (e.g., 3-302.11) designed to protect food against cross-contamination in retail settings.

We also note that rarely consumed raw produce commodities that are exempt from this rule under § 112.2(a)(1) are and will continue to be covered under the adulteration provisions and other applicable provisions of the FD&C Act and applicable implementing regulations, irrespective of whether they are included within the scope of this rule.

(Comment 63) One commenter suggests revising the rarely consumed raw exemption so that it would be invalidated for a specific farm if that farm's otherwise rarely consumed raw produce were marketed for fresh consumption.

(Response) We are not adopting this approach. The § 112.2(a)(1) exemption from the requirements of part 112 is based on our finding that commodities that are almost always consumed only after being cooked constitute very low to no risk with respect to biological hazards (see Ref. 29) and, therefore, it is not reasonably necessary to apply the standards established in part 112 to these commodities. This determination applies without regard to the manner in which such commodities may be marketed. Such commodities are and will continue to be covered under the adulteration provisions and other applicable provisions of the FD&C Act and applicable implementing regulations, irrespective of whether they are included within the scope of this rule. Manufacturers and producers of food, including produce, for human consumption have the responsibility to ensure the safety of their food.

(Comment 64) Some comments, while not opposed to exempting certain produce commodities rarely consumed raw, disagree with FDA establishing an exhaustive list of such exempted produce. Multiple comments express a preference for guidance documents to indicate to industry which foods FDA considers to be rarely consumed raw and therefore exempt from the rule. These commenters argue that such an approach would be preferable because it would allow the exemption to reflect new data and changes in dietary habits without requiring FDA to conduct rulemaking to update an exhaustive list.

(Response) We considered and rejected the possibility of providing a list of rarely consumed raw commodities in guidance without establishing any specific criteria for what

“rarely consumed raw” means in the regulation, because such an approach would present significant challenges for compliance and enforcement. For example, such an approach would require covered farms to implement the standards in part 112 without FDA clearly identifying in the rule itself whether and which of the farm’s commodities would be subject to those standards. We also considered providing a list of rarely consumed raw commodities in guidance with accompanying underlying quantitative criteria listed in the regulation. We rejected this approach because it, too, would not be adequate for the purposes of clarity of coverage and could present challenges for compliance and enforcement. The complexity of the analysis (see Ref. 73) necessary to obtain consumption patterns that consistently and adequately represent consumption among consumers across the United States does not make this a viable approach. Therefore, we are adopting the proposed approach, in which we explicitly provide an exhaustive list of rarely consumed raw commodities within § 112.2(a)(1). However, we are revising our proposed list based on an analysis of more recent data and taking into account comments received. Moreover, we intend to consider updating the list of rarely consumed raw commodities in the future as appropriate, such as if new data become available.

Section 112.2(a)(1) provides an exhaustive list of produce that is rarely consumed raw and is, therefore, exempt from coverage under this rule. We conclude these commodities are predominantly eaten cooked by most consumers across the United States at this time. The identification of a commodity on this list does not mean that the produce is never eaten raw or that it is not eaten raw, typically or occasionally, in specific regions of the United States (or among specific ethnic communities in the United States). This list also does not reflect the form in which these commodities are consumed by populations in other countries, where the produce may be grown and/or from which the produce may be imported into the United States.

Furthermore, our analysis underlying the development of this list reflects dietary intake information that consumers across the United States reported in a national survey. The most recent of these data that are currently available show consumption that was reported only as recently as 2010, but not consumption as it occurs today. Therefore, this list may not necessarily reflect or fully reflect current or emerging patterns of forms in which produce is consumed or new dietary trends toward consumption of raw foods.

As revised, § 112.2(a)(1) lists the following produce as rarely consumed raw among United States consumers: asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

For this final rule, we conducted an updated analysis of dietary consumption of produce in the United States to identify those produce RACs that we consider to be rarely consumed raw. We evaluated food consumption data available in the National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA) database, specifically the datasets available from the 2003-2010 NHANES/WWEIA surveys (Ref. 74). By comparison, in the 2013 proposed rule, we were using the datasets available from the 1999-2006 NHANES/WWEIA surveys (Ref. 75). In addition, in both this final rule and the 2013 proposed rule, we used the Food Commodity Intake Database (FCID) (Ref. 76), developed by the EPA's Office of Pesticide Programs, to identify proportions of produce (as that term is defined for purposes of this rule) present as ingredients in foods/food categories listed in the NHANES/WWEIA datasets. Moreover, where NHANES/WWEIA datasets provide the necessary data, we made additional

modifications to our analysis compared to the analysis described in the 2013 proposed rule to provide a more robust evaluation of consumption in the United States. For example, in our updated analysis, we evaluated all produce commodities included in FCID as applied to the NHANES/WWEIA surveys rather than just a subset of the FCID commodities. In our updated analysis, we characterized each eating occasion based on meals and snacks reported by survey respondents (e.g., breakfast, brunch, lunch, dinner, supper, snacks) such that each snack is considered a separate eating occasion. In our updated analysis, we also considered consumption based on both one-day dietary intakes and 2-day dietary intakes reported by survey respondents in the NHANES/WWEIA datasets.

In addition, we added a third element to the set of criteria we applied to determine whether a commodity is rarely consumed raw. In the 2013 proposed rule, we applied two criteria, i.e., the commodity is consumed uncooked by less than 0.1 percent of population and it is consumed uncooked on less than 0.1 percent of eating occasions. As mentioned above, we considered these two criteria together, and for the final analysis we considered that these two criteria were satisfied for a commodity if either the 1-day dietary intake data, the 2-day dietary intake data, or both met both criteria. For the final analysis, we also added a third criterion, i.e., we identified those commodities for which consumption (in any form – raw, processed, or other) was reported by at least 1 percent of weighted number of survey respondents. We added this threshold in response to comments and anecdotal evidence suggesting that our proposed criteria were not sufficiently robust because they resulted in exemptions for several commodities that seem likely to be consumed raw with significant frequency. For example, kale, which we proposed to exempt, was identified by many commenters as being regularly consumed raw. This is reflected in the inclusion of raw kale in popular restaurant dishes (Ref. 77) (Ref. 78) (Ref. 79);

recipes from nationally-recognized chefs (Ref. 80) (Ref. 81); and reports in public media (Ref. 82) (Ref. 83) (Ref. 84) (Ref. 85) (Ref. 86) (Ref. 87). To improve the robustness of our analysis and to ensure that our conclusions that commodities are rarely consumed raw are sufficiently reliable to justify removing those commodities from the rule's coverage, we concluded that we should add another criterion to the analysis. We concluded that where fewer than 1 percent of the weighted number of survey respondents reported consuming the commodity in any form, we did not have sufficient data to provide a reasonable representation of how the commodity is consumed in the U.S. for the purposes of exempting commodities from the coverage of this rule. Thus, in addition to meeting the criteria we originally proposed, at least 1 percent of the weighted number of survey respondents over the eight year timespan of the NHANES/WWEIA surveys must have reported consuming the commodity (all forms, taken together, excluding juice/juice drinks) for us to conclude that the commodity is rarely consumed raw and should therefore be exempt from this rule. Accordingly, for all commodities meeting the first two criteria, we also analyzed whether the commodity's 2-day consumption number "N" was equal to or greater than 2,938,915 ($293,891,529 \times 0.01$), whether its 1-day consumption number "N" was equal to or greater than 2,938,517 ($293,851,741 \times 0.01$), or both. Our analysis is described in greater detail in an accompanying memo to the record (Ref. 73).

Based on our analysis of the NHANES/WWEIA datasets, we identified a list of produce commodities that we consider to be rarely consumed raw, applying the revised criteria. First, there are the commodities for which quantitative data about uncooked consumption is available and that meet three numerical thresholds either in the one-day reported intakes, 2-day reported intakes, or both, based on FCID analyses of NHANES/WWEIA datasets, i.e., at least 1 percent of weighted number of survey respondents having reported consuming the commodity in any

form; commodities consumed uncooked by less than 0.1 percent of the United States population; and commodities consumed uncooked on less than 0.1 percent of eating occasions. See column 1 of Table 5.

Second, there are commodities included in the NHANES/WWEIA datasets for which categories of reported consumption in the NHANES/WWEIA surveys do not include an “uncooked” food form. We conclude that such commodities may also be reasonably considered to fall beneath the numerical thresholds of being consumed uncooked by less than 0.1 percent of the United States population and consumed uncooked on less than 0.1 percent of eating occasions because lack of an “uncooked” reported food form indicates that they were not consumed uncooked in any measurable quantity. To such commodities, we applied the new numerical threshold, i.e., at least 1 percent of weighted number of survey respondents must have reported consuming the commodity in any form for the data to provide a reasonable representation of how that commodity is consumed by U.S. consumers. See column 2 of Table 5.

Third, the consumption of certain produce RACs is reported in the NHANES/WWEIA not as RACs, but only in the form of certain processed foods. For example, coffee beans are only reported consumed in beverage form as coffee; and cocoa beans are only reported consumed as cocoa beverage, chocolate beverage, chocolate, or related products. We conclude that these commodities are rarely consumed raw when the only forms in which they are reported in the NHANES/WWEIA surveys indicates they were cooked as part of the process of being made into the identified processed foods, and therefore we infer that they fall beneath the numerical thresholds of being consumed uncooked by less than 0.1 percent of the United States population and consumed uncooked on less than 0.1 percent of eating occasions because they were not consumed uncooked in any measurable quantity. To such commodities, we applied the new

numerical threshold, i.e., at least 1 percent of weighted number of survey respondents must have reported consuming the commodity in any form for the data to provide a reasonable representation of how that commodity is consumed by U.S. consumers. We are therefore adding them to the list of rarely consumed raw produce in § 112.2(a)(1). See column 3 of Table 5.

Table 5.-- List of Produce That Are Rarely Consumed Raw in the United States (Based on an Analysis of the National Health and Nutrition Examination Survey/What We Eat in America Survey Datasets Using the Food Commodity Intake Database).

“Complete data” NHANES analysis: At least 1% of weighted number of respondents consuming commodity in any form; less than 0.1% of population consumed uncooked; AND on less than 0.1% of eating occasions, using either 1-day or 2-day survey	“No uncooked code” NHANES analysis: At least 1% of weighted number of respondents consuming commodity in any form; and no uncooked code reported in NHANES, using either 1-day or 2-day survey	“Processed food” NHANES analysis: At least 1% of weighted number of respondents consuming commodity in any form; and reported consumed only in processed food form with cook step using either 1-day or 2-day survey
Asparagus	Beans, black	Coffee beans
Beans, lima	Beans, great Northern	Cocoa beans
Beets, garden (roots and tops)	Beans, kidney	
Beets, sugar	Beans, navy	
Cherries, sour	Beans, pinto	
Chickpeas	Cashews	
Collards	Hazelnuts	
Corn, sweet	Lentils	
Cranberries	Okra	
Dates	Peanuts	
Dill (seeds and weed)	Peppermint	
Eggplants	Squash, winter	
Figs	Sweet potatoes	
Ginger		
Horseradish		
Pecans		
Potatoes		
Pumpkins		
Water chestnuts		

Table 6 shows a comparison of proposed to final rarely consumed raw commodities.

Table 6.-- Comparison of Proposed to Final List of Rarely Consumed Raw Commodities Identified in § 112.2(a)(1) (All Analyses Combined, Alphabetical by Commodity)

Proposed	Final
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Arrowhead ¹ ; Arrowroot ¹ ; Artichokes ¹ ; Asparagus; Beets; Black-eyed peas ¹ ; Brussels sprouts ¹ ; Bok choy ¹ ; Chick-peas; Collards; Crabapples ¹ ; Cranberries; Eggplant; Figs; Ginger root; Kale ¹ ; Kidney beans; Lentils; Lima beans; Okra; Parsnips ¹ ; Peanuts; Pinto beans; Plantains ¹ ; Potatoes; Pumpkin; Rhubarb ¹ ; Rutabaga ¹ ; Sugarbeet; Sweet corn; Sweet potatoes; Taro ¹ ; Turnips ¹ ; Water chestnut; Winter squash; Yams ¹	Asparagus; Beans, black ² ; Beans, great Northern ² ; Beans, kidney; Beans, lima; Beans, navy ² ; Beans, pinto; Beets, garden (roots and tops); Beets, sugar; Cashews ² ; Cherries, sour ² ; Chickpeas; Cocoa beans ² ; Coffee beans ² ; Collards; Corn, sweet; Cranberries; Dates ² ; Dill (seeds and weed) ² ; Eggplants; Figs; Ginger; Hazelnuts ² ; Horseradish ² ; Lentils; Okra; Peanuts; Pecans ² ; Peppermint ² ; Potatoes; Pumpkins; Squash, winter; Sweet potatoes; Water chestnuts
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¹ Removed from list in final rule

² Added to list in final rule

Table 7 shows changes in the nomenclature for rarely consumed raw commodities in proposed § 112.2(a)(1) to final § 112.2(a)(1).

Table 7.-- Changes in Commodity Nomenclature From Proposed to Final List of “Rarely Consumed Raw” Commodities

Commodity Name in Proposed List	Commodity Name in Final List
Beets	Beets, garden (roots and tops)
Chick-peas	Chickpeas
Ginger root	Ginger
Kidney beans	Beans, kidney
Lima beans	Beans, lima
Pinto beans	Beans, pinto
Sugarbeet	Beets, sugar
Sweet corn	Corn, sweet
Winter squash	Squash, winter

We acknowledge there are certain limitations to this analysis. Although the NHANES/WWEIA datasets are the most comprehensive and robust, nationally-representative datasets currently available on dietary intakes in the United States, we recognize that they do not cover all commodities and that the data are incomplete or limited in certain cases, as discussed previously. In addition, we agree with several commenters who point out that dietary consumption patterns can change over time such that produce not currently consumed raw may be consumed raw (and reported as “uncooked” based on FCID analyses of NHANES/WWEIA datasets) in the future, or vice versa. Nevertheless, we can only analyze consumption patterns using data that necessarily lags behind changes in consumption. While the data source we have

has certain limitations, it is the best we could identify for this purpose. Moreover, we believe it is consistent with providing standards that minimize the risk of serious adverse health consequences or death to exempt from such standards as “rarely consumed raw” only those commodities for which we have robust, quantitative data from nationally representative data sources (such as NHANES/WWEIA and FCID) supporting a conclusion that the commodity is rarely consumed raw. We recognize that our current list of produce that is rarely consumed raw may need to be updated as new information becomes available.

As discussed previously, we also understand that the overall consumption rates of some produce in the United States are too low for the NHANES/WWEIA data to be useful to evaluate whether the produce is rarely consumed raw or even whether it is consumed in any form. In this final rule we are establishing a factor of weighted number of respondents of at least 1 percent of the total respondents to the eight year span of 2003-2010 NHANES/WWEIA surveys to apply as a threshold that provides a reasonable representation of the frequency with which a commodity is consumed by U.S. consumers. For foods that are reported consumed (in any form) by fewer than a weighted number of 2,938,915 respondents (for 2-day intakes) or 2,938,517 (for 1-day intakes), we consider the overall reported rate to be too low to justify relying on these data as a reasonable representation of consumption among U.S. consumers for purposes of this rule. Therefore, we consider that such commodities should be covered by the rule. For example, certain tropical fruits (such as guava, kumquat, and lychee) meet two of the three criteria (i.e., consumed uncooked by less than 0.1 percent of the United States population and consumed uncooked on less than 0.1 percent of eating occasions) based on the NHANES/WWEIA datasets. However, these commodities are reported consumed by fewer than 1 percent weighted number of respondents, and we conclude that this is insufficient to provide a reasonable representation of

consumption across U.S. consumers for purposes of excluding such commodities from the coverage of this rule as rarely consumed raw. As another example, certain regional or ethnic foods that are not widely consumed by the United States population are not covered in the NHANES/WWEIA datasets and, therefore, we have no robust, nationally-representative data from which to determine whether or not such foods are typically consumed cooked among United States consumers. As a result, we are not exempting such commodities, but we intend to consider updating the list of rarely consumed raw commodities in the future as appropriate, such as if new data become available. We encourage stakeholders who have information about produce commodities not currently reported in NHANES/WWEIA datasets or included in FCID recipes, or reported consumed in any form by fewer than 1 percent weighted number of respondents in the NHANES/WWEIA surveys to identify relevant data for FDA’s review and evaluation. To be useful, such data would need to be sufficiently robust and representative of consumption of relevant commodities across the United States to allow us to draw scientifically-valid conclusions.

(Comment 65) Some comments seek clarification regarding the meaning of “raw” and “uncooked” as those terms apply to proposed § 112.2(a)(1). One comment states that their interpretation of “raw” extends beyond cooking at the consumer level, and that although both consumer-level cooking and commercial processing can reduce pathogen populations, these are treated differently in the proposed regulation. The comment urges FDA to recognize the broad range of commercial practices that could similarly justify designating a food as rarely consumed raw. Other comments suggest that commodities treated with propylene oxide (PPO) to reduce levels of Salmonella and other vegetative pathogens should be exempt as rarely consumed raw.

These comments state that, although such PPO-treated products are likely to be seen as “raw” by consumers, they undergo an appropriate pathogen reduction control step.

(Response) We are exempting produce that is “rarely consumed raw” from the requirements of part 112 in § 112.2(a)(1) because such fruits and vegetables are almost always consumed only after being cooked, which is a kill-step that can be expected to adequately reduce the presence of microorganisms of public health significance in most cases. Our use of “produce that is rarely consumed raw”, therefore, is intended to mean that such produce commodities are almost always eaten only after being cooked (i.e., heat treated in some form). We do not distinguish between cooking conducted by a consumer or a food manufacturer.

The exemption provided for rarely consumed raw produce (in § 112.2(a)(1)) is separate and distinct from the eligibility for exemption provided for produce that receives commercial processing (in § 112.2(b)). Produce commodities exempt under § 112.2(a)(1) are almost always eaten only after being cooked and, therefore, the exemption applies generally for that commodity regardless of the method of preparation prior to consumption. For example, we consider that potatoes meet the criteria for rarely consumed raw and, although they may be consumed in different forms, they are almost always cooked prior to consumption. We also recognize that foods that are rarely consumed raw may be cooked in a home setting by the consumer or in a commercial setting by a food manufacturer/processor. In contrast, produce may be exempt, if eligible, under § 112.2(b), even if the commodity involved is not always consumed only after cooking. For example, tomatoes are frequently consumed raw, without any cooking, but also can be consumed after they receive commercial processing that adequately reduces pathogens, such as treating with a validated process (e.g., as processing to produce tomato paste or shelf-stable tomatoes) to eliminate spoilage organisms and destroy vegetative pathogens (such as Salmonella,

L. monocytogenes, and E. coli O157:H7). Tomatoes are eligible for exemption under § 112.2(b) only in the latter case (where the farm is required to take certain actions (see section IX.A.4 of this document), including establishing and keeping certain documentation), but not in the former case where the tomatoes do not receive such a commercial processing step. Therefore, it would not be appropriate to combine the exemptions in § 112.2(a)(1) and (b) into a single general exemption. We note that produce that receives a PPO treatment may be eligible for the exemption in § 112.2(b) if all relevant conditions are met, including that the treatment adequately reduces the presence of microorganisms of public health significance.

We recognize, however, that a produce commodity that is generally exempt from this part because it is rarely consumed raw may, in some cases, also receive commercial processing that adequately reduces the presence of microorganisms of public health significance. However, because such commodity is already exempt under § 112.2(a)(1), we would not consider the commodity under the provision in § 112.2(b)(1) or expect the farm to take the steps required under § 112.2(b)(2).

4. Produce That is Eligible for Exemption Based on Receipt of Commercial Processing That Adequately Reduces Pathogens (§ 112.2(b))

(Comment 66) Some comments that are generally supportive of the exemption for produce that undergoes commercial processing that adequately reduces pathogens state that it is essential to ensure that such produce does not then re-enter the fresh produce supply chain if it does not eventually receive the required processing. One comment expresses concern about the exemption and states that diversion of “processing grown” cannery, Roma, or plum tomatoes is a common practice. This comment states that there are numerous instances where tomatoes grown

for commercial processing that would adequately reduce pathogens were shipped to Mexico, relabeled for sale as RACs in the fresh produce market, and then shipped back into the United States as RACs. One comment states the documentation requirements described under proposed § 112.2(b) would not be practicable for some farms. According to this comment, for example, wine grapes delivered to a winery are generally made into wine, but the farm will usually not be privy to the specific production processes that the crop undergoes nor who performs them. The comment further notes that wine grapes delivered to a winery may be crushed and converted to grape must at the first facility, and then transferred to another winery for fermentation and additional processing, without any knowledge by the farm.

(Response) The exemption in § 112.2(b) applies to produce that receives commercial processing that adequately reduces the presence of pathogens. Thus, the exemption is only available to produce that is actually processed in a manner that adequately reduces pathogens. The failure to comply with the requirements of part 112 is a prohibited act under section 301(vv) of the FD&C Act, as set forth in § 112.192, for which FDA may take appropriate action. Therefore, it is important that covered farms that rely on the exemption in § 112.2(b) ensure that the relevant produce meets the exemption criteria and take the steps required in revised § 112.2(b).

We are adding certain examples to this paragraph to make clear that such commercial processing includes processing produce into products in which the nature of the product or its production process as a whole, rather than a single “kill step,” adequately reduces the presence of pathogens. We are adding as examples of commercial processing that adequately reduces the presence of microorganisms of public health concern “otherwise manufacturing/processing produce into products such as... wine, beer, or similar products.” Winemaking and brewing

beer adequately reduce the presence of microorganisms of public health significance (Ref. 88).

Fresh-cut processing does not qualify as commercial processing that adequately reduces the presence of pathogens for the purposes of the exemption in § 112.2(b). As described in FDA's Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables (Ref. 89), processing produce into fresh-cut products can increase the risk of bacterial growth and contamination. Adding antimicrobial substances to produce wash water at a fresh-cut manufacturing/processing facility can reduce the likelihood of produce contamination, including for example to help prevent the cross-contamination of surrounding produce with any pathogens that may be introduced into the wash water from a single fruit or vegetable. However, washing does not adequately reduce the presence of pathogens (see also our response to Comment 334). FDA's Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables (Ref. 89) clearly identifies the need for use of both good agricultural practices and good manufacturing practices to prevent or minimize microbial hazards in fresh-cut produce.

In light of the comments about farms' limited knowledge of the specific production processes that their crop undergoes at later stages of the supply chain and the entities performing such processes; and in light of our approach to similar issues in the PCHF regulation, we have revised the conditions of this exemption. The revised requirements are more practicable for farms with respect to their limited knowledge of the entities and processes involved in the distribution chain subsequent to the farm's own customer. The revised requirements are also consistent with similar requirements in §§ 117.136 and 117.137 of the PCHF regulation, and in § 1.507 of the FSVP regulation, which allow facilities and importers, respectively, to rely on customers and subsequent entities in the distribution chain to control

hazards under certain circumstances.

Under the first of the new provisions (§ 112.2(b)(2)), you must disclose in documents accompanying the produce that the food is not processed to adequately reduce the presence of microorganisms of public health significance. The documents that accompany the produce could be bills of lading or other papers that accompany the produce, or the containers may be labeled with this information. Under the next of the new provisions, (§ 112.2(b)(3)), you must annually obtain certain written assurances from your customer with respect to the produce for which you rely on this exemption. This may be an assurance from the customer that the customer has established and is following procedures that adequately reduce the presence of microorganisms of public health significance (§ 112.2(b)(3)(i)), or it may be an assurance from the customer that an entity after the customer in the distribution chain will perform such processing (§ 112.2(b)(3)(ii)). In the latter case, the customer's written assurance must also affirm that the customer will disclose in documents accompanying the food that the food is not processed to adequately reduce the presence of microorganisms of public health significance and that the customer will only sell to another entity that agrees, in writing, that it will either: 1) follow procedures (identified in a written assurance) that adequately reduce the presence of microorganisms of public health significance or 2) obtain a similar written assurance from its customer that the produce will receive the required commercial processing and that there will be disclosure in documents accompanying the food that it is not processed to adequately reduce microorganisms of public health significance. Under § 112.2(b)(4), we are requiring you to keep documentation of the disclosures required under § 112.2(b)(2), and the annual written assurances obtained from customers required under § 112.2(b)(3). This replaces the requirement in the 2013 proposed rule that you keep documentation of the identity of the

recipient of the produce that performs the commercial processing, as we recognize that a farm may not have knowledge of the identity of the entity performing such processing. We are finalizing the requirement in § 112.2(b)(5) (proposed as § 112.2(b)(3)) that the requirements of this subpart and subpart Q apply to produce exempt under this section, without change.

In addition, while we are not requiring specific language for the written assurances described in § 112.2(b)(3), we are specifying in § 112.2(b)(6) that the entities that provide them must act consistently with the assurances and document the actions taken to satisfy the assurance. Section 112.2(b)(6) applies not just to covered farms, but to other entities that voluntarily agree to provide the written assurances described in § 112.2(b)(3). The application of this requirement to facilities subject to the section 418 of the FD&C Act is consistent with section 419(h) of the FD&C Act. Providing, complying with, and documenting compliance with the written assurances described in § 112.2(b)(3) are not activities that are subject to section 418 of the FD&C Act. We believe the combination of the written assurance, the disclosure in accompanying documents that the food is not processed to adequately reduce microorganisms of public health significance, and the requirements to act consistently with the written assurance will provide a reasonable level of protection to ensure that produce that is exempt from the requirements of part § 112 under this section actually receives the required commercial processing and will not be diverted to the fresh produce market.

(Comment 67) One comment recommends that frozen vegetables should be eligible for exemption under § 112.2(b) because, according to this commenter, most commercially frozen vegetables are blanched before freezing and are subsequently not intended to be eaten raw. This commenter also states that blanching involves temperatures from 140 °F to 180 °F for one or

more minutes, and effectively eliminates harmful bacteria. In addition, the commenter believes that a frozen or previously frozen, thawed vegetable is typically not desirable for raw consumption and is rarely consumed raw.

(Response) Produce, including vegetables, that receive commercial processing that adequately reduces the presence of pathogens is eligible for exemption under § 112.2(b) if all of the conditions in that section are met. Blanching and/or freezing processes may qualify if they are validated to ensure that the specific procedures followed adequately reduce pathogens in the food. Whether frozen or thawed vegetables are typically consumed raw is not relevant to the analysis.

5. Specific Produce Commodities and §§ 112.2(a) and 112.2(b)

(Comment 68) Several comments request that we consider or reconsider our treatment of certain commodities as covered produce or rarely consumed raw (and therefore not covered produce), where such commodities are those for which data about uncooked consumption is available. Some comments request removing the following commodities from the list of rarely consumed raw produce so that they would be covered produce, stating that such commodities are regularly consumed raw: asparagus, beets (including, specifically, beet greens), bok choy, Brussels sprouts, collard greens, figs, ginger root, rhubarb, sweet corn, turnips (roots and greens), and water chestnuts. Some comments specifically asked FDA to finalize its tentative conclusion that bean sprouts are covered produce and are not exempt as rarely consumed raw produce. On the other hand, some comments request exempting the following commodities as rarely consumed raw that were not in FDA's proposed list: almonds, burdock roots, olives, pecans, pistachios, soybean beans, sunflower seeds, walnuts, and yuca.

(Response) NHANES/WWEIA data are available with respect to uncooked consumption of each of these commodities. Based on the analysis described previously (see our response to Comment 64), asparagus, beets (garden (roots and tops)), beet (sugar), collards, figs, ginger, sweet corn, and water chestnuts are reported consumed (all forms, taken together) by more than 1 percent weighted number of survey respondents, and consumed uncooked by less than 0.1 percent of the United States population, and consumed uncooked on less than 0.1 percent of eating occasions (Ref. 73). Therefore, despite commenters' suggestions that these commodities might not meet the criteria for rarely consumed raw, they are in fact rarely consumed raw per our established criteria (see column 1 of Table 5) and they are therefore included in the list in § 112.2(a)(1).

On the other hand, bok choy, Brussels sprouts, rhubarb, and turnip, all of which we had proposed as rarely consumed raw commodities are now shown, using the more recent NHANES/WWEIA data and applying our revised criteria for rarely consumed raw, not to satisfy our criteria for rarely consumed raw produce (Ref. 73).

Bok choy does not meet our revised criteria for rarely consumed raw in that less than 1 percent weighted number of survey respondents reported consumption of this commodity in any form. Therefore, we are removing bok choy from the list of rarely consumed raw produce in § 112.2(a)(1). Instead, bok choy is covered produce subject to the requirements of part 112 as applicable.

For Brussels sprouts, in the 2013 proposed rule, we based our tentative conclusion that they are rarely consumed raw on the lack of an uncooked code reported in the 1999-2006 NHANES/WWEIA dataset. (We note that we incorrectly described our categorization of this commodity in the 2013 proposed rule in a way that did not affect the ultimate result, but did

affect the reason given for that result (Ref. 73)). In contrast, the current NHANES/WWEIA datasets provide quantitative information about uncooked consumption of Brussels sprouts, which shows that they do not meet the revised criteria for rarely consumed raw in that less than 1 percent weighted number of survey respondents reported consumption of this commodity in any form. Therefore, we are removing Brussels sprouts from the list of rarely consumed raw produce in § 112.2(a)(1). Instead, Brussels sprouts are covered produce subject to the requirements of part 112 as applicable.

We did not propose to exempt sprouts as rarely consumed raw and we are not changing this conclusion. Alfalfa sprouts do not meet the first two criteria for rarely consumed raw. Mung bean sprouts also do not meet the first two criteria for rarely consumed raw. Soybean sprouts meet the first two criteria for rarely consumed raw but do not meet the third criterion in that less than 1 percent weighted number of survey respondents reported consumption of this commodity in any form (Ref. 73). Sprouts are covered produce subject to the requirements of part 112 as applicable, including those in subpart M.

With respect to requests to add new commodities for which uncooked consumption data are available to the rarely consumed raw list, we analyzed the data and agree that pecans meet the revised criteria for rarely consumed raw (see Table 5) (Ref. 73). Therefore, we have added pecans to the list in § 112.2(a)(1).

On the other hand, almonds, olives, pistachios, walnuts, and yuca (cassava) do not meet the first two criteria for rarely consumed raw (Ref. 73). Burdock meets the first two criteria for rarely consumed raw but does not meet the third criterion in that less than 1 percent weighted number of survey respondents reported consumption of this commodity in any form (Ref. 73). Therefore, these commodities are not included in the list of rarely consumed raw commodities

in § 112.2(a)(1) and, instead, are covered produce subject to the requirements of part 112 as applicable. (Note that we consider oilseeds, such as soybeans and sunflower seeds, to be grains and therefore not “produce” (see our response to Comment 58).

Note that our analysis of beets (garden), dasheen (or taro), turnips, and chicory accounts for both roots and greens, collectively, of each commodity. Similarly, our analysis for dill accounts for both seeds (dill seed) and greens (dillweed) (Ref. 73). Although for each of these commodities, NHANES/WWEIA includes separate reported entries for “roots” and “tops” (and for dill, NHANES/WWEIA includes separate entries for “dill seed” and “dillweed”), for purposes of determining coverage under this rule, we find it appropriate to analyze consumption collectively to account for the entire harvested or harvestable portion of the plant. Based on our analysis using the combined data for roots and tops for each of these commodities, we conclude that beets (garden (roots and tops)) and dill (seeds and weed) are rarely consumed raw (see column 1 of Table 5). Therefore, beets (garden) and dill listed under § 112.2(a)(1) specify “root and tops” and “seeds and weed”, respectively. Conversely, dasheen (corn and leaves), chicory (roots and tops), and turnip (roots and tops) do not meet our criteria for rarely consumed raw. Regarding dasheen (or taro), we had proposed to exempt “taro” as rarely consumed raw in the 2013 proposed rule. However, based on the current NHANES/WWEIA datasets, dasheen (corn and leaves) does not meet our revised criteria for rarely consumed raw in that although it meets the first two criteria, it does not meet the third criterion. Similarly, we had proposed to exempt turnip as rarely consumed raw in the 2013 proposed rule. However, based on the current NHANES/WWEIA datasets, turnip (roots and greens) does not meet our revised criteria for rarely consumed raw in that although it meets the first two criteria, it does not meet the third criterion. Therefore, we are removing “taro” and

“turnip” from the list of rarely consumed raw produce in § 112.2(a)(1). Instead, both dasheen (corm and leaves) and turnip (roots and greens) are covered produce subject to the requirements of part 112 as applicable.

In addition, two other commodities (i.e., artichokes and plantains) that we had proposed to exempt as rarely consumed raw produce (based on previously available uncooked consumption data) are now not on our final list in § 112.2(a)(1) because less than 1 percent weighted number of survey respondents report consumption of these commodities in any form and therefore they do not meet our revised criteria for rarely consumed raw (Ref. 73).

Artichoke is reported in the current NHANES/WWEIA datasets under two separate entries: Artichoke, Jerusalem, for which there is quantitative information on uncooked consumption, and Artichoke, globe for which there is no “uncooked” consumption code. Neither Artichoke, Jerusalem nor Artichoke, globe meets our revised criteria for rarely consumed raw in that although both meet the first two criteria, they do not meet the third criterion. Likewise, plantain, for which there is quantitative information on uncooked consumption, does not meet our revised criteria for rarely consumed raw in that although it meets the first two criteria, it does not meet the third criterion (Ref. 73). (See also Comment 69 for other commodities for which there is no reported “uncooked” consumption code that we proposed to exempt as rarely consumed raw but that are not on our final rarely consumed raw list).

(Comment 69) Several comments request that we consider or reconsider our treatment of certain commodities as covered produce or rarely consumed raw (and therefore not covered produce), where such commodities are those reported in NHANES/WWEIA data but for which there is no “uncooked” consumption category reported. Several comments argue that kale, which

was on the proposed list of rarely consumed raw produce, has greatly grown in popularity and is often consumed raw. These comments provide various types of evidence that kale is frequently consumed raw by United States consumers, and recommend removing kale from the list of rarely consumed raw produce such that it would be “covered produce” subject to the requirements of part 112. Some comments also suggested removing parsnips from the list of rarely consumed raw produce for similar reasons. On the other hand, some comments request exempting brazil nuts, breadfruit, cashews, chestnuts, hazelnuts, macadamia nuts, palm heart leaves (palm heart, palmito, chonta, or jebato), peppermint (mint), pigeon peas, and pine nuts as rarely consumed raw. Finally, some comments ask that FDA finalize its conclusion that peanuts are rarely consumed raw without change.

(Response) As discussed previously (under Comment 64), we have concluded that commodities included in the NHANES/WWEIA datasets for which categories of reported consumption in the NHANES/WWEIA surveys do not include “uncooked” can be reasonably considered to fall beneath the numerical thresholds of being consumed uncooked by less than 0.1 percent of the United States population and consumed uncooked on less than 0.1 percent of eating occasions because lack of an “uncooked” reported food form indicates that they were not consumed uncooked in any measurable quantity by most consumers across the United States. To such commodities, we applied the new numerical threshold of weighted number of survey respondents of at least 1 percent of the total number of survey respondents having reported consumption of the commodity in any form.

Brazil nuts, breadfruit, cashews, chestnuts, hazelnuts, kale, macadamia nuts, palm heart leaves, parsnips, peanuts, peppermint, pigeon peas, and pine nuts are all commodities included in the NHANES/WWEIA datasets for which categories of reported consumption in the

NHANES/WWEIA surveys do not include “uncooked.” We find brazil nuts, breadfruit, chestnut, kale, macadamia nuts, palm heart leaves, parsnips, pigeon peas, and pine nuts do not meet our revised criteria for rarely consumed raw in that less than 1 percent weighted number of survey respondents reported consumption of these commodities in any form (Ref. 73). In contrast, cashews, hazelnuts, peanuts, and peppermint meet the revised criteria for rarely consumed raw in that more than 1 percent weighted number of survey respondents reported consumption of these commodities in any form (Ref. 73).

Therefore, we conclude that brazil nuts, breadfruit, chestnuts, kale, macadamia nuts, palm heart leaves, parsnips, pigeon peas, and pine nuts do not meet the criteria for rarely consumed raw and we do not include them in the list in § 112.2(a)(1). Instead, these commodities are covered produce subject to the requirements of part 112 as applicable. We also conclude that cashews, hazelnuts, peanuts, and peppermint are rarely consumed raw and, therefore, we include them in the list in § 112.2(a)(1). See column 2 of Table 5. (We note that hazelnuts have been associated with one outbreak in 2010-2011 (Ref. 28); however, hazelnuts meet our criteria for rarely consumed raw, which are based on consumption of produce commodities by U.S. consumers as indicated by NHANES/WWEIA surveys, as described in response to Comment 64. While hazelnuts are exempt from this rule under § 112.2(a)(1), we note that the FD&C Act still applies to the production of hazelnuts.)

In addition, five other commodities that we proposed to exempt as rarely consumed raw based on lack of uncooked code reported in the previous NHANES/WWEIA dataset are now not on our final list in § 112.2(a)(1). Black-eyed pea (or cowpea bean) does not meet the revised criteria for rarely consumed raw in that less than 1 percent weighted number of survey respondents reported consumption of this commodity in any form (Ref. 73). Crabapple is not a

survey item in the current NHANES/WWEIA datasets, so we have no current data to which the revised criteria for rarely consumed raw may be applied for this commodity. Rhubarb, rutabaga, and yam also do not meet our revised criteria for rarely consumed raw in that less than less than 1 percent weighted number of survey respondents reported consumption of these commodities in any form (Ref. 73). Therefore, we are removing black-eyed pea, crabapple, rhubarb, rutabaga, and yam from the list of rarely consumed raw produce in § 112.2(a)(1). Instead, these commodities are covered produce subject to the requirements of part 112 as applicable. We intend to review the status of these commodities upon availability of updated dietary consumption information, including data obtained from NHANES/WWEIA 2015-2016 surveys. We encourage stakeholders who may have data or information relevant to this analysis to consult with us. (See also Comment 68 for other commodities for which there is quantitative information on uncooked consumption that we proposed to exempt as rarely consumed raw but that are not on our final rarely consumed raw list).

(Comment 70) Some comments requested exemption of coffee beans and hops as rarely consumed raw because they are typically consumed in beverage form as coffee and beer, respectively.

(Response) As discussed previously (under Comment 64), we are adding coffee beans to the list of exempt commodities in § 112.2(a)(1). The consumption of coffee beans is reported in the NHANES/WWEIA only in roasted form as the beverage, coffee. Similarly, the consumption of cocoa beans is only reported as cocoa beverage, chocolate beverage, chocolate, or related products. We conclude that these commodities are rarely consumed raw because the only forms in which they are reported in the NHANES/WWEIA surveys indicates they were cooked as part

of the process of being made into the identified processed foods (such that we infer that they were not consumed uncooked in any measurable quantity), and they satisfy the new numerical threshold (i.e., at least 1 percent of weighted number of survey respondents must have reported consuming the commodity in any form for the data to provide a reasonable representation of how that commodity is consumed by U.S. consumers). We are therefore adding them to the list of rarely consumed raw produce in § 112.2(a)(1) (see column 3 of Table 5). On the other hand, while the consumption of hops is reported in the NHANES/WWEIA only in beverage form as beer, we cannot conclude that this indicates that hops were cooked as part of the process of being made into beer. We are aware that hops are regularly added to beer after all cook steps are completed in a process known as “dry hopping” (Ref. 90). Therefore it would not be reasonable to infer on this basis that hops were not consumed uncooked in any measurable quantity by most consumers across the United States, and we are not adding hops to the list of rarely consumed raw produce. Instead, hops are covered produce subject to the requirements of part 112 as applicable. However, we note that hops used in the making of beer will be eligible for exemption from the requirements of part 112 under the provisions of § 112.2(b)(1), provided the covered farm establishes and maintains documentation in accordance with § 112.2(b)(2). Brewing beer adequately reduces the presence of microorganisms of public health significance through means other than a cook step (e.g., pH, alcohol content, fermentation) (Ref. 88). We are adding this to our list of examples of products of commercial processing in § 112.2(b)(1).

(Comment 71) Some comments request exempting the following commodities that are not covered in the NHANES/WWEIA datasets as rarely consumed raw: ackee, aronia, atemoya, butterbur, chipilin, dragon fruit, fiddleheads, ginkgo nut, komatsuna, longan, loroco, pomelo,

ramp, tamarillo, ti plant, and ulluko (melloco). We also received comments asking about the status of lotus root and swamp cabbage.

(Response) As discussed previously (under Comment 64), where a commodity is not included in the NHANES/WWEIA data at all, we have no robust, nationally-representative data from which to determine whether or not such foods are typically consumed cooked among United States consumers, and commenters did not provide any such information. As a result, we are not exempting ackee, aronia, atemoya, butterbur, chipilin, dragon fruit, fiddleheads, ginkgo nut, komatsuna, longan, loroco, pomelo, ramp, tamarillo, ti plant, or ulluko (melloco) (Ref. 73). Instead, they are covered produce subject to the requirements of part 112 as applicable.

While lotus root and swamp cabbage are reported in NHANES, they are reported only in cooked forms, and there are no data from which their raw consumption may be analyzed. However, neither commodity satisfies the third criterion in that less than 1 percent weighted number of survey respondents reported consumption of these commodities in any form (Ref. 73).

Two other commodities that we proposed, in the 2013 proposed rule, to exempt as rarely consumed raw based on non-NHANES data and other references are arrowhead and arrowroot. Neither of these commodities is reported in the current NHANES/WWEIA datasets, and we have no data to which the revised criteria for rarely consumed raw may be applied for these commodities. Therefore, we are removing arrowhead and arrowroot from the list of rarely consumed raw produce in § 112.2(a)(1). Instead, arrowhead and arrowroot are covered produce subject to the requirements of part 112 as applicable.

We intend to consider updating the list of rarely consumed raw commodities in the future as appropriate, such as if new data become available. We encourage stakeholders who have information relevant to consumption of these produce commodities to identify relevant data for

FDA's review and evaluation. To be useful, such data would need to be sufficiently robust and representative of consumption of relevant commodities by consumers across the United States to allow us to draw scientifically valid conclusions.

(Comment 72) One comment argues that, although tree fruits and berries are frequently consumed raw, they should nevertheless be added to the list of "rarely consumed raw" as being "low-risk" because, according to the comment, as long as ground irrigation is used there is no scientific evidence that E. coli or other bacterial contamination can be carried through the roots to the fruit, which the comment contrasts with lettuce and other leafy green vegetables. The comment adds that all consumers should be aware of the need to wash produce before consumption to prevent foodborne illnesses.

(Response) Our criteria for determining which produce commodities are rarely consumed raw relate only to the frequency with which produce commodities are consumed uncooked and not to commodity characteristics, agricultural practices, or other consumer practices (such as washing) as suggested by the comment. We do not agree that either tree fruits generally or berries generally should be considered to be exempt as rarely consumed raw for the reasons suggested by the comment. In section IV of this document, we address our integrated approach and how it reflects relevant differences across commodities, such as the use of agricultural practices presenting varying levels of risk.

(Comment 73) Several comments urge FDA to exempt wine grapes as rarely consumed raw. These comments state that wine grapes are not grown or selected for raw consumption, but rather are selected for properties that make good wine. According to these comments,

winemakers select specific grape varieties based on skin, color, and texture, among other things, and virtually all wine grapes are grown, harvested, and then delivered for processing at a winery rather than sold into the fresh market. These comments state that wine grapes are substantially different from grape cultivars selected for fresh consumption in that wine grapes usually have seeds, and have thick skins and high sugar content. These comments also cite wine's inherent anti-microbial properties and a lack of evidence of microbial illness resulting from either wine grapes or wine, to argue that wine grapes should be exempt from the standards established under this rule under proposed § 112.2(b) for produce that receives commercial processing that adequately reduces pathogens.

(Response) Based on the data available to us, we do not agree that wine grapes meet the criteria for rarely consumed raw. Uncooked consumption data are available for “grapes, wine and sherry” in the 2003-2010 NHANES/WWEIA datasets, and our analysis shows that “grapes, wine and sherry” do not meet the first two criteria for rarely consumed raw (Ref. 73). Although this category (“grapes, wine and sherry”) includes grapes used in the making of both wine and sherry, we consider the NHANES/WWEIA data to be the best data available for this purpose, and using this data it appears that “wine grapes” do not meet the criteria for rarely consumed raw. We do not have information on the specific grape cultivars or varieties that are solely and exclusively grown for use in winemaking that would allow us to establish a category covering only “wine grapes” and evaluate their eligibility using currently available dietary consumption data. In addition, according to the National Grape Registry (Ref.91), many Vitis vinifera cultivars are multi-purpose in use. For example, the Malvasia Bianca grape cultivar can be used as a wine grape or a table grape, and the Muscat of Alexandria grape cultivar can be used to make wine or raisins, or as a table grape. For these reasons, FDA concludes that “wine grapes”

are not rarely consumed raw, and we do not include them in § 112.2(a)(1). Instead, wine grapes are covered produce subject to the requirements of part 112 as applicable.

However, we note that grapes used in the making of wine are eligible for exemption from the requirements of part 112 under the provisions of § 112.2(b)(1), provided the covered farm takes the required steps in accordance with § 112.2(b). Winemaking adequately reduces the presence of microorganisms of public health significance through means other than a cook step (e.g., pH, alcohol content, fermentation) (Ref. 88). We are adding this to our list of examples of products of commercial processing in § 112.2(b)(1).

B. Definitions Other Than Small Business, Very Small Business, and Produce (§ 112.3(c))

In the 2013 proposed rule, under proposed § 112.3(c), we proposed to establish the various definitions that would apply for the purposes of part 112 (78 FR 3504 at 3539-3549). In addition, in the supplemental notice, taking into account public comment, we proposed to amend our originally proposed definitions of “covered activity,” “farm,” “harvesting,” “holding,” and “packing” in proposed § 112.3(c) (79 FR 58434 at 58438-58440). In both the 2013 proposed rule and in the supplemental notice, we asked for public comment on our proposed definitions.

In this section of this document we discuss comments that we received on the definitions proposed in the 2013 proposed rule, but that we did not address in the supplemental notice. We also discuss comments that we received on the amended proposed definitions in the supplemental notice.

Several comments received in response to the amended proposed definitions of “farm,” “harvesting,” “packing,” and “holding” in the supplemental notice are also the same comments we received in response to those amended proposed definitions in the supplemental human

preventive controls notice. Because we already considered and discussed these comments in the final human preventive controls rule that established revised definitions for “farm,” “manufacturing/processing,” “harvesting,” “packing,” and “holding” in § 1.227 (Ref. 11), and because we are adopting definitions of these terms in this rule that are the same as the definitions established in the final human preventive controls rule, in this section of this document, we focus on comments related to these definitions that are specific to part 112 that were not otherwise addressed in the final human preventive controls rule.

1. Definitions of Farm and Related Terms (Manufacturing/Processing, Harvesting, Holding, and Packing)

We revised the proposed definitions of farm, manufacturing/processing, harvesting, holding, and packing in the final human preventive controls rule (see 80 FR 55908 at 55925-55936), and established the revised definitions in §§ 1.227 and 117. We are adopting the same definitions of farm, manufacturing/processing, harvesting, holding, and packing established in § 1.227 for purposes of the PCHF regulation, now in § 112.3(c) for purposes of the Produce Safety regulation.

Definition of “farm.” In the supplemental notice, taking into account public comment on our proposed definition of “farm” in the 2013 proposed rule and consistent with our proposed amendments to the definition of “farm” as it applies to proposed part 117, we proposed to amend the definition of “farm” in proposed § 112.3(c) such that establishments that pack or hold produce that is grown or harvested on another farm would be subject to the produce safety

standards of proposed part 112 regardless of whether or not that farm is under the same ownership.

We proposed to amend the originally proposed definition of farm to mean “an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term “farm” as proposed in the supplemental notices would include establishments that, in addition to these activities: (1) Pack or hold RACs; (2) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (iii)(B)(1) of the “farm” definition; and (3) Manufacture/process food, provided that:

- All food used in such activities is consumed on that farm or another farm under the same ownership; or
- Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:
 - Drying/dehydrating RACs to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and
 - Packaging and labeling RACs, when these activities do not involve additional manufacturing/processing.

Even after the revisions we proposed in the supplemental notice and the supplemental human preventive controls notice, some comments asserted that the overall “farm” definition still presented an unrealistic and incomplete understanding of how most farms in the United States are structured with regard to their physical location(s) and business models. Most of the comments suggested alternative or additional regulatory text or asked us to clarify how we will

interpret the provisions. After considering these comments, we revised our proposed definition of “farm” (as well as the definitions of “manufacturing/processing,” “harvesting,” “packing,” and “holding”) and have established the revised definition in § 1.227, as explained in section IV of the final human preventive controls rule (80 FR 55908). In that document, we discussed in detail our consideration of comments received and revisions to our proposed definitions of “farm” (and of “manufacturing/processing,” “harvesting,” “packing,” and “holding”). See also relevant discussion in section V of the final human preventive controls rule, where we respond to comments on the organizing principles for how the status of a food as a RAC or as a processed food affects the requirements applicable to a farm under sections 415 and 418 of the FD&C Act.

Consistent with the definition of “farm” in § 1.227, we are defining “farm” in § 112.3(c) to indicate that there are two types of farms: (1) a Primary Production Farm and (2) a Secondary Activities Farm. A Primary Production Farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. In addition to these activities, the term “farm” includes operations that (1) pack or hold raw agricultural commodities; (2) pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food as described below, and (3) manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same management; or any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of the following: drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional

manufacturing/processing (an example of additional manufacturing/processing is slicing); treating to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation). A Secondary Activities Farm is an operation, not located on a Primary Production Farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the Primary Production Farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the Secondary Activities Farm owns, or jointly owns, a majority interest in the Secondary Activities Farm. A Secondary Activities Farm may also conduct those additional activities allowed on a Primary Production Farm.

(Comment 74) Some comments ask us to use the phrase “jointly controlled farm business operation” within the farm definition and to define it “as a business that supplies raw agricultural commodities and is majority controlled by two or more farm operators.”

(Response) We do not see the need to define “jointly controlled farm business operation” or to use it in the farm definition, given the revisions to the farm definition explained in the final human preventive controls rule, and “farm” as defined does not refer to farm operators.

(Comment 75) Some comments request the revised proposed farm definition should not result in foreign farms being considered to be a part of a domestic farm under the same ownership.

(Response) There are two relevant considerations in the revised “farm” definition. First, in the revised “farm” definition established in § 1.227, we replaced the phrase “under one ownership” in the proposed “farm” definition with the phrase “under one management.” Although the original phrase “under one ownership” was not referring to a single owner, we agreed that the “farm” definition should reflect modern business models (such as cooperatives, on-farm packinghouses under ownership by multiple farms, food aggregators, and food hubs) and use language that the modern farming community understands (80 FR 55908 at 55925-55932). Second, a “farm” is defined to be in “one general physical (but not necessarily contiguous) location.” While a domestic farm and foreign farm might be under the same management for purposes of the business model, they would not likely be in the same general location, unless the farm straddled an international border. So, we believe it is unlikely that a domestic and foreign farm with the same owner would be considered a single farm under the revised definition.

(Comment 76) Some comments point to the inconsistency in treatment of packing and holding of produce that occurs on a farm versus at an off-farm location using the same practices even though there is no difference in risk. Some comments suggest adding a new paragraph to § 112.4 that extends the produce safety rule to registered establishments that perform holding and packing activities of covered produce consistent with covered activities performed by a farm, but not growing or harvesting activities. Other comments suggest, alternatively, providing an exemption from part 117 for those off-farm activities that adhere to the produce safety standards in part 112, if appropriate documentation is maintained.

(Response) Under the revised definition of “farm” we established in § 1.227, an operation devoted only to the harvesting (such as hulling or shelling), packing, and/or holding of RACs is within the “farm” definition, provided that the farms that grow or raise the majority of the RACs harvested, packed, and/or held by the operation own, or jointly own, a majority interest in the operation. See “secondary activities farm” within the farm definition. Under this definition, off-site packinghouses that are managed by a business entity (such as a cooperative) that is different from the business entity growing crops (such as individual farms) can be within the “farm” definition provided that the ownership criteria are met. We are adopting this definition of farm in § 112.3(c).

(Comment 77) Another comment asks to clarify that “produce” does not include wild-harvested produce where produce is not cultivated but harvested wild, such as some blueberries.

(Response) Under the revised definition of “farm” we established in § 1.227, an operation that is devoted only to the harvesting of covered produce grown in the wild is within the “farm” definition. We are adopting this definition of farm in § 112.3(c). Because, in this circumstance, the farm is not engaged in the growing of the covered produce, the standards in part 112 relating to growing activities do not apply to such a farm (see § 112.4(a), providing that covered farms subject to part 112 must comply with all applicable requirements when conducting a covered activity on covered produce). However, the harvesting activity and any other covered activities conducted by the farm on covered produce are required to comply with those requirements in part 112 that are applicable. We also expect that a large proportion of such operations (i.e., those that harvest covered produce grown in the wild) may not be covered under this rule (see § 112.4(a)) or may be eligible for a qualified exemption (see § 112.5) based

on their size.

(Comment 78) In the supplemental notice, we requested comment on whether to include in the final rule a requirement that a farm supplying produce to another farm that will pack or hold that produce should provide to the farm that receives the produce its name, complete business address, and description of the produce in any individual shipment (79 FR 58434 at 58440). Several comments express concern that the proposed definition of “farm” would negatively impact the ability to trace produce, and ask FDA to ensure it has access to necessary records to fulfill its public health goals. One commenter supports requiring records that identify the immediate previous source and subsequent recipient of the produce to allow timely and effective recalls, when needed. Another commenter argues that FSMA does not authorize FDA to require traceability records for all covered farms, and states that, if we decide to require farms that pack and hold RACs from other farms to maintain records for traceability purposes, the record requirements: (1) should not exceed a one-up-one-down record of the transaction; (2) should be limited to those documents generated in the ordinary course of business; (3) should not include records retention for more than one year; and (4) should allow written records, and not require electronic records.

(Response) At this time, we are not requiring documentation when a covered farm packs or holds covered produce from a farm under a different management. We recognize that many small or very small farms may routinely pack or hold produce grown and harvested at a neighbor’s farm or at a farm that is not under their management, as a course of business or when necessary to fulfill a specific volume of produce to be delivered to their supplier. We encourage covered farms to keep and maintain a documentation of such exchange of covered produce, but

we do not believe a requirement for the covered farm to maintain documentation of each such transaction is warranted at this time given the small volume of produce that we expect would fall under such scenarios and their likely minimal contribution to the overall produce in the marketplace. We note that, under the Perishable Agricultural Commodities Act (PACA), which is administered by USDA, there are certain recordkeeping requirements for persons who buy or sell more than 2,000 pounds of fresh or frozen fruits and vegetables in any given day. Such records may be helpful in the event of a traceback. In addition, section 204 of FSMA mandates that FDA conduct a rulemaking on additional recordkeeping requirements for tracing of certain high risk foods. We will address issues related to traceability of high risk foods, in that rulemaking.

(Comment 79) One comment asks if FDA can consider a group of farms in one general location as one farm to lessen the cost of compliance.

(Response) A “farm” is defined for purposes of this rule in § 112.3(c), and all covered farms are required to comply with all applicable requirements of this rule. We encourage farms to work together to help each other achieve compliance to the extent practicable. For example, this rule allows for sharing water testing data under certain circumstances (see § 112.47(a)). In addition, farms may find it useful to share training materials or record templates. We are aware of certain pilot projects using a collaborative model, and we encourage industry to explore these innovative approaches to help achieve compliance. For example, AMS is piloting a Group GAP Certification Program (Ref. 92).

Definition of “manufacturing/processing”. In the final human preventive controls rule, we revised our proposed definition of “manufacturing/processing” (which we proposed in the 2013 proposed rule and the supplemental human preventive controls notice) in relation to our revision to the farm definition. We have established the revised definition in § 1.227, as explained in section IV of the final human preventive controls rule (80 FR 55908 at 55934-55935). In that document, we discussed in detail our consideration of comments received and revisions to our proposed definition of “farm” and the corresponding revisions to the proposed definition of “manufacturing/processing.”

Consistent with the definition of “manufacturing/processing” in § 1.227, we are defining “manufacturing/processing” in § 112.3(c) to mean “making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.”

Definition of “harvesting”. In the supplemental notice, taking into account public comment on our proposed definition of “harvesting” in the 2013 proposed rule and consistent

with our proposed amendments to the definition of “harvesting” as it applies to proposed part 117, we proposed to amend the definition of “harvesting” in proposed § 112.3(c).

We proposed to amend the originally proposed definition of “harvesting” to apply to farms and farm mixed-type facilities and to mean activities that are traditionally performed on farms for the purpose of removing [RACs] from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on [RACs] on a farm. Harvesting does not include activities that transform a [RAC], as defined in section 201(r) of the [FD&C Act] (21 U.S.C. 321(r)), into a processed food as defined in section 201(gg) of the [FD&C Act]. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling [RACs] grown on a farm are examples of harvesting.

In response to the supplemental notice and the supplemental human preventive controls notice, some comments asked us to consider additional activities within the “harvesting” definition and to provide more examples of harvesting activities, in the regulatory text and in guidance. After considering these comments, we revised our proposed definition of “harvesting” and have established the revised definition in § 1.227, as explained in section IV of the final human preventive controls rule (80 FR 55908 at 55932-55933). In that document, we discussed in detail our consideration of comments received and revisions to our proposed definition of “harvesting”.

Consistent with the definition of “harvesting” in § 1.227, we are defining “harvesting” in § 112.3(c) to apply to farms and farm mixed-type facilities and to mean “activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to

activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the [FD&C Act]. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.”

(Comment 80) Some comments ask us to include field coring as an example of harvesting activity, consistent with the definition proposed in the supplemental human preventive controls notice.

(Response) The revised definition of harvesting in § 1.227, which we are adopting in § 112.3(c), includes field coring in the list of examples of harvesting.

Definition of “holding.” In the supplemental notice, taking into account public comment on our proposed definition of “holding” in the 2013 proposed rule and consistent with our proposed amendments to the definition of “holding” as it applies to proposed part 117, we proposed to amend the definition of “holding” in proposed § 112.3(c).

We proposed to amend the definition of “holding” to mean “storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the

distribution of that food (such as blending of the same [RACs] and breaking down pallets)), but does not include activities that transform a [RAC], as defined in section 201(r) of the [FD&C Act], into a processed food as defined in section 201(gg) of the [FD&C Act]. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.”

In response to the supplemental notice and the supplemental human preventive controls notice, some comments asked us to consider additional activities within the “holding” definition and to provide more examples of holding activities, in the regulatory text and in guidance. After considering these comments, we revised our proposed definition of “holding” and have established the revised definition in § 1.227, as explained in section IV of the final human preventive controls rule (80 FR 55908 at 55933-55934). In that document, we discussed in detail our consideration of comments received and revisions to our proposed definition of “holding”.

Consistent with the definition of “holding” in § 1.227, we are defining “holding” in § 112.3(c) to mean “storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the [FD&C Act]. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.”

Definition of “packing.” In the supplemental notice, taking into account public comment on our proposed definition of “packing” in the 2013 proposed rule and consistent with our proposed amendments to the definition of “packing” as it applies to proposed part 117, we proposed to amend the definition of “packing” in proposed § 112.3(c).

We proposed to amend the definition of “packing” to mean “placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform a [RAC], as defined in section 201(r) of the [FD&C Act], into a processed food as defined in section 201(gg) of the [FD&C Act].” (For reference, we previously proposed to define “packaging” (when used as a verb) to mean placing food into a container that directly contacts the food and that the consumer receives.)

In response to the supplemental notice and the supplemental human preventive controls notice, some comments asked us to consider additional activities within the “packing” definition and to clarify the distinction between “packing” and “packaging.” After considering these comments, we revised our proposed definition of “packing” and have established the revised definition in § 1.227, as explained in section IV of the final human preventive controls rule (80 FR 55908 at 55935-55936). In that document, we discussed in detail our consideration of comments received and revisions to our proposed definition of “packing”.

Consistent with the definition of “packing” in § 1.227, we are defining “packing” in § 112.3(c) to mean “placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw

agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.”

(Comment 81) Some comments ask us to clarify that packaging and labeling activities include repackaging and relabeling, and state that repackaging or relabeling may be incidental to packaging and labeling activities and does not introduce new or different risks to public health.

(Response) We agree that packaging and labeling activities may include repackaging and relabeling and do not necessarily introduce new or different risks to public health.

2. Additional Definitions

We are making various revisions to our proposed definitions, as discussed in this section (see Table 4). For the following terms, we did not receive any comments or received only general comments in support of the proposed definition and, therefore, we do not specifically discuss them in this section: “agricultural water,” “application interval,” “food-contact surfaces,” “manure,” “pest,” “pre-consumer vegetative waste,” “raw agricultural commodity,” “sewage sludge biosolids,” “spent sprout irrigation water,” “table waste,” “water distribution system,” and “we”. We are finalizing the definitions of these terms as proposed, except as described in Table 4.

Definitions of “adequate” and “adequately reduce microorganisms of public health significance”. We proposed to define “adequate” to mean that which is needed to accomplish the intended purpose in keeping with good public health practice. We also proposed to define

“adequately reduce microorganisms of public health significance” to mean reduce the presence of such microorganisms to an extent sufficient to prevent illness.

(Comment 82) Some comments state that these proposed definitions are not clear and, as proposed, they would not ensure uniformity or consistency in safe practices. Comments suggest clarifying the phrase “to an extent sufficient to prevent illness” to refer to “reducing the presence of microorganisms, for example, through cleaning and sanitizing using EPA-registered or FDA-regulated antimicrobials for food use or through other means such as heat and ozone.”

(Response) As explained in the 2013 proposed rule, the definition of “adequate” we are applying in this rule is the same as the long-standing definition used in relation to current good manufacturing practices in manufacturing, packing, or holding human food. We have provided clarification for how this term relates to specific requirements in part 112 through examples throughout the 2013 proposed rule and this final rule. We are finalizing the definition of “adequate” as proposed.

We finalizing the definition of “adequately reduce microorganisms of public health significance” as proposed. The extent of minimization of pathogens sufficient to prevent illness is usually determined by the estimated extent to which a pathogen may be present in the food combined with a safety factor to account for uncertainty in that estimate and, therefore, is different for different circumstances. For example, as noted in our previous guidances to industry (Ref. 93) (Ref. 94), if it is estimated that there would be no more than 1,000 (i.e., 3 logs) Salmonella organisms per gram of food, and a safety factor of 100 (i.e., 2 logs) is employed, a process that adequately reduces Salmonella spp. would be a process capable of reducing Salmonella spp. by 5 logs per gram of food. In addition, we are not including the

specific examples requested by the comment, or other examples of processes that achieve adequate reduction, within this definition as we believe that doing so would be confusing because this is only a definition of the term “adequately reduce the presence of microorganisms of public health significance,” and not a definition of commercial processing steps that achieve such reductions. We conclude that a better place for examples is in § 112.2(b), the exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, and we have included examples there, including new examples added in this rule (see section IX.A.4 of this document). We have not added the specific examples identified by the commenter in that section, however, because although use of certain antimicrobial substances, heat, or ozone treatments may adequately reduce pathogens depending on the circumstances, we cannot categorically conclude that they would do so under all circumstances.

Definitions of “agricultural tea” and “agricultural tea additive”. We proposed to define “agricultural tea” to mean a water extract of biological materials (such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. We also proposed that agricultural teas are held for longer than one hour before application.

We proposed to define “agricultural tea additive” to mean a nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.

(Comment 83) Some comments ask that we use the term “compost tea” instead of “agricultural tea.” Some comments also asked that we align our definitions of “agricultural tea” and “agricultural tea additive” with similar definitions used by the NOP.

(Response) We believe “agricultural tea” is a more appropriate term for applicability to part 112 because we intend this definition to cover “teas” intended for agricultural use and prepared from various feedstocks, and not only those extracts prepared from compost. There also may be compost teas that are not intended for agricultural use and we do not intend to cover those.

With regard to the request that we align our definition of “agricultural tea” with the definition of “compost tea” used by the NOP, we note that the NOP does not have a definition of “compost tea” but the National Organic Standards Board (NOSB) 2006 recommendation has a definition of “compost tea” (Ref. 95). The NOSB recommendation defines “compost tea” as “a water extract of compost produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase, intending to maintain or increase the living, beneficial microorganisms extracted from the compost.” We believe these definitions are sufficiently aligned and see no benefit to narrowing the broader scope of FDA’s definition (including various feedstocks) to cover only teas prepared using stabilized compost as a feedstock. Because we are not making these changes to the definition of “agricultural tea”, we do not believe it is appropriate to modify our definition of “agricultural tea additive” (which is based on the definition of “agricultural tea”) to match the NOSB recommended definition of “compost tea additive.” Because the end product of composting is better described as “stabilized compost” rather than “humus,” we are changing this term in the definition of “agricultural tea.” We discuss this change in additional detail under the definition of “stabilized

compost”. In addition, we are adding a sentence to the definition of “agricultural tea” to specify that “[a]gricultural teas are soil amendments for the purposes of this rule.” See section XIV of this document for discussion of this change.

Definition of “animal excreta”. We proposed to define “animal excreta” to mean solid or liquid animal waste.

(Comment 84) One comment requests that fish excreta be excluded from the definition of “animal excreta.”

(Response) All solid or liquid animal waste is considered animal excreta, and this includes fish excreta. See also discussion in section III.G of this document.

Definitions of “biological soil amendment” and “biological soil amendment of animal origin”. We proposed to define “biological soil amendment” to mean any soil amendment containing biological materials such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination. In addition, we proposed to define “biological soil amendment of animal origin” to mean a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts, or table waste, alone or in combination; and that it does not include any form of human waste.

Because the end product of composting is better described as “stabilized compost” rather than “humus,” we are changing this term in the definition of “biological soil amendment.” We discuss this change in additional detail under the definition of “stabilized compost”.

(Comment 85) Some comments request that we align the definition of “biological soil amendment of animal origin” with that established by the American Plant Food Control Officials. Some comments also request that the definition clarify whether mortality compost is included.

(Response) We are not aware that the American Plant Food Control Officials have a definition of ‘biological soil amendment of animal origin’ and the comments did not provide such a definition for consideration. With regard to the question about mortalities as a feedstock, animal mortalities or animal mortality compost are materials of animal origin that could be used as a component of a biological soil amendment of animal origin within the terms of the definition. Since the comment requested clarity, we are adding animal mortalities as an example in the definition of biological soil amendment of animal origin.

(Comment 86) One comment asks that definitions clearly specify “treated” versus “untreated” biological soil amendments, to clarify that if one component of the “treated” biological soil amendment is untreated, then the entirety of the biological soil amendment should be considered “untreated.”

(Response) Section 112.51 establishes the requirements for determining a biological soil amendment as treated (§ 112.51(a)) or untreated (§ 112.51(b)), and we do not think it is necessary to incorporate these concepts in the definition of biological soil amendment, or biological soil amendment of animal origin. Under § 112.51(b), a biological soil amendment is untreated if, among other conditions, the biological soil amendment has become contaminated after treatment; has been recombined with an untreated biological soil amendment of animal

origin; or is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness. Under these provisions, if the biological soil amendment of animal origin contains a component that is an untreated biological soil amendment of animal origin, or it contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with a foodborne illness, the entire biological soil amendment of animal origin is considered untreated.

Definition of “composting”. We proposed to define “composting” to mean a process to produce humus in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature (for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions.

(Comment 87) Some comments state this proposed definition does not sufficiently address the biological degradation and transformation of organic solid waste that has been subjected to controlled aerobic degradation at a solid waste facility in compliance with relevant requirements. Some comments also disagree that the process produces “humus.” In addition, some comments note that the proposed definition does not encompass various processes that can be used to create safe, usable, and mature compost. For example, commenters point to mixing of organic waste with bulking agents, volatile organic compounds, heat, or water, and state that composting can occur under both thermophilic and mesophilic conditions, but is not always

followed by curing. Some comments suggest establishing performance standards rather than establishing a definition for composting.

(Response) We have revised § 112.54 to indicate that “composting” is only one type of biological process that may meet the requirements in that section and § 112.55(a) and (b) (see section XIV of this document). However, we also continue to believe that the process of composting involves a time and temperature treatment, followed by curing. We agree that the end product of composting is better described as “stabilized compost” rather than “humus” and have made this change both here and in the proposed definition of “humus,” which we are now finalizing as a definition of the term “stabilized compost” and which we discuss in detail under the definition of “stabilized compost”.

Definition of “covered activity”. In the supplemental notice, we proposed to amend the definition of “covered activity” to mean “growing, harvesting, packing, or holding covered produce on a farm, and that “covered activity” includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on RACs and only to the extent that such activities are within the meaning of “farm” as defined in this chapter. We also noted that part 112 does not apply to activities of a facility that are subject to 21 CFR part 110.

(Comment 88) Some comments support the coordinated revisions to the definitions of covered activity, harvesting, holding, and packing to support the broader definition of farm, while others request FDA to provide additional clarity by adding specific examples to the definition of “covered activity.”

(Response) We do not see the need for additional examples in the definition of "covered activity." Throughout the discussion of the definitions of farm, harvesting, packing, and holding, both here and in the final human preventive controls rule, we believe we have provided sufficient examples to help covered farms understand whether an activity is a covered activity subject to part 112 (see 80 FR 55908 at 55925-55932), and we will consider issuing guidance on these issues as appropriate.

We are revising the definition of "covered activity" to reflect new § 112.2(b)(6) (see section IX.A.4 of this document). We are adding a statement to this definition to make clear that providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in § 112.2(b) of this part are also covered activities.

Definition of "covered produce". We proposed to define "covered produce" to mean produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term "covered produce" refers to the harvestable or harvested part of the crop.

(Comment 89) Some comments suggest stating, within the definition of "covered produce," that circumstances where contamination of crops during early stages of production does not pose a public health risk would not be covered under this rule. Other commenters request inclusion of a statement that "covered produce" includes only the harvested portion of the plant.

(Response) Covered produce is produce that is subject to part 112 as provided in §§ 112.1 and 112.2, and our proposed definition already specified that this term refers to the harvested or harvestable portion of the crop. For the purposes of determining which produce

should be subject to part 112, it would not be appropriate to exempt some produce based on the point in time at which contamination may occur. The fact that contamination may occur during the early stages of production does not, in and of itself, provide a reasonable assurance of lack of potential contamination at a later point in the growing, harvesting, packing, or holding of that produce. Note also, under § 112.2(a), we have exempted certain produce because it is rarely consumed raw, and in § 112.2(b), we have provided for produce to be eligible for exemption from the requirements of this rule if it receives commercial processing that adequately reduces the presence of microorganisms of public health significance.

(Comment 90) Some comments suggest referring to produce covered under this rule as “fresh produce” rather than as “covered produce.”

(Response) The term “fresh produce” would not convey the meaning we intend to convey with the term “covered produce.” We use “covered produce” to describe produce that is within the scope of the rule under § 112.1 and not exempt from the rule under § 112.2. Not all “fresh produce” commodities fall within the scope of this rule. For example, although produce that is rarely consumed raw, for example, asparagus, may be viewed as “fresh produce” when they are presented to the consumer in their raw, natural, and unprocessed state, such commodities are not “covered produce” because they are exempt from this rule under the provisions of § 112.2(a)(1). The term “covered produce” helps us to distinguish the subset of “produce” (as defined herein) that falls within the scope of this rule. The term “fresh produce” is not an acceptable substitute.

Definition of “curing”. We proposed to define “curing” to mean the maturation stage of

composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition.

(Comment 91) Some comments suggest defining “curing” as the final stage of the composting process rather than the maturation stage, and that adequate curing would be achieved when a state of “stable” or “very stable” is reached.

(Response) We agree that “curing” may be more accurately described as the “final” stage of the composting process, so we are making this change. We have also replaced the term “humus” in the related definition of “composting” with “stabilized compost,” which captures the fact that the end product of the composting process is a stabilized product.

Definition of “direct water application method”. We proposed to define “direct water application method” to mean using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water. We also noted in the preamble of the 2013 proposed rule, by cross-reference to the definitions of “covered produce” and “produce”, this term would only apply to methods in which the water is intended to, or is likely to, contact the harvestable part of the covered produce.

(Comment 92) Some commenters believe direct water application methods should include postharvest water application, but not drip or trickle irrigation of root crops.

(Response) We have defined direct water application methods in terms of the intent or likelihood of contact as opposed to specific irrigation practices because it is contact of the agricultural water with the harvestable portion of the covered commodity that could result in contamination of the covered crop if the water is not appropriately managed. With respect to root crops, the analysis is the same. A water application method is a direct water application method if it is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water. For example, irrigating carrots using drip irrigation that is intended to filter through the soil and contact the carrots growing underground is a direct water application method because the water is intended to, and likely to, contact the covered produce.

Definition of “food”. We proposed to define food to mean food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes seeds and beans used to grow sprouts.

(Comment 93) One comment requests that we definitively indicate that the seeds and sprouts included in the definition for food (as defined in section 201(f) of FD&C Act) are those for human consumption and to differentiate such seeds and sprouts from those grown for planting or transplanting.

(Response) For the purposes of the produce safety regulation, in § 112.3, we define “food” to mean food as that term is defined in section 201(f) of the FD&C Act, and we explicitly include seeds and beans used to grow sprouts in this definition for clarity because sprouts are covered by this rule. Food is defined in section 201(f) of the FD&C Act, in part, as articles used as food or drink for man or other animals, and articles used for components of any

such article. We have long considered seeds and beans used to grow sprouts to be “food” within the meaning of section 201(f) of the FD&C Act (Ref. 96). Seeds and beans used to grow sprouts are both articles used as food as well as articles used as components of articles used as food.

As defined, the terms “produce” and “covered produce” for the purposes of part 112 refer to the harvestable or harvested part of a crop. When seeds and/or sprouts are the harvestable or harvested part of a crop, they may be covered produce for purposes of this rule if they fall within the definition of produce and are not otherwise exempt. On the other hand, when seeds or sprouts are not part of the harvestable or harvested part of a crop, they are not covered produce for purposes of this rule.

Definition of “ground water”. As discussed under Comment 232, we are adding a definition for the term “ground water,” and making corresponding revisions to the term “surface water” to clarify the differences between the two sources of water.

Definition of “hazard”. We proposed to define “hazard” to mean any biological agent that is reasonably likely to cause illness or injury in the absence of its control.

(Comment 94) Comments express a view that the terms “reasonably” and “likely” used in this proposed definition are ambiguous, and request clarification.

(Response) We are revising the definition by replacing the phrase “that is reasonably likely to cause illness or injury” with “that has the potential to cause illness or injury” to more clearly distinguish “hazard” from “known or reasonably foreseeable hazard.” This increases the

alignment of the definition of “hazard” in this rule with the Codex definition of “hazard” and the definition of “hazard” in the PCHF regulation.

Definition of “microorganisms”. We proposed to define “microorganisms” to mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and to include species having public health significance. We also proposed that the term “undesirable microorganisms” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

(Comment 95) One comment suggests that “microorganisms” should include non-bacterial agents of disease. Another comment believes that the term “undesirable microorganisms” should not include those that subject food to decomposition.

(Response) As discussed in section VI of this document, we focus the produce safety standards established under part 112 on biological hazards only. The biological hazards that are addressed through this regulation include bacteria, parasites, and viruses. With respect to the comment about “undesirable microorganisms,” we are retaining this term and its inclusion of microorganisms that subject food to decomposition because such decomposition microorganisms may also be undesirable for food safety or produce substances (for example, mycotoxins) that are undesirable for food safety. We believe it is appropriate to include microorganisms that subject food to decomposition to generally define microorganisms, although the standards in part 112 are not targeted at addressing undesirable microorganisms but at addressing microorganisms of public health concern (i.e., pathogens).

Definition of “mixed-type facility”. We proposed to define “mixed-type facility” to mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

(Comment 96) Some comments argue that Congress included provisions in both sections 418 and 419 of the FD&C Act to ensure an appropriate, coordinated, and targeted regulatory framework, with the intent that one operation would not be subject to multiple sets of regulations under FSMA, and that farms would continue to be exempt from the facility registration requirement. These comments ask FDA to adhere to congressional intent in defining “farm mixed-type facility” and to apply a broad reading of the term farm and a narrow reading of the term facility.

(Response) We are revising the definition of “mixed-type facility,” consistent with the definition of this term in part 117, to mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act (21 U.S.C. 350d) and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but that also conducts activities outside the farm definition that require the establishment to be registered.

Whether a particular establishment that falls within the definition of “mixed-type facility” is subject to the requirements for hazard analysis and risk-based preventive controls of part 117

is governed by the exemptions established in § 117.5. The definitions of “farm,” “harvesting,” “packing,” and “holding,” too, reflect our careful consideration of the different types of activities that occur on-farm, off-farm, or on farm mixed-type facilities. We have been careful to establish that the activities of a farm mixed-type facility that fall within the farm definition are subject to the produce safety regulation and activities falling outside the farm definition are potentially subject to the PCHF regulation; we do not subject the same activity to duplicative requirements under both rules. In the revisions we have made to the “farm” definition we have made an attempt to interpret the activities that may occur on a farm very broadly, with a consequent reduction in certain activities that would be subject to part 117. See the final human preventive controls rule and the supplemental human preventive controls notice for discussion of related issues.

Definition of “monitor”. We proposed to define “monitor” to mean to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control, and, when applicable, to produce an accurate record of the observation or measurement.

(Comment 97) Some comments suggest that the use of the phrase “when applicable” in this definition should be replaced with “when required.”

(Response) We agree with this suggestion, and we are making this change.

Definition of “non-fecal animal byproduct”. We proposed to define “non-fecal animal byproduct” to mean solid waste (other than excreta) that is animal in origin (such as meat, fat,

dairy products, eggs, carcasses, blood meal, bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal) and is generated by commercial, institutional, or agricultural operations.

(Comment 98) Some comments support this proposed definition, although a few suggest making it clear that wastes generated by other operations, including fish waste, are included within this definition.

(Response) We are revising this definition to replace the phrase “other than excreta” with “other than manure.” Under this definition, solid wastes that do not fall within the definition of “manure” and that are generated by fish operations, such as fish meal and fish emulsions, are considered non-fecal animal byproduct. On the other hand, fish excreta is animal excreta. See discussion in section III.G of this document regarding aquaculture operations.

Definition of “packaging (when used as a verb)”. We proposed to define “packaging (when used as a verb)” to mean placing food into a container that directly contacts the food and that the consumer receives.

(Comment 99) Some comments express concern about establishing the definition of “packaging (when used as a verb)” in part 112. These comments ask us to clarify how this proposed definition relates to other uses of the word “packaging” in part 112, including use as an adjective in the common phrase “food-packaging materials”. Some comments focus on the differences between the definition of the term “packing” and “packaging” with respect to activities conducted on RACs. Some comments ask us to clarify how the term “packaging (when

used as a noun)” would apply when used in part 112, even though we did not propose to establish a definition for “packaging (when used as a noun)” in part 112.

(Response) We have decided not to establish the definition “packaging (when used as a verb)” in part 112. That definition was established in the section 415 registration regulations and the section 414 recordkeeping regulations, in part, to identify those food establishments that would be subject to those regulations. In addition, the section 414 recordkeeping regulations established a definition of “packaging (when used as a noun)” because it was also necessary for the purposes of those recordkeeping regulations. However, the term “packaging” has long been used in our existing Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food regulation (current 21 CFR part 110; “the Food CGMP regulation”) to generally refer to the container that directly contacts the food, rather than to the outer packaging of food that does not contact the food (as it means in the section 414 recordkeeping regulations). Thus, the very specific connotation for the term “packaging (when used as a noun)” that was established in the section 415 registration regulations and the section 414 recordkeeping regulations does not apply, and is causing confusion. As the comments point out, our proposed definition is already causing confusion in the context of part 112. Therefore, for clarity and simplicity in part 112 we are not including in the final rule a definition of “packaging (when used as a verb).” This deletion is consistent with our decision to not establish such a definition in part 117. The definition of “manufacturing/processing” we are establishing in this rule makes clear that “packaging” (when used as a verb) is a manufacturing/processing activity. The comments that express confusion about the distinction between “packing” and “packaging (when used as a verb)” with respect to activities conducted on RACs no longer apply in light of the revised “farm” definition. The revised “farm”

definition provides for packaging RACs when packaging does not involve additional manufacturing/processing (such as cutting).

Definition of “production batch of sprouts”. We proposed to define “production batch of sprouts” to mean all sprouts that are started at the same time in a single growing unit (e.g., a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown within a single growing unit).

(Comment 100) Some comments note that various types and sizes of growing units are typically used by sprout operations, and the proposed definition would have varying impacts on sprouting operations based on their equipment type and capacity. Some comments state this proposed definition would disproportionately impact small sprout operations, which tend to germinate smaller batches of seed, because the sampling and testing requirements that relate to this definition are specific to each production batch, regardless of the amount of seed in each batch.

(Response) Our definition is intended to treat product that is exposed to the same conditions during sprouting as one production batch, and we are finalizing it as proposed. This definition is consistent with our 1999 guidance for industry on sampling and microbial testing of spent irrigation water during sprout production (Ref. 97). We recognize there is a diversity of growing practices and a variety of growing units that may represent different product volumes and, therefore, production batches can vary greatly in size. However, as noted in the 2013 proposed rule, we are limiting the definition of “production batch of sprouts” to a single

growing unit to prevent “pooling” of samples from multiple growing units within an operation whereby contamination in spent water in one unit could be diluted by non-contaminated water from other units, increasing the point that pathogens might not be detected. We discuss the related sampling and testing requirements of subpart M in section XVIII of this document.

(Comment 101) Some comments ask us to establish definitions for the terms “batch,” “sprouts,” and “soil-grown sprouts.”

(Response) We define “production batch of sprouts” in § 112.3 and do not see a reason to also provide an additional definition of “batch” in relation to sprouts. The requirements in subpart M of this rule relate to production batches of sprouts, making this the relevant term to define in this rule. We have added a new section, § 112.141, to clarify the types of commodities that are subject to the requirements of subpart M of part 112. See section XVIII of this document. With this addition, we conclude it is sufficiently clear what commodities are subject to subpart M and we need not also establish a definition of “sprouts” or “soil-grown sprouts” for this purpose.

Definition of “qualified end-user”. We proposed to define “qualified end-user,” with respect to a food, to mean the consumer of the food; or a restaurant or retail food establishment (as those terms are defined in § 1.227) that is located (1) in the same State as the farm that produced the food; or (2) not more than 275 miles from such farm. We proposed that the definition would also state that the term “consumer” does not include a business.

We are editing this definition to move the phrase “The term ‘consumer’ does not include a business” from out of paragraph (ii) and into a parenthetical phrase within the

definition of “qualified end-user” because the term “consumer” is used in the definition of “qualified end-user” and not in paragraph (ii). We are also adding “or the same Indian reservation” to the definition of “qualified end-user” to clarify for purposes of this rule that “in the same state” under 21 U.S.C. 350h(f)(4)(A)(ii)(II) includes both within a State and within the reservation of a Federally-recognized tribe.

(Comment 102) Some comments argue that Congress only intended the 275 mile distance criterion in the definition of “qualified end-user” to be applied within the United States, its territories, and the Commonwealth of Puerto Rico. On the other hand, other comments asked FDA to clarify that the 275 mile criterion also applies within foreign countries, such that there is an equitable treatment of domestic and foreign farms.

(Response) The definition of “qualified end-user” in § 112.3(c) implements section 419(f)(4) of the FD&C Act. Section 419(f)(4)(A) of the FD&C Act does not provide for a different analysis for when an international border falls within the 275 miles and, therefore, we proposed that international borders would not affect the distance calculation. We are not aware of any basis from which to conclude that Congress intended the distance criterion to be limited to domestic application, or to be otherwise affected by international borders, and the comments did not provide any information from which we might draw such a conclusion. We see no reason to treat sales to restaurant and retail food establishment buyers within 275 miles of a farm differently based on the presence of an international border for the limited purpose of calculating which of a farm’s sales are to qualified end-users. We note that some of the commenters seem to confuse criteria for which sales may be counted as sales to qualified end-users with criteria for exemption from the rule. Sales to qualified end-users, in and of

themselves, do not amount to exemptions from the rule. A farm must meet all the criteria provided in § 112.5(a) to be eligible for the qualified exemption. These criteria in § 112.5(a) are based only in part on sales to qualified end-users. For all of these reasons, we conclude that international borders do not affect the 275 mile distance calculation in the definition of qualified end-user. Therefore, for example, a farm in Mexico or Chile selling food to a restaurant or retail food establishment that is located in a neighboring country (for example, the United States and Argentina, respectively) that is within 275 miles of the farm would be able to count that sale as a sale to a qualified end-user. The same would also be true for United States farms that sell food to a restaurant or retail food establishment in a neighboring country that is within 275 miles of the farm. In short, a farm in any country can be eligible for a qualified exemption, provided it meets the criteria established in § 112.5(a).

(Comment 103) Several comments ask FDA to clarify what would be considered a sale “directly to consumers” for purposes of the definition of “retail food establishment” in § 1.227(b)(11), which is used in the definition of “qualified end-user” in § 112.3(c). Some comments ask us to revise the definition of “restaurant or retail food establishment” to include enterprises such as supermarkets, supermarket distribution centers, food hubs, farm stands, farmers markets, and CSA.

(Response) FDA is addressing the definition of “retail food establishment” in a separate rulemaking. In a recent notice of proposed rulemaking titled, “Amendments to Registration of Food Facilities” (80 FR 19160; April 9, 2015), FDA proposed various amendments, including to the definition of “retail food establishment” in § 1.227(b)(11).

(Comment 104) Some comments suggest sales to qualified end-users should include internet or mail-order sales. Some comments suggest sales that they term “secondary” should be considered sales to qualified end-users. These commenters provide the example of dairy farmers who grow produce for what they consider to be “ancillary” or “incidental” sales.

(Response) The definition of “qualified end-user” implements section 419(f)(4) of the FD&C Act. A sale conducted online or through mail-order can be considered a sale to a qualified end-user if the buyer meets the definition of a qualified end-user. We note that the definition of “qualified end-user” includes the consumer of the food, without regard to that consumer’s location relative to the farm. We are not aware of any basis from which to conclude that Congress intended that what one commenter describes as “secondary” sales should be considered sales to qualified end-users on the basis of the farm’s impression that such sales are only ancillary or incidental to their business. Moreover, we note that for the purposes of determining eligibility for a qualified exemption under § 112.5, sales to a qualified end-user are calculated based on the sale of all “food,” and not on sales of “produce” only.

Definition of “known or reasonably foreseeable hazard” (proposed “reasonably foreseeable hazard”). We proposed to define “reasonably foreseeable hazard” to mean a potential hazard that may be associated with the farm or the food.

(Comment 105) Some commenters ask for clarification of the proposed definition, and express concern that it is not sufficiently clear to ensure uniformity and consistency in safe practices. One commenter suggests including the word “biological” within this proposed definition, consistent with the proposed definition of “hazard”.

(Response) We are making revisions to define the term “known or reasonably foreseeable hazard” to mean “a hazard that is known to be, or has the potential to be, associated with the farm or the food” to better align with definition of the same term in the PCHF regulation. This term is used in section 419(c)(1)(A) of the FD&C Act, and is reflected in several requirements in part 112. We have provided clarification for how this term relates to specific requirements in part 112 through examples throughout this final rule. In addition, by cross-reference to the definition of “hazard,” a “known or reasonably foreseeable hazard” as defined for the purposes of part 112 is limited to biological hazards because those are the only hazards we are addressing in this rule. For clarity, we are adding the term “biological” to the definition of “known or reasonably foreseeable hazard.”

Definition of “sanitize”. We proposed to define “sanitize” to mean to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

We are retaining this definition with one change. In the PCHF regulation, we defined “sanitize” to mean “to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.” We are making a corresponding revision to the definition of “sanitize” as it applies to part 112 by referring to adequately treating “surfaces” rather than “food-contact surfaces.” Adequately treating any cleaned surface—regardless of

whether it is a food-contact surface—by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer, is “sanitizing” the surface. This change to clarify the definition of “sanitize” does not affect the requirements to sanitize, when applicable, which are established throughout part 112.

Definition of “stabilized compost” (proposed “humus”). We proposed to define “humus” to mean a stabilized (i.e., finished) biological soil amendment produced through a controlled composting process.

(Comment 106) Several comments disagree with our proposed use of the term “humus” (see also discussion of definition of “composting”). These commenters state that the term “humus,” as proposed, would be better described by reference to the static state of compost at the end of the composting process. These commenters note that the organic material at the end of the composting process is beyond the active stage, with reduced biological activity marked by reduced temperature and respiration rate. These commenters further explain that composting requires specific time and temperature conditions to achieve controlled biological decompositions and stabilization of organic material, and that it is in this stabilized state that the material is useful and beneficial to plant growth. Thus, these commenters argue that the biologically stable material that is derived from the composting process should be referred to as “compost” rather than “humus.” These commenters explain that humus forms naturally (in forests and other landscapes) as a component of soils, and may be only one component of finished or mature compost and should not be used to refer to “compost” as a whole. One

comment asked that we align the definition of “humus” (compost) with the NOP definition of “compost”.

(Response) We agree the term “stabilized compost” is a better representation of the finished product of composting. We are revising the codified to use the term “stabilized compost” rather than “humus” everywhere it appears, and we are replacing the defined term “humus” with the defined term “stabilized compost” (with the same defined meaning). This change affects the definitions of “agricultural tea,” “biological soil amendment,” “composting,” “growth media,” “soil amendment,” “static composting,” and “turned composting.” We do not believe it is necessary to align our revised definition of “stabilized compost” with the NOP definition of “compost” in 7 CFR part 205. The NOP definition of “compost” includes a great deal of detail about the process of composting which we do not believe is necessary for our use of the term “stabilized compost” in part 112 and also could be viewed as limiting the mechanisms by which compost can be made, which is not our intent.

Definition of “static composting.” We proposed to define “static composting” to mean a process to produce humus in which air is introduced into biological material (in a pile (or row) covered with at least 6 inches of insulating material, or in an enclosed vessel) by a mechanism that does not include turning. We further proposed to state that examples of structural features for introducing air include embedded perforated pipes and a constructed permanent base that includes aeration slots, and that examples of mechanisms for introducing air include passive diffusion and mechanical means (such as blowers that suction air from the composting materials or blow air into the composting material using positive pressure).

(Comment 107) Arguing that the definition should exclude passively aerated systems, some commenters recommend using the term “aerated static composting” to ensure proper treatment to achieve time and temperature conditions.

(Response) We disagree that the definition of “static composting” should exclude passively aerated systems. In fact, we indicate in the definition that passive diffusion is one method for introducing air to the composting material. Therefore, we decline to change the definition to “aerated static composting.” We recognize that composting that includes passively aerated systems may have cold spots due to uneven aeration; however, it is not our intent to narrowly limit the way compost is produced as long as the stabilized compost meets the standards of § 112.54(a) or (b).

As discussed previously, we are replacing the term “humus” with “stabilized compost” in the definition of “static composting.” We are also making a change to indicate that static composting may or may not involve the use of insulating material. The revised definition of “static composting” reads “static composting means a process to produce stabilized compost in which air is introduced into biological material (in a pile (or row) that may or may not be covered with insulating material, or in an enclosed vessel) by a mechanism that does not include turning. Examples of structural features for introducing air include embedded perforated pipes and a constructed permanent base that includes aeration slots. Examples of mechanisms for introducing air include passive diffusion and mechanical means (such as blowers that suction air from the composting materials or blow air into the composting material using positive pressure).”

Definition of “yard trimmings.” We proposed to define “yard trimmings” to mean

purely vegetative matter resulting from landscaping maintenance or land clearing operations, including materials such as tree and shrub trimmings, grass clippings, palm fronds, trees, tree stumps, untreated lumber, untreated wooden pallets, and associated rocks and soils.

(Comment 108) We received mixed comments on the use of terms “yard trimmings,” “yard trash,” and “yard debris”. Some commenters suggest using the term “yard debris” to refer to plant material commonly created in the course of yard and garden maintenance through horticulture, gardening, brush, weeds, flowers, roots, windfall fruit, and vegetable garden debris. Some comments note that yard trimmings and pre-consumer vegetative waste could contain arthropods or dog waste, and suggest using a term that would be more restrictive so as to avoid such potential inclusions, such as “vegetation trimmings,” “vegetable debris,” “foliage,” “excess flora,” or “plants, bushes and tree parts.” Other comments recommend defining a new category of vegetative waste, referred to as “wood waste,” to include materials such as wood pieces or particles generated as byproducts from the manufacturing of wood products, construction, demolition, handling and storage of raw materials, trees and stumps, sawdust, chips, shavings, bark, pulp, hogged fuel, and log sort yard waste. These commenters note that wood waste does not include wood pieces containing paint, laminates, bonding agents, or chemical preservatives.

(Response) We are retaining the term “yard trimmings” to refer to purely vegetative matter resulting from landscaping maintenance or land clearing operations. Commenters were split on whether we should use this term or an alternate term such as “yard debris,” “vegetation trimmings,” or “wood waste” to express the same meaning, and no comment provided a reason to think “yard trimmings” would be confusing or problematic. The materials commenters listed as yard debris, vegetation trimmings, or wood waste are encompassed within our definition of

“yard trimmings.” We use the term “yard trimmings” to avoid potentially negative connotations associated with the word “trash,” even though some components of our definition (e.g., untreated wooden pallets) arguably are not “trimmings.” Dog droppings and other animal wastes are not yard trimmings. However, we recognize that even in purely vegetative material such as that described in the definition of “yard trimmings,” there is the potential for unknown and unavoidable contamination with animal waste. We have concluded that the likelihood of contaminating produce with pathogens by use of biological soil amendments that are not known to contain, and not likely to contain significant animal waste or human waste (e.g., yard trimmings, pre-consumer vegetative waste) is low, and therefore they are not subject to the requirements of this rule. We decline to define the term “yard trimmings” in a way that makes such materials subject to the requirements in this rule.

Definition of “you.” We proposed to define “you” to mean a person who is subject to some or all of the requirements in this part.

(Comment 109) Some comments ask that we revise this proposed definition to directly link it to the owner or operator in charge of the covered farm. One comment also states the person responsible for compliance with the produce rule is not necessarily the owner of the farmland, but could sometimes be the owner of the business or the person with effective operational control over the farm business, such as owners, tenants, partners, or employees.

(Response) We are revising this definition to state that “you,” for the purposes of part 112, means the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of part 112. We are also making corresponding edits to the questions

and provisions in §§ 112.4, 112.5, 112.6, and 112.7 to reflect this revision. Specifically these edits include replacing the term “you” or “I” with “farm(s).”

3. Other Comments

(Comment 110) Some comments state that terms such as “minimize,” “periodic,” “regular,” and “when necessary and appropriate” as used within the proposed provisions have no clear definitions, and suggest that these terms should be defined.

(Response) As explained in the 2013 proposed rule (see section IV.D of that document; 78 FR 3504 at 3529-3521), we developed the regulatory framework for this rule taking into account the need to tailor the requirements to specific on-farm routes of contamination. We have incorporated flexibility into our requirements, wherever appropriate, relying on an integrated approach that employs various mechanisms. In some cases, the produce safety standards in part 112 are very similar to those contained in the Food CGMP regulation, especially where the routes of contamination are well-understood and appropriate measures are well-established and generally applicable across covered produce commodities (e.g., personnel qualifications, training, health, and hygiene; harvesting, packing, and holding activities; equipment, tools, buildings, and sanitation). We rely on this approach where possible, in part, because of the diversity of the industry with respect to size, agricultural practices, and knowledge of food safety. Such standards are intended to be flexible and inherently necessitate the use of terms such as “periodic,” “when necessary,” and “when appropriate.” While we believe these terms are generally understood, we have provided examples throughout the rule to help covered farms better understand the requirements.

(Comment 111) Some comments request that we define the term “crop” to mean both edible and inedible cultivated plants. These commenters state that such a definition is necessary to avoid confusion in instances where edible portions of a plant come into contact with harvested but inedible portions of the plant that may be used, for example, in the production of biofuels, clothing, and bio-degradable household products.

(Response) The science-based minimum standards that we are establishing in part 112 apply to the growing, harvesting, packing, and holding of produce for human consumption. Produce that is not reasonably expected to be directed to a food use (for example, produce that is reasonably expected to be used in the production of biofuels, clothing, or household products) is not subject to the requirements of part 112. Therefore, we do not agree that we should establish a definition for the term “crop” as suggested by these commenters.

(Comment 112) Some comments request that we provide clear definitions for the terms “greenhouse,” “germination chamber,” and “other protected environment production areas.” Some commenters request that FDA define the term “greenhouse” using the following statement in a Federal Register document issued by the International Trade Administration, Department of Commerce: “Controlled environment tomatoes are limited to those tomatoes grown in a fully-enclosed permanent aluminum or fixed steel structure clad in glass, impermeable plastic, or polycarbonate using automated irrigation and climate control, including heating and ventilation capabilities, in an artificial medium using hydroponic methods” (78 FR 14967 at 14970).

(Response) None of these terms is used to describe any requirements in part 112, including in subpart L of 112, and, therefore, their inclusion in the list of definitions in § 112.3 is not necessary. We respond to comments about the applicability of subpart L to such

buildings in section XVII of this document.

(Comment 113) Some comments ask that we establish a definition of the term “standard.”

(Response) As required by section 419 of the FD&C Act, we have established science-based minimum standards for the safe production and harvesting of produce in part 112, and we have included definitions that are relevant to those standards. We do not see the need to further establish a definition for the term “standard.” In addition, FDA has established many standards related to food safety and we believe this term is generally understood by the regulated community.

(Comment 114) Some comments request that we define the term “visitor,” and suggest that such definition should exclude visitors who visit the farm, but do not come into contact with produce or any other RAC being produced on the farm.

(Response) We stated in proposed § 112.33(a) that a visitor is any person (other than personnel) who enters your covered farm with your permission. We do not expect all visitors to present a reasonable likelihood of introducing hazards into covered produce. However, we decline to limit the requirements in this rule related to visitors to only those visitors who come into contact with produce or other RACs. See discussion under Comment 172. We do agree, however, that the definition of “visitor” that appeared in proposed § 112.33(a) should instead appear in § 112.3 with the other definitions, and we are making this change to § 112.3 and eliminating proposed § 112.33(a).

(Comment 115) Some comments request definitions for other terms related to biological soil amendments, including for the terms “aging,” “feedstock,” “green waste,” and “maturity.”

(Response) None of these terms is used to describe the requirements in part 112, including in subpart F of part 112, and, therefore, their inclusion in the list of definitions in § 112.3 is not necessary.

C. Small Businesses, Very Small Businesses, and Farms That are Not Covered or are Eligible for a Qualified Exemption

In the 2013 proposed rule, under proposed § 112.3(b), we proposed to establish the definitions for very small business and small business, and under proposed § 112.4, we proposed to apply part 112 only to farms above a certain specified average monetary value of sales (78 FR 3504 at 3549). We also proposed §§ 112.5 and 112.6 to establish the eligibility criteria and modified requirements related to farms with a qualified exemption. In addition, in the supplemental notice, taking into account public comment, we proposed to amend the originally proposed definitions of very small business and small business in § 112.3(b) as well as the provision in § 112.4 regarding farms not covered under this rule (79 FR 58434 at 58436-58438). In both the 2013 proposed rule and in the supplemental notice, we asked for public comment on our proposed provisions.

We are finalizing §§ 112.4, 112.5, and 112.6 with changes, and adding new § 112.7, as discussed in this section (see Table 4). In this section, we also discuss comments we received in response to the 2013 proposed rule, but that we did not address in the supplemental notice. We also discuss comments that we received on the amended proposed provisions in the supplemental notice.

1. Suggestions Related to Farms Not Covered or Eligible for a Qualified Exemption

(Comment 116) Some comments suggest that farms not covered by this rule based on their size, or farms that are eligible for a qualified exemption from this rule should be regulated under scale-appropriate State-run food safety programs. Some comments also request that FDA provide support for States to implement such programs.

(Response) FDA is not requiring States to set up food safety programs for farms eligible for the qualified exemption, nor are we prohibiting States from establishing such programs. We do intend to continue to work collaboratively with our State and other partners in facilitating compliance with this rule. Such efforts will be appropriately focused on covered farms, not on farms eligible for the qualified exemption. However, we do anticipate that some of the materials and programs generated in that effort are likely to be helpful to farms eligible for the qualified exemption as well as to covered farms. Our existing guidance documents, such as the GAPs Guide, provide relevant recommendations. In addition, we expect that the training materials being developed by the PSA and SSA will be useful resources, including for training farms eligible for the qualified exemption in safe produce growing, harvesting, packing, and holding practices.

(Comment 117) One comment recommends that farms not covered by this rule based on their size or eligible for a qualified exemption should not be allowed to supply produce to entities such as schools or hospitals.

(Response) We do not agree that farms not subject to coverage under part 112, or eligible for a qualified exemption should be precluded from marketing their produce to schools or

hospitals. Produce marketed in the United States must be safe for consumption, regardless of whether the farm that grew the produce is required to comply with part 112. There is no reason to believe that produce is unsafe or otherwise unfit for consumption by individuals at schools or hospitals simply because it was produced by a farm not subject to part 112 or eligible for a qualified exemption.

(Comment 118) One comment requests that any requirements for supplier verification in other FSMA rules should not prevent other food businesses from purchasing produce from farms that are eligible for the qualified exemption from the produce safety regulation or otherwise not subject to the produce safety regulation.

(Response) Nothing in the produce safety regulation, PCHF regulation, or FSVP regulation precludes food businesses from purchasing produce grown, harvested, packed, or held by farms that qualify for a qualified exemption from the produce safety regulation or are otherwise not subject to the produce safety regulation. In the rulemakings establishing the PCHF regulation (80 FR 55908) and FSVP regulation (published elsewhere in this issue of the Federal Register), FDA explained how the supplier verification requirements in those rules relate to farms that are not subject to the produce safety regulation.

2. Calculating Farm Sizes

(Comment 119) Some comments request clarification on how sales will be calculated for the purpose of determining a farm's size and, therefore, whether the farm is a covered farm, eligible for a qualified exemption, and/or eligible for an extended compliance period. Comments ask whether the value of produce donated to non-profit organizations such as food banks and

senior centers would be counted towards sales. In addition, comments ask whether sales or donations to public institutions, such as prisons, would be counted towards sales.

(Response) For purposes of the sales thresholds in this rule, FDA does not consider a donation in which there is no payment of money or anything else of value in exchange for produce to be a “sale.” Such donations, including to public institutions or non-profit organizations, are not counted toward a farm’s sales revenue. However, sales of produce to any public institutions or non-profit organizations in which money or anything else of value is exchanged for produce must be counted as sales for purposes of this rule.

(Comment 120) Some comments seek clarification on the applicability of small or very small business definitions in proposed § 112.3 versus the eligibility criteria for a qualified exemption in § 112.5 in the circumstance where a farm meets the conditions for both. Some comments point out that because the monetary thresholds are based on produce sales for the former and all food sales for the latter, it would be possible for certain diversified farms to qualify for extended compliance periods (as small or very small businesses) as well as for a qualified exemption and modified requirements. Additionally, one commenter is concerned that this difference in monetary threshold basis means that a farm will have to be aware of the implications of its sale of “all produce” and “all food.”

(Response) We acknowledge that because of the difference in the bases for monetary cut-offs established in § 112.3 and in § 112.5, there could be circumstances where a farm that is a small business or very small business (as defined in § 112.3) is also eligible for a qualified exemption (in accordance with § 112.5). Farms eligible for a qualified exemption (in accordance with § 112.5) that also qualify as a small or very small business (as defined in § 112.3(b)), must

comply with the modified requirements of §§ 112.6 and 112.7 within the compliance periods established for either a small business or a very small business, whichever is applicable. A farm can be both a farm eligible for a qualified exemption and a small or very small business. We are revising the definitions of small business and very small business to acknowledge that such businesses may be subject to only some of the requirements of part 112, if they are also a farm eligible for a qualified exemption, and to all of the requirements of part 112 if they are only a small or very small business. We have replaced the phrase “if it is subject to this part” with “if it is subject to any of the requirements of this part” in the definitions of both small business and very small business in § 112.3(b).

(Comment 121) Some comments ask whether annual sales will be calculated per owner or per operator, where the farm owner and operator are different. Other comments ask whether farms may alter their business structures for the purpose of evading this rule.

(Response) We have revised the definition of “farm” to make clear that the relevant entity is the farm business, which is either (1) a Primary Production Farm, an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities; or (2) a Secondary Activities Farm, an operation devoted to harvesting, packing, and/or holding of RACs, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. Thus, a farm’s sales are those attributable to the farm business. Limits on permissible business structures for farms are beyond the scope of this regulation. Thus, it is possible that

some farms may attempt to evade this regulation as suggested by the comment. However, we do not expect this to occur on a broad scale given that many farms currently already participate in voluntary industry guidelines or marketing agreements, many of which include provisions similar to those required under this regulation.

(Comment 122) One comment finds the requirements for calculating sales for the purposes of the coverage threshold and the qualified exemption to be confusing and notes that small farms may resist a financial evaluation to determine the applicability of this rule at the beginning of an inspection.

(Response) The \$25,000 coverage threshold is based on sales of produce, which we expect a farm to be able to demonstrate using existing sales records. The criteria for the qualified exemption are more complex, but are a product of requirements in section 419(f) of the FD&C Act. In section IX.C.5-7 of this document we discuss how a farm can demonstrate its eligibility for the qualified exemption and the associated requirement for farms to maintain necessary documentation. We expect that farms that are not covered by this rule, or that are eligible for an exemption, will be willing to provide supporting documentation to FDA at relevant times, including during an inspection. We intend to target our education efforts on small farms to help them come into compliance. We also plan to work closely with State, territorial, tribal and local partners to develop the education and enforcement tools and training programs needed to facilitate consistent inspection and regulatory activities associated with this rule.

(Comment 123) Some comments recommend including a multiplier ratio in the sales thresholds to take into account the growing seasons of different areas. Another comment recommends replacing monetary income thresholds for farm size with either produce-unit thresholds or with the cost of non-farm inputs purchased.

(Response) We believe it is unnecessary to include a multiplier ratio because we consider total annual production, rather than seasonally-adjusted production. We use monetary value of sales of produce as a proxy for the quantity of produce sold in the United States marketplace. This provides a clearer picture of volume contribution to the United States marketplace than produce units or cost of non-farm inputs purchased, which do not appear to indicate consumption or even yield.

(Comment 124) Some comments recommend adjusting the sales thresholds for all purposes for inflation and recommend using 2011 as the baseline year for such adjustment, consistent with the monetary threshold for farms eligible for a qualified exemption (§ 112.5). One comment recommends including adjustments to the sales thresholds in the rule based on the Consumer Price Index to account for future inflation.

(Response) We do not agree that the monetary thresholds for determining whether a covered farm is a “small business” or “very small business” need to be adjusted for inflation. These thresholds are used only to determine the first date upon which a small or very small business must comply with the rule, with applicable compliance periods ranging from two years to a maximum of six years from the effective date of this rule. In contrast, the \$25,000 monetary threshold in § 112.4(a) affects whether or not a farm is covered under this rule, with indefinite effect. Therefore, we agree that this monetary threshold should be adjusted for

inflation, and we are revising § 112.4(a) accordingly. With respect to the monetary threshold related to eligibility for a qualified exemption, we are finalizing § 112.5, as proposed. Section 112.5(a)(2) provides that the \$500,000 figure will be adjusted for inflation, and § 112.5(b) provides that 2011 is the baseline year for calculating such adjustment. We intend to use the federal calculation for inflation adjustments provided by the Bureau of Economic Analysis (Ref. 98), and to make the adjusted dollar value available on our Internet site.

(Comment 125) One comment asks how farm size will be calculated if a farm has properties in two States.

(Response) We have revised the definition of “farm” to make clear that the relevant entity is the farm business. Thus, provided that a farm is limited to one general (but not necessarily contiguous) physical location, whether a farm’s operation crosses State borders does not affect the calculations of a farm’s size, which are based on annual sales.

(Comment 126) Comments request revisions and/or clarification on the applicability of the farm size monetary thresholds to foreign farms. Some comments express concern that applying the thresholds equally to domestic and foreign farms will have significant unintended consequences. Some comments state that the proposed \$25,000 threshold has significant consequences in relation to imported foods. According to these comments, foreign farms that export foods to the United States from around the world are often very small, and produce from these farms is aggregated for export to the United States. Another comment states that any gross sales threshold gives an unfair advantage to foreign farms who sell produce at a low price index, disadvantaging domestic farmers, who the commenter asserts will sell less produce than foreign

farmers before exceeding any given threshold. This comment asks FDA to define farm size thresholds based on tonnage, with separate categories for different classes of produce, rather than on monetary value of sales.

(Response) We do not agree that the coverage threshold presents a particular problem with respect to imported produce. Produce is aggregated for sale both domestically and abroad. We conclude that the farms below the threshold do not contribute significantly to the volume of produce in the marketplace that could become contaminated and, therefore, have little measurable public health impact. We acknowledge that dollar amounts are directly related to product value, but nonetheless disagree that we should base the monetary thresholds in the rule on the volume or amount of product sold. We see no practical way to identify a threshold based on volume or amount of product that could be applied across all applicable commodities and operations, and the commenter provided no specific suggestions for how this recommendation could be carried out.

(Comment 127) Some comments ask us to count only United States sales to calculate the size of foreign farms that export food to the United States. Some comments also assert that most foreign farms export only a small portion of their total produce to the United States, and that this limited volume of produce poses a relatively low risk to United States consumers. In addition, one comment also states that because the farm's coverage or qualified exemption status would be influenced by fluctuations in foreign exchange rates, monetary thresholds based on global sales would jeopardize the predictability of business and have negative effects on trade.

(Response) We decline this request. The purpose of the definitions of "very small business" and "small business" in this rule is to allow such farms extended periods before their

initial compliance with the rule. We are providing this flexibility because they may have fewer resources to direct to compliance with the rule under the shorter timeframes provided to larger farms. As such, we are applying this rule equally to foreign and domestic farms of the same size. Just like a similarly situated domestic farm, a foreign farm that sells more than the threshold dollar amount of food is likely to have the capability of complying with the rule within the applicable time period, even if not all of that dollar amount reflects United States sales. We also decline this request with respect to the monetary threshold in § 112.4(a), maintaining consistency to the maximum extent possible. The criteria for eligibility for a qualified exemption (and, therefore, associated modified requirements) established in § 112.5 are as mandated by section 419(f)(1) of the FD&C Act. Because these criteria are mandated by the statute, FDA must include them and we are finalizing them, as proposed.

Although it is true that foreign exchange rates fluctuate, we believe the effect of such fluctuations on a farm's average revenue over a three year period would be minimal. Foreign exchange prices fluctuate, but so too, do crop prices. If a covered farm is able to make more money either by switching crops or selling to new markets overseas these changes in practice could affect the farm's coverage. And while such opportunities may present themselves in the short term, both crop prices and exchange rates tend to stabilize over the long term.

(Comment 128) Several comments request that farm sizes be based on the sale of "covered produce," rather than on the sale of "all produce." Although supportive of the change from "all food" to "all produce," these comments urge FDA to calculate all monetary thresholds for businesses based on sales of covered produce to provide what the commenters believe would be a clear standard and support farm diversification efforts. Some comments argue that section

419 of the FD&C Act placed limitations on the scope of the rule that should be reflected in the rule's calculation of sales by basing them only on food covered by the rule. One commenter asserts that it would not be difficult to determine produce that is "covered" versus "not covered" or to keep track of "produce sold" versus "produce grown for personal consumption." Some commenters opine that defining coverage in terms of "covered produce" versus "all produce" would likely continue to cover only a small fraction of the total volume of covered produce in the United States food supply, resulting in minimal changes to total coverage of the rule. In contrast, some comments support FDA's revised provisions, and state that basing farm monetary thresholds on "covered produce" might be too difficult to be practical in that, compared to "all produce," identifying "covered produce" is distinctly more challenging and will change on a more frequent basis.

(Response) In the supplemental notice, we considered and rejected basing farm size on sales of covered produce, and commenters did not provide specific suggestions responsive to our stated concerns about the feasibility of this approach. This scenario continues to present a number of challenges, including the difficulty of determining the scope and public health impact of not covering farms based on the sales of covered produce, particularly considering the likely variability in produce commodities grown year to year; variability resulting from provisions under which certain commodities would not be considered "covered produce" (for example, produce that is rarely consumed raw); changes in the amount of produce that is used for personal consumption or for consumption on the farm or another farm under the same management; and whether and how to account for produce that would be eligible for exemption under certain conditions, which may be inherently variable based on market conditions (for example, produce that is destined for commercial processing). We continue to find it difficult

to quantitatively determine the extent to which businesses with an average annual monetary value of “covered produce” sold of more than \$25,000 would contribute to the overall produce market, or the public health impact of not covering such businesses under part 112. However, it can be reasonably expected that applying the same monetary thresholds to covered produce sales (rather than to total produce sales) would exclude more produce acres and, therefore, a larger volume of product potentially associated with foodborne illness. Moreover, the possibly frequent changes to a farm’s covered or non-covered status may also be challenging for compliance and enforcement purposes. We also disagree that our legal authority requires us to use “covered produce” only as the basis for sales thresholds in this rule. As explained elsewhere, the monetary threshold for a qualified exemption is established by statute as calculated based on all food, and we use this basis in § 112.5. Section 419 gives FDA the discretion to define the terms “small business” and “very small business,” and to determine which farms and which produce should be covered. For all of these reasons, we are not adopting this approach.

3. Definitions of Small and Very Small Businesses (§ 112.3(b)) and Extended Compliance Periods

(Comment 129) A number of comments asked us to raise the sales thresholds in the definitions of “very small business” and “small business” set forth in proposed § 112.3(b). These comments cite the relative proportion of farms that would meet each definition and the economic burden of compliance with the rule as justification. Sales thresholds suggested for “very small business” and “small business” ranged across the comments, including suggestions up to

\$1,000,000 or even \$2,000,000 in average annual monetary value of sales over the previous 3-year period.

(Response) As required by section 419(a)(3)(A) and (c)(1)(B) of the FD&C Act, we have formulated this rule to provide sufficient flexibility to be practicable for all sizes and types of entities engaged in the production and harvesting of fruits and vegetables that are RACs, including small businesses and entities that sell directly to consumers, and to be appropriate to the scale and diversity of the production and harvesting of such commodities. Small businesses and very small businesses are provided extended compliance periods as a means of providing such businesses with additional flexibility (see section XXIV of this document). In the supplemental notice, we revised the proposed definitions of small business and very small business by replacing the sales thresholds based on sales of all food with sales thresholds based on sales only of produce, which we expect would increase the number of farms that would fit within those definitions and therefore qualify for extended compliance periods (79 FR 58434 at 58437). Small businesses and very small businesses, as defined for the purpose of this regulation, together account for an estimated total of 17.2 percent of covered produce acres and about 13.6 percent of all produce acres in the United States, and are significant contributors to the volume of produce marketed in the United States. We considered the suggestions to set the monetary thresholds for very small or small businesses at \$1 million or \$2 million. Using these thresholds, applied to annual sales of produce, such businesses account for an estimated total of 40.6 percent of covered produce acres and about 32 percent of all produce acres in the United States for the \$1 million cutoff, and an estimated total of 54.6 percent of covered produce acres and about 43 percent of all produce acres in the United States for the \$2 million cutoff. Neither of these cutoffs is appropriate to consider a business as “very small business” or “small

business” because it would delay compliance dates significantly for about a third of all produce marketed in the United States using the \$1 million cutoff, and for nearly a half of all produce marketed in the United States using the \$2 million cutoff. We also considered and rejected the possibility of basing the thresholds on sales of covered produce, as explained in Comment 128. Therefore, we believe that the sales thresholds in the definitions of very small business and small business, as revised in the supplemental notice, are appropriate, and we are finalizing them as proposed in the supplemental notice. We intend to target our education and technical assistance efforts to help these farms to comply with the standards established in part 112.

(Comment 130) One comment disagrees with providing extended compliance periods for small and very small businesses, stating that these provisions would allow such farms to operate at increased risk for a significant time.

(Response) We are providing extended compliance periods for small and very small businesses to incorporate additional flexibility into the regulation, consistent with the statutory provisions in section 419(a)(3)(A) and (c)(1)(B) of the FD&C Act, which direct us to provide sufficient flexibility to be practicable for all sizes and types of businesses, including small businesses. Small and very small businesses may have fewer resources available to, for example, invest in new equipment, or fewer staff with formal training in food safety and, therefore, may need additional time to come into compliance with the regulation. Providing extended compliance periods to small and very small businesses is consistent with our approach to compliance dates in recent rules directed to food safety (see, e.g., 74 FR 33029 at 33034, July 9, 2009 and 72 FR 34751 at 34752, June 25, 2007). This allowance for extended compliance periods does not eliminate or otherwise affect their responsibility under the FD&C

Act to ensure the safety of their produce.

4. The \$25,000 Threshold for Coverage Under the Rule (§ 112.4(a))

(Comment 131) Several comments support the proposed threshold of more than \$25,000 in average annual monetary value of produce sales during the previous 3-year period. Some comments request that the threshold be raised. These comments recommend varying thresholds ranging from \$75,000 to \$5,000,000 of annual sales of either produce, covered produce, or all food. One comment suggests that the threshold should be higher than the majority of farms that could reasonably be considered viable family-sustaining businesses. Other commenters suggest using a threshold in line with an average single family income.

Other comments object to the inclusion of any monetary or otherwise size-based threshold for coverage under this rule. These comments argue that this approach creates an “uneven playing field” advantaging small farms over large farms, that pathogens do not discriminate based on the size of a farm, that such a threshold will minimize the impact of this rule in terms of consumer confidence in the safety of produce, and that small farms are nevertheless able to comply in a cost-effective manner with the same best practices for food safety that larger producers follow. Some comments also argue that inclusion of such a threshold puts pressure on State and local agencies to regulate the smallest farms, and that the smallest operations may be the highest risk for hazards and contamination because large farms typically utilize third-party audits but smaller farms do not.

(Response) We believe it is appropriate to establish a threshold for coverage of this rule to establish only those requirements that are reasonably necessary to meet the public health objectives of the regulation. Because farms below the threshold do not contribute significantly to

the volume of produce in the marketplace that could become contaminated, we conclude that imposing the requirements of part 112 on these businesses is not warranted. We note that farms that are not subject to this rule are and will continue to be covered under the adulteration and other applicable provisions of the FD&C Act and applicable implementing regulations, irrespective of whether they are included within the scope of this rule. We recommend that farms that are not covered under part 112 follow good agricultural practices to ensure that the produce they grow, harvest, pack or hold does not serve as a vehicle for foodborne illness.

In the supplemental notice, we revised the proposed \$25,000 threshold for coverage by replacing sales of “food” with sales only of “produce.” We tentatively concluded that the farms below this revised proposed threshold would not contribute significantly to the volume of produce in the marketplace that could become contaminated and, therefore, would have little measurable public health impact. We believe that applying the limit to produce sales rather than all food sales would accommodate the concerns expressed by some comments without adversely affecting the level of public health protection envisioned under the 2013 proposed rule (79 FR at 58434 at 58437). We are finalizing the \$25,000 threshold, based on sales of produce, as proposed in the supplemental notice. Our analysis shows that farms with less than \$25,000 of annual produce sales account for an estimated total of 2.5 percent of covered produce acres, and about 2 percent of all produce acres in the United States. Such businesses do not contribute significantly to the volume of produce in the marketplace that could become contaminated and, therefore, we believe that imposing the requirements of part 112 on these businesses is not warranted. We also considered and rejected the possibility of basing the threshold on sales of covered produce, as explained in Comment 128.

We also considered alternative monetary value thresholds suggested by commenters.

We find that setting a monetary threshold greater than \$25,000 based on sales of produce would adversely affect the level of public health protection provided by this regulation. For example, if we were to set the coverage threshold at \$1 million or \$2 million, applied to sales of produce, an estimated total of about 32 percent of all produce acres in the United States for the \$1 million cutoff and an estimated total of about 43 percent of all produce acres in the United States for the \$2 million cutoff would not be subject to this rule. This would remove about a third to nearly half of all produce marketed in the United States from coverage, providing significantly less public health protection. We have incorporated flexibility in the rule to help smaller farms to comply. We also intend to work with our State, tribal, and local partners and target our education and technical assistance efforts to smaller farms to help farms meet the standards established in subparts A to O, within the specified compliance periods.

5. Qualified Exemptions Generally (§§ 112.5 and 112.6)

(Comment 132) Several comments express support for the qualified exemption provisions for farms, as proposed, and urge FDA to retain the modified requirements for such farms. Conversely, some comments oppose the proposed qualified exemption provisions and recommend that this exemption be eliminated, arguing that it is not science- or risk-based.

(Response) As explained in the 2013 proposed rule, the provisions in §§ 112.5 and 112.6 reflect the fact that section 419(f) of the FD&C Act mandates this exemption. Section 112.5 establishes the criteria for eligibility for a qualified exemption (and, therefore, associated modified requirements) based on a farm's average monetary value of all food sold and direct farm marketing, as mandated by section 419(f)(1) of the FD&C Act. Similarly, § 112.6

establishes the modified requirements applicable to those farms that are eligible for a qualified exemption as mandated by section 419(f)(2) of the FD&C Act. Because these provisions are mandated by the statute, FDA must include them and we are finalizing them as proposed. We note, however, that the qualified exemption from part 112 does not eliminate a farm's responsibility to comply with all applicable requirements of the FD&C Act. We encourage such farms to continue following procedures, processes, and practices that ensure the safety of produce grown, harvested, packed, or held on their farm or in their operation.

6. Criteria for Eligibility for a Qualified Exemption (§ 112.5)

(Comment 133) Some comments suggest altering the criteria for eligibility for a qualified exemption in various ways. One comment recommends exempting farms that sell at least 50 percent of their produce directly to consumers or retail stores within a 250-mile radius, and argues that buyers in such circumstances can visually inspect the growing areas, converse with farmers, and closely examine their purchasing options. Another comment recommends increasing the average annual sales monetary limit for eligibility for a qualified exemption from \$500,000 to a minimum of \$1,000,000. This commenter states that the \$500,000 limit in § 112.5(a) would not adequately protect smaller farms, particularly because it would be applied to all food sales. In this regard, the commenter also recommends that the monetary value limit should be applied to the sale of covered produce only, and not all food. Another comment recommends applying the monetary value limit to sales of produce.

(Response) Sections 112.5, 112.6, and 112.7 establish the criteria for eligibility for a qualified exemption and associated modified requirements, consistent with section 419(f) of the FD&C Act (21 U.S.C 350h(f)). The criteria established in § 112.5(a), including the

requirements related to sales directly to qualified end-users, are derived from section 419(f) of the FD&C Act. Similarly, the definition of a qualified end-user in § 112.3(c) implements section 419(f)(4) of the FD&C Act. Because these provisions are mandated by the statute, FDA must include them and we are finalizing them as proposed. We have identified no basis that would allow us to make the changes suggested by the commenters, such as applying a distance criterion of 250 miles, applying a monetary limit of \$1,000,000, or changing the basis for the monetary limit to apply to sales of produce or covered produce rather than all food. We also addressed this last request regarding monetary limit based on sales of covered produce in the supplemental notice (see 79 FR 58434 at 58438).

(Comment 134) Several comments request that FDA allow small farms that market through produce auctions or CSA operations to be eligible for the qualified exemption.

(Response) Consistent with section 419(f) of the FD&C Act, the provisions in § 112.5 do not identify any produce market arrangements as specifically eligible for the qualified exemption. Rather, these provisions establish the criteria that must be met for any covered farm to be eligible for a qualified exemption. As we discussed in the 2013 proposed rule (78 FR 3504 at 3549-50), it does seem likely that many farms that use arrangements such as CSAs, you-pick operations, or farmers markets, will meet the established criteria for a qualified exemption. Each covered farm, including farms using such arrangements to market their produce, should analyze its sales under the terms of § 112.5 to determine its eligibility for the qualified exemption.

In the case of a CSA farm or a farm using a produce auction as a sales platform, the farm's direct sales to individual consumers enrolled in the CSA operation, or individual consumers at the auction, can be counted as sales to qualified end-users (because consumers are

qualified end-users, regardless of location). A direct sale to a restaurant or retail food establishment enrolled in the CSA or at the auction can be counted as a sale to a qualified end-user if the restaurant or retail food establishment is located either in the same State or the same Indian reservation as the farm or is located not more than 275 miles from the farm. Considering sales of all food, if the farm's sales to qualified end-users exceeds sales to all other buyers, and the farm's average annual monetary value of sales over the previous 3-year period is less than \$500,000, the farm would be eligible for the qualified exemption.

The definition of a "qualified end-user," which is derived from section 419(f)(4) of the FD&C Act, explicitly states that the term "consumer" does not include a business. In a circumstance where the CSA farm sells its produce to a separate business that runs a CSA, rather than directly to individual consumers enrolled in the CSA, these sales would not be sales to consumers. The analysis is the same in a circumstance where a farm sells its produce to a separate business that runs a produce auction, rather than directly to specific buyers at the auction. Such sales would only be sales to a qualified end-user if the CSA operation, or the produce auction, fits the definition of a retail food establishment or a restaurant, and meets the location requirements explained previously. As noted in response to Comment 103, FDA is addressing the definition of "retail food establishment" in a separate rulemaking. This rulemaking includes topics related to various types of sales platforms and the definition of "retail food establishment."

7. Applicable Requirements for Qualified Exemption (§§ 112.6 and 112.7)

(Comment 135) One comment requests that we clarify the cross-references in § 112.6(a) regarding the subparts applicable to farms eligible for the qualified exemption.

(Response) We are amending § 112.6(a) to provide the requested clarification, separating applicable subparts and including their titles.

(Comment 136) Some comments ask whether the required content of the label and point of purchase display requirements in § 112.6(b) includes only the name and address of the farm, or whether the notification must also include a statement notifying consumers of the farm's qualified exemption from the produce safety regulation.

(Response) Label and point of purchase displays required under § 112.6(b) must include the name and the complete business address of the farm where the produce was grown. You are not required to include a statement notifying consumers of your qualified exemption.

(Comment 137) We requested comment on the feasibility of the labeling and point of purchase display provisions in § 112.6(b), particularly in the case of consolidating produce from several farm locations. One comment states that our request was confusing and, assuming that we meant produce from multiple locations of one farm is packed or held at one location, the farm name and business address that is required to be displayed under § 112.6(b) should be the name and business address of the farm that is eligible for the qualified exemption.

(Response) We agree that the relevant farm for purposes of the requirements in § 112.6(b) is the farm where the produce was grown that is eligible for the qualified exemption. We acknowledge that our request for comment was unclear. We did not receive comments suggesting that consolidating (or commingling) produce from different farms would create a feasibility problem with respect to this requirement. We are finalizing the requirement as proposed. If needed, we will consider issuing guidance in the future with respect to the

application of this requirement when produce from different farms has been commingled.

(Comment 138) Some commenters question the requirement to disclose the name and business address of a farm eligible for the qualified exemption, citing concerns about biosecurity and unannounced or unplanned visitors to the farm. These comments suggest that FDA consider alternative approaches. One comment points out that farms that sell to local retailers, restaurants, co-ops or that sell at produce auctions are often assigned a farm identification number as a means of traceability, and suggests that FDA consider relying on such identification. Another comment suggests providing flexibility for farms to choose whether to disclose its phone number, website, email address, or business address.

(Response) Sections 112.6 and 112.7 establish the modified requirements applicable to farms that meet the criteria under § 112.5 for a qualified exemption. As explained in the 2013 proposed rule, these requirements are derived from the provisions in section 419(f)(2) of the FD&C Act. We conclude that the use of the term “business address” in section 419(f)(2)(A) demonstrates Congress’ intent to require the farm’s full address, including the street address or P.O. box, to appear on labels or other required notifications when the farm qualifies for the exemption (under § 112.5). The use of the term “business address” in section 419(f)(2)(A) of the FD&C Act contrasts with Congress’ use of a different term, “place of business,” in section 403(e) of the FD&C Act (21 U.S.C. 343(e)). Section 403(e) provides that foods in package form are misbranded unless the product label bears the name and place of business of the manufacturer, packer, or distributor of the food. If Congress had considered the less complete address already required under section 403(e)(1) of the FD&C Act and the “place of business” labeling regulation (§ 101.5(d)) to be adequate for notification to consumers for foods required to

bear labels, there would have been no need to impose a new, more specific requirement in section 419(f)(2)(A)(1) for the farm's "business address" to appear on the food label (78 FR 3504 at 3550.). Similarly, if Congress had intended that other information (such as a farm identification number, phone number, website, or email address) could substitute for the required information, there would have been no need to impose the specific requirement for the business address to be disclosed. Section 112.6(b) does not prevent farms from voluntarily disclosing such additional information if desired. We consider that Congress has already struck the specific balance it intended between farms' need to control visitor access to the farm for biosecurity purposes and the amount of information required to be disclosed to consumers when a farm is eligible for a qualified exemption from this rule. Therefore, we are finalizing § 112.6(b), as proposed.

(Comment 139) Comments generally support FDA requiring farms eligible for the qualified exemption to maintain adequate documentation to demonstrate the basis for their qualified exemption, and to make such records available to FDA for inspection upon request. One comment asks that FDA not require farms eligible for the qualified exemption to submit documentation to FDA or to establish and maintain records in accordance with subpart O, and suggests issuing recordkeeping guidance for these farms instead.

(Response) If farms were not required to maintain adequate documentation of their eligibility for a qualified exemption, we would have no way to determine whether a farm claiming the qualified exemption, in fact, met the criteria for that exemption. This could be important, for example, if a farm claiming a qualified exemption is directly linked to a foodborne illness outbreak during an active investigation or if FDA determines, based on conduct or

conditions associated with the farm that are material to the safety of the food produced or harvested at such farm, that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak to withdraw the farm's qualified exemption (see discussion of subpart R in section XXIII of this document). In such circumstance, because the withdrawal procedures in subpart R would only apply to farms eligible for the qualified exemption, we would need to verify the status of a farm to consider appropriate follow-up actions, in accordance with subpart R. Therefore, we are adding a new provision § 112.7 to establish certain recordkeeping requirements in relation to a qualified exemption.

However, we agree that it is not necessary for farms to submit documentation to FDA of their status with respect to the qualified exemption, unless FDA requests such information for official review (for example, during an inspection or investigation). We also do not oppose the use of existing records or documents (for example, documents that are developed and maintained during the normal course of a farm's business) to document the farm's eligibility for a qualified exemption, provided that they meet all applicable requirements.

Specifically, in new § 112.7, we are requiring that, if you are eligible for a qualified exemption in accordance with § 112.5, you must establish and keep records required under this provision in accordance with the requirements of subpart O of this part. This means that the general requirements for maintenance of records in subpart O apply to the records required under § 112.7, except that we are not requiring sales receipts kept in the normal course of business to be signed or initialed by the person who performed the sale (§ 112.7(a)). Under § 112.7(b), we are requiring that you must establish and keep adequate records necessary to demonstrate that you satisfy the criteria for a qualified exemption as described in § 112.5. Such records may include receipts of your sales to different buyers; the location of any buyers that are restaurants

or retail food establishments; the monetary value of sales of all food, adjusted for inflation using 2011 as the baseline year; and any other documentation that FDA can use, as necessary, to verify your eligibility for a qualified exemption. For example, if you relied on records kept in the normal course of your business bearing on the criteria for the qualified exemption to determine your eligibility, you must retain such records. Under § 112.7(a) we are not requiring sales receipts kept in the normal course of business to be signed or initialed by the person who performed the sale. We are requiring that such receipts be dated, however, because the dates of sales are relevant to the computation of eligibility.

Because the criteria for eligibility for a qualified exemption are based on calculations regarding the preceding 3-year period (see § 112.5(a)(2)), you must review your sales annually to confirm your continued eligibility for the qualified exemption for the upcoming year. Under § 112.7(b), we are now specifying that you must establish and keep a written record reflecting that you have performed an annual review and verification of your farm's continued eligibility for the qualified exemption. Under § 112.161(a)(4), these records must be dated, and signed or initialed by the person who performed the activity documented. Thus, we expect that the annual review and verification document will be signed and dated by the owner, operator, or agent in charge of the farm. We believe it is necessary for the party responsible for the covered farm to attest to the status of the farm with respect to the qualified exemption. As we noted with regard to § 112.161(a)(4) in the 2013 proposed rule, the signature of the individual who made the observation (in this case, the annual review and verification of eligibility for the qualified exemption) will ensure responsibility and accountability. Moreover, any FDA action related to withdrawal of the qualified exemption, if necessary, would be directed to the owner, operator, or agent in charge of the farm, in accordance with subpart R of part 112. In accordance with subpart

O, records required under this provision must be available and accessible to FDA for review upon request within 24 hours (see § 112.166). We will consider issuing guidance on the types of records or documents that may be used to demonstrate a farm's status with respect to the qualified exemption.

We also are establishing an earlier compliance date for the records that a farm maintains under § 112.7 to support its eligibility for a qualified exemption in accordance with § 112.5. Specifically, the compliance date for a farm to retain records to support its status under this provision (e.g., sales receipts and other records as applicable) is the effective date of this rule, i.e., [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Farms need not comply with the requirement for a written record reflecting that the farm has performed an annual review and verification of continued eligibility for the qualified exemption until the farm's general compliance date, however. Even with this earlier compliance date for the records supporting eligibility for the qualified exemption, we realize that although the calculation in the codified is based on 3 calendar years, there may be circumstances where a farm will not be required to have 3 calendar years of records as of their general compliance date. Under such circumstances, it would be reasonable for the farm to make the calculation based on records it has (i.e., for one or two preceding calendar years), and we will accept records for the preceding one or two years as adequate to support its eligibility for a qualified exemption in these circumstances. When a farm does not begin operations until after relevant compliance dates have passed, it would be reasonable for the farm to rely on a projected estimate of revenue (or market value) when it begins operations. We would evaluate the credibility of the projection considering factors such as the farm's number of employees. After the farm has records for one or two preceding calendar years, it would be reasonable for the farm to make the calculation

based on records it has (i.e., for one or two preceding calendar years) and we will accept records for the preceding one or two years as adequate to support its eligibility for a qualified exemption in these circumstances. See also section XXIV of this document.

X. Subpart B – Comments on General Requirements

In proposed subpart B of part 112, we proposed to establish the general requirements applicable to persons who are subject to this part (§ 112.11) and to establish a framework for alternatives to certain requirements established in this part that would be permitted, under specified conditions (§ 112.12). We asked for comment on all provisions in subpart B.

We are finalizing these provisions with revisions (see Table 8). We discuss these changes in this section. We are finalizing the other provisions of subpart B without change.

Table 8.-- Description of Revisions to Subpart B

Final Provision	Description of Revisions
§ 112.12	<ul style="list-style-type: none"> - Revision to refer to new § 112.49, which lists all of the requirements in subpart E for which we allow the use of alternatives - Revision to eliminate proposed § 112.12(a)(2), consistent with revisions to proposed § 112.54 - Revision to replace “listed in” in proposed § 112.12(b) and (c) with “specified in” to reflect new reference to § 112.49 - Revision to delete “(including the same microbiological standards, where applicable)” and “including agro-ecological conditions and application interval” as unnecessary in light of other revisions - Revision to clarify in § 112.12(c) that “You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative under this section”

A. General Requirement in § 112.11

(Comment 140) One comment states that the definition and application of the term “reasonably” is unclear in § 112.11, and expresses concern about disagreements between farmers and FDA over what measures are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards and provide reasonable assurances that the produce is not adulterated.

(Response) In § 112.3, we revised our proposed term “reasonably foreseeable hazard” and corresponding definition to now use “known or reasonably foreseeable hazard” to mean a

biological hazard that is known to be, or has the potential to be, associated with the farm or the food. We provide a definition for this phrase as it is used in section 419(c)(1)(A) of the FD&C Act and reflected in several requirements that we are establishing in part 112. The use of this phrase in the produce safety regulation is also consistent with its use in the PCHF and PCAF regulations.

(Comment 141) Some comments express concern about the possibility of indirect contamination of covered produce by animal excreta. Comments state that animal fecal matter could reach produce through indirect means, such as irrigation water, runoff, wind-blown dust, or vehicles, particularly in areas where dairies and feedlots exist close to farms producing covered produce. In addition, one comment suggests that farms should be required to assess their farm for the possibility of airborne contamination and should take reasonable steps to avoid it, whereas another comment suggests that farms should assess and mitigate the potential for contamination by runoff from storage areas.

(Response) We agree that animal fecal matter may reach produce through indirect means. However, various other provisions under part 112 (in particular, within subparts E and F) that focus on the safety of agricultural water, biological soil amendments of animal origin, and other growing considerations already address the routes of contamination that we identified in the QAR. In addition, we have included a requirement in § 112.11, under which covered farms are required to take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not

adulterated under section 402 of the FD&C Act on account of such hazards. As we explained in the 2013 proposed rule, among other things, § 112.11 accounts for the variety of possible circumstances that might arise in which unique farm circumstances would justify preventive measures. Thus, for example, if a farm's circumstances are such that airborne or runoff fecal contamination is a known or reasonably foreseeable hazard to the farm's covered produce, the farm must take those measures reasonably necessary to prevent introduction of those hazards and to provide reasonable assurances that the produce is not adulterated on account of those hazards.

B. General Comments About Alternatives in § 112.12

(Comment 142) Several comments spoke to the use of alternatives generally. Some comments generally support the allowance for use of alternatives and state that alternatives provide flexibility for covered farms to consider and accommodate the particularities of the commodities, practices and conditions specific to their operations and new scientific information, as it becomes available. On the other hand, some comments express concern that the provision on use of alternatives is unclear, limited in scope, burdensome, and/or is not a realistic option for farmers. One comment states that by requiring farmers to have adequate scientific data or information to show that the alternative would provide the same level of public health protection as the applicable requirement, FDA is placing the burden on farmers and private entities to conduct research on public health risks generally. The commenter believes this is a research and investigative task that FDA should fulfill.

(Response) We agree that the allowance for use of alternatives in § 112.12 provides flexibility for covered farms and disagree that the allowance for the use of alternatives is unclear, too limited in scope, or burdensome. We are providing for the use of alternatives to

certain minimum science-based requirements that we have established in part 112 in order to provide flexibility for farms to identify measures that are suitable for their operations, in light of conditions, processes, and practices on their farms and that provide the same level of public health protection as the applicable requirement. FDA has conducted the necessary scientific evaluation to determine reasonable measures that are broadly applicable across a wide range of conditions, and this scientific analysis is reflected in the codified requirements for which alternatives are permitted. Our decision to allow the use of alternatives in lieu of the established requirements does not negate the underlying scientific basis upon which those requirements are derived. Rather, we determined that, in the case of certain specified requirements, alternative measures may be demonstrated to be scientifically valid, considering the practices and conditions on a farm and circumstances unique to a specific commodity or types of commodities and in light of evolving science. FDA cannot reasonably conduct the necessary scientific evaluation for every set of circumstances that exist on covered farms.

(Comment 143) Some comments assert that FDA should recognize certain guidance (commodity-specific or otherwise), as meeting the requirements for alternatives in § 112.12. See also comments under section IV.F of this document. For example, one comment states the Citrus GAPs developed and implemented by the citrus industry should be recognized by FDA as an acceptable alternative or variance under the produce safety regulation.

(Response) In accordance with § 112.12(c), for any alternative that you use under the provisions of § 112.12(a), you must establish and maintain documentation of scientific data or information in support of your alternative. The scientific data or information may be developed by you, available in the scientific literature, or available to you through a third party. Such

scientific support may be derived from or include commodity-specific or other guidance or recommendations (or the science underlying such guidance or recommendations), including those developed by industry, academia, trade associations, or other stakeholders. Such guidance or recommendations, taken together with any other scientific data or information on which you rely, must satisfy the requirements in § 112.12(b) to support the use of the alternative.

We decline the request that FDA recognize certain commodity-specific guidelines developed by industry (such as the Citrus GAPs) as an acceptable alternative to the produce safety regulation. Alternatives are permitted for only certain of the specified requirements of part 112, specifically related to agricultural water, which are listed in § 112.49 and cross-referenced in § 112.12(a), and not for all of the provisions of the produce safety regulation, in general. Moreover, you do not need to notify or seek approval from FDA prior to establishing and using an alternative, and we are revising § 112.12(c) to add a sentence making this clear. To the extent this commenter requests FDA to consider existing commodity-specific industry guidelines under the variance provisions in subpart P, such requests must be submitted by a State, tribe, or foreign government to FDA using the citizen petition process in § 10.30. We ask industry to work with their relevant State, tribe, or foreign government agencies to submit such requests to FDA, following the provisions in subpart P of part 112.

(Comment 144) One comment suggests that we should expand the entities eligible to establish alternatives beyond States and foreign governments to include entities such as commodity boards and State associations.

(Response) This comment appears to be confusing the provision allowing farms to establish certain alternative standards and processes in subpart B, § 112.12, with the provisions

allowing States, tribes, and foreign governments to request variances from one or more requirements of the rule in subpart P, §§ 112.171-112.182. Unlike the variance provisions, the alternative provisions do not require submission of a request by a State, tribe, or foreign government to FDA before a covered farm may use a procedure, process, or practice that varies from the requirements established in this rule. See our discussion of the variance provisions and entities eligible to request a variance in section XXI of this document.

C. Alternatives for Additional or All Requirements

(Comment 145) Several comments ask us to permit the use of alternatives for all provisions of the rule, rather than to restrict the use of alternatives to only those specified by FDA in the regulation. Comments state that it is unclear why FDA limited the use of alternative approaches to only the provisions listed in proposed § 112.12, and argue that the same option of using alternative methods should be applicable to all requirements of the rule. Some comments specifically identified provisions related to animals (subpart I), worker health and hygiene (subpart D), microbial quality requirements (proposed § 112.44(a) for certain uses of agricultural water and proposed § 112.55 for soil amendment treatment processes), and water testing frequency (proposed § 112.45) as additional provisions for which we should allow alternatives.

(Response) As discussed in the 2013 proposed rule, given various considerations, we proposed an integrated approach that draws on our past experiences and appropriately reflects the need to tailor requirements to specific on-farm routes of contamination. In some cases, our standards are very similar to those contained in the Food CGMP regulation, especially where the routes of contamination are well-understood and appropriate measures are well-established and generally applicable across covered produce commodities (e.g., personnel qualifications,

training, health, and hygiene; harvesting, packing, and holding activities; equipment, tools, buildings, and sanitation). We are not convinced by comments suggesting that we should allow alternatives for these types of provisions because these measures are well-established, generally applicable, and flexible enough to apply across the spectrum of farming conditions and practices. Moreover, these types of provisions do not involve specific numerical criteria.

In other cases, our standards require the farm to inspect or monitor an on-farm route of contamination and take appropriate measures if conditions warrant. We rely on such a monitoring approach where the diversity of conditions that can be expected relative to an on-farm route of contamination is very high and it would be impractical and unduly restrictive to set out a standard that specifies the appropriate measures for each possible circumstance (e.g., requirements for assessment related to animal intrusion in § 112.83 and inspection of agricultural water system in § 112.42). We are not convinced by comments suggesting that we should allow alternatives for these types of provisions because these provisions already provide built-in flexibility as a result of their monitor-and-respond structure. Moreover, these types of provisions do not involve specific numerical criteria.

In still other cases (e.g., sprouts), our standards require the farm to develop a written plan, committing itself to specific measures (e.g., sprout environmental testing and spent sprout irrigation water testing). The use of written plans is important, for example, where the details may change over time and a historical record of the evolution of the measures is important for the operator to assess whether further changes to the measures are needed (e.g., changes or rotation in the sampling sites for sprout environmental testing). We are not convinced by comments suggesting that we should allow alternatives for these types of provisions because they also provide built-in flexibility as a result of their structure. Moreover, these types of

provisions do not involve specific numerical criteria.

Finally, in certain other cases, we are establishing specific numerical standards against which the effectiveness of a farm's measures would be compared and actions taken to bring the operation into conformance with the standards, as necessary (e.g., standards for agricultural water in subpart E; and standards for biological soil amendments of animal origin in subpart F). We rely on the numerical standards approach where our evaluation of current scientific information to determine reasonable measures allows us to establish numerical criteria that are broadly applicable across a wide range of conditions, while acknowledging that such criteria may be tailored, as appropriate, when applied specifically to a commodity (or group of commodities) or under a set of farm practices. It is in the case of this numerical standards approach that an allowance for alternatives may be warranted because, under this approach, there is a concrete measurable standard against which the effectiveness of measures that a farm may take for its operations can be evaluated. In the absence of specific numerical criteria, such as in the case of the other types of provisions explained previously, the use of alternative measures would not be needed because the standards are inherently flexible and already allow the farm to identify and take measures tailored to the practices, procedures, and processes specific to that farm's operations. In addition, alternatives can potentially be warranted for provisions with specific numerical standards in light of their relatively prescriptive nature, the diversity of operations, and the likelihood of new or emerging science.

The relevant numerical requirements in §§ 112.44(b), 112.45(b)(1)(i), 112.46(b)(1)(i) and 112.46(b)(2)(i) for which we are allowing alternatives include measures that we conclude are appropriate to require under a wide range of conditions. However, recognizing that other measures, if properly validated, may also be suitable, we are providing for the use of

scientifically-supported alternatives to these required measures.

With respect to application intervals for certain uses of soil amendments, in the 2013 proposed rule, we proposed specific minimum application intervals for use of raw manure (proposed § 112.56(a)(1)(i)) and compost (proposed § 112.56(a)(4)(i)), and we proposed to allow alternatives to these minimum application intervals. However, in the supplemental notice, we proposed certain amendments to proposed §§ 112.56(a)(1)(i) and 112.56(a)(4)(i) removing the application interval requirements, which makes the corresponding alternatives provisions unnecessary. We are finalizing § 112.56 with some changes, under which alternatives continue to be unnecessary (see section XIV.G of this document).

For other provisions that include numerical criteria, i.e., §§ 112.44(a) and 112.55, we considered and have decided that the use of alternatives for these provisions is either not appropriate or not necessary. Section 112.44(a) lists certain uses of agricultural water that present a high risk because the conditions associated with those uses of water are conducive to multiplication of pathogens, if present. Even a low number of pathogens introduced into or onto covered produce through contaminated water during those uses could rapidly increase to levels that could present risk of serious adverse health consequences or death. Therefore, we adopt an appropriately protective generic E. coli standard (zero detectable generic E. coli per 100 mL) for uses of agricultural water specified in § 112.44(a), without further provision for use of an alternative standard. Section 112.55 establishes the microbial standards applicable to the treatment processes established as acceptable in § 112.54. We do not intend § 112.55 to require that farms test their treated biological soil amendments for compliance with the microbial standards. Rather, we intend these provisions to provide the standards against which treatment processes described in § 112.54 must be validated. Farms would be able to use

treatment processes that are validated to meet the relevant microbial standard in § 112.55 without the need to test the end products of their treatments to confirm that the microbial standard was achieved. Because our revisions to § 112.54(a) already provide for the use of any scientifically valid, controlled treatment processes that are demonstrated to satisfy the microbial standard in § 112.55(a) for L. monocytogenes, Salmonella spp., and E. coli O157:H7, further provision under § 112.12 for use of alternatives is not necessary. Similarly, because in revised § 112.54(b) we already explicitly provide for the use of any scientifically valid, controlled treatment process that is demonstrated to satisfy the microbial standards in § 112.55(b) for Salmonella and for fecal coliforms (see § 112.54(c)(3)), a corresponding alternatives provision under § 112.12 is not needed. Given these revisions to § 112.54 (see section XIV of this document), we have eliminated proposed § 112.12(a)(3) in finalizing § 112.12(a).

Furthermore, unlike alternatives, variances may be requested for any of the provisions of part 112 under the conditions provided in subpart P, which involve the submission of a citizen petition by a State, tribe, or foreign government to FDA. This process builds additional flexibility into the rule within limits that allow for FDA to review and approve new approaches outside the alternatives allowed by § 112.12. An allowance for alternatives to be established and used for all provisions of part 112 would make the variance process superfluous.

For these reasons, we do not believe it is appropriate to provide for the use of alternatives for provisions of part 112 beyond those listed in § 112.12.

D. Additional Clarification

(Comment 146) A number of comments ask what is meant by the requirement in § 112.12(b) that an alternative “provide the same level of public health protection as the applicable requirement” and how that is to be measured. Some comments seek clarification on the types of scientific data and documentation necessary to support the use of alternatives.

(Response) Under § 112.12(a), you may establish an alternative to one or more of certain requirements established in subpart E, as specified in § 112.49. Because, for clarification, we have listed all of the requirements in subpart E for which we permit alternatives within new § 112.49, in § 112.12(a), we simply provide a cross-reference to § 112.49 rather than listing out each of the specific requirements for which alternatives are permitted (as we did under proposed § 112.12(a)). As a conforming edit, we are changing two occurrences of “listed in [§ 112.12(a)]” in § 112.12(b) and (c) to read “specified in [§ 112.12(a)].” As specified in § 112.49, in accordance with § 112.12, you may establish and use alternatives to the following specific requirements related to agricultural water: §§ 112.44(b), 112.45(b)(1)(i), 112.46(b)(1)(i)(A), and 112.46(b)(2)(i)(A).

Sections 112.44(b), 112.45(b)(1)(i), 112.46(b)(1)(i)(A) and 112.46(b)(2)(i)(A), all establish requirements for the microbial quality, testing, and taking action based on test results when agricultural water is used during growing operations for covered produce (other than sprouts) using a direct water application method.

The § 112.44(b) microbial water quality criteria are a statistical threshold value (STV) of 410 or less CFU of generic E. coli per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution) and a geometric mean (GM) of 126 or less CFU of generic E. coli per 100 mL (GM is a measure of the central tendency of your water quality distribution). We

are establishing these numerical criteria based on our analysis of current scientific information; it relies on an underlying dataset that has the necessary scientific rigor and describes illness rates due to incidental ingestion that can be generalized across different bodies of water. In addition, our microbial quality criteria use generic E. coli as an indicator organism because the intent is to detect measurable levels of fecal contamination and monitor the microbial quality of agricultural water (see discussion on 79 FR 58434 at 58443-445; see also (Ref. 44)). Nevertheless, we acknowledge that circumstances unique to a farm's operation or commodities may justify the use of an alternative microbial quality criterion (or criteria). Under § 112.49(a), you may establish an alternative to the microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, in lieu of the microbial quality criteria we established in § 112.44(b). We recommend that the scientific data or information to support the use of an alternative indicator organism include peer reviewed scientific material. An example of a potential alternative microbial quality criterion is use of a different fecal indicator organism as a basis for a GM and STV that are demonstrated to detect measurable levels of fecal contamination in agricultural water used for the purposes identified in § 112.44(b). We expect any such alternative indicator to be as sensitive to the presence and level of fecal pollution as generic E. coli. We also expect that any alternative microbial quality criteria that you establish and use, in lieu of the FDA-established criteria, would be supported by an equally robust and rigorous scientific analysis and would be quantitatively demonstrated to be equivalent to the FDA-established criteria, thus "providing the same level of public health protection" as the FDA-established criteria and ensuring that your alternative standard would not increase the likelihood that your covered produce will be adulterated. In addition, for any use of an alternative indicator, you should also consider whether the microbial die-off rate that we established in § 112.45(b)(1)(i), if you choose

to apply it in conjunction with your alternative microbial quality criteria, continues to be appropriate.

Similarly, under § 112.49(b), you may establish an alternative to the microbial die-off rate between last irrigation and harvest and accompanying maximum time interval established in § 112.45(b)(1)(i). The microbial die-off rate of 0.5 log per day to determine an adequate time interval (in days) between last irrigation with untreated water and harvest is established in § 112.45(b)(1)(i). We derived this die-off rate based on a review of currently available scientific literature, and recognize that microbial die-off rates are dependent on various environmental factors, including sunlight intensity, moisture level, temperature, pH, the presence of competitive microbes, and suitable plant substrate. Generally, pathogens and other microbes die off or are inactivated relatively rapidly under hot, dry, and sunny conditions compared to inactivation rates observed under cloudy, cool, and wet conditions. Our analysis led us to conclude that a rate of 0.5 log per day provides a reasonable estimate of microbial die-off under a broad range of variables to include microbial characteristics, environmental conditions, crop type, and watering frequency (see discussion on 79 FR 58434 at 58445-446; see also (Ref. 45)). In final § 112.45(b)(1)(i), we also stipulate a maximum time interval of four consecutive days. Nevertheless, we acknowledge that practices and conditions on a farm and circumstances unique to a specific commodity could result in higher die-off rates between last irrigation and harvest, especially under conditions of high ultraviolet radiation, high temperature exposures or low humidity, coupled with little or no precipitation and, therefore, we are providing for the use of appropriate alternative microbial die-off rate(s) and an accompanying maximum time interval. We expect that any alternative microbial die-off rate between last irrigation and harvest, and an accompanying maximum time interval, that you establish and use, in lieu of the FDA-established

requirement, would be supported by an equally robust and rigorous scientific analysis specific to the region and crop, and would be quantitatively demonstrated to be equivalent to the FDA-established standard, thus “providing the same level of public health protection” as the FDA-established standard and ensuring that your alternative standard would not increase the likelihood that your covered produce will be adulterated.

In § 112.49(c) and (d), we are providing for the use of alternative water testing frequency in lieu of the FDA-established required number of samples for the initial survey (established in § 112.46(b)(1)(i)(A)) and the annual survey (established in § 112.46(b)(2)(i)(A)) for the testing of untreated surface water. In the 2013 proposed rule, we proposed specific numerical requirements for frequency of testing agricultural water when used during growing in a direct water application method, and we did not propose to allow alternatives to these testing frequencies. In the supplemental notice, we made these requirements more flexible by proposing a tiered approach to testing untreated surface water used for this purpose (proposed § 112.45(b)), which we are retaining with some changes (final § 112.46(b)). This approach allows farms to make decisions about safe use of available water sources prior to the beginning of the next growing season; adjust testing frequencies dependent on long-term test results; and ultimately reduce the required frequency of testing. Among the testing requirements in § 112.46(b), we specify that a certain specified minimum number of samples must be collected for the initial and annual surveys. We derived these minimum testing frequencies (i.e., the minimum number of samples) from our statistical analysis based on average variability among surface water sources (i.e., a standard deviation of 0.4) (Ref. 99). In our review of available information (Ref. 44) (Ref. 99), we cited that among the water bodies studied by EPA in developing the recreational water quality criteria, EPA reported an estimate of average standard

deviation of \log_{10} E. coli abundance measurements in surface waters is 0.4 (Ref. 100). We acknowledge that circumstances unique to the variability of the microbial quality of a farm's water source may justify the use of an alternative water testing frequency. Therefore, if a covered farm determines through analysis of historical samples that the standard deviation of \log_{10} E. coli abundance measurements for their surface water source(s) is less than 0.4 and the difference is statistically significant, then the farm could utilize the lower variability rate to determine the appropriate minimum number of samples necessary to establish and characterize the microbial quality of the farm's water source(s). We expect that any alternative frequency of testing that you establish and use, in lieu of the FDA-established minimum number of samples in § 112.46(b)(1)(i)(A) or 112.46(b)(2)(i)(A), would be supported by an equally robust and rigorous scientific analysis and would be quantitatively demonstrated to be equivalent to the FDA-established testing frequency, thus "providing the same level of public health protection" as the FDA-established standard and ensuring that your alternative standard would not increase the likelihood that your covered produce will be adulterated. Note also that this allowance for use of an alternative testing frequency relates only to the minimum number of samples required under § 112.46(b)(1)(i)(A) and 112.46(b)(2)(i)(A), and does not extend to the other required elements of testing, specified in § 112.46(b). Likewise, we are not providing for an alternative to the testing frequency specified in § 112.46(b)(1)(i)(B) or (b)(2)(i)(B) for the testing of untreated ground water when used during growing in a direct water application method because ground water sources are less influenced by external sources and, therefore, their water quality is less variable, and we conclude the testing frequency we established in § 112.46(b)(1)(i)(B) and (b)(2)(i)(B) is the minimum necessary to ensure the quality of ground water sources for that purpose.

These provisions for use of alternatives are also responsive to comments that expressed concern about FDA-established quantitative metrics for water quality or testing in the regulation because the commenters believed such generally-applicable numerical criteria may not adequately take into account the unique circumstances related to different commodities or practices. The allowance for alternatives also responds to comments that urged us to incorporate flexibility in any established requirement to allow for appropriate changes to the microbial quality standards based on advances in scientific information on water quality. In light of the specific provisions for which we are allowing alternatives in this rule, we are deleting two phrases from proposed § 112.12 as unnecessary: “including meeting the same microbiological standards, where applicable,” and “including agro-ecological conditions and application interval.”

The scientific analysis on which you rely may be developed by you, available in the scientific literature, or available to you through a third party. It does not need to be published in a peer-reviewed journal, although we encourage use of peer-reviewed data and information, to the extent available.

FDA is collaborating with partners on research that will add to the scientific information that may help inform specific alternatives. For example, in an effort to support scientific research in the area of agricultural water, one of FDA’s Centers of Excellence, the Western Center for Food Safety at University of California, Davis, partnered with the Center for Produce Safety to provide seed money through a competitive grants program to fund produce safety projects focused on agricultural water issues that are topical and/or region specific. Research areas that have received funding through this process include transfer and survival of organisms on produce after exposure from contaminated surface irrigation water,

application of biocide technology on manure-contaminated irrigation water, the potential role of overhead sprinkler irrigation systems in the contamination of produce, and the survival of pathogens during the growing, harvesting, and storage of dry bulb onions after exposure with contaminated water. We intend to disseminate useful scientific information, when available, and issue commodity- and region-specific guidance as appropriate, such that farmers would be able to consider our recommendations and apply the new scientific information to their operations, as appropriate.

(Comment 147) Some comments recommend that FDA specifically state that individual producers or commodities, where there is commonality, should be able to rely on scientifically credible research and publications of commodity boards and trade associations that support potential alternative measures.

(Response) In § 112.12(c), we provide that the scientific data and information used to support an alternative may be developed by you, available in the scientific literature, or available to you through a third party. The scientific support you rely on to justify the use of an alternative can be developed by third parties such as industry or trade associations and commodity boards. You may establish the alternatives under § 112.12 for which you have adequate data and information to support a conclusion that the relevant standards are met in light of your covered produce commodities, practices, and conditions, in accordance with § 112.12(b). Thus, you must take your farm's specific commodities, practices, and conditions into account when evaluating the relevant scientific information. There may be circumstances in which scientific data and information specific to one commodity may be appropriately applied to other commodities, conditions, or practices, allowing that data to support alternatives across multiple commodities,

conditions, or practices. However, such generalizations may not always be appropriate. We also intend to disseminate useful scientific information, when available, and issue commodity- and region-specific guidance as appropriate, such that farmers would be able to consider our recommendations and apply the new scientific information to their operations, as appropriate.

E. Prior Approval of Alternatives

(Comment 148) Some comments request us to provide a voluntary process for pre-approval of alternatives, either by FDA or by recognition of private sector experts. These comments seek protection for farms using pre-approved alternatives, as well as guidance for farmers and researchers to follow when developing alternatives that will meet FDA standards. Similarly, one comment suggests amending proposed § 112.12 to specifically state that use of alternative procedures does not require prior approval by FDA.”

(Response) We are not requiring you to notify or seek prior approval from FDA regarding your decision to establish or use an alternative or to otherwise submit relevant scientific data or information to FDA prior to using an alternative. We are adding an explicit statement to § 112.12 that FDA pre-approval of alternatives is not required. However, we note that if FDA determines that the use of an alternative is not in compliance with the provisions of § 112.12, FDA may take enforcement or other action, as appropriate. However, we are requiring that you maintain a record of any such scientific data or information, including any analytical information, under § 112.12(c), and make such data and information available to us to evaluate upon request, under § 112.166. We are not establishing a voluntary pre-approval process; however, FDA intends to continue encouraging and supporting development of useful scientific data and information, as well as conducting significant education and outreach related

to this rule. We also intend to disseminate useful scientific information, when available, and issue commodity- and region-specific guidance as appropriate, such that farmers would be able to consider our recommendations and apply the new scientific information to their operations, as appropriate.

XI. Subpart C – Comments on Personnel Qualifications and Training

In subpart C of proposed part 112, we proposed minimum standards directed to personnel qualifications and training that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the covered produce is not adulterated under section 402 of the FD&C Act. We asked for comment on our proposed provisions, including the proposed requirements for training on principles of food hygiene and food safety and the feasibility of the proposed training requirements, particularly with respect to harvest activities.

We are finalizing these provisions with revisions (see Table 9). We discuss these changes in this section. For § 112.23, we did not receive any comments or received only general comments in support of the proposed provision and, therefore, we do not specifically discuss this provision.

Table 9.-- Description of Revisions to Subpart C

Final Provision	Description of Revisions
§ 112.21(a)	- Revision such that required training must be repeated periodically thereafter, at least once annually
§ 112.21(b)	- Revision to require that personnel must have a combination of education, training, and experience necessary to perform the person's assigned duties
§ 112.22	- Revision to change "should" to "must" in § 112.22(b)(1)
§ 112.30	- No change

A. General Comments

(Comment 149) One comment expresses concern that under subpart C, as proposed, agricultural workers are viewed as “disease vectors” and a “potential pathway for contamination” rather than as “fundamental partners.”

(Response) Agricultural workers are invaluable and fundamental partners in ensuring food safety on the farm. However, as discussed in the 2013 proposed rule, it is well-documented in the scientific literature that bacteria, viruses, and parasites are frequently transmitted from person to person and from person to food. In addition, our QAR demonstrates that humans (i.e., workers and visitors) are potential carriers of foodborne pathogens and can be a source of contamination of produce. Therefore, farm workers need training on the importance of health and hygiene. In addition, employees need training on subparts C through O that are applicable to the employee’s job responsibilities and on how to recognize and prevent potential contamination problems (e.g., a leafy green vegetable contaminated with manure, contaminating the water supply during sample collection for testing, etc.) and to be trained to know what to do when those situations present themselves. The farm worker is a key component in the food chain for ensuring the safety of covered produce.

(Comment 150) Several comments object to proposed subpart C based on the size of the farm or number of full-time employees.

(Response) We have considered the burden to small businesses and provided sufficient flexibility within the final rule to be practicable for different sizes and types of businesses, including for small and very small businesses. See section IX.C of this document. We do not agree that additional flexibility should be incorporated by exempting farms from the training

requirements based on the size of the business. Training farm workers is important regardless of the size of the farm.

(Comment 151) Two commenters question the need for the provisions in subpart C and state that a farm should instead be responsible for developing its own training programs that are shown to meet specified regulatory outcomes.

(Response) The requirements in part 112 do not preclude farmers or industry associations from developing training materials or programs uniquely suited to their commodities or operations; however, we have determined that the training must cover the specified topics in order to ensure that farm workers have sufficient training.

(Comment 152) Some comments recommend that we develop a process or system whereby workers who are properly trained would receive a “training certificate” or a “food safety certificate,” which commenters believe would be particularly useful for workers who work on multiple farms during the year. These comments suggest that such certificates may be received (and updated) after undergoing training using an FDA-approved standardized curriculum or an equivalent curriculum. According to these comments, such a certificate could be valid for a harvest season or a calendar period, such as one year, and could also be valid for multiple crops of a similar nature, such as all deciduous tree fruits. Some comments state that a certificate should not obviate the need for training upon hire, at the beginning of each growing season and periodically thereafter, but could provide covered farms with a better sense of the food safety capacity of their workforce.

(Response) We see the value of workers receiving a “training certificate” or a “food safety certificate” documenting the training they have received. However, at this time, we are not requiring use of such a program (either as a new requirement or to satisfy any of the requirements of this rule), nor are we able to develop such a system or recommend a specific certification process or certification body to enable such an approach. Note, under § 112.30(b)(1), you must establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the persons(s) trained. We are willing to work with an organization that is interested in developing and implementing a training certification program, including through the PSA and SSA and using corresponding training materials.

(Comment 153) Some comments urge the use of website(s) (or web-based training) for educating employees about food safety and hygiene as a means to reduce the cost burden of training requirements, especially for smaller farms. One comment notes the advantages of using online resources, including that it can be continuously updated over time.

(Response) Internet-accessible training materials are a convenient way for workers, supervisors, and other farm staff to obtain rapid access to training materials and other resources. We are considering whether and to what extent the Alliance courses can be made available online or offered as Internet-based training. At a minimum, we will make the standardized curriculum available online.

(Comment 154) One comment (from a foreign government) requests that we provide training materials or guidelines to the foreign government in a timely manner so relevant parties

(including manufacturers, exporters, and regulators) can understand and properly implement the rule.

(Response) We are working to ensure the Alliance courses and training resources to be generated by the NCC and RC are consistent with the requirements of this rule. We intend to publish a notice of availability of these documents in the Federal Register, and our domestic and foreign stakeholders will be informed of and have access to these documents. We will partner with our foreign government counterparts as well as industry stakeholders to identify areas for outreach and technical cooperation to achieve greater understanding and implementation of the Produce Safety standards. In this regard, organizations such as the PSA, SSA, and JIFSAN can aid in providing appropriate qualification and training materials for foreign governments as well as training of foreign industry entities.

B. Qualification and Training for Personnel Who Handle (Contact) Covered Produce or Food-Contact Surfaces (§ 112.21)

(Comment 155) Some comments suggest exceptions to proposed subpart C based on types of employees. Although many commenters believe all types of employees should be covered by the provisions, including temporary, part-time, seasonal, and contracted employees, some other commenters believe complying with proposed subpart C would be prohibitively difficult and, therefore, certain types of employees should be exempted. Comments state that requiring seasonal training for all employees, including long-term, non-seasonal workers, is unnecessary and wasteful. One commenter believes that training should not be required “periodically” but instead only for new hires, when rules are changed, or when problems are observed. Another comment is additionally concerned that, because the term “season” is not

defined, the mandatory training provisions might be interpreted to require a separate training for each crop, some of which may have short planting-harvest cycles.

(Response) We continue to believe that adequate and appropriate training of all personnel who handle covered produce or food-contact surfaces, or who are engaged in the supervision thereof, is an essential component of standards for produce safety. Therefore, we disagree that certain types of farm workers should be exempt from a requirement that they receive training. Rather, we agree the content of the required training can be tailored to the specific duties of the type of farm worker or supervisor. Under § 112.21, all personnel (including temporary, part time, seasonal and contracted personnel) who handle (contact) covered produce or food-contact surfaces and their supervisors must receive training that is appropriate to the person's duties (§ 112.21(a)), and must have a combination of education, training, and experience to perform their assigned duties in a manner that ensures compliance with part 112 (§ 112.21(b)).

With respect to the comments about when training should be conducted, all personnel who contact covered produce and food-contact surfaces must receive training when hired, before they participate in the growing, harvest, packing or holding of covered produce in which they contact covered produce, and must be periodically reminded about the need to follow these practices through refresher training. However, we acknowledge the concerns raised by commenters about our proposed requirement that training must be conducted at the beginning of each growing season, if applicable. We agree that requiring all personnel to receive training at the beginning of each growing season could be unduly burdensome for certain farms, such as those that grow multiple crops annually, grow crops with short harvest cycles, or grow certain types of year-round crops with no set growing season. Therefore, in lieu of the proposed requirement to train workers at the beginning of each growing season if applicable, we are

revising the requirement to specify that periodic training must be conducted at least once annually. This requirement is in addition to the training that is conducted at the time of hiring. Periodic training can be conducted at a time that is appropriate, but must be conducted at least once annually. This allows farms to take into account such issues as the crop cycle, type and number of crops grown and harvested, and the timing when employee was hired and initially trained. As discussed in the 2013 proposed rule, periodic training serves to remind employees of the proper procedures including any changes in those procedures. Such updates may not need full training sessions, but only short descriptive sessions to ensure that all personnel remain aware of all procedures necessary to maintain the safety of produce.

(Comment 156) One comment asks us to recognize that “education or experience” can replace the need for specific training.

(Response) As discussed in the 2013 proposed rule, the standards in subparts C through O often involve action by farm personnel (e.g., assessment for animal intrusion, inspecting agricultural water system) that require specific knowledge, skills, and abilities, without which the standard cannot be properly achieved. Therefore, it is important those farm personnel have the training so they will have the necessary knowledge, skills, and abilities to perform their duties. In addition, experience at farming does not necessarily convey knowledge of food safety, particularly of microbial food safety hazards, and therefore specialized training is needed to address the specific concerns of on-farm food safety. Consequently, we disagree with the suggestion that education or experience can serve as a substitute for appropriate training.

(Comment 157) Some comments seek clarification on whether “pick-your-own” farms would be required to provide training to customers who pick their own produce.

(Response) We are establishing requirements for training of on-farm personnel. We are not establishing any requirements for training of visitors or customers at any farm, including at a “pick-your-own” farm. However, we note that this rule requires, in § 112.33, that covered farms make visitors aware of policies and procedures to protect covered produce and food-contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures, and make toilet and hand-washing facilities accessible to visitors. As discussed in section XII of this document, for example, a “pick-your-own” farm could comply with these requirements by indicating the location of restrooms and hand-washing facilities that are accessible to visitors, and by clearly posting such information where it is likely to be seen and read by visitors at the beginning of their visit to the farm, such as near the entrance or a cash register of the farm.

(Comment 158) One comment states people harvesting remnant crops following the main harvest for non-profit organizations (referred to as “gleaners”), often for donation to food banks, should not be subject to training requirements. Another comment states that in scenarios where a farm has completed its main harvest, and a third party purchases and harvests the remaining unharvested crop, it should be the responsibility of the remnant harvesting entity to ensure that their harvesters are appropriately trained.

(Response) An operation that harvests crops but does not grow them, such as a “gleaner” operation or other remnant harvester operation, may meet the revised definition of “farm” as established in the PCHF regulation and as we are establishing it in this rule (see definition of

“farm” in § 112.3(c)). While we are not exempting operations that harvest remnant crops from the provisions of part 112, we believe that it is likely that most such operations (including those who do so for donation to food banks) will not be covered by this rule because they will have \$25,000 or less in annual sales of produce or will be eligible for a qualified exemption.

Specifically, in response to the comment about harvesting remnant crops, we expect those farms conducting the covered activities (harvesting of remnant crop and any subsequent packing or holding) to comply with the applicable requirements of the rule. Personnel employed by such entities must be trained appropriately.

(Comment 159) One comment states that, when a farm contracts with another company for a contracted harvest crew, the company providing the harvest crew should be responsible for the initial, more comprehensive, food safety training, and the harvest crew should be made aware of food safety specifics at each farm at which they are harvesting, including standard operating procedures specific to the farm.

(Response) Where a covered farm uses contracted harvest crews to harvest covered produce on the farm’s behalf, the farm continues to be required to fulfill all relevant duties applicable under this rule. Thus, the farm is responsible for ensuring that the harvest crew has received required training. The farm may rely on the company that provides the harvest crew to provide or conduct the training, or the farm may provide or conduct the training. For example, if the harvest crew company provides training to workers who move from farm to farm under the employment of the harvest crew company, farms that employ such harvest crews may choose to rely on the harvest crew company to provide or conduct the training, request relevant

certification from the harvest crew company, and maintain appropriate records to demonstrate compliance with the applicable training requirements.

In addition, as discussed previously, an operation that harvests crops but does not grow them, such as a contract harvest crew company, may meet the revised definition of “farm” as established in the PCHF regulation and as we are establishing it in this rule (see definition of “farm” in § 112.3(c)). Thus, if they are covered farms, contracted harvest crew companies also have duties to comply with this rule.

(Comment 160) Some comments object to the “education or experience” clause in proposed § 112.21(b). Comments argue the level of education or experience that would satisfy this requirement is unclear, and it would unnecessarily limit the pool of workers eligible to work on farms. One comment further notes a requirement for “experience” would, by definition, preclude inexperienced workers from seeking such employment, although training could provide the knowledge necessary to perform tasks appropriately. A few comments recommend revising this provision to use the phrase “must have the training, education or experience to perform the person’s assigned duties” whereas others recommend incorporating flexibility for personnel to be “otherwise qualified through job experience”, in the same manner as allowed in 21 CFR parts 120 and 123 and in the proposed human preventive controls rule.

(Response) We are revising this provision to require that personnel have “a combination of education, training, and experience necessary to perform the person’s assigned duties in a manner that ensures compliance with this part.” This provides flexibility for how personnel are qualified to perform their duties. Depending on the job duties, this could include training (such

as training provided on-the-job), in combination with education, or experience (e.g., work experience related to an employee's current assigned duties).

(Comment 161) Several comments support making the trainings easily accessible and understood by all employees, regardless of native language or education level. One comment asks that we provide, via guidance, specific examples, such as pictograms, that can help facilitate understanding across language barriers.

(Response) We recognize that the goals of training cannot be achieved if the persons receiving the training do not understand the training. Training could be understood by personnel being trained if, for example, it was conducted in the language that employees customarily speak and at the appropriate level of education. In some cases, it may be necessary to use easily understood pictorials or graphics of important concepts. The PSA and SSA are developing training materials to be easily understood by farm workers of different languages, literacy, and educational levels by using pictorials or graphics of important concepts, along with offering the materials in multiple languages.

C. Training Personnel Who Conduct a Covered Activity (§ 112.22)

We are revising § 112.22(b)(1) to replace “covered produce that should not be harvested” with “covered produce that must not be harvested” to reflect the mandatory nature of the requirements in this rule and specifically, the requirements of § 112.112.

(Comment 162) Several comments request that we recognize existing food safety education and training programs that either meet or exceed the PSA materials, as an efficient

way to gain compliance with subpart C. One comment asks that FDA allow existing educational programs that wish to gain equivalency with PSA materials to be able to modify their materials and program structure to fit the PSA learning objectives, rather than be required to adopt the exact format and materials developed by the PSA. The commenter further requests us to provide guidance on how existing programs can obtain equivalency with the PSA standardized curriculum, when it becomes available. Still other comments request that FDA develop approved curricula to meet the training requirements under subpart C. Yet another comment asks whether and what accreditation FDA would accept for training of on-farm trainers.

(Response) See our response to Comment 3. The PSA and SSA training materials will include a standardized curriculum. FDA is working with the PSA and SSA to ensure that FDA will be able to recognize this curriculum, once developed, as adequate (see requirement under § 112.22(c)). We expect this standardized curriculum to be available in time for covered farms to be able to use it, as they work toward achieving compliance with the produce safety regulation. Under § 112.22(c), at least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by FDA. Accordingly, successful completion of training using the standardized curriculum by your farm personnel (at a minimum, by one supervisor or responsible party for your farm) is sufficient to satisfy the requirements of § 112.22(c). Alternatively, at least one supervisor or responsible party for your farm must successfully complete training using any other training material or program, provided such training is at least equivalent to the standardized curriculum, and all of your other farm personnel must be trained in accordance with § 112.22(a) and, as applicable, § 112.22(b). We encourage trainers outside the PSA and SSA to evaluate their courses against the PSA and SSA materials

when they become available and to modify or adapt curricula, where necessary, to ensure that they are consistent with, and provide at least an equivalent level of instruction to, the Alliance courses. We agree that existing programs can modify their training program structures and curriculum to ensure consistency with, and provide at least an equivalent level of instruction to, the standardized curriculum without necessarily adopting the PSA or SSA training structure or materials. We also intend to fund the development of certain alternate training programs for specific target audiences through cooperative agreements. The agency will work closely with the participants in those agreements and expects to recognize the training programs that are developed through these collaborations. We intend that the standardized curricula being developed by the Alliances and the alternate curricula to be developed through cooperative agreements are the only ones that will be officially recognized by the FDA. We emphasize, however, that official recognition by FDA is not required for training curricula to be “at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration” as stated in § 112.22(c). Any training curricula that are at least equivalent to the officially recognized curriculum satisfy this requirement. We have no plans to establish an accreditation system for the training of on-farm trainers, although it is an area that is being explored through the PSA and SSA.

(Comment 163) Some comments ask for clarification on the content of the food safety training based on the standardized curriculum recognized by FDA. One comment asks FDA to better define the elements of “food hygiene and food safety” that should be covered in comprehensive training, and offers suggestions on such elements.

(Response) FDA concludes that the broad topic areas addressed in § 112.22(a) are those minimum topic areas necessary to be covered during training for all employees who handle or contact covered produce. Training in the principles of food hygiene and food safety is a necessary component of such required training because it will provide an overall framework for job performance. We expect the standardized curriculum, when it becomes available, will provide information about the content to be covered under these minimum required topic areas, including with respect to principles of food hygiene and food safety.

D. Records Related to Personnel Qualifications and Training (§ 112.30)

(Comment 164) One comment states it is not reasonable for operations to be required to keep training records for personnel who received training at another operation or for contract workers (e.g., harvest crew, sanitation crew). This comment recommends revising proposed § 112.30(b) to be limited to records of trainings performed or paid for by the operation, supplemented by additional records providing a rationale for personnel who did not receive such training at or by the operation.

(Response) We are not making the requested change. A covered farm must ensure and keep records that document the required training received by personnel, regardless of whether the training is offered and the applicable records are generated by the farm or by another entity, such as the harvest crew company (see also our response to Comment 159). The records required under § 112.30(b)(1) are intended to enable a covered farm to track the content and timing of training personnel have received, identify personnel and training topics for periodic updates, and identify personnel that have the necessary training for assignment to certain responsibilities; and to allow FDA to verify compliance with the rule's training requirements.

XII. Subpart D – Comments on Health and Hygiene

In subpart D of proposed part 112, we proposed minimum standards directed to health and hygiene that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act. We asked for comment on our proposed standards directed to health and hygiene, including provisions related to use of gloves and antiseptic hand rubs (commonly referred to as “hand sanitizers”); provisions related to hand-washing; and our proposed requirements related to worker health.

We are finalizing these provisions with revisions (see Table 10). We discuss these changes in this section.

Table 10.-- Description of Revisions to Subpart D

Final Provision	Description of Revisions
§ 112.31	- Fixed grammatical error in § 112.31(a) (deleted “a” before “communicable illnesses”)
§ 112.32(b)	- Updated list of examples of hand drying devices in § 112.32(b)(3) (deleted “clean cloth towels” and added “electric hand dryers”) - Revision to § 112.32(b)(3) to allow the use of “other effective surfactants” in lieu of soap during hand-washing - Added new § 112.32(b)(5) to require removing or covering hand jewelry under certain circumstances - Added new § 112.32(b)(6) to prohibit eating, chewing gum, and using tobacco products in areas used for covered activities (except that drinking beverages is permitted in designated areas)
§ 112.33	- Deleted proposed § 112.33(a) defining “visitor” (moved definition of visitor to § 112.3(c))

A. General Comments

(Comment 165) We received several comments on this subpart, many of which support the proposed provisions under subpart D. Many commenters agree that personnel who work in an operation in which covered produce or food-contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to protect against contamination. Several comments note the importance of health and hygiene and generally believe that the proposed provisions are similar to those already established and commonly recognized as basic requirements for personal sanitation and hygiene. Another comment supports the promotion of hand hygiene as a mandatory element for self-protection and protection of others for the agricultural sector, including among small farms.

(Response) Health and hygiene of personnel and visitors is a crucial component of produce safety, and we are establishing certain standards that are reasonably necessary to prevent personnel and visitors from introducing known or reasonably foreseeable hazards into or onto covered produce or food-contact substances in subpart D of part 112. Unless exempted or subject to any applicable modified requirements, covered farms conducting covered activities on covered produce are required to comply with the requirements for health and hygiene in subpart D.

(Comment 166) One comment suggests that FDA recognize that postharvest treatment of food is an inadequate substitute for the fundamentals of hygiene.

(Response) FDA generally agrees with this statement and encourages all firms to use appropriate hygienic practices in the production of produce, regardless of whether they are subject to this rule. Under § 112.2(b) covered produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance is eligible for exemption from the requirements of part 112. In addition, produce that is rarely consumed raw

(i.e., it is typically cooked before consumption) is not subject to this rule under § 112.2(a). Thus, by definition, covered produce is produce that is not likely to receive a postharvest processing or treatment step that will adequately reduce the presence of microorganisms of public health concern. Therefore, personnel and visitor hygiene, while always important in the production of food, are particularly important with respect to covered produce under this rule. Our rule takes an approach consistent with the requirement in section 419(c)(1)(A) that this regulation set forth the procedures, processes, and practices the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into fruits and vegetables.

B. Ill or Infected Persons (§ 112.31)

(Comment 167) Some comments seek clarification on compliance with this provision and express concerns about the feasibility of continuously monitoring workers for signs of illness. Some comments state that ill workers do not notify supervisors of their illness, that workers hide their illness due to fear of not being able to work, and that employees may not be aware that they have an infectious disease until days have passed and covered produce has already been handled.

(Response) We are requiring you to take measures to prevent contamination of covered produce and food-contact surfaces with microorganisms of public health significance from any person with an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea) (§ 112.31(a)). We are correcting a grammatical error that appeared in this section as proposed by deleting “a” before “communicable illnesses.”

One measure that you must take to satisfy this requirement is to exclude any person

from working in any operations that may result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance when the person (by medical examination, the person's acknowledgement, or observation (for example, by a supervisor or responsible party) is shown to have, or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health (§ 112.31(b)(1)). Note also that all personnel who handle covered produce during covered activities or supervise such activities must receive training on the importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance (§ 112.22(a)(2)).

Another measure we require is that you instruct your personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have, an applicable health condition (§ 112.31(b)(2)). Consistent with the training requirement in § 112.22(a)(2), these requirements emphasize that individual workers have a responsibility to take action to prevent contamination due to their own illness or infection. Although we have not specified, under § 112.31(b)(1), when or how often workers' health must be considered, we expect covered farms to take reasonable measures, as necessary, to exclude infected or ill employees from working in operations that may result in contamination of covered produce until the person's health condition no longer presents a risk to public health. For example, where harvesting of covered produce is conducted over multiple days, a farm could have a supervisor inquire about the health of the harvest crew daily when they report to work, prior to allowing the crew to enter the field to begin harvesting, and make appropriate decisions about whether any workers should be reassigned to different duties.

We provided other examples in the 2013 proposed rule. As one example, if an employee tells you that his or her physician (by medical examination) has diagnosed that the employee has a fever, and the employee normally handles your covered produce, you must take steps to ensure that the employee does not come into contact with your covered produce because the fever may suggest that the employee has an infection and there is a reasonable possibility of contamination. FDA is not requiring (nor are we authorizing) you to obtain medical records of your employees to determine or verify their applicable health condition(s).

Similarly, if you see that an employee has an open wound, boil, cut, or sore, and the employee normally handles covered produce, you must take steps to ensure that he or she is excluded from handling covered produce if the wound, boil, cut, or sore could be a source of microbial contamination. However, the employee may be allowed to handle covered produce, for example, if the wound, boil, cut, or sore is adequately covered (e.g., by an impermeable cover) in a manner that prevents it from becoming a source of contamination for the covered produce. In addition, note that applicable health conditions do not include non-communicable diseases such as cancer, diabetes, or high blood pressure, or non-communicable conditions such as pregnancy.

C. Personnel Hygienic Practices (§ 112.32)

(Comment 168) Some comments raise concern with the provision that would require washing hands after certain specified occasions. Some comments point out that some farmers rely on working animals, and state that a requirement to wash hands after every contact with animals would be impractical and unnecessary, especially when contact with produce following contact with animals, is not likely or expected. Instead, these comments recommend requiring

hand-washing before handling produce and throughout handling, as needed, taking into account the presence of debris or other unsanitary conditions. Another comment incorrectly interprets proposed § 112.32(b) to require that hands must be sterile and free of microbial contaminants, and seeks clarification on the type(s) of microbial pathogens that must be avoided.

(Response) Section 112.32(b)(3) requires (in relevant part) the washing of hands thoroughly, including scrubbing with soap (or other effective surfactants) and running water, on specified occasions, including as soon as practical after touching animals (such as livestock and working animals) or any waste of animal origin. Hand-washing, when done effectively, can significantly reduce both resident bacterial populations (such as on the hands of a worker who may not realize he or she is ill or infected) and transient microbial contamination (such as bacteria, viruses, and parasites that gets onto hands through contact with the environment). We are not requiring hands to be sterile and free of microorganisms. Instead, we are requiring reasonably necessary steps to be taken to reduce the likelihood of potential presence of pathogens. Hand-washing is a key control measure in preventing contamination of covered produce and food-contact surfaces.

We are not requiring personnel to wash their hands immediately after touching animals or after every contact with animals or their waste. Rather, we require washing hands as soon as practical after contact with animals or any waste of animal origin, a requirement aimed at minimizing the potential for transmission of pathogens from animals onto produce. We recognize the importance of working animals on farms. This provision ensures that farms are cognizant of the potential for animals (including livestock and working animals) or their waste to be a source of contamination of produce, and that appropriate measures are taken to minimize or avoid such potential. Personnel working with animals must know when and how to

wash their hands. In addition, under § 112.32(b)(2), which requires taking appropriate steps to minimize the likelihood of contamination when in direct contact with working animals, particular attention should be given to clothing, especially footwear, to ensure that fecal material from barns and barnyards does not contaminate covered produce and food-contact surfaces.

Note also, consistent with the revision to § 112.130(b)(3), we are making a revision to the examples of hand drying devices in § 112.32(b)(3) to list “single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices.” We refer you to section XVII of this document for the corresponding discussion. In addition, we are updating this provision to allow the use of other effective surfactants in lieu of soap that is required during hand-washing. This revision is consistent with § 112.130(b)(1), which we are retaining as proposed.

(Comment 169) One comment suggests that FDA encourage use of fluorescent substances to highlight unwashed or neglected areas of the hands.

(Response) We are not requiring this practice in this rule. However, technologies such as these, when used in conjunction with appropriate training, may be a useful tool to teach hand hygiene (Ref. 101) (Ref. 102).

(Comment 170) One comment seeks more specific provisions under proposed § 112.32(b)(4) on glove use, specifically the type of gloves to be used and the meaning of “sanitary condition.” The commenter notes that, for example, farm workers in California use both disposable gloves and reusable gloves for different activities, and that whereas disposable gloves

can be easily replaced, cotton or leather gloves are more difficult to replace frequently and to determine whether they are in a sanitary condition.

(Response) We are not requiring the use of gloves, or that gloves, when used, be of a certain type (e.g., disposable, cotton, leather, or other types). Under § 112.32(b)(4), if gloves are used in handling covered produce or food-contact surfaces, you are required to maintain the gloves either in an intact and sanitary condition, or else replace them. We recognize that heavier gloves are commonly used during certain covered activities, such as harvesting (for example, of tomatoes or peppers), to protect workers' hands from cuts or blisters. We are not aware of any reason to require that covered farm workers use only certain types of gloves, and therefore we decline to do so. We recognize that different types of gloves, or no gloves, may be appropriate depending on the circumstances, and § 112.32(b)(4) as written provides covered farms with flexibility to choose the practice that is appropriate for their operations. Regardless of the type of gloves that a farm may choose to use, gloves would not be in an intact and sanitary condition if, for example, they have visible feces on them or have holes or cracks in them such that soil or contaminants can enter the inside of the glove.

(Comment 171) Some comments recommend that FDA expand requirements for hygienic practices to include prohibitions on jewelry, gum, spitting, chewing, eating, and drinking (excluding drinking water) in growing areas.

(Response) We are revising § 112.32(b) to add two new provisions. New § 112.32(b)(5) requires removing or covering hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand. This provision addresses the potential biological hazard posed by jewelry that is not effectively cleaned and could serve as a

harborage for pathogens. New § 112.32(b)(6) requires not eating, chewing gum, or using tobacco products in an area used for a covered activity (however, drinking beverages is permitted in designated areas). Eating, chewing gum (and potentially spitting the gum out), and using tobacco products (and potentially dropping used cigarettes or cigars or spitting chewing tobacco juice) all constitute potential avenues of dissemination of enteric foodborne pathogens (Ref. 103) (Ref. 104) (Ref. 105) (Ref. 106). However, we are not prohibiting the consumption of beverages by personnel in designated areas. For example, drinking beverages is often necessary to prevent dehydration during outdoor activities, including in growing areas. The best practice is to have water (or other beverage) and drinking cups readily accessible to workers near an area where they are working outdoors, such as at the end of a row of covered produce being harvested.

These requirements are consistent with, although not identical to, the requirements for food facilities, under the PCHF regulation (§ 117.10(b)(4) and (b)(8)), and our long-standing provisions in the Food CGMP regulation (§ 110.10(b)(4) and (b)(8)).

In addition, these requirements are consistent with the Industry Harmonized GAPs standard for field operations and harvesting, which recommends that operations have a policy that personal effects such as jewelry, watches, or other items must not be worn or brought into production areas if they pose a threat to food safety. This standard also states that smoking, chewing, eating, or drinking (other than water) should not be permitted in any growing areas, and recommends that operations adopt a policy to prohibit these practices except in designated areas (Ref. 49) (Ref. 50). Section 112.32(b)(5) is also similar to provisions in another industry guidance (Ref. 60) and the Codex Guide. Section 112.32(b)(6) is also similar to provisions in the AFDO Model Code (Ref. 62), a marketing agreement (Ref. 40), and the Codex Guide. In addition, the AFDO Model Code (Ref. 62) and a marketing agreement (Ref. 40) direct farms to

have a written policy regarding jewelry. We believe many farms are already implementing the measures required by § 112.32(b)(5) and (6) based on these industry recommendations, and we believe they are practical measures for produce safety that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act.

D. Visitors (§ 112.33)

(Comment 172) One comment questions whether or how proposed § 112.33 would help prevent the spread of foodborne illness, especially if the visitor does not come into contact with the food and merely tours the facility and observes the farm's operations. Other comments express concern that these provisions hold the farm accountable for the actions of customers who visit their operation. One of these comments requests that we establish a requirement that farm visitors who are sick must not enter areas where covered activities are taking place, or that visitors who will be handling covered produce must notify a farm of any significant health conditions before entering the farm.

(Response) As with workers, visitors can transmit microorganisms of public health significance to covered produce or food-contact surfaces. For example, a visitor who is ill or infected touring a produce field during a harvesting activity can be an indirect source of contamination, even if the visitor does not come into direct contact with the covered produce or a food-contact surface. We recognize that visitors to a farm often enter areas where covered produce is grown or harvested, particularly in the case where a farm offers consumers the opportunity to pick their own fruits or vegetables. Section 112.33 is not aimed at restricting visitors from entering your farm as part of the routine course of your business. Rather, they are

measures that reasonably minimize the potential for visitors to become a source of produce contamination, provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act.

As noted in response to Comment 114, we have included a definition for the term “visitor” within § 112.3(c) using the text in proposed § 112.33(a). As a result, we have eliminated proposed § 112.33(a), and we are renumbering proposed § 112.33(b) and (c) as final § 112.33(a) and (b), respectively.

Under final § 112.33(a), you must make visitors aware of your policies and procedures to protect covered produce and food-contact surfaces from contamination by people, and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures. For example, a farm could comply with § 112.33(a) by explaining the importance of health and personal hygiene, including proper hand-washing procedures and the potential for contamination from ill or infected visitors, to all visitors who are likely to come into contact with covered produce or food-contact surfaces, at the beginning of a visitor’s visit. As another example, a farm could clearly post the rules applicable to visitors where they are likely to be seen and read at the beginning of a visitor’s visit, such as near the entrance or cash register at a “pick-your-own” farm operation. As another example, a farm might choose to voluntarily establish a policy that visitors who are visibly ill may not enter specific areas of the farm (and/or during specific times, such as during harvesting). We are not requiring farms to establish such a policy, however. For a farm with such a policy, informing visitors of the policy and taking steps to implement it would satisfy the requirements of § 112.33(a).

We believe that the requirements of § 112.33 are those reasonably necessary to prevent contamination of covered produce by visitors. As such, we decline to include requirements that

apply directly to visitors.

(Comment 173) Other comments express concern with proposed § 112.33(c). Comments state that requiring full-scale bathroom and hand-washing facilities in the fields would not be practical, and points out that many operations can provide only portable toilets and hand sanitizers for visitors. Stating that it is common courtesy for farms to provide toilet facilities to visitors, another comment finds FDA's requirement related to this issue unnecessary for the purpose of ensuring food safety. This commenter also states that having personnel and visitors share the same toilet facilities would increase the likelihood of spreading infections. Another comment requests that proposed § 112.33(c) include a "grandfather clause" for current farms.

(Response) As discussed in section XVII of this document, under the requirements outlined in subpart L of part 112, covered farms are required to have clean and well-maintained toilet and hand-washing facilities for their personnel as a measure to prevent contamination of produce and food-contact surfaces (see §§ 112.129 and 112.130), and § 112.33 establishes only the incremental requirement that such facilities must be made accessible to visitors. This provision does not prescribe the number, specific location, type, or designated use of such facilities. Therefore, it is not required for a covered farm to provide "full-scale" bathrooms in the field for visitors to use; nor is it required for a covered farm to provide separate toilet or hand-washing facilities for visitors and for farm personnel. For example, portable toilets may be a feasible option for use by personnel and/or visitors when in the field. Note, however, that the general requirements that apply to toilet facilities and hand-washing facilities are specified in §§ 112.129 and 112.130, respectively. As noted in the 2013 proposed rule, a farm could comply with the requirements of § 112.33 by, for example, indicating the location of restrooms

and hand-washing facilities that are accessible to visitors and clearly posting rules applicable to visitors where they are likely to be seen and read at the beginning of a visitor's visit, such as near the entrance or cash register at a "pick-your-own" farm operation. Given the minimal nature of this requirement, we disagree that this provision causes undue economic burden to farms or is impractical, or that a specific exemption(s) is warranted for certain farms. We also disagree that visitors and personnel sharing the same restrooms and/or hand-washing facilities would increase the risk of spreading communicable disease and thereby contaminating covered produce. Compliance with the provisions of the rule related to hand-washing requirements and hygiene generally for personnel (§ 112.32), adequacy of toilet and hand-washing facilities (§§ 112.129 and 112.130), and visitors (§ 112.33) are expected to minimize risk, not to increase risk. Any possible increase in use of toilet or hand-washing facilities caused by visitors should not increase the risk presented to covered produce if the farm is in compliance with these relevant provisions.

XIII. Subpart E – Comments on Agricultural Water

In subpart E of proposed part 112, as described in the 2013 proposed rule and the supplemental notice, taken together, we proposed science-based minimum standards directed to agricultural water that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act. In addition, in the supplemental notice, taking into account comments on the 2013 proposed rule, we proposed to amend our water quality and testing requirements in proposed §§ 112.44 and 112.45 (79 FR 58434 at 58440-58457).

In the 2013 proposed rule and the supplemental notice, we asked for comment on our proposed provisions, including the proposed requirements that all agricultural water must be safe and of adequate sanitary quality for its intended use; the measures that must be taken with respect to agricultural water sources, water distribution systems, and pooling of water; the treatment of agricultural water; the microbial quality standards required for agricultural water used for certain specified purposes; the testing required for agricultural water, including our tiered approach to testing; the measures that must be taken for agricultural water used during harvest, packing, and holding activities for covered produce; and the requirements regarding records related to agricultural water.

In this section of this document we discuss comments we received on the standards directed to agricultural water in the 2013 proposed rule, but that we did not address in the

supplemental notice. We also discuss comments that we received on the new and amended proposed provisions in the supplemental notice.

We are finalizing these provisions with several changes. We re-structured subpart E to better organize the requirements related to agricultural water into the following categories: (1) General requirements for agricultural water quality (§ 112.41); (2) Inspection of agricultural water distribution systems and pooling of water (§ 112.42); (3) Treatment of agricultural water (§ 112.43); (4) Specific microbial quality criteria for certain uses of agricultural water (§ 112.44); (5) Follow-up measures or corrective actions if agricultural water does not meet applicable requirements, including microbial quality criteria (§ 112.45); (6) Frequency of testing of agricultural water (§ 112.46); (7) Who must perform water tests and what analytical methods must be used (§ 112.47); (8) Agricultural water that is used during harvesting, packing, and holding (§ 112.48); (9) Permitted alternatives (§ 112.49); and (10) Records requirements (§ 112.50). In Table 11, we identify the new final provision corresponding to each proposed provision, and describe the nature of substantive revisions to that proposed provision. We discuss all of the revisions to the proposed requirements in this section.

Table 11.-- Description of Re-arrangement and Revisions to Subpart E

Proposed Provision	Final Provision	Description of Revisions
§ 112.41	§ 112.41	- No change
§ 112.42(a), (b), (c)	§ 112.42 (a), (b), (c)	<ul style="list-style-type: none"> - Revision to clarify inspection requirement in § 112.42(a) applies to the extent agricultural water distribution systems are under your control, but including consideration of factors that may not be under your control - Revision to replace “the entire agricultural water system” with “all of your agricultural water systems” and corresponding edits to refer to “water sources” and “water distribution systems” given a farm may have multiple agricultural water systems - Revision of § 112.42(a) to clarify inspection is required at the beginning of a growing season, as appropriate, but at least once annually - Revision of § 112.42(a)(4) to make clear both adjacent and nearby lands are to be included in required considerations - Reordered § 112.42(b) and (c) - Revision of § 112.42(b) to clarify maintenance requirement for agricultural water distribution systems applies to the extent such systems are under your control - Revision of § 112.42(c) to clarify measures required to adequately maintain agricultural water sources
§ 112.42(d)	§ 112.45(a) and 112.45(b)	<ul style="list-style-type: none"> - Revisions to clarify measures that are required when agricultural water is not safe or of adequate sanitary quality for its intended use; does not meet the microbial quality criterion in § 112.44(a); or does not meet the microbial quality criteria in § 122.44(b) - Revision to replace “the entire agricultural water system” with “the entire affected agricultural water system” to clarify re-inspection requirement
§ 112.42(e)	§ 112.42(d)	- Revision to clarify the intent to focus on reducing the potential for contamination as a result of “contact of covered produce with” pooled water
§ 112.43(a), (b), (c)	§ 112.43(a) and (b)	<ul style="list-style-type: none"> - Revision to clarify that treatment of water is one among other permitted options to ensure the safety of water for its intended use - Revision to clarify that water treatment options are not limited to chemical methods, and to include physical treatment, including using a pesticide device, and other suitable method as additional treatment options
§ 112.44(a)	§ 112.44(a)	<ul style="list-style-type: none"> - Revision to separate testing requirements and required follow-up measures from microbial quality criteria - Revision to prohibit use of untreated surface water for purposes listed in § 112.44(a) - Revision to delete proposed § 112.44(a)(3) reference to water used to make agricultural teas

	§ 112.47(b)	<ul style="list-style-type: none"> - Rearrangement of requirements to use specified analytical methods into a separate provision within § 112.47 - Requirement that samples must be aseptically collected
§ 112.44(b)	§ 112.45(a)	<ul style="list-style-type: none"> - Revisions to clarify measures that are required when agricultural water is not safe or of adequate sanitary quality for its intended use, and/or does not meet the microbial quality criteria in § 112.44(a)
§ 112.44(c)	§ 112.44(b)	<ul style="list-style-type: none"> - Revision to separate testing requirements and required follow-up measures from microbial quality criteria
	§ 112.47(b)	<ul style="list-style-type: none"> - Rearrangement of requirements related to analytical methods as a separate provision within § 112.47 - Requirement that samples must be aseptically collected
§ 112.44(c)(1), (c)(2), and (c)(3)	§ 112.45(b)	<ul style="list-style-type: none"> - Revisions to clarify measures that are required when agricultural water does not meet the microbial quality criteria in § 112.44(b), including the timing when such measures must be taken - New limitation in § 112.45(b)(1)(i)(A) that a time interval of no more than four consecutive days may be applied between last irrigation and harvest to achieve the microbial quality criteria in § 112.44(b) - Revision to provide that an alternative microbial die-off rate permitted under § 112.45(b)(1)(i)(B) may be accompanied by a maximum time interval, in accordance with § 112.49
§ 112.44(d)	§ 112.49	<ul style="list-style-type: none"> - Consolidation of all provisions that provide for the use of alternatives into new § 112.49, with additional provisions to permit alternatives to testing frequencies required under § 112.46(b)
§ 112.45(a)	§ 112.46(a)	<ul style="list-style-type: none"> - Revision to add reference to relevant EPA definition of a State approved to administer the SDWA public water supply program, in 40 CFR 141.2
§ 112.45(b) and (c)	§ 112.46(b)	<ul style="list-style-type: none"> - Revision to combine testing requirements for untreated surface water and untreated ground water used for purposes specified in § 112.44(b), differing only in number of samples required for initial and annual surveys - Revision to require updating the microbial quality profile annually, using annual survey data and based on a rolling dataset of 20 samples for untreated surface water or 4 samples for untreated ground water - Revision to require that previous years' data, when used, must be limited to samples collected within the previous 4 years - Elimination of requirement to re-characterize the water quality profile every 10 years - Corresponding revisions to requirement to re-

		<p>establish the microbial quality profile if you know or have reason to believe that your microbial quality profile no longer represents the quality of water</p> <ul style="list-style-type: none"> - Revisions to clarify timing of sample collection
§ 112.45(c)	§ 112.46(c)	<ul style="list-style-type: none"> - Revisions to separately state testing requirements for use of untreated ground water for uses specified in § 112.44(a)
§ 112.45(d)	§ 112.44(a)	<ul style="list-style-type: none"> - Revision to prohibit the use of untreated surface water for the purposes specified in § 112.44(a)
§ 112.45(e)	§ 112.47(a)	<ul style="list-style-type: none"> - No substantive change
§ 112.46	§ 112.48	<ul style="list-style-type: none"> - No substantive change
§ 112.50	§ 112.50	<ul style="list-style-type: none"> - Revision to combine two proposed records requirements related to test results (proposed § 112.50(b)(2) and (5)) into one requirement (§ 112.50(b)(2)) - Revisions corresponding to elimination of § 112.161(b), requiring records of actions taken in accordance with § 112.45, and establishing specific requirements for application of time intervals under § 112.45(b) (§ 112.50(b)(6)) - Revisions to require records of scientific data or information related to use of alternatives permitted under § 112.49 (§ 112.50(b)(8)) - Addition of new § 112.50(b)(9) to require documentation of any analytical methods used in lieu of the prescribed method in § 112.151(a)

A. General Comments

1. Research

(Comment 174) Several comments state that further research is needed to determine appropriate standards for water quality, and recommend that FDA partner with various land grant universities, and other agencies, including NRCS and EPA, utilizing both funded research programs and incentive-based programs to promote safe water management practices. Some comments suggest that FDA conduct a risk assessment based on research findings and seek public comment on the results of the risk assessment, prior to finalizing a standard(s) for the quality of agricultural water. Other comments offer various suggested topics for future research, including some comments that maintain that landscapes, weather patterns, and water sources vary significantly and, therefore, further research should be done to understand the physical differences of the national landscape as it pertains to produce safety.

(Response) We do not agree that more research, followed by a risk assessment based on that research, is needed for us to finalize the provisions of this rule relating to agricultural water. As discussed in the 2013 proposed rule, the supplemental notice, and in the paragraphs that follow, there is sufficient scientific information from which we conclude that the requirements in this rule minimize the risk of serious adverse health consequences and death, and are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated. In addition, as discussed in section V of this document, we have conducted a qualitative assessment of risk of hazards associated with produce production, which indicates that agricultural water is a potential route of contamination of produce during growing, harvesting,

and on-farm postharvest activities and that use of poor agricultural practices could lead to contamination and illness even where the potential for contamination is relatively low. The science-based minimum standards established in subpart E of part 112 address this on-farm route of contamination.

However, we do support additional research as a means of facilitating implementation of this rule and continuing advancement of scientific knowledge in this area. As discussed in the 2013 proposed rule, we are pursuing regulatory science and research activities in collaboration with various partners. We have supported extramural research and collaborated with other federal agencies, academic institutions, and industry-supported entities to leverage research efforts, expertise, and resources (such as experimental stations for field research). For example, we are working with USDA to conduct research of mutual interest in key areas, including agricultural water.

In addition, FDA has provided funding to develop a produce safety research network at the Western Center for Food Safety (WCFS) at the University of California, Davis. Research studies at WCFS include projects related to the microbiological quality of irrigation water in catchments and distribution systems; evaluation of agricultural water quality parameters and the cost-benefit of farm-level interventions; and microbial water quality of moving surface waters. We intend for these collaborative efforts to result in the collection of data that will help advance the state of scientific knowledge on the safe use of agricultural water. WCFS also partnered with the Center for Produce Safety to provide seed money through a competitive grants program to fund produce safety projects focused on agricultural water issues that are topical and/or region specific. WCFS has further partnered with academic institutions located in various regions in the United States, including in California, Florida, Hawaii, Oregon, and

Washington, to conduct research on a variety of commodities including apples, citrus, and onions. We intend to disseminate useful scientific information obtained from these efforts, when available. We support additional research as a means for forming a basis for possible future rulemaking in this area.

2. Generic E. coli as an Indicator

(Comment 175) Some comments consider testing for indicators of water quality to be inappropriate because the final objective is to prevent pathogen contamination. Therefore, these commenters believe the microbiological standards for agricultural water in this rule should be based on direct pathogen detection rather than on indicator organism(s). These comments recommend that FDA provide a list of pathogens of concern and specify the levels in agricultural water at which they pose a risk. Some comments also suggest where water exceeds any specified level of indicator organism, the farm should not be required to discontinue use of the water, and instead should directly test for specified pathogens of concern.

(Response) We discussed our review of current scientific literature, potential approaches, and complexity associated with microbiological indicators of water quality in the 2013 proposed rule (78 FR 3504 at 3561-3563; 3567-3568). As described in that document, we considered two general approaches to establishing a microbiological water quality testing program, i.e., to either test for the presence of an indicator organism(s) that may signal the presence of pathogens or test for pathogens themselves.

In the United States, bacterial indicators have a long history of being used to demonstrate the safety of drinking water and adequacy of its treatment. They have also been used to monitor the status of drinking water in distribution systems and determine if surface

waters are microbiologically safe for recreational use (e.g., swimming) and shellfish harvest (Ref. 107). Although no single indicator is universally accepted, indicator microorganisms are widely used in water quality testing because of their broad utility across many types of water (Ref. 107). We acknowledge that pathogen detection has the obvious advantage of directly targeting microorganisms in water that are a risk to public health; however, we continue to believe sampling water for pathogens presents additional challenges, including significantly larger sample sizes, inherently higher costs, and the wide array of potential target pathogens (i.e., the presence or absence of one pathogen may not predict for the presence or absence of other pathogens). The comments did not provide information from which we could conclude that pathogen testing would be a viable approach, either for initial testing or for follow-up testing as suggested by some comments. Therefore, rather than requiring testing for the presence or levels of various pathogens of public health significance, we are requiring testing for a microbial indicator as a measure to monitor and assess the potential for contamination in agricultural water.

(Comment 176) Some comments support our proposal to use generic E. coli as an indicator of water quality in the proposed standards for microbial quality of water. These comments agree that, while imperfect, it is the most indicative of currently available indicators of fecal pollution and support its use to monitor the quality of agricultural water. In contrast, some other comments argue that E. coli is not a suitable indicator for monitoring water used in an agricultural setting, and cite different reasons, including that (1) in the view of these commenters, the correlation between pathogen presence and E. coli presence is not strong and E. coli cannot predict the presence of certain bacterial and non-bacterial pathogens; (2)

pathogens may be present even if the E. coli threshold in the microbial quality standard is not exceeded, or conversely, that pathogens may not be present even if the threshold is exceeded; and (3) although the proposed indicator may provide valid information in one region of the country, it may not provide valid information in another region. Some commenters also view current data on the use of E. coli as an indicator organism to be conflicting and, therefore, recommend waiting until science on this issue evolves to identify better indicator(s) of fecal pollution, rather than developing microbial quality standards based on E. coli as an indicator, which they believe could be overly burdensome.

(Response) A number of indicator microorganisms have been used to predict the presence of fecal pollution (thereby the potential for enteric pathogens) in water, with varying degrees of success. These include total coliforms, fecal coliforms, enterococci, generic E. coli, and coliphages. However, as comments noted, the presence of indicators does not always signal the presence of pathogens, and the absence of detection of indicators does not guarantee that pathogens are absent (Ref. 108) (Ref. 109) (Ref. 110) (Ref. 111).

We reviewed the most widely used fecal indicator(s) or indicator groups for their potential in assessing the microbial quality of water used for purposes described in § 112.44(a) and (b). We considered total coliforms and fecal coliforms as indicators of fecal contamination but determined that neither of them can serve as reliable indicators of a fecal contamination event (Ref. 112) (Ref. 113) (Ref. 114). Generic E. coli is a member of both the coliform and fecal coliform groups and it has been shown using various detection methods to be the coliform most consistently associated with fecal contamination (Ref. 112) (Ref. 113) (Ref. 115) (Ref. 116) (Ref. 117). Generic E. coli alone, as an easily distinguishable member of the fecal coliform group, is more likely than the fecal coliform group as a whole to indicate fecal

pollution (Ref. 118). Used in this way, indicator organisms are not used specifically to predict the presence of pathogens, but are useful predictors of undesirable conditions (e.g., ineffective treatment or presence of fecal material) that may lead to contamination of water used in an agricultural setting.

As explained in the 2013 proposed rule, generic E. coli has an extensive history of and support for use as an indicator of fecal contamination. Recently, it has emerged as the preferred indicator for monitoring water quality, not only because of the problems with other fecal indicator groups noted previously, but also due to the development of superior methods of detection with greater accuracy, sensitivity, and simplicity over those previously used (Ref. 113). Generic E. coli is also recognized as a water quality criterion indicative of the suitability of water for domestic, industrial, and other uses (Ref. 100) (Ref. 116). We also recognize that, despite widespread use of and support for generic E. coli as an indicator of fecal contamination, its ability to signal contamination events is not without challenges. Sampling frequency and location relative to the source of contamination are reported to affect the performance of generic E. coli as an indicator of fecal contamination (Ref. 107) (Ref. 119). Thus, non-detection cannot be considered absolute confirmation that fecal contamination has not occurred. Further, the persistence and transport of generic E. coli takes different paths in different watersheds, and reservoirs have been identified, particularly sediments, where E. coli may escape detection in the water column (Ref. 110) (Ref. 120) (Ref. 121) (Ref. 122). Nevertheless, based on our review of current literature, we conclude that generic E. coli serves as the most appropriate microbial indicator of fecal contamination of water at this time. We are not aware of any new scientific data or information, nor have the comments submitted any such data or information, to support a different conclusion. Therefore, we are finalizing our microbial quality criteria for

agricultural water in § 112.44(a) and (b) relying on generic E. coli as the indicator organism.

We acknowledge the difficulty of associating specific indicator concentrations with specific produce related health risks. Even so, we conclude that such difficulty does not negate the value of applying generic E. coli test results to the criteria in § 112.44(a) and (b) because elevated indicator organism concentrations indicate increased levels of fecal contamination and therefore elevated likelihood of the presence of human pathogens of fecal origin (Ref. 107) (Ref. 111).

(Comment 177) Some comments recommend that FDA should allow covered farms to develop alternative microbial water quality criteria to those in proposed § 112.44(c) using indicator organisms other than generic E. coli.

(Response) Sections 112.12(a) and 112.49(a) allow for the use of an alternative microbial water quality criterion (or criteria) based on an indicator of fecal contamination, in lieu of that established in § 112.44(b) (proposed as § 112.44(c)). A potential example of such an alternative microbial quality standard is the use of a different fecal indicator organism as a basis for a corresponding GM and STV that are demonstrated to detect measurable levels of fecal contamination in agricultural water used during growing of produce (other than sprouts) using a direct water application method with at least equivalent sensitivity to the criteria we established in § 112.44(b). Farms may establish such alternative microbial criterion (or criteria), provided that the farm has adequate scientific data or information to support a conclusion that the alternative criterion (or criteria) would provide the same level of public health protection as the criteria in § 112.44(b) and would not increase the likelihood that the covered produce will be adulterated.

3. Scope of “Agricultural water” and Applicability of Subpart E

(Comment 178) Several comments request clarification on whether the requirements in subpart E apply to water used during growing of various types of crops. For example, some comments ask whether subpart E applies to water used to irrigate root crops, such as onions and carrots, using drip irrigation. Some comments also ask us to clarify whether and how subpart E applies to water used during growing those commodities, such as tomatoes, cantaloupe, or cucumbers, where the produce may contact the ground or be in a splash zone versus those commodities, such as tree crops, that do not come in contact with the ground or irrigation water. One comment suggests produce grown using drip irrigation or otherwise not directly exposed to irrigation water should not be covered under subpart E.

(Response) Section E establishes requirements applicable to agricultural water. Whether or not water used during the growing, harvesting, packing, or holding of covered produce is subject to the requirements of subpart E depends on whether the specific use of the water fits within the definition of “agricultural water.” If a specific use of water does not fit within the definition of agricultural water, then the provisions of subpart E do not apply to that specific use of water. Because irrigation practices vary widely, we do not believe it is necessary or appropriate to categorize specific commodities or types of irrigation, generally, as being subject to or not subject to the requirements of subpart E. In addition, we note that subpart E applies to more than just water used during growing (e.g., irrigation water).

For purposes of this rule, we define agricultural water as water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities (including irrigation water applied

using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce). Related to this definition is our definition of “direct water application method,” which means agricultural water used in a manner whereby the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water (§ 112.3(c)).

Water that is intended to or likely to contact covered produce that is a root crop, including water used for drip irrigation of root crops, fits within the definition of “agricultural water” and the definition of “direct water application method.” For example, irrigating carrots using drip irrigation that is intended to filter through the soil and contact the carrots growing underground is agricultural water applied using a direct water application method because the water is intended to, and likely to, contact the covered produce. Similarly, water used to make a crop protection spray applied to tree fruit just before harvest is agricultural water applied using a direct water application method. However, irrigation water that is neither intended to nor likely to contact covered produce, such as water used for drip irrigation of tree crops that grow high above the ground and are not likely to touch the ground, is not “agricultural water” and, therefore, not subject to subpart E.

B. General Agricultural Water Quality Requirement (§ 112.41) and Corresponding Corrective

Measures (§ 112.45(a))

(Comment 179) A number of comments agree that agricultural water can be a source of contamination of produce and, therefore, support the proposed requirement that all agricultural water must be safe and of adequate sanitary quality for its intended use. Several comments

suggest modifying proposed § 112.41 to require that all water used in the production of covered produce, not just agricultural water as defined in the 2013 proposed rule, must be safe and of adequate sanitary quality for its intended use. These comments state that water outside the definition of agricultural water could still spread contamination through runoff or practices such as dust abatement in close proximity to covered produce.

(Response) Our QAR shows that water used in ways that are intended to, or likely to, contact covered produce or food-contact surfaces is more likely to contaminate produce than water that is not intended to, or not likely to, contact covered produce or food-contact surfaces. This rule, therefore, targets the hazards associated with water that is intended to, or likely to, contact covered produce or food-contact surfaces (“agricultural water” as defined in the rule). We are not expanding the scope of “agricultural water” (see section IX.B of this document) or the applicability of the requirement in § 112.41, to include water that is not intended to, or not likely to, contact covered produce or food-contact surfaces because we conclude it is not reasonably necessary to apply the requirements in this rule, or in § 112.41 in particular, to such water to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated.

We agree, however, that water that is not intended to or likely to contact covered produce or food-contact surfaces can still present a possibility of produce contamination, albeit with lower likelihood than that associated with agricultural water as defined in the rule. Therefore, the safe and appropriate use of all water that is used in growing, harvesting, packing, and holding of produce is important, including water that is outside of the scope of “agricultural water” and, therefore, not subject to the standards in this rule. Uses of such water that are outside the scope of “agricultural water” subject to the standards in this rule may

adulterate produce under section 402(a)(4) of the FD&C Act if, considering the water quality and the manner of its application, the use of the water causes produce to be prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Moreover, if a pathogen is detected in or on produce, such produce would be considered adulterated under section 402(a)(1) of the FD&C Act, in that it bears or contains a poisonous or deleterious substance which may render it injurious to health.

(Comment 180) Some commenters request clarification regarding the specific standard(s) that must be met to ensure agricultural water is safe and of adequate sanitary quality in compliance with proposed § 112.41. Comments also ask how the microbial quality criteria in proposed § 112.44 should be interpreted in relation to the requirement in proposed § 112.41.

(Response) As discussed in the 2013 proposed rule, the principle of “safe and of adequate sanitary quality for its intended use” contains elements related both to the attributes of the source water used and the activity, practice, or use of the water. The way in which water is used for different commodities and agricultural practices can affect the risk of contamination of the produce, for example, the use of overhead irrigation on lettuce versus drip irrigation of tree crops. Moreover, as discussed in the QAR, the timing of irrigation water application also plays a role in minimizing the persistence of contamination.

The requirements for agricultural water in subpart E of part 112 reflect our consideration of these issues. We are establishing a general requirement in § 112.41 that all agricultural water used in the growing, harvesting, packing, or holding of covered produce must be safe and of adequate sanitary quality for its intended use. We view this requirement as a general standard of water quality applicable to all covered activities that involve the use of

water where the water is intended to or likely to contact covered produce or food-contact surfaces. In addition to this general water quality requirement, we are establishing two separate microbial water quality criteria specifically to address the potential for fecal contamination and relying on generic E. coli as an indicator. These criteria apply to agricultural water when used for certain purposes: the microbial water quality requirement of zero detectable generic E. coli for agricultural water applies to those purposes specified in final § 112.44(a); and the microbial water quality criteria of certain GM and STV values of generic E. coli applies to agricultural water used during growing activities for covered produce (other than sprouts) using a direct water application method as stated in final § 112.44(b). Each of these microbial quality requirements has a different purpose, as discussed in the paragraphs that follow.

First, the microbial quality requirement of zero-detectable generic E. coli, in final § 112.44(a), for the purposes specified in that provision, is intended to address the known or reasonably foreseeable hazards associated with fecal contamination of agricultural water. In addition, it is targeted at uses of agricultural water where if pathogens or fecal contamination are present, it is reasonably likely they could be transferred directly to covered produce through direct or indirect (via food-contact surfaces) contact with the water. In this regard, we consider the agricultural water that does not meet the microbial quality requirement in final § 112.44(a) also does not meet the general requirement of safe and of adequate sanitary quality in final § 112.41. Therefore, in final § 112.45(a), we establish certain immediate corrective measures that you must take if you determine that your agricultural water does not meet the microbial quality requirement in § 112.44(a), which are the same corrective measures that are necessary when your agricultural water does not meet the general requirement in § 112.41.

We note, however, that agricultural water that meets the microbial water quality

criterion in § 112.44(a) may not necessarily be safe or of adequate sanitary quality for its intended use. Section 112.44(a) addresses the potential for agricultural water to be a source of fecal contamination, and we have concluded that, at this time, generic E. coli is the preferred indicator of fecal contamination. Nevertheless, we acknowledge that generic E. coli has limitations as an indicator organism and, therefore, non-detection of generic E. coli cannot be considered absolute confirmation that fecal contamination has not occurred. However, generic E. coli has been shown using various detection methods to be the coliform most consistently associated with fecal contamination. See discussion in the 2013 proposed rule (78 FR 3504 at 3562). Therefore, although a test result indicating the agricultural water does not meet the applicable microbial water quality requirement in § 112.44(a) demonstrates that the water is not safe or of adequate sanitary quality for those specified uses, the converse is not necessarily true. That is, agricultural water that meets § 112.44(a) may not be safe or of adequate sanitary quality, for example, due to the presence of pathogenic organisms.

Second, the microbial quality criteria of specified levels of GM and STV values of generic E. coli, in § 112.44(b), for agricultural water used in a direct application method during growing of produce (other than sprouts), like § 112.44(a), are intended to address the known or reasonably foreseeable hazards associated with fecal contamination of agricultural water. However, we view this provision as a water management tool for use in understanding the microbial quality of your water over time, and determining how to appropriately use water from that source, rather than as a direct indicator of the safety or adequacy of the sanitary quality of water for its immediate purposes. Consistent with our intent for § 112.44(b) to support your long-term strategy for use of water sources, under final § 112.45(b), if your water does not meet the microbial quality criteria in § 112.44(b), we require you to take certain

corrective measures as soon as practicable, and no later than the following year. Those corrective measures provide additional means by which to achieve the microbial quality criteria, allowing you to continue to use agricultural water that does not initially satisfy those criteria but that satisfies the criteria after accounting for microbial die-off. Moreover, our corresponding testing scheme (§ 112.46(b)) similarly facilitates a long-term strategy to help covered farms to understand the quality of their water sources and plan the use of water from those sources accordingly, per § 112.45(b).

The stringency of the applicable microbial quality criteria (and related flexibility) varies between § 112.44(a) and (b), reflecting the likelihood of microbial contamination of covered produce from agricultural water when used for the respective specified purposes. In both cases, however, meeting the microbial quality criteria in § 112.44 ((a) or (b)) does not automatically ensure that the requirement in § 112.41 is satisfied. See also examples discussed under Comment 246.

(Comment 181) Several comments state that many farms effectively have only a single source of water that can be used to irrigate their crops and that this is often a surface water source with the only alternate source of water potentially requiring the construction of a new ground water well. Some comments also note that, for many farms, constructing a new well is often geologically or economically not feasible and that this is a significant problem if the current water source is not safe and of adequate sanitary quality for its intended use as required by proposed § 112.41.

(Response) Under final § 112.45, we are providing for different options that a covered farm can consider when agricultural water is found to be not safe or of adequate sanitary

quality for its intended use (including when water does not meet the microbial quality criterion in § 112.44(a)) (see § 112.45(a)) or when agricultural water does not meet the microbial quality criteria in § 112.44(b) (see § 112.45(b)).

Under § 112.45(a), a covered farm can re-inspect the entire affected agricultural water system to the extent it is under the farm's control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and take adequate steps to determine if the changes were effective, and, as applicable, adequately ensure that the agricultural water meets the microbial quality criteria in § 112.44(a). The covered farm may also treat the water in accordance with the requirements in § 112.43. Depending on the circumstances, the farm may be able to use the water for a different purpose, as appropriate (for example, agricultural water that does not satisfy the more stringent microbial quality criterion in § 112.44(a) may be appropriate for use as irrigation water for produce (other than sprouts) if it meets the criteria in § 112.44(b)). See examples under Comment 246.

Under § 112.45(b), specifically in relation to irrigation water and other water directly applied to covered produce other than sprouts during growing, we have incorporated flexibility by providing additional means to achieve the microbial quality criteria. A covered farm may apply a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day, but not more than four consecutive days (§ 112.45(b)(1)(i)); and/or apply a time interval (in days) using an appropriate microbial die-off rate between harvest and end of storage and/or appropriate microbial removal rates during activities such as commercial washing, provided the farm has adequate supporting scientific data and information for the microbial die-off and/or removal rates (§ 112.45(b)(1)(ii)). We also provide for the use of an

alternative microbial die-off rate between last irrigation and harvest and an accompanying maximum time interval, in new § 112.49(b). We expect covered farms will be able to consider and implement these options, as appropriate. In particular, we expect the increased flexibility provided in § 112.45(b)(1) to reduce the likelihood that a covered farm will need to alter the source of its irrigation water. In addition, when water subject to the § 112.44(b) standard does not meet that standard, a farm may re-inspect the entire affected agricultural water system to the extent it is under the farm's control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and adequately ensure that your agricultural water meets the microbial quality criteria (§ 112.45(b)(2)). It would also be an option for the farm to treat agricultural water in accordance with § 112.43 (§ 112.45(b)(3)). See examples discussed under Comment 246.

We note, however, that there will likely be some situations in which a farm's water source is unsafe and/or of inadequate sanitary quality for a particular use, or where it cannot and does not meet the microbial quality criteria in § 112.44(b), such that it may not be used for that specific purpose in compliance with this rule unless it is treated in accordance with § 112.43. Violation of this rule is a prohibited act that may subject a farm to enforcement or other appropriate action (see § 112.192).

(Comment 182) Some comments ask for clarification on whether recycled, reclaimed, or gray water may be used during growing of covered produce.

(Response) The requirements for agricultural water quality established in §§ 112.41 and

112.44, apply regardless of the source or type of water that you use as agricultural water, except that untreated surface water is not permitted for uses identified in § 112.44(a). You must determine the appropriate use of agricultural water in light of the conditions and practices on your farm, and taking into account the general safe and of adequate sanitary quality standard in § 112.41 as well as any specific microbial quality criteria relevant to your intended use(s) of that agricultural water in § 112.44. See also Comment 222. We will consider providing guidance on the use of various types of water, including recycled, reclaimed, and gray water, in the future.

C. Agricultural Water Sources, Water Distribution Systems, and Pooling of Water (§ 112.42)

(Comment 183) Several comments express concern regarding the identification of conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces in proposed § 112.42(a). These comments state that it is unclear what specifically should be considered to be reasonably foreseeable hazards in making such a determination.

(Response) In § 112.3, we define “known or reasonably foreseeable hazard” to mean a biological hazard that is known to be, or has the potential to be, associated with the farm or the food. We are establishing a definition for this term as this term is used in section 419(c)(1)(A) of the FD&C Act and reflected in several requirements in part 112. Under final § 112.42(a), you are required to inspect all of your agricultural water systems to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces in light of your covered produce,

practices, and conditions. The specific known or potential hazards that may be associated with your farm and food, in relation to your agricultural water, will likely vary dependent on your specific agricultural water source(s), water distribution system(s), practices on your farm, and your covered produce. Section 112.42(a) requires you to identify and characterize those activities and situations that may lead to contamination of your agricultural water with pathogens. Some examples of such activities and situations are described in the 2013 proposed rule (see 78 FR 3504 at 3565). For example, we noted that ground water could be compromised and its water quality degraded if wells are improperly constructed, poorly maintained, or improperly located (e.g., near areas of extensive livestock production). As another example, we noted that if you use water from a river and are downstream from a waste water treatment plant that discharges into that river, this provision would require you to consider the likelihood that the wastewater treatment plant introduces hazards into the water before it reaches your farm, such as the likelihood of accidental discharge of untreated municipal sewage into the river. We will consider providing guidance on the identification of conditions that are reasonably likely to introduce known or reasonably foreseeable hazards in the produce safety regulation implementation guidance to be issued in the near future.

(Comment 184) Several comments express concern about the identification of conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces when the source of the hazards is out of their control. A comment, agreeing with the proposed requirement in § 112.42(a), states that farms should not shoulder the burden of ensuring the quality of agricultural water when the source of water contamination is off-farm. Several comments state that a farm cannot assess the presence of

hazards before the water reaches the farm and external water sources (e.g., a canal) are neither under control of the farm nor subject to decisions that are within the farm's control.

(Response) As discussed in the 2013 proposed rule, inspection of your water source(s) provides an opportunity to identify and characterize activities and situations that may lead to contamination of your agricultural water with pathogens. Inspection results (and initial survey results, when required under § 112.46(b)) provide you with historical knowledge of your water sources, their quality, and factors that may affect their quality. Inspection of the water sources and any equipment used to obtain the water from the source (e.g., well head, pumps, pipes) can ensure that the portions of the agricultural water system(s) that are under your control are not likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces. We recognize that not all aspects of a water source or system may be under your control and, therefore, under § 112.42(a)(2), we are requiring you to consider the extent to which you have control over your agricultural water source(s) to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces. For example, you may have more control over a ground water source such as a small spring if the expanse of the spring is under your control and you are able to protect the spring from the influence of surface activities. You may have greater access to and control of on-farm surface water sources such as impoundments, catches, and ponds, than you would for flowing surface waters that only course through but do not originate on your land. Similarly, under § 112.42(a)(4), we are requiring you to consider the use of adjacent and nearby land. While you may have little or no control of other agricultural water user practices, this requirement to consider those nearby uses of which you are aware will help you determine appropriate and safe use of your water source(s). Under § 112.42(a)(5),

we are requiring you to consider the likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your farm. This, too, is something over which you may have little or no control. Considering factors such as these, which may affect the quality of your water source(s) even though they are not necessarily under your control, is an important part of evaluating whether your water source(s) meets the requirement in § 112.41 that your agricultural water must be safe and of adequate sanitary quality for its intended use.

We are also revising § 112.42(c) to clarify that adequate maintenance of your agricultural water sources includes regularly inspecting each source to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces; and correcting any significant deficiencies (e.g., repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections), in addition to keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.

(Comment 185) One comment recommends that farm operators should be allowed to design a water sampling program for their operations based on the level of control over the water source and the manner in which water is used. Acknowledging that proposed § 112.42 requires every covered farm operator to conduct an inspection of their water systems to evaluate the associated risk of microbial contamination, the comment proposes that farm operators should then be allowed to use information from their inspection to tailor operation-specific sampling frequencies and start-stop acceptance criteria based on the capacity of their system.

(Response) In the supplemental notice, which we issued subsequent to the submission of these comments, we proposed to provide tiered approaches for specific water testing frequency requirements to test untreated surface water as well as untreated ground water, which would entail testing at a reduced frequency than that proposed in the 2013 proposed rule. Under these tiered approaches to testing, we are establishing a sampling design that incorporates flexibility for covered farms to adjust the frequency and timing of sampling and number of samples beyond the minimum necessary parameters, based on the farm's operations. In light of comments in response to the supplemental notice, some of which similarly request additional flexibility to tailor water testing frequency based on operations on the farm, we are providing, in new § 112.49(c) and (d), for the use of an alternative testing frequency for untreated surface water sources (in lieu of those required in § 112.46(b)(1)(i)(A) or § 112.46(b)(2)(i)(A)), under the conditions specified in § 112.12.

(Comment 186) We received several comments that request clarification on the phrase in § 112.42(a), "the entire agricultural water system under your control." The requests for clarification include questions regarding how far upstream farms are responsible for monitoring for potential sources of contamination and whether the responsibility stops at the farm's property line or extends to properties beyond the farm's control. Comments also state that many water systems are vast and incredibly complex, and the 2013 proposed rule does not adequately or realistically account for such complexity.

(Response) The agricultural water systems referred to in § 112.42(a) include the water source(s), water distribution system(s), facilities, and equipment. (See also Comment 192 regarding multiple water sources and water systems.) Recognizing the diversity in water

sources and the extent to which you can protect the water source or its distribution system, we incorporated into § 112.42(a) a list of factors that must be considered during an inspection of your agricultural water system(s). The identification of potential hazards related to agricultural water systems must consider the nature of each agricultural water source (for example, ground water or surface water), the extent of the farm's control over each agricultural water source, the degree of protection of each agricultural water source, the use of adjacent and nearby land, and the likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm. We understand that water systems can be complex, and we are not requiring covered farms to inspect portions of an agricultural water system that are beyond their control. However, the extent to which you control your agricultural water source(s), and certain factors over which you may have little or no control will likely influence the identification or characterization of potential hazards associated with your agricultural water system(s), and evaluating these factors as part of your inspection under § 112.42(a) will help you determine the appropriate and safe use of the agricultural water from your water source(s). To make our intent clear, we are revising "under your control" in § 112.42(a) to read "to the extent they are under your control," and making similar changes in descriptions of maintenance requirements for water distribution systems and water sources in §§ 112.42(b) and (c). See also the discussion under Comment 184.

(Comment 187) Several comments request clarification of the timing of inspection, particularly in circumstances where crops are grown throughout the year (such as almonds) or where covered farms have multiple or year-round growing seasons. To account for such

circumstances, some comments suggest that the phrase “at the beginning of the growing season” in § 112.42(a) should be replaced with “as applicable or at least annually.”

(Response) We recognize that many crops have year-round growing seasons and also that covered farms may have operations or multiple crops with year-round or staggered growing seasons throughout the year. In light of these comments, and to make our intent clear, we are revising § 112.42(a) to require inspection of agricultural water systems “at the beginning of a growing season, as appropriate, but at least once annually.” Thus, for example, a farm that has multiple crops that have different growing seasons is only required to inspect once annually, at the beginning of one of the growing seasons. As another example, a farm that has a single crop with a continual, year-round growing season is also required to inspect at least once annually, and such a farm may consider an appropriate time to be the beginning of the growing season. We have incorporated flexibility in this requirement to allow farms to independently determine the appropriate timing and number of inspections that are necessary to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces in light of the covered produce, practices, and conditions and based on the knowledge of the water system, its inherent variability, and the vulnerability of their water source to contamination.

(Comment 188) A comment suggests that the language of § 112.42(a)(4) should be limited to adjacent land, and not include “nearby land” because “adjacent” is not the same as “nearby”.

(Response) We agree that “adjacent” and “nearby” have different meanings, and we intend to require you to consider both adjacent land and nearby land uses in identifying and

characterizing the potential hazards affecting your agricultural water system. By “adjacent” land we are referring to land sharing a common border with the farm’s land. By “nearby” land we are referring to a broader category of land, including land that does not adjoin the farm’s land but has the potential to affect the farm’s water source(s) based on the land’s location. For example, agricultural water may be affected by upstream agricultural practices and runoff from those operations into surface water sources that are used as agricultural water even if the upstream operations’ lands are not adjacent to your farm’s land. While you may have little or no control of other agricultural water users’ practices, this requirement to consider those adjacent and nearby land uses of which you are aware will help you determine the appropriate and safe use of that water source. We are revising this provision to read “use of adjacent and nearby land” to make clear that both adjacent and nearby land uses are included.

(Comment 189) Several comments request clarification on whether, if there is a reason to believe that a farm’s agricultural water is not safe and of adequate sanitary quality for its intended use, the farm is required to take measures specified in proposed § 112.42(d)(1) or proposed § 112.42(d)(2), and whether or not the farm is required to follow proposed § 112.42(d)(2) if the requirements in proposed § 112.42(d)(1) are met. In addition, one comment focusing on proposed § 112.42(d) states that although it may be feasible and reasonable to discontinue the use of water used in postharvest activities when there are doubts about the sanitary quality of water that is being used, immediately discontinuing the use of water used in irrigation is not a feasible option for the health or maintenance of the crop. This commenter also suggests specific thresholds or “action levels” that could be identified for water used during postharvest and growing activities.

(Response) See our response to Comment 181 and Table 11. We have now consolidated proposed § 112.42(d) and proposed § 112.44(b) into final § 112.45(a), which establishes the corrective measures that must be taken, and the required timing, when agricultural water does not meet the general requirement in § 112.41 and/or when it does not meet the microbial quality requirement in § 112.44(a) for those specified purposes. In addition, in final § 112.45(b), we specify the corrective measures that must be taken, and the required timing, when agricultural water does not meet the microbial quality criteria in § 112.44(b) for the specified purpose.

Specifically, § 112.44(a) establishes the microbial quality requirement for certain specified uses of agricultural water. Water used for washing hands during and after harvest, sprout irrigation, directly contacting covered produce during or after harvest (such as in washing and cooling, or to make ice that directly contacts covered produce), and water or ice that will contact food-contact surfaces that contact covered produce presents a greater likelihood of microbial contamination of covered produce and, therefore, we are applying a more stringent standard for water quality without options to account for die-off or other microbial reduction for these intended uses. For these specified uses, we are retaining the requirement, in final § 112.45(a), for you to immediately discontinue the use of the water that does not meet the applicable microbial quality requirement until you take the necessary required measures in § 112.45(a)(1) or (a)(2).

In addition, with respect to the microbial quality criteria in § 112.44(b) for agricultural water used during growing for covered produce other than sprouts using a direct water application method, we are retaining our proposed flexible options in the final provisions §§ 112.45(b)(1) and 112.49, making it less likely that a farm will have to discontinue use of the

water used for these purposes due to small fluctuations in water quality. In addition, under § 112.45(b)(2) and (3), farms also have similar options to those in § 112.45(a). Moreover, under § 112.45(b), these corrective actions are not required to be taken immediately. They are required to be taken as soon as practicable, and no later than the following year. See examples discussed under Comment 246.

With respect to thresholds suggested by one commenter, we have also made revisions to the water testing requirements that eliminate the need to re-characterize the water quality profile for § 112.44(b) uses in response to specific annual survey results that are over a particular “threshold” (final § 112.46(b)). This structure was a limitation to our proposed tiered-approach that we acknowledged in the supplemental notice (79 FR 58434 at 58453), which we believe is now adequately addressed under our revised final testing scheme. See also Comment 244.

(Comment 190) Some comments, referring to proposed § 112.42(e), note that water pooling in produce fields occurs often and it would be impractical to expect that all pooling water can or should be eliminated. Some commenters also believe it is unclear how pooled water increases the likelihood of produce microbial contamination, particularly if agricultural water and soil amendments with only a rare probability of containing human pathogens (in accordance with proposed requirements) are used. Another comment states that there should be a length of time identified for how long water can stand before it is considered a potential hazard. This commenter states that seasonal flooding causing water to pool and drain naturally should not be considered the same as overflow from a polluted source of water.

(Response) As noted in the 2013 proposed rule, we acknowledge the potential for small pools of water to temporarily form in field areas or at the base of plants after irrigation. Small amounts of water of this nature are temporary and occur in the normal course of irrigation practices. We are not suggesting that it will always be possible to eliminate pooling. However, pooled water that remains for extended periods of time can be a source of contamination (Ref. 14) (Ref. 40) and pooled water in close proximity to the crop may serve as an attractant for pests and other animals, which may in turn introduce hazards into the pooled water that may contaminate produce. Therefore, we are retaining this proposed requirement with some revisions. In final § 112.42(d), we clarify our intent to reduce the potential for contamination as a result of contact of covered produce with pooled water. After the phrase “reduce the potential for contamination...” we have replaced “as a result of pooling of water” with the phrase “as a result of contact of covered produce with pooled water.” However, we believe additional specificity in this requirement beyond this revision, such as establishing a maximum acceptable length of time for standing of pooled water, is unnecessary and would not provide sufficient flexibility for covered farms to implement measures as necessary and appropriate.

(Comment 191) Regarding proposed § 112.42(c), one comment suggests adding the phrase “under your control” to the first sentence as a qualifier applied to “agricultural water distribution systems.”

(Response) We agree with this recommendation, and are revising final § 112.42(c) to refer to agricultural water distribution systems to the extent they are under your control.

(Comment 192) One comment states that agricultural water entering the produce production areas may be serviced by more than one “water system” that is in turn fed by one or more water sources. The commenter recommends that inspections should be conducted at each water source and re-inspections under proposed §§ 112.42(d)(1) and 112.44(b) and (c) should be limited to locations serviced by the source where the problem was identified. The commenter suggests clarifying the codified text to read “the water system under your control that is serviced by that source.”

(Response) We consider each agricultural water source in your operation to be from a discrete body of water (e.g., a canal, a pond, a river) that represents the microbial quality of agricultural water as it is used in your growing, harvesting, packing, or holding activities. Where this rule establishes a testing requirement for a water source, that requirement applies to each discrete source of water used for the relevant purpose, regardless of whether the water is used for multiple commodities, or applied over non-contiguous fields. The annual agricultural water system inspection required under § 112.42(a) includes each discrete water source if a farm has more than one water source, and must also include all relevant water distribution systems, facilities, and equipment. We are revising § 112.42(a) to reflect this by clarifying that you must inspect “all of your agricultural water systems, to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment).”

When a re-inspection is conducted to satisfy § 112.45(a)(1) or (b)(2) after identification of a problem with agricultural water, such re-inspection can be limited to the affected agricultural water system with which a problem was identified, but the entirety of the affected system must be re-inspected to enable potential problems to be identified. We are revising § 112.45(a)(1) and (b)(2) to specify that such requirements apply to the “entire affected

agricultural water system,” which includes the relevant water source(s), water distribution system(s), facilities, and equipment. For a discussion on identifying a “source,” see our response to Comment 237.

(Comment 193) Referring to proposed § 112.42(d)(1), which requires covered farms to take certain steps “when you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use,” a commenter asserts that this provision leaves the decision to test or not to test agricultural water up to farms – and that such decision is dependent upon knowing or having reason to believe that water is not safe or of adequate sanitary quality for its intended use.

(Response) We disagree with the interpretation offered by this commenter, which appears to be based on proposed § 112.42(d)(1) alone, disregarding other applicable provisions in subpart E of part 112. Other provisions in subpart E establish the minimum science-based microbial quality standards for agricultural water for specified intended uses and for testing agricultural water (including minimum sampling requirements) to ensure its safe and appropriate use (§§ 112.44, 112.45, and 112.46). See the discussion in section XIII.G of this document.

D. Treatment of Agricultural Water (§ 112.43)

(Comment 194) Several comments express concerns about the potential adverse environmental impacts that could occur as a result of implementation of the water treatment provisions in proposed § 112.43. For example, one comment states that widespread use of antimicrobial pesticides on ground water and surface water sources by farms across the country

would have a detrimental effect on the environment, water quality, and human health. Citing the potential for environmental contamination and destruction to soil health, some comments also recommend that FDA should not encourage chemical treatment of irrigation water. Some comments also worry that proposed § 112.43 would encourage the use of pesticides to treat agricultural water because treating water may be the most viable option for some farms, particularly when they are limited to a single water source. One comment maintains that it is unlikely that any untreated surface water would meet the proposed microbial standards and that, as a result, farmers would be forced to either treat their water or find a different water source. Another commenter states that some farms may use unorthodox approaches to treating water, such as pouring bleach into a pond, which could result in environmental problems. Yet another comment recommends that FDA provide an option to develop practices, such as an interval between irrigation and harvest, to reduce the potential for antimicrobial treatment of irrigation water. Another comment asserts that packing shed discharge may create significant impacts on downstream water quality. In addition, some comments support § 112.43(a), as proposed, and affirm that treatment of water should be an option available to farms who believe their water is contaminated, based upon their experience and risk assessment. In contrast, other comments state that the use of chemical sanitizers to treat irrigation water should not be allowed, encouraged, or required.

(Response) Certain methods of treating water and wastewater are effective means of achieving microbial reduction (Ref. 123). However, water treatments that are inadequate or improperly applied, interrupted, or intermittent have been associated with waterborne disease outbreaks (Ref. 124). Failures in treatment systems are largely attributed to suboptimal particle removal and treatment malfunction (Ref. 125). For this reason, when treating water, it is

important to monitor the treatment parameters to ensure the treatment is delivered in an effective manner. Therefore, we are retaining the provisions for treatment of water in § 112.43, with some revisions as explained here.

In § 112.45, we are providing for different options that a covered farm can consider when agricultural water is found to be not safe or of adequate sanitary quality for its intended use and/or to not meet the relevant microbial quality criteria in § 112.44(a) or (b), and treatment is only one of those options. In Comment 181 and Comment 189, we discuss the flexible options provided in final §§ 112.45(a) and (b) and 112.49, and we anticipate that covered farms will consider and implement these options, as appropriate, prior to or in conjunction with considering whether to treat water to ensure that it meets the applicable requirements for its intended use. As such, the produce safety regulation does not require covered farms to consider treating agricultural water as an immediate first step where the water is not safe or of adequate sanitary quality for its intended use. Rather, covered farms have a range of viable options to consider based on practices and conditions specific to the farm, treatment of water being only one such option. Indeed, we believe some of these other options are likely to be more feasible than the option to treat water. Moreover, covered farms will have two additional years (beyond the date of compliance for the remainder of this rule) to comply with many of the water provisions of this rule for covered activities involving covered produce (except sprouts), which is intended to help farms to consider and implement measures that are most appropriate for their operations. See our discussion of compliance dates in section XIII.K of this document.

We acknowledge that proposed § 112.43 might have been read to suggest that the treatment of water is always a required measure to ensure the safety of water for its intended

use. We did not intend such a meaning. In light of comments we received, and to make our intent clear, we are revising the question and paragraph (a) in final § 112.43 to read as follows: “§ 112.43 What requirements apply to treating agricultural water? (a) When agricultural water is treated in accordance with § 112.45 of this part:” In addition, in final §§ 112.43(a)(1), 112.43(a)(2), and 112.43(b), we are revising the purpose of treating water to acknowledge that treatment is an option that a farm may use either to meet the general requirement in § 112.41 and/or to satisfy the microbial quality criteria in §§ 112.44(a) and/or (b).

We recognize that improper use, management, or disposal associated with chemical treatment of agricultural water can create adverse environmental impacts. Subsequent to publishing the 2013 proposed rule, FDA determined that the proposed produce safety rule may significantly affect the quality of the human environment (21 CFR 25.22(b)), and, therefore, an EIS is necessary for the final rule. In accordance with the National Environmental Policy Act (NEPA) and its implementing FDA regulations, we have evaluated the potential effects of the produce safety regulation on the human environment in the United States. Our evaluation and conclusions based on that evaluation are described in the final EIS (Ref. 126). We refer you to that document for a detailed discussion of the potential environmental effects of the produce safety regulation, including those associated with the standards for agricultural water in subpart E of part 112. This analysis includes potential impacts related to pesticide use, chemical treatment of agricultural water, changes in ground water demand, and existing water quality standards.

With respect to environmental concerns related to chemical treatment of agricultural water, we note that environmental and health-related risk assessments of pesticide products are conducted by EPA prior to their registration and use. The FIFRA provides for federal

regulation of pesticide distribution, sale, and use. All pesticides distributed or sold in the United States must be registered (licensed) by EPA. For more information, see <http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide#laws> (Ref. 127). The EPA receives and examines large amounts of test data from producers of pesticides demonstrating that their products, if used, will not harm the environment or human health. These data are reviewed by EPA during their determination of whether to issue a registration for a pesticide product and/or a specific use of that product (Ref. 52).

(Comment 195) Several comments discuss the potential use of chlorine, in particular, to treat agricultural water to meet the proposed water quality standards. Noting that chlorine is likely to be used to disinfect agricultural water because it is inexpensive and readily available, these comments express various concerns, including that: chlorine products pose a hazard to farmworker health and safety; chlorine products can cause corrosive damage to stainless steel and aluminum farm equipment; many crops and plants experience chlorine damage, such as salt injury to fruit trees; applying large volumes of chlorinated surface irrigation water on agricultural lands could result in the formation of trihalomethanes; chlorine interacts with many crop protection chemicals, potentially resulting in crop damage and reduced efficacy; and water treated with chlorine can infiltrate soil, run off into surface waters, and contaminate ground water, with potentially toxic effects to soil microbes and aquatic organisms. Another comment questions the ability of chlorine to kill pathogenic bacteria, and states that its use to treat water can increase costs and contaminate the environment, without concurrent benefit. Yet another comment suggests that chlorine treatment of water is logistically challenging for orchardists, in

particular, due to the volume of water needed for irrigation and cooling within orchards. Several comments also suggest that FDA recommend that the residual effluent of any use of chlorine should be limited to 4 ppm, consistent with the organic certification and Safe Drinking Water Act standards.

(Response) As noted in response to Comment 194, the produce safety regulation does not require covered farms to consider treating agricultural water as an immediate first step where the water does not meet the applicable requirement for its intended use. Rather, covered farms have a range of viable options to consider based on practices and conditions specific to the farm, treatment of water being only one such option. When a covered farm does choose to treat water, we are providing for the treatment of water using any effective treatment method (such as physical treatment, including using a pesticide device as defined by EPA; EPA-registered antimicrobial pesticide product; or other suitable method).

FDA has analyzed the potential environmental impacts of the agricultural water standard in Chapter 4.2 of the EIS. As part of the analysis, FDA has determined that presently, there is no EPA-approved chemical treatment for contaminated water used to irrigate cropland (Ref. 128). FDA does not have specific information on the pesticides that might be submitted to EPA for registration for uses to control specific target organisms, such as pathogens, specifically in agricultural water applied to produce. However, as described in greater detail in Chapter 3.1 and 4.2 of the EIS, we agree that the most commonly used antimicrobials for microbial population reduction are chlorine chemicals, specifically sodium hypochlorite, calcium hypochlorite, gaseous chlorine and chlorine dioxide. It is anticipated that chlorine compounds would be among the preferred chemicals for which industry would be likely to seek FIFRA registration. FDA has considered the potential impacts of this rule on the environment

and worker health as part of the EIS (Ref. 126). With respect to environmental concerns related to chemical treatment of agricultural water, we note that environmental and health-related risk assessments of pesticide products are conducted by EPA prior to their registration and use (see Comment 194).

Should a covered farm choose to treat their agricultural water to ensure it meets the applicable requirements for its intended use, we expect any treatment that is used would be applied in accordance with all applicable federal, State, tribal, and local regulations.

(Comment 196) Several comments discuss EPA's registration requirements related to pesticide use. Acknowledging our statement in the 2013 proposed rule that no EPA registrations currently exist under FIFRA for chemicals used in the treatment of irrigation water, comments express concern about the current lack of available EPA-approved antimicrobial treatments for irrigation water and the purported lack of an available EPA process by which such chemicals could be approved. Such comments state diverse concerns, including that: providing treatment of irrigation water as an alternative under the produce safety regulation may not be a viable option; the absence of available treatment methods may jeopardize the use of some agricultural water sources and could force some farms to stop irrigating crops and to suffer economic hardship; treating irrigation water without available registered options is illegal, in that the use of unapproved substances would violate both State and federal pesticide-use regulations; and, due to the lack of approved treatments, farms may treat water with unapproved methods that could lead to environmental and public health concerns. Another commenter recommends eliminating proposed § 112.43(a) because no approved treatment products for this use currently exist.

Similarly, another commenter recommends that the water treatment provisions should not be implemented until a registry of approved water disinfection agents exists.

Several comments also request that FDA work with EPA and other relevant agencies to provide clear direction to industry regarding acceptable and available water treatment options. One commenter believes that reliance on a process that is regulated by another government agency may create uncertainty for farms. This commenter recommends that FDA collaborate with EPA to: 1) Identify and make information available about currently-registered compounds and 2) establish a priority review process to ensure that farms have effective options available for the treatment of irrigation water prior to the compliance dates for the water requirements. One comment requests clarification on the approval that would be required to use an existing microbial pesticide to meet the requirement in § 112.43.

Other comments state that EPA-approved products for treating irrigation water are currently available. For example, one comment reports that the National Pesticide Information Retrieval System (NPIRS) database shows that nearly 90 federally-registered disinfectant products are available for uses in fruit or vegetable wash water or processing water, and that other products are labeled for use in treatment of agricultural and irrigation water systems, including drip irrigation systems. Another comment provides an example of a treatment, asserting that it is registered with EPA for use in all types of irrigation water systems, including in USDA-inspected fruit and vegetable wash water operations.

(Response) We are retaining § 112.43 with some modifications, as explained under Comment 194. This provision applies to agricultural water (as defined in § 112.3) that is used in growing, harvesting, packing, and holding activities related to covered produce. We consulted with EPA on currently available options for treating agricultural water in a manner

consistent with § 112.43.

At this time, no EPA registrations exist for chemical substances (classified by EPA as “pesticide products”) for antimicrobial treatment of agricultural water used during the growing of crops (Ref. 128). However, as discussed in Chapter 4.2 of the EIS, EPA maintains a list of “Antimicrobial Products Registered with the EPA as Sterilizers.” Each of these products received approval under FIFRA as amended in 1996 (40 CFR parts 152, 156, and 158). Like all registered pesticide products, registrations for antimicrobial products are specific to the use that was considered as part of the registration process, and thus the products may be legally used for the specified registered use only. Among compounds on the list of EPA’s registered antimicrobial products as sterilizers are certain registered antimicrobial washes, which are authorized for use during postharvest fruit and vegetable washing. These products can be used to treat agricultural water that is used to wash produce postharvest, such as in packing houses. However, because these antimicrobial products are not authorized by EPA for use on agricultural fields, they cannot be used to treat irrigation water that is applied prior to harvest. Also on this list are certain registered antimicrobial products for use in the treatment of irrigation water systems or irrigation ponds to control bacterial and algae growth. However, because these antimicrobial products are not authorized by EPA for use to control human pathogens or indicator organisms, they cannot be used to treat irrigation water to comply with the microbial quality criteria in § 112.44(b).

We anticipate that the delayed compliance dates for certain water quality provisions in this rule (see our discussion of compliance dates in section XIII.K of this document) provide adequate time to address the current lack of EPA-registered chemical treatments for agricultural water used in growing activities. We will work with EPA, as appropriate, regarding

registration of pesticide products for treatment of agricultural water during growing. In response to comments requesting priority review for registration of irrigation water chemicals, we note that EPA has statutory timelines under which it must consider registration applications (i.e., 15 to 21 months for a “new food use” of a compound). Information about EPA’s pesticide registration process is available on its website at <http://www2.epa.gov/pesticides> (Ref. 129), and is also explained in chapters 3.8 and 4.2 of the EIS.

Section 112.43 also allows for non-chemical suitable methods for treatment of agricultural water. Unlike pesticide products, pest control devices that work by physical means and are classified by EPA as “pesticide devices” do not require registration by EPA under FIFRA. According to EPA, FIFRA defines a device as any instrument or contrivance (other than a firearm) that is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom (Ref. 130). (Note that “pesticide devices” do not include medical devices, which are regulated by FDA.) Although not required to be registered, pesticide devices are regulated by EPA in that false or misleading claims cannot be made about the effectiveness of the device. Physical treatment of agricultural water, including using a pesticide device(s), or by any other suitable treatment method can be employed provided the method is effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in § 112.44, as applicable. In addition, the treatment must be delivered and monitored in a manner and with a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in §

112.44, as applicable, as required under final § 112.43(a)(2) and (b). Examples of pesticide devices used to treat water include filter units, ultraviolet light units, and ozonator units. Information about EPA's regulation of pesticide devices is available on its website (Ref. 130), and we advise you to consult EPA for information about appropriate use of pesticide devices. Note also that some States require registration of pesticide devices, and we refer you to the appropriate State pesticide regulatory agency for more information on a particular State's requirements related to pest control devices (Ref. 131). Information about EPA's Tribal Pesticide Programs is available on EPA's website at: <http://www2.epa.gov/pesticide-advisory-committees-and-regulatory-partners/tribal-pesticide-programs> (Ref. 132). In addition, information regarding current EPA-registered pesticide products is available on EPA's website at: <http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1> (Ref. 133).

With respect to environmental concerns related to chemical treatment of agricultural water, we note that environmental and health-related risk assessments of pesticide products are conducted by EPA prior to their registration and use (see Comment 194).

(Comment 197) One comment expresses concern that adding an antimicrobial treatment to irrigation water would be considered a point source discharge of a pollutant, requiring farms to obtain a National Pollution Discharge Elimination System (NPDES) permit, and that implementation of agricultural water treatment in compliance with § 112.43 would expose farms to liability under the Clean Water Act (CWA), including a potential citizen suit. The commenter also maintains that requiring farms to treat surface irrigation water with antimicrobial pesticides could subject farms to liability under the ESA or potential increased scrutiny regarding their effects on anadromous (i.e., ascending rivers from the sea for breeding) species. The commenter

notes that the 2013 proposed rule did not indicate whether FDA would conduct ESA consultation, and recommends that we outline our intentions with respect to ESA compliance and the potential impact of implementation of the produce safety regulation.

(Response) We have evaluated the potential effects of the produce safety regulation on the human environment in the United States. Our evaluation and conclusions based on that evaluation are described in the final EIS (Ref. 126). We refer you to that document for a detailed discussion of the potential environmental effects of the produce safety regulation, including those associated with the standards for agricultural water in subpart E of part 112. With respect to the CWA, only a portion of agricultural facilities are considered point source dischargers that would require NPDES permits. This form of regulatory oversight is discussed in Chapter 3.1.2 of the EIS. The provisions of the produce safety regulation do not authorize covered farms to violate existing laws and regulations, including the CWA. This rule also does not affect the status of any farm that is currently subject to NPDES permits.

We also considered the effects of the produce safety regulation on threatened and endangered species. In the supplemental notice, we proposed a new provision § 112.84 that explicitly states that part 112 does not authorize or require covered farms to take actions that would constitute the “taking” of threatened or endangered species in violation of the ESA, or require covered farms to take measures to exclude animals from outdoor growing areas, or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. We are finalizing this provision, as proposed. FDA has concluded informal consultation with FWS under the ESA. We have also been involved in conversations with National Marine Fisheries Service regarding our ESA obligations. See (Ref. 134) (Ref. 135) for additional information.

(Comment 198) Several commenters discuss the interface between proposed § 112.43 and State or regional policies related to water or water treatment, such as permit requirements. One comment notes that, in most States, application of pesticides to any surface waters (including irrigation waters) is subject to permit requirements. Another comment mentions that, if a farm installs a chlorination facility in order to comply with the produce safety regulation, then the applicable State and/or Regional Water Board might issue a permit to that farm to make sure that any disinfection by-products running out of the farm's fields do not damage the environment or water quality. This comment asserts that the issuing of such permits could be a significant burden on farms and on State and Regional Water Boards. One comment mentions that water treatment products used in California must be registered with the California EPA's Department of Pesticide Regulation (CDPR). This comment speculates that if the produce safety regulation results in significant increase in use of pesticides to treat water, that the CDPR's requirement to register treatment products may result in time delays and antimicrobial products may become less available.

(Response) As noted in response to Comment 194, the produce safety regulation does not require covered farms to consider treating agricultural water as an immediate first step where the water is not safe or of adequate sanitary quality for its intended use and/or does not meet the microbial quality criteria in § 112.44. Rather, covered farms have a range of viable options to consider based on practices and conditions specific to the farm, treatment of water being only one such option. When a covered farm does choose to treat water to ensure its safety for its intended use, we are providing for the treatment of water using any effective treatment method (such as physical treatment, including using a pesticide device as defined by EPA;

EPA-registered antimicrobial pesticide product; or other suitable method). Nothing in the regulations in part 112 requires or authorizes farms to take measures in conflict with existing federal, State, or local regulations related to water treatment. We also considered the environmental impacts associated with the standards for agricultural water, as discussed in the final EIS (Ref. 126).

When agricultural water is treated to ensure that it is safe and of adequate sanitary quality for its intended use, we expect any treatment that is used would be applied in accordance with all applicable federal, State, tribal, or local regulations. For example, any pesticide chemicals used in the treatment of water require EPA registration before they can be lawfully used.

(Comment 199) Several comments request that we provide additional clarification, instruction, and/or examples regarding how farms can treat water in order to comply with proposed § 112.43. One commenter claims that proposed § 112.43 is vague, in that it outlines neither the level of microbial reduction that must be achieved nor the microbial standard that must be met. Several comments request that FDA clarify which economical water treatments exist that might be used to bring water into compliance with levels established in the rule, and ask that we give examples of such treatments, provided that they do not conflict with other federal or State regulations. Other commenters maintain that farms need agricultural water treatment alternatives to chlorine, and request that FDA clarify which water treatments beyond chlorination are available to comply with proposed § 112.43. Another comment asks that, if FDA chooses to provide examples of water treatment methods, that we cite methods, such as hydrogen peroxide and UV treatment, which minimize the potential for environmental and public health

impacts. Relatedly, another commenter contends that FDA should explicitly recommend methods of water treatment that do not involve chemicals. Although supporting the requirement in proposed § 112.43(c)(2) that any treatment of agricultural water must be monitored, some comments seek additional specification, such as a defined interval for monitoring, the resulting water quality, and the point of monitoring (either at the place where the treatment is added or at the point of use of water).

(Response) If a covered farm chooses to treat agricultural water to make the water safe and of adequate sanitary quality for its intended use and/or to meet the relevant microbial quality criteria in § 112.44, § 112.43 requires that the treatment that is applied, regardless of the specific method employed, must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in § 112.44, as applicable. The required quality is dependent on the intended use of the agricultural water, with specific microbial quality criteria established in § 112.44(a) for certain specified uses; in § 112.44(b) for use during growing of produce (other than sprouts) using a direct application method; and in § 112.41, generally.

The specific level and frequency of treatment, the point at which treatment should be applied, and the intervals for monitoring treatments required under § 112.43 also vary, and are dependent, in part, on the method of treatment and the farm's operations, including its water source, intended use of the water source, and the water distribution system. As discussed in the 2013 proposed rule, an example of an effective monitoring program for use of a chemical treatment method would measure the level of active compound as well as those factors that may affect its activity, such as pH, temperature, and contact time. For example, adequate monitoring of water treated with hypochlorite in an orange postharvest wash must include, at a minimum,

monitoring the level of active antimicrobial (free available chlorine) and pH, since it is known that hypochlorite activity is reduced both by organic material (e.g., soil, plant debris) and pH values outside its effective range (pH 6.0–7.5) (Ref. 136) (Ref. 137) (Ref. 138) (Ref. 139). The concentration of active disinfectant and pH must be adjusted, as necessary, taking into account variations in water quality in order to maintain the effectiveness of the treatment. In addition, the frequency at which you monitor agricultural water treatment must be adequate to ensure that the conditions for proper treatment are consistently met and adjusted, as necessary, to result in water that is safe and of adequate sanitary quality for its intended use and/or meets the relevant microbial quality criteria in § 112.44, as applicable. Research has shown that, in other settings, monitoring of physical parameters, such as temperature, pH and disinfectant concentration, can be done in real-time and in an inexpensive, automated manner, facilitating good control of the treatment process (Ref. 136). As a verification that the treatment process, monitored in accordance with § 112.43(b), is effective in achieving a certain microbial quality requirement (e.g., no detectable generic E. coli in 100 mL of water), you may choose to perform periodic microbiological analysis of the treated agricultural water. Although not a requirement, we encourage farms to perform such testing to provide further assurance of the effectiveness of their treatment under the specific conditions that exist on their farm. We will consider discussing these issues further in the Produce Safety Regulation implementation guidance to be issued in the near term.

(Comment 200) Several comments focus on the treatment of harvest and postharvest water. For example, one comment requests clarification on whether the proposed standard would require water for dump tanks to have an added disinfectant, whereas another commenter

recommends that farms should use, as appropriate, antimicrobials in fruit and vegetable wash water for pathogen reduction. Comments also provide other suggestions, including: (1) that farms with more than \$5 million in gross sales should be required to include a disinfectant in their wash water, if such farms are immersing in dump tanks either leafy greens or produce that can take up water through a temperature differential; (2) that farms should be permitted to continue their current use of a chlorine-free product to treat water in a dunk or flume, which in the commenter's view renders the proposed water standards excessive; and (3) that the provisions should address the use or validation of compounds authorized for use.

(Response) As noted in response to Comment 194, the produce safety regulation does not require covered farms to consider treating agricultural water as an immediate first step where the water is not safe or of adequate sanitary quality for its intended use and/or does not meet the relevant microbial quality criteria in § 112.44, as applicable. Rather, covered farms have a range of viable options to consider based on practices and conditions specific to the farm, treatment of water being only one such option. This includes agricultural water used during or after harvest. Under § 112.44(a)(2), agricultural water must contain no detectable generic E. coli per 100 mL when it is applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities. This microbial quality criterion, therefore, applies to wash water in dump tanks, flumes, or wash tanks used to wash covered produce. Where water does not meet this microbial quality requirement, farms have different options to ensure the water is safe to use for this purpose. A covered farm may choose to add an EPA-approved disinfectant to the wash water in dump tanks

to ensure the water contains no detectable E. coli and is safe and of adequate sanitary quality for its intended use. However, treatment of water is not the only option. In addition to treatment, another option available to farms includes re-inspecting the entire affected system, identifying conditions that are reasonably likely to introduce hazards, making changes to the system and re-testing the water successfully (§ 112.45(a)(1)) or using water from a different source that does meet the microbial quality requirement.

The commenter who suggested a sales-based requirement for use of a disinfectant in wash water did not provide a rationale for such a requirement. We are establishing a microbial quality requirement for such water in § 112.44(a), and options for taking action when water does not meet that standard in § 112.45(a). We are not requiring any farms to treat wash water regardless of whether it meets the quality requirement, nor are we requiring only certain farms to do so based on their sales or the type of commodity they produce.

With respect to comments asking us to address the use or validation of compounds authorized for use, we note that although some antimicrobial substances are regulated by FDA, most antimicrobial substances that might be used by covered farms in agricultural water are regulated by the EPA. A decision tree regarding whether an antimicrobial substance would be regulated by the EPA or the FDA is available at:

<http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/RegulatoryAuthorityAntimicrobialSubstances/default.htm> (Ref. 140). See also the discussion of available antimicrobial products registered with EPA as sterilizers in Comment 194.

(Comment 201) Several commenters assert that proposed § 112.43 would create a preference for the use of antimicrobial pesticides as an appropriate water treatment method; these

comments point out that the proposed provision provides only an example of using an EPA-registered antimicrobial pesticide product to treat water, without offering any additional examples. Another commenter observes that the proposed provision appears flexible, but that the related commentary in the preamble only discusses chemical treatment of water. This commenter also notes that various non-chemical treatment methods, such as mechanical or physical methods (e.g., filtration) are currently being explored.

(Response) As noted in response to Comment 194, when a covered farm chooses to treat its agricultural water to ensure it is safe and of adequate sanitary quality for its intended use and/or meets the relevant microbial quality criteria in § 112.44, as applicable, we are providing for the treatment of water using any effective treatment method (such as physical treatment, including using a pesticide device as defined by EPA; EPA-registered antimicrobial pesticide product; or other suitable method). We recognize that methods other than chemical treatment are either available or being explored for the treatment of agricultural water, for example, pesticide devices (such as filter units, ultraviolet light units, and ozonator units), reverse osmosis, and solar methods (Ref. 141). We also agree that water treatment options should not be, and are not, limited to chemical methods. As part of the EIS, FDA has considered a range of management decisions that a farm might take to be in compliance with the water quality requirements. These management decisions are outlined in Table 2.1-2 of the EIS and discussed in further detail in Chapter 4.2 of the EIS (Ref. 126). To make clear that water treatment options are not limited to chemical methods, we are revising § 112.43(a) to include additional examples besides chemical treatment methods.

(Comment 202) Some comments state that, under the NOP standards, only certain specified substances may be used as disinfectants and sanitizers in organic crop production (provided that the use of such substances does not contribute to contamination of crops, soil, or water), and that currently no pesticide chemicals are allowed under the NOP that organic farmers would be able to use to treat water. Similarly, a trade organization comments that they are unaware of any antimicrobial pesticide that would be effective, allowed for use under the NOP, and allowed for use according to its label. A State department of agriculture states that a surface water irrigator treating water with antimicrobial pesticides could result in organic producers located downstream to use water that has been treated, which could cause them to have their organic certifications revoked. Another comment expresses concern that water treatment chemicals will damage the microbiology of the soil, thus compromising the ability of organic farmers, who depend on the soil biology ecosystem, to grow safe and healthy food.

(Response) Throughout the development of the produce safety regulation, we have been working with USDA on a number of issues, including on whether and how this rule affects compliance with the NOP regulations. Compliance with the provisions of this rule does not preclude compliance with the requirements for organic certification in 7 CFR part 205. As discussed previously, this rule does not require covered farms to consider treating agricultural water as an immediate first step where the water is not safe or of adequate sanitary quality for its intended use and/or does not meet the relevant microbial quality criteria in § 112.44, as applicable. Rather, covered farms have a range of viable options to consider based on practices and conditions specific to the farm, treatment of water being only one such option. Thus, this rule does not require organic farms to use a substance that is prohibited in organic production.

We understand that substances which are prohibited in organic production are described

in 7 CFR 205.105. We advise you to consult with the NOP for additional information related to concerns about downstream effects of chemical treatment of water. In addition, as discussed previously, current options for EPA-registered pesticide chemicals for use in agricultural water are limited for all produce production, including organic produce. However, non-chemical water treatment options (such as filter units, ultraviolet light units, ozonator units, reverse osmosis, and solar methods) are either currently available or being explored, and such treatments may be used in compliance with § 112.43. In addition, options other than treating agricultural water are also available under this rule for organic farms, just as for all other covered farms. See also our responses to Comment 194 and Comment 196.

FDA has acknowledged in Chapter 4.2 of the EIS that certified organic farms are restricted to pesticides approved on the National List of Allowed and Prohibited Substances. However, FDA has determined that sustained, long-term water treatment may not be required because the added flexibility to account for microbial die-off and/or removal may be as simple as allowing sufficient time between final application of irrigation water and harvest. Certified organic farms will have sufficient flexibility to choose management decisions that allow them to retain their certification, including non-chemical water treatments, postharvest options with and without chemicals, using alternative water sources and others as discussed in further detail in Chapter 4.2 of the EIS. The EIS also considers impacts of water quality criteria established in this rule on various resources, including soils (Ref. 126).

(Comment 203) Some comments discuss the costs associated with treating water under proposed § 112.43. Comments assert that some irrigation districts, municipalities, and farms lack the necessary infrastructure or financial resources to build such infrastructure. An additional

comment states that increased use of antimicrobials in postharvest water will increase farm operating costs, and could lead to capital costs to mitigate increased amounts of contaminated waste water discharges.

(Response) See our responses to Comment 194, Comment 195, Comment 200, and Comment 201. We also recognize that covered farms will need time to consider the various options, and may need some adjustments to their existing practices or operations, to comply with the water provisions in this rule. Therefore, for covered activities involving covered produce (except sprouts), we are providing extended compliance periods for certain water provisions, as explained in section XIII.K of this document. We also intend to work with our State, tribal, and local partners and target our education and technical assistance efforts to smaller farms to help farms meet the requirements of the rule.

With respect to the comment about increased costs, we estimate costs of antimicrobial use and related capital investments in our RIA. See the final RIA for a discussion of costs (Ref. 142).

(Comment 204) One comment asks that we clarify that agricultural water should not be treated under § 112.43 if such treatment would conflict with applicable laws.

(Response) There is nothing in § 112.43, specifically, or in part 112, generally, that requires or authorizes violations of other applicable laws. Should a covered farm choose to treat their agricultural water to ensure it meets the applicable requirements for its intended use, we expect any treatment that is used would be applied in accordance with all applicable federal, State, tribal, and local regulations.

E. Microbial Quality Criterion for Agricultural Water Used for Certain Specified Purposes (§ 112.44(a)) and Corresponding Corrective Measures (§ 112.45(a))

(Comment 205) Some comments support the applicability of the microbial quality criterion in proposed § 112.44(a) (i.e., no detectable E. coli) for uses of water specified under this provision. Some comments also state that water used during harvest, packing, and holding activities should be tested on a more frequent basis than other water used for agricultural purposes, and request FDA to provide guidance on the specifics of a sampling plan.

(Response) We are finalizing proposed § 112.44(a), such that the no detectable E. coli requirement applies to agricultural water that is used for purposes specified in that section. We are deleting proposed § 112.44(a)(3) because we received comments indicating that this reference to treated agricultural teas in subpart E was confusing (see Comment 270 and Comment 271). We have amended § 112.51(a) and (b) in subpart F, and the definition of “agricultural tea” in § 112.3(c), to clarify the requirements applicable to water used to make an agricultural tea.

We address testing frequency requirements in Comment 224. In addition, we refer you to the discussion under Comment 180 and Comment 181, where we explain the requirements for corrective measures that must be taken, and the timing for when such corrective measures must be taken, in accordance with § 112.45(a), when your agricultural water does not meet the microbial quality criterion in § 112.44(a) for those specified purposes.

In the supplemental notice, we did not propose specific testing frequency requirements applicable to untreated surface water that is used for the purposes in § 112.44(a). Instead, we proposed that you must test the quality of each source of the untreated surface water with an adequate frequency to provide reasonable assurances that the water meets the required microbial

standard and that you must have adequate scientific data or information to support your testing frequency (proposed § 112.45(d)). We also noted that although we were not restricting use of untreated surface water solely to growing activities (e.g., irrigation, crop protection sprays), we anticipated that the primary use of untreated surface water would be during growing activities. Thus, in the supplemental notice we did not specifically prohibit a farm from using untreated surface water for any purpose described in § 112.44(a), provided that the water meets the no detectable E. coli standard for those purposes. We asked for comment on the prevalence of use of untreated surface water for the purposes listed under § 112.44(a), and on an appropriate approach(es) to sampling and testing of untreated surface water intended for such uses. We also asked for comment on whether we should require treatment of surface water sources used for the purposes specified in § 112.44(a), rather than provide for a testing scheme, if the latter is not practical (79 FR 58434 at 58454).

Some comments that responded to this request ask for clarification on what would be an adequate frequency or for guidance on an appropriate sampling plan. We continue to find it challenging to establish a generally applicable sampling scheme or frequency that would provide sufficient confidence that any source of untreated surface water, given the inherent variability associated with such sources, will consistently meet the no detectable E. coli microbial water quality criterion in proposed § 112.44(a). Moreover, none of the comments explicitly recommended or supported retaining this testing requirement as a means to allow use of untreated surface water for the purposes in 112.44(a). Under the Surface Water Treatment Rule (40 CFR 141.70–141.75), EPA requires public water systems to treat surface water or ground water sources under the direct influence of surface water to meet the requirements of the Safe Drinking Water Act (SDWA) (42 U.S.C. 300f et seq.). The intended uses listed in §

112.44(a) have high potential to serve as a vehicle of fecal contamination because if fecal contamination is present (along with the corresponding potential for pathogen presence), it is reasonably likely it could be transferred directly to covered produce through direct or indirect (via food-contact surfaces) contact with the agricultural water. Considering this, as well as the inherent variability of the quality of untreated surface water sources; the absence of an identifiable, appropriate testing and sampling scheme to ensure the safe use of such untreated surface water for the purposes of § 112.44(a); and the lack of comments persuading us to retain proposed § 112.45(d), we are eliminating proposed § 112.45(d) from subpart E and adding a prohibition in § 112.44(a) on using untreated surface water for any of the purposes identified in that section.

(Comment 206) One comment recommends that we establish less protective water quality requirements than those in proposed § 112.44(a) and § 112.44(c) that would be applicable to produce commodities that may be cooked or that are often cooked, and that we establish for such commodities a labeling requirement similar to “Safe Handling” labeling instructions for consumers that appear on meat products.

(Response) We do not agree that such an approach would appropriately minimize the risk of serious adverse health consequences or death from consumption of contaminated produce. We believe the provisions in §§ 112.2(a) and 112.2(b) sufficiently address the circumstances where produce is either rarely consumed raw or receives commercial processing to adequately reduce pathogens. For produce that is not “rarely consumed raw” or receives commercial processing to adequately reduce pathogens, we do not believe that less protective water requirements along with labeling instructions would be appropriately protective of public health or fulfill our FSMA

mandate to establish science-based minimum standards for the safe production and harvesting of produce that minimize the risk of serious adverse health consequences or death. It is unclear how we could determine appropriate microbial criteria for such a “less protective” set of microbial water standards. It is also not clear that consumers would always cook such produce even if it were labeled with instructions that it should only be consumed after cooking or that consumers would understand why there were cooking instructions on a product that is often consumed uncooked.

(Comment 207) Some comments suggest the microbial quality requirement in proposed § 112.44(a) should apply to postharvest activities only.

(Response) As discussed in the QAR, water used for the purposes listed in § 112.44(a) has high potential to serve as a vehicle of fecal contamination because if fecal contamination is present (along with the corresponding potential for pathogen presence), it is reasonably likely it could be transferred directly to covered produce through direct or indirect (via food-contact surfaces) contact with the agricultural water. We explained our rationale for subjecting the intended uses of agricultural water listed in § 112.44(a) to the stringent zero detectable E. coli microbial quality standard in the 2013 proposed rule (see 78 FR 3504 at 3568). Therefore, we disagree with the commenters’ suggestion that the microbial quality criterion in § 112.44(a) should be limited to postharvest uses only (See also discussion in section XIV.A.1 of this document).

(Comment 208) One comment points out that under the proposed provisions of part 112, on-farm postharvest handling of produce (such as packing) grown on the farm or other farms

under the same ownership would be required to comply with the proposed § 112.44(a) requirement to test water used for the listed purposes to ensure there is no detectable generic E. coli; but that the same activities, when subject to proposed part 117 (e.g., when the produce is packed off-farm, or on-farm packing of produce from a farm under separate ownership) would not be subject to specific provisions requiring testing of such water.

(Response) First, we note that there is no requirement to test water from certain types of public water systems used for the purposes listed in § 112.44(a), nor is there any requirement to test water treated in accordance with § 112.43 used for the same purposes (see § 112.46(a)). See Comment 222. In addition, we are prohibiting use of untreated surface water for these purposes (see § 112.44(a)), which means that only untreated ground water must be tested when used for these purposes (see § 112.46(c)).

Second, as discussed in section IX.B. and in the supplemental notice, we have revised the definition of “farm” so that farms that pack or hold produce RACs that are grown on a farm that is under different ownership would no longer necessarily be “farm mixed-type facilities” subject to the requirements of the PCHF regulation. Rather, packing or holding others’ produce RACs on a covered farm will be subject to this rule unless the farm or the produce is otherwise exempt or not covered. Thus, there is no longer a difference in what requirements will apply to testing water used in on-farm postharvest handling of produce based on where the produce was grown. Moreover, we are also revising the definition of “farm” to include certain operations (Secondary Activities Farms) devoted to harvesting, packing, and/or holding of RACs, provided that the Primary Production Farm(s) that grow or raise the majority of the RACs harvested, packed, and/or held by the Secondary Activities Farm own, or jointly own, a majority interest in the Secondary Activities Farm. Thus, farm-owned cooperative packing

houses, for example, will be considered Secondary Activities Farms, and water used in their postharvest handling of produce will be subject to this rule unless the farm or the produce is otherwise exempt or not covered.

This rule does not apply to activities of a facility subject to section 418 of the FD&C Act. Such activities are addressed in the final human preventive controls rule and the final animal preventive controls rule (80 FR 55908 and 80 FR 56170, respectively).

F. Microbial Quality Criteria for Agricultural Water Used for Direct Application During Growing Activities of Produce (Other Than Sprouts) (§ 112.44(b) and Corresponding Corrective Measures (§ 112.45(b))

1. Microbial Quality Criteria (§ 112.44(b))

(Comment 209) Several comments assert that the use of EPA's Recreational Water Quality Criteria (RWQC) is inappropriate or insufficient for use in setting the microbial quality standard for agricultural water, as established under proposed § 112.44(c). Comments express various concerns, including that: (1) FDA has not established a correlation between the RWQC and food safety and applying recreational water standards to irrigation water does not meet the statutory obligation to establish science-based standards for food safety; (2) the RWQC were developed more than two decades ago and do not reflect current science; (3) FDA has not provided sufficient explanation for how the RWQC would serve to minimize risk of known or reasonably foreseeable hazards, and that FDA, itself, acknowledges the limitations of using the RWQC; (4) the RWQC are likely appropriate for some, but not all, crops; and (5) the RWQC may not be achievable in areas of the country that use surface water for irrigation. These comments recommend that any microbial quality standard established in a final rule should be

based on data that are specific to produce safety and agricultural water. In contrast, some comments support the use of RWQC in developing the microbial quality criteria in proposed § 112.44(c).

(Response) We disagree with the assertion that the use of the science underlying the RWQC is inappropriate for informing the development of microbial quality criteria for agricultural water used in direct application during growing of produce (other than sprouts), which are now established in final § 112.44(b). We agree that the RWQC (which are based on data collected from recreational waters), in and of themselves, do not sufficiently reflect the circumstances associated with agricultural water used in produce production. However, we are not simply applying the RWQC as the safety standard for agricultural water. Rather, as discussed in the supplemental notice, we find that the science underlying the RWQC provides a starting point for quantitative microbial criteria that are generally applicable to minimize the risk of known or reasonably foreseeable hazards associated with the use of agricultural water on produce (other than sprouts) during growing using a direct water application method. The RWQC, which have been updated in 2012, are based on several recent epidemiological studies and use a broader definition of illness to recognize that gastrointestinal symptoms may occur without a fever (Ref. 100). Among other evidence, EPA considered the latest research and epidemiological data that demonstrate a link between fecal contamination in recreational waters and illness, and characterizes the rate of illness based on the epidemiological data. Using those data, the EPA criteria demonstrate the microbial threshold at which an exceedance of the threshold increases illness occurrence to protect primary contact recreation where immersion and incidental ingestion are likely (Ref. 100). In addition, the EPA analysis does not distinguish the illness rates between different bodies of water (i.e., marine or fresh) due to incidental

ingestion. Overall, we find the scientific rigor underlying the RWQC to be sufficient for us to rely on to inform our thinking on agricultural water used in produce production, which is also consumed via incidental ingestion. We described the rationale for our use of the science underlying the RWQC and our thinking on its relevance to agricultural water in a reference memorandum that accompanied the supplemental notice, and we reiterate those conclusions here (Ref. 44).

In the supplemental notice, we acknowledged that there are different ways to determine STV, including through sample-based empirical estimation and model-based calculation, and requested comment on whether there is a specific statistical method(s) that we should either require or recommend be used for the derivation of GM and/or STV values (79 FR 58434 at 58453). We did not receive comments recommending any specific method(s) for calculation. On further evaluation, we find a parametric estimation method based on the lognormal distribution to be appropriate for deriving the STV for purposes of determining the microbial water quality criteria and any necessary follow-up measures specified in §§ 112.44(b) and 112.45(b)(1), respectively. Unlike empirical methods, model-based methods of calculating the STV are more sensitive to the range of extreme values that may be obtained among the sample outcomes when the STV is being determined based on a relatively small number of samples. Therefore, we are specifying that the STV of your water samples calculated to determine whether your water meets the microbial quality criteria specified in § 112.44(b), must be derived as a model-based calculation based on the lognormal distribution. (See Comment 229 where we address guidance related to this issue.)

Therefore, we are finalizing the microbial quality criteria for agricultural water used during growing activities for covered produce (other than sprouts) using a direct water

application method of: (1) a geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic E. coli per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and (2) a statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic E. coli per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).

Using the RWQC as a starting point, we then considered available scientific information and recommendations to account for circumstances that are unique to produce growing (including irrigation), such as microbial die-off after application of water, which are factors that were not accounted for in formulating water quality requirements in the EPA RWQC (Ref. 123) (Ref. 143). We considered the World Health Organization's (WHO) Guidelines for the Safe Use of Wastewater, Excreta, and Greywater, Volume II, Wastewater Use in Agriculture, which were developed with the primary aim of "maximizing public health protection and the beneficial use of important resources" (Ref. 123). These guidelines are intended to be relevant "to the intentional use of wastewater in agriculture and [are] also relevant where faecally [sic.] contaminated water is used for irrigation unintentionally" and provide "an integrated preventive management framework for safety." These guidelines recommend various health protection measures that can be used alone or in combination to achieve a specific microbial log reduction, or range of reductions, necessary to meet the desired health outcome. The health protection measures reflected in the WHO guidelines are intended to achieve a tolerable disease burden from consumption of raw food crops irrigated by treated wastewater of $\leq 10^{-6}$ disability-adjusted life years per person, per year (Ref. 44). The post-irrigation microbial die-off and/or microbial removal provisions in final § 112.45(b)(1) were

informed by our analysis of these WHO guidelines.

(Comment 210) In the supplemental notice, in relation to the microbial quality criteria in proposed § 112.44(c), we asked for comment on whether we should establish a single sample maximum level of E. coli above which the water should not be permitted for use in direct application (until specific follow-up actions are taken to ensure it meets the recommended microbial quality requirements) and, if so, what would be an appropriate maximum level (78 FR 58444). Some comments oppose a maximum threshold level of E. coli, arguing that it could lead to discontinuation of water unnecessarily because of the variability in quality of irrigation water, and one of these comments argues that any such maximum levels should be included in guidance rather than in regulation.

(Response) We are not establishing a single sample maximum threshold of generic E. coli in relation to the microbial quality criteria in § 112.44(b). Our approach to developing the standard for safe use of agricultural water during growing covered produce (other than sprouts) relies on measures taken by covered farms to know and respond to the quality of their agricultural water over the long term. Rather than setting a single sample maximum generic E. coli standard, we are establishing a STV of 410 CFU or less generic E. coli per 100 mL of water. The STV is a value that is derived as a model-based calculation based on the lognormal distribution and approximates the 90th percentile of the water quality distribution. The use of an STV rather than a single sample maximum is designed to account for the variability of water sources, in particular of surface water sources.

(Comment 211) Several comments recommend FDA set an “interim” microbial water quality requirement in proposed § 112.44(c), and then pursue additional research to inform the development of a final microbial quality standard that accounts for the diversity in farming practices and produce commodities. Such comments advise that such an “interim” standard should include a mandatory sunset provision, which they expect would provide an opportunity for stakeholders to work together to conduct research and develop meaningful commodity- and situation-specific microbial quality standards for agricultural water.

(Response) As previously noted, we do not agree that more research is needed for us to finalize the provisions of this rule relating to agricultural water. We also disagree that we should establish requirements with sunset provisions as suggested by these commenters. As discussed in the 2013 proposed rule, the supplemental notice, and in this document, there is sufficient scientific information from which we conclude that the requirements in this rule minimize the risk of serious adverse health consequences and death, and are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated. However, we do support additional research as a means of facilitating implementation of the rule and continuing advancement of scientific knowledge in this area, and we are pursuing regulatory science and research activities in collaboration with various partners (see Comment 174).

(Comment 212) Several comments recommend other approaches for us to consider in establishing microbial quality requirements for § 112.44(b) uses, including: (1) using the WHO standard, asserting it may be easier to implement and more easily understood by foreign producers; (2) adopting a qualitative standard to require that water must be of adequate quality

for its intended use; and (3) applying the microbial standard for drinking water to agricultural water for a certain specified period prior to harvest, and evaluating whether water meets this standard using a single water test taken at a certain time prior to harvest. In addition, several other commenters argue that any agricultural water requirement for this purpose should be no more restrictive than the WHO standard.

(Response) See Comment 209. The WHO guidelines present several illustrations for how to reduce risks associated with consuming raw crops irrigated by wastewater. However, these are only examples of how to apply the guidelines to reach the health-based target. They do not represent specific water quality criteria for particular commodities. The guidelines recommend several health protection measures, each of which can be used alone or in combination to achieve a specific microbial log reduction or range of microbial reductions necessary to meet the desired ($\leq 10^{-6}$ disability-adjusted life years) health outcome. This rule draws upon the WHO water guidelines, but not as a fixed microbial quality standard, per se. As discussed in the supplemental notice, the WHO values (i.e., 1,000 CFU per 100 mL and 10,000 CFU per 100 mL for root crops and surface crops, respectively) are better explained as illustrations of how specific health protection measures could be used together after waste water treatment to achieve the additional log reductions recommended for waste water reuse, and were not intended as absolute end points or maximum permitted levels for generic E. coli in irrigation water. As explained in (Ref. 44) regarding the review of water quality standards in development of the microbial quality criteria in § 112.44(b), the WHO guidelines do not include any specific criteria for maximum acceptable E. coli levels in wastewater for agricultural use in the growing of produce. We also conclude that a quantitative microbial quality requirement that is enforceable and requires action by industry to ensure the criteria are

met would be both more practicable and more protective of public health than a qualitative water quality standard alone. The microbial quality criteria we have established serve as objective measures to be applied to indicate the quality of agricultural water when used for certain specified purposes. Note that we are also retaining the general “safe and of adequate sanitary quality” qualitative standard in § 112.41, which applies to all agricultural water regardless of the specific intended use.

In response to the comment suggesting requiring agricultural water to meet the drinking water standard for a specified period of time pre-harvest and only requiring a single test, we do not believe it is necessary to require water used in the field to meet the drinking water standard in light of the die-off of microorganisms that can be expected to occur after application of agricultural water. As described in Comment 214, we conclude it is appropriate to account for microbial die-off between last irrigation and harvest, as well as between harvest and end of storage, as provided in § 112.45(b)(1).

(Comment 213) Several comments support the use of the GM and STV as proposed in the supplemental notice and prefer that approach over the original approach in the 2013 proposed rule (using a GM and a single sample maximum). These comments state that the GM and STV approach is risk-based, appropriately protective, flexible, and does not unduly burden farmers. However, other comments state the calculations related to GM and, in particular, STV required under proposed § 112.44(c) are complicated and are likely to be confusing and challenging for farmers to implement. Some comments request that FDA provide assistance to farms regarding the calculation of GM and STV, and the application of the microbial die-off and/or removal

provisions. Comments also ask FDA to develop guidance and web-based tools to help with these calculations.

(Response) We appreciate the comments that recognize the value of the GM and STV approach as opposed to our original proposed approach that included a single sample maximum. However, we also recognize the need for outreach regarding how to calculate the GM and STV, how to use microbial die-off and/or removal rates, and how to calculate related time intervals. We intend to provide guidance on these topics in the Produce Safety Regulation Implementation guidance, which we expect to issue in the near future. In addition, we are exploring the development of an on-line tool that you can use to derive the GM and STV values and appropriate time intervals (in days) between last irrigation and harvest using the 0.5 log per day die-off rate, based on input of sample data, such that a farmer would not need to perform the necessary calculations themselves.

2. Allowance for Microbial Die-Off and/or Removal (§ 112.45(b)(1)) and Other Corrective Measures (§ 112.45(b)(2) and (b)(3))

(Comment 214) Several comments support proposed § 112.44(c)(1) and (c)(2) that would allow farms to account for microbial die-off or removal between last irrigation and harvest and between harvest and end of storage, or during activities such as commercial washing. These comments state these mechanisms provide flexibility; serve as a reasonable approach to identifying practices that reduce risk; and minimize the need for chemical water treatment. In addition, several comments suggest that these provisions should be expanded and applied to operations where there is no reasonable likelihood of direct water contact with the harvestable portion within a specified number of days before harvest.

(Response) We are retaining the microbial die-off and removal provisions in final § 112.45(b)(1)(i) and (b)(1)(ii). For the purposes of this rule, we define agricultural water as water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities and in harvesting, packing, and holding activities. Moreover, we use “covered produce” to refer to the harvestable or harvested part of the crop. Therefore, the provisions in subpart E, including § 112.44(b) and corresponding § 112.45(b), do not apply to water that is not intended to or likely to come into contact with covered produce, and we are not establishing microbial quality criteria (or related microbial die-off or removal provisions) for such water. See also Comment 179.

We are also making other revisions within final § 112.45(b) to consolidate and clarify applicable options for corrective measures when agricultural water used during growing activities for covered produce (other than sprouts) using a direct water application method does not meet the microbial quality criteria in § 112.44(b). That is, available options include (1) applying a time interval (in days) between last irrigation and harvest (§ 112.45(b)(1)(i)) and/or between harvest and end of storage and/or applying a (calculated) log reduction during activities such as commercial washing (§ 112.45(b)(1)(i)); (see also Comment 218 discussing certain revisions to these provisions); (2) re-inspect your entire affected agricultural water system to the extent it is under your control, and among other steps, make necessary changes and adequately ensure that your water meets the criteria in § 112.44(b) (§ 112.45(b)(2)); or (3) treat the water in accordance with § 112.43 (§ 112.45(b)(3)). Consistent with our intent for the microbial quality criteria in § 112.44(b) to serve as a long-term water management tool, we further clarify in § 112.45(b) that these corrective actions must be taken as soon as practicable,

and no later than the following year. We expect you to apply these corrective measures as soon as it is practicable, considering various factors specific to your practices and commodities, including, for example, the timing when water testing results are obtained in relation to the current harvest of your commodity or commodities; whether you have a single or multiple commodities with different harvest cycles; and whether your commodity is of a nature such that the time intervals and/or (calculated) log reductions in § 112.45(b)(1)(i) and/or (b)(1)(ii) can be applied. However, we require you to implement such corrective measures no later than the following year. If none of the corrective measures in § 112.45(b)(1)-(3) are used, or if such measures are not effective in achieving the required criteria, you must discontinue that use of the water from that source.

(Comment 215) Several comments express concern that the burden is placed on covered farms to conduct research and identify appropriate microbial die-off or removal rate(s) that can be applied between harvest and end of storage or during activities such as commercial washing.

(Response) As noted in the supplemental notice, at this time, we are not establishing a specific microbial die-off rate(s) between harvest and end of storage or specific microbial removal rate(s) during postharvest activities such as commercial washing because we do not have sufficient information to support the derivation of appropriate, broadly applicable microbial die-off or reduction rate(s) for these purposes. Nevertheless, we provide this option in final § 112.45(b)(1)(ii), along with revisions requiring you to use an accompanying maximum time interval or log reduction. See Comment 218. We are retaining this option so covered farms may establish and apply an adequate time interval or calculated log reduction using microbial die-off or removal rate(s) relevant to the covered produce and dependent on

practices and conditions on the farm, provided the farm has adequate scientific data or information to support the conclusions. We are working with our stakeholders to facilitate research into appropriate die-off and/or removal rates for these activities, and we intend to disseminate useful scientific information, when available, such that farmers would be able to consider our recommendations and apply the new scientific information to their operations, as appropriate.

(Comment 216) Several comments ask about the science underlying the microbial die-off rate in proposed § 112.44(c)(1) that is used to determine the time interval between last irrigation and harvest. Comments state that the established rate may not be uniformly applicable across diverse real-world conditions on farms producing different commodities across the country.

(Response) The microbial die-off rate in § 112.45(b)(1)(i) is based on our review of currently available science. As explained in the supplemental notice, we determined that a microbial reduction rate of 0.5 log per day provides a reasonable estimate of die-off under a broad range of variables including microbial characteristics, environmental conditions, crop type, and watering frequency. (See (Ref. 45) (Ref. 144) for information about the studies we reviewed, our criteria for study selection, and our conclusions.) We recognize that microbial die-off rates are dependent on various environmental factors, including sunlight intensity, moisture level, temperature, pH, the presence of competitive microbes, and suitable plant substrate. Although our analysis led us to conclude that a rate of 0.5 log per day provides a reasonable estimate of microbial die-off under a broad range of variables, we understand that different microbial die-off rates may occur between last irrigation and harvest under different circumstances (Ref. 45) (Ref. 144). For example, higher microbial die-off rates may occur

under conditions of high ultraviolet radiation, high temperature exposures or low humidity, coupled with little or no precipitation in comparison to the die-off rates observed under cloudy, cool, and wet conditions (Ref. 123). Therefore, in final §§ 112.45(b)(1)(i)(B), 112.49(b), and 112.12, we are providing for the use of appropriate alternative microbial die-off rate(s) (as well as an accompanying maximum time intervals), provided you have adequate scientific data or information to support a conclusion that the alternative die-off rate would provide the same level of public health protection as the 0.5 log per day die-off rate in § 112.45(b)(1)(i)(A), and would not increase the likelihood that your covered produce will be adulterated under section 402 of the FD&C Act, in light of your covered produce, practices, and conditions. We expect that covered farms that rely on an alternative die-off rate under these provisions to use a rate that is supported by an equally robust and rigorous scientific analysis applicable to the region and crop for which the alternative would be used. We would expect such an alternative rate to be quantitatively demonstrated to be equivalent to the FDA-established rate under the relevant conditions, thus “providing the same level of public health protection” as the FDA-established rate and ensuring that the alternative rate would not increase the likelihood that the farm’s covered produce will be adulterated, as required under § 112.12.

(Comment 217) One comment notes the importance of end-of-season irrigation water to overall yields, and asks FDA to consider the detrimental effects of ceasing irrigation in establishing the water standards.

(Response) We recognize the importance of irrigation during produce production, and have provided options in § 112.45(b)(1) that account for microbial die-off and/or removal post irrigation, as additional means to achieve the microbial quality criteria for agricultural water

that is used in a direct application method during growing of produce (other than sprouts). We also note that we have incorporated flexibility for covered farms to use an alternative microbial die-off rate in lieu of our established die-off rate, under certain specified conditions (see § 112.49(b)). We expect that, in most cases, these provisions will provide sufficient flexibility for covered farms to achieve our microbial quality criteria, as soon as practicable, and no later than the following year, without having to cease irrigation. See also Comment 214 regarding timing of corrective actions and other available options.

(Comment 218) Several comments state the microbial die-off and/or removal provisions in proposed § 112.44(c)(1) and (c)(2) should not be allowed to be used when agricultural water exceeds a certain level of generic E. coli. These comments recommend a maximum time interval between last irrigation and harvest of 4 days, applying a microbial die-off rate of 0.5 log per day. One comment provides the example that if the water quality is uncontrollable or testing results are between 410 and 41,000 CFU E. coli /100 mL, a time interval between last irrigation and harvest at a rate of 0.5 log per day, to a maximum of 4 days should be permitted, but that such flexibility for microbial die-off is not appropriate when water testing results indicate a level of above 41,000 CFU E. coli/100 mL.

(Response) As discussed in the QAR, the timing of water application can affect the potential for produce contamination. For example, water containing elevated generic E. coli used in overhead irrigation shortly before harvest may increase the likelihood of covered produce being contaminated at the time of harvest, but the same water could be used to establish a crop because microbes die-off over time on the surface of produce. Studies reporting decay constant(s) measured over time have concluded that microbial die-off rates are highest

immediately following contamination and slow over time (Ref. 45) (Ref. 144). This phenomenon, known as “tailing,” suggests microbial die-off curves are biphasic, i.e., two decay constants may be needed to accurately describe microbial die-off over time. Moreover, it suggests the initial time period immediately following a contamination event via irrigation is the most important time period in reducing the numbers of microbes (including pathogens) present on the crop.

We also reviewed available literature for a maximum time interval that is appropriate when applying a microbial die-off rate of 0.5 log per day. The studies we reviewed indicate that greater microbial die-off or decay rates occur during the early timeframe post-contamination, and although the die-off rate in these studies was established from survival data or decay rates for bacterial studies ranging from 2-7 days, the specific timeframe for the biphasic shift in die-off was not identified (Ref. 45) (Ref. 144). Within this range identified in the literature, a maximum time interval of 4 days is reasonable because it serves as a general mid-point in time representing neither end of the range where microbial die-off was observed in these studies. A maximum time interval of four consecutive days is also consistent with recommendations by commenters. Therefore, we are adding a new limitation in § 112.45(b)(1)(i)(A) that a time interval of no more than four consecutive days may be applied between last irrigation and harvest to achieve the microbial quality criteria in § 112.44(b). In addition, we expect any scientifically-supported die-off rate that a farm applies as an alternative under § 112.45(b)(1)(i)(B) between last application and harvest; or to determine the appropriate time interval between harvest and end of storage, in accordance with § 112.45(b)(1)(ii), to be similarly characterized in a manner that addresses the likely biphasic nature of microbial die-off (i.e., the two different decay constants of a rapid short-term die-off and a gradual long-term

die-off). We also expect that if you develop an alternative to the microbial quality criteria in § 112.44(b) and if you intend to take advantage of the provision in § 112.45(b)(1)(i) applying die-off between last application and harvest, then you must also appropriately characterize a microbial die-off rate between last irrigation and harvest that relates to your alternative microbial quality criteria, including consideration of the likely biphasic nature of microbial die-off.

(Comment 219) One comment requests flexibility to apply the 0.5 log per day die-off rate in proposed § 112.44(c)(1) on a per hour, rather than a per day, basis.

(Response) We have determined the microbial die-off rate of 0.5 log per day between last irrigation and harvest in final § 112.45(b)(1)(i)(A) based on our review and analysis of currently available evidence. There is not enough evidence to support modifying the die-off rate that is reported in time periods of days in current literature to microbial die-off per hour. Moreover, decay constants have been found to vary within the 24 hour cycle, depending on climatic and other conditions (Ref. 145) (Ref. 146) (Ref. 147) (Ref. 148) (Ref. 149). Therefore, we do not believe it is appropriate to extrapolate the per day die-off rate to a per hour die-off rate.

(Comment 220) Some comments question the need to subject water that is used in the growing of dry bulb onions using a direct water application method to the testing requirements in proposed § 112.45, particularly in light of the microbial die-off and removal provisions in proposed § 112.44(c)(1) and (c)(2). These comments find the testing requirements burdensome and unnecessary for water used in the growing of dry bulb onions because harvest typically

occurs weeks or months after irrigation. One comment suggests a 6-day time interval between last irrigation and harvest would be sufficient to account for a “worst case scenario of 20,000 CFU generic E. coli /100 mL” water quality, and that dry bulb onion farms should be allowed to “opt out” of testing requirements for untreated surface water in proposed § 112.45(b), if they allow 6 days to elapse between last irrigation and harvest.

(Response) We recognize that covered farms growing dry bulb onions typically have an extended period between last irrigation and harvest and between harvest and end of storage, which should help them comply with the microbial water criteria in final § 112.44(b) for agricultural water that is used during growing of dry bulb onions using a direct application method. However, unless untreated surface water that is used during growing in a direct application method is tested, there would be no way to determine whether there is a need to apply a time interval between last irrigation and harvest and, if so, the appropriate time interval. Therefore, when required under final § 112.46, agricultural water testing and calculation of the GM and STV must be done to inform and determine the appropriate way(s) in which the water may be used. To take advantage of the die-off and/or removal options in § 112.45(b)(1), you must first characterize the water quality by testing in accordance with § 112.46(b) and calculate a GM and STV. Moreover, under § 112.45(b)(1)(i), the use of the microbial die-off rate of 0.5 log per day between last irrigation and harvest is limited to four consecutive days (see Comment 218). At a rate of 0.5 log per day and a maximum of four days, the die-off option provided in § 112.45(b)(1)(i)(A) could not, on its own, effectively achieve the microbial quality criteria for water containing 20,000 CFU generic E. coli /100 mL if this value represents the GM, as presented in the comment. You may instead apply an alternative microbial die-off rate under §§ 112.45(b)(1)(i)(B), 112.49(b), and 112.12. To do so, you must have adequate

scientific data and information to support your conclusions, as required in those provisions, and you must determine an accompanying appropriate maximum time interval associated with your alternative die-off rate, similar to the 4-day maximum under § 112.45(b)(1)(i)(A). Also, under § 112.45(b)(1)(ii), you may apply a microbial die-off rate between harvest and end of storage, and/or a microbial removal rate for activities such as commercial washing, that is relevant to your covered produce and dependent on practices and conditions on your farm, provided you have adequate scientific data or information to support your conclusions (see also corresponding documentation requirement in § 112.50(b)(5)). As for the die-off or removal rates in § 112.45(b)(1)(ii), you must also determine an accompanying maximum time interval or log reduction associated with these die-off rates, similar to the 4 day maximum under § 112.45(b)(1)(i)(A). See Comment 216.

While these flexible options make it less likely that a dry bulb onion farm will find that its untreated surface water cannot meet the § 112.44(b) criteria, the fact that each of these die-off or removal rates may have a maximum appropriate application limit means that they cannot be presumed to reduce the GM and STV of the most contaminated water sources to a level compliant with § 112.44(b). Testing must be conducted to determine the quality of the water and determine whether it is usable within the requirements of the rule.

(Comment 221) In the supplemental notice, we asked for comment on whether we should require farms to establish and maintain any documentation in relation to the option to apply a time interval between last irrigation and harvest. One comment recommends requiring records to be maintained on the time interval applied, how the time interval was calculated, and/or the dates of last irrigation and harvest corresponding to that time interval. The commenter also notes,

however, that such records should be required only in the case where the agricultural water tested in accordance with proposed § 112.45 does not meet the microbial quality criteria established in proposed § 112.44(c).

(Response) We agree that documentation of the time interval applied, calculation of the time interval based on water testing results, and the dates of last irrigation and harvest corresponding to that time interval, must be prepared and maintained, when the provision in § 112.45(b)(1)(i) is applied to achieve the microbial quality criteria in § 112.44(b). Likewise, records must be made and kept of the time interval or calculated log reduction applied, calculation of the time interval or log reduction based on water testing results, and the dates of harvest and end of storage or other relevant activities corresponding to that time interval or log reduction, when the provision in § 112.45(b)(1)(ii) is applied to achieve the microbial quality criteria in § 112.44(b). Such records would be required only when such a time interval or log reduction is applied, in accordance with § 112.45(b)(1), and not when no such time interval(s) is applied. We are adding this records requirement in new § 112.50(b)(6) (corresponding with our elimination of proposed § 112.161(b)), which requires you to document any actions you take in accordance with § 112.45. This new section also provides specifically that you must prepare and maintain documentation of any time interval or (calculated) log reduction applied in accordance with § 112.45(b)(1)(i) and/or (b)(1)(ii), including the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities (such as the dates of last irrigation and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing).

G. Testing of Agricultural Water (§ 112.46)

1. Testing of Agricultural Water Not Required Under Certain Conditions (§ 112.46(a))

(Comment 222) Some comments believe proposed § 112.45(a) would allow farms to draw and hold municipal water with no further requirement to test that water. These comments state that the provision, as proposed, is not sufficiently protective of the quality of water from public water system to forgo testing.

(Response) In final § 112.46(a), we are retaining proposed § 112.45(a), which establishes that there is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when: (1) you receive water from a public water system, under the conditions specified in that provision (§ 112.46(a)(1)); (2) you receive water from a public water supply that furnishes water that meets the microbial quality requirement in § 112.44(a), under the conditions specified in that provision (§ 112.46(a)(2)); or you treat water in accordance with § 112.43 (§ 112.46(a)(3)).

This exception from the testing requirements that follow in § 112.46(b) and (c) applies only when water received from a public water system (as in § 112.46(a)(1)) or a public water supply (as in § 112.46(a)(2)) is not held under your control in a way that meets the definitions of “ground water” or “surface water” before you use it as agricultural water. See the definitions of “ground water” and “surface water” in § 112.3(c). If you hold water received from a public water system or public water supply in either a ground water or a surface water capacity, the water is exposed to potential contamination in a manner similar to other ground water or surface water sources, such that it becomes a “ground water” or “surface water” source as applicable, and the testing requirements applicable to untreated ground water or untreated surface water will apply, as established in § 112.46(b) and (c).

We are also revising § 112.46(a)(1) to add a reference to the relevant EPA definition of a State approved to administer the SDWA public water supply program by adding a cross reference to the relevant definition in 40 CFR 141.2. The definition of “State” for this purpose includes, in relevant part, the agency of the State or tribal government which has jurisdiction over public water systems.

(Comment 223) One comment asks why a body of water, such as a river, would need to be tested if it meets the federal water quality standards.

(Response) The Water Quality Standards (WQS), issued under the CWA, define the goals for a waterbody by designating its uses, setting criteria to protect those uses, and establishing provisions such as anti-degradation policies to protect waterbodies from pollutants. The WQS regulation at 40 CFR part 131 describes the requirements and procedures for States and authorized tribes to develop, adopt, review, revise, and submit water quality standards. It also establishes the requirements and procedures for EPA to review, approve, disapprove, and promulgate water quality standards as authorized by section 303(c) of the CWA (33 U.S.C. 1313(c)). Water that is determined to be within the established WQS for the waterbody does not necessarily meet the agricultural water requirements in this rule, which as discussed throughout this section, are intended to prevent the introduction of known and reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated. For example, many farms rely on ditches to direct water to the field, and these ditches are normally open to the environment and can cover significant distances. There are no controls in the CWA that would account for potential contamination in these ditches.

2. Approach to Testing Untreated Surface Water (§ 112.46(b)) and Untreated Ground Water (§ 112.46(b) and (c))

(Comment 224) Several comments support the revisions we proposed in the supplemental notice to proposed § 112.45 that we had proposed in the 2013 proposed rule. These comments state the tiered approach to testing described in the supplemental notice better reflects current sources of agricultural water and farmers' practices related to use of those sources of water. These comments also find the proposed tiered approach less burdensome than the originally proposed requirements. Conversely, several other comments state the revisions to proposed § 112.45 proposed in the supplemental notice result in a testing scheme that is overly complicated, burdensome, lacks scientific justification, and does not incorporate sufficient flexibility. These comments state the proposed requirements would impose significant costs on farmers, particularly when agricultural water is derived from multiple water sources and/or when the quality of water from a source is highly variable.

(Response) In the 2013 proposed rule, we proposed requirements for specific frequencies of testing untreated surface water used for the purposes in proposed § 112.44, ranging from once every 7 days to once per month during the growing season, depending on certain specified circumstances related to the source of untreated surface water. A majority of stakeholder concerns with those proposed testing frequencies centered on the financial burden imposed on farms, in particular, under a weekly testing requirement; arguments that FDA did not provide scientific data in support of the proposed testing frequencies; and the need for a more flexible approach accounting for the variability in water quality associated with various water sources and the particular use of the water during growing, harvesting, or postharvest activities. Taking into account these comments, in the supplemental notice, we made the proposed requirements

more flexible by proposing tiered approaches to testing untreated surface water (proposed § 112.45(b)) and untreated ground water (proposed § 112.45(c)).

We continue to believe our proposed tiered approaches for testing untreated surface water and untreated ground water used for certain purposes will allow farms to make decisions about safe use of available water sources prior to the beginning of the next growing season; adjust testing frequencies dependent on long-term test results and historically derived data; and reduce the required frequency of testing from the testing requirements of the originally proposed rule. A key objective of our requirements for water testing in relation to the microbial quality criteria in § 112.44(b), specifically, is to establish a testing approach sufficient to adequately characterize the quality of the agricultural water such that the information can be used by farms to make informed and appropriate decisions about its use and/or the need for any appropriate corrective actions, prior to such use in the future.

We explained our scientific basis, and underlying statistical analysis, for these testing frequencies in a reference memo that accompanied the supplemental notice, which we have updated for the purposes of this rule (Ref. 99). Our evaluation indicates that minimum sample sizes of 20 samples for initial survey and of 5 samples for annual survey, which we are establishing in our testing scheme for untreated surface water in § 112.46(b), are necessary to provide sufficient precision of estimation of the microbial quality profile (which includes GM and STV values for generic E. coli) in order to then use that information to determine and verify appropriate conditions of use of that water (Ref. 99). Similarly, for untreated ground water, we conclude that a minimum sample size of 4 samples for initial survey and of 1 sample for annual survey is necessary when the previous samples have met the microbial quality criteria under the testing scheme that we are establishing in § 112.46(b).

We have introduced flexibility into the testing requirements to minimize burden to the extent possible. For example, we provide flexibility with respect to the timing of sample collection, recognizing the timing of the use of agricultural water in a direct application method during growing varies by crop, region, season, and/or from year to year. This flexibility is intended to permit farms to tailor their sampling of water to the unique circumstances relevant to their crop(s) and practices and conditions on their farm. In addition, in new § 112.49(c) and (d), we are allowing, under certain specified conditions, the use of an alternative water testing frequency in lieu of the required minimum number of samples for initial and annual surveys under § 112.46(b)(1)(i)(A) and (b)(2)(i)(A), respectively, for testing untreated surface water that is used during growing activities using a direct application method for produce (other than sprouts). We are also adding a corresponding provision, in new § 112.50(b)(8) to require documentation of the scientific data or information you rely on to support any such alternative to the required water testing frequencies. In addition, we have also included provisions to permit data sharing among farms as well as to permit covered farms to use data collected by third parties, under certain specified circumstances (see § 112.47(a)). We realize that the testing requirements may be particularly challenging for farms that have multiple agricultural water sources and we encourage farms to provide us with details of their specific situations so that we can consider flexible approaches to testing multiple sources.

Moreover, in final § 112.46(b), we apply the same approach to testing untreated ground water as the approach for testing untreated surface water used during growing for covered produce (other than sprouts) using a direct water application method, except that fewer tests are required at each stage for ground water as compared to surface water (see Comment 225 and Comment 232). We have combined the testing frequency provisions for untreated surface and

ground water used for § 112.44(b) purposes into one provision for editorial reasons and to more clearly demonstrate the differences and similarities between the testing required for the two types of sources when the water is used for the same purpose. We note that this retains the same ground water testing frequency for these purposes as proposed in the supplemental notice as § 112.45(c).

In addition, we are revising proposed § 112.45(c) to separately address the testing of untreated ground water when used for purposes of § 112.44(a) (see final § 112.46(c)).

Similarly, in final § 112.46(c), we have retained the general approach as well as the specific frequency for testing of untreated ground water when used for purposes of § 112.44(a), as proposed in the supplemental notice in proposed § 112.45(c).

(Comment 225) One comment states that it is critical to monitor the quality of water used during growing of produce, and supports testing untreated surface water and untreated ground water used during growing at a greater frequency than the frequency we proposed, to allow earlier detection of any contamination of the water.

(Response) The requirements for testing untreated surface water and untreated ground water used for § 112.44(b) purposes represent science-based minimum standards for the safe production and harvesting of covered produce that we have determined minimize the risk of serious adverse health consequences or death. These testing protocols will enable farms to make decisions about safe use of available water sources prior to the beginning of the next growing season, and to adjust testing frequencies based on long-term test results and historically-derived data. We specify the required testing frequencies that we conclude, based on our statistical analysis, are necessary for sufficient precision of estimation of the microbial

quality profile, considering the average variability in the quality of untreated surface water and ground water sources. However, these provisions do not preclude a covered farm from testing at a greater frequency than that required under § 112.46(b)(1)(i) or 112.46(b)(2)(i), as appropriate based on your observations, experience, and practices related to your agricultural water source(s), farming operation, and commodities.

(Comment 226) One comment suggests that FDA should allow each State to develop its own testing regime for ensuring water meets the microbial quality standard in proposed § 112.44(c), subject to FDA approval. This commenter believes such an approach would allow States to tailor testing requirements to the unique circumstances farms encounter in a particular region and suited to growing conditions and variability of water sources in that region.

(Response) Under the provisions in subpart P of part 112, a State (or tribe or foreign country) may request a variance from one or more of the requirements in part 112. A competent authority in a State that considers a water testing approach that deviates from the requirements in § 112.46 to be more appropriate for covered farms within that State may submit a request for a variance, in accordance with the provisions in subpart P. The request for a variance in relation to the testing requirements may include requests for a different testing scheme for untreated surface water and/or ground water sources (in lieu of the tiered approaches we have established in § 112.46(b)), whereas the provisions for alternatives under § 112.49(c) and (d) are restricted only to the use of alternative testing frequencies in lieu of the frequencies we identified in § 112.46(b)(1)(i)(A) and (b)(2)(i)(A) for untreated surface water, and do not extend to the entire tiered scheme set forth in § 112.46(b) more broadly.

(Comment 227) Some comments assert that the proposed testing frequency requirements in proposed § 112.45 significantly favor use of ground water over surface water, which the commenter believes may be contrary to regional efforts to prevent overdraft of aquifers.

(Response) The differences between the testing frequency requirements for untreated surface water and untreated ground water sources in § 112.46(b) are based on the difference in the expected variability in quality between these two types of sources (see Comment 225 and Comment 232). We have evaluated the potential effects of the produce safety regulation on the human environment in the United States. Our evaluation and conclusions based on that evaluation are described in the final EIS (Ref. 126). We refer you to that document for a detailed discussion of the potential environmental effects of the produce safety regulation, including those associated with the standards for agricultural water in subpart E of part 112. This analysis includes potential impacts related to pesticide use, chemical treatment of agricultural water, changes in ground water demand, and existing water quality standards. FDA has considered these potential impacts when making its decision on the provisions to be finalized (Ref. 150).

(Comment 228) Some comments express concern that the testing approach places burden on covered farms to test water sources, including water they receive from irrigation districts, over which they have no control. One commenter believes the responsibility should be on the government or on the irrigation districts, not the farm. Similarly, another comment points out it may not be possible for farms to correct a contamination problem when the source of contamination is not in their control. Another commenter states that if a farm is receiving water

from an irrigation district, the farm may not know the water quality and cannot establish the appropriate time interval to account for microbial die-off.

(Response) Regardless of the source of water or who supplies it to the farm, a covered farm is responsible for ensuring the safe and appropriate use of that water in covered activities. Therefore, whether or not the irrigation districts provide information about the quality of water they supply to a farm, the covered farm must take measures to understand the quality of water under their control that is used as agricultural water during the growing, harvesting, packing, or holding of covered produce, including complying with the testing requirements in § 112.46 when applicable. Test results obtained through such testing will give farms information about the quality of their water and how it may be used in compliance with the rule.

We understand that many covered farms are dependent on irrigation districts to supply water for use in farming, and some covered farms have no control over the quality of the water at the time and place at which they receive the water. We encourage irrigation districts to conduct sampling and testing around the watershed that they manage and to share the data on its water quality with farms that receive the water from that watershed. As described in the supplemental notice, for example, covered farms sourcing water from an irrigation district may consider using water testing data from the district sampling program. A covered farm considering the district sampling program data would need to determine whether the water source(s) sampled adequately represent the covered farm's agricultural water. The covered farm would also need to consider whether the district's data set includes samples collected during a time period(s) as close as practical to the covered farm's harvest time; whether the district's data set satisfies the minimum number of samples the farm is required to have under the rule; and whether the district's data were obtained using appropriate test methods, as

described in subpart N of part 112 and cross-referenced in new § 112.47(b). In addition, the covered farm would need to get and keep records of the district's testing that satisfy the rule's recordkeeping requirements.

(Comment 229) Several comments ask for guidance, technical assistance, and outreach related to water testing requirements, including sampling methods and procedures, so farms know how to properly collect samples, process them for testing, and transport them in a sanitary manner. Some comments state that the GM and STV calculations and subsequent analysis necessary to test, verify, and ensure compliant use of agricultural water, are complicated, and that most farmers do not have the expertise necessary to implement these provisions.

(Response) In section XXII of this document, we discuss our plans to work with various organizations on outreach and education for effective implementation of the produce safety regulation. We agree training and outreach will be necessary to ensure covered farms understand the water testing requirements. Relevant staff will need to be appropriately trained to properly sample, test, and make the necessary calculations to determine how best to use their water. We will consider addressing relevant issues, including appropriate water sampling methods and procedures, in the Produce Safety Regulation implementation guidance to be issued in the near term. In addition, we are exploring the development of an online tool to allow covered farms to derive their GM and STV values and appropriate time intervals between last irrigation and harvest using the 0.5 log per day die-off rate, based on input of sample data, such that farms would not need to perform the necessary calculations themselves.

(Comment 230) Several comments ask for clarification on whether and how testing requirements apply in relation to water used during different stages of growing or production, particularly in reference to contact with the “harvested or harvestable portion” of the crop. For example, one comment asks whether and how proposed § 112.45(b) applies to water used in frost protection sprays, prior to any flowering or fruit production, in tree crops.

(Response) The testing requirements in § 112.46(b) require samples to be collected as close in time as practicable to, but prior to, harvest. These requirements are intended to provide a true reflection of the agricultural water that is representative of your use of the water and near the time of harvest, so the data can then be used to determine the appropriate use of that water. In § 112.3(c), we define “agricultural water” to mean water used in covered activities on covered produce, where water is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce). Moreover, we define the term “covered produce” in relevant part to refer to the harvestable or harvested part of the crop. Under these definitions, water used on a tree crop prior to any flowering or fruit production does not constitute “agricultural water” because it is not intended to, or likely to, contact covered produce (meaning the harvestable or harvested part of the crop) or food-contact surfaces.

(Comment 231) One comment expresses concern about the extent to which imported produce would be subject to the agricultural water quality requirements, and recommends that

foreign producers be required to have evidence of water testing and monitoring to ensure that they are meeting the same requirements as domestic farms.

(Response) Under the final FSVP rule (published elsewhere in this issue of the Federal Register), FDA is establishing requirements for importers to verify that imported food, including produce, is produced in compliance with applicable FDA food safety regulations, including this rule, or is produced in accordance with processes and procedures that ensure the same level of public health protection as is required under these regulations in the United States. For imported produce, this will mean that importers must verify that imported produce was grown, harvested, packed, and held in accordance with the same agricultural water requirements, or equally protective measures, as domestic produce. Importers must have documentation of this verification which, in the case of produce that will not be manufactured/processed, is likely to be accomplished through an on-site audit.

(Comment 232) Several comments support the use of greater minimum testing frequencies for untreated surface water sources as compared to untreated ground water sources used for the same purposes. Conversely, several other comments state that there should be no difference between minimum testing frequencies for surface water and ground water sources. This latter set of commenters believe the testing parameters should instead be consistent across the different water sources but should still be science-based and reflect risks assessed for each operation.

(Response) We disagree with comments arguing that water from surface water and ground water sources should be tested at the same frequency. The approach we are adopting for water testing in § 112.46 is responsive to comments that requested that we establish a risk-based,

flexible testing approach that accounts for variability in microbial water quality from different sources, considers the specific use of water from a particular water source, and contemplates the reduced likelihood of contamination from well-designed and adequately maintained water systems. As described in the 2013 proposed rule, surface watersheds are subject to a great number of external forces that shape their overall composition, chemistry, and microbial water quality (e.g., erosion, run-off, dust, suspended sediments). In contrast, ground water sources typically contain microorganisms, including pathogens, much less frequently, due to the natural filtering mechanism of soil (Ref. 118). We recognize, however, that ground water, which is often believed to be more protected from contamination, can be contaminated. Ground water can be compromised and its microbial water quality degraded if wells are improperly constructed, poorly maintained, improperly located (e.g., near areas of extensive livestock production or fields where manure is applied) or if the wells are drawing water from a contaminated aquifer (Ref. 119) (Ref. 151) (Ref. 152) (Ref. 153) (Ref. 154). On the other hand, by their nature, surface waters are open systems, subject to the influence of various environmental factors that can impact the safety of the water. For example, increased precipitation levels, storm events, or run-off may result in a spike in microbial population of the water due to external inputs. We conclude that, although there exists significant potential for contamination of both ground and surface waters, surface water sources are inherently subject to a greater potential for contamination than properly designed, constructed, and well-maintained ground water sources. Therefore, although we require you to test both ground water and surface water sources used for certain purposes, where both types of sources may be used for the same purpose under § 112.44(b), we require a lesser frequency of testing for ground water than for surface water sources (see § 112.46(b)). We acknowledge that ground water sources can become contaminated, for example, if they are

improperly maintained. The testing frequencies established in § 112.46 for such sources, and the requirements in § 112.42 to regularly inspect and maintain such sources, are designed to address this possibility.

It is important to note that some water that comes from underground is subject to direct influence by surface water, and therefore is not considered “ground water” for purposes of this rule. In the 2013 proposed rule, we proposed a definition of “surface water” as, “all water which is open to the atmosphere and subject to surface runoff, including water obtained from an underground aquifer that is held or conveyed in a manner that is open to the atmosphere, such as in canals, ponds, other surface containment or open conveyances” to distinguish such water sources from other water sources that are less likely to become contaminated, i.e., “ground water” sources (see 78 FR 3504 at 3548). We are now establishing a definition of “ground water” in § 112.3(c), and revising the definition of “surface water” in that section, to clarify the differences between the two sources for the purposes of this rule. The definition of “ground water” is “the supply of fresh water found beneath the Earth’s surface, usually in aquifers, which supply wells and springs. Ground water does not include any water that meets the definition of surface water.” We are amending the definition of “surface water” to read, “All water open to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors that are directly influenced by surface water.” Through inclusion of the phrase, “all springs, wells, or other collectors that are directly influenced by surface water,” the definition of “surface water” includes, for example, water drawn from an underground aquifer that has been recharged with surface water (i.e., an aquifer into which humans have injected surface water to replenish the aquifer). The definition of “ground water” also specifies that “[g]round water does not include any water that meets the definition of surface

water.” Thus, where a ground water source is directly influenced by surface water, it no longer meets the definition of “ground water” and must be considered to be surface water for the purposes of this rule. “Directly influenced by surface water” includes direct influences that are significant, such as a consistent inflow of surface water. The term “collectors” in the definition of “surface water” means sources of accumulated water or vessels that collect and hold accumulated water such that it may be subject to external influence. See also discussion under Comment 184.

The specific frequencies for testing that we have established in § 112.46 are intervals that are reflective of the varying potential for changes in water quality between ground water sources and surface water sources. Our analysis suggests that a minimum number of samples required in “average” surface water sources would be 20 samples, assuming a standard deviation of 0.4 (of log abundance of E. coli). If you have a discrete surface water source that is minimally impacted by external forces, such as run-off, such that there is less variation in its microbial quality than an average surface water source, you may be able to test the water at frequency lower than that required in § 112.46(b)(1)(i)(A) or § 112.46(b)(2)(i)(A). To account for such circumstances, we are providing in § 112.49(c) and (d) for the use of an alternative testing frequency (in lieu of those required in § 112.46(b)(1)(i)(A) or § 112.45(b)(2)(i)(A)), under the conditions specified in § 112.12. On the other hand, because ground water sources (as we have defined “ground water” in § 112.3(c)) are generally less variable, the required testing frequency for ground water in the rule is lower than for surface water when both types of sources may be used for the same purpose (see § 112.46(b)), and no alternative option for different testing frequencies is available for ground water sources.

(Comment 233) Several comments state the importance of making sure that water tests are conducted properly by certified and accredited labs. Some comments ask FDA to establish standards and procedures for third-party laboratories that perform the tests.

(Response) We are currently working on a proposed rule to implement section 202 of FSMA (section 422 of the FD&C Act), which addresses “Laboratory Accreditation for Analyses of Foods.” Neither model laboratory standards nor laboratory accreditation are within the scope of the produce safety regulation in part 112.

Water testing required under this rule must be conducted using certain methods in accordance with § 112.151, as required under § 112.47(b). In addition, we are specifying in 112.47(b) that agricultural water samples must be aseptically collected. Aseptic sampling, often used for product and environmental samples, is a sampling technique used to assure that the microbial load of a sample is not affected by the sampling method and/or the sample collector does not contaminate the source from which the sample is collected. The use of sterile sampling implements and containers and a prescribed sampling method defines aseptic sampling (Ref. 155) (Ref. 156) (Ref. 157). Collecting and delivering samples to the laboratory using an aseptic technique also helps assure the microbiological findings accurately reflect the agricultural water at the time of sampling.

3. Timing of Collection of Water Samples for Testing Required Under § 112.46(b) and (c)

(Comment 234) Some comments request clarification on the meaning of the phrases, “as close to harvest as practical,” “during growing activities,” and “as it is used”, which we used in proposed § 112.45(b) and/or § 112.45(c). Some comments point out the time period for harvesting varies across regions and ranges from a few days to several months or year round.

Other comments support the provision as proposed, and state that it allows the time frame to be determined by the farmer based on the wide variation in growing seasons, overlap of growing seasons for multiple crops, and likelihood of pathogen die-off prior to harvest.

(Response) For testing of untreated surface water or untreated ground water used during growing activities using a direct water application method, the initial and annual survey samples must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest (see § 112.46(b)(1)(ii) and § 112.46(b)(2)(ii)). We recognize the timing of the use of agricultural water using a direct application method varies by crop, region, season, and/or from year to year. By revising the rule to use the term “representative of your use of the water” in lieu of “as it is used,” we intend to clarify that agricultural water should be collected for analysis around the time of harvest so that samples will be representative of the water that is applied during the end of the growing season. Samples collected from the source water when it is not being applied to the crop would not fulfill this requirement. We intend the wording “collected as close in time as practicable to, but prior to, harvest” to permit farms to tailor their sampling of water to the unique circumstances relevant to their crop(s) and practices and conditions on their farm. The agricultural water applied prior to harvest must be targeted for sampling, recognizing that in some circumstances such applications may not be preplanned (e.g., application of crop protection water due to early frost or unusually hot, dry weather). Further, sample collection should be designed to represent events that can reasonably be expected to both impact water quality (e.g., rainfall wildlife and domesticated animal movement through upstream water systems) and occur during the end of the growing season. We expect covered farms to determine the appropriate time for sampling to meet the requirements that samples be collected during a time period(s) as close as practicable

to harvest, while recognizing that samples of agricultural water taken more than a few weeks prior to harvest are less representative of the agricultural water applied at the end of growing when the risk of produce contamination is greater. We anticipate seasonal trends in microbial water quality that can be captured in the long-term microbial water quality profile. In addition, we do not consider multiple samples collected in a single day to provide adequate variation as the distribution estimates resulting from such a sampling plan would defeat the purpose of the microbial water quality profile. We also do not consider samples collected after the final harvest of the crop (for a single crop farm) to be representative of the agricultural water applied to that crop.

In addition, we intend the wording “representative of your use of the water” and the requirement that samples must be “collected as close in time as practicable to, but prior to, harvest” to ensure that, when testing water used for growing activities of produce (other than sprouts) using a direct application method, the samples for initial and annual surveys are collected prior to harvest and at a time that can be reasonably expected to represent the quality of the water when it is being applied to the crop. Collection before harvest is necessary in order for the samples and the microbial water quality profile to represent the water used for the purposes in § 112.44(b). Collection close to harvest is necessary because there are certain seasonal variations in water quality that may be relevant to the microbial water quality profile, such as harvesting during a time of heavy, seasonal rains or harvesting of commodities at the end of the summer when water temperatures may be elevated compared to the beginning of the summer. The microbial water quality profile is intended to capture long-term trends related to quality of water as it is used close to harvest, and sample collection must be done with the understanding that recurring patterns of water quality variations are often seen on an annual

basis. See also a discussion of the definition of “direct water application method” in section IX.B of this document.

On the other hand, for untreated ground water used for purposes of § 112.44(a), considering the nature of different uses spanning across different covered activities specified in that provision, we require that samples be taken at least four times either during the growing season or over a period of one year, as applicable, using a minimum total of four samples collected to be representative of the intended use(s) (see § 112.46(c)). See Comment 229.

4. Clarification of Terms Used in § 112.46

(Comment 235) Some comments oppose the use of the term “water quality profile,” stating the concept is not clearly explained and/or not necessary.

(Response) As used in this rule, “microbial water quality profile” generally refers to the set of data that provides information about the microbial quality of water from a specific water source, based on which a covered farm can determine whether the water meets the microbial quality criteria in § 112.44(b) and make a decision regarding corrective measures, as necessary, under § 112.45(b). The microbial water quality profile consists of two numerical values of generic E. coli in the water: the GM and the STV. The GM and STV values are initially calculated using data obtained in an initial survey and updated annually thereafter. The GM and STV values are initially derived based on the initial survey data set (described in § 112.46(b)(1)), which consists of a minimum total of 20 samples for untreated surface water sources (taken over at least 2 and no more than 4 years) and 4 samples for untreated ground water sources (taken during the growing season or over a period of one year). The GM and STV values are then revised annually based on annual survey data (described in §

112.46(b)(2)). For untreated surface water sources this entails taking at least 5 new samples, and for untreated ground water this entails taking at least one new sample. The new samples are then combined with your most recent data from within the previous 4 years, to make up a rolling dataset of 20 samples for untreated surface water and 4 samples for untreated ground water, and the GM and STV values are recalculated using this updated data set to update the microbial water quality profile.

(Comment 236) Some comments request clarification on the meaning of “statistical threshold value.”

(Response) The “statistical threshold value” is a value that approximates a specified percentile of a distribution, which depends upon the inherent variability of the observations in a sample set as well as their central tendency. For purposes of the testing requirements in § 112.46(b) and (d), STV is a value that is derived as a model-based calculation based on the lognormal distribution and approximates the 90th percentile of the water quality distribution. For clarity, we are specifying in § 112.44(b) that “STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution.” See also our discussion in the supplemental notice at 79 FR 58434 at 58444 for additional information. We note that we are exploring the development of an on-line tool that you can use to derive STVs and certain other values (such as GM values and appropriate time intervals (in days) between last irrigation and harvest using the 0.5 log per day die-off rate) based on input of sample data, such that a farmer would not need to perform the necessary calculations themselves.

(Comment 237) Several comments request clarification on the meaning of the term “water source,” as it relates to the water testing requirements in proposed § 112.45(b), (c), and (d). One comment recommends that FDA broadly define “water source” as “any reasonable portion of a watershed where a sanitation survey identifies no reasonably foreseeable point or nonpoint source of microbial discharge between agricultural water and withdrawal points.” Another comment provides an example of an open irrigation ditch and questions whether water samples would be required for each irrigation district, at each pump site or water box, for each block or branch of the irrigation system, or for each sprinkler head. This commenter also asks whether a farm using multiple sources of water for irrigation would need to conduct a baseline survey of 20 samples over two years for each source. Comments ask whether a single source can be used for multiple commodities or to irrigate noncontiguous fields. Another comment notes testing agricultural water stored in holding containers (such as barrels) would be impractical and expensive.

(Response) We consider each agricultural water source in your operation to be a discrete body of water that is representative of the microbial quality of agricultural water from that source used in your growing, harvesting, packing, or holding activities. For example, if you have a surface water impoundment on your farm that stores water to be used as agricultural water, but you also source water from a river that you use for the same purpose, you would need to consider these two to be two different water sources, as each delivers water that is distinctly different in origin and likely to differ in overall composition and characteristics. Or if, for example, you source some water directly from a properly constructed well on your property, and you also draw water from the same source and hold it in a holding pond on your property that is open to environmental influences before you use it, you would need consider

the well and the holding pond to be two separate water sources (the well would be a ground water source, and the holding pond would be a surface water source). Where water testing requirements apply, they apply to each water source individually. There is no difference in testing requirements based on whether the water is used for multiple commodities, or applied over non-contiguous fields. We realize that the testing requirements may be particularly challenging for farms that have multiple agricultural water sources and we encourage farms to provide us with details of their specific situations so that we can consider flexible approaches to testing multiple sources.

Section 112.42(a) requires you to inspect your water distribution systems to the extent that they are under your control, including considering different factors identified in (a)(1) through (a)(5). Therefore, for example, provided you have inspected your water distribution systems in compliance with § 112.42 and you have determined there is no additional exposure to potential contamination along your distribution system from your ground water to the sprinkler heads, collecting water samples from the ground water would sufficiently represent your water source such that you would not need to additionally collect water samples at the sprinkler head(s). This rule is not prescriptive about the exact point of collection of water samples when testing is required, but it requires that all water samples must be representative of your use of the water (see § 112.46(b) and (c)).

5. Minimum Number of Samples for Initial Survey (§ 112.46(b)(1)(i)(A)) and/or Annual Survey (§ 112.46(b)(2)(i)(A)) Related to Testing of Untreated Surface Water Used in a Direct Water Application Method During Growing Activities

(Comment 238) Some comments oppose the proposed minimum number of samples required for the proposed baseline and annual surveys for untreated surface water used in a direct water application method during growing activities for covered produce other than sprouts. These comments ask that we align the testing frequency requirements with the guidelines in USDA GAPs, which according to these comments recommend testing three water samples during the growing season.

(Response) The testing frequency we proposed, and are now finalizing in § 112.46(b) for untreated surface water used for § 112.44(b) purposes, is based on the minimum number of samples needed to do the relevant calculations to characterize the untreated surface water source used as agricultural water for purposes of § 112.44(b), given certain expectations about the variability of that source. For untreated surface water sources, where measurements of \log_{10} abundance of generic E. coli are expected to exhibit an average (population) standard deviation of 0.4, our evaluation indicates that when water quality is stable, neither deteriorating nor improving over time, a sample size of 20 for initial or for a moving window of most recent observations from initial and/or annual surveys would provide sufficient precision of estimation of the microbial water quality profile (GM and STV of indicator bacteria) to determine appropriate conditions of use. In the absence of detailed information concerning how frequently changes occur in water quality of surface water sources, and what patterns and magnitude of changes are most likely, it is not possible to determine a best or optimal frequency by which prior data should be replaced by more current survey data within a moving window of observations collected over multiple years. However, based on an assessment of the magnitude of bias in estimates of \log_{10} GM and \log_{10} STV for hypothetical changes in population \log_{10} GM, a minimum sample size of 5 for annual surveys, being 25 percent of the minimum of 20

samples found to be sufficient to determine appropriate conditions of use, provides a reasonable degree of compromise between the competing objectives of having estimates of the microbial water quality profile sensitive to sudden and substantive changes in water quality and minimizing the number of samples collected annually when water quality is relatively stable and unchanging (Ref. 99). Therefore, we are establishing the minimum testing frequencies as 20 samples for the initial survey required under § 112.46(b)(1)(i) and 5 samples for the annual survey required under § 112.46(b)(2)(i). To provide flexibility and account for sources of water that have less variability in their quality than that assumed in our calculations, we are providing for the use of an alternative testing frequency in lieu of the required minimum number of samples, in § 112.49(c) and (d), provided the conditions in § 112.12 are met. With respect to comments about USDA's GAP guidelines, we plan to work with USDA as they update their GAPs audit program to align with the requirements of the produce safety regulation.

(Comment 239) Several comments state that the proposed minimum number of 20 samples for the proposed baseline survey, under proposed § 112.45(b)(1)(ii), is excessive, too stringent, and/or does not take into consideration critical site-specific variables of surface waters. Comments also point out that the 20-sample minimum requirement is a statistical construct, and argue that it was not selected as an indicator of food safety, arguing that the time and location of sampling are far more important than the number of samples. Others contend that 20 samples over two years would be burdensome or impracticable for certain commodities or in certain regions. For example, one comment states that the proposed frequency is not practicable in the mid-Atlantic States, where the commenter notes overhead irrigation is often used fewer than ten times per year, depending on the crop. This commenter also points out strawberry farms often

only apply overhead irrigation as frost control one to three times per season, and crops are often rotated and farms may change water sources every three to four years. Similarly, another comment argues that the proposed 20-sample minimum would be impracticable for certain crops, such as cherries and berries, which have a harvest period of approximately 20 days. Another comment recommends that baseline characterization should be done once a month during the growing season with a minimum of three times per season, but that the required testing frequency should never be greater than the frequency of irrigation. Still other comments that suggest aligning the frequency for baseline characterization for untreated surface water with that for untreated ground water, recommend requiring testing at least four times during the growing season or over a period of 1 year, using a minimum total of four samples. These comments argue that four tests for untreated surface water, particularly when based on effective sample collection (e.g., time of day, depth, and at high or low flow of water), provide an appropriate range for farms to use in establishing the profile of their water quality.

(Response) As previously explained, a sample size of 20 for the initial survey for untreated surface water used in a direct application method is the minimum necessary to provide sufficient precision of estimation of the microbial water quality profile to determine and verify appropriate conditions of use of the water based on certain expectations about the average variability of \log_{10} E. coli abundance (Ref. 99). Therefore, we are retaining the requirement for a minimum sample size of 20 samples in § 112.46(b)(1)(i)(A). However, we acknowledge the concerns commenters raised about the impracticability of collecting 20 samples in 2 years, as the water is used during growing activities using a direct water application method and collected as close in time as practicable to, but prior to, harvest, particularly for certain commodities or irrigation practices where the time period of direct application of agricultural water is short or

variable. The minimum 20 samples for the initial survey are required to be collected over a minimum (not maximum) of 2 years such that, in the circumstances where direct application periods are short, you may collect your samples over more than 2 years. We believe a minimum period of 2 years is necessary to provide an adequate representation of the microbial quality of agricultural water to enable informed decisions about its use in a direct application method. However, we are also adding a requirement that the 20 samples for the initial survey must be collected within a time period not greater than 4 years. This limitation on the use of older data is intended to ensure that the data used adequately represent the current microbial quality of your untreated water source. Therefore, you may collect your water samples for the initial survey over a period of four years to make up the minimum sample size of 20 samples to then establish your microbial water quality profile. We expect that farms will use this option to collect initial survey samples over more than 2 years and up to 4 years in circumstances with short timeframes for direct application of agricultural water, for example.

(Comment 240) One comment recommends the necessary number of samples for the proposed baseline survey should be based on a study of available historical data on quality of that water source.

(Response) As previously explained, we conclude a minimum sample size of 20 samples is necessary for the initial survey, assuming a standard deviation of 0.4 (of log abundance of E. coli). If you have evidence the microbial quality of your untreated surface water source is less variable than that assumed in our calculations, including based on your historical data (provided such data are representative of the current quality of your water and were gathered within the previous four years), you may be able to use a testing frequency that

is lower than that required in § 112.46(b)(1)(i)(A) or § 112.46(b)(2)(i)(A). To account for such circumstances, we are providing for the use of an alternative testing frequency in lieu of the required minimum number of samples (see §§ 112.49(c) and (d) and 112.12).

(Comment 241) Some comments state the proposed minimum 20 samples for baseline survey for each untreated surface water source would be economically burdensome, especially for small farms, with no appreciable increase to produce safety. These comments also contend that reducing the testing frequency (and thereby reducing the significant burden on small farmers) would be consistent with the public health goals of the rule.

(Response) See our response to Comment 235 where we explain our rationale for the minimum testing frequencies we are establishing in § 112.46(b)(1)(i)(A) for the initial survey. We intend to work with stakeholders to develop a network of institutions that can provide technical assistance to the farming community, especially small and very small farms, as they endeavor to comply with the provisions of the final rule. Moreover, we are providing for extended compliance periods of an additional 2 years each for covered activities involving covered produce (except sprouts), which results in compliance periods of 6 years for very small farms, 5 years for small farms, and 4 years for all other farms for compliance with certain water provisions, § 112.46(b) among them (except § 112.46(a) and (b)(1) with respect to untreated surface water sources) as explained in response to Comment 240 and in section XIII.K of this document. (See also section XXIV for compliance dates for covered activities involving sprouts, which are subject to all of part 112 including subpart M). We also have included certain size-based provisions, including a coverage threshold and a qualified exemption described in §§ 112.4 and 112.5.

(Comment 242) Several comments oppose the minimum sample size of five samples for the annual survey, under proposed § 112.45(b)(2)(i), stating that such a frequency of testing is unnecessary, burdensome, and not scientifically determined. These comments suggest different acceptable minimum samples sizes ranging from three samples annually (along with a request to align with USDA GAPs guidelines) to one sample annually.

(Response) See our response to Comment 238 where we explain our rationale for the minimum testing frequency we are establishing for the annual survey in § 112.46(b)(2)(i)(A) and our intent to work with USDA as they update their GAPs audit program to align with the requirements of the produce safety regulation.

6. Use of Historical Data for Testing Untreated Surface Water Used in a Direct Water Application Method During Growing Activities (§ 112.46(b))

(Comment 243) Some comments note farms currently conduct water testing (including, for example, consistent with relevant industry guidelines) and maintain these historical data, and ask that these farms be allowed to use such data in their baseline survey to establish the water quality profile. Comments also request FDA to clarify that farms would be able to start collecting samples immediately on publication of the final produce safety rule to allow sufficient time to conduct the proposed baseline survey.

(Response) To develop the microbial water quality profile required under § 112.46(b)(1) for untreated surface water used in growing covered produce other than sprouts using a direct water application method, covered farms are required to conduct an initial survey over a minimum period of 2 years and not greater than 4 years, using a minimum total of 20 samples.

We do not expect farms to incur additional sampling costs to satisfy the initial survey requirement in § 112.46(b)(1), if they already possess sufficient microbial water quality data (consisting of the minimum required number of samples) collected in the manner required under § 112.46(b). Under these circumstances, a farm is permitted to use available historical microbial water quality data, from the previous four years, to make up the minimum 20 samples to calculate the current microbial water quality profile. Moreover, covered farms will have an additional 2 years, i.e., a total of 4 to 6 years, depending on farm size, from the effective date of this rule for compliance with the water testing provisions in § 112.46, except § 112.46(a) and (b)(1) with respect to untreated surface water, for covered activities involving covered produce (except sprouts).

We exclude § 112.46(b)(1), with respect to untreated surface water only, from the 2-year extended compliance period provided for the remainder of § 112.46 because, in order to comply with the microbial quality criteria in 112.44(b), farms must have developed a microbial water quality profile based on the initial survey conducted over a minimum of 2 years and not greater than 4 years. Accordingly, to develop the microbial water quality profile prior to the point at which they must comply with all of the requirements of subpart E, covered farms must begin water sampling and subsequent testing not later than 4 years after issuance of this rule for very small farms; not later than 3 years after issuance of this rule for small farms; and not later than 2 years after issuance of this rule for all other farms. If they choose to, a farm that is not small or very small can begin water sampling and subsequent testing as early as when this rule is published, and expect to use those test results to comply with the rule by the compliance date. Initiating water sampling upon publication of this rule will allow those covered farms to collect 5 samples per year over the next four years, sufficient to make up the minimum 20 samples

necessary to develop the microbial water quality profile required under § 112.46(b) at the point at which they must comply with all of the requirements of subpart E. On the other hand, if these covered farms initiate water sampling two years after issuance of this rule, the farms will need to collect 10 samples per year over the next two years to make up the minimum 20 samples necessary to develop the microbial water quality profile. In either instance, the covered farms will have sufficient time to develop a microbial water quality profile and determine the appropriate way(s) in which to use water from that source based on that profile, in accordance with § 112.45(b)(1) through (b)(3). Covered farms that are small and very small may decide not to begin testing upon issuance of this rule with the expectation of using those test results at their compliance date because they are not required to have established the microbial water quality profile under § 112.46(b) until 5 and 6 years, respectively, after the effective date of this rule and because farms must use data that are no more than 4 years old to establish their microbial water quality profile. We are not similarly excluding § 112.46(b)(1) with respect to untreated ground water from the extended compliance period because the amount of time needed for the initial survey for such sources is significantly shorter (compare § 112.46(b)(1)(i)(A) and (B)).

Note that the exclusion of § 112.46(b)(1) with respect to untreated surface water from the extended compliance period does not mean that covered farms must bring untreated surface water used for § 112.44(b) purposes into compliance with that microbial quality requirement within the 2-4 year compliance period (depending on farm size) applicable to the remaining provisions of this rule. Rather the exclusion is intended to ensure that covered farms will begin collecting and testing samples and obtain data to develop the microbial water quality profile necessary to then comply with the remainder of the water requirements, for which the extended compliance period of 4 to 6 years (depending on farm size) applies.

We are also excluding § 112.46(a) from the extended compliance period because this provision provides an important exception to the testing requirements in § 112.46(b)(1) and is referenced therein. Section 112.47 is also subject to the shorter compliance period because it establishes requirements that are relevant to testing requirements when they become applicable.

We are not similarly providing extended compliance periods for these specified water requirements, in the case of covered activities involving sprouts, as discussed in section XVIII.J of this document. Therefore, covered farms must comply with all of the applicable requirements of part 112, including subpart E, for all covered activities involving sprouts, within one to three years of the effective date of the rule, depending on the size of the farm. See also section XXIV for additional information.

7. Updating the Microbial Water Quality Profile Annually for Water Used in a Direct Water Application Method During Growing Activities (§ 112.46(b)(2))

In the supplemental notice, we acknowledged that there are certain limitations to our proposed tiered approach, particularly regarding whether and how annual verification data may be used to identify the need for changes to water use practices in the current season and/or the need for a new water quality profile. For example, we asked if there is a threshold based on magnitude of deviation indicated in an annual survey that would suggest that the existing water quality profile is no longer representative of the current water quality.

(Comment 244) Some comments disagree that water quality profiles should be re-characterized every ten years, as would have been required under proposed § 112.45(b)(1)(iii)(A), and, instead, recommend applying a rolling set of samples such that the

water quality profile is updated on an ongoing basis. Similarly, one other comment recommends eliminating the concept of a baseline water quality profile followed by an annual verification survey, in favor of a rolling geometric mean coupled with appropriate guidance on steps to take when a test exceeds a threshold limit; however, this commenter did not further specify what such threshold limit should be. One comment states that a single high test result should be followed-up by retesting to confirm the previous finding and rule out a potential false positive. Another comment finds it unclear whether and when the water quality profile would need to be re-characterized based on annual survey test results.

(Response) We are making several revisions to our proposed baseline and annual survey provisions to simplify the requirements related to developing a new or updated microbial water quality profile, while retaining the advantages of the tiered approach proposed in the supplemental notice. We are also combining the testing provisions for untreated surface water and untreated ground water sources used for direct water application during growing covered produce other than sprouts into the same provision (§ 112.46(b)).

We are revising our tiered approach to testing by, first, eliminating (1) the proposed requirement to develop a new water quality profile at least once every 10 years (proposed § 112.45(b)(1)(iii)(A)); and (2) the proposed requirement that, if the GM and/or STV values of the annual survey samples do not support your water quality profile and therefore your existing water use as specified in § 112.44(c), you must develop a new water quality profile (proposed § 112.45(b)(2)(ii)).

Second, in lieu of the eliminated provisions, we are adding these revised requirements in final § 112.46(b)(2): (1) Following the development of the microbial water quality profile based on an initial survey, you must test water annually to update your existing microbial water quality

profile to confirm that the way(s) in which the water is used continues to be appropriate. You must analyze a minimum number of five samples per year (for untreated surface water) or one sample per year (for untreated ground water). These samples must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest (§ 112.46(b)(2)(i) and (ii)); and (2) To update the microbial water quality profile, you must calculate revised GM and STV values using your current annual survey data, combined with your most recent initial or annual survey data from prior years, but within the previous 4 years, to make up a rolling data set of at least 20 samples (for untreated surface water) or 4 samples (for untreated ground water) (§ 112.46(b)(2)(iii)); and (3) You must modify your water use, as appropriate, based on the revised GM and STV values in your updated water quality profile, in accordance with § 112.45(b)(1) through (3) (§ 112.46(b)(2)(iv)), as soon as practicable, and no later than the following year.

This revised approach, which relies on an annually updated microbial water quality profile comprised of rolling GM and STV values, has several advantages compared to the approach proposed in the supplemental notice. It maintains the advantages of the tiered approach proposed in the supplemental notice compared to the originally proposed approach in the 2013 proposed rule in that it reduces the required frequency of testing compared to the originally proposed requirements. It also maintains the flexibility of the tiered approach by allowing farms to make decisions about safe use of available water sources as soon as practical, but no later than the following year, as well as adjusting testing frequencies based on long-term test results. In addition, unlike the approach in the 2013 proposed rule, use of GM with accompanying STV values eliminates the need for a single sample maximum threshold, while accounting for variability of water quality and occasional high sample results that could highlight potential risk

associated with use of the water. Moreover, the revised approach established in § 112.46(b) eliminates the need for specific thresholds based on annual verification survey data to determine whether and when a new microbial water quality profile is needed (using, for example for untreated surface water sources, previous years' 15 samples versus a complete new set of 20 samples).

Under this revised approach, codified in § 112.46(b), covered farms must develop an updated microbial water quality profile, consisting of revised GM and STV values based on each year's annual survey of a minimum of 5 samples or 1 sample (for untreated surface water, or untreated ground water, respectively) plus the data of the most recent 15 samples or 3 samples (for untreated surface water, or untreated ground water, respectively) collected within the previous 4 years to make up the minimum 20 samples or 4 samples (for untreated surface water, or untreated ground water, respectively) necessary to establish the GM and STV values. Under this approach, the microbial water quality profile is continually updated on an annual basis so that changes in the water quality can be identified to inform any necessary modifications to practices. You must make those modifications to practices as soon as practical, and no later than the following year. If you are aware, based on your GM and STV, that you need to make modifications in your water use practices and it is practicable for you to make those modifications for the crop in the field at the time you receive your test results, at your next harvest if you have multiple harvests of a crop, or during the next growing season if you have multiple growing seasons within a calendar year, you must do so. If none of these timeframes are practicable or applicable to your operation, you must make the modifications to your water use practices no later than the following year.

This approach also alleviates the complexity around determining when to re-characterize the microbial water quality profile. For example, if a single crop farm with a single surface water source calculates the GM of 20 untreated surface water samples at the end of the growing season in year 3 to be 126 CFU generic E. coli /100 mL and the STV of 20 samples to be 300 CFU generic E. coli /100 mL, and then determines the updated GM at the end of the growing season in year 4 to be 200 CFU generic E. coli /100 mL and his STV to be 450 CFU generic E. coli /100 mL, the farm can adjust its practices for year 5, such as to include a 1 day die-off interval, reflecting the change in the water quality profile. In year 5, the farm finds the GM to be 230 CFU generic E. coli /100 mL, and STV to be 460 CFU generic E. coli /100 mL. No further mitigation strategy (beyond the 1 day die-off interval) is required in this scenario from the previous year, because the farm's existing practices reflect the required mitigation strategies to achieve the microbial water quality criteria in § 112.44(b). While the GM and STV do not match exactly those from the previous year, the farm recognizes that its mitigation strategies are still sufficient to meet the § 112.44(b) criteria, and so does not have to make changes to its current water use. We believe that annually-updated, rolling GM and STV calculations address commenters' concerns about false positives or single high test results, by allowing any high data to be incorporated into the long-term profile.

As another example, a diversified farm growing multiple crops per year using a surface water source for direct water application measures the GM at the end of the growing season for the first crop of the season in year 3 to be 150 CFU generic E. coli /100 mL and the STV to be 400 CFU generic E. coli /100 mL of agricultural water. The STV achieves the microbial water quality criteria, but the GM exceeds the criteria of 126 CFU generic E. coli /100 mL. The farm calculates the values for the microbial water quality profile prior to the harvest of the second

crop of the year, and is therefore able to adjust the growing practices for the harvest of this crop to provide 1 day of microbial die-off between last irrigation and harvest to achieve the specified GM of the microbial water quality criteria.

The GM and STV are sensitive to extremes among individual sample measurements and a sufficiently high level (spike) in even one sample can elevate the GM (and/or STV) over the microbial quality criteria in § 112.44(b). For example, a grower calculates his/her microbial water quality profile and find that the GM is 118 CFU generic E. coli per 100 mL, and the STV is 140 CFU generic E. coli per 100 mL. In the next year the grower collects five new samples as part of the annual survey and the sample results include 95, 147, 96, 6,000 and 137 CFU generic E. coli per 100 mL. These values are rolled into the previous year's microbial water quality profile, and it now includes the latest five samples. The updated microbial water quality profile has a GM of 143 CFU generic E. coli per 100 mL, and STV of 448 generic E. coli per 100 mL. The grower uses this information to apply a one-day die-off period between last irrigation and harvest, as soon as practicable, but no later than the following year. This sensitivity is one of the reasons we believe that the rolling GM and STV calculations are the appropriate tool for determining microbial water quality while protecting public health. We realize that farms have concerns about single high samples and we encourage farms to treat each sample as a marker in the variability of the water source to identify trends over long periods of time. This approach will help covered farms understand how their water sources may vary in the long term.

Even though we are finalizing a rolling GM and STV measurement so covered farms can develop a microbial water quality profile over time, we are also retaining the requirement, in § 112.46(b)(3), that if you have determined or have reason to believe that your microbial water quality profile no longer represents the quality of your water (for example, if there are significant

changes in adjacent land use that are reasonably likely to adversely affect the quality of your water source), you must develop a new microbial water quality profile reflective of the time period at which you believe your microbial water quality profile changed. To develop a new microbial water quality profile, you must calculate new GM and STV values, using your current annual survey data (if taken after the time of the change), combined with new data, to make up a data set of at least 20 samples or 4 samples (for untreated surface water, or untreated ground water, respectively). You must then modify your water use based on the new GM and STV values in your new microbial water quality profile in accordance with § 112.45(b) (see § 112.46(b)(3)).

8. Testing Highly Variable Untreated Surface Water Sources

(Comment 245) In the supplemental notice, we requested comment on whether, for a highly variable water source (e.g., a moving water body), we should require more than a five-sample annual verification survey. Some comments oppose increasing the sampling frequency, stating that most, if not all, surface water sources would qualify as a “moving water body.” In addition, comments argue if a water source does not consistently achieve the proposed GM and STV standard because of uncontrolled variability, an increased frequency of testing would not achieve compliance. These comments suggest, in such instances, the farm should acknowledge the uncontrolled variability and implement proposed mitigation measures, rather than test more frequently.

(Response) We are not establishing water testing requirements specific to highly variable untreated surface water sources. Rather, under our revised approach established in § 112.46(b), such water sources would be subject to the same testing requirements as all other

untreated surface water used during growing of covered produce (other than sprouts) using a direct water application method. We have incorporated flexibility in the requirements in § 112.46(b) to allow farms to independently determine, in compliance with §§ 112.49(c) and (d) and 112.12, the appropriate number of samples required to characterize an untreated surface water source based on their knowledge of the water system, its inherent variability, and the vulnerability of their water source to contamination. The untreated surface water testing requirements are used to inform the appropriate use of the water source, by accounting for the variability of the source. Therefore, you must first characterize the microbial water quality of the water source by testing in accordance with § 112.46(b) and developing a microbial water quality profile. If the GM or STV do not meet the microbial quality criteria in § 112.44(b), then you must consider and implement the options provided in § 112.45(b)(1) through (b)(3), as appropriate for your commodity and practices and conditions on your farm.

9. Follow-up Actions Based on Water Testing Results or Other Information (§§ 112.45 and 112.46)

(Comment 246) Some comments state that FDA did not clearly outline the actions a covered farm must take under the tiered testing approach for untreated surface water. For example, comments ask for clarification about the steps a farm must take if the annual test results indicate a change in microbial water quality and do not confirm the baseline water quality profile. Some comments also request clarification of necessary actions if the test results are not available prior to harvest and additional storage die-off rates and/or appropriate microbial removal rates have not been developed. Some comments also point out the proposed provisions

do not provide an exception for circumstances where a high positive finding is later corrected and confirmed to be within the established water quality profile.

(Response) With the revisions we have made to § 112.46(b), you will have a rolling microbial water quality profile consisting of 20 samples for untreated surface water sources (e.g., 5 samples from your annual survey and the most recent 15 samples, taken within the last 4 years) or 4 samples for untreated ground water sources (e.g., 1 annual sample and the most recent 3 from within the last 4 years). From this data set, you will update the GM and STV values each year. If the GM and STV do not meet the microbial quality criteria in § 112.44(b), you must take actions in accordance with § 112.45(b). See also discussion in Comment 214 regarding taking action at your next harvest or in the next growing season, if more immediate changes are not practicable.

We appreciate the concerns of commenters seeking additional information and clarification on follow-up corrective measures that are required under the different provisions, including in response to results of testing required in § 112.46 and/or in response to your knowledge or determination that water is not safe or of adequate sanitary quality and/or does not meet the microbial quality criteria in § 112.44. We discuss some examples in the paragraphs that follow.

Example 1: Knowledge of Upstream Change in Conditions – A concentrated animal feeding operation (CAFO) is established upstream and is discharging untreated wastewater into your water source. In this example, a farmer uses water from a stream for direct water application method irrigation during growing covered produce that is not sprouts. The farm has established a water quality profile for the stream over the years and is using the water from the stream in compliance with the relevant provisions of the rule. The farm now learns that a CAFO

has started operation upstream from the farm and within a close distance and is regularly discharging untreated wastewater into its water source. The farm has reason to believe that its microbial water quality profile no longer represents the quality of the water from the stream. This is because, under the circumstances, the addition of the CAFO upstream and its regular discharge of untreated wastewater is a significant change in nearby land use that is reasonably likely to adversely affect the quality of the water source. Thus, under § 112.46(b)(3), the farm must develop a new microbial water quality profile reflective of the time period at which the farm believes the microbial water quality profile changed. In this case, the farm's new microbial water quality profile must reflect only data from after the time the CAFO began operation upstream. The farm must take new samples of the water, combined with as many test results as it already has from its previous data set from samples taken after the CAFO began operations, to make up a data set of at least 20 samples, and calculate new GM and STV (the new water quality profile) from that data set. Then the farm must modify its water use based on the new GM and STV values in its new microbial water quality profile in accordance with § 112.45(b).

Example 2: Knowledge of Likely Contamination Event -- Dead deer in stream. In this example, as in Example 1, a farmer uses water from a stream for direct water application method irrigation during growing covered produce that is not sprouts. The farm has established a microbial water quality profile for the stream over the years and is using the water from the stream in compliance with the relevant provisions of the rule. During the growing season, the farm finds deceased and decaying deer in the area of the stream under the farm's control, upstream from where the farm draws its water and at a close distance. The farm now has reason to believe that its agricultural water is not safe or of adequate sanitary quality for its intended use as required under § 112.41 because the water is reasonably likely to contain human pathogens

transferred by the dead and decaying deer. Therefore, under § 112.45(a), the farm must immediately discontinue using the water for irrigation until it completes one of the actions described in § 112.45(a). The approach that the farm is most likely to take (as most likely the most feasible option) is to re-inspect the entire affected agricultural water system to the extent it is under the farm's control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and take adequate measures to determine if the changes were effective (§ 112.45(a)(1)). In this case, that would entail, at a minimum: re-inspecting the entire water system potentially affected by the dead deer to the extent it is under the farm's control to identify any relevant conditions (such as additional dead deer, including carcass materials that may have contaminated the farm's water distribution system if applicable); removing the dead deer and any related hazards identified during the re-inspection; cleaning any necessary equipment that may have been contaminated (such as the water distribution system impacted by the deer); and visually verifying that all carcass materials have been removed. Once the farm has taken all of the appropriate steps in light of its specific circumstances, it may resume using the water for direct water application irrigation of its covered produce.

Example 3: Exceedance of no detectable generic E. coli criterion in § 112.44(a) in water used for hand-washing and rinsing produce during and after harvest. In this example, a farmer uses water drawn directly from a properly protected well that qualifies as an untreated ground water source for hand-washing and rinsing produce during and after harvest. The farm has tested the well over the years and is using the water from the well in compliance with the relevant provisions of the rule (in this example, the farm has never detected generic E. coli in the well water before). This year, the farm conducts its annual test of the well water, taking a sample that

is representative of the intended use (in this case, taken during the time the farm is using the water for hand-washing and produce rinsing), and detectable generic E. coli is found, thus exceeding the required criterion in § 112.44(a). Under § 112.45(a), the farm must immediately discontinue using the water for hand-washing and produce rinsing and may not re-use it for those purposes until it completes one of the actions described in § 112.45(a). The farm's choices are to re-inspect the entire affected agricultural water system to the extent it is under the farm's control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and take adequate measures to determine if the changes were effective (§ 112.45(a)(1)), or to treat the water in accordance with § 112.43 (§ 112.45(a)(2)). The farm may, of course, also choose to use a different water source that does meet the microbial quality criterion in § 112.44(a) for hand-washing and rinsing of produce either permanently or while it pursues these corrective actions. The farm may not use untreated surface water for these purposes (see § 112.44(a)). If the circumstances allow the farm to use § 112.45(a)(1) to correct the problem (for example, if a fixable problem is identified with respect to the farm's affected water distribution system that the farm is able to adequately correct in compliance with that provision), a required aspect of compliance with this provision under the circumstances is to re-test the water to adequately ensure that it now meets the microbial quality criterion in § 112.44(a) (see § 112.45(a)(1)). Making necessary changes to address the identified conditions (as required by § 112.45(a)(1)) also includes steps such as cleaning affected food contact surfaces, for example. Moreover, under § 112.46(c), the farm must also test the well at least four times per growing season or year in the next year because of the test result that failed to meet the microbial quality criterion in §

112.44(a). If all four tests in the next year meet the criterion, the farm may switch back to testing once per year.

Example 4: Exceedance of GM/STV generic E. coli criteria in § 112.44(b). In this example, a farmer uses water from a stream for direct water application method irrigation during growing covered produce that is not sprouts. The farm has established a water quality profile for the stream over the years and is using the water from the stream in compliance with the relevant provisions of the rule. In past years, the GM and STV calculated using the farm's test results have been within the bounds of the microbial water quality criteria of § 112.44(b) (so no time intervals based on microbial die-off, or log reductions based on microbial removal rates have been applied). This year, however, the calculation of the GM and STV values for the updated microbial water quality profile (calculated, in this case, after the harvest has been completed and the water is no longer being used for direct water application method irrigation) exceed the microbial quality criteria. In this case, the covered farm must take actions, as appropriate, based on the revised GM and STV values in the updated microbial water quality profile, in accordance with § 112.45(b)(1) through (3) as soon as practicable, and no later than the following year. The farm's practices related to that water use can be modified through applying an adequate time interval (in days) between last irrigation and harvest in accordance with § 112.45(b)(1)(i); or applying a time interval (in days) between harvest and end of storage, or applying a calculated log reduction during activities such as commercial washing, provided the farm has adequate supporting scientific data and information in accordance with § 112.45(b)(1)(ii). If these mitigation options are not selected or cannot be appropriately applied to achieve the microbial water quality criteria, the farm may consider the options in § 112.45(b)(2) or (b)(3), i.e., the farm must either re-inspect the entire affected agricultural water system to the extent it is under the

farm's control and take other steps, including make necessary changes and retesting the water to determine if the changes were effective and the water now meets the criteria; or treat the water in accordance with § 112.43. If none of the above mitigation options are selected and appropriately applied to achieve the microbial water quality criteria, the farm must discontinue using water from that source for direct water application method irrigation of covered produce no later than one year from the time that the farm determined that the water did not meet the required criteria.

There may be circumstances that allow the farm to use § 112.45(b)(2) to correct the problem. For example, the farm might reasonably determine, under the circumstances, that the change in microbial water quality was due to non-recurring point-source contamination that can be adequately corrected in compliance with this provision. An example of such a finding would be visible damage to a water dam on the farm's property (and under the farm's control) upstream from where the farm draws its water, where the dam serves to reduce water flow by holding back water from a stream that would otherwise converge with the stream water the farm uses. The farm might reasonably conclude, under these circumstances, that the damage to the dam is a correctable, non-recurring point-source of contamination. If the farm is able to stop the leak and repair the damaged dam, the farm may use § 112.45(b)(2) as a mitigation option. In such cases, a required aspect of compliance with this provision under the circumstances is to re-test the water after the correction has been made to adequately ensure that the water meets the microbial quality criteria in § 112.44(b) (see § 112.45(b)(2)). Under § 112.45(b), the farm in this example has up to a year before it must discontinue use of the water for direct application method irrigation of covered produce, and post-correction sampling should be conducted and analyzed within such time if the farm wishes to continue using the water for this purpose without interruption. We note that to meet the requirements of § 112.46(b)(2) for the annual survey,

samples must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest. However, we also encourage farms in such situations to voluntarily conduct additional sampling earlier (such as immediately post-correction, even if not close in time to harvest) as may be appropriate.

In rare situations such as that described in this example, the farm need not include in its rolling dataset of 20 samples for calculation of the GM and STV the set of 5 samples that caused the exceedance, leading it to re-inspect, find, and correct the non-recurring point source contamination. In this rare situation the data set should be made up only of samples that are not reasonably likely to have been affected by the non-recurring point-source contamination. With respect to calculations for the microbial water quality profile, we encourage farms in such situations to take more than the minimum 5 samples in the following year(s), because doing so would make it unnecessary to include data older than 4 years in the microbial water quality profile. However, because the circumstances in which you need not include the samples that caused the exceedance in your microbial water quality profile are likely to be rare (i.e., we consider that such situations most likely only involve non-recurring point-source contamination that can be immediately eliminated), we intend to exercise enforcement discretion with respect to the 4 year limitation in § 112.46(b)(2)(iii) in such situations. This would allow the farm in this example to make up its microbial water quality profile in the following year using its new annual survey data, combined with its most recent initial or annual survey data (not including the samples that caused the exceedance), to make up a rolling data set of 20 samples.

(Comment 247) One comment argues the proposed water testing approach fails to respond to significant changes in water quality in a timely manner. Similarly, another comment

points out the proposed approach for testing untreated surface water reflects a retrospective testing scheme, where results of water testing may not be available in time to take actions on the harvested produce because the harvested produce may already be in commerce by the time the analysis is completed and the farm receives the results.

(Response) The goal of our framework for testing of agricultural water that is used for direct water application during growing activities for covered produce other than sprouts is to establish a microbial water quality profile to help covered farms characterize their water sources, understand the variability of those sources, and make appropriate long-term decisions about the use of that water for the specific purpose of direct water application during growing. As explained in response to Comment 180, our framework for the microbial quality criteria for water used in direct water application coupled with our decision to test for generic E. coli as an indicator organism means that exceeding the microbial water quality criteria in § 112.44(b) does not result in a determination that, based on this testing in and of itself, the produce is adulterated. Therefore, the follow-up actions listed in § 112.45(b) that must be taken when the microbial water quality criteria in § 112.44(b) are not met involve longer-term decisions (rather than the immediate decisions required under § 112.45(a)) about the use of that water as soon as practicable (considering crop in the field, next harvest, or next growing season), and no later than the following year. Given the logistical realities of sampling and testing close to harvest, there may not be time for a farm to adjust water use practices for the current year's crop because they may not receive test results in sufficient time to take actions related to that crop (for example, test results may not be received until after the crop is out of the field and into distribution). However, the point of this testing is to develop a long-term strategy to ensure that covered farms understand the quality of their water, pay attention to changes (such as the

establishment of a CAFO upstream) that may affect water quality, and make appropriate decisions going forward about use of that water. Regardless, if the farm has reason to believe that its agricultural water is contaminated such that it would render the produce adulterated under section 402 of the FD&C Act (e.g., a finding of a pathogen in dump tank water), the farm must take appropriate actions to ensure that affected food does not enter commerce.

Under our framework where the microbial quality criteria in § 112.44(b) and the corresponding testing scheme in § 112.46(b) serve as a long-term strategy to help covered farms to understand the quality of their water sources and plan the appropriate use of water from those sources accordingly, and in light of the options for corrective measures in § 112.45(b)(1) through (b)(3), a requirement to immediately implement corrective actions on the current crop during growing or harvested crop solely based on the results of § 112.46(b) is not warranted. Rather, we conclude the general requirement in §§ 112.41 and corresponding 112.45(a) sufficiently address those circumstances and necessary immediate actions when water is not safe or of adequate sanitary quality for its intended use.

H. Sharing of Water Testing Data (§ 112.47(a))

(Comment 248) One comment requests that FDA provide for the establishment of water quality profiles for common water sources affecting various farms in a specific geographic area or region.

(Response) Section 112.47(a)(2) explicitly allows data sharing under certain circumstances. However, we do not expect that it will typically be possible to develop water quality profiles as described under § 112.46(b) on a regional basis for large water sources such as rivers. As provided in § 112.47(a)(2), you may use data collected by a third party or parties

only if the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s) and all other applicable requirements of the rule are met. As explained in the supplemental notice (79 FR 58434 at 58455), a water source sampled by a third party adequately represents your water source if the third party takes its samples from the same water source you use (e.g., the same river), and there is no reasonably identifiable source of likely microbiological contamination (e.g., an untreated sewage discharge point, a source of significant amounts of untreated animal feces such as a livestock farm) between the point(s) at which the third party collects its samples and the point(s) at which you draw the water. Thus, under this provision, testing data may only be shared if there is no reasonably identifiable source of likely microbiological contamination between the sampling site(s) and the farm(s) involved. For a regional water source such as a river, we expect that in most cases there will be reasonably identifiable source(s) of likely microbiological contamination at various points along the river that will prevent all users of the river from sharing the same data under this provision. Some users of a river may be able to share data under this provision, but only if there are no reasonably identifiable source(s) of likely microbiological contamination between their sampling point(s) and draw point(s) and all other requirements of the rule are met.

(Comment 249) One comment recommends that FDA work with EPA and other agencies to develop and share water testing data with relevant parties.

(Response) To the extent this commenter is referring to water from a Public Water System, as defined under EPA's Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State (as defined in 40 CFR 141.2) approved to administer the

SDWA public water supply program, we note that under § 112.46(a)(1), there is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when you receive water from such a system and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement.

(Comment 250) Referring to leased lands where an owner may lease a field or a portion of the land each year to different farms, one comment recommends that, in such cases, the current tenant farmer should be able to use the previous tenant farm's water sampling results to establish the water quality profile when one is required under proposed § 112.45(b), rather than having to conduct a new baseline survey.

(Response) Under § 112.47(a)(2), you may use test data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water and all other applicable requirements of the rule are met. A water source sampled by a third party adequately represents your water source if the third party takes its samples from the same water source you use (e.g., the same canal, stream, or reservoir) and there is no reasonably identifiable source of likely microbiological contamination between the point(s) at which the third party collects its samples and the point(s) at which you draw the water. Thus, if a farmer of leased land has access to previous years' water testing data that meets the requirements of § 112.47(a)(2), the farmer may use such data to satisfy relevant testing requirements under § 112.46, including those required under § 112.46(b). On the other hand, if a farmer of a leased land does not have access to previous years' water testing data, or the farmer has access to such data but those data do not meet the requirements of § 112.47(a)(2), the farm will need to perform its own testing to develop the initial microbial

water quality profile.

I. Agricultural Water Used During Harvest, Packing, and Holding Activities (§ 112.48)

(Comment 251) Some comments state that it would be impossible to maintain a potable water standard for postharvest water at all times. Comments also state that FDA should include a cost-effective recommendation for visual monitoring, and clearer criteria for how farms should deal with organic build-up in water and when to change the water. Some of these comments also maintain that reliance on visual inspection in place of other testing mechanisms may not be safe.

(Response) Section 112.48(b) requires you to visually monitor the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for build-up of organic material (such as soil and plant debris). We are including this monitoring requirement to highlight conditions that require action, such as a water change in a dump tank, and take appropriate measures, as necessary. The specific method and criteria for monitoring to maintain water quality will need to be operation-specific and, therefore, we recommend that you consider establishing protocols specific to your harvesting, packing, or holding activity. We note that this requirement is not the only requirement applicable to agricultural water used for these purposes. Section 112.44(a) establishes a microbial quality criterion for such water and prohibits using untreated surface water for such purposes. We consider the § 112.44(a) criterion to apply to the water as it is being added to a dump tank, flume, or wash tank. Section 112.45(a) establishes steps that a farm must take when the water does not meet the § 112.44(a) microbial criterion. In addition, § 112.46(a) establishes the circumstances in which water used for the purposes listed in §

112.44(a) is not required to be tested, and § 112.46(c) requires testing untreated ground water used for these purposes. Thus, this rule does not rely on visual inspection in place of testing water quality as suggested by some comments. Where we have determined that a testing requirement is appropriate (i.e., for untreated ground water used for these purposes), we have established such a requirement.

(Comment 252) One comment suggests requiring disinfection treatment of re-circulated water used during and after harvest. By contrast, another comment states that disinfection of re-circulated water in case of dump tanks is unnecessary and impractical.

(Response) Section 112.48(a) requires you to manage the water used during harvest, packing, and holding activities for covered produce as necessary, including by establishing and following water-change schedules for re-circulated water to maintain the safety and adequate sanitary quality and minimize the potential for contamination of covered produce and food-contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce). In addition, under § 112.44(a), agricultural water applied in any manner that directly contacts covered produce during or after harvest activities is required to meet the zero detectable generic E. coli in 100 mL microbial quality criterion. This requirement applies to the water as it is being added to a dump tank, flume, or wash tank (see Comment 251). Recognizing the wide-range of handling procedures, washing line set-ups, and commodity-specific practices where agricultural water directly contacts covered produce during or after harvest activities, we are not requiring treatment of re-circulated water. Instead, we have provided flexibility for farms to implement

measures appropriate to their practices to comply with § 112.48(a), which may include disinfection treatment during re-circulation. See also Comment 196.

(Comment 253) Some comments express a need for commodity-specific research to tailor requirements for the use of water during harvest, packing, and holding activities to specific covered produce commodities. Some commenters also believe that, although maintaining a positive temperature differential between the produce and wash water could be a good practice, it may not be practicable based on current industry practices. In addition, some commenters do not believe applying a water temperature differential has been demonstrated to minimize the risk of infiltration of microorganisms.

(Response) As described in the 2013 proposed rule, water temperature can influence processes leading to infiltration of microorganisms into many types of produce. In the QAR, too, we noted that infiltration of water containing pathogens into produce has been demonstrated in apples (Ref. 158), oranges (Ref. 159), tomatoes (Ref. 160) (Ref. 161), and mangoes (Ref. 162), and was suggested to play a role in a 1999 Salmonella outbreak associated with mangoes (Ref. 163). In the development of the 2013 proposed rule, we considered proposing a specific temperature differential between water and product core temperature (e.g., water must be at least 10 °F warmer than core), and tentatively concluded that there is insufficient scientific evidence supporting the application of such a specific temperature differential requirement across all covered produce. Instead, we proposed and now finalize § 112.48(c), which requires that you must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of

microorganisms of public health significance. Thus, the requirement is tailored to apply only to appropriate commodities and practices, and only as needed to minimize the potential for infiltration of pathogens.

Although research suggests that water temperature can influence the infiltration of microorganisms into various types of produce, including apples, oranges, mangoes and tomatoes, other studies demonstrate that infiltration can occur without a temperature differential (Ref. 159) (Ref. 164). For example, it was demonstrated that internalization of Salmonella into tomatoes via their stem scar can occur even under a zero temperature differential, and temperature differentials up to 10 °F have no effect on the internalization frequency and have limited impact on Salmonella spp. cell populations internalized in tomatoes. In addition, factors such as tomato variety and the time delay between tomato stem removal and water immersion have a significant impact on the frequency and population of internalized Salmonella spp. in tomatoes (Ref. 164). We did not receive data or information in response to the 2013 proposed rule that would support a requirement for a specific temperature differential to be maintained in agricultural water used during harvest, packing, and holding activities across all covered produce.

J. Records Related to Agricultural Water (§ 112.50)

(Comment 254) In response to the 2013 proposed rule, several comments support the recordkeeping requirements of proposed § 112.50, and state that effective water management includes recordkeeping that is sufficient to confirm that agricultural water is safe throughout the growing season. Comments also agree that farms must establish and keep records relating to the findings of the inspection of the agricultural water system; the results of any analytical tests

conducted to determine whether water is safe and of adequate sanitary quality for its intended use; and scientific data relied on to support the adequacy of methods used to treat agricultural water. One comment also agrees with the proposed requirement to maintain annual documentation from a public water system, if applicable. Another comment suggests that FDA should require documentation of any corrective actions that farms employ to address problems identified with their water system and to verify that those corrective actions were effective.

(Response) We conclude that certain records are necessary for you to ensure your own compliance with the requirements in this rule for use of agricultural water, and so that FDA can verify your compliance with the relevant requirements of subpart E. We agree that documentation of corrective actions is necessary to verify effectiveness of the corrective actions and compliance with the relevant requirements. In proposed § 112.161(b), we proposed a general provision applicable to records required under subparts C, E, F, L, and M of part 112 that you must establish and keep documentation of actions you take when a standard in any of these subparts is not met. For clarification, we are eliminating proposed § 112.161(b) and, instead, adding that requirement within the records provisions of two relevant subparts, subparts E and M. In subpart E as edited, under new § 112.50(b)(6), you must establish and keep documentation of actions you take in accordance with § 112.45. For example, if you determine that water you use for a purpose listed in § 112.44(a) does not meet the microbial quality criterion established in that section, § 112.45(a) provides that you must take certain steps as a result. This § 112.50(b)(6) requires that you establish and keep documentation of the steps taken to satisfy § 112.45(a). In addition, in this section we are also establishing specific requirements for documentation of time intervals or calculated log reductions applied in accordance with § 112.45(b)(1).

We are also adding new § 112.50(b)(9) to require that you retain documentation of any analytical methods you use in lieu of the method that is incorporated by reference in § 112.151(a). Under § 112.151(b)(1), you may use any scientifically valid method that is at least equivalent to the method of analysis in § 112.151(a) in accuracy, precision, and sensitivity to satisfy the water testing requirements under § 112.46. In addition, under § 112.151(b)(2), if you use an alternative indicator of fecal contamination in accordance with § 112.49(a), you must use a scientifically valid method to test for the indicator. We conclude such records are necessary for us to verify and for you to ensure that appropriate methods are used for testing agricultural water. This provision is consistent with proposed § 112.150(b)(5), which we have retained in this rule and which requires similar records regarding alternative analytical methods used when conducting testing required under subpart M for sprouts. We are also combining two proposed records requirements related to water testing results (proposed § 112.50(b)(2) and (5)) into one requirement in final § 112.50(b)(2).

(Comment 255) A comment requests clarification on the type of record that will sufficiently verify that the inspection of each water source and identification of potential hazards has been conducted as required in proposed § 112.42.

(Response) Under § 112.50(b)(1), you are required to establish and keep records of your agricultural water system inspection findings under § 112.42(a). Other than as provided generally for records required under this rule in subpart O, we are not further specifying the manner or format in which you prepare the record(s) to satisfy this recordkeeping requirement. We note that under § 112.161(a)(1), all records required under this part must include, as applicable, the name and location of your farm, actual values and observations obtained during

monitoring, an adequate description of covered produce applicable to the record, the location of a growing area or other area applicable to the record, and the date and time of the activity documented. Under § 112.161(a)(2), records must be created at the time an activity is performed or observed, under § 112.161(a)(3) they must be accurate, legible, and indelible, and under § 112.161(a)(4) they must be dated, and signed or initialed by the person who performed the activity documented. Covered farms may prepare and maintain documentation of their inspections and associated findings in a manner that is appropriate for the farm’s operation provided that the records contain all necessary information and satisfy subpart O. Under § 112.163(a), you are not required to duplicate any existing records if those records contain all of the required information and satisfy the requirements of this rule. Similarly, if you have records containing some but not all of the required information, § 112.163 provides you the flexibility to keep any additional information required either separately or combined with your existing records, even where the formats for each record may not be the same.

K. Compliance Periods Related to Agricultural Water

For covered activities involving covered produce (except sprouts subject to subpart M), the compliance dates for water quality requirements in § 112.44 and certain related provisions are two years beyond the compliance date for the rest of the final rule applicable to the covered farm based on its size. See Table 12.

Table 12.-- Compliance Dates for Requirements in Subpart E for Covered Activities Involving Covered Produce (Except Sprouts Subject to Subpart M). See also Table 30.

Compliance Dates of 2-4 years Applicable to the Farm Based on its Size	Extended Compliance Date of Additional 2 years Beyond the Compliance Date Based on Size of Farm
§ 112.41	§ 112.44
§ 112.42	§ 112.45(a) with respect to § 112.44(a) criterion
§ 112.43	§ 112.45(b)
§ 112.45(a) with respect to safe and adequate standard	§ 112.46(b)(1) with respect to untreated ground water
§ 112.46(a)	§ 112.46(b)(2) and (b)(3) § 112.46(c)
§ 112.46(b)(1) with respect to untreated surface water	

§ 112.47	
§ 112.48	
§ 112.49	
§ 112.50	

Note that although most of § 112.46 is subject to the extended compliance periods, § 112.46(a) is not, and § 112.46(b)(1) with respect to untreated surface water is not. Therefore, covered farms must initiate actions in compliance with § 112.46(a) and, with respect to untreated surface water, § 112.46(b)(1) under the regular compliance periods applicable to the remaining sections of this rule. Similarly, § 112.47 is subject to the shorter compliance period because it establishes requirements that are relevant to testing requirements when they become applicable. See our response to Comment 243 for an explanation for treating § 112.46(b)(1) with respect to untreated surface water differently from the remaining water testing requirements for purposes of compliance. We recognize that farms may need additional time to prepare for implementation of the water quality testing, monitoring, and related record-keeping provisions. This additional 2-year compliance period for water quality requirements is also expected to permit farms to consider alternatives to the microbial quality criteria in § 112.44(b), the microbial die-off rate in § 112.45(b)(1)(i), or the testing frequencies in § 112.46(b)(1)(i)(A) and § 112.46(b)(2)(i)(A), and develop adequate scientific data or information necessary to support a conclusion that the alternative would provide the same level of public health protection as the relevant requirement, and would not increase the likelihood that the covered produce will be adulterated under section 402 of the FD&C Act, in light of the farm’s covered produce, practices, and conditions. Therefore, for covered activities involving covered produce (except sprouts subject to subpart M), the extended compliance dates for certain water quality testing, monitoring, and related recordkeeping requirements identified in column 2 of Table 12 are six years from the effective

date for very small businesses, five years from the effective date for small businesses, and four years from the effective date for all other farms.

We are not similarly providing extended compliance periods for these specific water requirements, in the case of covered activities involving sprouts, as discussed in section XVIII.J of this document. Therefore, covered farms must comply with all of the applicable requirements of part 112, including subpart E, for all covered activities involving sprouts subject to subpart M, within one to three years of the effective date of the rule, depending on size of the farm. See also section XXIV.A of this document for additional information.

XIV. Subpart F – Comments on Biological Soil Amendments of Animal Origin and Human Waste

In subpart F of proposed part 112, we proposed minimum standards directed to treated and untreated biological soil amendments of animal origin and human waste that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonable necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the covered produce is not adulterated under section 402 of the FD&C Act. In the 2013 proposed rule and the supplemental notice, we asked for comment on our proposed provisions, including our decision not to establish requirements for chemical or physical soil amendments, or biological soil amendments that are not of animal origin; the appropriateness of treatment options considered for treated soil amendments; the appropriateness of the microbial standards selected and potential alternatives; and the proposed waiting periods between application and harvest (“application intervals”). In the supplemental notice, we withdrew our proposal for an application interval for untreated biological soil amendments of animal origin (including raw manure) and deferred our decision on an appropriate minimum application interval until such time as necessary for us to pursue certain steps, including a risk assessment and research to supplement the science on an appropriate interval.

In this section of this document, we discuss comments we received on the standards directed to biological soil amendments of animal origin and human waste in the 2013 proposed rule, but that we did not address in the supplemental notice. We also discuss comments that we received on the new and amended proposed provisions in the supplemental notice.

We are finalizing these provisions with revisions (see Table 13). We discuss these changes in this section. There are also revisions relevant to subpart F in the Definitions section in § 112.3, which are described in section IX of this document.

Table 13.-- Description of Revisions to Subpart F

Final Provision	Description of Revisions
§ 112.51	<ul style="list-style-type: none"> - Revision to (a) and (b)(1) clarify that agricultural teas covered are those for which the biological materials include materials of animal origin, and to replace reference to § 112.44(a) with clarifying text - Revision to (b)(5) to clarify that agricultural teas covered are those for which the biological materials include materials of animal origin - See Table 14 for additional information
§ 112.52	<ul style="list-style-type: none"> - Revision to (a) to add other soil amendments and to clarify that drip fertigation with agricultural teas that are biological soil amendments of animal origin is permitted in compliance with other requirements of this rule - Revision to (c) to replace “that has become” with “that you know or reasonably believe may have become” - See Table 15 for additional information
§ 112.53	<ul style="list-style-type: none"> - No change
§ 112.54	<ul style="list-style-type: none"> - Revision to (a) and (b) to add biological processes and replace “demonstrated” with “validated” - Rearrangement to combine relevant provisions of proposed (c) into revised (b) - Renumbering of proposed (c)(1) to (b)(1) and proposed (c)(2) to (b)(2) as a conforming change to combining (b) and (c) - Elimination of proposed (c)(3) as not necessary - Revision to descriptions of static composting (in (b)(1)) and turned composting (in (b)(2)) to further clarify the processes - See Table 17 for additional information
§ 112.55	<ul style="list-style-type: none"> - Revision to (a)(1) to add liquid sampling - Revision to (a)(2) and (a)(3) to add liquid sampling and indicate that it is a ‘non-detect’ standard - Revision to (b) to add liquid sampling and indicate that the <u>Salmonella</u> method is a ‘non-detect’ standard - See Table 18 for additional information
§ 112.56	<ul style="list-style-type: none"> - Revision to (a) to delete “except as provided in paragraph (b) of this section” - Revision to combine proposed (a)(3) and proposed (a)(4) as renumbered (a)(2), corresponding to revised § 112.54(b) - Renumbering of proposed (a)(2) as (a)(3) - See Table 19 for additional information

§ 112.60	<ul style="list-style-type: none"> - Revision to (b)(1) to eliminate proposed (b)(1)(ii) and as a conforming change to renumber (b)(1)(iii) to (b)(1)(ii) and to require such documentation at least annually - Elimination of (b)(3) as a conforming change since proposed § 112.54(c)(3) has been deleted - See Table 20 for additional information
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A. General Comments

(Comment 256) Many comments state that biological soil amendments of animal origin can contain pathogenic bacteria that can cause foodborne illness in humans and therefore special precautions must be taken in their use. Some comments further cite certain provisions within subpart F that address the need for such special precautions and state that they were in alignment with current GAPs, some marketing orders, certain industry standards (in particular the mushroom industry standards), and that they are currently being followed by segments of the industry. These commenters generally agree with FDA’s approach.

Conversely, many comments take exception to our coverage of biological soil amendments and our approach to doing so, particularly the original proposal to require a 9-month application interval for untreated biological soil amendments of animal origin, including raw manure. Some comments state that mandatory requirements for biological soil amendments of animal origin are not needed, or should be in guidance rather than a regulation.

(Response) FDA continues to conclude that biological soil amendments of animal origin are an important route of contamination on farm and, therefore, we do not believe it would be sufficient merely to make recommendations related to biological soil amendments of animal origin in guidance. We have finalized our QAR and it supports this conclusion. With regard to comments on the application interval for untreated biological soil amendments of animal origin, including raw manure, which was proposed in the 2013 proposed rule and withdrawn in the supplemental notice, see Comment 257.

(Comment 257) Many commenters suggest that provisions within subpart F should be written to align with NOP standards. Some comments expressed concern that the provisions of subpart F would cause farms to use specific methods of agriculture, including use of synthetic fertilizers, which would eliminate a farm's ability to become certified organic. Some comments state that organic farming provides a benefit in protecting the public health from consequences associated with the use of harmful chemical pesticides, herbicides, and synthetic fertilizers, and already includes a food safety component and has an excellent track record on food safety. Other comments suggest FDA adopt NOP standards because farms are already accustomed to implementing them. Further, other comments recommended that FDA and USDA collaborate to align their respective regulations to be maximally protective of the public health from both foodborne illness and environmental health perspectives.

(Response) We do not agree that the provisions of subpart F are in conflict with NOP standards or would require farms to use synthetic amendments such that they could not achieve organic certification. The provisions of subpart F allow use of both treated and untreated biological soil amendments of animal origin, as long as they are applied in accordance with § 112.56. The provisions of § 112.54 allow for biological (including composting), chemical, and physical treatment processes, or combinations thereof, for producing treated biological soil amendments of animal origin, as long as they meet the microbial standards in § 112.55. We do not believe it would be appropriate to broadly adopt USDA's NOP standards for biological soil amendments of animal origin because they were established for purposes of organic certification and not for produce safety. However, we do agree that inter-agency collaboration to align goals and approaches, in order to minimize individual requirements placed on the industry, is

beneficial. FDA has worked, and will continue to work, with USDA to ensure our programs do not have conflicting or duplicative measures.

With regard to the application interval for use of untreated biological soil amendments of animal origin, including raw manure, in response to our original proposal we received many comments taking issue with our proposed 9-month interval. In response to these comments, we indicated in the supplemental notice (79 FR 58434 at 58460-58461) that we were deferring action on an application interval until we pursued certain steps including a risk assessment and research to supplement the science on an appropriate interval. We anticipate that these efforts will take 5 to 10 years to complete. Following the completion of the risk assessment and research work, we expect to: (1) provide stakeholders with data and information gathered from scientific investigations and risk assessment; (2) consider such new data and information to develop tentative scientific conclusions; (3) provide an opportunity for public comment on our tentative decisions; and (4) consider public input to finalize the provision(s) establishing an appropriate minimum application interval(s).

(Comment 258) Several comments agree with our decision in the supplemental notice to pursue a risk assessment and research prior to establishing an application interval for untreated biological soil amendments of animal origin, including raw manure. However, other comments state that 5-10 years would be too long to wait for the public health benefits of setting such an application interval, that there is science demonstrating that a 120-day interval would be an appropriately protective interim standard while FDA pursues its risk assessment and research, that many in the agricultural community are already applying a 120-day interval, and that FDA should establish a 120-day application interval for raw manure as an “interim” standard for the

intervening 5-10 years while FDA pursues its risk assessment and research agenda and additional rulemaking. Conversely, some comments state it is not appropriate for FDA to establish an application interval based on the NOP interval (90/120 days depending on the crop), because the NOP standards require incorporating manure into the soil after application and were established for the purpose of maintaining organic integrity, and not for produce safety.

Some other comments relating to application intervals include a suggestion that we subject only liquid manures to a 9-month application interval based on an asserted greater risk presented by liquid manure as compared to non-liquid manure, a suggestion that we count the time period when soil is frozen toward any application interval, and a request that we conduct research to determine the impact of hard freezes on survivorship of pathogens in northern climates.

(Response) As explained in the supplemental notice (79 FR 58434 at 58460-58461), FDA withdrew its proposal for an application interval for untreated biological soil amendments of animal origin, including raw manure, and indicated that it would establish such an interval after pursuing a risk assessment and research agenda to supplement the science regarding an appropriate interval. Because FDA withdrew its proposal for such an application interval, we do not have a proposal to finalize at this time. To establish an application interval for untreated biological soil amendments of animal origin, FDA will need to undertake notice-and-comment rulemaking consistent with the Administrative Procedure Act (5 U.S.C. § 553). We recognize that we could provide public health protection by applying an application interval for untreated biological soil amendments of animal origin while we pursue our risk assessment and research, and the familiarity of the farm community with the NOP 90/120-day interval. We also recognize that FDA stated in the supplemental notice that it would pursue its risk assessment and research

agenda before proposing to establish such an application interval, and that some comments oppose establishing an interval by regulation before completion of that agenda. FDA is considering appropriate next steps. However, we will not establish an application interval for untreated biological soil amendments of animal origin without giving the public a chance to provide comment on a proposed interval.

As noted in the supplemental notice, we continue to believe that a quantitative application interval standard, established in part 112, is necessary to minimize the likelihood of contamination of produce resulting from the use of untreated biological soil amendments of animal origin, including raw manure, in a manner that contacts covered produce. We acknowledged in the supplemental notice that many farms currently employ the NOP standard of 90 days or 120 days, as specified in 7 CFR 205.203(c)(1), and we recognize that such farms will likely continue their current practice to use this standard in organic crop production, in the absence of an FDA regulation that establishes a food safety standard for minimum application intervals associated with the use of untreated biological soil amendments of animal origin such as raw manure. Given that the scientific literature demonstrates that the probability of pathogen survival decreases as the length of time between application of untreated biological soil amendments of animal origin and harvest increases, and that more rapid die-off occurs during the months immediately following application (e.g., three to four months) as compared to subsequent months (followed by prolonged survival of pathogens at low levels), we believe adherence to the NOP standard to be a prudent step toward minimizing the likelihood of contamination while the above described risk assessment and research program is ongoing. At this time, we do not intend to take exception to the continuation of this practice in the interim period.

(Comment 259) One comment recommends only stabilized compost that has not been subjected to cross-contamination and re-growth of pathogens be allowed for use on agricultural lands designated for production of ready-to-eat foods.

(Response) FDA agrees that stabilized compost (or any treated biological soil amendment of animal origin) must be handled, conveyed, and stored in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin (§ 112.52(b)) and that it should be considered untreated if it has become contaminated (§ 112.52(c)). However, we do not agree that only stabilized compost should be allowed to be used during the growing of covered produce (or more broadly as suggested by the comment). As described in Comment 277 there are several different types of biological soil amendments of animal origin that are appropriate for use on land used to grow covered produce, and this rule does not restrict use of other types of soil amendments not subject to subpart F (such as chemical and physical soil amendments and biological soil amendments that are not of animal origin). All such soil amendments may be used in the growing of covered produce, provided that all biological soil amendments of animal origin and human waste are used in accordance with the requirements in subpart F.

(Comment 260) A commenter requests only mammalian and avian species be included in the definition of “biological soil amendments of animal origin” and therefore subject to the requirements of subpart F.

(Response) Animals other than mammalian and avian species, such as fish, amphibians, and reptiles, are known to carry human pathogens (e.g., Salmonella) (Ref. 165) (Ref. 166) (Ref.

167) and fecal contamination by such animals is a concern. The comment did not provide information to support the request that only certain species be covered. FDA concludes that the risks posed by biological soil amendments from all animal sources should be addressed through inclusion in the term “biological soil amendments of animal origin” and resulting requirements under subpart F of this rule.

(Comment 261) Some comments state that food safety on a farm is related to the microbial soil ecology, and that biological diversity adds to soil health and protects the environment, while “sterile” soils lack this healthy fertility. Some comments also suggest healthy soils are essential to food safety, can boost the nutrient content of food, and contribute to long-term food security by ensuring land is viable for diverse, long-term production systems. Comments request that we explore ways to enhance the safety of covered produce while promoting biological diversity in soil ecology.

(Response) FDA agrees that soil health, environmental stewardship, and reducing the risk of food becoming contaminated with pathogens are all important and are not mutually exclusive. We intend to work with stakeholders to address co-management of produce safety and the environment.

(Comment 262) Comments focusing on environmental concerns associated with chemical fertilizer use requested that FDA revise the proposed produce safety rule to remove any incentives it may create for using chemical fertilizers as a replacement for biological soil amendments of animal origin.

(Response) As discussed in the 2013 proposed rule (78 FR 3504 at 3576), animal waste is likely to contain human pathogens. Material that does not contain any animal waste is far less likely to harbor these food safety hazards at microbial populations that can reasonably be expected to lead to severe adverse health consequences or death, and we are still not aware of any situation in which chemical or physical soil amendments, such as elemental fertilizers, soil stabilizers, or others typically made of mined or synthetic materials, have served as sources of microbial contamination. Therefore, neither chemical nor physical soil amendments are a focus of this rule. Instead, we focus on biological soil amendments of animal origin and human waste, which present a reasonable likelihood of harboring human enteric pathogens. We do not believe our focus on biological soil amendments of animal origin incentivizes the use of chemical fertilizers. However, we did consider the effect of farms switching to chemical fertilizers in the EIS and concluded that a switch away from biological soil amendments of animal origin to chemical fertilizers could cause moderate adverse environmental impacts to soils, but not to a significant level because such effects are reversible and may be mitigated through other practices that are growing in popularity such as green manuring, no-till practices, and use of cover crops. FDA expects that the cumulative effects nationwide related to soil health and biological soil amendments of animal origin will not be significant. See discussion in Chapter 5.5 of the EIS (Ref. 126).

(Comment 263) One comment suggested that biological soil amendments that do not contain animal waste, such as yard trimmings from a municipal source, residential, or public properties, have the potential to be contaminated with domestic and wild animal feces and pose a risk to public health. The commenter therefore suggests FDA include requirements for complete

composting before allowing use of any “green waste” (meaning biological soil amendments not of animal origin). Another comment noted a study (Ref. 168) that concluded the presence or absence of manure is not a suitable predictor of the pathogen load of a stabilized compost, suggesting that “green waste” should not be treated as less risky than biological soil amendments of animal origin. Conversely, other comments agreed with FDA’s tentative conclusion that biological soil amendments that do not contain animal or human waste products are low-risk products, suggesting that the tentative conclusion to exclude biological soil amendments not of animal origin from the requirements of the rule is sensible. These commenters believed that restrictions on the use of biological soil amendments that are not of animal origin, as defined in this subpart, would be unnecessary due to an extremely low likelihood of contamination from these soil amendments.

(Response) FDA appreciates the comments indicating that there is some risk associated with biological soil amendments not of animal origin (or “green waste”). First, we note that the definitions of “yard trimmings” and “pre-consumer vegetative waste” in § 112.3(c) stipulates that these are purely vegetative materials. To the extent that vegetative waste is known to include animal feces, it would not meet the definitions of “yard trimmings” or “pre-consumer vegetative waste,” and a soil amendment made from such material would instead be a biological soil amendment of animal origin included in the scope of the provisions of subpart F. However, we recognize that even in purely vegetative material such as that described in the definition of “yard trimmings” or “pre-consumer vegetative waste,” there is the potential for unknown and unavoidable contamination with animal waste. We have concluded that the likelihood of contaminating produce with pathogens by use of biological soil amendments that are not known to contain, and not likely to contain significant animal waste or human waste (e.g., yard

trimmings, pre-consumer vegetative waste) is low, and therefore they are not subject to the requirements of this rule.

With regard to the comment that highlighted a paper on the presence of pathogens of public health concern in purely vegetative material, we agree that no biological soil amendment is without risk. However, we conclude that the relative risks are greatest with untreated biological soil amendments of animal origin due to the highly likely presence of human pathogens in such materials, and that is where we are choosing to focus our regulatory efforts. We note that there is currently not a great deal of research on pathogen presence in biological soil amendments not containing animal material. We will continue to follow the science pertaining to this issue and will consider appropriate next steps should there be additional evidence that this is an area of public health concern.

Finally, we note that § 112.52(a) requires that a biological soil amendment of animal origin be handled, conveyed, and stored in a manner and location such that it does not become a potential source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems. We are revising this provision to include a requirement that biological soil amendments be handled, conveyed and stored such that they do not contaminate other soil amendments. In addition, if you know that a soil amendment that had originally not contained animal material has been in contact with, or otherwise contaminated by, a biological soil amendment of animal origin, you should consider the possibility that, depending on the circumstances, the soil amendment may meet the definition of a biological soil amendment of animal origin and therefore be subject to the requirements of subpart F.

(Comment 264) Some comments suggest that the provisions in subpart F would disallow farmers from utilizing manure produced on their own farms as part of a “closed-loop” or “zero-input” sustainability program, or that farms would be disallowed from having compost curing and storage on site.

(Response) The provisions of subpart F do not prohibit farms from using manure produced on the farm, including manure produced as part of a sustainability program, nor does it prohibit farms from curing or storing compost on site. Covered farms must conduct relevant activities in accordance with the provisions of subpart F.

(Comment 265) One comment requests clarification on whether “table waste” would be an example of a biological soil amendment of animal origin. In addition, other comments request clarification on what is included in the category “table waste,” and express concern that this may also include food preparation waste such as raw meat. Some comments state stabilized compost derived from “table waste” or “post-consumer food waste,” and stabilized compost derived from manure represent different types and levels of risk and should be examined separately.

(Response) FDA proposed to define, and is now finalizing its definition of “table waste” as “any post-consumer food waste, irrespective of whether the source material is animal or vegetative in origin, derived from individuals, institutions, restaurants, retail operations, or other sources where the food has been served to a consumer” (§ 112.3(c)). Table waste is explicitly included within the definition of “biological soil amendment of animal origin” in § 112.3(c), making it subject to the requirements in subpart F of this rule. As discussed in the 2013 proposed rule (78 FR 3504 at 3548-9), the definition of “table waste” is intended to distinguish post-consumer food waste from pre-consumer vegetative waste. Also as discussed in the 2013

proposed rule (78 FR 3504 at 3574), post-consumer food waste, or table waste (such as plate scrapings), has a greater likelihood of being contaminated, or being contaminated at higher populations, with human pathogens of public health significance due to its unknown content (e.g., animal products, vegetable products, etc.) and its greater likelihood of containing human fluids or waste (e.g., spittle, vomitus, etc.). On the other hand, food preparation waste that is solely of plant origin may be considered “pre-consumer vegetative waste” (and therefore not subject to the requirements in subpart F) if it meets the terms of that definition (§ 112.3(c)).

Notably, we are defining “pre-consumer vegetative waste” in part to require that these materials may not have come in contact with animal products, byproducts or manure or with an end-user (consumer). We are also excluding table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, and any waste generated by restaurants. Any material of animal origin (such as meat) that is added to a soil amendment, regardless of whether it has been served to or come in contact with a consumer, renders that soil amendment a biological soil amendment of animal origin subject to the requirements of subpart F. We acknowledge that a variety of feedstocks may be used to produce treated biological soil amendments of animal origin, including stabilized compost, and that feedstocks differ with respect to their inherent risk. Therefore, in subpart F we chose to establish requirements for the end product of treatment (i.e., the stabilized compost) rather than the feedstock. If a feedstock is treated to meet the standards of §§ 112.54 and 112.55, we conclude that the end product may be used in accordance with requirements for treated biological soil amendments of animal origin rather than untreated biological soil amendments of animal origin in § 112.56. We note that, depending on the level of treatment received, the end products present differing levels of risk reflected in the different application requirements established in § 112.56.

(Comment 266) One comment requests FDA not subject manure from grass-fed animals to the requirements of subpart F. The comment states manure from grass-fed animals does not contain harmful levels of E. coli and other noxious bacteria.

(Response) FDA is not providing an exemption from subpart F for manure from grass-fed animals used as a soil amendment. We are not aware of evidence to support the assertion made by the commenter and the comment did not provide any such data or other information.

(Comment 267) Some comments recommend FDA specifically exempt tree nuts from the biological soil amendment requirements in the rule. These comments state that certain types of tree nuts never touch the ground and most tree nut farms use non-biological soil amendments.

(Response) If a covered farm does not use biological soil amendments of animal origin, then the provisions of subpart F are not applicable to that covered farm. In addition, the requirements we are establishing in § 112.56 allow use of both treated and untreated biological soil amendments of animal origin in situations where there is no contact between the covered produce and the soil amendment. Thus, we do not believe it is necessary or appropriate to exempt tree nuts from this subpart, as suggested by the comment.

(Comment 268) Some comments stated that raw manure is preferable to stabilized compost because raw manure has greater nitrogen content. These comments indicated that farms that switch from raw manure to stabilized compost will need to use additional stabilized compost to make up the loss in nitrogen content. These comments expressed concern that such changes would interfere with nutrient management programs and increase nutrient runoff into waterways.

(Response) As we noted in the supplemental notice, we recognize that some loss of nitrogen during the composting process is likely (Ref. 169) and that adjustments to fertility management will be necessary when shifting to use of stabilized compost. However, we continue to believe that use of stabilized compost is preferable to use of raw manure for growing covered produce because of the higher likelihood of pathogens associated with raw manure. With regard to concerns about nutrient management programs and runoff, we note that stabilized compost has stabilized forms of nitrogen, which are less susceptible to leaching or runoff than unstabilized forms (Ref. 170) (Ref. 171). At the same time, stabilized compost also retains many other key values of raw manure, including serving as a supply of carbon to support diverse and abundant soil microbial communities, which serve important functions in nutrient cycling, conditioning of soil physical and chemical properties, and in some cases crop protection from phytopathogenic diseases (Ref. 171) (Ref. 172) (Ref. 173). Concerns about runoff from biological soil amendments of animal origin are also addressed in the final EIS (Ref. 126).

(Comment 269) One comment points out that the ability to safely and responsibly handle waste from animal livestock production and processing, primarily swine and poultry operations, is critical to the agricultural economy. The comment further states swine and poultry waste is applied primarily to crops such as corn or soybeans, or in forestry plantations.

(Response) Nothing in this rule prevents the use of waste from animal livestock production and processing as biological soil amendments of animal origin, provided that the amendments are produced and used in accordance with the relevant provisions of subpart F. We also note that dent- or flint-corn and soybeans are excluded from the definition of “produce” in this rule because they are grains (§ 112.3(c)) and are therefore not subject to this rule. Sweet corn

is exempt from the rule because it is on the list of produce that FDA has determined is “rarely consumed raw” in § 112.2(a)(1). Further, lumber is also not “produce” for purposes of this rule and forestry plantations producing lumber are therefore not subject to this rule.

1. Use of Agricultural Teas

(Comment 270) Many comments recommend agricultural teas should be regulated using the same standards as stabilized compost. Specifically, some comments suggest that agricultural tea used as a soil amendment in direct soil application with covered produce poses a significant risk, and that such teas are often produced on-farm, with little emphasis on minimizing the presence of pathogens. Several other comments discuss agricultural tea as having unique food safety risks and request that FDA address agricultural teas separately within § 112.56. These comments ask FDA to establish reasonable, scientifically based minimum application intervals for use of agricultural teas as soil amendments and to require that they be applied in a manner that has minimal potential for contact with covered produce during and after application. On the other hand, some comments argue that agricultural teas prepared from stabilized compost in accordance with NOP standards do not carry any food safety risks and therefore should have no application interval requirements. One such comment provides two literature citations to argue that pathogens such as E. coli and Salmonella, are poor at surviving on plants and are quickly overrun by normal, plant colonizing bacteria. The comment argues that more significant risks are posed by anaerobically prepared manure or non-NOP compliant agricultural teas, which the comment argues should be banned from use as soil amendments.

(Response) FDA agrees that agricultural teas that are biological soil amendments of animal origin (see Comment 271) should be regulated similarly to other biological soil

amendments of animal origin, with appropriate attention given to their unique qualities, and we believe we have done so in this rule. Under § 112.51, the components of an agricultural tea (of animal origin) must be processed to the same standards as other biological soil amendments of animal origin to be classified as a treated biological soil amendment of animal origin, with the addition of specific requirements for the quality of the water used to produce the tea (see §§ 112.51(a) and (b)(1)) and the heightened risk presented by the use of agricultural tea additives (see § 112.51(b)(5)). We consider that, in connection with the provisions of § 112.51 just described, the treatment processes described in § 112.54 and the microbial standards of § 112.55 are adequate for all biological soil amendments of animal origin, including agricultural teas (of animal origin), and it is not necessary to also include a separate section in § 112.56 regarding agricultural teas (of animal origin). We have addressed the unique risks of agricultural teas (of animal origin) by limiting in § 112.51 the circumstances under which they may be considered “treated.” Thus, agricultural teas (of animal origin) made with untreated surface water, or water that has detectable generic E. coli in 100 mL of water; and agricultural teas (of animal origin) that contain agricultural tea additives are considered “untreated” and must be applied in accordance with § 112.56(1)(i) or (ii). In addition, like all other biological soil amendments of animal origin, agricultural teas (of animal origin) must be considered untreated and applied in accordance with § 112.56(1)(i) or (ii) if they fall within any of the categories in § 112.51(b) (for example, if the biological materials of animal origin used to make the tea are not processed to completion in accordance with the requirements of § 112.54, or if they have been contaminated after treatment).

The comment asserting the safety of agricultural teas produced from stabilized compost following NOP standards did not provide data or information supporting that assertion. However,

we note that under §§ 112.56(a)(2) or (a)(3), biological soil amendments of animal origin that are agricultural teas prepared from properly handled stabilized compost (i.e., biological materials of animal origin are processed to completion in accordance with § 112.54 to meet relevant microbial standards in § 112.55; made with water satisfying the requirements of § 112.51(a); and not otherwise considered “untreated” under § 112.51(b)) have an application interval of zero days, and application method restrictions that vary based only on the level of treatment provided by the processing. Under § 112.56(a)(1), other biological soil amendments of animal origin that are agricultural teas and that are considered “untreated” under § 112.51(b) must be applied in a manner that does not contact covered produce at application and minimizes potential for contact after application, or in a manner that does not contact covered produce during or after application. See Comment 257 regarding our plans relating to a minimum application interval for untreated biological soil amendments of animal origin applied in a manner that contacts covered produce.

With regard to the comment about anaerobic preparation, FDA does not consider that there is enough evidence in the literature to link the method of agricultural tea production (actively aerated or anaerobic brewing) to a difference in E. coli risk. Most enteric bacterial pathogens (such as E. coli and Salmonella spp.) are classified as facultative anaerobic organisms; these organisms will grow faster and out-compete other organisms at a faster rate in an aerobic environment, as compared to an anaerobic environment, provided the same amount of nutrients and conditions for growth are present in both environments. It is a common misperception that these pathogens thrive better in an anaerobic environment than in an aerobic one (Ref. 174). The scientific literature points to agricultural tea additives, and not brewing method, as the main factor associated with human pathogen growth in agricultural teas (Ref. 174).

(Comment 271) Several comments state that agricultural teas are not typically considered to be agricultural water; are applied sporadically, sometimes very close to harvest; and are used in conjunction with plants, other microbes, nutrients, and the soil to suppress disease, improve soil structure, maintain nutrients, and increase water holding capacity. These comments recommend that FDA clarify that the water used to make agricultural tea, or the resulting agricultural tea, does not need to meet the requirements for “agricultural water” in subpart E.

(Response) In § 112.3(c) of this rule, we are revising the definition of “agricultural tea” to include an explicit statement that “[a]gricultural teas are soil amendments for purposes of this rule.” We recognize that agricultural teas may be applied in some cases for purposes in addition to those specified in our definition of “soil amendment,” that is, “to improve the chemical or physical condition of the soil in relation to plant growth or to improve the capacity of the soil to hold water.” However, we understand that even when such additional purposes exist, agricultural teas are generally used for the purposes described in the definition of “soil amendment” in this rule. In addition, we believe that the appropriate requirements to apply to agricultural teas made with materials of animal origin are those we have established in subpart F of this rule for biological soil amendments of animal origin, and not the requirements in subpart E that apply to agricultural water. We are removing the reference to agricultural tea in subpart E of this rule, in proposed § 112.44(a)(3), because it was confusing. Water used to make an agricultural tea must not be untreated surface water, and must meet the same microbial criteria as that set forth in § 112.44(a) for the resulting agricultural tea to be considered “treated” under § 112.51 in subpart F. Whether a biological soil amendment of animal origin is “treated” or “untreated” under § 112.51 affects the application restrictions that apply to its use in § 112.56. However, we do not intend to

require that agricultural teas, or the water used to make them, meet other requirements in subpart E for agricultural water. Thus, we are deleting the reference to agricultural teas in subpart E, making the revision discussed previously to the definition of “agricultural tea,” and revising to § 112.51(a) and (b)(1) to clarify this. As revised, § 112.51(a) provides that “a biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54, or, in the case of an agricultural tea, the biological materials of animal origin used to make the tea have been so processed, the water used to make the tea is not untreated surface water, and the water used to make the tea has no detectable generic Escherichia coli (E. coli) in 100 milliliters (mL) of water.” As revised, § 112.51(b)(1) provides that “a biological soil amendment of animal origin is untreated if it has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials of animal origin used to make the tea have not been so processed, or the water used to make the tea is untreated surface water, or the water used to make the tea has detectable generic Escherichia coli (E. coli) in 100 milliliters (mL) of water.”

We also note that to the extent agricultural teas are being used as pesticides, FIFRA provides for federal regulation of their distribution, sale, and use. All pesticides distributed or sold in the United States must be registered (licensed) by EPA. The term “pesticide chemical” is also defined in section 201(q) of the FD&C Act. Food bearing or containing a pesticide chemical residue is adulterated under 402(a)(2)(B) unless a tolerance is in effect and the quantity of the residue is within the limits of the tolerance, or an exemption from the requirement of a tolerance is in effect (see section 408(a) of the FD&C Act). EPA has established tolerances, and exemptions from the requirement of a tolerance, in 40 CFR part 180, subparts C and D,

respectively. For more information, see <http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide#laws> and <http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions> (Ref. 127) (Ref. 174a)

(Comment 272) One comment states that the 2013 proposed rule does not distinguish between “compost extracts” and “compost teas.” Compost extracts as described by the commenter are simply water infusions of compost, without any “compost tea additive” (what we have termed “agricultural tea additive”). The comment states that compost extracts without “compost tea additives” should have no greater restrictions than the compost that was used to make the tea.

(Response) As discussed in response to Comment 270, this rule regulates agricultural teas that are biological soil amendments of animal origin similarly to other biological soil amendments of animal origin, with appropriate attention given to their unique qualities, including whether they contain agricultural tea additives as we have defined that term in § 112.3(c). Further, this rule does distinguish between agricultural teas, as we have defined that term in § 112.3(c), and other extracts. FDA defines “agricultural tea” to mean “a water extract of biological materials (such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural teas are held for longer than one hour before application. Agricultural teas are soil amendments for purposes of this rule.” An agricultural tea (of animal origin) must be used in accordance with the provisions of § 112.56 in

accordance with its status as a ‘treated’ or ‘untreated’ biological soil amendment of animal origin. In response to Comment 270, we describe how those requirements differ for agricultural teas that are biological soil amendments of animal origin as compared to other biological soil amendments of animal origin. A water extract of biological materials of animal origin that is not an agricultural tea (such as extracts that are held (i.e., “steeped”) for less than one hour before application) may still be a biological soil amendment of animal origin if it fits that definition, in which case it is subject to the requirements for biological soil amendments of animal origin in subpart F.

(Comment 273) One comment argues that the rule places restrictions on agricultural teas made from biological materials not of animal origin that are not reasonable, given the proposed exclusion of other biological soil amendments of non-animal origin from the coverage of subpart F.

(Response) We based our proposed definition of “agricultural tea” in part on a similar definition of “compost tea” used by the NOSB (78 FR 3545). We did not limit this definition to teas made from biological materials of animal origin because we intended to describe the wide range of agricultural teas used in the production of produce in this definition. However, we agree that, consistent with the scope of this rulemaking, agricultural teas made entirely from vegetative material are excluded from the requirements of subpart F that apply to biological soil amendments of animal origin. This is achieved not through the scope of the definition of “agricultural tea,” but by the fact that the requirements in subpart F refer in all relevant locations to biological soil amendments of animal origin, thus requiring that there be some component of animal origin in the biological soil amendment feedstock (or, in the case of § 112.53, human

waste). To improve clarity, we are amending the three appearances of the term “agricultural tea” in § 112.51 to specify that the biological materials used to make the tea include materials of animal origin.

B. Determining the Status of a Biological Soil Amendment of Animal Origin (§ 112.51)

In proposed § 112.51, we proposed to establish requirements for determining the status of a biological soil amendment of animal origin as being treated or untreated, for use in covered activities. In Table 14, we describe the codified provisions of § 112.51 and any changes we made to those provisions in the final rule. Comments specific to § 112.51 follow the table.

Table 14.-- Description of Revisions to § 112.51

Proposed Provision	Proposed Language	Final Revisions, if Any
§ 112.51(a)	A biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials used to make the tea have been so processed and the water used to make the tea satisfies the requirements of § 112.44(a)	Revised to clarify that agricultural teas covered are those for which the biological materials include materials of animal origin, , and to replace reference to § 112.44(a) with clarifying text.
§ 112.51(b)(1)	A biological soil amendment of animal origin is untreated if: (1) It has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials used to make the tea have not been so processed or the water used to make the tea does not satisfy the requirements of § 112.44(a)	Revised to clarify that agricultural teas covered are those for which the biological materials include materials of animal origin, and to replace reference to § 112.44(a) with clarifying text.
§ 112.51(b)(2)	A biological soil amendment of animal origin is untreated if: (2) it has become contaminated after treatment;	No change
§ 112.51(b)(3)	A biological soil amendment of animal origin is untreated if: (3) it has been recombined with an untreated biological soil amendment of animal origin	No change
§ 112.51(b)(4)	A biological soil amendment of animal origin is untreated if: (4) it is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness	No change
§ 112.51(b)(5)	A biological soil amendment of animal origin is untreated if: (5) it is an agricultural tea that contains an agricultural tea additive	Revised to clarify that agricultural teas covered are those for which the biological materials include materials of animal

		origin.
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(Comment 274) A comment recommends that FDA make a distinction between raw animal manures and other animal-based fertilizers such as bone, feather, and blood meal, which are commercially processed.

(Response) FDA’s approach does distinguish between “treated” and “untreated” biological soil amendments of animal origin. The distinction is established in § 112.51 and is made based upon the components, processing, handling, and other information about the soil amendment, and not the particular type of animal component that was the feedstock (starting material). Application restrictions for treated and untreated biological soil amendments of animal origin are described in § 112.56.

(Comment 275) One comment generally agrees with our regulatory descriptions in § 112.51(b) of biological soil amendments of animal origin that are untreated, but asked us to modify § 112.51(b)(4) so that if any discrete component of a soil amendment is untreated, the entirety is considered untreated. The comment argues that whether any untreated component part renders the entirety “untreated” should not depend on whether the farm knows or has reason to believe that the untreated component is contaminated.

(Response) FDA agrees that if any discrete component of a soil amendment is untreated, the entirety is considered untreated. However, such situations are addressed in § 112.51(b)(1) (not processed to completion), (b)(2) (contaminated after treatment), and (b)(3) (recombined with an untreated biological soil amendment of animal origin). The comment misunderstands § 112.51(b)(4), which refers to a situation in which, for example, you find out that your feedstock (or a portion of it) was contaminated with a pathogen, or associated with foodborne illness. In

such cases, FDA concludes that you should be required to consider the biological soil amendment to be untreated for purposes of subpart F, including the application restrictions in § 112.56. If there is reason to think that materials used in a biological soil amendment of animal origin are actually contaminated or associated with foodborne illness, there is a need to apply the most stringent controls to such materials, even if they have undergone a treatment process meeting the requirements of §§ 112.54 and 112.55.

(Comment 276) One comment disagrees with FDA’s decision to treat agricultural teas (of animal origin) that contain additives as “untreated” because FDA cited only one study by Ingram and Millner (Ref. 174). This comment cites a reference (Ref. 175) which, according to the commenter, showed that while the addition of molasses as an agricultural tea additive at 1 percent enhanced growth of Salmonella and E. coli O157:H7 in an agricultural tea, the addition of 0.2 percent molasses did not. Further, the comment argues that the addition of carrot juice as an agricultural tea additive was shown to inhibit the growth of nonpathogenic E. coli in swine manure compost extract (Ref. 176). This comment contends that FDA should focus on factors other than the addition of additives to determine requirements for agricultural teas.

(Response) FDA recognizes that many agricultural tea production practices include the addition of nutrient additives (such as molasses) during the steeping process, a practice designed to rapidly increase the indigenous heterotrophic microbiological populations extracted from the biological feedstock. The two studies mentioned in the comment do, however, provide scientific evidence to support FDA’s conclusion that even when stabilized compost or other biological materials of animal origin used as feedstock for an agricultural tea meet the microbial standards of § 112.55(a) or the microbial standard of § 112.55(b), when an agricultural tea additive is used,

it can result in a final product that contains human pathogens capable of causing serious adverse health consequences or death (Ref. 174) (Ref. 175) if used as a soil amendment in growing covered produce without restriction. In these same studies, when agricultural teas were produced using the same compost feedstocks without the addition of agricultural tea additives, pathogens were undetectable in the final product.

The scientific body of evidence is inconclusive as to what component or components (e.g., soluble carbon content) in agricultural tea additives may be contributing to the propagation of human pathogens during the production of agricultural teas, so it is difficult for FDA to ascertain the significance between 0.2 percent (vol:vol) molasses that did not support growth in the Duffy et al. 2004 study and 0.5 percent (vol:vol) of Soil Soup Additive (contains molasses) in the Ingram study that supported pathogen growth. It should be noted that Kannangara (2006) noticed a population increase in generic E. coli during aerated agricultural tea production amended with only 0.01 percent molasses, but did document a reduction (but not elimination) of generic E. coli in response to the addition of carrot juice extract used as an agricultural tea additive. We continue to believe the preponderance of evidence supports the conclusion that the use of an agricultural tea additive will increase the likelihood of pathogen growth in an agricultural tea (of animal origin). However, FDA supports innovation and encourages development and scientific evaluation of agricultural tea additives that can reliably suppress the growth of, or eliminate, foodborne pathogens in agricultural tea. Should consistently safe production and use of agricultural tea additives become established, we will consider appropriate next steps, including possibly revisiting these requirements.

(Comment 277) Several comments disagree with the proposed distinctions related to treated and untreated biological soil amendments. These commenters believe that, as proposed, various types of biological soil amendments of animal origin (such as static compost, vermicompost, compost teas with additives such as molasses or sea kelp, and compost that is produced outside of the proposed time and temperature requirements) would be treated as raw manure even though, in the view of these commenters, such biological soil amendments may not pose the same risks as raw manure.

(Response) We disagree that our requirements would result in all the listed biological soil amendments of animal origin being subject to the same requirements as raw manure. Section 112.51 distinguishes between ‘treated’ and ‘untreated’ biological soil amendments of animal origin, and § 112.56 describes the application restrictions that apply to biological soil amendments of animal origin depending on whether they are treated or untreated (and if treated, depending on which level of treatment they received). The provisions of § 112.51 refer to the treatment processes of § 112.54, which in turn refers to the microbial standard provisions of § 112.55. We have revised the text throughout § 112.54 to refer to “biological process[es],” and we use “composting” as an example of a biological process. Thus, under the revised options for treatment processes in § 112.54, this rule classifies the end products of any scientifically valid controlled biological processes that have been validated to satisfy the microbial standard in § 112.55(a) or (b) as “treated” biological soil amendments of animal origin (provided there is no other reason to consider them untreated under § 112.51(b), such as contamination after treatment). Therefore, stabilized compost produced by static composting processes, end products of vermicomposting processes, or stabilized compost produced through time/temperature combinations other than those described in § 112.54(c)(1) and (2) may be considered “treated”

provided that they meet the requirements of § 112.54, including satisfying one of the microbial standards in § 112.55. On the other hand, raw manure must be regarded as “untreated” under § 112.51. An agricultural tea made with biological materials of animal origin that contains an agricultural tea additive (such as molasses or sea kelp) is considered “untreated” under § 112.51(b)(5) due to the heightened risk presented by the use of such additives (see also Comment 44), and is therefore in the same category as raw manure with regard to application restrictions in § 112.56.

C. Handling, Conveying, and Storing Biological Soil Amendments of Animal Origin (§ 112.52)

As proposed, § 112.52 would establish requirements for handling, conveying and storing soil amendments of animal origin. In Table 15, we describe the codified provisions of § 112.52 and any changes we made to those provisions in the final rule. Comments specific to § 112.52 follow the table.

Table 15.-- Description of Revisions to § 112.52

Proposed Provision	Proposed Language	Final Revisions, if Any
§ 112.52(a)	You must handle, convey, and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems	Revised to add other soil amendments and to clarify that drip fertigation with agricultural teas that are biological soil amendments of animal origin is permitted in compliance with other requirements of this rule.
§ 112.52(b)	You must handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin	No change
§ 112.52(c)	You must handle, convey, and store any biological soil amendment of animal origin that has become contaminated as if it was untreated	Revised

(Comment 278) One comment states that many farms store animal manure purchased from animal production facilities for several months before application. The comment maintains that this practice can threaten produce safety through potential contamination of water and air, just like animal manure stored on adjacent animal production facilities.

(Response) FDA agrees that stored animal manure can be a source of contamination. Section 112.52(a) requires biological soil amendments of animal origin to be handled, conveyed, and stored in a manner and location such that they do not become a potential source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments.

(Comment 279) One comment interprets § 112.52(a) as forbidding drip “fertigation” with biological soil amendments of animal origin, even if the material is not reasonably likely to contact covered produce. The commenter requests that FDA clarify the provision by adopting the following edit: “...such that it does not become a potential source of contamination to...water distribution systems, if such contamination may reasonably be likely to result in contamination of covered produce.”

(Response) We did not intend for § 112.52(a) to forbid drip fertigation with biological soil amendments of animal origin. Biological soil amendments of animal origin may be used in water distribution systems in accordance with § 112.56 and their status as “treated” or “untreated” and, if “treated”, to what standard. If “untreated” or “treated” to the standard in § 112.55(b), then the biological soil amendment of animal origin must not contact covered produce at application and contact later must be minimized. If the biological soil amendment of animal origin is “treated” to the standard in § 112.55(a), then there are no restrictions on use. We are

revising § 112.52(a) to add a statement that agricultural teas that are biological soil amendments of animal origin may be used in water distribution systems provided that all other requirements of this rule are met.

(Comment 280) One comment is concerned that the proposed language of § 112.52(c) does not specify the basis for the knowledge or suspicion that a soil amendment has become contaminated. The commenter recommends FDA make the following change to § 112.52(c) (additions underlined): “(c) You must handle, convey, and store any biological soil amendment of animal origin that you know or have reason to believe may have become contaminated as if it was untreated.”

(Response) FDA is making this change. FDA agrees that you should be required to regard as “untreated” under § 112.51 any biological soil amendment of animal origin that you know or have reason to believe may have become contaminated, and not only biological soil amendments of animal origin that have actually become contaminated. This revision makes clear that covered farms must regard biological soil amendments of animal origin as untreated as soon as they have information giving them reason to believe contamination of the biological soil amendment may have occurred.

D. Prohibitions Regarding Use of Human Waste (§ 112.53)

In § 112.53 we proposed to prohibit the use of human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements. In Table 16, we describe the codified

provisions of § 112.53 and any changes we made to those provisions in the final rule. Comments specific to § 112.53 follow the table.

Table 16.-- Description of Revisions to § 112.53

Proposed Provision	Proposed Language	Final Revisions, if Any
§ 112.53	You may not use human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.	No change

(Comment 281) Some comments express concern that FDA’s proposed rule allowed the use of untreated human waste and biosolids for the production of covered produce, even if users were following the EPA requirements in 40 CFR part 503, subpart D, or equivalent regulatory requirements. Comments express particular concern that the rule would allow foreign producers to use human waste as a soil amendment, even though their use may not meet EPA standards, and some comments noted that farms in some countries have historically used human waste in growing produce. Many commenters request that FDA prohibit the use of human waste in the production of covered produce. Conversely, at least one comment requests that FDA allow for the use and application of human waste in the growing of covered produce.

(Response) Section 112.53 clearly states that the use of human waste is prohibited for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements. In consultation with EPA, FDA has concluded that adherence to 40 CFR part 503 remains an appropriate approach to the use of biosolids for the growing of covered produce. We continue to believe that these requirements are appropriately protective of public health.

With regard to concerns about ensuring that the provisions are followed for imported produce, we note that § 112.53 refers to “equivalent regulatory requirements” to provide for the

possibility that other competent authorities have established such requirements in other jurisdictions. In addition, please see the response to Comment 50 regarding the provisions of the FSVP regulation. We also note that the use of human waste for food production has been addressed by the Codex (Ref. 22). FDA plans to conduct outreach activities regarding the produce safety rule to help farms understand how to comply (see section XXII for additional information).

(Comment 282) Several comments object to referencing the requirements in 40 CFR part 503. A few comments argue that part 503 is out of date. One comment points to a National Academy of Sciences review of part 503, and argues that the requirements for using human waste for growing covered produce should be strengthened in accordance with this NAS report, and should use current risk assessment methods. One comment questions the validity of the application intervals in part 503 and expresses concerns about the environmental implications of applying biosolids to agricultural land.

(Response) FDA, in consultation with EPA, has determined that 40 CFR part 503 remains the most appropriate approach to safe use of sewage sludge biosolids on land involved in the production of covered produce. We point out that the NAS 2002 report (Ref. 177) noted that there is "...no documented evidence to indicate that part 503 has failed to protect public health"; that EPA responded to the NAS review with a 14-point action plan, which it is carrying out; and that under section 405(d)(2)(C) of the CWA, EPA is required to publish a biennial review of part 503 (Ref. 178). FDA concludes that the provisions of 40 CFR part 503 are appropriate standards for protecting public health with respect to the use of sewage sludge biosolids in growing covered produce.

(Comment 283) A comment requests that source separated human urine be classified separately from sewage sludge biosolids, thus allowing it to be used in growing covered produce. The comment maintains that human urine is sterile, contains bioavailable nutrients, and is an otherwise wasted resource that could be important to agriculture and is used in other countries as a fertilizer.

(Response) Urine is not covered by 40 CFR part 503 and, therefore, as human waste, § 112.53 prohibits its use in growing covered produce. The commenter did not provide data or information from which we could conclude that source separated human urine should be allowed to be used in growing covered produce, and therefore we are not making this change.

(Comment 284) One comment argues that even if human sewage has been adequately treated to be free of pathogens, it would still be susceptible to recontamination. This comment suggests that recontamination should be explicitly addressed in this rule.

(Response) FDA's requirement is that sewage sludge biosolids be used in accordance with 40 CFR part 503. Under those requirements if sewage sludge biosolids that met the standards to be Class A biosolids have human waste added to them, they become Class B biosolids and need to be used in accordance with the requirements for Class B biosolids. However, whether they are Class A or Class B sewage sludge biosolids, they may be used in accordance with 40 CFR part 503. Therefore, we do not believe that recontamination needs to be explicitly addressed in our rule because it is already addressed in 40 CFR part 503 in the various standards that apply to sewage sludge biosolids.

E. Treatment Processes (§ 112.54)

Section § 112.54 describes acceptable processes for the treatment of biological soil amendments of animal origin to be used for growing covered produce. In Table 17, we describe the codified provisions of § 112.54 and any changes we made to those provisions in the final rule. Comments specific to § 112.54 follow the table.

Table 17.-- Description of Revisions to § 112.54

Proposed Provision	Proposed Language	Final Revisions, if Any
§ 112.54	Each of the following treatment processes are acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce, providing that the resulting biological soil amendments are applied in accordance with the applicable requirements of § 122.56:	No change
§ 112.54(a)	A scientifically valid controlled physical process (e.g., thermal), chemical process (e.g., high alkaline pH), or combination of scientifically valid controlled physical and chemical processes that have been demonstrated to satisfy the microbial standard in § 112.55(a) for <u>L. monocytogenes</u> , <u>Salmonella spp.</u> , and <u>E. coli O157:H7</u> ;	Revised to add biological processes and replace “demonstrated” with “validated.”
§ 112.54(b)	A scientifically valid controlled physical process, chemical process, or combination of scientifically valid controlled physical and chemical processes, that has been demonstrated to satisfy the microbial standard in § 112.55(b) for <u>Salmonella</u> and fecal coliforms; or	Revised to add biological processes and replace “demonstrated” with “validated.”
§ 112.54(c)	A scientifically valid controlled composting process that has been demonstrated to satisfy the microbial standard in § 112.55(b) for <u>Salmonella</u> and fecal coliforms. Scientifically valid controlled composting processes include:	First sentence eliminated because biological processes meeting the § 112.55(b) standard are now included in revised § 112.54(b). Second sentence is now part of § 112.54(b) and has been revised to refer again to the microbial standard in § 112.55(b).
§ 112.54(c)(1)	Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 days and is followed by adequate curing, which includes proper insulation;	Renumbered to § 112.54(b)(1) as a conforming change to the combination of § 112.54(b) and (c); clarified that “3 days” is consecutive; and deleted “which includes proper insulation” as it is covered by adequate curing
§ 112.54(c)(2)	Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days, with a minimum of five turnings, and is followed by adequate curing, which includes proper insulation; or	Renumbered to § 112.54(b)(2) as a conforming change to the combination of § 112.54(b) and (c); revised to state that “15 days” does not have to be consecutive; deleted “which includes proper insulation” as it is covered by adequate curing; and deleted “or” at end because § 112.54(c)(3) is deleted.
§	Other scientifically valid, controlled	Eliminated as not necessary. All scientifically

112.54(c)(3)	composting processes, provided you satisfy the requirements of § 112.12, including that the alternative has been demonstrated to satisfy the microbial standard in § 112.55(b).	valid, controlled biological treatment processes, including composting, that meet the microbial standards of § 112.55 are allowable under revised § 112.54(a) and (b), making the allowance for alternative processes unnecessary.
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(Comment 285) Some comments states that the rule inappropriately treats use of physically and chemically treated soil amendments as less risky than soil amendments treated by composting. One comment proposes an alternative approach to regulating stabilized compost, including an additional process to be added for stabilized compost that 1) meets the time and temperature requirements specified in § 112.54(b)(1) and (b)(2); and 2) has been demonstrated to satisfy the microbial standard in § 112.55(a).

(Response) FDA agrees that flexibility needs to be added to the provisions of § 112.54 to broaden the allowable methods for producing stabilized compost that may be regarded as “treated” under § 112.51 and also to allow farms to regard as “treated” biological soil amendments of animal origin processed using biological processes other than composting, such as vermicomposting, provided that such processes meet the microbial standards in either § 112.55(a) or (b). We also recognize that the structure of proposed § 112.54 should be revised to better reflect the application requirements in § 112.56, which we proposed to change in our supplemental notice without making conforming changes to § 112.54. Thus, we are adding options for biological treatment processes (including, but not limited to, composting) in § 112.54(a); and collapsing § 112.54(b) and (c) to allow for a “scientifically valid, controlled biological (e.g., composting), chemical, or physical process, or combinations thereof, that has been demonstrated to satisfy the microbial standard in § 112.55(b) for Salmonella and fecal coliforms.” Importantly, because these changes retain the requirements that all such treatment processes be demonstrated to satisfy either the microbial standards in § 112.55(a) or (b), we

believe these changes address the comments, make these provisions as flexible as possible for farms, and provide sufficient public health protection.

(Comment 286) A comment recommends that subpart F, in reference to biological soil amendment treatment processes, change the term “scientifically valid” to “scientifically validated.” The comment recommends this revision to clarify the need for validation of the treatment method(s) used to treat biological soil amendments of animal origin to meet the microbial standards of § 112.55. The comment notes that the need for validation is discussed in the preamble, but contends that it should also be explicitly stated in the codified so that there is no confusion.

(Response) We do not agree that we should replace the term “scientifically valid” in this subpart with the term “scientifically validated,” as these terms have different meanings. However, a biological soil amendment of animal origin does not meet the definition of “treated” per this subpart unless the treatment process is scientifically valid and controlled and has been demonstrated (i.e., validated) to meet the applicable microbial standards of § 112.55. A treatment process that has been demonstrated to satisfy the microbial standards of § 112.55 has been validated to meet those microbial standards. Therefore, because this comment suggested that there may be some confusion on this, we are revising §§ 112.54(a) and (b) to replace the word “demonstrated” with the word “validated.” We note that consistent with language in other regulations (see the PCHF regulation and 21 CFR part 111), we use the term “scientifically valid” in this rule to mean using an approach that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research.

(Comment 287) A comment requests that FDA add the following language to § 112.54 “...provided that the resulting biological soil amendments meet the microbial standards for the treatment processes as stated in § 112.55 and are applied in accordance with the applicable requirements of § 112.56...”

(Response) It is not necessary to add this language to the introductory text of § 112.54 as the requirements to meet the microbial standards in § 112.55(a) or (b) are contained within the provisions of § 112.54(a)–(b). To add the language as suggested by the comment would be duplicative.

(Comment 288) Comments request that, in order to ensure that whatever scientifically valid controlled process is chosen by a farm (or their supplier) to comply with proposed § 112.54 has been effectively followed, FDA add a required “condition-specific” verification as a requirement in the language of the regulation, which would include appropriate microbial testing using scientifically valid sampling techniques that include timing and location parameters, to establish that the appropriate microbial results stated in the proposed § 112.55 have been achieved.

(Response) FDA is not making this change. As discussed in the 2013 proposed rule (78 FR 3504 at 3578), FDA is not requiring microbial testing of treated biological soil amendments of animal origin to ensure that they meet the relevant microbial standards. Rather, we have provided the microbial standards against which treatment processes must be validated. Proper validation to show that a process satisfies the microbial standards of § 112.55 needs to include specific process variables, and the person applying the treatment process will need to monitor the

physical parameters of the process (e.g., the temperature of a compost pile) to ensure they meet the conditions under which the process was validated. See also our response to Comment 286.

(Comment 289) One comment suggests there may be a higher risk of microbial contamination and a greater threat to public health associated with the use of commercial compost than with compost made on-farm.

(Response) FDA is not aware of a greater threat to public health from the use of commercial compost than compost made on individual farms. The comment did not provide additional information in support of this assertion.

(Comment 290) One comment urges FDA to issue a regulation specifically for the use of manure from animal production facilities. The comment states that FDA should require animal production facilities that sell or give manure to produce farms to take specific steps to minimize contamination, including by harmful pathogens, in their animal waste.

(Response) FDA declines this request. While we recognize the risk presented by the use of manure in growing of covered produce, manure comes from many sources, including from produce farms on which it is used. We believe that it is appropriate to focus this rule's requirements regarding biological soil amendments of animal origin on the operations that are using those materials in the growing of covered produce to minimize the risk presented by such uses.

(Comment 291) Several comments request clarification on whether FDA requires testing of individual feedstocks used to prepare an agricultural tea, at intervals during the brewing

process, or the final agricultural tea product, with attention to the fact that by the time the tea is applied, the test will no longer be representative of the original sample. One comment notes that if an agricultural tea is prepared from a stabilized compost feedstock that meets the microbiological standard of § 112.55(b), then the remaining populations of these microorganisms have the potential to experience rapid population growth. The commenter also notes that the microbiological criterion set in § 112.55 are based on a dry weight (MPN/gram) basis, which would not be representative of an agricultural tea, in which the solid fraction is mostly removed prior to application.

(Response) Like other biological soil amendments of animal origin, FDA is not requiring that agricultural teas (of animal origin) be tested. Rather, for an agricultural tea (of animal origin) to be considered “treated” for the purposes of § 112.51, the components used to make the tea be treated via a process described in § 112.54 (a) or (b) to meet the microbial standards of § 112.55(a) or (b). If a scientifically valid controlled process has been followed, there is no need to test the tea to consider it “treated.” Agricultural teas (of animal origin) that are not treated to such standards, or that contain agricultural tea additives or are made with water not meeting the requirements in § 112.51(a), must be considered “untreated” for purposes of § 112.51. With regard to the potential rapid growth of pathogens in agricultural teas that meet the microbial standards of § 112.55, we note that agricultural teas cannot contain agricultural tea additives if they are to be considered “treated” for purposes of § 112.51, which are the primary contributing factor to rapid growth of microflora in teas (Ref. 174). Finally, we agree that the proposed microbial standards in § 112.55 were established on a dry weight basis, which would not be appropriate for agricultural teas. Therefore, we have modified § 112.55 to add a liquid weight basis for sampling (for use in validation).

(Comment 292) At least one comment suggests that stabilized compost be regulated according to a two-tier approach, whereby a farm could use a zero day application interval if the stabilized compost meets stringent criteria, but would have a 45-day interval for stabilized compost meeting general safety standards and being used on certain covered crops.

(Response) FDA originally proposed a two-tiered strategy for the application interval for use of compost (78 FR 3504). However, in the supplemental notice, FDA proposed that all stabilized compost would have a zero day application interval (see discussion in 79 FR 58434). We are finalizing the provision in § 112.56 for a zero-day interval for stabilized compost. Depending on the microbial standards that the stabilized compost meets (§ 112.55(a) or (b)), the allowable application methods differ (compare § 112.56(a)(3) and (a)(2)).

(Comment 293) A comment requests that FDA focus on compost maturity at the time of field application and requested that FDA provide a specific definition of “curing” along with guidance that would help farms ensure adequate pathogen reduction in stabilized compost, prior to field application. Several other comments also support requiring a curing stage in composting for purposes of considering a biological soil amendment of animal origin to be “treated,” stating that heating manure during the composting process uniformly and to a sufficient temperature through one phase of microbial activity is only part of the pathogen-control process. Other comments indicate that curing must be done in a manner that prevents cross-contamination and which may include proper insulation. Some comments express confusion about insulation, including the type (some comments suggested the use of a plastic tarp) and the timing of insulation (many comments suggested compost needs to be turned many times during the

compost curing process). These comments suggest such use of insulation would be neither economically feasible nor operationally practical. Another commenter suggests that the specific requirements for use of insulating material on compost piles during the curing process are impractical for small-farm methods of composting. Some comments indicate that the proposed requirement for insulated curing of compost in § 112.54 (b)(1) and (b)(2) (originally proposed as § 112.54(c)(1) and (c)(2)) is overly burdensome and not necessary for all approaches to the composting process.

(Response) Curing is an important part of any type of composting process (i.e., static or turned), and reduces pathogens if performed in an adequate manner. The definition of “composting” in § 112.3(c) reflects that curing is an integral part of the process: “Composting means a process to produce stabilized compost in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature (for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions.” Curing involves the complete decomposition of cellulose and lignin in feedstock such that it cannot be further broken down by microbial metabolism. Curing may or may not need to include insulation to be adequate to reduce pathogens to a specified level, depending on environmental conditions. For example, insulation may be needed to ensure that compost temperatures do not drop too fast; proper curing involves a gradual temperature decline. Thus, we are clarifying the definition of “curing” by adding a statement that “[c]uring may or may not involve insulation, depending on environmental conditions.” When there is a need to protect compost from external temperature changes, a plastic tarp would typically not be expected to provide effective insulation. Materials such as a layer of straw, hay, or stabilized compost are effective for use in insulation.

We also acknowledge that, for static composting, insulation may also be used during the first stage of composting as well as during the curing stage. We have made a change to the definition of “static composting” to reflect this (see Comment 107) such that the definition reads, in relevant part, “[s]tatic composting means a process to produce stabilized compost in which air is introduced into biological material (in a pile (or row) that may or may not be covered with insulating material, or in an enclosed vessel) by a mechanism that does not include turning.

As noted previously, curing may or may not involve insulation. We are removing the requirements for proper insulation in § 112.54(b)(1) and (b)(2) because these provisions are examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in § 112.55(b). We agree that insulation may not be necessary to meet the microbial standard of § 112.55(b) under all circumstances and so we have removed the reference to insulation in § 112.54(b)(1) and (b)(2). However, those employing the static and turned composting processes described in § 112.54(b)(1) and (b)(2) will need to make a determination whether insulation is needed as part of the curing phase to achieve stabilized compost.

(Comment 294) A comment requests clarification regarding whether animal manure, or another biological soil amendment of animal origin, that is passively composted (that is, simply left in place without turning or monitoring) for nine months or more, would be considered “untreated” or “treated” for purposes of § 112.51 and associated application restrictions in § 112.56. The commenter suggests that it would be reasonable to consider manure to be “treated” if it has been aged for a period equal to the proposed application interval for untreated biological soil amendments of animal origin.

(Response) Processes that meet the requirements of § 112.54 must be scientifically valid, controlled processes that have been validated to meet the microbial standards in either § 112.55(a) or (b). We are not aware of any data or information supporting a conclusion that “passive composting” as described by the commenter (stockpiling or aging manure) meets the microbial standards in either § 112.55(a) or (b).

(Comment 295) One comment asks for a revision to the example process provided for “turned composting” in § 112.54(b)(2) (originally proposed as § 112.54(c)(2)) to read, “Composting that maintains a minimum average temperature of 131 °F (55 °C) or higher for 15 days or longer and is followed by adequate curing, storage and handling practices. During the period when the compost is maintained at 131 °F (55 °C) or higher, there shall be a minimum of five turnings of the windrow with a minimum of 3 days between turnings. The 15 or more days at or above 131 °F (55 °C) do not have to be continuous.”

(Response) We believe it would be appropriate to make some, but not all, of the changes to the example process for “turned composting” in § 112.54(b)(2) suggested by the commenter. The distinctions between our language and that suggested by the comment are: (1) the commenter’s additional mention of storage and handling; (2) the commenter’s suggestion of requiring a minimum of 3 days between turnings; and (3) the commenter’s suggestion that the 15 days need not be continuous.

With respect to storage and handling, the rule already covers these topics sufficiently in § 112.52, and those requirements apply equally to all processes used under the rule, including those described in § 112.54(b)(2).

With respect to the commenter's suggestion of requiring a minimum of 3 days between turnings, we are not aware of science sufficient to support a conclusion that this is required to meet the microbial standard in § 112.55(b). Every compost pile has a unique size, shape and feedstock composition, all of which affects how the pile will generate and maintain heat. For example, many compost windrows will reach 55 °C relatively quickly, at which time the operator will begin monitoring the 'degree days' above this temperature toward meeting the fifteen days of exposure to 55 °C per § 112.54(b)(2). To continue this 'thermophilic phase' of the process, the operator will typically manage both oxygen and influx of new nutrient materials (via turning), and in some situations even moisture, to maintain the 55 °C temperature for a total of 15 days to rely on the option in § 112.54(b)(2). Turning the piles also serves the purpose of maximizing the exposure of as much of the compost material as possible to the elevated temperatures. To ensure that as much of the compost as possible is exposed to the 55 °C temperature, to rely on the option in § 112.54(b)(2), we are requiring a minimum of 5 turnings but we are not specifying a timeframe for the turns. The timing will be driven by the size, shape and feedstock composition. It is our understanding that, in order to maintain a compost temperature of at least 55 °C for the required 15 days, the operator will likely need to turn the windrow approximately three times per week (within the first two weeks) and then decrease the frequency to once or twice per week for the following month(s) as the compost matures.

As discussed in response to Comment 293, § 112.54(b)(1) and (b)(2) provide two example processes that farms may use to satisfy the microbial standard in § 112.55(b), but these are not the only means of achieving adequate composting to meet the microbial standard in § 112.55(b). Thus, we do not discourage farms from using processes that allow a minimum of 3 days between turnings if those processes are validated to meet the microbial standards in §

112.55(a) or (b), but we are not revising our example process in § 112.54(b)(2) because we do not believe it is necessary.

With respect to the commenter's suggestion that the 15 days need not be continuous, we agree that the 15 days at 55 °C need not be continuous and, given the nature of turned composting, it is unlikely that they would be continuous (Ref. 179). We are revising § 112.54(b)(2) to indicate that the 15 days at 55 °C need not be consecutive. For clarity, we are also revising § 112.54(b)(1) to indicate that the 3 days at 55 °C is consecutive. For static aerated composting, 3 consecutive days at or above 55 °C ensures that the microbial standard in § 112.55(b) is achieved, considering the expected die-off rates of various classes of thermophilic and thermotolerant pathogens (Ref. 180).

(Comment 296) One comment asks for confirmation that covered produce grown using biological soil amendments of animal origin containing pathogens at or below the microbial standards set forth in § 112.55(a) and (b) are considered "safe."

(Response) In this regulation, FDA is establishing those standards that we conclude minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that are reasonably necessary to prevent the introduction of hazards into produce, and to provide reasonable assurances that process is not adulterated under section 402 of the FD&C Act. We do not expect that compliance with these standards will eliminate all occurrences of hazards in covered produce.

(Comment 297) One comment recommends that rather than focusing on process standards, which the commenter criticizes as ambiguous, the rule should instead require that

stabilized compost be tested for indicator microbial species to determine appropriate application restrictions.

(Response) FDA disagrees. We have established an approach where we define “treated” and “untreated” biological soil amendments of animal origin through the application of a scientifically valid, controlled process (described in § 112.54) that has been validated to satisfy the microbial standards of either § 112.55(a) or (b). We do not agree that such process standards are ambiguous. See discussions in Comment 286 and Comment 288. Moreover, we conclude that our approach is more protective of public health than relying on lot testing for indicator species. Appropriate indicator species in biological soil amendments of animal origin may be difficult to identify, and routine pathogen testing is not an effective indicator of the presence or absence of pathogens. In addition, such testing could require multiple target organisms, which could be very costly.

(Comment 298) Some comments request that accepted treatment processes be backed by scientific evidence that they will protect public health.

(Response) As discussed in the 2013 proposed rule (78 FR 3580-1), the microbial standards set out in § 112.55 are protective of public health. Treatments for biological soil amendments of animal origin must be scientifically valid, controlled processes that have been validated to satisfy the relevant microbial standard in § 112.55(a) or (b). In § 112.54(b)(1) and (b)(2) we have described processes for static and turned composting that have been previously validated to meet the standard in § 112.55(b) for Salmonella and fecal coliforms when done properly.

(Comment 299) Some comments request that FDA require suppliers to provide a guarantee to purchasers that a biological soil amendment the supplier claims is not of animal origin indeed not include any components of animal origin.

(Response) FDA declines to require provision of such guarantees. Soil amendments that do not contain components of animal origin are not subject to the requirements in subpart F. This rule does not require covered farms to receive such guarantees to use soil amendments that are not of animal origin other than as provided by subpart F. However, covered farms are responsible for their compliance with the rule, and we do not discourage farms from requesting such guarantees from their suppliers, which seems likely to be a prudent practice.

F. Microbial Standards Applicable to the Treatment Processes in § 112.54 (§ 112.55)

Section 112.55 establishes microbial standards applicable to the treatment processes in § 112.54. In Table 18, we describe the codified provisions of § 112.55 and any changes we made to those provisions in the final rule. Comments specific to § 112.55 follow the table.

Table 18.-- Description of Revisions to § 112.55

Proposed Provision	Proposed Language	Final Revisions, if Any
§ 112.55	The following microbial standards apply to the treatment processes in § 112.54 as set forth in that section.	No change
§ 112.55(a)	For <u>L. monocytogenes</u> , <u>Salmonella</u> species, and <u>E. coli</u> O157:H7, the relevant standards [are those in (a)(1)-(a)(3)] or;	No change
§ 112.55(a)(1)	<u>L. monocytogenes</u> ... Not detected using a method that can detect one colony forming unit (CFU) per 5 gram analytical portion.	Revised to add liquid sampling.
§ 112.55(a)(2)	<u>Salmonella</u> species... Less than three most probable numbers (MPN) per 4 grams of total solids (dry weight basis)	Revised to add liquid sampling and indicate that it is a ‘non-detect’ standard.
§ 112.55(a)(3)	<u>E. coli</u> O157:H7... Less than 0.3 MPN per 1 gram analytical portion.	Revised to add liquid sampling and indicate that it is a ‘non-detect’ standard.
§ 112.55(b)	Less than three MPN <u>Salmonella</u>	Revised to add liquid sampling and indicate that the

	species per four grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).	<u>Salmonella</u> method is a 'non-detect' standard.
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(Comment 300) One comment suggests that should FDA consider end-use risk in establishing final microbial standards for treated biological soil amendments of animal origin. The comment pointed to Austrian ÖNORM standards for compost, which differ by end-use categories.

(Response) We believe we have appropriately considered end-use risk in establishing the microbial standards for treated biological soil amendments of animal origin. First, we note that this rule does not apply to end uses such as home gardening or growing crops other than covered produce. The end uses to which the requirements of subpart F apply are more limited than those in the Austrian standards noted in the comment. Second, we conclude that all treated biological soil amendments of animal origin must meet the standards in § 112.55(a) or (b), and those that meet the standards of § 112.55(b) must also be applied in accordance with the restrictions in § 112.56(a)(2). We also conclude that untreated biological soil amendments of animal origin must be applied in accordance with the restrictions in § 112.56(a)(1). See Comment 257 regarding our plans for application intervals for such biological soil amendments of animal origin.

(Comment 301) Some comments indicate a belief that the standards in proposed § 112.55 are metrics for required microbial testing. The comments suggest the use of guidance documents, which can be more easily updated, in lieu of incorporating metrics in the provisions of the rule.

(Response) FDA is not requiring microbial testing of treated biological soil amendments of animal origin to ensure that they meet the relevant microbial standards. Rather, we have provided the microbial standards against which treatment processes must be validated. Proper

validation to show that a process satisfies the microbial standards of § 112.55 needs to include specific process variables, and the person applying the treatment process will need to monitor the physical parameters of the process (e.g., the temperature of a compost pile) to ensure they meet the conditions under which the process was validated. See also our response to Comment 286. In §§ 112.54(b)(1) and (b)(2) we have also described processes for static and turned composting that have been previously validated to meet the standard in § 112.55(b) for Salmonella and fecal coliforms when done properly.

(Comment 302) One comment recommends FDA change the microbial standards for Salmonella spp. and E. coli O157:H7 in § 112.55(a) to “negative” or less than detectable limit (<1/30 grams).

(Response) The microbial standards as proposed in § 112.55(a) represented “less than the detectable limit” for each pathogen, though only § 112.55(a)(1) was phrased as “not detected using a method that can detect...” We are revising the standards in §§ 112.55(a)(2) and (a)(3) and the Salmonella standard in 112.55(b) to provide a parallel structure. As revised, § 112.55(a)(2), (a)(3), and (b) read as set forth in the regulatory text of this rule.

G. Application Requirements and Minimum Application Intervals (§ 112.56)

Section 112.56 establishes application restrictions based on whether biological soil amendments of animal origin are treated or untreated; and for those biological soil amendments of animal origin that are treated, based on the level of treatment they received (with reference to the microbial standards in § 112.55). In Table 19, we describe the proposed codified provisions of § 112.56 (considering the 2013 proposed rule and the supplemental notice, taken together) and

any changes we made to those provisions in the final rule. Comments specific to § 112.56 follow the tables.

Table 19.-- Description of Revisions to § 112.56(a)

Proposed Provision	Proposed Language	Final Revisions, if Any
§ 112.56(a)	Except as provided in paragraph (b) of this section, you must apply the biological soil amendments of animal origin specified in the first column of the table in this paragraph in accordance with the application requirements specified in the second column of the table in this paragraph and the minimum application intervals specified in the third column of the table in this paragraph [table follows containing (1)-(4)].	Deleted “Except as provided in paragraph (b) of this section” as a conforming change to the deletion of (b) (made in the supplemental notice). Revised (a)(1)-(4) to (a)(1)-(3)

Proposed § 112.56(a)(1)-(4) was published at 78 FR 3504, January 16, 2013.

Final § 112.56(a)(1)-(3) is set forth in the regulatory text of this rule.

The revisions in final § 112.56(a)(1)-(3) consist of conforming amendments to match changes made in § 112.54 (including biological processes in both § 112.54(a) and (b), and collapsing § 112.54(b) and (c)); and to renumber proposed (a)(2) as (a)(3).

(Comment 303) Several comments request that FDA clarify the meanings of “does not contact,” and “minimizes contact.” Some comments suggest that the phrase “In a manner that does not contact covered produce during or after application” might be read to require that there is absolutely no possibility of contact of the soil amendment with the covered produce, and one comment suggested that such a requirement could never be met in light of the variety of activities performed on farms and the potential that dust from fields may contact covered produce. Another comment seeks clarification on whether the harvestable portion of

underground crops would be considered to come into contact with the biological soil amendments of animal origin used on the soil.

(Response) FDA intends “does not contact” in § 112.56 to mean there is no intended or likely contact between the biological soil amendment of animal origin and covered produce during the relevant time period. For example, when an amendment is applied beneath a high tree crop that is not intentionally dropped to the ground for harvest, there would be no intended or likely contact either during or after application. We do not agree with the comment suggesting that a “does not contact” requirement could never realistically be met. We realize that there is always a chance that some soil amendment could be present in dust such that it settles on covered produce; however, we do not believe at this time that this type of potential contact is significant enough to be considered intended or likely for purposes of § 112.56. However, we intend to include consideration of wind-blown contamination in our upcoming risk assessment on untreated biological soil amendments of animal origin (See discussion under Comment 257).

FDA intends “minimizes contact” to mean there is no intended contact between the biological soil amendment of animal origin and covered produce during the relevant time period, but some unintentional contact is likely due to incidental or environmental action. For example, a farm choosing to side-dress a leafy green crop with a soil amendment in the alley between crop rows could apply the amendment in a manner that does not contact the covered produce at application. However, it would be likely that some portion of the amendment would migrate to the area where the crop is located. This post-application contact would not be intended, but it is likely. Conversely, if the farm were to apply the soil amendment in the previous example not in the alley between crop rows but instead in a broadcast manner, it could be reasonably expected that there would be widespread contact between the amendment and the harvestable portion of

the leafy greens both during and after application, and that such contact is both intentional and likely.

A root crop grown in soil that has been amended with biological soil amendments of animal origin is both intended and likely to be in contact with those soil amendments both during and after application.

We will consider addressing this topic further in our forthcoming implementation guidance.

(Comment 304) Some comments state that use of raw manure should be subject to additional application restrictions beyond those in § 112.56(a)(1)(i) and (a)(1)(ii) because there is risk even if the manure is applied in such a way that there is no intended or likely contact with covered produce, noting that there will always be opportunities for indirect contact from forces such as wind and dust. These comments provide several references to support their conclusion that raw manure poses a significant risk to covered produce.

(Response) As discussed in response to Comment 257, FDA is pursuing a risk assessment and research agenda to supplement the science on an appropriate application -to-harvest interval for raw manure. FDA will consider the information provided by these comments during future risk assessment and research efforts. We agree that raw manure can be an important route of contamination for covered produce and encourage farms to consider use of stabilized compost as an alternative to raw manure.

H. Records Related to Biological Soil Amendments of Animal Origin (§ 112.60)

Section 112.60 requires that you establish and keep records for subpart F in accordance with the requirements of subpart O of this part and that you establish and keep certain records. In Table 20, we describe the codified provisions of § 112.60 and any changes we made to those provisions in the final rule. Comments specific to § 112.60 follow the table.

Table 20.-- Description of Revisions to § 112.60

Proposed Provision	Proposed Language	Final Revisions, if Any
§ 112.60(a)	You must establish and keep records required under this subpart F in accordance with the requirements of subpart O of this part	No change
§ 112.60(b)	For any biological soil amendment of animal origin you use, you must establish and keep the following records:	No change
§ 112.60(b)(1)	For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) that: (i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; (ii) The applicable treatment process is periodically verified through testing using a scientifically valid analytical method on an adequately representative sample to demonstrate that the process satisfies the applicable microbial standard in § 112.55, including the results of such periodic testing; and (iii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin	Revision to eliminate proposed (1)(ii) and as a conforming change to renumber (1)(iii) to (1)(ii) and to require such documentation at least annually.
§ 112.60(b)(2)	For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature and turnings) were achieved	No change
§ 112.60(b)(3)	Scientific data or information you rely on to support a process used to treat a biological soil amendment of animal origin in accordance with the requirements of § 112.54(c)(3).	Elimination of § 112.60(b)(3) as a conforming change since § 112.54(c)(3) has been deleted

(Comment 305) One comment requests clarification on what compost suppliers should document to ensure covered farms could rely on such documentation to satisfy the rule and on

documentation needed when using alternative composting procedures. Another comment asks us to clarify the requirements for records related to process verification in composting.

(Response) With regard to documentation that a farm receives from a third party, such as a stabilized compost supplier, we have revised the proposed requirements. We are sensitive to requests that we minimize the burden of testing. Therefore, we are eliminating proposed § 112.60(b)(1)(ii) that would have required documentation of testing of treated biological soil amendments of animal origin received from third parties to verify that the treatment process satisfies the applicable microbial standard in § 112.55 and the results of the periodic testing. We consider such periodic verification testing to be a best practice, but we conclude it is not necessary to mandate that farms maintain documentation of such testing performed by their suppliers. We are requiring in § 112.60(b)(1)(i) that, with respect to treated biological soil amendments of animal origin received from a third party, covered farms must maintain documentation demonstrating that the process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring. Parameters will be process specific and may include, for example, time/temperature, moisture content, and pH. We are also renumbering proposed § 112.60(b)(1)(iii) to § 112.60(b)(1)(ii) and maintaining the requirement, as proposed, that with respect to treated biological soil amendments of animal origin received from a third party, covered farms must maintain documentation that the biological soil amendment of animal origin has been handled, conveyed, and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin.

Regarding documentation that a farm producing its own treated biological soil amendment of animal origin must have, in accordance with § 112.60(b)(2) a farm must have

documentation that process controls (for example, time, temperature and turnings) were achieved. As a conforming change to the elimination of § 112.54(c)(3), we are eliminating proposed § 112.60(b)(3) which would have required records documenting the scientific data or information relied on to support any alternative composting process used to treat biological soil amendments of animal origin in accordance with § 112.54(c)(3).

(Comment 306) Several comments agree with FDA's decision to require certain documentation for any treated biological soil amendment of animal origin received from a third party. These comments stated this was consistent with established industry programs. Other commenters suggest that requiring certificates of conformance will be economically burdensome to compost suppliers, and requested clarification on how often such documentation would need to be obtained from a supplier.

(Response) FDA agrees that documentation, meeting the requirements in § 112.60(b)(1) should be required for a treated biological soil amendment of animal origin that you receive from a third party. Note that FDA proposes "such as a Certificate of Conformance" in the codified language only to serve as one possible example of adequate documentation. Any form of documentation is acceptable provided that it includes the information required in § 112.60(b)(1); it need not be named a "Certificate of Conformance." We disagree with the comment suggesting that such documentation is economically burdensome as we understand that such documentation is already frequently provided and is consistent with industry standards. Documentation must be obtained from third-party suppliers at least annually. We are adding the annual requirement to the codified in § 112.60(b)(1).

(Comment 307) Some comments suggest that, in order to best protect consumers from the risk of pathogens, FDA should require adequate recordkeeping for application intervals for all biological soil amendments of animal origin, whether treated or untreated, and without regard to whether produce contacts the soil.

(Response) FDA agrees that robust recordkeeping is a best practice. However, FDA disagrees that it is reasonably necessary to require covered farms to maintain records of dates of application and harvest when they use biological soil amendments of animal origin that have a required application interval of zero days as described in § 112.56, which at this time includes all biological soil amendments of animal origin. Should FDA establish application intervals greater than zero days for any uses of biological soil amendments of animal origin at a later date, we will also establish appropriate recordkeeping requirements related to those intervals. See Comment 257 regarding our plans on this topic.

(Comment 308) One comment states that FDA should require farms to document the particular fields on which biological soil amendments of animal origin received from a supplier are applied. This comment states that such a requirement could help facilitate traceback investigations if problems are identified, and may help limit the scope of a recall or product withdrawal.

(Response) While we agree that this information could be useful in some very limited circumstances, we do not agree that it is reasonably necessary to establish such a requirement to minimize the risk of serious adverse health consequences or death, to prevent the introduction of hazards into or onto produce, or to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. We will consider addressing this topic in guidance.

I. Other Comments

(Comment 309) Several comments address our request regarding how to classify spent mushroom mulch (growth media already used in the production of mushrooms for subsequent use as a biological soil amendment of animal origin in the growing of other covered produce). Some comments argue that spent mushroom mulch should not be defined as a biological soil amendment of animal origin regardless of the contents of its feedstock because it is processed with a steam treatment after the mushrooms are harvested and it originally met the microbial standards of § 112.55(a) prior to use in growing mushrooms. These comments argue that spent mushroom mulch should have no restrictions on its use. On the other hand, many comments agree with FDA's tentative conclusion that if the spent mushroom mulch has been subject to a treatment process which met the microbial standard in § 112.55(a), it would still be considered a "treated" biological soil amendment after use for growing mushrooms and therefore available for use as "treated" in growing any covered produce commodity without any intervening treatment unless you know or have reason to believe it has been otherwise contaminated with a hazard or has been associated with foodborne illness.

(Response) FDA disagrees with the commenters that argued that spent mushroom mulches or other spent growth media should not be defined as biological soil amendments of animal origin, when it was defined as such before it was used. We conclude that if a substrate such as spent mushroom mulch previously met the requirements to be considered a "treated" biological soil amendment of animal origin under § 112.51, then it retains that status after use as a growth media, unless you know or have reason to believe it has been otherwise contaminated with a hazard or has been associated with foodborne illness.

XV. Subpart I – Comments on Domesticated and Wild Animals

In subpart I of proposed part 112, we proposed science-based minimum standards that are directed to domesticated and wild animals. As proposed, subpart I included standards that would be directed to the potential for biological hazards from animal excreta to be deposited by your own domesticated animals (such as livestock, working animals, and pets), by domesticated animals from a nearby area (such as livestock from a nearby farm), or by wild animals (such as deer and wild swine) on covered produce or in an area where you conduct a covered activity on covered produce. We requested comment on all provisions in subpart I, including specifically on the scope of the subpart’s proposed applicability, including the meaning of the phrase “under the circumstances” and our tentative conclusion that crops that grow completely underground would not be subject to the proposed requirements of subpart I. We also requested comment on the interactions of the proposed provisions of subpart I with the NOP.

In addition, in the supplemental notice, taking into account comments on the 2013 proposed rule, we proposed § 112.84 to state that part 112 does not authorize or require covered farms to take certain actions. We asked for comment on our current thinking, including on proposed § 112.84 (79 FR 58434 at 58463-58464).

We solicited additional comments on the potential impact of the proposed produce safety rule on wildlife and animal habitat. We considered these comments in our EIS (see section XXVII of this document. In this section of this document we discuss comments we received on the standards directed to wild or feral animals and domesticated animals, in the 2013 proposed rule, but that we did not address in the supplemental notice. We discuss comments received on proposed § 112.84 in the supplemental notice in section III.E of this document.

We are finalizing these provisions with revisions (see Table 21). We discuss these changes in this section. We are finalizing the other provisions of subpart I without change.

Table 21.-- Description of Re-arrangement and Revisions to Subpart I

Proposed Provision (as Proposed in the 2013 Proposed Rule and Amended in the Supplemental Notice)	Final Provision	Description of Revisions
§ 112.81	§ 112.81	- Revision to § 112.81(b) to state that subpart I does not apply to fish used in aquaculture operations
§ 112.82	§ 112.83	- Revision to combine and unify requirements related to grazing and working animals and animal intrusion - Revision to require farms to assess relevant areas and take certain steps to prevent covered produce that is reasonably likely to be contaminated when, under the circumstances, there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce - Revision to clarify that § 112.83 applies during the growing season, in contrast to the related § 112.112, which applies during and immediately prior to harvest - Revisions to further clarify what type of evidence of potential contamination requires a covered farm to take action under § 112.83 (observation of significant quantities of animals, significant amounts of animal excreta, or significant crop destruction), and what kind of action is required (evaluate whether the covered produce can be harvested and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard)
§ 112.83		-
§ 112.84	§ 112.84	- No change

A. Subpart I and Prevention of Contamination

(Comment 310) Some comments suggest that FDA should address contamination of produce from domesticated and wild animals through postharvest processing or treatment (including steps such as washing) rather than requiring measures to prevent contamination of covered produce with fecal material.

(Response) We disagree that postharvest processing or treatments provide viable options for addressing the potential for contamination of covered produce by domesticated or wild animals. Produce that receives commercial processing that adequately reduces the presence of

microorganisms of public health significance is eligible for exemption from this rule with certain documentation under § 112.2(b). In addition, produce that is rarely consumed raw (i.e., it is typically cooked before consumption) is not subject to this rule under § 112.2(a). Thus, by definition, covered produce is produce that is not likely to receive a postharvest processing or a treatment step that will adequately reduce the presence of microorganisms of public health concern. As discussed in the 2013 proposed rule, studies have concluded that wash water, with or without an active antimicrobial agent, does not completely disinfect produce that may contain microorganisms of public health significance (Ref. 181) (Ref. 182) (Ref. 183). In addition, bacteria may find harborage and protection on plants through hydrophobic areas, stomata, lenticels, punctures, and bruises and where it is not readily washed off (Ref. 184) (Ref. 185). Thus, our rule takes an approach consistent with the requirement in section 419(c)(1)(A) that this regulation set forth the procedures, processes, and practices the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into fruits and vegetables.

B. Limited Scope of Applicability of Subpart I (§ 112.81)

(Comment 311) Several comments support limiting the applicability of subpart I to outdoor areas and partially-enclosed buildings, and not to fully-enclosed buildings. In contrast, some comments express concerns about intrusion by pests in both fully- and partially-enclosed buildings, and suggest that the scope of subpart I be expanded to include fully-enclosed buildings for this reason. One commenter believes we exempted activities that take place in fully enclosed buildings from subpart I on the basis that mammals and other carriers of human pathogens are less likely to come into contact with produce that is grown in controlled areas.

(Response) We are maintaining the limitation on applicability of subpart I to outdoor areas and partially-enclosed buildings, as proposed. We are not expanding the applicability of subpart I to fully-enclosed buildings. We identified mammals (such as cows, dogs, swine, and deer) as examples, and not to suggest that these are the only animals that can be a potential source of contamination of covered produce. We acknowledge that domesticated animals and intrusion by pests can be potential hazards for covered activities that take place in fully-enclosed buildings, and we are establishing requirements addressing these hazards in subpart L of part 112. Specifically, measures directed at domesticated animals in a fully-enclosed building are described under § 112.127, and requirements regarding pest control in both fully-enclosed and partially-enclosed buildings are described under § 112.128. We have also revised § 112.181(b) to reflect that subpart I does not apply to fish used in aquaculture operations (See Comment 17).

(Comment 312) One comment disagrees with our tentative conclusion that there would not be a reasonable probability of contamination by animals when covered produce grows completely underground, and that therefore such produce would not be subject to the requirements in subpart I. This comment stated that different scenarios of animal interaction with produce operations entail different levels of risk, and that it may not be appropriate to harvest covered produce grown underground in areas where there is a prolonged, high concentration of animals known to be vectors of key human pathogens, and suggested that the provisions of subpart I should apply under such circumstances.

(Response) We agree that there may be situations in which even produce that grows completely underground should not be harvested as a result of wild animal activity, e.g., if the produce is visibly contaminated with animal excreta. We are revising both § 112.112 and §

112.83 to make explicit when and how these provisions apply and how they differ from each other, clarifying that § 112.112 applies immediately prior to and during harvest, while § 112.83 applies during the growing season. The requirement in § 112.112 of subpart K requires covered farms to take all measures reasonably necessary to identify and not harvest covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including produce that is visibly contaminated with animal excreta. At a minimum, identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of all covered produce to be harvested, regardless of the harvest method used. This requirement (§ 112.112) applies even to covered produce grown completely underground and FDA concludes that it is sufficient to address the majority of potential scenarios in which animals may contaminate covered produce grown completely underground.

For example, section 112.112 requires farms to take steps to identify and not harvest covered carrots that are reasonably likely to be contaminated, including carrots that are visibly contaminated with animal excreta. At a minimum, with respect to animal excreta, this requires a covered farm to conduct a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used. Underground produce that is not visible prior to harvest must be visually assessed during harvest to comply with this requirement. If, during your assessment of the growing area or of the covered carrots, you see evidence of animal excreta on or surrounding a carrot, you must not harvest that carrot; and you must not harvest an area of carrots if animal excreta that is present in the growing area would be likely to contaminate carrots or food-contact surfaces of harvest equipment. By contrast, the requirements in subpart I include assessing relevant areas for evidence of potential contamination of covered

produce as needed during the growing season, with required follow-up actions to be taken during the growing season if evidence of potential contamination is found (§ 112.83). FDA concludes it is not necessary to apply the additional requirements in subpart I to covered produce that grows completely underground because the growth habit of such commodities means that there will not be a reasonable probability of contamination of such commodities by animals as a general matter. We acknowledge that there is a rare and limited range of potential scenarios in which animals may contaminate covered produce grown completely underground during the growing season but where no evidence of such contamination would be visible immediately prior to or during harvest of that produce. For example, it is theoretically possible that pigs may root in a field of carrots, exposing those carrots to potential contamination from the pigs' excreta, and weather events may remove the evidence of the pigs' activity prior to harvest. However, we do not think this rare and limited scenario presents a reasonable probability of contamination during the growing season as a general matter that warrants application of the additional requirements in § 112.83 during the growing season. Our QAR, too, suggests limited concerns of contamination of such underground produce from animals during the growing of these produce. Given the limited chance that animals will contaminate covered produce that grows completely underground in a manner not visible at harvest such that appropriate measures may be taken at that time, we do not think it is necessary to require covered farms to take the measures required in subpart I with respect to such produce. We emphasize, however, that covered produce commodities that grow completely underground will be subject to the rest of this rule, as applicable, including § 112.112. We note that even covered produce grown completely underground is reasonably vulnerable to contamination with known or reasonably foreseeable hazards during and after harvest, as harvesting exposes such produce to contamination through

various pathways. Thus, we conclude that it is warranted to apply § 112.112 even to covered produce grown completely underground. We also emphasize that covered produce commodities that do not grow completely underground (for example, spinach or tomatoes) are subject to the requirements of subpart I.

(Comment 313) One comment asserts that occasional animal intrusions should not represent a threat for the harvest of apples, in particular, given that the fruit is located above the ground while it grows and is typically hand-harvested, suggesting that such produce should not be subject to subpart I.

(Response) We cannot draw a categorical conclusion with regard to the applicability of subpart I to all tree crops that grow high above the ground and are hand-harvested. Animal intrusion is outside the farm's control, and may include intrusion by significant quantities of birds that may, in some circumstances, be reasonably likely to contaminate such crops. There may be circumstances in which subpart I does not apply to such crops, and there will likely be circumstances in which subpart I does apply to such crops. That determination must be based on the farm's specific circumstances.

C. Grazing and Working Animals (§ 112.83)

(Comment 314) Some comments request that FDA clarify what would be considered an adequate waiting period under proposed § 112.82(a) and request that FDA specify a minimum waiting period between grazing of animals in a field and harvest of covered produce from that field. Some comments suggest that FDA should not require a waiting period between grazing and harvesting, or that certain commodities should not be subject to such a requirement. Several

comments express concern about the ability of farmers who employ diversified crop-livestock farming systems that integrate or rotate livestock farming and produce growing to comply with proposed § 112.82(a). Several comments express concerns with FDA's statement in the 2013 proposed rule that we would not expect it to be necessary for an adequate waiting period between grazing and harvest to exceed 9 months, which was the application interval we proposed for use of raw manure as a soil amendment in originally proposed § 112.56(a)(1)(i). In contrast, other commenters recommend that FDA require a waiting period of nine months. One comment asks whether a visual evaluation of the presence of fecal material, as required in certain situations under § 112.83 relating to wildlife, could be used to satisfy the requirements of proposed § 112.82(b) for working animals. Several comments noted the importance of working animals to farm operations and expressed concerns about how farmers who rely on working animals would comply with proposed § 112.82(b). For example, some comments suggest that § 112.82(b) may limit the use of working animals such as horses used for tilling and harvest activities and transporting produce, stating that it would be difficult to maintain a designated path completely segregated from growing produce to be used by draft animals such as working horses. Some comments express concerns about whether proposed § 112.82(b) would prevent covered farms from using dogs, cats, or chickens to deter pests in growing areas; or prevent farms from using guard dogs to keep other animals out of fields.

(Response) We are removing § 112.82 from the rule and replacing it with revised requirements related to grazing and working animals in § 112.83, discussed further in the paragraphs that follow. FDA continues to believe that an adequate waiting period between grazing and harvest is an important consideration when, under the circumstances, there is a reasonable probability that grazing animals will contaminate covered produce. As discussed in

the 2013 proposed rule and our QAR, domesticated animals can be a source of human pathogens. Some human pathogens of public health concern (e.g., E. coli O157:H7) that have been associated with produce-related foodborne outbreaks are zoonotic. Moreover, domesticated animals, due to their close proximity and interaction with humans, are generally more likely to harbor zoonotic pathogens than are wild animals (Ref. 186). The likelihood of contaminating produce with human pathogens from excreta from grazing animals is determined by numerous factors, including, but not limited to, the species of the animal and its association with human or domesticated animal activity or waste, the number of animals per unit area of land, agro-ecological conditions, the type of commodity and the time period between animal grazing in fields and the harvest of produce (Ref. 187) (Ref. 188) (Ref. 189) (Ref. 190) (Ref. 191).

However, currently available science does not allow us to identify a specific minimum time period between grazing and harvesting that is generally applicable across various commodities and farming practices. Rather, the appropriate minimum time period between grazing and harvesting would need to be determined based on the specific factors applicable to the conditions and practices associated with growing and harvesting the commodity. We are eliminating the proposed requirement for an adequate waiting period between grazing and harvesting in proposed § 112.82(a). However, we encourage covered farms to voluntarily consider applying such waiting periods, as appropriate for the farm's commodities and operations. We will consider providing guidance on this practice in the future, as needed.

In response to comments suggesting that the assessment strategy in proposed § 112.83 was a reasonable approach not only to the risk of animal intrusion, but also to the risk posed by working animals, we evaluated applying that strategy more broadly to grazing animals, working animals, and animal intrusion. We have concluded that such an approach was reasonable,

scientifically sound, and simpler than establishing different requirements based on different types of animal activity. Therefore, we are removing the proposed requirements for a waiting period between grazing and harvesting in relation to grazing animals (proposed § 112.82(a)) and measures to prevent introduction of hazards from working animals into or onto covered produce (proposed § 112.82(b)), and we are adopting an approach that unifies the requirements addressing the potential for contamination from grazing animals, working animals, and animal intrusion. Under revised § 112.83, we are requiring that you take the same steps if, under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce (§ 112.83(a)). In such cases, you must assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience) (§ 112.83(b)(1)). If you find evidence of potential contamination during that assessment (such as observation of significant quantities of animals, significant amounts of animal excreta, or significant crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112, and you must take measures reasonably necessary during growing to assist you later during harvest when under § 112.112 you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard (§ 112.83(b)(2)).

Assessing the growing areas as needed during the growing season will enable you to identify instances when covered produce cannot be harvested for safe consumption, such as produce that was directly exposed to animal excreta or that may be cross-contaminated during harvest (e.g., contamination of covered produce by contact with a food-contact surface that

contacted animal excreta). Depending on the quantity of animals, extent of animal excreta, or extent of crop destruction, the affected growing areas may be localized (for example, a specific area of the field where you allowed grazing) or more widespread. We expect that, in cases of grazing and working animals, in particular, it is more likely that affected areas will be localized because grazing or working animals are expected to be present intermittently and in known areas of the field. Once you identify produce, or an area of produce, that cannot be harvested in accordance with § 112.112, § 112.83(b)(2) requires you to take measures reasonably necessary during growing to assist you later during harvest in complying with the requirements of § 112.112. For example, if you have identified an area with significant animal excreta that is likely to cross-contaminate any covered produce harvested from that area such that the area may not be harvested, you could mark that area in a manner that will ensure it is not harvested, even if weather events or other occurrences remove the animal excreta so it is not visible later during harvest. For example, you might mark such an area by placing flags outlining the affected area. This provides additional protection in the event that the evidence of animal intrusion or other animal activity is no longer visible by the time of harvest, such as if a significant rain event washes away fecal deposits.

FDA recognizes the longstanding co-location of animals and plant food production in agriculture. This rule does not prohibit the use of grazing or working animals on covered farms. We believe this approach addresses concerns regarding the feasibility of compliance with the rule for farms that rely on grazing animals (such as integrated or diversified farms with crop-livestock rotation systems) and farms that rely on working animals for various purposes, including horses, dogs, cats, and chickens. Under revised § 112.83, farms would be required to apply the same approach to any of these uses of animals, and only if under the circumstances

there is a reasonable probability that animals will contaminate covered produce (§ 112.83(a)). Farms in such circumstances must assess the relevant areas as needed during the growing season (§ 112.83(b)(1)), and if evidence of potential contamination is found, evaluate whether the covered produce can be harvested and take measures reasonably necessary to assist the farm later during harvest in identifying and not harvesting affected covered produce (§ 112.83(b)(2)). We also note that § 112.83, like the rest of this rule, applies only to covered produce. Farms may graze animals on growing areas used for crops other than covered produce, or use working animals in such areas, without triggering § 112.83. We will consider providing guidance on issues related to integrated or diversified farming practices in the future, as needed.

(Comment 315) One comment suggests that farmers should be prohibited from cultivating covered produce and grazing animals on the same soil.

(Response) FDA believes this suggestion goes beyond what is reasonably necessary to minimize the risk of serious adverse health consequences or death, to prevent the introduction of known or reasonably foreseeable hazards into or onto produce, and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. We acknowledge the longstanding co-location of animals and plant food production in agriculture, and we do not believe it is necessary to prohibit grazing in areas where covered produce is grown to achieve the statutory purposes set forth in section 419 of the FD&C Act. We are requiring farms to assess relevant areas used for a covered activity as needed during the growing season for evidence of potential contamination, to evaluate whether produce can be safely harvested, and to take measures reasonably necessary during growing to assist the farm later during harvest when the farm must identify, and not harvest, covered produce that is reasonably likely to be contaminated

with a known or reasonably foreseeable hazard when, under the circumstances, there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce (§ 112.83). We believe this rule requires an appropriate level of public health protection while also appropriately providing sufficient flexibility considering the diversity of production and harvesting of produce (sections 419(a)(3)(A) and (c)(1)(B) of the FD&C Act).

(Comment 316) Some comments suggested that proposed § 112.82(a) would require covered farms to implement a waiting period every time they suspected that a domesticated or wild animal had intruded upon a growing area, and expressed concern that such a requirement would lead to a de facto requirement for farms to exclude wildlife from areas where covered produce is grown.

(Response) We are eliminating proposed § 112.82(a) for the reasons discussed in response to Comment 314. In addition, to remove any possible confusion, FDA has added § 112.84 to the rule explicitly stating that the rule does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

(Comment 317) Some comments ask that FDA clarify that working animals are permitted in growing areas and that terminating the use of working animals is not necessary to comply with the regulation.

(Response) Working animals are permitted in growing areas, and the regulation does not require termination of the use of working animals on covered farms. As discussed in response to

Comment 314, we are revising requirements related to working animals, now established in § 112.83. Revised § 112.83 does not prohibit the use of working animals on covered farms. Therefore, covered farms can use working animals provided that the farm complies with § 112.83, as applicable.

(Comment 318) One comment suggests requiring domesticated animals to be vaccinated.

(Response) We do not agree that we should specifically require vaccination of domesticated animals on covered farms, including working animals. We are not aware of currently available vaccines that would prevent animal excreta from containing human pathogens, and the comment did not provide information from which we could conclude that such vaccines are available.

D. Animal Intrusion (§ 112.83)

(Comment 319) In response to the 2013 proposed rule, several comments express support for the monitoring requirement in proposed § 112.83, and assert that the proposed provisions provide sufficient flexibility to accommodate regional, operational, and commodity diversity in farming operations, and are consistent with current industry practices. On the other hand, several comments argue that proposed § 112.83 would be impracticable or burdensome. Some of these comments state that any requirement to monitor for animal intrusion is untenable, particularly in the case of monitoring for birds on open-air farms. Such comments argue that farms would not be able to prevent all wildlife interaction with covered produce or detect every animal intrusion that occurs and, therefore, no reasonable effort to monitor animal intrusion could provide assurance that covered produce is not contaminated or adulterated. Some comments suggest

FDA should use an “outcome-based approach” to animal intrusion, and suggest that monitoring of crop during harvest as set out in § 112.112 is the most appropriate control point at which to ensure contaminated produce is excluded. These comments appear to argue that monitoring as required by proposed § 112.83, during the growing season and immediately prior to harvest, is unnecessary in light of the requirements of § 112.112 that apply immediately prior to and during harvest.

(Response) We disagree with comments that state that monitoring for evidence of animal intrusion is burdensome or impracticable. As discussed in the preamble of the 2013 proposed rule, periodic monitoring for evidence of animal intrusion and deposition of their excreta is a reasonably necessary measure to prevent contamination of covered produce with biological food safety hazards when there is a reasonable probability that animals will contaminate covered produce. We consider that such assessment during the growing season is a practical and reasonably necessary standard to sufficiently ensure that potential hazards related to animal intrusion are identified for appropriate follow-up actions, including the requirements that apply immediately prior to and during harvesting in § 112.112. Section 112.83 provides flexibility for farmers to consider the nature of their covered produce, their practices and conditions, and their observations and experience to determine when and how often to assess the relevant areas during the growing season when there is a reasonable probability that animals will contaminate covered produce (see § 112.83(b)(1)). We do not expect the requirements of § 112.83 to, as one comment suggested, prevent all wildlife interaction with covered produce or detect every animal intrusion that occurs. We have added a new provision, § 112.84, to make explicit that this rule does not require exclusion of wild or feral animals from covered farms. By “wild” animals we refer to those animals living in a state of nature and not

ordinarily tamed or domesticated, and by “feral” animals we refer to those that have escaped from domestication and become wild. In the title of subpart I, “Domesticated and Wild Animals,” we use the term “wild” to refer collectively to both wild and feral animals. These provisions are intended to provide you with information about animal movements on your farm, allow you to recognize significant animal intrusion, and facilitate your taking appropriate measures following significant animal intrusion without being unduly restrictive.

As discussed in response to Comment 314, §§ 112.83 and 112.112 are complementary rather than duplicative, and we have revised them to remove overlap and clarify how they are different from each other, as well as revising § 112.83 to apply to grazing animals, working animals, and animal intrusion. We have deleted requirements from proposed § 112.83 that would have applied “immediately prior to harvest” and limited its application to “during the growing season.” By contrast, § 112.112 is a generally applicable requirement that applies immediately prior to and during harvest activities. We are revising both §§ 112.83 and 112.112 to make this distinction clear. We believe that § 112.83 adds an important level of public health protection beyond the general harvest-related requirement in § 112.112, and that the additional requirements of § 112.83 should apply whenever, under the circumstances, there is a reasonable probability that grazing animals, working animals, or animal intrusion will result in contamination of covered produce. Under such circumstances, covered farms must do more than just identify and not harvest covered produce that is reasonably likely to be contaminated based on observations made during and immediately prior to harvest (§ 112.112). In these situations, covered farms must take proactive steps under § 112.83 to assess relevant areas during the growing season for evidence of potential contamination. Moreover, if such evidence is found (such as significant quantities of animals, significant amounts of animal excreta, or

significant crop destruction), § 112.83 requires covered farms to evaluate whether covered produce can be harvested and take measures reasonably necessary during growing to assist the farm later during harvest when the farm must identify and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard. For example, if you have identified an area with significant animal excreta that is likely to cross-contaminate any covered produce harvested from that area such that the area may not be harvested, you could mark that area in a manner that will ensure it is not harvested, even if weather events or other occurrences remove the animal excreta so it is not visible later during harvest. For example, you might mark such an area by placing flags outlining the affected area. This provides additional protection in the event that the evidence of animal intrusion or other animal activity is no longer visible by the time of harvest, such as if a significant rain event washes away fecal deposits.

We understand that when covered produce is grown in an outdoor environment, wild or feral animals are likely to have access to production fields. We reiterate that the presence of animals in a production field of covered produce, in and of itself, is not a significant food safety risk. However, wild or feral animals are known zoonotic disease reservoirs for human pathogens, and therefore their excreta may contaminate growing covered produce crops (Ref. 186) (Ref. 188). Therefore, we conclude that assessing for evidence of potential contamination and taking appropriate follow-up actions, as described in § 112.83, is a reasonably necessary when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce. We note that, as discussed in our response to Comment 314, not all circumstances present a reasonable probability that animals will contaminate covered produce, such that not all covered farms or growing areas will be subject to the requirements in § 112.83.

(Comment 320) Some comments request that any requirements for recordkeeping related to animal intrusion be eliminated from the regulation. In contrast, one comment suggests requiring records to be maintained in relation to the requirements in subpart I.

(Response) Part 112 does not include requirements for establishing or maintaining records related to subpart I. We do not believe such a requirement is warranted, although we encourage covered farms to prepare and keep documentation as appropriate to facilitate their implementation of the provisions of subpart I. Therefore, a covered farm is not required to develop or keep a record of its activities related to assessment for animal intrusion.

(Comment 321) One comment suggests that FDA add a requirement that covered farms take reasonable measures to keep animals out of growing areas and water sources based on the farm's observations from assessment for animal intrusion.

(Response) We do not believe it is necessary to establish such a requirement in subpart I. The presence of animals in a production field of covered produce, in and of itself, is not a significant food safety risk. We believe that assessing for animal intrusion and taking appropriate follow-up actions, as described in § 112.83, is an appropriate approach to ensure the safety of covered produce when, under the circumstances, there is a reasonable probability that animal intrusion will contaminate covered produce. Moreover, § 112.42(c) requires covered farms to adequately maintain all agricultural water sources that are under the farm's control (such as wells), including by regularly inspecting each source and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.

(Comment 322) One comment requests that FDA define more specifically the time period that would be appropriate for fulfilling the proposed requirement in proposed § 112.83(a)(2) to monitor for animal intrusion “immediately prior to harvest.”

(Response) We are eliminating the phrase “immediately prior to harvest” in § 112.83. As described in response to Comment 314, revised § 112.83 applies during the growing season. We are, however, retaining similar language in § 112.112. As discussed in section XVI.B of this document, we use “immediately prior to harvest” in § 112.112 to refer to the time period prior and as close to commencing harvesting as is practicable.

(Comment 323) One comment suggests that FDA consider including in the regulation the CA LGMA Animal Hazard/Fecal Matter Decision Tree.

(Response) We are aware that some decision-making tools, such as the CA LGMA Animal Hazard/Fecal Matter Decision Tree (the CA LGMA animal hazard decision tree) and the Cornell University National GAPs Program Wildlife and Animal Management Decision Tree (the Cornell animal management decision tree), are intended to help covered farms evaluate their fields for signs of animal intrusion and take follow-up action. Although these may be useful resources, we find the information and variables addressed in these tools to be more prescriptive than we consider necessary in this rule, and not necessarily applicable across all commodities and agro-ecological conditions. For example, the CA LGMA animal hazard decision tree is commodity-specific and tailored specifically for leafy greens operations in California. We decline to incorporate these decision-making tools into this regulation as requirements.

(Comment 324) Some comments argue that the requirements of proposed § 112.83 are vague and request that FDA provide guidance regarding methods for evaluating potential contamination of produce and determining if it is safe to harvest.

(Response) As discussed in section XVI of this document, we have revised § 112.112 to provide more specificity regarding the evaluation that is necessary during and immediately prior to harvest to identify and not harvest covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta. At a minimum, this requires a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used. We also explain in that section that this may be achieved by, for example, visually examining each article of produce and surrounding areas immediately prior to harvesting the article of produce by hand; or by conducting a visual assessment of all of the growing area and the produce in the growing area to be harvested immediately prior to the start of mechanical or hand harvesting. For example, if you identify an article of covered produce that is visibly contaminated with excreta, you may not harvest that article of covered produce (e.g., watermelon with cow feces on it). As another example, if you identify an area with significant animal excreta that is likely to cross-contaminate any covered produce harvested from that area, the covered produce in that area may not be harvested (e.g., a “no harvest zone” in an area of a spinach field containing wild hog feces).

Section 112.83 applies during the growing season rather than during or immediately prior to harvest. It requires an additional step during the growing season applicable only when under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce. In such cases, covered farms must assess relevant areas used for a covered activity for evidence of potential contamination. This requires a

visual assessment of all of the relevant areas used for a covered activity (including growing areas and any other areas in which there is a reasonable probability of contamination of covered produce from animals) and the covered produce. If evidence of potential contamination is found (such as significant quantities of animals, significant amounts of animal excreta, or significant crop destruction), § 112.83(b)(2) requires covered farms to evaluate whether covered produce can be harvested. This evaluation described in § 112.83(b)(2) is the same type of evaluation described in § 112.112, but under § 112.83(b)(2) an evaluation is also performed earlier, during the growing season. This evaluation requires a farm that becomes aware of potential contamination to evaluate affected areas and produce, and to take appropriate measures to facilitate its identification of produce that may not be harvested later in the season (such as marking affected areas or produce, as discussed in response to Comment 314).

(Comment 325) Some comments suggest that farms should be required to evaluate whether their covered produce can be harvested in accordance with § 112.112 upon finding any evidence of animal intrusion; suggesting that the phrase “significant quantities of” in proposed § 112.83(b) should be removed.

(Response) We disagree. As noted previously, we do not expect the requirements of § 112.83 to detect every animal intrusion that occurs or to require farms to take measures in response to every such intrusion. The requirements of § 112.83 are intended to provide you with information about animal movements on your farm, allow you to recognize significant animal intrusion, and facilitate your taking appropriate measures following significant animal intrusion without being unduly restrictive. We believe that the harvest-related requirement in § 112.112 provides sufficient protection to address less than significant animal intrusion (i.e., intrusion that

occurs without the farm observing, during required assessment, significant quantities of animals, significant animal excreta, or significant crop destruction).

(Comment 326) One comment suggests that, for tree crops, covered farms should be required to cover and remove animal excreta from the harvest area so that it does not contaminate workers or equipment. Other comments suggest that covered farms should be required to cordon off areas of ground crops where potential contamination may have occurred as a result of animal intrusion and ensure that covered produce is not harvested from those areas.

(Response) Specific determinations about whether certain covered produce can be harvested, and what specific measures to take to assist the farm later during harvest will likely vary dependent on the specific circumstances relevant to the commodity and/or the farm's practices, procedures, and processes. The requirements of § 112.83 and related § 112.112 are purposefully flexible, to allow covered farms to take steps in compliance with those requirements that are most appropriate to their operations, in light of their covered produce and the nature of their covered activities. We note that section 419(c)(1)(D) of the FD&C Act directs us to minimize, as appropriate, the number of separate standards that apply to separate foods. We believe it is appropriate to establish one standard addressing the risk of contamination of covered produce from grazing animals, working animals, and animal intrusion, which is applicable whenever under the circumstances there is a reasonable probability that animals will contaminate covered produce. Therefore, we decline to establish more specific requirements such as those suggested by the comments. We will consider providing more specific recommendations with respect to how farms may implement these requirements for specific situations in the Produce Safety Regulation implementation guidance, which we expect to issue in the near term. We agree

that the practices suggested by the commenters may be appropriate strategies for compliance with § 112.83, depending on the circumstances.

(Comment 327) One comment maintains that the provisions should differentiate between produce that is hand-harvested and that harvested by a machine. The comment urges FDA to create a less stringent standard with respect to animal intrusion for producers who employ hand harvesting, noting that a machine cannot detect animal intrusions or animal excreta and, therefore, the presence of animals on large-scale farms that employ machine harvesting poses a significantly different level of risk than on farms that use hand harvesting.

(Response) As discussed in section XVI of this document, we have revised § 112.112 to provide more specificity regarding the evaluation that is necessary during and immediately prior to harvest to identify and not harvest covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta. At a minimum, this requires a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used. We also explain in that section that this may be achieved by, for example, visually examining each article of produce and surrounding areas immediately prior to harvesting the article of produce by hand; or by conducting a visual assessment of all of the growing area and the produce in the growing area to be harvested immediately prior to the start of mechanical or hand harvesting. Thus, we have revised § 112.112 to address the differences between hand harvesting and machine harvesting with respect to the ability to detect evidence of potential contamination. We have also revised § 112.83 to specify that it applies only during the growing season and not during or immediately prior to harvest.

Thus, we do not consider it to be necessary to take into account harvesting practices in § 112.83 because we consider that they are sufficiently addressed in § 112.112.

(Comment 328) Several comments express concern that proposed § 112.83 could be perceived as requiring measures to exclude wildlife from growing areas. Citing concerns that some on-farm food safety certification programs have resulted in farmers' abandoning conservation practices and actively excluding wildlife from farms, some comments ask FDA to explicitly clarify that the regulation does not require producers to exclude wild animals from the growing area. Some comments express concern that this proposed provision can be interpreted to conflict with other federal and State programs to establish buffer zones or other natural vegetation buffer strips intended to improve water quality, protect endangered species, and enhance wildlife habitat.

(Response) We believe that these concerns have been addressed through our addition of § 112.84, as discussed in the supplemental notice.

E. List of "Animals of Concern"

(Comment 329) Several commenters express support for FDA's tentative conclusion to not establish a list of "animals of concern," agreeing that current scientific evidence is inadequate to develop such a list. On the other hand, some comments request FDA to establish a list of "animals of concern" to assist farms in determining the risk of animal intrusion in growing area. One such comment states that some research indicates that certain types of animals are not routine carriers of specific pathogenic organisms.

(Response) We continue to find that currently available scientific data and information are insufficient to develop a list of specific animals that present the greatest risk for pathogens. The commenters that requested us to establish such a list did not provide specific scientific research or data in support of their request. Therefore, we decline the request to establish a list of “animals of concern.”

XVI. Subpart K – Comments on Growing, Harvesting, Packing, and Holding Activities

In subpart K of proposed part 112, we proposed science-based minimum standards directed to growing, harvesting, packing, and holding activities that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act. We asked for comment on our proposed provisions, including proposed § 112.114 related to dropped produce; and proposed § 112.115 related to measures to prevent formation of botulinum toxin.

We are finalizing these provisions with revisions (see Table 22). We discuss these changes in this section. We are finalizing the other provisions of subpart K as proposed.

Table 22.-- Description of Revisions to Subpart K

Final Provision	Description of Revisions
§ 112.111(a)	- Revision to add “(except when covered produce and excluded produce are placed together in the same container for distribution)” to make our intent clear that this provision does not preclude the placing together of covered and excluded produce in containers for distribution, such as in gift baskets.
§ 112.112	- Revision to clarify that § 112.112 applies during and immediately prior to harvest, in contrast to the related § 112.83, which applies during the growing season - Revision to specify that “[a]t a minimum, identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used”
§ 112.113	- Revision to add the phrase “to the degree practicable” considering covered commodities that are harvested near the soil line, where avoiding contact of cut surfaces of harvested produce with soil may not be practicable
§ 112.114	- Revisions to clarify meaning of “dropped covered produce,” including explicitly state that dropped covered produce does not include root crops (such as carrots) that grow underground, crops (such as

	cantaloupe) that grow on the ground, or produce that is intentionally dropped to the ground as part of the harvesting method (such as almonds) - Deletion of “unless it is exempt under § 112.2(b)” as confusing and unnecessary
§ 112.115	- No change
§ 112.116	- Revision to § 112.116(a) to clarify that food-packing materials used must be adequate for their intended use, which includes being: (1) cleanable or designed for single use and (2) unlikely to support growth or transfer of bacteria - Revision to § 112.116(b) to remove the reference to “sanitizing” and to make clear the steps taken, including the frequency of cleaning or replacing liners, must be adequate

A. Growing, Harvesting, Packing, or Holding Both Covered and Excluded Produce (§ 112.111)

(Comment 330) Some comments generally express support for this provision. Some comments request further clarification regarding the requirement to keep covered produce separate from produce not covered under this rule. One commenter suggests defining “separate” as “preventing the ability of cross-contamination by separating in space so that covered and non-covered produce is not in direct contact with one another.” Another commenter asks FDA to explain how this requirement would apply to covered and excluded produce items that are sold together, as in the case of gift baskets. This commenter asks whether gift baskets with other ingredients such as chocolate, would be covered under this rule, and whether the place where the non-produce item is originally packed is a factor in this determination.

(Response) Section 112.111 requires covered farms to keep covered produce separate from excluded produce (that is not grown, harvested, packed or held in accordance with part 112) during growing, harvesting, packing, and holding as applicable, to avoid physical contact between the two categories so as to minimize risk of transfer of pathogens from one to the other. We do not believe it is necessary to define the term “separate;” as used in this provision, we

believe the common meaning of this term to be sufficiently descriptive for the purposes of conveying the intent of this requirement.

For the purposes of part 112, covered produce includes not only fruits and vegetables, but also mixes of intact fruits and vegetables (see § 112.1(b)(2)). However, it was not our intent to preclude the placing together of covered and excluded produce in containers for distribution, such as in gift baskets. We are revising § 112.111(a) to make this intent clear. This provision also does not prevent you from placing covered produce into the same container (such as a gift basket) with other food items not covered under part 112. Excluded produce and/or other food items not covered under part 112 must adhere to all other applicable requirements under the FD&C Act. In addition, to the extent the establishment that assembles the basket or package is a mixed-type facility (including a farm mixed-type facility) or other facility that is required to register with FDA, such an establishment may be subject to the requirements of part 117, the PCHF regulation.

B. Harvesting Covered Produce (§ 112.112)

(Comment 331) Some comments cite specific circumstances where contamination is likely and request clarification regarding applicable requirements under § 112.112. One comment argues that produce is likely to be contaminated with animal excreta when a flock of birds land on an iceberg lettuce field, and should not be harvested under § 112.112 although the excreta may not be visible. According to this commenter, some farms may routinely harvest produce that has been in contact with fecal material if the outer layers of the fruit or vegetable can be removed before depositing it into the harvest container, as in the case of lettuce. The commenter is concerned that, in such instances, all surfaces that come in contact with excreta

may not have been identified or removed. Another comment points to an instance where covered produce comes into contact with water that is thought to be contaminated, and suggests that such produce should not be harvested under § 112.112.

(Response) Section 112.112 requires covered farms to take all reasonably necessary measures to identify, and not harvest, produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard. See section IX of this document for a discussion of the definition of “known or reasonably foreseeable hazard.” We have revised § 112.112 to clarify when and how this provision applies, and to distinguish it from the related § 112.83. See our discussion of § 112.83 in section XV of this document. Section 112.112 applies immediately prior to and during harvest, while § 112.83 applies during the growing season. Section 112.112 applies generally to covered farms with respect to all covered produce, while § 112.83 only applies when under the circumstances there is a reasonable probability that animals will contaminate covered produce. Section 112.112 applies generally to all covered produce that is reasonably likely to be contaminated with any known or reasonably foreseeable hazards covered under this rule, while § 112.83 applies only when the reasonably likely source of contamination is animal activity.

Within § 112.112, we explicitly identify as an example one known or reasonably foreseeable hazard in relation to harvest activities, i.e., pathogens are likely to be introduced into or onto covered produce by animal excreta when it is present. Thus, one important aspect of § 112.112 is that it requires farms to identify and not harvest covered produce that is reasonably likely to be contaminated with animal excreta, or that is visibly contaminated with animal excreta. We are clarifying in the text of § 112.112 that identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is

visibly contaminated with animal excreta requires a visual assessment of all covered produce to be harvested, regardless of the harvest method used. This may be achieved by, for example, visually examining each article of produce and surrounding areas immediately prior to harvesting the article of produce by hand; or by conducting a visual assessment of all of the growing area and the produce in the growing area to be harvested immediately prior to the start of mechanical or hand harvesting. Underground produce that is not visible prior to harvest must be visually assessed during harvest to comply with this requirement.

Section 112.112 includes, but is not limited to, visibly contaminated articles of covered produce. For example, you would comply with this provision by not harvesting a head of lettuce if you see excreta on the head of lettuce. As another example, if you see significant evidence of crop destruction from animal activity in an area of your field of carrots, you would comply with this provision by not harvesting the carrots from that area of the field, even if some of the carrots (not grazed on) may be intact, to the extent that these carrots, too, are reasonably likely to be contaminated as a result of the animal activity.

Section 112.112 requires that these actions be taken “immediately prior to and during harvest.” We use the term “immediately prior to... harvest” in § 112.112 to refer to the time period prior and as close to commencing harvesting as is practicable. We expect that in most cases covered farms will choose to take steps to identify covered produce that may not be harvested “immediately prior to harvest,” although this step may also be done during harvest. The required visual examination is most effective when done as close in time before beginning harvesting as is practicable, under the circumstances of the farm’s operation, or during harvesting itself. We are not specifying the exact time period when such visual assessment must be done, given the practicability of such assessment is dependent, in part, on the farm’s

operation and commodity.

In addition to potential pathogen contamination from animal activity, there may be other known or reasonably foreseeable hazards that a covered farm would need to identify and address under § 112.112. We consider, for example, the circumstance a commenter raised where covered produce may come into contact with water that is likely to be contaminated with pathogens. In subpart E, we are establishing requirements related to agricultural water, including that all agricultural water must be safe and of adequate sanitary quality for its intended use (§ 112.41). Subpart E provides the relevant requirements for what farms must do when agricultural water does not meet this standard (§ 112.45(a)), or other specific microbial quality criteria we are establishing for certain uses (§§ 112.45(a) and (b)), and therefore, we do not believe additional standards are needed under § 112.112 with respect to harvesting based on agricultural water quality. Circumstances may arise, however, in which water that is likely to be contaminated with known or reasonably foreseeable hazards, such as flood water, contacts covered produce. Flood water is outside the definition of agricultural water established in this rule and is therefore not subject to the requirements in subpart E. However, both §§ 112.11 and 112.112 apply to flooding situations. In accordance with § 112.11, covered farms must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce as well as to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act on account of such hazards. Moreover, in accordance with § 112.112, a covered farm that has experienced flooding will be required to assess the extent of flooding and not harvest covered produce that is reasonably likely to be contaminated with

known or reasonably foreseeable hazards through contact with flood water.

(Comment 332) One commenter suggests revising § 112.112 to provide that “harvesting covered produce that is visibly contaminated with excreta should be avoided to the extent practicable.”

(Response) We disagree with the suggestion to revise § 112.112 to provide that “harvesting covered produce that is visibly contaminated with excreta should be avoided to the extent practicable.” As discussed in the QAR, it is well established that animal excreta is a source of pathogens. Transmission of pathogens from animal excreta to covered produce and, subsequently, to humans through consumption is reasonably likely in cases where the presence of animal excreta can be visually confirmed. Therefore, we conclude that covered produce that is visibly contaminated with animal excreta must not be harvested. Accordingly, § 112.112 requires that you take all measures reasonably necessary to identify and not harvest produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard. Section 112.112 further specifies, to remove any possible confusion, that this includes taking steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. For these reasons, we are not making the requested change.

C. Handling Harvested Covered Produce (§ 112.113)

(Comment 333) One commenter recommends that we include the following types of explicit and specific requirements in § 112.113, and that such requirements should also be commodity-specific: ideal harvest time of day, postharvest chill requirement, chill temperature, wash requirement(s), wash specifications, and ideal storage temperature(s). In addition, noting

that many produce commodities cut during harvest grow near or in contact with the soil, the commenter questions the feasibility of the example provided in § 112.113, i.e., “by avoiding contact of cut surfaces of harvested produce with soil,” and suggests revising it by adding the phrase “to the degree practicable.”

(Response) Due to the diversity of covered produce commodities and our desire to allow appropriate flexibility, FDA is not establishing commodity-specific handling requirements for harvested produce in this rule. We note, however, that FDA is working on certain commodity-specific guidance documents. We have issued draft guidances for tomatoes, melons, and leafy greens and will consider developing guidances covering other commodities.

With respect to the comment about the example listed within § 112.113, we agree that adding the phrase “to the degree practicable” is appropriate, considering covered produce commodities that are harvested near the soil line, such as herbs and celery, where avoiding contact of cut surfaces of harvested produce with soil may not be practicable. However, § 112.113 requires covered farms to handle harvested covered produce in a manner that protects against contamination with known or reasonably foreseeable hazards, including pathogens that may be present in soil. This includes taking all measures that are reasonably necessary and practicable.

Accordingly, we are revising § 112.113 to read as set forth in the regulatory text of this rule.

(Comment 334) Several comments support our tentative conclusion not to require washing of produce after harvesting. Some of these comments acknowledge that disinfectants

added to wash water cannot be expected to kill all pathogens that may be present on produce, and may also accelerate decomposition of certain commodities.

(Response) In light of these comments, and in the absence of new data or factual information, we are not establishing any requirement to wash harvested produce in this rule. Wash water, with or without an active antimicrobial agent, does not completely disinfect produce that may contain microorganisms of public health significance (Ref. 181) (Ref. 182) (Ref. 183). Bacteria may find harborage and protection on plants through hydrophobic areas, stomata, lenticels, punctures, and bruises and where it is not readily washed off (Ref. 184) (Ref. 185). As appropriate, farms may choose to wash covered produce, and to add safe and suitable disinfectants to wash water, according to label instructions, to reduce the likelihood of produce contamination, including for example to help prevent the cross-contamination of surrounding produce with any pathogens that may be introduced into the wash water from a single fruit or vegetable.

(Comment 335) Specifically in the context of harvested produce, one comment requests FDA to require facilities handling “high-risk” produce to periodically test the finished product for pathogens, and cites cantaloupe as an example of a produce commodity that should be subject to such a requirement.

(Response) In the 2013 proposed rule (78 FR 3504 at 3533), we discussed the challenges associated with requiring microbiological product testing, either routinely or under specific conditions, as a strategy to minimize known or reasonably foreseeable hazards in covered produce. We have no new information suggesting that we should change our conclusion, nor did this commenter provide any new data or factual information. Therefore, we

are not establishing a requirement for microbiological product testing of covered produce, except as established in subpart M under certain circumstances for sprouts (§ 112.144(b) and (c)). See section III.F of this document.

D. Dropped Covered Produce (§ 112.114)

In § 112.114, we proposed to prohibit you from distributing covered produce that drops to the ground before harvest (dropped covered produce) unless it is exempt under § 112.2(b) (i.e. if it receives commercial processing to adequately reduce the presence of microorganisms of public health significance). We also proposed to clarify in this provision that dropped covered produce does not include root crops (such as carrots) that grow underground or crops (such as cantaloupe) that grow on the ground. We also noted that produce that is intentionally dropped to the ground as part of the harvesting method would not be considered “dropped covered produce” as defined in proposed § 112.114 (i.e., produce that drops to the ground before harvest). We are finalizing this section with certain changes as described in the paragraphs that follow.

(Comment 336) Several comments favor the requirements of this provision, as proposed. However, one comment expresses a view that this requirement should be applied by a farm according to an operational assessment of risk specific to that farm.

(Response) We refer you to the discussion in section VII of this document, where we explain our conclusion not to require covered farms to conduct operational assessments or develop farm-specific food safety plans, although we encourage farms to do so voluntarily to identify any specific risks and operational efficiencies appropriate for their circumstances. We

recognize the importance of tailoring your food safety practices to the commodities, practices, and conditions applicable to your individual operation. Covered farms may take steps to ensure the safety of their dropped covered produce as determined by a farm-specific operational assessment, as long as those steps are consistent with and do not violate the requirements of this rule, including § 112.114.

(Comment 337) Several comments express that certain produce commodities are intentionally dropped on the ground as part of their regular harvesting practice. For example, some comments refer to the harvesting practices of the tree nut industry in which some types of tree nuts (e.g. hazelnuts, chestnuts, and almonds) are typically shaken from the trees onto the ground as part of harvesting, and agree with our proposal that tree nuts and other commodities that are intentionally dropped as a part of harvesting should not be covered under this provision. Other comments request that FDA exclude from this provision any commodity that has an outer covering (such as a rind or husk) that is not typically consumed. Some comments generally question the scientific basis supporting this requirement. These commenters argue that there is no certainty that pathogens transfer into produce after contact with the ground, and assert that the likelihood of pathogens being at the exact spot where the produce drops is remote.

(Response) In the 2013 proposed rule, we acknowledged that some produce is intentionally dropped to the ground as a part of the harvesting practice (e.g., some tree nuts), and that we expect that such harvesting practices were developed because the fall does not damage the edible crop, which is protected by a durable shell. Accordingly, we proposed to define “dropped covered produce” within § 112.114 in a manner that excludes produce that is intentionally dropped as part of harvesting (i.e., produce that drops to the ground before

harvest). Taking this into account and in light of other comments (see our response to Comment 338) we are revising § 112.114 to explicitly state that dropped covered produce does not include produce that is intentionally dropped as part of the harvesting method (for example, when trees bearing tree nuts, such as almonds, are intentionally shaken to drop tree nuts to the ground to be harvested). We note that this rule, including § 112.114, is not applicable to produce commodities that are identified in 112.2(a)(1) as rarely consumed raw, such as hazelnuts.

However, we have concluded that we should not similarly exclude all produce that has an outer peel that is inedible or not typically consumed. Evidence from studies of tree fruit (e.g., apples and pears) indicates that dropped and damaged fruit contain coliform bacteria in significantly higher numbers than intact tree fruit (Ref. 192). In addition, risk assessment models for apple contamination (Ref. 193) show that dropped apples are more likely to be contaminated with bacteria than tree-picked apples, and dropped fruit used in the production of apple products (e.g., apple cider) are likely to increase rates of product contamination (Ref. 193). Moreover, fruits with outer layers that are inedible or typically not consumed have been implicated in illness outbreaks. In 2011-2012, outbreak events have been linked to whole, intact mangoes, papayas, and cantaloupes (Ref. 194) (Ref. 195) (Ref. 196). Although these outbreak investigations did not conclude that contamination was a result of dropped produce that was harvested and sold, each of these fruits has an outer covering that is either inedible or typically not consumed. Moreover, as discussed in our QAR, there are limited data on the effect of peeling (and cutting) on the levels of pathogens across the range of commodities. Some produce commodities have an inedible rind that is generally removed in such a way that minimizes the potential for any surface contamination to come in contact with the edible

portion of the fruit. In such commodities, for example bananas and coconuts, peeling before consumption may significantly reduce the potential for contamination. However, other produce commodities (e.g., mangos, oranges, carrots) are usually peeled in such a way (e.g., using a knife) that contamination on the surface can be carried to the edible portion of the produce. Thus, FDA maintains that provision § 112.114 should apply generally to covered produce with only the exclusions specified in the provision, irrespective of whether such produce also has an inedible or rarely consumed outer layer. This conclusion is based on the likelihood of damage to the outer layer allowing access to the interior of the commodity, increased rates of contamination observed on some types of dropped produce, and the uncertainty that having some kind of inedible or rarely consumed outer layer provides sufficient protection to counteract these concerns as a general matter.

(Comment 338) Several comments note that proposed § 112.114, as worded, suggests that covered produce that is unintentionally dropped to the ground during harvest would be acceptable for distribution. One comment recommends revising this provision to clarify that covered farms must not distribute covered produce that falls to the ground “before and during harvest.” Another comment states that dropped produce should not include produce that is still attached to the plant at the time of harvest.

(Response) Covered produce is subject to the requirements in § 112.114 unless it is specifically identified as not being included within the meaning of “dropped covered produce.” Under revised § 112.114, dropped covered produce does not include root crops (such as carrots) that grow underground, crops (such as cantaloupe) that grow on the ground, or produce that is intentionally dropped to the ground as part of the harvesting method (such as almonds).

However, produce that grows off the ground, such as tomatoes and apples, and that drop to the ground before harvest is considered dropped covered produce, even if articles of produce are still attached to the plant when they contact the ground. Moreover, an article of covered produce that drops to the ground before that specific article can be harvested, regardless of whether the farm has started harvesting generally, is still dropped covered produce subject to § 112.114 unless it is otherwise excluded (e.g., if dropping is an intentional part of the harvesting process). For example, when an apple drops to the ground before it is harvested, it is dropped covered produce, whether or not the covered farm has already begun harvesting apples from that orchard such that the farm might consider the apple to have unintentionally fallen “during” its harvesting of the orchard. The apple in this example dropped before the apple was harvested.

(Comment 339) One commenter requests that FDA clarify that dropped covered produce may be used for personal consumption, for commercial processing, or for food for animals.

(Response) We are removing the reference to produce that is exempt under § 112.2(b) from the codified text of this section. We are making this change because produce that is exempt from the requirements of part 112 under § 112.2(b) is exempt from all the requirements in part 112 except those specified in § 112.2(b). We are concerned that including a specific reference to exempt produce in § 112.114 might have misleadingly and incorrectly suggested that produce that is not covered by part 112 (under § 112.2(a), because it is rarely consumed raw, produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management, or not a RAC), or produce that is exempt from part 112 (under § 112.2(b), because it receives commercial processing that adequately

reduces the presence of microorganisms of public health significance), is subject to certain requirements other than as specified in § 112.2. In fact, neither produce that is not covered by part 112 (under § 112.2(a)), or produce that is exempt from part 112 (under § 112.2(b)) is subject to § 112.114.

E. Packaging Covered Produce (§ 112.115)

(Comment 340) Several comments generally support this provision. One such comment finds no reason to highlight mushrooms as an example, and requests removing it from the text of the codified provision. This commenter states that there have been significant updates to packaging practices since the research FDA cited, which was conducted in 1978. In addition, this commenter believes that packaging mushrooms is likely done in a packinghouse that would be subject to the PCHF regulation, rather than to the produce safety regulation. Furthermore, some commenters express a view that it is important to consider whether Clostridium botulinum (C. botulinum) is a potential hazard for any commodity, just as it is important to consider all pathogens, and not just anaerobic bacteria, to ensure appropriate packaging.

(Response) The provision in § 112.115 requires you to package covered produce in a manner that prevents the formation of C. botulinum toxin, if such toxin is a known or reasonably foreseeable hazard. This requirement applies to the packaging of any covered produce where the formation of C. botulinum toxin is a known or reasonably foreseeable hazard. Within this provision, we explicitly list mushrooms as an example because the formation of C. botulinum toxin in mushrooms, when packaged under certain conditions, is a known or reasonably foreseeable hazard. As discussed in the 2013 proposed rule, the potential for toxin production by C. botulinum in mushrooms packaged under reduced oxygen conditions

is well-established (Ref. 197). Mushrooms grow close to the ground, which is a source of C. botulinum spores, and mushrooms remain metabolically active after harvest, which may quickly reduce the amount of oxygen, particularly when mushrooms are packaged under conditions that limit the transfer of oxygen across the layer of packaging (Ref. 198). In such reduced oxygen or anoxic conditions, C. botulinum spores can germinate and multiply resulting in the formation of botulinum toxin, which can occur before any overt signs of mushroom spoilage (Ref. 197). Therefore, we continue to believe that mushrooms are an appropriate example.

Modified atmosphere or other reduced-oxygen packaging of produce other than mushrooms may present a similar risk for botulinum toxin formation (Ref. 199). Therefore, it would be incorrect to infer that packaging of mushrooms is the only circumstance where C. botulinum toxin formation is a known or reasonably foreseeable hazard. We continue to include mushrooms as an example, but they are only an example.

Moreover, covered farms must ensure their food packing (including food packaging) material is adequate for its intended use, as required in § 112.116 (discussed in the paragraphs that follow). Section 112.116 relates to all pathogens, and is not limited to C. botulinum toxin. Section 112.115 goes beyond the packing material requirements in § 112.116 and applies specifically to the hazard of formation of C. botulinum toxin. Whereas § 112.116 is aimed at ensuring that packing materials themselves do not introduce hazards into produce, § 112.115 is aimed at the specific hazard of C. botulinum toxin when produce is packaged in a manner that allows C. botulinum spores to germinate and multiply, resulting in the formation of botulinum toxin, which can occur before any overt signs of spoilage of the produce. A farm using reduced oxygen packaging might comply with this requirement by applying means to reduce the potential

for toxin formation. For example, perforated packaging film allows free air access and is a means to reduce the potential for toxin formation in mushrooms (Ref. 200) (Ref. 201). Other means of preventing toxin formation in reduced oxygen packaging may include use of time-temperature integrators on individual packages of produce to signal when a cumulative time-temperature combination has been reached that presents a risk for C. botulinum toxin formation, or use of antimicrobial compounds (Ref. 199). Scientific information should support the use of methods used to prevent toxin formation, such as use of perforated packaging film, time-temperature integrators and antimicrobial compounds.

We also note that, even if some packing or packaging of mushrooms may be done in facilities subject to the PCHF regulation, it is also likely that covered farms will conduct relevant activities within the coverage of the produce safety regulation. The definition of “farm” as provided in both this regulation (in § 112.3(c)) and the PCHF regulation includes packing of RACs, and packaging of RACs when such packaging does not include additional manufacturing/processing. An example of additional manufacturing/processing is irradiation. However, § 112.115 applies to packaging that does not include additional manufacturing/processing; such packaging includes modified atmosphere packaging and other methods of packaging of covered produce in a manner that creates anaerobic conditions where the formation of C. botulinum toxin is a known or reasonably foreseeable hazard. For example, packaging of mushrooms or other covered produce in semipermeable plastic films is a covered activity that fits within the farm definition and is, therefore, subject to this rule and to § 112.115.

Accordingly, we are finalizing § 112.115, as proposed, with no changes.

F. Food-Packing (Including Food Packaging) Material (§ 112.116)

(Comment 341) Several comments agree that food-packing and packaging material must be adequate for its intended use. One comment requests clarification of what is meant by “adequate for its intended use,” and suggests incorporating the following text from the preamble of the 2013 proposed rule into the codified provision: “To implement this provision, you would have to use food-packing materials that are: (1) cleanable or designed for single use and (2) unlikely to support growth or transfer of bacteria.”

(Response) In the 2013 proposed rule, we provided some examples of what food-packing material would be adequate for its intended use in compliance with § 112.116(a). For example, food packing material that is adequate for its intended use includes plastic bins for holding fresh-picked fruit, wax impregnated corrugated cardboard for broccoli to be hydro-cooled or top-iced after packing, plastic clamshells used for packaging strawberries for retail sale, and single-use cardboard containers for packing tomatoes. Wooden bins or boxes, and canvas bags that are used during harvest also must meet the requirement in § 112.116(a), and can be used if they are adequately clean and sanitary for their intended use. This section requires that you use food-packing materials that are adequate for their intended use, which includes being: (1) cleanable or designed for single use and (2) unlikely to support growth or transfer of bacteria. We are revising § 112.116(a) to include this additional information.

(Comment 342) Several comments discuss the use of containers (or bags or sacks) made from wooden, plastic, or cloth-like materials and pulp materials, as well as decorative containers used to enhance retail presentation. Many of these comments discuss the variety of on-farm and off-farm uses of such containers, and request that we allow the continued use of wooden

containers and other porous materials during harvesting. Several other commenters point out requiring farms to switch to plastic containers would cause significant economic burden and may also result in loss of crop due to reduced air flow observed with plastic packing materials.

(Response) The only restriction we are establishing on the types of food packing materials you may use for covered produce is that such materials must be adequate for their intended use (§ 112.116(a)). As discussed in response to Comment 341, this includes being (1) cleanable or designed for single use and (2) unlikely to support growth or transfer of bacteria. Thus, you may re-use food-packing material provided that it is cleanable and it is unlikely to support growth or transfer of bacteria. Moreover, if you re-use food packing material, you must take steps to ensure that food-contact surfaces are clean; for example, you must clean the food packing containers or use a clean liner on the food packing container to protect produce from contamination (§ 112.116(b)). The necessary frequency of such cleaning, and the necessary frequency with which liners must be replaced, will likely vary depending on the circumstances. Therefore we are not specifying a single required cleaning frequency in this regulation. However, we are revising this section to make clear that the steps you take, including the frequency of cleaning or replacing liners, must be adequate.

We are not requiring farms that use wooden or other porous food packing materials to stop using them, but we are requiring that such materials be used only to the extent they are cleanable and unlikely to support the growth or transfer of bacteria. As noted in the 2013 proposed rule, although some food-packing materials are sufficiently sturdy to be used multiple times, such materials may serve as a source of contamination if they are not adequately clean and/or if the material is used beyond its shelf life and adequate cleaning cannot be achieved.

(Comment 343) One comment generally supports requiring that food-contact surfaces of reusable food packing material be cleaned and sanitized between uses. In contrast, a few comments object to provision § 112.116(b) to the extent it may require sanitizing food containers. One such comment states that it is not feasible for farmers to sanitize all harvest containers, and another comment notes some current practices involve using wooden bins, carpet-cushioned or cardboard-cushioned trailers and transporters, and other materials that cannot be sanitized. Yet another comment states that wooden bins used on farms during harvesting should be required to be kept clean, but not required to be sanitized.

(Response) We are not requiring you to sanitize all food packing containers or food-contact surfaces that you re-use during harvesting, packing, or holding of covered produce. Rather, per § 112.116(a), you must use food-packing material that is adequate for its intended use and, per § 112.116(b), if you re-use a food packing container, you must take measures to ensure that the food-contact surfaces of that container are clean. We recognize the use of “sanitizing” in the example we provided within proposed § 112.116(b) (i.e., “such as by cleaning and sanitizing, when necessary, food-packing containers”) is confusing and implies a requirement that goes beyond that described in the established measure (i.e., “if you reuse food-packing material, you must take steps to ensure that food-contact surfaces are clean”). Therefore, we are revising § 112.116(b) by removing the reference to “sanitizing” such that the provision reads as follows: “if you reuse food-packing material, you must take adequate steps to ensure that food-contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.”

However, under § 112.111(b), you are required to adequately clean and sanitize, as necessary, any food-contact surfaces that contact excluded produce before using such food-

contact surfaces for covered activities on covered produce. For example, if you use food packing containers that were previously used to pack or hold excluded produce, and the excluded produce is not grown, harvested, packed, or held in accordance with part 112, you must clean and sanitize, as necessary, the food-contact surfaces of the containers that came into contact with the excluded produce before subsequently using the same containers for packing covered produce. In summary, taking adequate steps to ensure that food-contact surfaces of food-packing materials are clean is required whenever you are re-using food packing material for covered produce, and sanitizing such surfaces is also required, as necessary, when re-using such materials after using them on excluded produce not handled in accordance with part 112.

XVII. Subpart L – Comments on Equipment, Tools, Buildings, and Sanitation

In subpart L of proposed part 112, we proposed to establish science-based minimum standards that are reasonably necessary to prevent equipment, tools, buildings, and inadequate sanitation from introducing known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, and to provide reasonable assurances that the covered produce is not adulterated under section 402 of the FD&C Act. We asked for comment on the proposed provisions of this subpart.

We are finalizing these provisions with revisions (see Table 23). We discuss these changes in this section.

Table 23.-- Description of Revisions to Subpart L

Final Provision	Description of Revisions
§ 112.121	- Revisions to delete the term “other contamination”, and replace “undesirable microorganisms” with “microorganisms of public health significance”
§ 112.123(d)	- Revision to move “when necessary and appropriate” before “sanitize” to clarify applicability
§ 112.124	- Revisions to delete the term “other contamination”, and replace “undesirable microorganisms” with “microorganisms of public health significance”
§ 112.126	- Revision to eliminate proposed § 112.126(a)(3) and, instead, establish new provision § 112.126(b) requiring measures to prevent contamination of covered produce and food contact surfaces in buildings, as appropriate, considering the potential for contamination through floors, walls, ceilings, fixtures, ducts, or pipes, and drip or condensate
§ 112.129	- Revision to clarify the required frequency of servicing and cleaning toilet facilities
§ 112.130	- Revision to amend the list of examples of adequate drying devices (removing clean cloth towels and adding electric hand dryers) - Revision to use the term “antiseptic hand rubs” in lieu of “hand antiseptic/sanitizer or wipes” - Revision to permit the use of “other effective surfactants” in lieu of soap
§ 112.140	- No change

We are finalizing the other provisions of subpart L as proposed. For §§ 112.127, 112.128, 112.131, 112.132, 112.133, and 112.140, we did not receive any comments or received only general comments in support of the proposed provision and, therefore, we do not specifically discuss these provisions.

A. Types of Buildings That are Subject to the Requirements of Subpart L (§ 112.122)

(Comment 344) Some comments express concern with the applicability of the proposed provisions in subpart L to greenhouses (including high tunnels), germination chambers, or other protected environment production areas. A comment states that applying the proposed building requirements to greenhouses would negatively impact small farmers in areas without a warm climate for most of the year, such as in the North east, where farmers rely on greenhouses to grow produce throughout the year. Other comments contend that protected environment production areas enable farms to control various aspects of growing, such as humidity, temperature, or light, and believe it is highly improbable that a pathogen of public health significance would find its way into the controlled system.

(Response) The provisions in subpart L apply to any fully or partially-enclosed buildings used for covered activities, including greenhouses, germination chambers, or other such structures. These structures used for growing activities can create an enclosed system where potential hazards can be amplified (Ref. 202). Therefore, we do not agree that greenhouses, high tunnels, germination chambers, or “protected environment production areas” should be generally exempt from the standards in subpart L.

We do not discourage the practice of growing produce inside greenhouses, germination chambers, or other such structures nor do we intend our requirements in subpart L to specifically

impact small farms that use such structures for growing produce. Rather, our concern is to establish those procedures, processes, and practices that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, and to provide reasonable assurances that the covered produce is not adulterated under section 402 of the FD&C Act. In response to these and other comments, we reviewed the provisions in subpart L to determine their appropriateness and practicability when applied to greenhouses (including high tunnels), germination chambers, and other such structures used for growing covered produce. We are deleting one provision in subpart L (i.e., § 112.126(a)(3)) and replacing it with a new provision we believe is more appropriate to apply to all covered farm buildings, including greenhouses, germination chambers, and other such structures (see Comment 352).

(Comment 345) Some comments state many existing on-farm structures will likely not meet the proposed building requirements, and one comment additionally states there are no data available on the number or quality of on-farm buildings such as packing sheds and storage facilities.

(Response) We used available data sources to inform proposed provisions and our estimates of economic burden associated with the provisions in subpart L (Ref. 142). Under § 112.122(b), storage sheds, buildings, or other structures used to store food-contact surfaces (such as harvest containers and food-packing materials) are subject to the requirements of subpart L. We believe it is important to apply the science-based minimum standards in subpart L to such buildings because contaminated food-contact surfaces can contaminate covered produce (Ref. 203) and, thus, present a potential hazard.

B. Equipment and Tools (§ 112.123)

(Comment 346) Some comments recommend covered farms be allowed to clean equipment and tools as an alternative to the requirement related to storage and maintenance of equipment and tools in proposed § 112.123(b)(2).

(Response) We are establishing the requirement in § 112.123(b)(2) because appropriate practices for storing and maintaining equipment and tools can protect against contamination and reduce the potential for attracting or harboring pests, which can carry human pathogens. Pest harborage by equipment not only can contaminate the equipment; it can also increase the prevalence of pests near a building, and provide a place for them to live and breed. We have included sufficient flexibility in this requirement such that you may store equipment and tools in a manner that is practical but also protects against contamination and prevents attraction and harborage of pests. For example, you may satisfy this requirement by storing equipment indoors or outdoors, provided that the location appropriately protects against contamination and you appropriately minimize surrounding debris, check periodically for pests, and take any other measures reasonably necessary under the circumstances. Separate and distinct from this requirement regarding storage and maintenance is the provision in § 112.123(d)(1), which requires you to inspect, maintain, and clean and sanitize (when necessary and appropriate) all food-contact surfaces of equipment and tools used in covered activities. This provision is intended to prevent transfer of contaminants on food-contact surfaces of equipment or tools to covered produce. Appropriate storage, maintenance, and cleaning of equipment are all reasonably necessary to minimize the risk of produce contamination, and we disagree that

cleaning of equipment and tools alone should relieve a covered farm of the need for proper storage and maintenance of equipment and tools.

(Comment 347) Two comments question the applicability and practicality of the requirement to “sanitize” food-contact surfaces of equipment and tools under § 112.123(d)(1) with respect to the knife that cuts the asparagus below the ground if the part of the spear that the knife contacts is cut off before the spear is shipped to consumers. One comment acknowledges that asparagus was not covered under the 2013 proposed rule, and asks us to clarify what would be required with respect to sanitation of “asparagus boxes” containers, if asparagus were to be covered by the final rule.

(Response) We are establishing the requirement in § 112.123(d)(1) taking into account evidence that pathogens can be transferred to produce from contaminated coring devices and contaminated food-contact surfaces of tools (Ref. 204) (Ref. 205). We acknowledge that sanitizing all food-contact surfaces of equipment and tools used in covered activities is impractical, considering the wide range of equipment and tools used in covered activities and the diversity of produce growing, harvesting, packing, and holding practices. Therefore, in § 112.123(d)(1), we are requiring you to sanitize only when necessary and appropriate, but to always inspect, maintain, and clean all food-contact surfaces of equipment and tools used in covered activities, and to do so as frequently as reasonably necessary to protect against contamination of covered produce. As the commenter noted, asparagus is not covered under this rule because it is rarely consumed raw (see § 112.2(a)(1)).

(Comment 348) With respect to proposed § 112.123(d)(2) related to non-food-contact surfaces, some comments point out that non-food-contact surfaces (such as on trailers, tractors, and vehicles) are, by definition, not expected to come into contact with produce and, as such, are rarely designed to be cleaned to the same degree of cleanliness as food-contact surfaces. These comments request us either to provide clarification on how operations would be expected to implement this requirement or to delete this requirement.

(Response) As discussed in the 2013 proposed rule, the potential for equipment or a tool to come into contact with covered produce varies with the type and intended use of the equipment or tool. Non-food-contact surfaces of tools and equipment used with covered produce can be sources of contamination. Therefore, it is important to maintain such surfaces of covered equipment and tools in a clean and sanitary condition. However, we acknowledge that such surfaces may not require cleaning as frequently as those that come into direct contact with produce, and also may not require sanitizing. Under this provision, you are required to maintain and clean all non-food-contact surfaces of equipment and tools used in covered activities during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce. We provide examples of equipment and tools subject to the requirements of subpart L in § 112.121.

In contrast to the requirements regarding food-contact surfaces in § 112.123(d)(1), the requirements related to non-food-contact surfaces in § 112.123(d)(2) do not require sanitizing such surfaces. As an example, the blades and conveyors in a harvesting machine that directly contact produce are considered a food-contact surface, but the portion of the truck that is used to hold boxes or crates containing harvested produce is not a food-contact surface. Likewise, the brush rollers on a sorting or grading machine where the rollers come in direct contact with the

produce are food-contact surfaces, and must be inspected, maintained, and cleaned and, as necessary and appropriate, sanitized per § 112.123(d)(1). In contrast, a gear box attached to the rollers that does not come into contact with produce is a non-food-contact surface, and must be maintained and cleaned per § 112.123(d)(2).

C. Instruments and Controls Used to Measure, Regulate, or Record (§ 112.124)

(Comment 349) One comment generally supports proposed § 112.124. Another comment requests clarification regarding what is meant or intended by “other contamination”.

(Response) We are revising §§ 112.121 and 112.124 to delete the term “other contamination” and to replace “undesirable microorganisms” with “microorganisms of public health significance.” The requirements in this rule are intended to address microorganisms of public health concern and not all forms of contamination or undesirable microorganisms generally.

D. Equipment Used in the Transport of Covered Produce (§ 112.125)

(Comment 350) Some comments express concern that requiring cleaning of surfaces that come into contact with covered produce during their transport would be problematic for the watermelon industry. Comments state that harvest transportation from field to packing shed for watermelons is often done by using buses that are adapted for this purpose by, for example, covering the interior of the bus at the beginning of the season with either carpet or cardboard to cushion and protect the watermelons from damage and pathogen contamination from bruises or cuts that could occur during transport.

(Response) Section 112.125 is not prescriptive about the manner in which farms ensure that their equipment used to transport covered produce is adequately cleaned before use in transporting covered produce and is adequate for use in transporting covered produce. This provision requires covered farms to take measures to minimize the risk that equipment used during transportation becomes a potential source of contamination of covered produce. In the specific instance described in these comments, we expect the cushioning material(s) that comes into contact with the watermelons to be adequately cleaned prior to transportation and to be adequate for its intended use (meaning it must be cleanable or designed for single use, and unlikely to support growth or transfer of bacteria).

E. Buildings (§ 112.126)

(Comment 351) One comment states that, under proposed § 112.126, a cooler in a packing house would be required to have 18" of separation from the wall around the entire perimeter on the inside of the cooler, such that a 10,000 sq. ft. cooler might lose 5 percent of its floor space. This comment also notes that such a requirement would discriminate against smaller operations, and also create an unsafe working environment due to “free standing” stacks of bins.

(Response) Under § 112.126(a)(1)(i), buildings must provide sufficient space for placement of equipment and storage of materials. We are not establishing a precise amount of space needed for the placement or storage of materials, or a minimum distance required between an interior wall and any stacked bins or pallets. The intent of this provision is to ensure that buildings are spacious enough for the maintenance of sanitary operations and the conduct of covered activities. In the specific circumstance described by the commenter, space between the

bins or pallets and the interior wall is not necessary if the bins or pallets can be moved to allow for cleaning activities.

(Comment 352) Some comments express concern regarding proposed § 112.126(a)(3) requiring that buildings must be constructed in a manner such that drip or condensate does not contaminate covered produce, food-contact surfaces, or packing materials. Comments note, by nature of the indoor growing process or cold-storage process, it would be impossible to prevent formation of condensate. Comments also note condensate sometimes is present in a produce growing room but that because growing rooms are cleaned and sanitized between each crop, the condensation does not come from an unsanitary surface and, therefore, poses no threat of contamination. Comments object to this proposed requirement particularly with respect to its applicability to certain types of buildings, such as greenhouses (including high tunnels) and cold storage buildings. Comments recommend excluding greenhouses (including high tunnels and low tunnels) and other season-extending, non-permanent structures used for growing, as well as cold storage buildings from coverage under proposed § 112.126(a)(3) and/or creating alternative standards, recognizing that condensation cannot be prevented in such buildings.

(Response) Proposed § 112.126(a)(3) would have applied equally to fully-enclosed structures used in growing activities as it would to storage sheds, packing sheds, barns, or other farm buildings used for packing or holding activities, and would have required that buildings be kept in good repair so as to prevent drip or condensate from pipes or ceilings to drop onto covered produce or food-contact surfaces. Upon review of these comments, we agree there is a need to incorporate flexibility in the implementation of this provision to account for differences inherent to certain covered activities conducted in fully- or partially-enclosed buildings. For

example, condensation is a common occurrence in fully-enclosed buildings used for growing activities (such as greenhouses, including high tunnels, which are substituting for growing conditions in an open field), and may not represent a likely source of contamination of covered produce if produce is physically protected from condensate drip or the interior of the fully-enclosed building (such as walls and ceiling) where condensate is formed (and may drip onto covered produce) is kept adequately clean. Similarly, condensation is a natural phenomenon during storage under high relative humidity conditions and if produce is physically protected from condensate drip or the interior of such cold-storage building is adequately clean, any condensate that forms on walls or ceiling is not likely to be a potential source of contamination. We are making revisions to the codified text so that a covered farm is required to take measures necessary to protect covered produce and food-contact surfaces from potential contamination from building surfaces such as floors, walls, ceilings, fixtures, ducts, or pipes, and generally through condensation or drip from these or other surfaces, rather than requiring farms to prevent condensation or drip contact with covered produce or food-contact surfaces

We are deleting proposed § 112.126(a)(3) and replacing it with a new provision under § 112.126(b), which requires that covered farms implement measures to prevent contamination of covered produce and food-contact surfaces in the farm's buildings, as appropriate, considering the potential for such contamination through: (1) floors, walls, ceilings, fixtures, ducts, or pipes; and (2) drip or condensate. For example, to comply with this provision, you must consider whether for your growing or storage practices in your buildings, the occurrence of drip or condensate presents a potential for contamination of your covered produce, and take measures to minimize or prevent that potential for contamination. Such measures include, for example, keeping buildings in good repair so as to prevent leakage of rainwater into the walls or ceilings

of buildings, so that any drip or condensate from overhead pipes or ceilings that may drop onto covered produce or food-contact surfaces does not contaminate covered produce. Such measures also include adequately and regularly cleaning fixtures, ducts, or pipes inside the building where covered activities occur in order to minimize the presence or persistence of hazards, such as in biofilms, and the potential for contamination of covered produce.

(Comment 353) With respect to the requirement in proposed § 112.126(a)(3) that buildings must be constructed in a manner such that floors, walls, ceilings, fixtures, ducts, and pipes can be adequately cleaned and kept in good repair, one comment suggests that this requirement may preclude use of certain older barns, and further asserts that “modern” warehouses have been associated with foodborne illnesses.

(Response) It is not our intent to preclude the use of any specific types of buildings or barns; rather, we are establishing the provisions in subpart L to ensure that buildings used in covered activities are suitable and facilitate sanitary operations, and can be adequately cleaned and maintained to prevent contamination of the covered produce, food-contact surfaces, or packing materials. We are deleting § 112.126(a)(3) and replacing it with a new provision under § 112.126(b) that we believe is more appropriate to apply to all covered farm buildings (see our response to Comment 352). We have no data or information to suggest that large warehouse-like structures pose a greater risk of produce contamination compared to smaller barn-like structures, and the commenter provided no data to support this claim.

(Comment 354) One comment expresses concern that proposed § 112.126(a)(3) would require farms to prevent the pooling of water on the floor and lay out the crops in a manner that workers may move freely without their clothes touching the produce.

(Response) We are deleting proposed § 112.126(a)(3) and replacing it with a new provision under § 112.126(b); see Comment 352. Under § 112.126(a)(2), you must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building. We acknowledge the potential for small pools of water to temporarily form on the floor of buildings used for growing activities, and that pooling of water of this nature, which is temporary and may occur in the normal course of watering practices, is not reasonably likely to contribute to the contamination of covered produce. We are not suggesting that it will always be possible to eliminate pooling. Avoiding pooling by careful control of greenhouse watering practices with consideration to your drainage system is ideal; however, to the extent pooling may be inevitable or may sometimes occur, despite adequate drainage, we expect covered farms to take steps to protect covered produce from any contamination that may build in the pooled water. Moreover, § 112.126(a), which addresses building design and construction requirements, does not impose any specifications regarding crop layout in buildings used for growing activities or establish measures for movement of workers within covered areas in a building. Rather, a covered farm is required to implement measures related to worker health and hygiene in accordance with subpart D of part 112.

F. Toilet Facilities (§ 112.129) and Hand-Washing Facilities (§ 112.130)

(Comment 355) A few comments note that it is not necessary for toilet facilities to be cleaned “on a schedule”, and request that § 112.129(b)(2) be revised to remove the reference to a

schedule and require instead that they must be “serviced and cleaned at a frequency sufficient to ensure suitability of use.”

(Response) We intend for this requirement to provide flexibility for covered farms to determine the frequency of servicing necessary to keep the toilet facilities clean and suitable for use. We are revising this provision, as suggested by commenters, to make our intent more clear.

(Comment 356) One comment recommends that the requirements applicable to toilet facilities (in § 112.129) and hand-washing facilities (in § 112.130) should either simply reference OSHA field sanitation standards in 29 CFR 1928.110 or mirror those standards as closely as possible to avoid confusion and conflicting requirements.

(Response) The requirements for toilet and hand-washing facilities in §§ 112.129 and 112.130 are generally similar and consistent with the requirements in the United States Occupational Safety and Health Administration’s (OSHA) field sanitation standards in 29 CFR 1928.110, although the OSHA standards are more prescriptive in some provisions. For example, whereas we are establishing a general requirement that you must provide personnel with adequate, readily accessible toilet facilities, including facilities readily accessible to growing areas during harvesting activities (§ 112.129(a)), the OSHA standards include specific requirements on the number and proximity of such facilities. The field sanitation standards in 29 CFR 1928.110 specify that one toilet facility and one hand-washing facility must be provided for each twenty employees or fraction thereof (with additional exception) (paragraph (c)(2)(i)), and that the toilet and hand-washing facilities shall be located within a one-quarter-mile walk of each hand laborer’s place of work in the field (paragraph (c)(2)(iii)).

Nevertheless, we disagree that the toilet and hand-washing provisions in part 112 should simply refer to the field sanitation standards in 29 CFR 1928.110. Unlike the OSHA field sanitation standards, the requirements in §§ 112.129 and 112.130 relate specifically to the growing, harvesting, packing, and holding of covered produce, with a focus on minimizing the risk of contamination of covered produce, food-contact surfaces, or areas used for a covered activity with human waste or by ill or infected workers. Moreover, the OSHA field sanitation standards apply only to an agricultural establishment where 11 or more employees are engaged on any given day in hand-labor operations in the field. (As defined in paragraph (b) of that regulation, hand-labor operations exclude those conducted in permanent structures such as in packing houses). It is not clear that this scope, established for the purposes of the OSHA field sanitation standards, sufficiently addresses the covered farms and covered activities defined in this rule for the purposes of produce safety standards. Therefore, we decline the request to simply refer to 29 CFR 1928.110 in lieu of establishing requirements for toilet and hand-washing facilities in part 112. Compliance with our provisions for toilet and hand-washing provisions in part 112 do not preclude compliance with OSHA field sanitation requirements, and we believe our requirements in part 112 can be met concurrently with those of OSHA field sanitation.

(Comment 357) According to one comment, hand-washing stations are typically located together with field toilets and, in the case of open fields, it would not be possible or realistic to have a hand-washing station located in a fully-enclosed building.

(Response) We are not requiring hand-washing stations to be located inside a fully-enclosed building. Rather, under § 112.129(c), during growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you are

required to provide a hand-washing station that is in sufficiently close proximity to toilet facilities, such that it is practical for persons who use the toilet facility to wash their hands.

(Comment 358) One comment generally notes that employers must provide agricultural workers with necessary training, protective equipment, and hygienic supplies (such as enough clean bathrooms and hand-washing facilities) while working on the farm.

(Response) We agree that employers must provide agricultural workers with necessary training, and hygienic supplies while working on the farm. In this subpart L, we are finalizing provisions §§ 112.129 and 112.130 to establish requirements for toilet and hand-washing facilities, and in subpart C of this rule, we are establishing requirements related to worker training.

(Comment 359) With respect to the provision related to hand-drying devices in proposed § 112.130(b)(3), one comment recommends that the use of “clean cloth towels” be limited to operations where only one person would be using the “clean cloth towel” to dry their hands. This comment notes that use of a “clean cloth towel” to dry multiple persons’ hands should not be allowed as this is likely to facilitate the transference of pathogens (if present) from one towel user to the next. An additional comment notes that the example of “clean cloth towels” listed as an adequate drying device conflicts with OSHA’s requirement of single-use towels. Finally, another comment requests that we provide for use of electric hand dryers because the quality of drying from these devices can be similar to paper towels.

(Response) Under OSHA’s field sanitation standards, a “hand-washing facility” means a facility providing a basin, container, or outlet with an adequate supply of potable water, soap and

single-use towels (29 CFR 1928.110). In light of the OSHA definition and comments, we are revising § 112.130(b)(3), which requires that hand-washing facilities be furnished with adequate drying devices, to revise the examples of “adequate drying devices” to no longer include “clean cloth towels” because the repeated use of towels or use by multiple users can increase the potential for contamination (Ref. 103). We are also revising the list of examples to include electric hand dryers, which we agree can be adequate drying devices. We acknowledge that this provides additional flexibility compared to OSHA’s field sanitation standards; however, this provision does not prevent covered farms that are subject to this OSHA requirement from complying with the OSHA requirement. We also note that our list of examples is not intended to be exhaustive.

(Comment 360) With respect to the provision related to hand antiseptic/sanitizer in proposed § 112.130(d), some comments state that although hand antiseptic/sanitizer or wipes may not be a substitute for soap and water, this requirement prohibits the use of future innovation in hand sanitizers. Comments recommend revising this requirement to read “. . . as a substitute for soap and water unless validated by the manufacturer as effective for that purpose.”

(Response) As discussed in the 2013 proposed rule, “hand sanitizers” have not been found to be effective substitutes for washing hands with soap and water, because the presence of dirt, grease, or soil reduces their effectiveness in eliminating bacteria. However, we are not prohibiting the use of antiseptic hand rubs because such products may be effective as an additional measure in reducing the number of bacteria on hands after proper washing with soap and water followed by drying. Should there be advancements in product development in this area, we will consider revisiting this issue in the future, as needed. We recognize, however, that

effective surfactants other than soap may be used in lieu of soap during hand-washing, and we are revising § 112.130(d) to be consistent with § 112.130(b)(1), which we are retaining as proposed. We are also revising § 112.130(d) to use the term “antiseptic hand rubs” to collectively refer to leave-on antiseptic products, such as hand sanitizers or wipes.

G. Controlling Animal Excreta and Litter From Domesticated Animals (§ 112.134)

(Comment 361) One comment requests clarification on whether § 112.134 would allow cats and dogs to be present on produce farms if the farmer can demonstrate reasonable precautions that can reasonably minimize the risk of their excreta contaminating covered produce.

(Response) You are permitted to have cats or dogs on your covered farm, provided that under § 112.134 you (1) adequately control their excreta and litter and (2) maintain a system for control of their excreta and litter. These measures are necessary to prevent contamination of covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with waste from your cats or dogs. In addition, you must comply with the requirements of § 112.127 regarding domesticated animals in and around a fully-enclosed building, and, when applicable, the requirements related to animals in subpart I.

XVIII. Subpart M – Comments on Sprouts

In subpart M of proposed part 112, we proposed to establish science-based minimum standards specific to the growing, harvesting, packing and holding of sprouts that are reasonably necessary to minimize the risk of known or reasonably foreseeable hazards that are associated with serious adverse health consequences or death (in combination with the standards in other subparts of part 112 that also would apply to sprout operations). We tentatively concluded that it is necessary to incorporate this subpart establishing additional standards specific to sprouts because sprouts present a special concern with respect to human pathogens compared to other covered produce. We asked for comment on our proposed provisions in subpart M for sprouts, including on whether, or to what extent, the measures in this subpart should be applied to soil-grown sprouts; and on whether, in a final rule, a food safety plan and/or an operational assessment should be required for farms conducting covered activities related to sprouts, either in addition to, or in place of, the standards proposed in this subpart. We also requested comments on whether a supplier approval and verification program for seeds and beans intended for sprout production is practical and effective.

We are finalizing these provisions with several revisions (See Table 24). We discuss these changes in this section.

Table 24.-- Description of Revisions to Subpart M

Proposed Provision	Final Provision	Description of Revisions
	§ 112.141	- New section to describe the scope of subpart M
§ 112.141	§ 112.142	- Revision to combine all requirements for seeds and beans into § 112.142 - Revision to § 112.142(b) to include a requirement to discontinue use of a lot of seeds or beans that you know or have reason to believe may be contaminated with a pathogen due to association with foodborne illness or positive microbial test results and adding actions that must be taken with regard to a lot that may be contaminated - Revision to establish in § 112.142(c) certain limited circumstances under which you are not required to take the steps set forth in § 112.142(b)
§ 112.142	§ 112.143	- Revision to summarize in this section all measures that need to be

		<p>taken for growing, harvesting, packing, and holding, with relevant cross-references to other parts of subpart M. (We have added § 112.143(c) referring to testing requirements in § 112.144; § 112.143(d) referring to the written environmental monitoring plan required in § 112.145; § 112.143(e) referring to the actions you must take when <u>Listeria</u> spp. or <u>L. monocytogenes</u> is detected in the growing, harvesting, packing, or holding environment as required in § 112.146; § 112.143(f) referring to the written sampling plan required in § 112.147, and § 112.143(g) referring to the actions you must take when samples of spent irrigation water or sprouts test positive for a pathogen as required in § 112.148.)</p> <p>- Revision to move requirement for treating seeds and beans into § 112.42</p>
§ 112.143	§ 112.144	<p>- Revision to clarify the soil-grown sprouts example in § 112.144(b)(2)</p> <p>- Addition of new § 112.144(c), and revision to § 112.144(b), to require additional pathogen testing when certain specified criteria are met</p>
§ 112.144	§ 112.145	<p>- Revision to clarify that you must aseptically collect environmental samples in § 112.145(d)</p> <p>- Addition of requirement in § 112.145(e) that your written environmental monitoring plan must include a corrective action plan that details the actions you will take if the environment tests positive for <u>Listeria</u> spp. or <u>L. monocytogenes</u></p>
§ 112.145	§ 112.146	<p>- New provision § 112.146(f) to indicate that you must take appropriate action to prevent any food that is adulterated from entering commerce</p>
§ 112.146	§ 112.147	<p>- Addition of requirement in § 112.147(b) that you must not allow a production batch of sprouts to enter commerce until you receive negative pathogen testing results on spent sprout irrigation water or sprouts</p> <p>- Addition of requirement in § 112.147(c) that your written sampling plan must include a corrective action plan if your spent irrigation water or sprouts test positive for a pathogen</p>
	§ 112.148	<p>- New section to describe actions that must be taken if spent irrigation water or sprouts test positive for <u>E. coli</u> O157:H7, <u>Salmonella</u> spp., or a pathogen identified in accordance with § 112.144(c)</p>
§ 112.150	§ 112.150	<p>- Revision to § 112.150(b)(3) to clarify recordkeeping requirement related to written sampling plan for each production batch of sprouts in accordance with § 112.147(a) and (c)</p> <p>- Revision to § 112.150(b)(4) to require documentation of results of all analytical testing conducted to comply with subpart M</p> <p>- Revision to § 112.150(b)(5) to clarify recordkeeping requirement related to any analytical methods used in lieu of methods incorporated by reference in §§ 112.152 and 112.153</p> <p>- Elimination of proposed § 112.150(b)(6) as a corresponding change to final § 112.150(b)(5)</p> <p>- Addition of new provision (i.e., final § 112.150(b)(6)) to clarify the recordkeeping requirement for actions taken in accordance with §§ 112.142(b) and (c), 112.146, and 112.148</p>

A. General Comments

(Comment 362) Several comments agree with FDA's proposal to establish additional standards specific to sprouts in subpart M. In contrast, one comment maintains that the proposed requirements for sprouts are unlikely to improve the safety of sprouts, and argues there is little known about the causes of sprout contamination and that many interventions, such as seed treatments, occur before sprouting whereas most pathogens of concern are introduced or proliferate during sprouting. Several comments also mention that additional research is needed to improve the safety of sprouts.

(Response) We are finalizing the rule with certain sprout-specific requirements in subpart M. We disagree with the comment arguing that little is known about the causes of sprout contamination. We have learned much in this area through extensive direct experience conducting inspections at sprout operations, as well as investigations to follow-up on foodborne illness outbreaks and/or positive sample findings. We also published guidances to industry (Ref. 97) (Ref. 206), and issued a letter to suppliers and distributors of seeds and beans to urge firms to review their operations in light of our guidances and other available information (Ref. 207), and to modify their operations accordingly. FDA's 2014 sprouts assignment suggested that although many operations were taking some steps to implement at least some of the recommendations in our sprout guidances, this effort was not universal across sprout farms visited nor was it across all recommendations within a single operation (Ref. 208).

Sprouts have been frequently associated with foodborne illness outbreaks. Between 1996 and 2010, there were a total of 34 outbreaks, 2,150 illnesses, and 123 hospitalizations associated with sprouts (Ref. 26) (Ref. 27). Moreover, there have been an additional nine outbreaks associated with sprouts, accounting for 255 illnesses and 48 hospitalizations,

between 2011 and 2014, including the first documented L. monocytogenes sprout outbreak in the United States that resulted in deaths (Ref. 28).

We have relied on available science and evidence to inform the development of the sprout-specific requirements in subpart M. For example, it is well-established that sprouts can become contaminated through the use of contaminated seeds for sprouting, and we are aware of outbreaks associated with multiple sprout farms using the same lot of seed (Ref. 29). In addition, although treatment of seeds prior to sprouting does not guarantee pathogen-free sprouts, treatment can be expected to reduce the percentage of contaminated batches (Ref. 209) (Ref. 210). Therefore, we are including certain requirements applicable to seeds or beans used to grow sprouts to help prevent seeds and beans from serving as a vehicle for introducing contamination in sprouts. We are also requiring testing of spent sprout irrigation water (or production batches of sprouts) for certain pathogens, which is consistent with current recommendations in our guidances, and existing international guidelines and regulations (Ref. 23) (Ref. 211) (Ref. 212) (Ref. 213). Such testing is appropriate in addition to the seed treatment requirements because pathogens that are not eliminated by seed treatment could potentially grow out again when subjected to enrichment conditions, as experienced during sprouting (Ref. 21) (Ref. 23). We are also requiring testing the growing, harvesting, packing, and holding environment for Listeria spp. or L. monocytogenes. Contamination from L. monocytogenes from the environment is common (Ref. 214) and, thus, targeted preventive controls to minimize L. monocytogenes in sprouts are warranted. While appropriate sanitation measures can minimize the presence of environmental pathogens in a sprouting operation, we conclude that environmental monitoring is still necessary for sprouting operations as an added safety measure. There have been positive sample findings and multiple recalls associated with

L. monocytogenes in sprouts (Ref. 215) (Ref. 216) (Ref. 217). Between 2002 and 2015, there have been 28 recalls involving multiple sprout types due to potential or confirmed contamination with L. monocytogenes (Ref. 218). In one of these recalls, the strain found in sprouts matched the strain isolated from 20 confirmed cases of Listeriosis in 6 States and positive sample findings from an environmental investigation at the sprouting operation (Ref. 215). Moreover, we are adding a requirement that sprout operations must not allow the production batch of sprouts to enter commerce unless the results of the testing of spent sprout irrigation water or sprouts are negative for certain specified pathogens (see § 112.147(b)). This requirement is consistent with current industry best practices (Ref. 219). Together with new § 112.148(a), this requirement will help ensure that sprout operations take appropriate steps to prevent contaminated sprouts from entering commerce.

We discuss these and other sprout-specific requirements in greater detail in this section. For additional information, see also sections II and V.M of the 2013 proposed rule.

The requirements in subpart M are consistent with recommendations in FDA's guidances (Ref. 97) (Ref. 206), industry guidance (Ref. 219), and international regulations and guidelines (Ref. 23) (Ref. 211) (Ref. 212) (Ref. 220).

We intend to promote and support additional research in this area, as needed. In addition, seeds have been the source of contamination in many, but not all, sprout outbreaks (Ref. 21) (Ref. 26) (Ref. 27) (Ref. 28)). Interventions applied before sprouting, such as those directed to seed, are meant to avoid, eliminate, or reduce pathogen load on seeds and, therefore, reduce the risk of pathogen proliferation during sprouting.

(Comment 363) Some comments ask whether microgreens would be subject to subpart M and/or to the general provisions of part 112. Some comments maintain that, because differences in the length of the growing period and practices followed for microgreen production result in a lower risk for cross-contamination than in sprout production, microgreens should not be subject to requirements directed to sprouts. Other comments suggest microgreens are a ready-to-eat produce item that is growing in popularity and could carry risks similar to sprouts.

(Response) Subpart M applies to the production of all types of sprouts, including alfalfa, clover, and mung bean sprouts, except for soil-grown sprouts harvested without roots (see Comment 364). FDA agrees that microgreens and sprouts are different products. Our longstanding guidances to industry on sprouts do not list microgreens as sprouts. This interpretation is also consistent with other public and private standards, e.g., the IFSH Sprout Taskforce sprout-specific audit check list and the Food Safety Australia New Zealand (FSANZ) standards for sprouts. In addition, in the 2013 proposed rule discussion of potential differences in practices and risk factors related to soil-grown versus hydroponically-grown sprouts, we did not specifically mention microgreens because we do not consider microgreens to be sprouts. Historically, the primary criterion FDA has used to distinguish between the two product categories has been the growth stage of the leaves (Ref. 221). Sprouts are usually harvested when the cotyledons (or seed leaves) are still un- or under-developed and true leaves have not begun to emerge. In contrast, microgreens reach a later stage of growth, typically associated with the emergence of “true” leaves. Microgreens are also typically grown in soil or substrate and harvested above the soil or substrate line. Because microgreens are not sprouts, they are not subject to the requirements in subpart M. However, microgreens are considered “covered produce” for the purposes of this rule and, unless exempt or excluded under the

provisions in subpart A, microgreens and microgreen farms are subject to all other subparts of part 112.

Additional research would be helpful to better define the risk profile of microgreens that are grown using conditions similar to those of sprouts (i.e., warm, moist, and nutrient-rich media) (Ref. 222). To the extent the specific microgreen production practices may present risks similar to those associated with sprouts, we encourage microgreen operations to consider voluntarily implementing the standards in subpart M, in addition to complying with the required provisions of part 112.

(Comment 364) Some comments seek clarification on whether soil-grown sprouts are covered under subpart M. One comment maintains that measures described under subpart M should be applied to both soil-grown and hydroponically-grown sprouts. This comment states that, although they are not aware of any outbreaks associated with sprouts grown in soil or media, contaminated soil has been a concern in the context of other produce commodities. In contrast, one comment requests different standards for soil-grown sprouts, and states that FDA should require that sprouters take steps to minimize cross-contamination between hydroponic and soil-grown sprouts.

(Response) Soil- or substrate-grown sprout shoots that are harvested above the soil or substrate line, such that their roots are not harvested for human consumption, do not present the same risks as other types of sprouts and we are therefore excluding them from coverage under subpart M. We have added new § 112.141 to address this. New § 112.141 states that the requirements of subpart M apply to growing, harvesting, packing, and holding of all sprouts, except soil- or substrate-grown sprouts harvested without their roots. However, soil- or

substrate-grown sprouts harvested above the soil line are “covered produce” and, unless exempt or excluded under the provisions of subpart A, are subject to all other applicable requirements of part 112.

We believe the potential risks are sufficiently different between sprouts where the entire plant is consumed and sprout products that are harvested without the roots (Ref. 223) (Ref. 224). Microscopic examination of sprouts has been reported to show that pathogens target root hairs of sprouts for colonization, with presence of few viable cells elsewhere on the sprout, which indicates that root hairs provide a niche for pathogen proliferation (Ref. 224) (Ref. 225). Therefore, we do not see the need to apply the additional sprout-specific safety standards in subpart M to soil- or substrate-grown sprouts that are harvested above the soil or substrate line. However, we are applying the requirements of subpart M to soil- or substrate-grown sprouts that are harvested with the roots. We also agree that all hydroponically grown sprouts should be covered under subpart M. Under typical conditions for growing hydroponic sprouts, water runs through sprouts in the same growing unit, and any pathogens present in the seed or sprouting seed can spread throughout the production lot of sprouts (Ref. 21) (Ref. 226) (Ref. 227) .

To avoid any confusion about the applicability of subpart M to soil- or substrate-grown sprouts, we are also revising the term “soil-grown sprouts” used as an example in proposed § 112.143(b)(2) so that the example now refers specifically to “soil-grown sprouts harvested with roots” in final § 112.144(b)(2). To the extent production practices for soil- or substrate-grown sprouts that are harvested above the soil or substrate line may present risks similar to those associated with other sprouts, we encourage such operations to consider voluntarily implementing the standards in subpart M, in addition to complying with the required provisions of part 112. We are also including, in the examples in renumbered § 112.144(b)(2),

“hydroponically grown sprouts that use very little water,” as another example for which testing spent sprout irrigation water may not be practicable such that you may, therefore, test each production batch of sprouts at the in-process stage (i.e., while sprouts are still growing) for E. coli O157:H7 and Salmonella spp. in accordance with the requirements of § 112.147.

The potential for soil or substrate to be a source of contamination in a soil- or substrate-grown sprout operation is a valid concern, and we agree with comments stating that measures must be taken to minimize the risk of the soil or substrate serving as a source of contamination, for either sprouts grown in the soil or substrate, or for other produce that may be grown or handled at the sprout operation. We are establishing minimum science-based standards directed to biological soil amendments of animal origin and human waste under subpart F of part 112, which are applicable to all covered produce, including soil- or substrate-grown sprouts (however they are harvested).

(Comment 365) Some comments question whether wheatgrass would be covered under subpart M as a sprout, particularly since the seed is not consumed whether grown hydroponically or in a medium.

(Response) Sprouts, as a category, include many varieties, including wheatgrass. Wheatgrass has long been considered a sprout within the industry. For example, it was considered a sprout in the NACMCF recommendations (Ref. 21), the Sprout Testing Guide, and the FDA/CDPH sprout video (Ref. 228). We consider it a sprout for purposes of this rule and in particular for the application of subpart M of this rule. However, wheatgrass is typically grown in soil or substrate and harvested above the soil or substrate-line, and in those circumstances, it is not subject to subpart M.

(Comment 366) One comment requests that we subject small onions that are thinned from a starter tray to the requirements of subpart M.

(Response) We understand that some operations use a starter tray, where seeds are sown thickly, and then weaker seedlings are thinned out, providing the stronger seedlings with more space to grow. When small onions are grown in starter trays, some operations discard the produce resulting from the first thinning and others sell that produce for use as food. In terms of potential hazards associated with production, such produce is akin to soil- or substrate-grown sprouts that are harvested above the soil line or to microgreens, both of which we are not subjecting to the requirements of subpart M. Therefore, we conclude that small onions grown in flats should not be subject to the requirements of subpart M, and we are not subjecting them to the requirements of that subpart. Such produce is subject to the other requirements of part 112, as applicable, however.

B. Seeds or Beans Used to Grow Sprouts (§ 112.142)

These requirements were proposed as § 112.141. We have now renumbered this section as § 112.142 as a consequential change from the addition of new § 112.141.

(Comment 367) Pointing out that seeds are often the source of contamination for sprouts, several comments argue that proposed subpart M lacks sufficient emphasis on the origin of seeds, their traceability, and the growing and production of seeds intended for sprouting. One comment suggests that seeds destined for sprouting should be labeled as such with the seed producer's name and full address. Some comments maintain that seeds and beans should be

covered under the produce safety regulation, and that FDA should require seeds to be grown and produced under good agricultural practices and specifically for sprouting for human consumption, rather than being potentially sourced from fields where the seeds were intended to be directed toward animal feed production. Several comments also support a requirement for a supplier approval and verification program for seeds and beans received by sprouters for sprouting purposes (including seed lot testing and use of a HACCP approach). In this regard, one comment suggests FDA should require documentation of the processes that the seeds are subjected to during their cleaning and preparation for sale while another argues that unless seeds from a particular crop or variety can be produced in a safe manner, industry should be required to cease production of sprouts from that crop or variety.

(Response) Since 1999, FDA has taken a number of steps to provide guidance to the sprouts industry, including those involved in the growing and production of seeds (78 FR 3504 at 3509). In developing this rule, FDA has carefully considered the growing and distribution of seeds for sprouting. As noted in the 2013 proposed rule, various crops may be grown to produce seeds and beans for sprouting with different production practices, growing seasons, conditions, and crop needs. Harvesting, packing, and holding may also vary by seed type and by the conditions needed to maintain seed quality, such as germination. Because of the diversity of practices, processes, and procedures, the controls reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that are used for sprouting may vary. Therefore, we did not propose to prescribe specific provisions to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans during growing, harvesting, conditioning, or holding. Instead, we referred to our recommendations in relevant guidances, including the GAPs Guide (78 FR 3504 at 3595).

In the 2013 proposed rule, we considered proposing a supplier approval and verification program for seeds and beans received by sprout operations for sprouting purposes. Such a program would provide assurance that seeds or beans received from a third party for use to grow sprouts are grown, harvested, stored, and handled using measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans used for sprouting. However, we also noted that a supplier approval and verification program may not be practical or effective for seeds and beans received by sprout operations for sprouting purposes because, for most crops, only a small percentage of the harvested seeds or beans is used for sprout production. In addition, seeds and beans often pass through a number of business entities before their final sale. Therefore, the ultimate end use of seeds and beans will likely not be known by many growers, handlers, or distributors (at 78 FR 3504 at 3595-3596).

Information we have received subsequent to the 2013 proposed rule suggests that seed distributors may request that their seed growers and handlers provide assurance, through the use of agreements, that safe growing and handling practices are employed during the growing, harvesting, conditioning, storage, handling, and transportation of the seeds that the distributor will sell to sprouting operations (Ref. 229). In addition, we believe that proposed § 112.141(a) would not have been effective at addressing hazards associated with the growing of seeds or beans used for sprouts because few, if any, sprout operations in the United States grow their own seeds or beans but instead, receive the seeds or beans from other entities, such as seed growers or distributors (Ref. 230). It is important that this rule includes measures to prevent the introduction of known or reasonably foreseeable hazards into seeds or beans that are used for sprouting. Therefore, and in light of information that sprouting operations typically receive

(rather than grow their own) seeds or beans, we are revising proposed § 112.141(a), renumbered as § 112.142(a), to require the sprout operation to take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that they will then use for sprouting regardless of whether the sprouter also grew the seeds or beans.

Measures required under renumbered § 112.142(a) include, for example, keeping the seed storage area clean and dry, and dedicated to seed storage. Seed containers must be tightly covered or closed, stored off the floor and away from the walls, clean, identified with lot numbers, and, for reusable containers, emptied, cleaned, and sanitized between uses. Sprout operations must also complete a visual examination of seeds/beans and their packaging upon receipt and prior to use for potential contamination (e.g. visual exam and/or black light/UV exam of seed bags for evidence of insects, rodents, or other contamination).

As noted previously, we also asked for comment on a seed supplier program. While we believe that the agreements and assurances made between seed suppliers and other entities in the supply chain providing assurances that the seeds and beans have been grown and handled under good agricultural practices and that seeds that may be used for sprouting have been conditioned, stored, and transported in a manner that minimizes the likelihood that the seeds will be contaminated with pathogens, are valuable, we are not requiring that sprouters request, receive, or provide such agreements and assurances. We recommend these practices, consistent with recommendations in our 1999 guidance to industry, “Reducing Microbial Food Safety Hazards for Sprouted Seeds,” (the Sprout Guide) and recommendations or requirements by other competent authorities (Ref. 211) (Ref. 212) (Ref. 231), and are encouraged that some comments indicated that this is already happening. However, we do not believe that it is

currently feasible for all seeds and beans used for sprouting to be produced under GAPs, particularly when the vast majority of seed is not produced for such use. If the situation changes, we may revisit this in the future. The other requirements in § 112.142 also address potential contamination in seeds and beans.

(Comment 368) Several comments state that sprout operations should not use sprouts if they have reason to believe that a lot of seeds or beans has been associated with foodborne illness. Comments also request that FDA further clarify that if a farm has reason to believe that a lot of seeds has been contaminated with a hazard likely to cause foodborne illness, the farm should not use that lot to produce sprouts, regardless of whether that contamination has caused illness. In this regard, one comment explains that farms will be unable to accurately and reliably assess whether a particular batch of seeds has been linked to consumer illness. Finally, one comment expresses concern with requiring sprout operations to discontinue use of a seed lot found to be contaminated through microbial testing. This commenter poses several questions regarding follow-up actions that a sprouter may have to take in response to a positive test finding.

(Response) Proposed § 112.141(b), now renumbered as § 112.142(b), focuses on reasonably necessary measures when it is known or there is reason to believe that a lot of seeds or beans that will be used for sprouting is contaminated. As proposed, § 112.141(b) would have required that if you know or have reason to believe that a lot of seeds or beans has been associated with foodborne illness, you must not use that lot of seeds or beans to produce sprouts. As discussed in the 2013 proposed rule, we concluded that once you know or have reason to believe that a lot of seeds or beans is contaminated, through microbial testing or

implication as the vehicle in an outbreak, there is reason to believe that other parts of that lot may also be contaminated, and you must not use that lot of seeds or beans to produce sprouts (78 FR 3504 at 3596). We are revising this section to make clear that relevant knowledge or reason to believe seeds or beans may be contaminated may be based either on an implication of the seeds or beans in a foodborne illness outbreak or on a positive microbial test result, including a finding made after testing spent sprout irrigation water or sprouts. For example, section 112.144(b) requires testing of spent sprout irrigation water from each production batch of sprouts or, if such testing is not practicable, testing of each production batch of sprouts at the in-process stage. In either circumstance, i.e., through implication in an outbreak or through microbial testing (including that required under § 112.144(b)), the information gathered is sufficient to indicate that the lot of seeds or beans may be contaminated and there is reason to believe that other parts of that lot may also be contaminated. Therefore, we continue to believe that it is reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into sprouts that you discontinue use of all seeds or beans from that lot for sprout production (§ 112.142(b)(1)). We are also expanding the duties you have under § 112.142(b) beyond simply not using the seeds or beans to produce sprouts, to include ensuring that sprouts grown from that lot of seeds or beans do not enter commerce (§ 112.142(b)(1)), and reporting the information (association with illness and/or findings of microbial testing) to the seed grower, distributor, supplier, or other entity from whom you received the seeds or beans (§ 112.142(b)(2)). Since the lot of seeds or beans may be contaminated, it is critical to discontinue use of the seeds and beans for sprout production for human consumption and ensure that sprouts grown from that lot do not enter commerce. Other national or international standards, too, require or recommend discontinuing use of a lot of seeds or beans that may be

contaminated and is likely to present a health hazard (Ref. 23) (Ref. 211) (Ref. 212).

It is also important that the sprout operation report the findings to the entity (seed grower, distributor, or supplier) that supplied the seeds or beans so that the seed grower, distributor, or supplier, upon receiving such information, could then take appropriate follow-up actions, which may include reporting the finding to other buyers of the suspected lot of seeds or beans, destroying or diverting any remaining seed or beans to other uses, including non-food uses and/or investigating the potential source of contamination, as necessary. In such circumstance, where applicable, the seed grower, distributor, or supplier may be required to submit a report to the Reportable Food Registry (RFR), in accordance with section 417 of the FD&C Act (21 U.S.C. 350d), which requires responsible parties for food facilities that are required to register under section 415 of the FD&C Act (21 U.S.C. 350d) to report certain information to FDA when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals.

In addition, we are adding two provisions under new § 112.142(c) that apply only if your reason for believing the lot of seeds or beans may be contaminated is based only on microbial test results. First, we are providing that you do not have to take the steps in § 112.142(b)(1) if you treat your lot of seeds or beans with a process that is reasonably certain to achieve destruction or elimination in the seeds or beans of the most resistant microorganisms of public health significance that are likely to occur in the seeds or beans (may also be referred to as a “pasteurization” step) (§ 112.142(c)(1)). We are including this option to allow sprout farms flexibility in responding to a finding that would otherwise mean they would have to discontinue use of the seeds and to encourage future innovation in seed treatment processes. However, we note that processes that meet the description in (c)(1) are not currently commonly

used in the sprouting industry. Such processes are far more robust than the seed treatment processes described in § 112.142(e) because the seed treatments described in § 112.142(e) typically only reduce microorganisms of public health significance (these treatments do not eliminate or destroy pathogens), and are therefore part of a multi-hurdle risk reduction framework that also includes spent irrigation water or sprout testing for pathogens on a lot by lot basis. Irradiation is an example of a process that may be able to meet the description in § 112.142(c)(1).

Second, we are adding new § 112.142(c)(2) to provide that you do not have to take the steps in § 112.142(b)(1) and (2) if you later reasonably determine through appropriate follow-up actions that the lot of seeds or beans is not the source of contamination (for example, the lot of seeds or beans is not the source of a pathogen found in spent sprout irrigation water or sprouts).

We expect that the situations in which you could take follow-up actions that would be adequate to make a reasonable determination that the lot of seeds or beans was not the source of the contamination are not extensive. However, the following are examples of situations in which we believe such a determination might be appropriate:

1. Seed lot A is recalled by the seed supplier due to contamination with Salmonella while an operation has sprouting in process with that seed lot. The sprout operation immediately stops production of sprouts using seed lot A, disposes of the sprouts and returns unused seed to the distributor. The sprouts operation cleans the equipment and starts using the same equipment to grow another batch of sprouts using seed lot B. Spent irrigation water from the next lot of sprouts using seed lot B then tests positive for Salmonella, and follow-up sample analysis shows the same Salmonella serotype that was identified as contaminating seed lot A.

The sprout operation discovers that cleaning and sanitizing protocols were not followed properly following sprout production using seed lot A, and swabs the equipment and finds a matching Salmonella serotype on the equipment that had been used to sprout both seed lots A and B. After adequately and thoroughly re-cleaning and sanitizing the equipment and re-testing food-contact surfaces for Salmonella with negative results, the sprout operation starts a new production batch of sprouts using seed lot B as a follow-up action to the positive test result to determine whether seed lot B may also be contaminated. The second time, all spent irrigation water tests from seed lot B sprouts come back negative. In this circumstance, the sprout operator could reasonably conclude that seed lot A had contaminated the equipment, which was not initially adequately cleaned and sanitized and therefore contaminated the first batch of sprouts produced from seed lot B. If the farm is following appropriate follow-up sanitation procedures, spent irrigation water from seed lot B is no longer testing positive for Salmonella, under these circumstances the farm may reasonably conclude that seed lot B was not the source of contamination that generated the positive test result when testing spent irrigation water from seed lot B sprouts. We note that in general a negative test for seeds or spent irrigation water would not, by itself, be enough evidence that seed lot B was not contaminated. However, in this example, the seed supplier's Salmonella serotype result from seed lot A that matches serotype found in the positive spent irrigation water sample and the swab from equipment used to sprout seed lot B, combined with the improper cleaning and sanitizing of equipment, negative subsequent test results, and the intervening improvements in cleaning procedures, supports the conclusion that the positive spent irrigation water sample from sprouts made with seed lot B was most likely due to contamination of shared production equipment with seed lot A .

2. A sprout operation mixes two seed lots (lot A and B) together to result in a mixed

sprout product for which the spent irrigation water tests positive for Salmonella. The sprout operation could sprout each seed lot individually. If upon follow-up serotype sample analysis, spent irrigation water from only one seed lot (lot A) tests positive for Salmonella matching the original positive, the sprout operation could reasonably determine that seed lot A was the source of the Salmonella positive in spent irrigation water from the mixed seed sprouts. The sprout operation would be required to discontinue use of all seeds from the affected seed lot for sprout production (unless it treats the seed lot in accordance with § 112.142(b)(1)), ensure that sprouts grown from that seed lot do not enter into commerce, and report the information to the grower, distributor, supplier, or other entity from whom the farm received the seeds, in compliance with § 112.142(b). Under § 112.142(c), the sprout farm could continue to use seed lot B, provided there were no subsequent positive test results and no information suggesting association of that seed lot with foodborne illness.

We recognize that there may be other microbial testing through which you may conclude that a lot of seeds or beans is contaminated. For example, testing of seeds (although not required under this rule) using statistically valid sampling and testing protocols may lead you to conclude that seeds or beans are contaminated. Information of this kind triggers the requirements in § 112.142(b) and requires farms to discontinue use of all seeds or beans from that lot, ensure that sprouts grown from that lot of seeds or beans do not enter commerce, and report the information to the grower, distributor, supplier, or other entity from whom the farm received the seeds.

Although we believe there may be follow-up actions that could allow a sprout operation to determine that a lot of seeds or beans that had been associated with a positive microbial test result from testing spent sprout irrigation water or sprouts at their operation (required under §

112.144(b)) were not the source of contamination, we do not believe the same is true of a lot of seeds or beans that have been associated with a foodborne illness. We are not aware of actions that a sprout farm could take to demonstrate that the lot of seeds or beans was not the source of contamination following an outbreak of foodborne illness. A sprout farm, along with regulators, may make a determination that the farm's seeds or beans were not associated with a foodborne illness outbreak, but it is unlikely that the sprout farm would have adequate information (e.g., epidemiological data and traceback information) to make that determination independently. Therefore, we are not providing a similar option to § 112.142(c) applicable in instances where there is knowledge or reason to believe that a lot of seeds or beans has been associated with foodborne illness.

(Comment 369) One comment asked whether, in sprout production, sampling and testing can be properly defined as a process control, or whether it should be defined simply as a confirmation that a process control has worked as intended. The comment maintained that if sampling and testing is a process control then a positive test may not be grounds for discontinuation of a seed lot since the control worked as intended.

(Response) In the case of sprouts, sampling and testing of spent sprout irrigation water can be viewed as both a verification of a process control (e.g. of seed treatment) as well as a process control itself ("hold and release" testing that is used to prevent a contaminated lot from entering commerce (see § 112.147(b)). Even if a sprout operation's spent irrigation water testing is effective and identifies pathogen-positive lots of sprouts where seed treatment failed to eliminate a pathogen, the fact remains that seed is most often the source of contamination and that current seed treatments cannot guarantee the elimination of pathogens on seed. Currently

available seed treatments typically reduce, but do not eliminate, pathogen presence on seeds, and these pathogens could potentially multiply when subjected to enrichment conditions, such as those experienced during sprouting. We view spent irrigation water sampling and testing as an additional reasonably necessary food safety measure to help ensure that contaminated product is not marketed. This measure is consistent with FDA’s Sprout Testing Guide and also consistent with the Codex Guide. See also revised and renumbered § 112.142 and new § 112.148.

(Comment 370) Some comments request that FDA either specify “pathogens of concern” that are the most often associated with foodborne illness linked to sprouts (e.g., Salmonella, E. coli O157:H7, and L. monocytogenes) in proposed § 112.141(a), or add language such as “contaminated with a hazard likely to cause foodborne illness” to that provision

(Response) For the purposes of the produce safety regulation, in § 112.3, we define “hazard” to mean “any biological agent that has the potential to cause illness or injury in the absence of its control” and “known or reasonably foreseeable hazard” to mean a hazard that is known to be, or has the potential to be, associated with the farm or the food. Given these definitions, we believe it is not necessary or appropriate to specify “hazard likely to cause foodborne illness” within § 112.142(a). We also do not believe it necessary or appropriate to list specific pathogens of concern or those most often associated with sprout-related illness outbreaks in lieu of the phrase “known or reasonably foreseeable hazards” in § 112.142(a). Although we agree that Salmonella, E. coli O157:H7, and L. monocytogenes have been most often implicated in sprout-related illness outbreaks, there may be other biological agents with the potential to cause illness or injury that may be associated with the sprouting farm or sprouts. We conclude that we should not restrict the scope of hazards that are expected to be controlled under this

provision. See discussion under Comment 375 of other pathogens that have been associated with sprouts.

(Comment 371) One commenter believes that seed suppliers should be required to test seed for the presence of pathogens using statistically valid sampling and testing protocols and to provide sprout operations with a Certificate of Analysis for the seeds and beans, despite the recognized limitations of testing.

(Response) We considered and tentatively rejected this approach in the 2013 proposed rule, and the commenter did not provide any new information suggesting we should change our conclusion. We recognize that at least one other competent authority has established microbiological criteria and requirements for testing all batches of seeds intended for sprouting (i.e., European Commission Regulation No. 2073/2005). However, as explained in the 2013 proposed rule, although epidemiological investigations often identify seeds and beans as the most likely source of contamination, contamination may be at very low levels (4 CFU/kg seed) (Ref. 21) and laboratory analyses have frequently been unable to isolate pathogens from implicated seeds or beans (Ref. 223). Nevertheless, we recognize that a positive test result can detect contaminated seeds and beans even though a negative test result is not a guarantee of the absence of pathogens. Therefore, we encourage seed suppliers and sprouters to test seed using statistically valid sampling and testing protocols. However, we continue to believe that testing seeds and beans is not sufficiently reliable to require it as a measure necessary to prevent the introduction of known or reasonably foreseeable hazards into sprouts.

C. Growing, Harvesting, Packing, and Holding Sprouts (§ 112.143)

These requirements were proposed as § 112.142. We have now renumbered this section as § 112.143 as a consequential change from the addition of new § 112.141. For purposes of clarification, we are revising final § 112.143 to summarize under this section the various measures related to the growing, harvesting, packing, and holding of sprouts required in this subpart M, with relevant cross-references to other sections of subpart M. Thus, we have added § 112.143(c) referring to testing requirements in § 112.144; § 112.143(d) referring to the written environmental monitoring plan required in § 112.145; § 112.143(e) referring to the actions you must take when Listeria spp. or L. monocytogenes is detected in the growing, harvesting, packing, or holding environment as required in § 112.146; § 112.143(f) referring to the written sampling plan required in § 112.147, and § 112.143(g) referring to the actions you must take when samples of spent irrigation water or sprouts test positive for a pathogen as required in § 112.148.

In addition, because the requirement for seed treatment proposed as § 112.142(c) establishes standards applicable to seeds and beans used for sprouting, it fits more directly under final § 112.142 rather than under final § 112.143 (which was proposed as § 112.142). Therefore, we are moving this provision, as revised, into renumbered final § 112.142 and finalizing it as § 112.142(e). We discuss other changes to this provision in response to Comment 368.

(Comment 372) Several comments agree with our proposed requirement for sprout operations to treat seeds or beans used for growing sprouts, and that prior treatment would not eliminate the sprout farm's responsibility for treatment immediately before sprouting. A number of these comments encourage FDA to support research to determine effective means of seed

treatment prior to sprout production. Some comments express concern that this rule may require treatment of seeds using extremely high levels of chlorine (e.g., 20,000 ppm), and recommend allowing alternative effective treatments. One commenter believes seed treatment resulting in at least a 3-log pathogen reduction should be required. Another comment suggests using the term “disinfect” rather than “treat” when referring to seed treatments. Some comments also ask that FDA not require seeds to be treated immediately before sprouting, and urge FDA to create an information-sharing portal where sprout farms can share valid treatment and testing methods and data to better inform the sprout community. Another comment requests that FDA reconsider allowing for the use of “proprietary research” to determine the scientific validity of seed treatment. Finally, one comment suggests that FDA require seeds used for sprouting to be irradiated by the seed supplier, noting that this sprout operation’s foreign seed supplier currently treats seeds in this manner.

(Response) We are retaining the term “treat” when referring to seed treatments because of its longstanding use in our guidances to industry and common use within the sprouts industry. Moreover, because most current seed treatments cannot guarantee the elimination of pathogens, we conclude that the term “disinfect” would not be an appropriate description. (See also Comment 368 comparing most current treatment processes to more robust treatments processes that are reasonably certain to achieve destruction or elimination in the seeds or beans of the most resistant microorganisms of public health significance that are likely to occur in the seeds or beans).

FDA has been working independently and in collaboration with others to develop a framework to conduct research on effective seed treatments, and we will support a variety of mechanisms to make this information available to sprout farms. For example, we are working

through the SSA to facilitate development of an educational curriculum and sharing of best practices among sprout farms. We acknowledge that a number of treatments have been shown to reduce levels of, but not eliminate, pathogenic bacteria present on seeds. Such treatments are likely to reduce the level of contamination if present and, in turn, decrease the risk for foodborne disease with sprouted seeds (Ref. 21). We cited 20,000 ppm calcium hypochlorite treatment in the Sprout Guide and in the 2013 proposed rule as an example of a treatment that has been shown to be effective for the reduction of pathogens. However, § 112.142 (e) (proposed § 112.142(c)) allows you to use any scientifically valid method to treat seeds or beans that will be used to grow sprouts. We are also not precluding the use of proprietary seed treatments. We would expect a farm using a proprietary seed treatment to take steps to ensure that it is in compliance with all relevant laws, including FIFRA, if applicable, and to ensure that its treatment is effective in reducing pathogens on seed. In the event of an inspection or investigation of a sprout operation, we may ask to review the science supporting the use of the proprietary treatment to ensure the scientific validity of the treatment.

We use the term “scientifically valid” in this rule to mean using an approach that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. Our use of proprietary research in this context is consistent with our considerations in other rulemakings (see Current Good Manufacturing Practice Requirements for Dietary Ingredients and Dietary Supplements; 68 FR 12157 at 12198).

Under proposed § 112.142(c), we proposed to require sprout operations to treat seeds or beans using a scientifically valid method immediately before sprouting to reduce microorganisms of public health significance. We have since conducted a thorough review of

currently available treatment methods as well as treatment methods under development and evaluation. Based on this review, we conclude that there are treatment methods that can be effectively applied by a grower, handler, or distributor of seeds or beans such that, when followed by good handling and packaging procedures, they can eliminate the need for follow-up treatment of the seeds or beans at the farm immediately before sprouting (Ref. 232). For example, as suggested by a commenter, irradiation is an option for seed treatment that could be applied by a seed supplier, handler, or distributor to reduce microorganisms of public health significance that may not be feasible for a sprout farm to apply on-site. In addition, hot water treatments have been demonstrated to reduce pathogens on seeds by more than 5 log CFU/g in one study (Ref. 233) and to undetectable levels in another (Ref. 234). However, these treatments can require use of equipment such as industrial-sized hot water pasteurization machines (Ref. 235) that might be cost-prohibitive for a small sprout farm. Therefore, in final § 112.142(e)(1), we are removing the requirement to treat seeds or beans used for sprouting “immediately before sprouting” as well as the provision that stated “prior treatment conducted by a grower, handler, or distributor of seeds or beans does not eliminate your responsibility to treat seeds or beans immediately before sprouting at your covered farm.” We are also adding § 112.142(e)(2) to explicitly allow covered sprout farms to rely on prior treatment of seeds or beans conducted by a grower, distributor, or supplier of the seeds or beans (whether to fulfill this requirement completely or for the purpose of considering such prior treatment when applying appropriate additional treatment of the seeds or beans at the covered sprout farm immediately before sprouting), provided that you obtain documentation (such as a Certificate of Conformance) from the grower, distributor, or supplier of the seeds or beans that (i) the prior treatment was conducted using a scientifically valid method to reduce microorganisms of

public health significance; and (ii) the treated seeds or beans were handled and packaged following the treatment in a manner that minimizes the potential for contamination.

Finally, as discussed previously, because this provision establishes standards applicable to seeds and beans used for sprouting, it fits more directly under final § 112.142 rather than under final § 112.143 (which was proposed as § 112.142). Therefore, we are moving this provision, as revised, into renumbered final § 112.142 and finalizing it as § 112.142(e). In addition, we are revising the corresponding recordkeeping provision in § 112.150(b)(1) to require you to establish and keep documentation of your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm; or alternatively, documentation (such as a Certificate of Conformance) from your seed supplier that seeds or beans are treated to reduce microorganisms of public health significance and are appropriately handled and packaged following the treatment, in accordance with the requirements of § 112.142(e).

D. Testing During Growing, Harvesting, Packing, and Holding Sprouts (§ 112.144)

These requirements were proposed as § 112.143. We have now renumbered this section as § 112.144 as a consequential change from the addition of new § 112.141.

(Comment 373) Some comments suggest that FDA issue through guidance, rather than in regulation, recommendations to test for pathogens that have been linked to a sprout outbreak causing human illness. Other comments support our proposed requirements for environmental testing and testing of spent sprout irrigation water or sprouts.

(Response) In developing the proposed provisions of subpart M, we tentatively

concluded that testing the growing, harvesting, packing and holding environment for Listeria spp. or L. monocytogenes is a necessary measure to ensure the safety of sprouts. We also tentatively concluded that testing spent sprout irrigation water or sprouts for E. coli O157:H7 and Salmonella spp. is a necessary measure to ensure the safety of sprouts. Given the outbreaks associated with sprouts and these pathogens, we are finalizing our conclusion that requiring this testing is warranted. These comments did not provide information that would change our conclusion.

(Comment 374) Some comments state that requiring testing for Listeria at the genus level does not confirm the presence of a pathogen of interest and, therefore, recommend that FDA require testing for Listeria at the species level. In contrast, one comment states that frequent testing for Listeria would be expensive, arbitrary, and difficult to implement. The comment recommends that we instead require initial swab testing for Listeria, followed by a program of testing and cleaning until repeated tests are negative and, as an alternative, suggests that routine cleaning of equipment and facility inspections should be sufficient for controlling Listeria.

(Response) The purpose of environmental monitoring is to verify the adequacy, or lack thereof, of cleaning and sanitizing practices through monitoring for the presence of pathogens in the environment and, if pathogens are present, to eliminate or minimize their presence and prevent transfer of pathogens to food-contact surfaces or to sprouts where they might cause illness. Testing for either the pathogen directly or an indicator organism facilitates accomplishing these objectives and, therefore, we are providing for the option to either directly test for L. monocytogenes (pathogen) or for an indicator organism (Listeria spp.). As discussed in the scientific literature, the term “indicator organism” means a microorganism or group of

microorganisms that is indicative that (1) a food has been exposed to conditions that pose an increased risk for contamination of the food with a pathogen or (2) a food has been exposed to conditions under which a pathogen can increase in numbers (Ref. 236). Listeria spp. is an appropriate indicator organism for L. monocytogenes because tests for Listeria spp. will detect multiple species of Listeria, including L. monocytogenes (Ref. 237) (Ref. 238), and because the available information supports a conclusion that modern sanitation programs, which incorporate environmental monitoring for Listeria spp., have public health benefits (Ref. 239) (Ref. 240). With regard to the suggestion for initial swab testing with repeated cleaning until negative findings, we agree that negative findings from repeated tests indicate that current cleaning and sanitizing is likely effective. However, because Listeria can be reintroduced into the environment through different routes which can vary over time, it is important to continuously monitor the environment with routine sampling and testing, at a regular frequency, to verify effectiveness of cleaning and sanitizing practices.

(Comment 375) With respect to testing of spent sprout irrigation water or sprouts in proposed § 112.143(b), several comments express concern that additional pathogen strains may be associated with sprouts in the future, similar to the 2012 outbreak of E. coli O104:H4 linked to sprouts in Europe, and that requiring testing just for Salmonella and E. coli O157:H7 is too limited. Other comments were supportive of testing for Salmonella spp. and E. coli O157:H7. Another comment supports FDA's tentative decision not to require testing of spent irrigation water for Listeria, and believes that it would not be an appropriate use of resources to require such testing given the ubiquity of Listeria spp. in water and the limitations of current testing methods to detect L. monocytogenes.

(Response) With respect to requiring testing of spent sprout irrigation water or sprouts, we focus on the two pathogens most commonly associated with sprout outbreaks, while also taking into consideration currently available analytical methodology. There is a long history of sprout-related outbreaks associated with E. coli O157:H7 and Salmonella spp. (Ref. 26) (Ref. 27) (Ref. 28) (Ref. 241) and we are retaining the requirement from proposed § 112.143(b) in renumbered § 112.144(b) for testing spent sprout irrigation water or sprouts for these two pathogens.

We also recognize that two recent sprout-associated outbreaks in the United States, as well as the large 2012 sprout outbreak in Europe, were due to non-O157 STEC (Ref. 28). In the 2013 proposed rule, we requested comments on whether pathogens other than Salmonella spp. and E. coli O157:H7 should be included in testing of spent sprout irrigation water or in-process sprouts, either by specifically listing the additional pathogens or by set criteria. We discussed the challenges of requiring testing for non-O157 STECs in the 2013 proposed rule (78 FR 3504 at 3598). For example, there are hundreds of serotypes of STECs, and many are non-pathogenic or of low pathogenicity such that detection of an STEC alone in spent sprout irrigation water or sprouts would not be necessarily indicative of a public health concern, as not all STECs cause illness. Moreover, although laboratory tests to detect non-O157 STECs are currently available, methods necessary for follow-up testing to determine pathogenicity are not readily available (Ref. 242). We also considered requiring STEC testing for the major six pathogenic STEC serogroups (O26, O103, O111, O121, O45 and O145) identified by FSIS for non-intact raw beef. In addition, we reviewed the European Commission Regulation No. 209/2013, which amended Regulation No. 2073/2005 and established microbiological criteria for the testing of sprouts in an approach similar to that of FSIS' serogroup testing. Four serogroups, i.e., O26,

O103, O111, and O145, are identified for testing in both the EC and FSIS approaches.

However, available sampling data from the AMS' Microbiological Data Program (MDP) and from FDA's sampling assignments infrequently recovered these STECs from fresh produce, including sprouts (Ref. 242), and so it is not clear that these serogroups should be prioritized in terms of testing for sprouts. Because we recognize that in the future there may be additional pathogens associated with sprouts for which scientifically valid test methods become available such that testing for those additional pathogens would be warranted, we have revised § 112.144(b) and added new § 112.144(c) to address this situation.

Revised § 112.144(b) adds to the pathogens that covered sprout operations are required to test for in either spent sprout irrigation water or in-process sprouts “any pathogens meeting the conditions identified in § 112.144(c).” New § 112.144(c) requires sprout operations to conduct the tests required in § 112.144(b) for additional pathogens when the following conditions are met: (1) Testing for the pathogen is reasonably necessary to minimize the risk of serious adverse health consequences or death from use of, or exposure to, sprouts; and (2) A scientifically valid test method is available to detect the pathogen in spent sprout irrigation water (or sprouts). These provisions require additional pathogen testing, in the future, if the criteria in § 112.144(c) are met. First, the association of the pathogen and sprout-related outbreaks or illness must be established to the point that routine testing for such a pathogen is reasonably necessary to protect public health and minimize the risk of serious adverse health consequences or death from use of, or exposure to, sprouts. As mentioned previously, both E. coli O157:H7 and Salmonella spp. have a long history of association with sprout-related illness. However, a new pathogen need not equal or surpass the history of association of E. coli O157:H7 and Salmonella spp. with sprout-related illness in order to warrant testing under § 112.144(b) and (c). To satisfy § 112.144(c)(1),

a new pathogen would need to have an established association with sprout-related illness. Second, there must be a scientifically valid test method available to detect the pathogen in spent sprout irrigation water (or sprouts). As mentioned previously with regard to STECs, we are not currently aware of an appropriate test to identify pathogenic non-O157 STECs in spent sprout irrigation water (or sprouts) that is available to industry. However, test methods are continually under development and there will likely be improved methods in the future.

In the event that, in the future, both criteria are met for a particular pathogen such that testing would be required, FDA intends to issue guidance in accordance with good guidance practices to advise sprout farms of FDA's assessment that: (1) there is a pathogen, in addition to E. coli O157:H7 and Salmonella spp., for which testing is reasonably necessary to minimize the risk of serious adverse health consequences or death from use of, or exposure to, sprouts, and (2) a scientifically valid test method is available to detect the pathogen in spent sprout irrigation water (or sprouts). In this guidance, we would address the history of the association of the pathogen and sprout-related illness and also any relevant information about the testing protocol. We anticipate issuing such guidance initially as a draft for comment, unless, due to urgent circumstances, it is not feasible or appropriate to issue the document first in draft. Under those circumstances, we would invite comment on the final guidance, and revise it as appropriate. FDA intends to enforce the requirements for additional pathogen testing required in accordance with § 112.144(b) and (c) of this rule only after FDA issues a final guidance advising industry and the public of FDA's assessment that the criteria for additional pathogen testing have been met.

With regard to testing spent sprout irrigation water for L. monocytogenes, for the reasons described in the 2013 proposed rule (78 FR 3505 at 3597-3599) and in light of

comments received, we conclude that, at this time, monitoring the environment, rather than spent sprout irrigation water, for Listeria spp. or L. monocytogenes is the most effective approach for controlling L. monocytogenes in a sprout operation (see next section).

E. Environmental Testing for Listeria Species or L. monocytogenes (§ 112.145)

These requirements were proposed as § 112.144. We have now renumbered this section as § 112.145 as a consequential change from the addition of new § 112.141.

(Comment 376) Several comments agree with our proposed requirement for establishing and implementing a written environmental monitoring plan for Listeria. These comments maintain that it is critical that sprout farms recognize the importance of designing and maintaining a monitoring plan that is not simply compliant with regulations, but is also sufficiently tailored to their operations to be appropriately protective of public health. According to another comment, sprout farms currently routinely test spent irrigation water, but are not familiar with and do not currently utilize environmental monitoring.

(Response) Testing the environment of a sprouting operation for L. monocytogenes (or for Listeria spp. as an indicator of potential contamination with L. monocytogenes), and taking actions to eliminate L. monocytogenes or Listeria spp. when found in the environment of a sprouting operation, is an important component of controlling microorganisms of public health significance (Ref. 214) (Ref. 243). We conclude that testing the growing, harvesting, packing and holding environment for Listeria spp. or L. monocytogenes is a reasonably necessary measure to prevent the introduction of hazards into sprouts and to provide reasonable assurances that sprouts are not adulterated. Therefore, we are retaining the provisions of

proposed § 112.144 in renumbered § 112.145, with three revisions. First, we are requiring that the sampling plan, a necessary aspect of the required environmental monitoring plan, must also specify the timing of collection of the environmental samples during production (see § 112.145(c)(2)). We believe this is an important addition to the sampling plan to ensure that sampling is conducted in a manner to optimize detection of Listeria, if present, and ensure consistency in the sampling strategy and facilitate the tailoring of the corrective action plan to the finding of a positive at a certain point during production. Second, we are requiring that environmental samples must be aseptically collected. This revision is consistent with proposed § 112.146(b) regarding aseptic collection of samples of spent sprout irrigation water or sprouts, which we are retaining in final § 112.147(b) (see also Comment 233 where we explain the importance of aseptic sampling). Third, we are requiring that the written environmental monitoring plan must include a corrective action plan that, at a minimum, requires you to take the actions in § 112.146, and details when and how you will accomplish those actions, if the growing, harvesting, packing, or holding environment tests positive for Listeria spp. or L. monocytogenes (see § 112.145(e)). Requiring that your written environmental monitoring plan include a corrective action plan aligns with the requirement for you to take appropriate actions under § 112.146. Establishing and implementing a written corrective action plan will help ensure that corrective actions are taken quickly in response to positive findings of testing the production environment. This requires you to review appropriate sprout safety resources and consider the likely scenarios in advance of needing to take corrective actions, rather than reacting to these scenarios on an ad hoc basis after the fact. The requirement to have a written plan is consistent with other FDA food safety regulations, such as our juice and seafood HACCP regulations.

(Comment 377) One comment suggests that daily verification of sanitation using rapid detection methods (such as bioluminescence, ATP, or protein tests) serves as a better indicator of sanitation than environmental sampling on food-contact surfaces.

(Response) While rapid detection methods such as those mentioned are very useful for monitoring overall sanitation, they cannot substitute for environmental monitoring for Listeria spp. or L. monocytogenes to help ensure that L. monocytogenes has not become established in a harborage site, or niche, in a sprout operation. Cleaning and sanitizing may not remove all microorganisms and rapid methods such as those mentioned may not detect the presence of L. monocytogenes in harborage sites. However, daily monitoring of sanitation with a rapid method such as those mentioned that allows for corrections to be made in “real time” if the cleaning and sanitizing have not been effective can be useful and we encourage sprout farms to use them in combination with required periodic sampling for Listeria spp. or L. monocytogenes to provide a robust approach to verifying cleaning and sanitization practices are adequately addressing L. monocytogenes in the environment.

F. Follow-Up Actions for Positive Environmental Testing Results (§ 112.146)

These requirements were proposed as § 112.145. We have now renumbered this section as § 112.146 as a consequential change from the addition of new § 112.141.

(Comment 378) Some comments state that the language in proposed § 112.145(d) is insufficient for public health protection. One comment notes that the requirement as written will cause sprout farms to target sampling in order to achieve negative results with a minimum

number of tests, rather than to target sampling to identify any potential sources of *Listeria*. According to another comment, finished product testing as a follow-up to a positive environmental finding is both useful and advisable, but is itself insufficient without a commensurate action step upon a positive result. This comment states that mandating testing throughout production and of finished product is a critically important part of ensuring that food is not contaminated--but it is logically necessary that a discovery of contamination must carry an appropriate response. Some commenters also maintain that FDA should require the disposal of any food that has come into contact with contaminated water or production equipment.

(Response) We agree that environmental monitoring is only effective when designed to identify *L. monocytogenes* if present and if followed by appropriate and effective corrective actions, where necessary. For this reason, we specify in § 112.145(a) that sprout farms must establish and implement a written environmental monitoring plan that is designed to identify *L. monocytogenes* if it is present in the growing, harvesting, packing, or holding environment. As previously discussed, we are revising the rule to require that you establish and implement a written corrective action plan (as required under § 112.145(e)) to help ensure that corrective actions are taken quickly in response to positive findings of testing the production environment. This requires you to consider the likely scenarios in advance, developed through review of appropriate sprout safety resources, rather than react to these scenarios on an ad hoc basis.

Specifically with respect to renumbered § 112.146(d), finished product testing can provide useful information in certain situations when pathogens have been detected in the environment. For example, finished product testing is likely appropriate if a food-contact surface tests positive for *Listeria* spp. in tests conducted following cleaning and sanitizing the surface to address an initial positive for *Listeria* spp., especially if production has occurred

between the positive findings. The finding of Listeria spp. after a production run on a food-contact surface following corrective actions indicates that product contamination is reasonably likely, because it may indicate that the Listeria has become established in a niche on the equipment and is being dislodged during production. Our draft guidance to industry, the Listeria Guide (Ref. 244), includes draft recommendations for responses to positive environmental testing. A positive finding from environmental testing, as appropriate, can be confirmed through finished product testing and, if confirmed, necessary steps must be taken to remove the contaminated sprouts from the market and/or prevent contaminated sprouts from entering the market. We expect to address this issue further as we finalize the Listeria Guide. Accordingly, we are retaining in renumbered § 112.146 the provisions proposed as § 112.145 to require sprout operations to take certain minimum actions when there is a positive finding of L. monocytogenes or Listeria spp. in the production environment. Among these actions, listed in renumbered § 112.146, we are also specifying that the sprout farm must take appropriate action to prevent any food that is adulterated under section 402 of the FD&C Act from entering into commerce (see § 112.146(f)).

G. Collection and Testing of Samples of Spent Sprout Irrigation Water or Sprouts (§ 112.147)

These requirements were proposed as § 112.146. We have now renumbered this section as § 112.147 as a consequential change from the addition of new § 112.141.

(Comment 379) Several comments support our proposed requirement to develop a written sampling plan and to test spent irrigation water or sprouts for E. coli O157:H7 and Salmonella. One comment states that testing of spent irrigation water should apply to “green

sprouts” (e.g. alfalfa, clover) only, and that mung bean sprouts should be exempt from this requirement. According to this commenter, mung bean sprouts are periodically irrigated with large volumes of water (i.e., 200 gallons per growing container) and it would be difficult to collect and analyze a meaningfully representative sample of spent irrigation water during mung bean sprout production.

(Response) Sampling spent sprout irrigation water or sprouts is an important testing procedure to ensure contaminated product does not enter commerce, and, therefore, we are retaining the provisions in proposed § 112.146 as renumbered § 112.147 with certain revisions, as explained in the paragraphs that follow. We expect the written sampling plan to be developed taking into account the farm’s specific growing and irrigation practices so the samples collected and tested are representative of the farm’s spent sprout irrigation water or sprouts. For example, in some situations, a sprout farm may want to temporarily adjust the volume of water that flows through a growing unit for the purposes of collecting spent irrigation water samples. With regard to mung bean sprout production, research has shown that testing spent irrigation water of sprouting mung bean beds can provide a useful assessment of its microbiological status, and we disagree that mung bean sprouts should be exempt from the requirements of § 112.147 in light of certain irrigation practices (Ref. 227). One means to comply with § 112.147(b) is to follow the recommendations in the Sprouts Testing Guide (Ref. 97).

We are revising § 112.147(b) to reflect the new provisions in § 112.144(b) and (c) for testing for additional pathogens when the criteria in the rule are met. Thus, we are revising the introductory text in § 112.147 to refer to testing “for pathogens as required in § 112.114(b)” and revising § 112.147(b) to refer not to testing for E. coli O157:H7 and Salmonella spp., but

instead generally to “pathogens,” by which we mean those pathogen tests required by § 112.144(b) and (c). We are also revising § 112.147(b) to require testing using a method as set forth in new § 112.153 (see discussion in section XIX.B of this document).

As we previously noted in Comment 369, testing of spent sprout irrigation water or sprouts is a process control as well as a verification step. Accordingly, we have added text in § 112.147(b) to require that you must not allow the production batch of sprouts to enter commerce unless the results of the testing of spent sprout irrigation water or sprouts are negative for E. coli O157:H7, Salmonella spp., and, if applicable, a pathogen meeting the criteria in § 112.144(c). This is consistent with the requirement in § 112.148(a) that, if samples of spent sprout irrigation water or sprouts are positive for E. coli O157:H7, Salmonella spp., or a pathogen meeting the criteria in § 112.144(c), you must take appropriate action to prevent any food that is adulterated under section 402 of the FD&C Act from entering commerce. The requirement to not allow sprouts to enter into commerce until pathogen testing results are negative is consistent with current industry best practices (Ref. 219).

In addition, as in § 112.145 for environmental testing (discussed in Comment 378), we are adding a requirement that your written sampling plan for spent sprout irrigation water testing (or sprout testing) include a corrective action plan that at a minimum, requires you to take the actions in § 112.148, and details when and how you will accomplish those actions, if the samples of spent sprout irrigation water or sprouts test positive for E. coli O157:H7, Salmonella spp., or a pathogen meeting the criteria in § 112.144(c) (see § 112.147(c)).

Establishing and implementing a written corrective action plan will help ensure that corrective actions are taken quickly in response to positive findings of pathogens in spent irrigation water or sprouts. This requires you to consider the likely scenarios in advance, developed through

review of appropriate sprout safety resources, rather than react to these scenarios on an ad hoc basis. The requirement to have a written plan is consistent with other FDA food safety regulations, such as our juice and seafood HACCP regulations.

H. Actions if Spent Sprout Irrigation Water or Sprouts Test Positive for a Pathogen (§ 112.148)

(Comment 380) Several comments state that FDA should establish the steps that sprouters must take on a finished batch or lot of sprouts found to be contaminated through the testing requirements of this subpart. One comment states that FDA should require the immediate destruction or disposal of any finished product that may be adulterated, as indicated by a positive finding in the tests required under proposed § 112.146.

(Response) In light of these comments, we are establishing new § 112.148 to require sprout operations to take certain actions if the samples of spent sprout irrigation water or sprouts test positive for E. coli O157:H7, Salmonella spp., or a pathogen meeting the criteria in § 112.144(c). In part, § 112.148 requires you to take appropriate action to ensure that adulterated food does not enter commerce (see § 112.148(a)).

Testing of spent sprout irrigation water or sprouts for Salmonella spp., E. coli O157:H7, or a pathogen meeting the criteria in § 112.144(c) is required under § 112.144(b). A production batch of sprouts for which any of these pathogens is detected in the spent sprout irrigation water is considered adulterated under section 402(a)(4) of the FD&C Act, in that it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. Similarly, a production batch of sprouts for which any of these pathogens is detected in the sprouts is considered adulterated under sections 402(a)(1) of the FD&C Act, in that the sprouts contain a poisonous or deleterious substance which may render them injurious

to health. In such a circumstance, the covered farm must take appropriate steps to ensure that the adulterated food does not enter commerce, including, as appropriate, destroying or diverting the product to non-food use.

In addition, new § 112.148(b) requires you to take the steps required in § 112.142(b) with respect to the lot of seeds or beans used to grow the affected production batch of sprouts (except as allowed under § 112.142(c)). This provision is intended to make clear that the requirements in § 112.142(b) relating to seeds or beans apply to all situations in which your required testing of spent irrigation water or sprouts results in a positive pathogen finding, except as otherwise provided in section § 112.142(c). For a detailed discussion of these requirements, see section XVIII.B of this document.

In addition, § 112.148(c) requires you to clean and sanitize the affected surfaces and surrounding areas. This provision is consistent with our recommendations in the Sprouts Testing Guide. Anything in the sprouting operation that has come into contact with the contaminated production batch or its water (e.g., drums, trays, bins, buckets, tools and other sprouting equipment, testing equipment, and other possible surfaces, such as floors, drains, walls, and tables), must be thoroughly cleaned and sanitized to avoid contamination of subsequent batches of sprouts (Ref. 97).

Finally, § 112.148(d) requires you to perform any other actions necessary to prevent reoccurrence of the contamination. For example, a sprout grower may consider re-evaluating their seed treatment protocol, consider switching their seed supplier, or consider switching to using seeds that have been grown under Good Agricultural Practices and conditioned, handled and stored under sanitary conditions.

I. Records Related to Sprouts (§ 112.150)

We are making conforming changes to this section to reflect renumbering and revisions to other provisions in this subpart. In addition, we note that while we have added requirements for covered sprout farms to establish corrective action plans, such plans are required as part of the written environmental monitoring plan already required under § 112.145 and the written sampling plan for each production batch of sprouts already required under § 112.147. Thus, we are not revising § 112.150 to add separate records requirements for these corrective action plans because they are already covered in § 112.150(b)(2) (written environmental monitoring plans) and § 112.150(b)(3) (written sampling plans for each production batch of sprouts). We are also adding new requirement in final § 112.150(b)(6), discussed further in Comment 381.

(Comment 381) Several comments state that the recordkeeping requirements should be expanded to include documentation of any corrective actions that farms employ to address problems identified and verification that those corrective actions were effective.

(Response) In proposed § 112.161(b), we proposed a general provision applicable to records are required under subparts C, E, F, L, and M of part 112 that you must establish and keep documentation of actions you take when a standard in any of these subparts is not met. For clarification, we are eliminating proposed § 112.161(b) and, instead, adding that requirement within the records provisions of two relevant subparts, including subpart M. As revised, under § 112.150(b)(6), you must establish and keep documentation of actions you take in accordance with §§ 112.142(b) and (c), 112.146, and 112.148. This requires covered sprout farms to keep documentation of actions taken related to seeds and beans that may be contaminated, in accordance with § 112.142(b) and (c), and corrective actions in accordance

with §§ 112.146 or 112.148. For example, if your testing required under § 112.144(a) indicates a detection of Listeria spp. or L. monocytogenes in the growing, harvesting, packing, or holding environment, this provision requires you to establish and keep a record of the corrective steps that you took in response to that positive finding in compliance with § 112.146.

In addition, in final § 112.150(b)(5), we are requiring records of any analytical methods you use in lieu of the methods that are incorporated by reference in new § 112.153 (see section XIX.B of this document). This requirement is consistent with proposed § 112.150(b)(5), in which we proposed to require records of any analytical methods you use in lieu of the methods that are incorporated by reference in § 112.152, which we have retained in final § 112.150(b)(5). That is, in final § 112.150(b)(5), we require records of any analytical methods you use in lieu of the methods that are incorporated by reference in §§ 112.152 and 112.153. In addition, we are eliminating proposed § 112.150(b)(6) as a corresponding change.

We are also revising proposed § 112.150(b)(4) to clarify that documentation of the results of all analytical tests conducted for purposes of compliance with subpart M is required. This revision is consistent with the records requirement for agricultural water in § 112.50(b)(2).

J. Compliance Periods for Covered Activities Involving Sprouts

(Comment 382) Some comments request clarification regarding coverage of sprout operations under part 112 and the applicability of the provisions of part 112 (other than subpart M) to sprout operations. Some comments request clarification on whether all sprout farms will be subject to part 112 in addition to proposed subpart M, and whether sprout farms may also be eligible for a qualified exemption or extended compliance periods based on the farm's size. Citing the high risk nature of sprout production, one commenter argues that sprout farms should

not be eligible for the qualified exemption or extended compliance periods. Some comments specifically asked us to shorten the compliance periods for sprouts to protect public health.

(Response) As described throughout the 2013 proposed rule and in this rule, part 112 establishes the minimum science-based standards that we determine to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that we determine to be reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into fruits and vegetables, and to provide reasonable assurances that the produce is not adulterated. Sprouts are produce (see definition of “produce” in § 112.3) and, therefore, sprout farms are subject to all of part 112, as applicable. In addition, as discussed in the 2013 proposed rule (78 FR 3504 at 3594), because sprouts present a special concern with respect to human pathogens compared to other covered produce due to the warm, moist, and nutrient-rich conditions required to produce sprouts, we have incorporated the additional standards in subpart M specifically targeted to sprout operations. Accordingly, covered sprout farms are subject to all applicable requirements of part 112, including the specific requirements of subpart M.

The threshold for coverage (under § 112.4(a)) and the qualified exemption and associated modified requirements (under §§ 112.4(b) and 112.5-112.7) all apply to sprout farms.

With regard to compliance dates for covered activities involving sprouts, we agree that our proposed compliance dates were not sufficiently protective of public health. There is a long history of food safety problems associated with sprouts (78 FR 3504 at 3594-3601) and, therefore, we agree that we should establish shorter compliance periods for sprouts as compared to other covered produce. Section 419(a)(4) of the FD&C Act provides that we shall prioritize the implementation of this rule for specific fruits and vegetables based on known risks which

may include a history and severity of foodborne illness outbreaks. We believe it is appropriate to expedite the implementation of the provisions of part 112, including subpart M, for covered activities involving sprouts, based in part on the history and severity of sprout-related foodborne illness outbreaks, to reduce the likelihood of future sprout-related outbreaks.

We also believe it is not necessary to give sprout farms extra time to comply with the certain water provisions of subpart E as we are doing with respect to other commodities (see section XIII.K of this document). Based on information available to us, we believe that most, if not all, sprout farms already use public water supplies and/or ground water sources for all relevant purposes subject to the microbial quality criterion in § 112.44(a) (Ref. 245). The other provisions in subpart E for which we are allowing extended compliance dates for other commodities are either (1) directly linked to compliance with the microbial quality criterion in § 112.44(a); or (2) are not relevant to sprouts (i.e., the criteria in § 112.44(b) are only for produce other than sprouts).

Therefore, for covered activities involving sprouts, we are establishing that businesses other than small and very small businesses would have one year after the effective date of the final rule to comply with all of the provisions of this rule, whereas small businesses would have two years and very small businesses would have three years to comply with all of the provisions of this rule. This is consistent with the requirements in section 419(b)(3) of the FD&C Act that this rule shall apply to a small business after the date that is 1 year after the effective date of the final regulation, and to a very small business after the date that is 2 years after the effective date of the final regulation. See also XXIV of this document for additional information.

K. Other Comments

(Comment 383) One comment recommends that FDA require a food safety plan, and that this plan should also include a sprout-specific section.

(Response) As explained in section VII of this document, although we are not establishing a general requirement for covered farms to conduct an operational assessment or develop and implement a food safety plan, we encourage all farms to do so because food safety plans can help a farm to be more effective in ensuring the safety of produce grown, harvested, packed, or held at that farm.

(Comment 384) One comment asks us to consider establishing audit and inspection requirements specific to the sprout industry, and to provide appropriate training to auditors and inspectors. This commenter also suggests that FDA should require GFSI audits and unannounced inspections of sprout operations to verify best practices and food safety and quality standards.

(Response) We are not establishing requirements in this rule for audits of covered farms, generally, or of sprout farms, specifically. We do not see a reason to impose audit requirements specific to sprout farms in this rule. However, we recognize the role that third-party audits can play in promoting food safety. In the final human preventive controls rule (80 FR 55908) and the final FSVP rule (published elsewhere in this issue of the Federal Register), we are establishing certain supplier verification requirements that we expect to play a role in achieving compliance with this rule. In addition, we note that in the final third-party certification rule (published elsewhere in this issue of the Federal Register), FDA is establishing a voluntary program for the accreditation of third-party certification bodies that may conduct audits and issue certifications for purposes of establishing an entity's eligibility to participate in the Voluntary Qualified Importer Program (VQIP) or to satisfy conditions set

forth under section 801(q) of the FD&C Act.

We are also working with our partners to develop sprout-specific training, including training for use by inspectors. See section XXII of this document where we discuss our strategy for the implementation of the produce safety regulation, including the role of our federal, State, local, territorial, and tribal partners as well as private entities.

XIX. Subpart N – Comments on Analytical Methods

In subpart N of proposed part 112, we proposed methods of analysis for testing the quality of agricultural water and the growing environment for sprouts, as required under proposed subparts E and M, respectively. We asked for comment on our proposed provisions in subpart N, including specific methods and an allowance for alternative methods to be used provided they are at least equivalent to the proposed methods in accuracy, precision, and sensitivity.

We are finalizing these provisions with revisions (see Table 25). We discuss these changes in this section.

Table 25.-- Description of Revisions to Subpart N

Final Provision	Description of Revisions
§ 112.151	<ul style="list-style-type: none"> - Revision to eliminate the Official Methods of Analysis of the AOAC International, the Standard Methods for the Examination of Water and Wastewater of the American Public Health Association, and the FDA’s Bacteriological Analytical Manual from the list of specified methods - Revision to specify as the prescribed method of analysis, and to incorporate by reference, Method 1603 published by EPA - Revision to clarify that methods used other than that specifically incorporated must be scientifically valid - Revision to indicate that methods used for other indicators of fecal contamination must be scientifically valid - Editorial revision, moving “a method of analysis” into subparagraphs - Conforming revision to change cross-reference in title to § 112.46
§ 112.152	<ul style="list-style-type: none"> - Revision to incorporate by reference a specific method that is based on methods and procedures described in FDA’s Bacteriological Analytical Manual (BAM), USDA’s Microbiology Laboratory Guidebook, and those used in FDA’s compliance activities (in lieu of specifying a chapter of FDA’s BAM)Revision to the locations where a copy of the specified method may be obtained or inspected - Revision to clarify that methods used other than that specifically incorporated must be scientifically valid

	<ul style="list-style-type: none"> - Editorial revision to shorten introductory text by removing duplicative phrase “by testing” and unnecessary reference to “in environmental samples” - Conforming revision to change cross-reference in title to § 112.144(a), and to add “harvesting, packing, and holding” to title and introductory text
§ 112.153	<ul style="list-style-type: none"> - New section to: (1) prescribe a method of analysis for testing spent sprout irrigation water (or sprouts) from each production batch of sprouts for <u>E. coli</u> O157:H7 and <u>Salmonella</u> to satisfy the requirements of § 112.144(b), and to provide flexibility for use of other scientifically valid methods (see § 112.153(a)) and (2) specify that a scientifically valid method must be used for any other pathogens meeting the criteria in § 112.144(c) (see § 112.153(b)).

A. Responses to Comments

(Comment 385) One comment suggests revising proposed § 112.151(a)(1) to cite the 19th edition of the Official Methods of Analysis published by AOAC INTERNATIONAL in 2012, rather than the 18th edition that was issued in 2011.

(Response) We are revising final § 112.151 to eliminate the method of analysis, as published in the Official Methods of Analysis of AOAC International, as a prescribed method for testing the quality of water to satisfy the requirements of § 112.46. See section XIX.B of this document.

(Comment 386) Some comments seek clarification on the allowance for use of equivalent methods. One comment asks whether FDA would review a method to determine its equivalency to the relevant specified method(s), and requests clarification on how such equivalency should be determined. In addition, another comment suggests FDA should consider EPA-approved test methods for water acceptable for purposes of testing the quality of water required under this rule.

(Response) We have specified in subpart N certain analytical methods for use to satisfy the testing requirements related to agricultural water and sprouts. We reviewed EPA-approved test methods for water, and determined that Method 1603, an EPA-approved test method identified in 40 CFR 136.3, Table IH, is appropriate for testing water quality to satisfy the requirements of § 112.46 (see section XIX.B of this document).

However, we recognize that other scientifically valid methods, particularly test kits, may be available or may become available in the future. Therefore, we provide flexibility for covered farms to use any other scientifically valid method that is at least equivalent to a prescribed analytical method in accuracy, precision, and sensitivity. See also Comment 9. We are clarifying in §§ 112.151(b), 112.152(b), and 112.153(a)(2) and (b) that such methods must be scientifically valid. As noted in response to Comment 26, the term “scientifically valid” means an approach that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. Any scientifically valid method can be used provided you ensure that the method is at least equivalent to the applicable prescribed analytical method in accuracy, sensitivity, and precision in detecting the relevant organism or indicator (e.g., generic E. coli, Salmonella, L. monocytogenes, or Listeria spp.) in the relevant sample matrix (e.g., ground water, surface water, environmental swabs, spent sprout irrigation water, or sprouts). We are not further requiring covered farms to notify or submit information about such methods of analysis for FDA’s review or approval prior to use, nor do we believe that such a requirement is warranted. We intend to disseminate useful scientific information, when available, including on any new scientifically valid methods of analysis at least equivalent in accuracy, precision, and sensitivity to our prescribed methods.

(Comment 387) Another comment states that if samples are not collected in a sanitary manner there is no guarantee that the results will be scientifically valid.

(Response) We agree aseptic collection of samples is important, and have added this requirement under §§ 112.47(b) and 112.145(d). In addition, we have retained the requirement to collect samples aseptically, as previously proposed, in renumbered § 112.147(b). See also Comment 233 and Comment 376.

B. Other Revisions

With respect to the prescribed methods for testing agricultural water, we are eliminating proposed §§ 112.151(a)(1), 112.151(a)(2), and 112.151(a)(3). On further review, we find the testing methods specified in proposed § 112.151(a)(1) to (3) inadequate for the purpose of testing the quality of water to satisfy the requirements of § 112.46. The methods of analysis in the Official Methods of Analysis of AOAC INTERNATIONAL and the Standard Methods for the Examination of Water and Wastewater specified in proposed §§ 112.151(a)(1) and 112.151(a)(2), respectively, are not intended to capture discrete concentrations of microbial populations in sources of water that may be turbid or whose microbial quality may potentially vary irregularly. Likewise, the FDA's Bacteriological Analytical Manual (BAM) method specified in proposed § 112.151(a)(3) covers examination of bottled water only and does not explicitly address testing of agricultural water. Instead, for analysis of environmental water, the FDA's BAM method refers to EPA-approved test methods, which we have reviewed and we are specifying EPA's Method 1603 as a prescribed method in final § 112.151(a). We are also adding § 112.151(b)(2) to clarify that if you use an alternative indicator of fecal contamination in accordance with § 112.49(a) you must use a scientifically valid method to test for the indicator.

With respect to the prescribed methods for testing the sprout growing, harvesting, packing, and holding environment for Listeria spp. or L. monocytogenes, we are retaining proposed § 112.152 with revisions. Under final § 112.152(a), we are prescribing the relevant method, i.e., FDA’s method of analysis described in “Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples,” October, 2015, rather than prescribing a particular chapter of FDA’s BAM (as in proposed § 112.152). On further review, we find the method that is described in the particular chapter of FDA’s BAM (cited in proposed § 112.152) has been validated for detection of Listeria spp. or L. monocytogenes primarily in food samples. For the purposes of testing environmental samples for detection of Listeria spp. or L. monocytogenes to satisfy the requirements of 112.144(a), we are incorporating by reference a method that is based on the methods and procedures in USDA’s Microbiology Laboratory Guidebook, FDA’s BAM, and those used in FDA’s compliance activities. In addition, consistent with § 112.151(b)(1), under § 112.152(b), we are retaining the proposed flexibility for the use of other method(s) in lieu of the prescribed methods of analysis, provided the other method is scientifically valid and is at least equivalent in accuracy, sensitivity, and precision to the method in § 112.152(a). We believe these changes in final § 112.152 are necessary to prescribe the appropriate testing methods, while retaining flexibility for use of other scientifically valid methods, to meet our testing requirements in § 112.144(a).

We are revising both proposed §§ 112.151 and 112.152 to provide current information about the location where you may obtain or inspect a copy of the prescribed methods. We are also making certain conforming changes in these sections to update the cross-references to other provisions. We are also making certain non-substantive editorial changes in these sections (moving the phrase “a method of analysis” in § 112.151, and shortening the introductory text in §

112.152 by removing the duplicative phrase “by testing” and an unnecessary reference to “in environmental samples”).

We are adding new § 112.153 to specify certain methods of analysis for testing spent sprout irrigation water (or sprouts) from each production batch of sprouts, which is required under § 112.144(b). We are specifying that you must test for E. coli O157:H7 and Salmonella spp. using FDA’s method of analysis described in “Testing Methodologies for E. coli O157:H7 and Salmonella species in Spent Sprout Irrigation Water (or Sprouts),” October, 2015 (§ 112.153(a)(1)); or using a scientifically valid alternative method (§ 112.153(a)(2)). The method described in § 112.153(a)(1) is based on the method described in the current edition of FDA’s BAM with additional details for testing spent irrigation water or sprouts, and we are incorporating by reference this particular method into part 112 for the purposes of testing required under § 112.144(b). In § 112.153(a)(2), consistent with §§ 112.151(b)(1) and 112.152(b), we are providing flexibility for the use of an alternative method(s) for E. coli O157:H7 or Salmonella spp., in lieu of the prescribed method of analysis, provided the alternative method is scientifically valid and is at least equivalent in accuracy, sensitivity, and precision to the method in § 112.153(a)(1). In addition, § 112.153(b) specifies that a scientifically valid method must be used to test spent sprout irrigation water (or sprouts) from each production batch of sprouts for any other pathogen(s) that meet the criteria in § 112.144(c). By prescribing the method of analysis and incorporating sufficient flexibility for the use of scientifically valid alternative methods, we expect new § 112.153 to help covered farms meet our testing requirements in § 112.144(b).

C. Incorporation by Reference

In § 112.152(a), FDA is incorporating by reference “Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples,” Version 1, dated October 2015, U.S. Food and Drug Administration and, in § 112.153(a)(1), FDA is incorporating by reference “Testing Methodologies for E. coli O157:H7 and Salmonella species in Spent Sprout Irrigation Water (or Sprouts),” Version 1, dated October 2015, U.S. Food and Drug Administration, which was approved by the Office of the Federal Register. You may obtain a free copy of the material from the Division of Produce Safety, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1600; the Docket at www.regulations.gov; or from the Food and Drug Administration, at FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039. These methods are related to the detection of pathogens in the production of sprouts. We are specifying the prescribed method for testing of the sprout production environment for Listeria in accordance with § 112.144(a). This is an enrichment method for the detection of Listeria spp. in the environment of sprout farms and the confirmation of the presence of L. monocytogenes in samples that are positive for Listeria spp. We are also specifying the prescribed method for testing of spent sprout irrigation water or sprouts for two pathogens in accordance with § 112.144(b). This method includes: (1) screening procedures by real-time PCR to establish the presumptive presence of E. coli O157:H7, followed by culture confirmation of E. coli O157:H7, and (2) screening procedures to detect a presumptive positive for the presence of Salmonella spp., followed by confirmation of the presence of Salmonella spp. by a variety of confirmatory tests. We are specifying these prescribed methods, while also providing the flexibility for use of other scientifically valid methods, to help covered farms to meet our testing requirements in § 112.144.

In § 112.151(a), FDA is incorporating by reference “Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC),” dated December 2009, U.S. Environmental Protection Agency (EPA), EPA-821-R-09-007, which was approved by the Office of the Federal Register. You may obtain a free copy of the material from EPA, Office of Water (4303T), 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. 202-564-6620; http://water.epa.gov/scitech/methods/cwa/bioindicators/upload/method_1603.pdf; the Docket at www.regulations.gov; or from the Food and Drug Administration, at FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039. This method is an EPA-approved analytical test method. It provides the procedures for testing agricultural water samples to determine the microbial quality of water to satisfy the requirements of § 112.46. We are specifying this prescribed method, while also providing the flexibility for use of other scientifically valid methods, to help covered farms to meet our testing requirements in § 112.46.

XX. Subpart O – Comments on Records

In subpart O of proposed part 112, we proposed requirements that would be applicable to all records required by part 112. We tentatively concluded that the requirements in subpart O describing how records must be established and maintained, including the general requirements, record retention requirements, and requirements for official review and public disclosure, are applicable to all records that would be required under all subparts, because records that would be required under each of the subparts would aid farms in complying with the requirements of part 112; and allow farms to show, and FDA to determine, compliance with the requirements of part 112. We asked for comment on our proposed provisions.

We are finalizing these provisions with revisions (see Table 26). We discuss these changes in this section. Some comments support one or more of the proposed provisions without change. We discuss the comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. For § 112.166, we did not receive any comments or received only general comments in support of the proposed provision and, therefore, we do not specifically discuss these provisions.

Table 26.-- Description of Revisions to Subpart O

Final Provision	Description of Revisions
§ 112.161	<ul style="list-style-type: none"> - Revision to eliminate proposed § 112.161(b) and, instead, add that requirement within the records provisions of the relevant subpart, i.e., §§ 112.50(b)(6) and 112.150(b)(6) - Renumber proposed § 112.161(c) as § 112.161(b) and make conforming edits to update cross references - Revision to add the phrase “except as otherwise specified” in § 112.161(a) to reflect that certain records requirements specified in the relevant subparts of part 112 include requirements that are different from the ones in subpart O - Revision to cover new provision § 112.7 within renumbered § 112.161(b)
§ 112.162	<ul style="list-style-type: none"> - Revision to remove “after 6 months following the date the record was made” to allow immediate offsite storage of records provided they can be retrieved and provided onsite within 24 hours of request for official review

§ 112.163	<ul style="list-style-type: none"> - Revision to clarify types of existing records that do not need to be duplicated to comply with this part - Revision to clarify that such records must satisfy the requirements of this part - Revision to add “Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this part 112” - Revision to clarify that the information required by this part need not be kept in one set of records, and any new information required by this part may be kept separately or combined with existing records
§ 112.164	<ul style="list-style-type: none"> - Revision to add new § 112.164(a)(2) to specify that records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption must be retained as long as necessary to support the farm’s status during the applicable calendar year - Revision to § 112.164(a)(1) to replace “2 years” with “at least 2 years” so the length of record retention in this provision is harmonized with new § 112.164(a)(2) - Revision to § 112.164(b) to specify that “records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations” must be retained for at least two years after the use of such records is discontinued
§ 112.165	<ul style="list-style-type: none"> - Revision to establish that electronic records maintained to satisfy this part 112 are exempt from the requirements of part 11 of this chapter, except to the extent that they are also required under other applicable statutory provisions or regulations and are therefore subject to part 11
§ 112.167	<ul style="list-style-type: none"> - Revision to clarify that records “obtained by FDA in accordance with this part” are subject to the disclosure requirements under part 20

A. General Comments

(Comment 388) Several comments express support for our proposed approach to limit recordkeeping requirements. These commenters state that records of required monitoring activities and corrective actions are sufficient for FDA to evaluate an operation’s level of compliance with the requirements of the rule. Conversely, one commenter recommends that fruits and vegetables with little or no associated risk of foodborne illness should have a lower recordkeeping burden, whereas another commenter, while not providing specific suggestions, urges us to reduce the recordkeeping requirements to a minimum.

(Response) The recordkeeping requirements in this rule are limited to those specific instances where: (1) maintenance of detailed information is needed to keep track of measures directed at minimizing the risk of known or reasonably foreseeable hazards; (2) identification of a pattern of problems is important to minimizing the risk of such hazards; and (3) records are important to facilitate verification and compliance with standards and such verification and compliance cannot be effectively done by means other than a review of relevant records. Therefore, we believe that the requirements for developing and maintaining records established in part 112 are the minimum necessary.

With respect to the comment about establishing different recordkeeping requirements for different commodities based on their associated risk of foodborne illness, we refer you to the discussion in section IV of this document, in which we explain our rationale for relying on an integrated regulatory approach that focuses on practices, processes, and procedures and the potential for contamination through common on-farm routes, rather than on a commodity-specific regulatory framework. The recordkeeping requirements in this rule stem from our integrated regulatory approach.

(Comment 389) Several comments state that recordkeeping may cause financial hardship, such as lost time and revenue, for small- to mid-size farms.

(Response) As we discussed in sections IV.E and V.O of the 2013 proposed rule, in determining the circumstances in which records are necessary as part of science-based minimum standards that minimize the risk of serious adverse health consequences or death and provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act, we considered the statutory direction in section 419(c)(1)(C) of the FD&C Act to comply with the

Paperwork Reduction Act (44 U.S.C. 3501 et seq.) “with special attention to minimizing” the recordkeeping burden on the business and collection of information as defined in that act.

We appreciate the concerns with respect to cost and burden to farms and, to the extent possible, we have established documentation requirements that are risk-based and capable of being tailored to an individual farm, taking into account the unique characteristics of the operation, the commodities handled, and the operation’s growing, harvesting, packing, and holding procedures. The recordkeeping requirements in subpart O of part 112 allow the use of existing records, provided such records satisfy all of the applicable requirements of part 112 (see § 112.163). We are further clarifying in this final rule that you are not required to keep all of the information required by part 112 in one set of records. In addition, per § 112.165, electronic records are acceptable, although not required. Records in forms as diverse as hard copies of handwritten logs, invoices, and documents reporting laboratory results are also acceptable, provided they are indelible and legible. We estimated the costs associated with our recordkeeping requirements (Ref. 142).

(Comment 390) A few comments request that we more clearly define the records that must be kept and the content of such records. One of these comments asks whether FDA will provide training, including specific forms, templates or checklists, for farmers to comply with the records requirements.

(Response) The records required under this regulation are dependent, in part, on the nature of practices and procedures related to the covered activities in your operation, and are listed under the applicable sections of part 112, including in subparts A, C, E, F, L, and M (i.e., §§ 112.2(b)(4), 112.7, 112.30, 112.50, 112.60, 112.140, and 112.150). We will consider

providing guidance on the required records and their content, as needed. We also expect that the training curriculum and materials being developed by the PSA will address recordkeeping, and the SSA intends to provide “model” forms and training for sprout farmers on how to develop and maintain appropriate records.

(Comment 391) One comment suggests that records related to safety, including testing reports, should appear as part of labeling that accompanies produce as the commodity moves through the food chain. This commenter also asks us to make labels an active component of the food safety system instead of establishing the recordkeeping requirements we proposed.

(Response) Documentation of some practices is critical to ensure that this rule is adequately implemented on the farm. Records are useful for keeping track of detailed information over a period of time, and can identify patterns of problems and, thus, enable a farm to find and correct the source of problems. Records are also useful during FDA inspections for investigators to determine compliance with relevant requirements of the rule. We are not establishing new labeling requirements in this rule other than as set forth in § 112.6(b) for farms eligible for the qualified exemption and § 112.2(b) for produce eligible for the commercial processing exemption. We do not agree that product labels or labeling should be used as a substitute for the recordkeeping requirements in subpart O of part 112. Produce commodities, in packaged form, are subject to certain labeling requirements specified in 21 CFR part 100; however, such requirements are outside the scope of this rule.

B. General Requirements Applicable to Records Required Under Part 112 (§ 112.161)

(Comment 392) Stating that on-farm records are often recorded in pencil, one comment expresses concern that, under the proposed requirements of § 112.161, records would have to be

recorded in ink. This commenter states that outdoor on-farm environmental conditions often dictate the use of pencils instead of pens because rain can cause smearing of ink-recorded paperwork.

(Response) This comment appears to be in response to the requirement in § 112.161(a)(3) that records must be, among other things, indelible. We believe it is important for records to be indelible, and are retaining this requirement, as proposed. If a covered farm were to prepare the required record in pencil, we could not be confident that the record had not been altered from its original content. In addition, we do not believe the requirement is impractical for farms because we understand that a number of products such as all-weather and ballpoint pens are available that can write on wet paper and also do not cause smearing. This requirement is consistent with the provisions of the PCHF regulation and we are finalizing it as proposed.

(Comment 393) Some comments express support for proposed § 112.161(c) requiring a supervisor or responsible party to review certain records. Another comment recommends that allowances be made for a situation where the person who is responsible for the initial record is the owner or supervisor, in which case he or she should also be allowed to document the review of the records.

(Response) We are making some changes by eliminating proposed § 112.161(b) and, instead, adding that requirement (as necessary) within the records provisions of the relevant subparts. Rather than a general requirement for documentation of actions you take when a requirement subparts C, E, F, L, or M is not met, we are limiting this requirement as compared to that in the 2013 proposed rule, and making our intent clear by specifying the corrective measures in relation to which your actions must be recorded and such records retained. As revised, under

final §§ 112.50(b)(6) and 112.150(b)(6), you must establish and keep documentation of actions you take in accordance with certain specified corrective measures established in subparts E and M, respectively. We do not see the need for a similar documentation requirement in subparts C or L because we are not establishing specific corrective measures in relation to requirements in those subparts. Subpart F, too, does not include specific corrective measures for which additional documentation requirements (beyond the provisions we are finalizing, as discussed in section XIV.H of this document) are necessary. Therefore, we are not adding additional documentation requirements in §§ 112.30, 112.60, or 112.140 solely as a result of eliminating proposed § 112.161(b). With the elimination of proposed § 112.161(b), we have renumbered proposed § 112.161(c) as § 112.161(b), and we have also made conforming edits to update the cross-references in the provision that is now § 112.161(b).

Regardless of who creates or prepares the initial documentation, if the record is one that is required under §§ 112.7(b), 112.30(b)(2), 112.50(b)(2), 112.50(b)(4), 112.50(b)(6), 112.60(b)(2), 112.140(b)(1), 112.140(b)(2), 112.150(b)(1), 112.150(b)(4), or 112.150(b)(6), it must be reviewed, dated, and signed by a supervisor or responsible party. This includes the records being required under new § 112.7(b) (see Comment 139). In addition, in accordance with § 112.161(a)(4), applicable records must be dated, and signed or initialed by the person who performed the activity that is documented. Where the owner or supervisor is both the person who performed the activity as well as the responsible party, by signing and dating the record, the owner or supervisor will have satisfied the requirements in both §§ 112.161(a)(4) and 112.161(b).

We have also revised § 112.161(a) to add “except as otherwise specified” to reflect the fact that certain records requirements specified in relevant subparts of part 112 include

requirements that are different from the ones in subpart O (e.g., § 112.7(a), providing that we are not requiring sales receipts kept in the normal course of business to be signed or initialed by the person who performed the sale) (see Comment 139).

C. Storage of Records (§ 112.162)

(Comment 394) Several comments express concern with our proposed provision § 112.162(a) that would prohibit off-site storage of records for the first six months after a record is created. These comments find this provision to be unnecessarily burdensome, and argue that operations that move seasonally or that operate multiple growing sites should be able to retain records at an offsite location. These comments recommend revising this provision to read: “Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.” Another comment recommends also adding “or a reasonable period of time” as an alternative to help alleviate the burden.

(Response) We understand the seasonal nature of certain farming operations and the fact that many farms have multiple growing sites that may not be contiguous. Proposed § 112.162(a) would not require a farm with multiple growing sites to establish multiple records storage locations. Where multiple growing sites are operated under one management in one general (but not necessarily contiguous) physical location, they are part of one farm under our definition of farm (see § 112.3(c)). We consider records to be on-site at a farm as long as they are located at a site on that farm (or in the case of electronic records, accessible from a site on that farm, see § 112.162(b)). Thus, a farm’s records would be considered to be on-site even if records related to field A are stored at field B, provided both fields are operated by the same farm under our definition. This allows a covered farm to store all of its records, including those records created

during covered activities on seasonally-rented field(s) or in multiple growing locations, in the main offices of the farm's operation, for example, and does not require a single farm to set up a mechanism to store records related to each field separately at different locations. Nevertheless, we are revising § 112.162(a) to permit offsite storage of required records provided such records can be retrieved and provided onsite within 24 hours of request for official review. Because the records will be available within 24 hours of an official request, and because we expect that a farm will also be able to retrieve and review all necessary records from its recent operations within a 24 hour period (allowing them to use the records to review detailed information needed to keep track of measures minimizing the risk of hazards, and identifying patterns of problems for the same purpose), we consider that this provision will satisfy the purposes of record retention. In order to maintain inspectional efficiency and to ensure that farms can use their own records as described previously, we are requiring that the time period between an FDA request for the records and their arrival not exceed 24 hours. Allowing for offsite storage of records under the conditions noted in § 112.162(a) is consistent with our regulation on Production, Storage, and Transportation of Shell Eggs, 21 CFR part 118, which allows for offsite storage of records, except for the written Salmonella Enteritidis prevention plan, which must be stored on-site (see § 118.10).

D. Use of Existing Records (§ 112.163)

(Comment 395) Several commenters express support for proposed § 112.163, and ask that we clarify that records already kept for other purposes and information presented across multiple records in different forms are sufficient to meet the recordkeeping requirements of the produce safety regulation.

(Response) We are revising proposed § 112.163 to provide additional clarity about the fact that the regulations in part 112 do not require duplication of existing records if those records contain all of the information required by part 112. We have minimized the burden of keeping records to that which is necessary to accomplish the intended purposes of part 112. As discussed in the 2013 proposed rule, for example, you are not required to duplicate existing records, such as records kept to satisfy the requirements of the NOP, if those records contain all of the information required by this part. Additionally, you are not required to keep all of the information required by this part in one set of records. Similarly, if you have records containing some but not all of the required information, the produce safety regulation provides you the flexibility to keep any additional information required by this part either separately or combined with your existing records, even where the formats for each record may not be the same. However, note that keeping records together in one place likely will expedite review of records in the event of a public health emergency or during an FDA inspection or investigation.

To make our intent clear, and consistent with a similar provision § 117.330 in the PCHF regulation, we are revising proposed § 112.163 to read as follows: (a) Existing records (e.g., records that are kept to comply with other federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this part 112. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this part 112; and (b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

We acknowledge that the records required by this part may be multi-component – a web of related documents. This provision provides flexibility, but it is not without limitations. As an example, a farm that collects spent sprout irrigation water samples and sends them to a laboratory for testing may have sampling records that contain the information required by § 112.161(a)(1), such as the name and location of the farm, the date when the samples were collected, the signature or initials of the person collecting the samples and an adequate description of the sprouts applicable to the record (including a lot number or other identifier, when available). The laboratory report may not include some of the information, such as the location of the farm, but would contain some identifying information relating to the sample tested, such as the date of the sample or the lot number for the applicable sprouts. These records together contain all the required information to associate them with a farm and a specific lot of product. However, the following example for monitoring records illustrates there can be limitations on supplementing existing records with required information kept in other documents. Monitoring records must be created concurrently with the monitoring activity and contain the signature or initials of the person conducting the monitoring. If the existing records document the monitoring activity and the date and time but do not provide space for the name and location of the farm or the signature or initials of the person performing the activity, it would not be acceptable to supplement that record with the name and location of the farm and signatures on a separate page.

E. Length of Records Retention (§ 112.164)

We received some comments generally supporting proposed § 112.164. We are retaining § 112.164 with certain changes. First, we are adding new § 112.164(a)(2) to require that records

that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with §§ 112.5 and 112.7, must be retained at the farm as long as necessary to support the farm’s status during the applicable calendar year. As discussed in section IX of this document, the criteria for a qualified exemption established in this rule (in § 112.5) are based, in part, on average sales during the 3-year period preceding the applicable calendar year. Thus, a farm that does not retain records documenting its sales during the 3 to 4 years prior to the applicable calendar year will not have documentation adequate to demonstrate its eligibility for the qualified exemption. The actual retention time necessary to support its eligibility during the applicable calendar year could be as long as 4 years. For example, if a farm were to be inspected on May 1, 2024, the farm would have retained the records from 2021-2023 for 3 years and four months. On the other hand, if a farm were to be inspected on December 28, 2024, the farm would have retained the records from 2021-2023 for nearly 4 years.

Second, we are making a corresponding revision to § 112.164(a)(1) to replace “2 years” with “at least 2 years” so the length of record retention in this provision is harmonized with new § 112.164(a)(2).

Finally, we are revising § 112.164(b) to make clear that it covers such records as those related to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations. For example, the initial or annual surveys that a farm conducts to develop or update the microbial water quality profile under § 112.46(b) can be comprised of data derived from water tests conducted within the previous 4 years, and these results inform the farm’s use of that agricultural water in accordance with § 112.45. Because these results are necessary to verify the use of the agricultural water in compliance with the

microbial quality criteria in § 112.44 as well as any time interval in compliance with the microbial die-off provisions in § 112.45(b)(1)(i) and/or (b)(1)(ii), we conclude a retention period of 2 years after their use is discontinued (i.e., 2 years after the test results are used to inform the microbial water quality profile) is warranted for these water test results. Likewise, the written environmental monitoring plan (required under § 112.145) and written sampling plan (required under § 112.147) that a sprouting operation establishes and implements must be retained at the farm for at least 2 years after their use is discontinued.

F. Acceptable Formats for Records (§ 112.165)

(Comment 396) Several comments express concern about the proposed requirement in proposed § 112.165(c) that any electronic records maintained to satisfy the requirements of part 112 be kept in compliance with part 11 of this chapter. These commenters state that while large operations may have invested in part 11-compliant software, other farm operations currently maintain electronic records using commonly available software, such as Excel. Comments also state that only a few farms currently have the computer training necessary to implement the requirements of part 11, and that adapting their existing systems to be in compliance with part 11 would require significant investments by many farms. These commenters request that the requirement for electronic records to comply with part 11 be deleted from the final produce safety regulation. In addition, one commenter recommends that FDA provide information in guidance as to how operations should protect electronic records from intentional or unintentional falsification. In contrast, another commenter agrees that electronic records should be required to be in compliance with part 11. This commenter notes that most electronic records include a date stamp indicating when they were last modified, suggesting that this should be considered

sufficient evidence of compliance with part 11 and allow such records to be considered original records.

(Response) We agree that the need to redesign large numbers of already existing electronic records and recordkeeping systems would create a substantial burden, particularly in light of frequent software patches and security updates and the use of open source software by some farms. Therefore, we are revising § 112.165(c) to provide that records that are established or maintained to satisfy the requirements of part 112 and that meet the definition of electronic records in § 11.3(b)(6) are exempt from the requirements of part 11. We also are specifying that records that satisfy the requirements of part 112, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11. This rule provides that a farm may rely on existing records to satisfy the requirements of this rule, and this rule does not change the status under part 11 of any such records if those records are currently subject to part 11. As we did in the PCHF regulation, we are establishing a conforming change in part 11 to specify in new provision § 11.1(k) that part 11 does not apply to records required to be established or maintained under part 112, and that records that satisfy the requirements of part 112, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11. Although we are not specifying that part 11 applies, covered farms should take appropriate measures to ensure that electronic records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

Note, however, that we are not requiring electronic records. Indeed, to minimize the burden this regulation may have on covered farms, FDA is not specifying the form or format of the records that must be established and maintained except as set forth in part O. To satisfy the requirements of the produce safety regulation, paper or electronic records or a combination of the

two may be used. We also expect that the training curriculum and materials being developed by the PSA and SSA will include training on how to develop and maintain appropriate records.

G. Disclosure of Records Submitted to FDA (§ 112.167)

(Comment 397) One comment asks FDA to affirm that the regulations under 21 CFR part 20 will be followed. This comment also generally expresses concern about disclosure of confidential information submitted by a covered farm to FDA, and that small businesses may not be fully aware of FDA's ability to disclose certain types of materials. The commenter asks FDA to provide guidance to assure that covered farms understand FDA's procedures for publicly disclosing certain submitted materials.

(Response) We understand the concerns regarding confidentiality. Section 112.167 explicitly states that records obtained by FDA in accordance with part 112 are subject to the disclosure requirements under 21 CFR part 20. Our disclosure of information is subject to the Freedom of Information Act (FOIA) (5 U.S.C. 552), the Trade Secrets Act (18 U.S.C. 1905), the FD&C Act, and our implementing regulations under 21 CFR part 20, which include protection for confidential commercial information and trade secrets. Our general policies, procedures, and practices relating to the protection of confidential information received from third parties would apply to information received under this rule. We will consider addressing this topic in our SECG to be issued in the near term following this rule. We are revising this provision to specify that records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20. FDA is making this change to clarify that the requirements in part 20 attach to those documents obtained by FDA under this rule.

XXI. Subpart P – Comments on Variances

In subpart P of proposed part 112, we proposed a process by which a State or a foreign country may request a variance(s) from one or more requirements of part 112, consistent with the statutory provisions in section 419(c) of the FD&C Act. We proposed that the competent authority for a State or foreign country submit the petition requesting the variance, what information must accompany such requests, and the procedures and circumstances under which FDA may grant or deny such requests, and modify or revoke such variances.

We asked for comment on our proposed provisions in subpart P for variances, including related process and scientific data and information to support a request for variance, and circumstances for approval or denial of a request for variance and for modification or revocation of an approved variance. We also asked whether there are any specific concerns that we should consider in finalizing the procedures and processes for requests for variances, as applicable to foreign governments.

We are finalizing these provisions with revisions (see Table 27). We discuss these changes in this section. We are finalizing the other provisions of subpart P without change. For §§ 112.174, 112.175, 112.177, 112.178, 112.179, 112.180, and 112.181, we did not receive any comments or received only general comments in support of the proposed provision and, therefore, we do not specifically discuss these provisions further.

Table 27.-- Description of Revisions to Subpart P

Final Provision	Description of Revisions
§ 112.171	- Revision to establish that Federally-recognized tribes may submit a variance petition; and corresponding changes throughout subpart P
§ 112.172	- Revision to make clear that a competent authority, for purposes of submitting a request for a variance in accordance with this rule, is the regulatory authority for food safety (replacing “e.g.,” with “i.e.”)

§ 112.176	<ul style="list-style-type: none"> - Revision of § 112.176(b) to replace “either” with “e.g.” to make clear that the situations described are merely examples and not limitations on who may comment - Editorial revision to treat “website” as one word
§ 112.177	<ul style="list-style-type: none"> - Editorial revision to treat “website” as one word
§ 112.179	<ul style="list-style-type: none"> - Editorial revision to add the word “on” before “the date of our written decision”
§ 112.181	<ul style="list-style-type: none"> - Editorial revision to treat “website” as one word
§ 112.182	<ul style="list-style-type: none"> - Revision to clarify that the permissible types of variances are not limited to the examples provided (adding “A variance(s) may be requested for one or more requirements in subparts A through O in part 112”) - Revision to include additional examples and delete examples that are no longer applicable due to revisions in other sections of part 112 - Revisions to update cross references in examples and descriptions of cross referenced requirements

A. Requesting a Variance (§§ 112.171 and 112.172)

(Comment 398) Several comments express concerns about the lack of allowance for tribes to request variances from the requirements of part 112.

(Response) Tribal governments may request a variance(s) from part 112 under the same provision that permits States to request a variance(s) from part 112. FDA interprets 21 U.S.C. 350h(c)(2) to allow Federally-recognized tribes (which we refer to in the rule as “tribes”) to be treated in the same manner as States for the purpose of the variance provision. Therefore, any one or more of Federally-recognized tribes may submit a variance petition, in accordance with § 112.171, and all other provisions in subpart P that apply to a petition submitted by a State apply equally to a petition submitted by a Federally-recognized tribe (Ref. 246). In light of comments, we are adding “tribe” in part 112 to clarify for purposes of this rule that “tribes” are included. To make this explicit, we are revising § 112.171 to establish that a State, tribe, or foreign country may submit a petition requesting a variance(s) from the requirements of part 112, and making corresponding revisions throughout subpart P.

(Comment 399) One comment seeks clarification on who would be considered a competent authority for a State or foreign government, as proposed in § 112.172.

(Response) A competent authority is commonly understood to be a person or organization that has the legally delegated or invested authority, capacity, or power to perform a designated function. For the purposes of the produce safety regulation, a competent authority is the regulatory authority for food safety for a State (e.g., State Department of Agriculture, etc.), tribe, or a foreign country importing food into the United States. Our reference to this term in the produce safety regulation is consistent with the use of term in other regulatory contexts. For example, competent authority is used in various Codex guidelines, referring to the official government agency having jurisdiction (Ref. 247) (Ref. 248). This term is also used to refer to relevant regulatory authorities in the European Union (Ref. 249). We are editing § 112.172 to replace “e.g.” with “i.e.” to make this clear.

(Comment 400) Some comments state that entities allowed to submit variance requests should not be limited to State and foreign governments. A number of comments contend that additional groups, including State and federal commodity organizations, commodity boards, commodity commissions, trade associations, or other coalitions of farms should also be permitted to request variances using the same procedures available to States and foreign governments. These comments maintain that such groups are more likely to encompass the affected industry and are in a better position to consider and represent the risks and practices of the covered commodity. One comment states that a commodity commission is a State entity and should be able to submit a variance on behalf of a State. Some comments note that commodity boards have long partnered with research institutions and farms to investigate ways to improve

produce safety, and are well positioned to present the information necessary to support a variance request. Some comments also state that allowing petitions for variances from parties other than State governments would reduce the burden currently placed solely on State agencies.

(Response) The provision in § 112.171 establishes that a State, tribe, or foreign country from which food is imported into the United States may request a variance from one or more of the requirements proposed in part 112. This provision implements the statutory provisions in sections 419(c)(1)(F) and 419(c)(2)(A) of the FD&C Act, which specify the criteria for the final regulation and explicitly provide for “States and foreign countries from which food is imported into the United States” to request variances from the requirements of the produce safety regulation. These statutory provisions do not identify private industry groups or trade associations. With respect to an entity that may be a State entity, such as a State commodity commission, but that is not the competent authority for that State, such entities are not eligible to request a variance. We are limiting this provision to competent authorities for a State, tribe, or foreign country because these entities with legally delegated or invested authority for food safety issues are the most appropriate to represent a State, tribe, or foreign country in food safety regulatory matters.

FDA recognizes the knowledge of industry groups and appreciates their contributions to public and private partnerships to improve produce safety. FDA also appreciates that many groups have already instituted or are developing their own commodity-specific programs and guidelines (for example, in the case of strawberries, tomatoes, leafy greens, potatoes, and mushrooms) as well as with programs and guidance that cut across different commodity groups (for example, the AFDO Model Code; the Global GAPs (Ref. 250); and the Produce GAPs Harmonization Initiative (Ref. 251) (Ref. 252)). As noted previously, the processes in part 112,

subpart P, do not preclude any entity from working with the competent authority (i.e., the regulatory authority for food safety) for their State, tribe, or foreign country to develop a petition to request a variance. FDA anticipates that industry groups and other relevant stakeholders would be willing to provide assistance to reduce the burden on States, tribes, and foreign governments, including, as appropriate, by developing the necessary scientific data to support a request for a variance and/or drafting the variance petitions for signature and submission by the State, tribe, or foreign country. As discussed in the paragraphs that follow, FDA also intends to take a number of steps, including providing for pre-submission consultations and making public scientific data and other information in petitions submitted, which may further ease the burden on States, tribes, and foreign governments with similarly situated covered farms.

(Comment 401) A comment states that the process of submitting a variance would require significant resources.

(Response) As noted previously, if a State, tribe, or foreign government chooses to submit a variance, we encourage them to work with other entities to develop variance petitions. FDA also intends to take a number of steps to provide assistance to States, tribes, and foreign governments interested in submitting petitions requesting a variance, including providing for pre-submission consultations and making public scientific data and other information in petitions submitted (see § 112.174), which may ease the burden on States, tribes, and foreign governments. In addition, in accordance with § 112.177, we may extend a variance granted to a State, tribe, or foreign government petition to another State, tribe, or foreign country that requests a similar variance for covered farms who are similarly situated within its jurisdiction.

(Comment 402) One comment requests us to follow the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) guidelines for the process for requests for variances from foreign competent authorities. This comment notes unfamiliarity with the petition process in § 10.30, but expects FDA to compare and contrast, and modify the currently proposed process to fit with WTO guidelines.

(Response) The process established under part 112 is appropriate not only for the petitioners for a variance, but also for the specific nature of the determinations that FDA is required to make when considering a variance request. In developing this process, FDA took into account WTO guidelines for considering petitions for variance, including documents by the relevant international organizations such as the Codex. Where appropriate, the petition process established by this rule should satisfy the recommendations of such guidelines.

B. The Statement of Grounds in a Variance Petition (§ 112.173)

(Comment 403) Comments generally support the proposed requirements related to processes, scientific data, and information to support a variance request. Contrastingly, some comments request additional clarification on the scientific data and information necessary to support variance requests. Comments express concern with the availability, accessibility, and adequacy of the scientific data or information needed to demonstrate that the variance provides the same level of public health protection as the requirements of the produce safety regulation. Comments note that the lack of peer-reviewed scientific information will hamper the practicality and usefulness of the flexibility of variances, and information does not need to be published in peer reviewed journals in order to be used in support of a request for variance. Comments also support the use of industry-generated scientific data conducted through accredited or university

laboratories, and suggest that data sets, methodology and analysis should be publicly shared so that other stakeholders can access and leverage such scientific information.

(Response) With regard to the scientific data and information necessary to support variance requests, States, tribes, and foreign countries may, among other things, consult scientific papers. FDA agrees that information does not need to be published in peer reviewed journals in order to be used in support of a request for variance, although we encourage use of peer-reviewed data and information, to the extent available. A State, tribe, or foreign country is required to submit relevant and scientifically-valid information or materials specific to the covered produce and/or covered activity to support the petitioner's request for a variance(s) from corresponding requirements established in part 112. Depending on the variance(s) requested, this could include information about the crop, climate, soil, and geographical or environmental conditions of a particular region, as well as the processes, procedures, or practices followed in that region. For example, a State, tribe, or foreign country may conclude that meeting certain requirements of the rule would be problematic in light of local growing conditions and that a variance from some or all provisions of this proposed rule is necessary. The State, tribe, or foreign country might consider the historical performance of an industry within their jurisdiction (e.g., as indicated by the epidemiological record) and the combination of measures taken by that industry merits requesting a variance. In requesting a variance, among other things, the State, tribe, or foreign country would submit information that, while the procedures, processes and practices to be followed under the variance would be different from those prescribed in this rule, the requested variance is reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act and provide the same level of public health protection as the

corresponding requirement(s) of the produce safety regulation for which a variance is requested. FDA encourages consideration of these types of information to support a request for a variance.

For example, the microbial die-off rate of 0.5 log per day to determine an adequate time interval, no greater than four consecutive days, between last irrigation and harvest is established in § 112.45(b)(1)(i). We derived this die-off rate based on a review of currently available scientific literature that shows a range of microbial die-off rates of 0.5 to 2.0 log per day, dependent on various environmental factors, including sunlight intensity, moisture level, temperature, pH, the presence of competitive microbes, and suitable plant substrate. Generally, pathogens and other microbes die off or are inactivated relatively rapidly under hot, dry, and sunny conditions compared to inactivation rates observed under cloudy, cool, and wet conditions. Our analysis led us to conclude that a rate of 0.5 log per day provides a reasonable estimate of microbial die-off under a broad range of variables to include microbe characteristics, environmental conditions, crop type, and watering frequency (see discussion on 79 FR 58434 at 58445-446; see also (Ref. 45)). Nevertheless, we acknowledge that practices and conditions on a farm and circumstances unique to a specific commodity could result in higher die-off rates between last irrigation and harvest, especially under conditions of high ultraviolet radiation, high temperature exposures or low humidity, coupled with little or no precipitation. A State, tribe, or foreign country may submit a petition for a variance to the microbial die-off rate, as well as to the accompanying maximum time interval between last irrigation and harvest, established in § 112.45(b)(1)(i), along with scientific information and data demonstrating that the requested microbial die-off rate is appropriate for the specific crop, based on climate, soil, and/or geographical or environmental conditions of a particular region, and/or the processes, procedures, or practices followed in that region for the specific crop, as described in its petition

to FDA. (Note that a covered farm can also establish an alternative microbial die-off rate and an accompanying maximum time interval, in accordance with §§ 112.12(a) and 112.49(b), without the need for a variance for this specific requirement, although a variance approved by FDA could provide assurance to covered farms of the scientific basis for the deviation from FDA-established microbial die-off rate and also minimize the resource burden on individual farms developing the scientific support for an alternative as opposed to a State requesting a variance for all covered farms for which a variance would apply in a specified region.) Such scientific information and data may include scientific literature, such as research data on microbial populations and survival and/or die-off rates under conditions representative of that specific region (e.g., temperature, humidity, precipitation); weather station data comparing their environment to that in the scientific literature; any historical, reliable water sampling or survey data relevant to the specific region; and/or data on current industry practices for the commodity in the specific region. The weather conditions are likely to vary based on factors such as topographic and environmental conditions. Therefore, we envision that the information and data supporting such a request for a variance would demonstrate the microbial die-off between last irrigation and harvest for a specific commodity, and under the environmental conditions of a particular region, that is requested in the petition to FDA.

Interested parties may work independently or in collaboration with their competent authority to compile supporting information for use by the State, tribe, or foreign country in its submission of a variance petition. In addition, § 112.177 ensures consideration of the application of variances to similarly situated persons and provides for transparency and accountability in FDA's review of requests and decision-making. FDA also welcomes pre-petition consultations with interested States, tribes, or foreign countries to facilitate the development of variance

petitions, including a discussion of the types of data and information that would be needed to support the specific variance the State, tribe, or foreign country expects to request in its petition.

C. Process for Requesting a Variance (§ 112.176)

(Comment 404) One comment recommends that we clearly delineate the processes associated with the approval or denial of the variance, while another comment asks us to establish criteria for how information supplied in support of variances will be evaluated.

(Response) We are establishing the general procedures applying to variance petitions in § 112.176. Under these procedures, a State, tribe, or foreign country from which food is imported into the United States may in writing submit a request for a variance(s) to the FDA using the process described in § 10.30. Such a request shall describe the variance requested and present information demonstrating that the variance does not increase the likelihood that the food for which the variance is requested will be adulterated under section 402, and that the variance provides the same level of public health protection as the requirements of the produce safety regulation. Under the procedures described in § 112.176, FDA will review such requests and may approve the variance requested either in whole or in part, as appropriate, and may specify the scope of applicability of the variance to other similarly situated persons. FDA will publish a notice in the Federal Register, requesting information and views on the filed petition, including information and views from persons who could be affected by the variance if the petition were to be granted. FDA will respond to the petitioner in writing and will publish a notice on our website announcing our decision to either grant or deny the petition. If the petition is granted, either in whole or in part, FDA will specify the persons to whom the variance would apply and the provision(s) of part 112 to which the variance would apply. If the petition is denied (including

partial denials), FDA will explain the reason(s) for the denial in its written response to the petitioner and will post this information on our website. We intend to make readily accessible to the public, and periodically update, a list of filed petitions requesting variances, including the status of each petition.

In evaluating petitions, FDA will look to see if the petition addressed the relevant requirements, for example, whether the petition included information on the need for the variance and that procedures, processes, and practices to be followed under the variance provide the same level of public health protection as the relevant requirement(s) of part 112 (see § 112.171). We will also look for a Statement of Grounds describing with particularity the variance requested, including the persons to whom the variance would apply and the provision(s) of part 112 to which the variance would apply (§ 112.173(b)). We will assess whether the scientific information, data, and materials included in the petition sufficiently support the variance requested and accompanying rationale for the request. If FDA finds that we need additional information to make a decision, we intend to communicate with the petitioner. As noted previously, we welcome pre-submission consultations so that data and information necessary to adequately support a specific variance can be identified. FDA anticipates providing guidance and other information, as appropriate, to assist States, tribes, and foreign countries in preparing petitions for requests for variances and developing the necessary scientific basis to support such requests.

(Comment 405) One comment asks whether we would be able to assess and provide a decision on variance requests before the implementation date if FDA were faced with large number of variance applications. This comment also suggests that, if we are not able to decide on

a variance request before the implementation date, variance requestors should be able to continue operating under their existing practices until the FDA decision has been made. Another comment states that rapid approval of variances is a critical component to ensuring continuity in farming operations in areas where water quality is an issue yet food safety of certain commodities has not been impacted.

(Response) We expect the compliance periods we have established for this rule allow sufficient time for variance petitions to be developed, submitted, and reviewed by FDA. Per section 419(c)(2)(A) of the FD&C Act, FDA will review variance petitions and respond to petitioners in a reasonable timeframe. FDA welcomes pre-petition consultations, which could facilitate FDA's timely review and decisions on variance petitions.

(Comment 406) Comments asked us to establish a stakeholder group to review variances.

(Response) We deny the request to establish a stakeholder group to review variances submitted to FDA. Rather, FDA will review all variance petitions submitted to the agency. However, the citizen petition process, which we are employing in relation to requests for variances, allows opportunity for stakeholders to provide comment on variance petitions filed with FDA, including on the requested variance and the scientific merits of the request.

D. Permissible Types of Variances (§ 112.182)

(Comment 407) One comment notes that while a variance can be requested for one or more requirements of the produce safety regulation, the examples of permissible types of variances provided in § 112.182 of the rule creates the impression that only variances in those

areas will be approved. This comment requests us to revise this provision to make it clear that a variance is not limited to certain elements of the rule.

(Response) The list in § 112.182 is intended to provide examples of the types of variances that may be requested and, if FDA deems appropriate, granted. Therefore, variance petitions are not intended or required to be limited to these examples. A State, tribe, or foreign country may request a variance from any one or more requirements in subpart A through subpart O in part 112, under the conditions described in § 112.171. We are revising § 112.182 to make our intent clear and to revise and update the list of examples. As revised, § 112.182 states that a variance(s) may be requested for one or more requirements in subpart A through O in part 112. Examples of permissible types of variances include: (1) variance from the microbial quality criteria when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method, established in § 112.44(b); (2) variance from the microbial die-off rate that is used to determine the time interval between last irrigation and harvest, and/or the accompanying maximum time interval, established in § 112.45(b)(1)(i); and (3) variance from the approach or frequency for testing water used for purposes that are subject to the requirements of § 112.44(b), established in § 112.46(b).

E. Other Comments

(Comment 408) One comment seeks clarification on how a variance request would work for countries seeking equivalence or systems recognition arrangements. This commenter states that FDA recognition of food safety systems in the foreign country should be an accepted variance to this rule. The organization also requests FDA to provide direction to foreign

governments to help them determine which of the two options – a request for variance or for systems recognition – is more appropriate given their particular circumstances.

(Response) Variances, systems recognition, and equivalence are distinct regulatory tools, each requiring different analyses, although they do overlap somewhat. As described in this rule, a foreign country may submit a request for a variance(s) by, among other things, demonstrating that local conditions and practices, while different, achieve the same level of public health protection as the relevant standard under the produce safety regulation. Variances may be requested for one or more requirements established under part 112. Systems recognition, as developed by FDA, applies to and evaluates the robustness of a foreign country's oversight of their food safety system and its comparability with United States controls and standards based on a comparison of key elements of the overall food control system and a rigorous in-country audit of food safety controls. Equivalence, as described in the WTO SPS Agreement, provides for exporting countries to demonstrate that they achieve the importing member's appropriate level of protection. Equivalence can be determined for a specific measure, a set of measures, or the entire food control system.

A country does not need equivalence or a systems recognition arrangement to obtain a variance. Systems recognition involves an intensive and extensive review of key aspects of the overall food safety control system. Indeed, an overall food safety system may not be comparable to that of the United States for FDA-regulated products, but the country may be able to successfully demonstrate that a specific produce production practice or set of practices provides the same level of public health protection for a specific measure or a set of measures as described in the requirements contained in part 112 of this rule.

Ideally, FDA's systems recognition of a food control system should include a successful assessment of its produce production practices. However, it is premature to determine that variances will not be needed or considered for countries with existing or future arrangements. We note that FDA's pilot systems recognition activities pre-date FSMA and FDA is currently refining the program and transitioning it from a pilot to the full program operations stage. Part of this process entails ensuring alignment, where appropriate, with FSMA. While all systems recognition assessments have followed a similar process, each assessment varies in scope of the review for oversight of specific products. In the future, FDA will likely consider including additional consideration for produce standards, oversight and production practices particularly with respect to the country's practices and oversight regarding the specific provision(s) in part 112 in its systems recognition assessments. Any proposed changes to our process for existing arrangements and future assessments will be transparent and publically notified. For existing arrangements, FDA will work with the regulatory partner to determine if additional evaluation may need to be considered for any proposed variances.

Given varying scenarios and possibilities regarding the scope of each respective systems recognition arrangement currently being considered, FDA concludes that whether or how requests for a variance relate to current and future systems recognition assessments will need to be evaluated on a case-by-case basis and will be undertaken in consultation with the foreign country involved.

More information on systems recognition can be found at FDA's website:
<http://www.fda.gov/food/internationalinteragencycoordination/ucm367400.htm>

(Comment 409) One comment asks whether FDA considered extending the applicability of a variance to produce that is subject to another United States government regulatory framework that provides the same level of public health protection as the produce rule. This comment maintains that not recognizing the requirements mandated by another United States government regulatory framework could result in duplicative or contradictory standards and costs, with no additional public health benefit.

(Response) We are not aware of any federal regulatory programs that are duplicative of the produce safety regulation. We welcome pre-petition meetings to discuss any such regulatory programs and how the provisions of subpart P might apply.

(Comment 410) One comment expresses concern that although State-by-State variances can provide appropriate relief and recognition for localized alternate approaches, they can create a patchwork effect instead of uniform protection, especially if one State has the resources to pursue a variance and another does not. This comment suggests that a different approach to variances may be to take a regional approach for certain aspects of the rule, or to implement first only those portions of the rule that can be applied uniformly or consistently while options for addressing more variable aspects are explored. The comment provides, as an example, that risk-based modeling or system-wide approaches may be appropriate methods for assessing risk and conditions such as water quality, and that tested, safe, and common alternatives could be accommodated within the body of the rule as regional or condition-based standards, thus reducing the need for some variances.

(Response) FDA agrees that some variances may be appropriate on a regional basis, not just at a State level. As discussed previously, this subpart provides a variety of mechanisms for

applying some or all parts of a variance to other similarly situated persons, including to a region, rather than to a single State.

XXII. Subpart Q – Comments on Compliance and Enforcement

In the 2013 proposed rule, we outlined our overall strategy for implementation and compliance (78 FR 3504 at 3608-3609). In subpart Q of proposed part 112, we included certain proposed provisions regarding how the criteria and definitions in part 112 relate to the FD&C Act and the PHS Act, the consequences of failing to comply with this part, and coordination of education and enforcement. We asked for comment on the overall implementation and compliance strategy and proposed provisions in subpart Q, including specific strategies we should employ in order to best prioritize our implementation of the rule, and coordination of education and enforcement activities by relevant State, territorial, tribal, and local authorities.

We are finalizing these provisions with revisions (see Table 28). We discuss these changes in this section. We did not receive any comments or received only general comments in support of proposed § 112.191 and 112.192 and, therefore, we do not discuss final § 112.192 further.

Table 28.-- Description of Re-arrangement and Revisions to Subpart Q

Proposed Provision	Final Provision	Description of Revisions
§ 112.191	§ 112.192	- Revision to combine proposed §§ 112.191 and 112.192, all of which relate to the applicability and status of part 112, including the results of failures to comply with part 112, into one section.
§ 112.192		- Revision to include proposed § 112.191 as new provision § 112.192(b), along with revisions for clarity to separate the authorities cited from FD&C Act from that cited from the PHS Act.
§ 112.193	§ 112.193	- Revision to clarify that FDA coordinates education and enforcement activities by State, territorial, tribal, and local officials “by helping develop education, training, and enforcement approaches”

A. General Comments on Compliance and Enforcement Strategy

(Comment 411) Several comments ask for information on FDA’s compliance strategy. One comment urges that inspections, which the commenter feels will assure compliance and promote consumer confidence, should be the center of FDA’s core strategy. Noting FDA’s

limited resources, one comment encourages FDA to adopt a voluntary program, rather than require compliance with a regulation, and asserts that FDA should pursue meaningful relationships with producers in order to make the goal of the produce safety rule a reality. One comment asks FDA and other relevant agencies to ensure their implementation strategies include and are informed by community input. Another comment suggests that FDA's priority during the first several years after the regulation is finalized should be on education rather than enforcement.

(Response) During this rulemaking process, our FSMA implementation teams have been working concurrently on developing strategies and frameworks to operationalize the new FSMA prevention-focused food safety standards, including the produce safety rule. In May 2014, FDA published "Operational Strategy for Implementing the Food Safety Modernization Act (FSMA)" which describes guiding principles for FSMA implementation, including for the produce safety rule (Ref. 253). Stakeholder engagement is also central to operationalizing FSMA. FDA has engaged and sought input from the farming community and other stakeholders consistently throughout this rulemaking process. In addition, FDA held a public meeting on April 23-24, 2015 and opened a public docket to present our current thinking and gather stakeholder input on our operational work plans (Ref. 254) (Ref. 255). FDA intends to make the FSMA operational work plans public, once they are finalized.

FDA's implementation of the produce safety rule will entail a broad, collaborative effort to foster awareness and compliance through guidance, education, and technical assistance, coupled with accountability for compliance from multiple public and private sources, including FDA and partner agencies, USDA audits, marketing agreements, and private audits required by commercial purchasers. In keeping with this broad vision, FDA intends to focus its efforts on:

- Deploying a cadre of produce safety experts in headquarters and the field with the depth and breadth of capacity to develop the guidance needed to support implementation and provide technical support to government and industry parties working to foster compliance;
- Actively supporting education and technical assistance for farms, primarily through collaboration with other public and private parties;
- Supporting public and private parties involved in audits and other accountability functions with technical assistance and other collaborative support;
- Conducting targeted on-farm surveys and inspections to understand current practices and identify gaps in compliance;
- Taking administrative compliance and enforcement action when needed to correct problems that put consumers at risk;
- Responding to produce outbreaks effectively to lessen impact on public health; and
- Conducting in-depth environmental assessments where appropriate to identify root causes of outbreaks associated with produce and inform future prevention efforts.

FDA's inspection resources will be targeted based on risk. In addition to conducting its own inspections, FDA also plans to rely heavily on States to conduct a large proportion of the routine inspections on farms. Thus, inspection will play an important role in the overall compliance effort.

B. FDA Enforcement Decisions

(Comment 412) Several comments suggest specific criteria that FDA should use in determining how to respond to violations of this rule, such as whether the violation represents an "immediate public health risk," and whether the farm demonstrates a willingness and effort to

correct violations. Another comment requests that FDA be clear in explaining to farmers what is wrong to allow them to come into compliance. Some comments express concern about the potential impact of FDA's compliance and enforcement determinations on their business.

(Response) We intend to assess a farm's compliance with this rule on a case-by-case basis. In considering what action is appropriate, we are likely to consider factors including the severity of the violation, the willingness of the farmer to cooperate and take corrective actions, and the risk to public health. While many farms already follow some or all of the requirements in this regulation, we recognize that this is the first national standard for on-farm practices related to produce safety and that it will take time and a concerted, community-wide effort for the wide range of farms to come into full compliance. Under the FD&C Act, FDA has authority to inspect produce farms and can take enforcement action when appropriate. However, we realize that no food safety regime can provide complete assurance against the emergence of foodborne illness, and there might be circumstances in which the failure to prevent foodborne illness might not mean that the farm has violated the Produce Safety rule. See also our response to Comment 411 describing our implementation and enforcement strategy.

(Comment 413) One comment suggests that compliance with FSMA should be presumed for certain farms. The comment cites North Carolina Session Law 2013-265 (Senate Bill 63) (NC Farm Act of 2013) as providing protection to farmers by entitling them to "a rebuttable presumption that the commodity producer was not negligent when death or injury is proximately caused by consumption of the producer's raw agricultural commodity" under certain conditions.

(Response) We are aware that North Carolina has passed this law in their State, and that other States may choose to establish similar laws. However, State law tort duties are not relevant for purposes of this rule.

C. Coordination of Education and Enforcement (§ 112.193)

(Comment 414) Several comments address the degree to which FDA will enforce the rule, and the extent to which States will be involved. Several comments request clarification, including on the framework for coordination, timeline for inspection-related activities, expectations from State agencies, and securing necessary funds and resources. Several comments favor FDA working with State governments using existing established efforts, including State-industry educational and regulatory interfaces and assistance programs, as well as education and standards of current protocols developed by extension services, State departments, other farming good management practices, and local regulations. Several comments express a belief that such an approach would be most successful because State governments best know the realities of agricultural practices within their borders and often have an established history of successful inspection processes. Some comments express a preference for State agricultural agencies to be involved in compliance activities related to this rule, rather than other State agencies (such as health- or environmentally-oriented agencies), arguing that State agricultural agencies have a deep understanding of local agricultural practices and have developed strong working relationships with farmers. One comment notes some potential challenges with implementation by States, including that in some circumstances, State agencies lack the authority to enter farms. Some comments also express concerns related to resources necessary for States to conduct inspections.

(Response) As discussed previously, we are revising § 112.193 to clarify that FDA coordinates education and enforcement activities by State, territorial, tribal, and local officials by helping develop education, training, and enforcement approaches. FDA plans to work closely with States to implement the produce safety rule. We agree that our State counterparts have substantial knowledge about the farms in their jurisdiction. FDA intends to work collaboratively with our federal and State regulatory partners to use available inspection resources to conduct risk-based inspections of farms for compliance with this rule. Section 702(a)(1)(A) of the FD&C Act (21 U.S.C. 372(a)(1)(A)) expressly authorizes FDA to conduct examinations and investigations for the purposes of the FD&C Act through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof (such as a locality), duly commissioned to act on behalf of FDA. Qualified State, territorial, tribal, or local regulatory officials may be commissioned or serve under contract with FDA to conduct examinations, inspections, and investigations for purposes of the FD&C Act. In addition, section 702(a)(2) [21 U.S.C. 372(a)(2)] expressly authorizes FDA to conduct examinations and investigations for the purposes of the FD&C Act through officers and employees of another federal department or agency, subject to certain conditions set forth in that section. We expect to continue to cooperatively leverage the resources of federal, State, tribal, and local government agencies in this and other ways as we strive to obtain industry-wide compliance with this rule. We agree that FDA should leverage existing State programs when feasible. The roles of FDA and State partners are likely to vary based on the nature of the task and the State involved.

We have entered into a cooperative agreement with NASDA to obtain critical information related to implementation of this rule, in partnership with State regulatory agencies (Ref. 256). As part of the cooperative agreement, NASDA will conduct an assessment of the

current foundation of State law, the resources needed by States to implement this rule, as well as develop a timeline for successful implementation.

In addition, FDA anticipates that some States may choose to adopt requirements modeled after the provisions of this rule and may choose to perform inspections under their own authorities to enforce the provisions of their State laws. Such actions would further drive compliance with the produce safety standards in this rule.

(Comment 415) One comment notes that a State agency would not be the appropriate enforcement agency on tribal lands regarding food and water systems. This comment also states the final produce safety rule should include issuance of a tribal regulatory authority for training and implementation and limit the authority of State law enforcement officers on tribal lands, or exclude tribal lands altogether from State enforcement unless at the request of the tribe.

(Response) FDA recognizes the importance of engaging tribal regulatory authorities for successful FSMA implementation on tribal lands. FDA intends to work collaboratively with tribal regulatory partners to develop the appropriate education, enforcement, and training needed to facilitate compliance with the produce safety regulation on tribal lands (see FDA's recently released FSMA training strategy at www.fda.gov/fsma). We do not expect to use State officials to conduct inspections on FDA's behalf on tribal lands, but rather we intend to work with tribal authorities to commission tribal officials, as appropriate, to conduct these inspections.

(Comment 416) One comment requests adding to § 112.193 a list of entities, including State and federal partners, that will be working with FDA to implement the rule, as well as a timeframe for when operations will begin.

(Response) FDA declines to establish a list of partnerships in the regulatory text. Such partnerships may change over time. Similarly, our operations timeframes will depend on the specific operational strategies we adopt in various circumstances. We plan to make information on our FSMA operational work plans public as previously described in Comment 411.

D. On-Farm Inspections

(Comment 417) Several comments seek information about on-farm inspections. Some comments argue that, because farmers make the majority of their money in a relatively small period of time, inspectors should be sufficiently familiar with agricultural production, harvesting, and handling methods to minimize potential disruptions to the farm business, particularly when inspections occur at the peak of harvest season. In addition, some comments ask FDA to develop specific training modules to ensure consistency in inspections and inspectors' awareness of farming practices. Some comments also recommend that inspectors should have familiarity with acceptable on-farm practices taking into consideration the diversity of agricultural practices, conditions and commodities.

(Response) See our response to Comment 411, in which we discuss our expectation that inspections will play an important role in the overall compliance effort, along with a range of other public and private efforts ranging from education, training, and technical assistance to private third-party audits. We anticipate developing educational materials related to compliance and enforcement activities for produce safety. As discussed previously (in Comment 411 and Comment 414), FDA plans to collaborate with State and other partners in implementing the produce safety rule. Personnel performing farm inspections may include federal investigators, State inspectors, or other authorities, and will likely vary by State. In addition, FDA plans to

deploy a cadre of produce safety experts in headquarters and the field with the depth and breadth of capacity to support implementation and provide technical support to government and industry parties working to foster compliance.

We anticipate that FDA and State investigators, as well as other partners conducting inspections, will receive joint training and education, which will include refresher training as needed. FDA intends to work closely with State, local, territorial, and tribal partners to develop the tools and training programs needed to help implementation activities, including inspections, to be conducted consistently. We expect to build on our collaboration with State, local, territorial, and tribal officials in the development of tools and training for use by inspectors in farm investigations on issues specific to food safety during growing, harvest, packing and holding produce. Funding may be made available through various mechanisms, such as grant programs, to support inspector training.

(Comment 418) Some comments ask questions regarding when farms would be inspected and for what reasons. Some comments ask FDA to clarify whether or not FDA may inspect a farm without prior notice. One commenter believes all farm inspections should be “for-cause” only, and that Congress did not intend for FDA to routinely inspect farms.

(Response) FDA’s authority to conduct on-farm examinations and investigations for the purposes of the FD&C Act is not limited to for-cause situations and FDA is not required to give a farm prior notice of an inspection. As discussed in Comment 411, FDA intends to prioritize inspections based on risk. FDA intends to develop a work plan regarding routine farm inspections. FDA is exploring the possibility of pre-announcing at least some farm inspections;

however, there will likely be instances where a farm will not receive prior notice regarding an inspection.

E. Third-Party Audits, Inspections, and Other Arrangements

(Comment 419) One comment urges FDA to encourage retailers and other customers who require audits to minimize the number of individual audits and align the standards against which farms are audited with the standards in the produce safety regulation. The comment notes that such an approach will minimize the economic and operational burden created by multiple audits, especially on smaller operations.

(Response) FDA supports streamlining audit standards for efficiency and supports harmonizing existing industry standards with the requirements of this rule. We also recognize the value in industry's continued development of innovative and effective methods to ensure the production of safe foods.

(Comment 420) Several comments note the existence of third-party audits, stating that existing groups already conduct various farm audits. Some comments suggest that FDA should utilize these third-party audits as part of FDA's compliance strategy for this rule. Some comments ask FDA to "recognize" certain types of audits as sufficient for certain purposes.

(Response) FDA anticipates that significant incentives and accountability for compliance with this rule will come through third-party audits and supply chain management initiated by produce farms, their customers, or other private entities. As outlined in Comment 411, third-party audits are an important part of our overall compliance strategy. We believe it is important to have significant oversight of farms to ensure compliance with the rule. Thus, as a complement

to State and FDA inspections of farms, we intend to leverage the conduct of reliable third-party farm audits by USDA and others, as well as compliance with marketing agreements, with a goal of annual verification of farms that must comply with the rule.

In addition to audits conducted to meet buyer-specific criteria, a number of retail produce buyers currently require, as a condition of sale, that their produce suppliers comply with and be audited by third parties for conformance with the GAPs guide, USDA GAP and GHPs, CA LGMA and AZ LGMA standards, and other voluntary programs. Whether conducted under such programs or in response to specific buyer demands, adequately rigorous and reliable private audits can be an important additional tool for fostering food safety and ultimately compliance with this rule. We note further that private audits may be relevant to some aspects of compliance with the supplier verification requirements in the FSVP and preventive controls regulations, where a farm supplies produce to an importer or receiving facility that seeks to verify that the farm has adequately controlled applicable hazards.

We intend to pursue the goal of making third-party audits an important part of our compliance strategy by building on current private audit activity and by working with the produce industry and other government and private partners to improve the rigor and reliability of private audits. We believe that strengthening both the quality and credibility of private audits will help improve food safety, especially if conducted on the basis of the standards in this rule, but it can also be the basis for streamlining current audit practices and making them more efficient. Potentially, a single annual audit that is recognized to be a rigorous and reliable means of verifying compliance with this rule could substitute for multiple audits conducted under disparate standards with less well-established credibility. We seek public-private collaboration to achieve this goal.

We also note that in the final third-party certification rule (published elsewhere in this issue of the Federal Register), FDA is establishing a voluntary program for the accreditation of third-party certification bodies that may conduct audits and issue certifications for purposes of establishing an entity's eligibility to participate in VQIP or to satisfy conditions set forth under section 801(q) of the FD&C Act.

FDA is not recognizing any auditing body in this produce safety rulemaking.

(Comment 421) Some comments recommend that FDA should both permit the use of any government-approved inspector or inspection service and also require farms' customers to accept certification or approval by any such approved inspector or service. The commenters believe that this step is necessary to protect farms from having to pay large fees to private companies.

(Response) It is beyond the scope of this rule to require that entities in a supply chain accept certifications or approvals provided by third-party inspection services for other entities in the supply chain. To the extent that the comments request that FDA allow farms to undergo inspections or audits, nothing in this rule prohibits such use of inspection or auditing services.

(Comment 422) One comment suggests that, where FDA has systems recognition arrangements with foreign governments, importers who import produce from such countries should be subject to lesser requirements than they otherwise would be, and FDA should not inspect covered farms from that country.

(Response) As discussed previously (see our response to Comment 408), systems recognition involves an intensive and extensive review of key aspects of a country's overall food safety control system. The comment addresses the requirements applicable to an importer when

there is a systems recognition arrangement. Requirements for importers are outside the scope of this produce safety rule. FDA addresses requirements applicable to importers who import food from countries whose food safety systems FDA has officially recognized as comparable or equivalent in the final FSVP rule (published elsewhere in this issue of the Federal Register).

This comment also addresses FDA inspections of covered farms in countries with which FDA has systems recognition arrangements. Ideally, FDA's systems recognition of a food control system should include a successful assessment of its produce production practices. We note that FDA's pilot systems recognition activities pre-date FSMA, and FDA is currently refining the program to ensure alignment, where appropriate, with FSMA. While all systems recognition assessments have followed a similar process, each assessment varies in scope of the review for oversight of specific products. In the future, FDA will likely consider including additional consideration for produce standards, oversight, and production practices particularly with respect to the country's practices and oversight regarding the specific provision(s) in part 112 in its systems recognition assessments. Further, systems recognition does not mean that no oversight of produce from such a country is warranted; therefore, it would not be appropriate to state that farms in countries with systems recognition are not subject to FDA inspection. It is also premature at this point to determine whether or how existing or future systems recognition arrangements may affect our inspections of foreign farms.

XXIII. Subpart R – Comments on Withdrawal of Qualified Exemption

In the 2013 proposed rule, under subpart R of proposed part 112, we proposed to establish the procedures that would govern the circumstances and process whereby we may issue an order withdrawing a qualified exemption applicable to a farm in accordance with the requirements of proposed § 112.5. Specifically, proposed § 112.201 listed the circumstances under which FDA may withdraw a qualified exemption applicable to a farm, while §§ 112.202 and 112.203 specified the procedure and information that FDA would include in an order to withdraw such qualified exemption. In addition, proposed §§ 112.204 through 112.207 provided for a process whereby you may submit a written appeal (which may include a request for a hearing) of an order to withdraw a qualified exemption applicable to your farm, and proposed §§ 112.208 through 112.211 provided a procedure for appeals, hearings, and decisions on appeals and hearings. We discussed each of the proposed provisions and explained our rationale (78 FR 3504 at 3611 through 3616). We requested public comment on our proposed provisions, including on related process and timeframes for actions to be taken by FDA and covered farms.

In the supplemental notice, in part, taking into account public comment on the 2013 proposed rule, we proposed certain amendments to §§ 112.201 and 112.202 related to the circumstances under which FDA may withdraw a qualified exemption and the procedure for issuing an order to withdraw a qualified exemption; and added a new proposed provision § 112.213 to list the circumstances under which FDA would reinstate a farm's qualified exemption that is withdrawn. We asked for public comment on our new and amended proposed provisions (79 FR 58434 at 58464-58467).

In this section of this document we discuss comments that we received on the withdrawal provisions in the 2013 proposed rule, but that we did not address in the supplemental notice. We

also discuss comments that we received on the new and amended proposed withdrawal provisions in the supplemental notice.

We are finalizing the provisions in subpart R with revisions (see Table 29). We discuss these changes in this section. For §§ 112.202, 112.209, 112.210, and 112.211, we did not receive any comments or received only general comments in support of the proposed provision and, therefore, we do not specifically discuss these provisions further.

Table 29.-- Description of Revisions to Subpart R

Final Provision	Description of Revisions
§ 112.201(b)(2)	- Revision to allow 15 calendar days from the date of receipt of an order to withdraw a qualified exemption, for a farm to respond in writing to our notification
§ 112.202	- Editorial change to insert the word “either” in § 112.202(a)
§ 112.203(c)	- Editorial changes to clarify that the order will specify which of two circumstances that may lead FDA to withdraw a qualified exemption apply, or whether both of these two circumstances apply
§ 112.203(d)	- Revision to require that the contents of an order must include a statement that the farm must either comply with or appeal the order - Revision to require compliance with an order to withdraw a qualified exemption within 120 days of the date of receipt of the order, consistent with the timeline in the PCHF regulation; and corresponding changes to §§ 112.204(a) and 112.205(b)
§ 112.203(e)	- Include a statement informing the farm that it may ask us to reinstate an exemption that was withdrawn by following the procedures in § 112.213
§ 112.204(b)	- Revision to require that a farm may request an informal hearing by submitting a written appeal within 15 calendar days from the date of receipt of the order; and corresponding changes to §§ 112.206(a)(1) and 112.207(a)(2)
§ 112.205(b)(2)	- Specifies that a farm that loses its qualified exemption would no longer need to comply with the modified requirements in §§ 112.6 and 112.7
§ 112.208(a)	- Revision to allow for the hearing to be held within 15 calendar days after the date the appeal is filed
§ 112.213(a)	- Editorial change to replace the word “shall” with “will”

A. Circumstances That May Lead FDA to Withdraw a Farm’s Qualified Exemption (§ 112.201)

(Comment 423) Some comments agree with the proposed provisions regarding certain actions we may take, and other actions we must take, before issuing an order to withdraw a

qualified exemption. For example, some comments agree that other regulatory actions should be considered before withdrawing a qualified exemption, and some comments agree that it is appropriate to assess corrective actions taken by a farm in response to a food safety problem when considering whether to withdraw its exemption. Some comments recommend revising the wording in § 112.201(b)(1) from “may consider” to “shall take” thus requiring FDA to take alternative actions prior to withdrawing a qualified exemption. Other comments agree that these provisions are reasonable and will provide farms due process and greater clarity on the withdrawal process, but suggest that we could issue guidance rather than include these provisions in the rule to allow us greater flexibility should we have to act quickly to protect the public health.

Other comments disagree with these proposed provisions and ask us to delete them from the final rule. These comments assert that FSMA does not require us to describe the actions that we may take prior to withdrawing a qualified exemption and that it is not necessary to do so because it is customary for us to work with regulated industry to address problems before taking enforcement actions. These comments also express concern that listing possible regulatory actions before we would issue an order to withdraw a qualified exemption could create an expectation that we will always exercise such regulatory actions before issuing the order. These comments also express concern that being bound by these provisions could prevent us from acting quickly to protect public health.

(Response) We are retaining the provisions regarding certain actions we may take, and other actions we must take, before issuing an order to withdraw a qualified exemption. We agree that it is customary for us to work with industry to address problems before taking enforcement actions but disagree that specifying this customary practice in the rule would prevent us from acting

quickly to protect public health. We consider that issuing an order to withdraw an exemption would be a rare event, in part because alternative actions such as those described in these provisions may provide a more expeditious approach to correcting a problem than withdrawing an exemption. We also disagree that the rule binds us to take alternative regulatory action before issuing an order to withdraw a qualified exemption, other than to notify the farm in writing of circumstances that may lead us to withdraw the exemption, provide an opportunity for the farm to respond in writing, and consider the actions taken by the farm to address the circumstances we describe. The rule clearly specifies that regulatory actions such as a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction are actions that we “may” (not “must”) take before issuing an order to withdraw a qualified exemption. Providing the farm with an opportunity to correct the problems before we take steps to withdraw an exemption has the potential to save agency resources associated with preparing an order, responding to an appeal of the order and request for a hearing, and administering a hearing. Directing resources to help a farm to correct problems, rather than to administer a withdrawal process that could be resolved by the time of a hearing, is appropriate public health policy.

(Comment 424) Some comments ask us to specify that the notification of circumstances that may lead FDA to withdraw the exemption must include facts specific to the situation and information about how the farm can remedy the situation.

(Response) By specifying that we must notify the farm of circumstances that may lead us to withdraw an exemption, we mean that we would include facts specific to the situation. It is the responsibility of the farm, not FDA, to remedy the situation.

(Comment 425) Some comments recommend that both the initial notice of intent to withdraw and the withdrawal order itself should be based on an individualized, case-by-case determination, and should not apply to a group or class of farms.

(Response) The decision to withdraw a qualified exemption is an individualized determination and will not be applied to a class of farms or farmers.

(Comment 426) Some comments ask us to provide additional time for a farm to respond, in writing, to a notification of circumstances that may lead us to withdraw its qualified exemption. Some of these comments request timeframes such as 2 weeks or 90 days for a farm to compile information and documentation of facts and to respond to FDA's notification.

(Response) We are revising § 112.201(b)(2) to provide for 15 calendar days, rather than 10 calendar days, for a farm to respond in writing to our notification. The 15-day timeframe is the same as the timeframe for responding to a warning letter. Circumstances that could lead us to withdraw a qualified exemption require prompt action on the part of a farm, just as circumstances that lead us to issue a warning letter require prompt action.

(Comment 427) Several comments request that FDA notify the appropriate State regulatory agency before a farm's qualified exemption is withdrawn or reinstated.

(Response) We decline this request. We are sensitive to the time required for various inspection activities and intend to communicate with States regarding our expectations for how to verify whether a farm meets the criteria for a qualified exemption. The qualified exemption status of a farm principally affects the requirements that it is subject to, and will be most useful to FDA and our food safety partners when preparing for inspection. At this time, we do not

intend to establish a system notifying the applicable State authorities at a point in time when the qualified exemption status of a farm changes, whether as a result of withdrawal or reinstatement of the farm's qualified exemption or because the farm's business has grown to the point where it exceeds the criteria that must be met for a farm to be eligible for a qualified exemption.

B. Contents of an Order to Withdraw a Qualified Exemption (§ 112.203)

(Comment 428) Some comments recommend that the order specify which of the two circumstances (§ 112.201(a)(1) or § 112.201(a)(2)) that could lead us to issue the order apply.

(Response) We have made editorial changes to the regulatory text to make it more clear that the proposed provision to require us to include a brief, general statement of the reasons for the order, including information relevant to (1) an active investigation of a foodborne illness outbreak that is directly linked to the farm; or (2) conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm, should specify which of these two circumstances apply, or whether both of these two circumstances apply. See the revised regulatory text for § 112.203(c).

(Comment 429) Several comments recommend that the written order withdrawing the qualified exemption should include a detailed description of the substantial, science-based evidence FDA has to support its finding for withdrawal of a qualified exemption, rather than a brief, general description, as described in § 112.203(c). Comments argue that a brief, general description supporting the order to withdraw a qualified exemption is not sufficient to allow the

farmer to adequately respond to the order or prepare for an appeal hearing. Comments also contend that FDA must be required to clearly and specifically identify the “material conduct or conditions associated with the farm that are material to the safety of the food” regulated under this rule. In addition, some comments assert that “material conditions” should be based on scientifically measureable traits that can be clearly identified as occurring on the individual farm and/or should be limited to conditions within the farm’s control. Some comments recommend that we require FDA to meet an explicit evidentiary threshold to find that conduct or conditions exist on a farm sufficient to warrant withdrawal of the farm’s exemption.

(Response) We agree that the order must provide sufficient information to enable a farm to respond with particularity to specific evidence about the circumstances leading to the order. However, we disagree that the order must do so by including the specific information recommended by the comments, or that we should include an explicit evidentiary threshold, and we have not revised the proposed withdrawal provisions to incorporate the suggestions of these comments. A number of these comments appear to be more focused on whether the circumstances that lead us to issue an order meet an evidentiary standard than on explaining the problem so that a farm can both understand the problem and respond with particularity to the facts and issues contained in the order. The withdrawal provisions that we are establishing in this provision require the order to include a brief, general statement of the reasons for the order, including information relevant to: (1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or (2) conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm. The requirements that we are establishing in this provision would enable the farm to understand the problem, have a dialogue with us as appropriate, and

respond to the problem. In addition, we intend that the process of responding to the notification that we must send before issuing an order to withdraw a qualified exemption, including discussing the problems with FDA as warranted, would provide additional information to the farm to enable the farm to both understand the problem and respond to it. Also, as discussed in Comment 184 and Comment 186, conditions that are not within a farm's control may be material to the safety of the produce grown on that farm, and this rule includes certain provisions requiring covered farms to consider certain conditions that may not be under the farm's control as an important part of minimizing the risks presented by such conditions.

(Comment 430) Some comments suggest that FDA should require confirmation of the delivery and receipt of the withdrawal order by the farm, such as through certified mail.

(Response) We are not specifying that we send an order in a way that ensures its receipt. Although certified mail with confirmation of delivery is one way to ensure receipt, other methods are available, including delivery through private carriers that provide mechanisms to document receipt. FDA will likely use one of these methods to document receipt. In light of the provisions in § 112.203, 112.204, 112.205, 112.206, and 112.207 linking the timeframes for you to comply with, or appeal, an order to the date of receipt of the order (rather than to the date of the order) (see our responses to Comment 433 and Comment 434), it will be up to us to deliver the order in a way that provides us with evidence of receipt.

(Comment 431) Some comments ask us to include in the order a statement that a farm may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 112.213.

(Response) We are revising the requirements for the contents of an order as requested by these comments (see § 112.203(e)).

(Comment 432) One comment recommends that the order specify the two options that a farm has upon receipt of the order, similar to the withdrawal provisions in proposed 117.257(d) in the proposed human preventive controls rule.

(Response) We agree that it would be useful for the order to itself specify the two options that a farm has upon receipt of the order, even though the order would otherwise include this information (because the order will contain the full text of the withdrawal provisions under § 112.203(f)). In § 112.203(d), we are requiring that the contents of an order must include a statement that the farm must either comply with or appeal the order.

C. Compliance With, or Appeal of, an Order to Withdraw a Qualified Exemption (§§ 112.204, 112.205, and 112.206)

(Comment 433) Several comments express that 60 calendar days in proposed § 112.204(a) is not sufficient time for a farm to comply with an order withdrawing its qualified exemption. Several comments recommend revising proposed §§ 112.203(d) and 112.204(a) to require compliance within 120 days of the date of receipt of the order, consistent with the parallel timeline in part 117. Other comments ask for 1 or 2 years to comply. Some comments also suggest that the timelines in both rules should be based on working or business days rather than on calendar days. Other comments ask us to consider provisions that would require compliance with only those portions of the rule that formed the basis for the revocation.

(Response) As in the case of facilities subject to the PCHF regulation, we conclude that

the nature of what a farm would need to do to comply with an order—i.e., comply with the full requirements for minimum science-based standards established in the produce safety regulation—makes the 60-day timeframe in the 2013 proposed withdrawal provisions insufficient. However, it is relevant that in contrast to the general compliance dates, the withdrawal provisions would only apply when a significant public health concern has been identified for a particular farm.

We are revising §§ 112.203(d), 112.204(a), and 112.205(b) to require compliance within 120 days of the date of receipt of the order, consistent with the parallel timeline in part 117. We believe that the 120-day timeframe is adequate, but we are adding flexibility such that a farm may request, with a justification in writing to FDA, a reasonable timeframe for compliance that exceeds 120 calendar days from the date of receipt of the order. FDA must grant the request for the farm to receive the extended timeframe. We are not generally extending the timeframe because circumstances that could lead us to withdraw a farm's qualified exemption require prompt action on the part of the farm. A farm that receives an order to withdraw its qualified exemption would have received advance notification of the circumstances leading to the order and would have had an opportunity to correct the problems rather than have us proceed to issue the order (see § 112.201(b)). If the farm requests a hearing, more than 40 days could elapse between the date that the farm receives the order and the date that the presiding officer for the hearing confirms the order to withdraw the exemption. Given that the circumstances that would lead us to issue the order involve either (1) an active investigation of a foodborne illness outbreak that is directly linked to the farm; or (2) a determination that withdrawal of the exemption is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with

the farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm, a delay of one to two years to comply with the rule is not warranted.

We also do not believe that it would be appropriate to require a farm to come into compliance with only those provisions that formed the basis of the revocation. The provisions of subparts B through O are interrelated and operate as a system and, therefore, are not optimized through piecemeal implementation. However, FDA may consider staggered implementation as an option in granting a request for an extension of the timeframe to comply with an order to withdraw the qualified exemption for a farm.

We also conclude that it is appropriate to link the timeframe for compliance to the date of receipt of the order, rather than to the date the order was issued. Doing so would be consistent with our other administrative procedures, such as appeal of an order for administrative detention (21 CFR 1.402).

In the supplemental notice, we acknowledged the difference in our proposed timelines for compliance when a qualified exemption is withdrawn between the PCHF and produce safety regulations (79 FR 58434 at 58467). We have made the administrative procedures associated with the withdrawal of a qualified exemption consistent to the extent practicable, and are revising the withdrawal provisions to require that a covered farm comply with an order to withdraw an exemption within 120 calendar days of the date of receipt of the order. See the revised regulatory text in provisions §§ 112.203(d), 112.204(a), and 112.205(b).

For clarification, we are specifying, in new § 112.205(b)(2), that a farm that loses its qualified exemption would no longer need to comply with the modified requirements in §§ 112.6 and 112.7. This revision is also consistent with provisions in the PCHF regulation.

(Comment 434) Several comments request longer than the proposed 10 calendar days to file a written appeal of the order of withdrawal of the qualified exemption. Comments cite various reasons, including possible issues in mail delivery such that the farmer would have less than 10 calendar days, potential need for legal counsel, and time needed to gather evidence. Some comments ask us to provide 15 business days from date of receipt of the order for the farm to appeal the order.

(Response) We have revised the timeframe for compliance with the rule to the date of receipt of an order to withdraw a qualified exemption (see our response to Comment 433). Likewise, we conclude that it is appropriate to link the timeframe for submitting a written appeal of a withdrawal order to the date of receipt of the order, rather than to the date the order was issued. Doing so would be consistent with our other administrative procedures, such as appeal of an order for administrative detention (21 CFR 1.402). Accordingly, we are revising the withdrawal provisions to require that a covered farm may request an informal hearing by submitting a written appeal in accordance with § 112.206 within 15 calendar days from the date of receipt of the order. See the revised regulatory text in provisions §§ 112.204(b), 112.206(a)(1), and 112.207(a)(2). We are also revising § 112.201(b)(2) to provide for 15 calendar days from the date of receipt of the order for a farm to respond in writing to FDA's notification. We are also extending the timeframe for the hearing to be held within 15 calendar days, rather than the proposed 10 calendar days, after the date the appeal is filed to provide more time for the farm to prepare for the hearing (see § 112.208(a)). The timeframe for the hearing to be held continues to provide for an alternative timeframe agreed upon in writing by both the farm

and FDA; a farm that would have preferred the proposed timeframe of 10 calendar days could request that the hearing be held more quickly than 15 calendar days.

The 15-day timeframe is the same as the timeframe for responding to a warning letter. As discussed in Comment 423, circumstances that could lead us to withdraw a qualified exemption require prompt action on the part of a farm, just as circumstances that lead us to issue a warning letter require prompt action.

D. Procedure for Requesting an Informal Hearing (§ 112.207)

(Comment 435) Some comments ask us to guarantee a hearing so that a farm can present its case in person before having its qualified exemption revoked.

(Response) We decline this request. We agree that a farm has a right to appeal an order to withdraw its qualified exemption, and we have provided for a right to appeal.

E. Informal Hearing (§ 112.208)

(Comment 436) One comment states that the two-day time period to review and respond to the presiding officer's report is not sufficient.

(Response) We decline this request. Circumstances that could lead us to withdraw a farm's qualified exemption require prompt action on the part of the farm, and we conclude that two calendar days is a reasonable timeframe, should the farm choose to review and comment on the presiding officer's report.

(Comment 437) Some comments object to our proposal that no party shall have the right, under 21 CFR 16.119, to petition FDA for reconsideration or a stay of the presiding officer's

final decision, and ask us to revise proposed § 112.208(c)(6) to specify that a farm with a qualified exemption shall have the right to file a motion for reconsideration or stay. These comments find insufficient our rationale that the circumstances that would lead to a withdrawal merit prompt action and that a farm has the opportunity for judicial review in accordance with 21 CFR 10.45.

(Response) We decline this request. In § 112.201(b), we are providing an additional mechanism for a farm with a qualified exemption to present its view that its exemption should not be withdrawn – i.e., by providing advance written notification to the farm if we are considering withdrawing an exemption and providing an opportunity for the farm to respond before we issue an order to withdraw an exemption. In addition, in § 112.213, we are providing an opportunity for reinstatement of a qualified exemption that had been withdrawn. We believe the multiple opportunities now available to a farm provide adequate opportunities for the farm’s views to be considered, and further mechanisms are not warranted.

F. Circumstances Related to Reinstatement of a Qualified Exemption That is Withdrawn (§ 112.213)

(Comment 438) Some comments agree with our tentative conclusion that the absence of a specific provision in section 418 of the FD&C Act for the reinstatement of an exemption that is withdrawn does not preclude us from providing for such a process (79 FR 58434 at 58466). Other comments disagree with that tentative conclusion and assert that Congress crafted the withdrawal provision as a “one strike, you’re out” provision. These comments also assert that including the withdrawal provision as a “one strike, you’re out” provision was an essential part of the legislative agreement that allowed for adoption of the qualified exemption of a farm. These

comments also assert that reinstatement would undermine the intent of the withdrawal provision, because it would reduce the incentive for small farms to ensure that the produce they sell is as safe as possible. These comments also assert that a recognized principle of statutory interpretation provides that exemptions to statutes should be strictly construed, particularly when the statute addresses public health and safety, and that FDA is giving the exemption an impermissibly broad construction.

Some comments ask why we believe that a farm deserves a “second bite of the apple” in light of the understanding (under proposed § 112.201(b)) that we will first seek to correct problems before considering withdrawal. These comments also question at what point a farm would apply for reinstatement, and ask why we would allow a farm that has already come into compliance with FSMA’s requirement to implement produce safety standards to abandon those measures in favor of reinstating its exempt status. These comments ask us to eliminate the proposed provisions allowing for reinstatement.

Some comments do not support the proposed reinstatement provisions when a farm has been directly linked to a foodborne illness outbreak. Some comments support the proposed reinstatement provisions only when we determine, after finishing an active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to the farm that had its exemption withdrawn.

(Response) We disagree that the proposed reinstatement provisions would give the exemption an impermissibly broad construction. The express statutory language of section 419(f) of the FD&C Act does not support the comments’ assertion that the withdrawal provision is a “one strike, you’re out” provision. We also disagree that reinstatement would undermine the intent of the withdrawal provision in that it would reduce the incentive for small

farms to ensure that the produce they sell is as safe as possible. We proposed that a farm would need to present data and information to demonstrate that it has adequately resolved the problems with the conduct or conditions that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at the farm, such that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak. In contrast to the assertion of the comments, we believe that the opportunity for reinstatement would be an incentive – not a disincentive – for farms that are eligible for a qualified exemption to ensure that the produce they sell is safe by continuing to adhere to procedures and practices that it develops to comply with the rule. For example, if a farm had to implement the provisions of the rule after having its exemption withdrawn and realized through testing to comply with the water provisions that it needed to apply a day of die-off in field before harvesting to come into compliance with the water standard, then the farm would likely continue to apply the die-off and delay harvesting by a day even after the exemption was reinstated. The farm would likely realize that if it did not continue to conduct activities that improve the safety of its produce that it might have a repeat food safety issue.

We disagree that we should categorically refuse to consider reinstating a qualified exemption if we had withdrawn the exemption because a farm had been directly linked to a foodborne illness outbreak. First, if information later comes to light to raise considerable doubt that a farm with a qualified exemption had, indeed, been directly linked to a foodborne illness outbreak, and conduct and conditions at the farm do not otherwise warrant withdrawing the farm's exemption, it would be appropriate for us to reinstate the farm's exemption. Second, as already discussed in this response, we consider the reinstatement provisions to be an incentive for a farm to continue adhering to procedures and practices that it develops to comply with the

rule.

(Comment 439) Some comments that support the reinstatement of a withdrawn exemption ask us to establish a timeframe within which FDA will reinstate an exemption. Some comments ask us to specify in the regulatory text that the reinstatement would occur in a reasonable period of time, both in circumstances where FDA has decided on its own initiative to reinstate the exemption and in circumstances where a farm submits a request for reinstatement. Some comments suggest 10 days is a reasonable period of time within which FDA should reinstate an exemption.

(Response) We decline the requests to establish a timeframe for reinstatement in the regulatory text. If we determine on our own initiative to reinstate an exemption (e.g., because we later determine, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to the farm), our determination would be effective immediately. If we receive a request to reinstate a withdrawn exemption, we intend to respond in a reasonable time frame consistent with available resources. In some cases, we may respond that we need more information in order to evaluate your request.

(Comment 440) Some comments ask us to establish a 1-year probationary period before the withdrawn qualified exemption of a farm could be fully reinstated.

(Response) We decline this request. We intend to act on a request for reinstatement based on the merits of the data and information presented in the request, not after a pre-determined timeframe.

(Comment 441) One comment believes that the word “will” in proposed § 112.213(c) implies discretion where none is warranted, and suggests changing it to “shall” consistent with 112.213(a).

(Response) We decline this request. Instead, we are replacing the word “shall” with “will” in § 112.213(a) to be consistent with § 112.213(c), in the interest of using plain language in drafting regulations.

G. Other Comments

(Comment 442) Several comments ask us to provide clarification through guidance, issued for public comment, on a variety of topics associated with the withdrawal provisions, including on science-based standards that FDA would use when making the final decision to either approve or deny an order to withdraw a qualified exemption, and the conduct, conditions, or activities that would trigger FDA’s actions toward withdrawal.

(Response) We will consider the need for guidance in the future. At this time, we consider that withdrawing a qualified exemption of a farm would be both rare and dependent upon the circumstances. We need to direct our resources to developing guidance on issues that would apply more broadly, and more generally, than the withdrawal provisions.

H. Conforming Amendment to 21 CFR Part 16

We proposed to amend § 16.1(b)(2) to include part 112, subpart R, relating to the withdrawal of a qualified exemption applicable to a farm, to the list of regulatory provisions under which regulatory hearings are available. We received no comments that disagreed with this proposed provision, and we are finalizing it as proposed.

XXIV. Comments on Effective and Compliance Dates

A. Effective and Compliance Dates for Part 112

In the 2013 proposed rule, we proposed that any final rule based on proposed part 112 would become effective 60 days after its date of publication in the Federal Register, with staggered compliance dates based on size of the farm. In addition, for certain specified proposed requirements related to agricultural water, we proposed the compliance dates would be 2 years beyond the compliance date for the rest of the final rule applicable to the farm based on its size.

Most comments generally support our proposed staggered compliance periods based on farm size as well as the extended compliance period for the specified water provisions, although some comments suggest further extensions whereas others find the proposed compliance periods too long. In this section, we discuss comments that express concern with the proposed compliance periods, suggest extensions to the proposed compliance dates, and/or ask us to clarify how the compliance dates will apply.

After considering comments, we are finalizing the effective date as proposed, i.e., 60 days after the publication of this rule. As shown in Table 30, we are establishing three sets of compliance dates, all of which vary based on size of the farm: one for covered activities involving sprouts covered under subpart M, which are subject to all of part 112; another for covered activities involving all other produce, which are subject to part 112 except subpart M; and another for modified requirements relating to the qualified exemption. In the second set of compliance dates, we are also providing extended compliance dates for certain specified requirements related to agricultural water. In the compliance dates relating to the qualified exemption, the compliance date for the records that a farm is required by § 112.7(b) to maintain to support its eligibility for the qualified exemption (e.g., sales receipts and other records as

applicable) is the effective date of this rule, i.e., [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER DATE]. Farms need not comply with the requirement for a written record reflecting that the farm has performed an annual review and verification of continued eligibility for the qualified exemption until the farm’s general compliance date, however. In addition, we are establishing January 1, 2020, as the compliance date for the modified requirement in § 112.6(b)(1).

Table 30.-- Compliance Dates

Size of covered farm	Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of part 112)	Covered activities involving all other covered produce (i.e., subject to part 112, except subpart M)		Farms eligible for a qualified exemption (if applicable)		
		Compliance date for certain specified agricultural water requirements	Compliance date for all other requirements	Compliance date for retention of records supporting eligibility in § 112.7(b)	Compliance date for modified requirement in § 112.6(b)(1)	Compliance date for all other requirements in §§ 112.6 and 112.7
Time periods starting from the effective date of this rule						
Very small business	3 years	6 years	4 years	Effective date of rule	January 1, 2020	4 years
Small business	2 years	5 years	3 years			3 years
All other businesses	1 year	4 years	2 years			N/A

(Comment 443) Some comments state the proposed compliance periods are too long and fail to protect public health. One such comment suggests we increase efforts to provide technical assistance, particularly to small and very small farms to help implement the rule, and decrease the length of compliance periods. Another comment suggests not delaying compliance period for the standards directed to worker health and hygiene because the commenter believes farms already implement those provisions to comply with other government regulations.

Conversely, some other comments find the proposed compliance periods unrealistic given, according to these commenters, the significant scope and number of changes required and

associated potential costs. One comment states implementation of the rule will require substantial investment and covered farms in its country will need additional time to comply with the rule. This comment suggests ten years as the compliance period for the water provisions and a minimum of four to six years for the remaining provisions.

Still other comments maintain we should apply a uniform 5-year compliance period for all covered farms, instead of the proposed staggered compliance periods based on farm sizes. These comments argue having different compliance dates for different covered farms will be confusing and difficult to manage across different entities in the produce supply chain.

(Response) We intend to prioritize our compliance and enforcement efforts. The purpose of tiered compliance dates is to give businesses of various sizes time to come into compliance with the rule technically, financially, and operationally. FDA and food safety partners will be targeting education and outreach efforts to smaller businesses that may not be as familiar with our requirements as some of the larger farms.

We conducted extensive stakeholder outreach during the 10-month comment period for the 2013 proposed rule. We also provided public notice about proposed changes to the farm-related definitions that affect the determination of whether a farm is subject to this rule or the PCHF regulation, and about specific potential requirements for agricultural water. We conducted outreach activities to discuss the new and amended proposed provisions in the supplemental notice (see section I.E of this document). In addition, we have been collaborating with relevant stakeholders to support the development of necessary training materials (see section XI of this document) as well as research in the areas of agricultural water and raw manure (see sections XIII and XIV, respectively, of this document). In light of the extensive outreach associated with this rulemaking, we disagree that farms will need more than the established compliance periods

(including the extended compliance periods for certain water provisions for covered activities involving covered produce (except sprouts covered under subpart M)) to fully adapt their programs to the specific requirements of this rule.

We disagree that we should establish a uniform compliance period across all farm sizes. Rather, these compliance periods provide an appropriate balance between public health protection and flexibility, in light of practical considerations for small and very small businesses. Moreover, the extended compliance periods for certain specified water provisions are intended to help businesses to develop the necessary expertise to implement the specified water requirements, and to consider appropriate alternatives and develop adequate scientific data or information necessary to support the use of that alternative.

1. Effective Date

Under this rule, the effective date is 60 days after the date of publication of this rule in the Federal Register.

2. Compliance Dates for Covered Activities Involving Sprouts Covered Under Subpart M

For covered activities involving sprouts covered under subpart M (i.e., all requirements of part 112 apply), the compliance dates are as follows: (1) 3 years from the effective date for covered farms that are very small businesses; (2) 2 years from the effective date for covered farms that are small businesses; and (3) 1 year from the effective date for all other covered farms. As discussed in section XVIII.J of this document, we conclude these compliance periods are appropriate for covered activities involving sprouts covered under subpart M, to protect public health. We are also not providing extended compliance dates related to certain water

requirements. Therefore, the one-to-three year compliance period applicable to the farm based on its size applies for compliance with all requirements of part 112.

3. Compliance Dates for Covered Activities Involving All Other Covered Produce

For covered activities involving all other covered produce (i.e., except sprouts covered under subpart M) (i.e., requirements of part 112 except those of subpart M apply), the compliance dates are as follows: (1) 4 years from the effective date (with the exception of compliance with certain requirements in subpart E, as discussed in the paragraphs that follow)) for covered farms that are very small businesses; (2) 3 years from the effective date (with the exception of compliance with certain requirements in subpart E, as discussed in the paragraphs that follow) for covered farms that are small businesses; and (3) 2 years from the effective date (with the exception of compliance with certain requirements in subpart E, as discussed in the paragraphs that follow) for all other covered farms. In addition, for covered activities involving covered produce (except sprouts covered under subpart M), we are providing the additional flexibility of extended compliance dates for certain water-related requirements. As discussed in section XIII.K of this document, the compliance period for the following requirements is 2 years beyond the compliance date for the rest of this rule applicable to the farm based on its size: §§ 112.44, 112.45, 112.46 (except § 112.46(a) and (b)(1)), 112.50(b)(5), 112.50(b)(6), 112.50(b)(7), and 112.50(b)(8). Accordingly, for these specified requirements, the compliance period is 6 years from the effective date for covered farms that are very small businesses, 5 years from the effective date for covered farms that are small businesses, and 4 years from the effective date for all other covered farms.

4. Compliance Dates for Farms Engaged in Covered Activities Involving Sprouts Covered Under Subpart M as Well as Other Covered Produce

For those covered farms that may be engaged in covered activities involving both sprouts covered under subpart M as well as other covered produce, both sets of compliance dates will apply depending on the produce involved in the covered activity. For those aspects of your operation relating to covered activities involving sprouts covered under subpart M, the compliance dates ranging from 1 to 3 years (based on size of your farm) will apply, and for other aspects of your operation relating to covered activities involving all other covered produce, the compliance dates ranging from 2 to 4 years (based on size of the farm) as well as the extended compliance dates ranging from 4 to 6 years (based on size of the farm) for certain specified water requirements will apply.

5. Compliance Dates Applicable to Farms Eligible for a Qualified Exemption

We are establishing three additional compliance dates applicable to farms eligible for a qualified exemption. First, as explained in section IX.C.7 of this document, the compliance date for the records that a farm maintains to support its eligibility for a qualified exemption in accordance with §§ 112.5 and 112.7 is the effective date of this rule, i.e., [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Farms need not comply with the requirement for a written record reflecting that the farm has performed an annual review and verification of continued eligibility for the qualified exemption until the farm's general compliance date, however. Second, we are establishing January 1, 2020, as the compliance date for the modified requirement of § 112.6(b)(1). A farm that is eligible for a qualified exemption must notify consumers as to the name and complete business address of the

farm where the food is grown, harvested, packed, and held (see § 112.6(b)). If a food packaging label is required, the required notification must appear prominently and conspicuously on the label of the food (see § 112.6(b)(1)). This modified requirement may require some farms to update the labels of their packaged food products. For many labeling requirements, the time frame for a food establishment to comply with new or revised labeling requirements is governed by a uniform compliance date (see, e.g., 79 FR 73201, December 10, 2014 and 77 FR 70885, November 28, 2012). Use of a uniform compliance date provides for an orderly and economical industry adjustment to new labeling requirements by allowing sufficient lead time to plan for the use of existing label inventories and the development of new labeling materials. This policy serves consumers' interests as well because the cost of multiple short-term label revisions that would otherwise occur would likely be passed on to consumers in the form of higher prices. We generally announce a uniform compliance date during November or December of even-numbered calendar years, and establish the uniform compliance date to be January 1 of an upcoming even-numbered calendar year. For example, in December, 2014, we issued a final rule establishing January 1, 2018, as the uniform compliance date for food labeling regulations that are issued between January 1, 2015, and December 31, 2016 (79 FR 73201). Likewise, in November, 2012, we issued a final rule establishing January 1, 2016, as the uniform compliance date for food labeling regulations that are issued between January 1, 2013, and December 31, 2014 (77 FR 70885, November 28, 2012). These uniform compliance dates provide a minimum of 1 year between the date when a food labeling regulation is issued and the date when a food establishment must comply with that regulation. Following this pattern, we intend that the next uniform compliance date will be January 1, 2020 for food labeling regulations that are issued between January 1, 2017 and December 31, 2018. A farm that is eligible for a qualified

exemption would become subject to the modified requirement in § 112.6(b)(1) during this timeframe – i.e., by December 31, 2018. The compliance date that we are establishing for the modified requirement of § 112.6(b)(1) (i.e., January 1, 2020) is consistent with the approach of a uniform compliance date and will provide such farms with more than 1 year from the applicable general compliance date to comply with this modified requirement. This compliance date also will provide such a farm with more than 4 years to comply with the modified requirement relative to the date of publication of this rule. Third, we are establishing the compliance dates for all other requirements in §§ 112.6 and 112.7. As explained under Comment 120, because of the difference in the bases for monetary cut-offs established in § 112.3 and in § 112.5, farms that are eligible for the qualified exemption may be either small businesses or very small businesses (as defined in § 112.3). Farms eligible for a qualified exemption (in accordance with § 112.5) must comply with all other modified requirements of §§ 112.6 and 112.7 within the compliance periods established for either a small business or a very small business, whichever is applicable. Based on the monetary cut-offs and definitions in § 112.3 and in § 112.5, a farm eligible for a qualified exemption must either be a small business or a very small business for purposes of this rule.

(Comment 444) Some comments further request clarification regarding the beginning of the compliance period. One comment asks us to account for the seasonal nature of farming operations and suggests the compliance period should begin on the date of the beginning of the first harvest period following the effective date of the rule.

(Response) See our response to Comment 443 for compliance dates, which are based on the size of a covered farm. Setting the compliance date for a farm based on the time of harvest,

as the comment suggested, is challenging because harvest periods will vary greatly based on commodity, region, and the farm's practices, which would result in widely variable compliance dates. Therefore, we decline this request.

B. Effective Dates for Conforming Changes

The conforming amendment to part 11 adds a reference to the scope of part 11 that the records required under part 112 are not subject to part 11. The conforming amendment to part 16 adds a reference to the scope of part 16 for new procedures in part 112, subpart R that provide a person with an opportunity for a hearing under part 16. These conforming amendments are effective on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], the same date as the effective date of part 112. We are not establishing compliance dates for these conforming amendments. As a practical matter, compliance will be implemented by compliance with part 112.

C. Effective Date for Certain Provisions in the PCHF Regulation

The final human preventive controls rule established six new provisions (§§ 117.5(k)(2), 117.8, 117.405(c), 117.410(d)(2)(ii), 117.430(d), and 117.475(c)(13)) that refer to provisions in part 112. We announced our intent to publish a document in the Federal Register announcing the effective dates of these provisions (80 FR 55908). These provisions are effective on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], the same date as the effective date of part 112.

D. Effective Date for Certain Provisions in the PCAF Regulation

The final animal preventive controls rule established five new provisions (§§ 507.12(a)(1)(ii), 507.105(c), 507.110(d)(2)(ii), 507.130(d), and 507.175(c)(13)) that refer to provisions in part 112. We announced our intent to publish a document in the Federal Register announcing the effective dates of these provisions (80 FR 56170). These provisions are effective on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], the same date as the effective date of part 112.

XXV. Executive Order 13175

In accordance with Executive Order 13175, FDA has consulted with tribal government officials. A Tribal Summary Impact Statement has been prepared that includes a summary of tribal officials' concerns and how FDA has addressed them (Ref. 257). Persons with access to the Internet may obtain the Tribal Summary Impact Statement at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm> or at <http://www.regulations.gov>. Copies of the Tribal Summary Impact Statement also may be obtained by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

XXVI. Economic Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) (Ref. 142). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts;

and equity). FDA believes this rule is a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because small farms will bear a large portion of the costs, FDA concludes that the final rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA expects this final rule to result in a 1-year expenditure that will exceed this amount.

The final analysis conducted in accordance with these Executive Orders and statutes is available in the docket for this rulemaking (Ref. 142) and at:
[http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/Economic Analyses/](http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/Economic%20Analyses/).

XXVII. Analysis of Environmental Impact

FDA has carefully considered the potential environmental effects of this action. FDA determined that the proposed action may significantly affect the quality of the human environment (21 CFR 25.22(b)) and, therefore, an EIS is necessary for the final rule (78 FR 50358, August 19, 2013). The Draft EIS was released for public comment (80 FR 1852, January

14, 2015). FDA considered the comments received on the Draft EIS when preparing the Final EIS (see (Ref. 258)). Table 31 lists Federal Register publications regarding the EIS related to this rule.

FDA's Final EIS and record of decision (Ref. 126) (Ref. 150) may be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

Table 31.-- List of Federal Register Publications Regarding the EIS

Description	Publication
Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Note: the categorical exclusion statement was cited as a reference in this document)	78 FR 3504; January 16, 2013
Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule	78 FR 50358; August 19, 2013
Extension of Comment Period for the Environmental Impact Statement	78 FR 69006; November 18, 2013
Public Meeting on Scoping of Environmental Impact Statement and Extension of Comment Period for the Environmental Impact Statement	79 FR 13593; March 11, 2014
Draft Environmental Impact Statement Notice of Availability	80 FR 1852; January 14, 2015

XXVIII. Paperwork Reduction Act of 1995

This rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the following paragraphs with an estimate of the annual recordkeeping and reporting burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption

Description: Section 105 of FSMA adds section 419 to the FD&C Act (21 U.S.C. 350h) requiring FDA to adopt a final regulation to provide for minimum science-based standards for fruits and vegetables that are RACs based on known safety risks, and directing FDA to set forth in the final regulation those procedures, processes, and practices that we determine to minimize the risk of serious adverse health consequences or death, including those that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act.

Description of Respondents: The regulation applies to farms that grow produce, meaning fruits and vegetables such as berries, tree nuts, herbs, and sprouts. There are 37,404 farms in the United States, excluding sprouting operations (Ref. 259), that would be covered by the rule. We estimate that there are approximately 285 sprouting operations covered by this rule. One section of the regulation also applies to some non-farm entities as described in the Third-Party Disclosure Burden sub-section of this section.

Exemptions or Eligibility for Exemptions

The rule includes provisions under which certain farms and produce are either not covered or eligible for an exemption and, instead, subject to certain modified requirements (see §§ 112.2 through 112.7).

Information Collection Burden Estimate

The estimated hourly burden is 20,484 one-time hours, and 1,112,641 annual hours. Furthermore, the estimated one-time third-party disclosure burden is 247 hours and the estimated annual third-party disclosure burden is 379,705 hours. FDA estimates the burden for this information collection as follows:

One-Time Hourly Burden

Agricultural Water—Documentation of Scientific Data

Section 112.50(b)(3) requires documentation of scientific data or information relied on to support the adequacy of a method used to satisfy the requirements of §§ 112.43(a)(1) and (a)(2). All covered farms that would treat their water to achieve a water quality requirement in the rule will be required to keep these records. Consequently, we estimate that 5,547 farms ([17,840 farms from table 18 of the RIA \times 20 percent that do not rely on die-off] + [3,958 farms from table 19 of the RIA \times 50 percent that do not re-inspect and correct]) would rely on documentation of scientific data or information to support the adequacy of a method used to satisfy these requirements. It is estimated that one recordkeeper for each of 5,547 farms will spend 0.5 hour one-time on this documentation, estimated to consist of gathering and maintaining the documentation of scientific data and information. Therefore, $5,547 \times 0.5 = 2,773$ one-time hours to meet the requirement of § 112.50(b)(3).

Section 112.50(b)(5) requires farms that rely on a microbial die-off or removal rate to determine a time interval between harvest and end of storage, including other activities such as commercial washing, to achieve a calculated log reduction of generic E. coli in accordance with § 112.45(b)(1)(ii) to have documentation of the scientific data or information they rely on to support that rate. We estimate that 25 percent of all farms that rely on die-off, 3,661 (17,840 farms from table 18 of the RIA \times 80 percent that rely on die-off \times 25 percent) would generate these records for postharvest die-off intervals. It is estimated that two recordkeepers for each of 3,661 farms will spend 0.5 hour one-time on this documentation, estimated to consist of gathering and maintaining the documentation of scientific data and information. Therefore, $3,661 \times 2 \times 0.5 = 3,661$ one-time hours to meet the requirement of § 112.50(b)(5).

Section 112.50(b)(8) requires all farms that choose to rely on an alternative under § 112.49 to have documentation of the scientific data or information they rely on to support that alternative. There are four types of alternatives that may be employed according to § 112.49(a)-(d).

Section 112.49(a) provides for an alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, in lieu of the microbial quality criteria in § 112.44(b). We estimate that approximately 8,757 farms that irrigate (35,029 total farms \times 25 percent) will generate these alternative records. It is estimated that one recordkeeper (one for each type of alternative offered) for each of 8,757 farms will spend 0.5 hour one-time on this documentation, estimated to consist of gathering and maintaining the documentation of scientific data and information. Therefore, $8,757 \times 0.5 = 4,376$ one-time hours to meet the requirements of §§ 112.50(b)(8) and 112.49(a).

Section 112.49(b) provides for an alternative microbial die-off rate and an accompanying maximum time interval, in lieu of the microbial die-off rate and maximum time interval in § 112.45(b)(1)(i). We estimate that approximately 3,661 farms that rely on die-off (14,643 farms that rely on die-off \times 25 percent) will generate these alternative records. It is estimated that one recordkeeper (one for each type of alternative offered) for each of 3,661 farms will spend 0.5 hour one-time on this documentation, estimated to consist of gathering and maintaining the documentation of scientific data and information. Therefore, $3,661 \times 0.5 = 1,830$ one-time hours to meet the requirements of §§ 112.50(b)(8) and 112.49(b).

Section 112.49(c) provides for an alternative minimum number of samples used in the initial survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(1)(i)(A). We estimate that approximately 2,551 farms that utilize

surface water (12,554 irrigated farms that use surface water less the percentage estimated on public water sources \times 20 percent) will generate these alternative records. It is estimated that one recordkeeper (one for each type of alternative offered) for each of 2,511 farms will spend 0.5 hour one-time on this documentation, estimated to consist of gathering and maintaining the documentation of scientific data and information. Therefore, $2,511 \times 0.5 = 1,255$ one-time hours to meet the requirements of §§ 112.50(b)(8) and 112.49(c).

Section 112.49(d) provides for an alternative minimum number of samples used in the annual survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(2)(i)(A). We estimate that approximately 2,551 farms that utilize surface water (12,554 irrigated farms that use surface water less the percentage estimated on public water sources \times 20 percent) will generate these alternative records. It is estimated that one recordkeeper (one for each type of alternative offered) for each of 2,511 farms will spend 0.5 hour one-time on this documentation, estimated to consist of gathering and maintaining the documentation of scientific data and information. Therefore, $2,511 \times 0.5 = 1,255$ one-time hours to meet the requirements of §§ 112.50(b)(8) and 112.49(c).

Section 112.50(b)(9) requires all farms that are required to test their agricultural water in compliance with § 112.46 to have documentation of any analytical methods that they choose to use for such testing in lieu of the method that is incorporated by reference in § 112.151(a). It is not known how many farms will use other analytical methods; however, it is estimated that one recordkeeper will work a total of 5 hours one-time to fulfill this requirement, estimated as the time needed to search for and collect the documentation of the alternative analytical methods.

Sprouts-Establishment of Environmental Monitoring Plan

Section 112.150(b)(2) requires sprout operations to establish and keep a written environmental monitoring plan in accordance with § 112.145. There is a one-time burden estimated for the establishment of this plan and an annual burden estimated for the maintenance of this plan. For 74 very small farms, it is estimated that the establishment of this environmental monitoring plan (that is, determining the information needed to be included in the monitoring plan, including the corrective action plan, and developing a template for the plan) record is a one-time burden of 7 hours. Therefore, $46 \text{ farms} \times 7 \text{ hours} = 321$ one-time hours to comply with § 112.150(b)(2). For 60 small farms, it is estimated that the establishment of this environmental monitoring plan (that is, determining the information needed to be included in the monitoring plan, including the corrective action plan, and developing a template for the plan) is a one-time burden of 12 hours. Therefore, $37 \text{ farms} \times 12 \text{ hours} = 446$ one-time hours to comply with § 112.150(b)(2). For 94 large farms, it is estimated that the establishment of this environmental monitoring plan (that is, determining the information needed to be included in the monitoring plan, including the corrective action plan, and developing a template for the plan) is a one-time burden of 17 hours. Therefore, $94 \text{ farms} \times 17 \text{ hours} = 1,592$ one-time hours to comply with § 112.150(b)(2).

Sprouts-Establishment of Sampling Plan

Section 112.150(b)(3) requires the documentation of the written sampling plan for each production batch of sprouts in accordance with § 112.147(a). It is estimated that there is a one-time burden to establish this record (that is, determining the information needed to be included in the sampling plan, including a corrective action plan, and developing a template for the plan) and an annual burden to maintain this record (such as updating or making needed changes to the plan). For each of 177 sprout farms, it is estimated that the one-time burden to establish a written

sampling plan is 8 hours. Therefore, 8 hours \times 177 sprout farms = 1,414 one-time burden hours for sprout farms to comply with § 112.150(b)(3).

Sprouts—Documentation of Scientific Data

Section 112.150(b)(5) requires sprout operations to have documentation of any analytical methods used in lieu of the methods for both environmental testing and batch testing that are incorporated by reference in §§ 112.152 and 112.153. It is not known how many sprout operations will use other analytical methods; however, it is estimated that one recordkeeper will work a total of 5 hours one-time to fulfill this requirement, estimated as the time needed to search for and collect the documentation of the alternative analytical methods.

In addition, § 112.144(c) requires sprout operations to conduct testing for additional pathogens when certain conditions are met, and § 112.150(b)(5) requires sprouting operations to have documentation of any analytical methods used for such testing because there is no specific method for such testing incorporated by reference in § 112.152 or 112.153. It is not known if or when there will be a pathogen(s) meeting the relevant criteria; however, it is estimated that one recordkeeper will work a total of 2 hours one-time to fulfill this requirement, estimated as the time needed to establish a new testing routine. Therefore, we estimate it will take 177 sprouters 353 records (177×2) to fulfill this requirement. At two hours per record, this represents a total hourly burden of 707 (353×2) to fulfill the requirements of §§ 112.150(b)(5) and § 112.144(c).

Variances

Section 112.171 of this rule allows States, tribes, and foreign countries to petition FDA for a variance from one or more requirements of the rule. Section 112.172 requires the competent authority (i.e., the regulatory authority for food safety) for a State, tribe, or a foreign country to

submit a petition to seek a variance, and § 112.173 describes what must be included in the Statement of Grounds in a petition requesting a variance.

Data on the number of hours needed to assemble the information required for a petition are not available. However, it is estimated that it will take one recordkeeper 80 hours to compile the relevant information and submit the petition to FDA. Furthermore, it is estimated that an additional recordkeeper (for example, a supervisor) will evaluate and review the petition before it is submitted. We estimate that it will take an additional 40 hours for the additional recordkeeper to review the submission. Therefore, it is estimated that a State, tribe, or foreign government would spend a total of 120 hours on a petition, and this would be a one-time burden. Data do not exist to estimate how many petitions FDA may get in a year; however, for the purposes of this analysis, it is estimated that FDA may receive seven petitions. Therefore, 120 hours \times 7 petitions = 840 hours to comply with the requirements of § 112.173.

Annual Hourly Burden

Qualified exempt farms – documenting eligibility

Section 112.7(b) requires farms eligible for the qualified exemption in accordance with § 112.5 to establish and keep adequate records necessary to demonstrate that the farm satisfies the criteria for a qualified exemption, including a written record reflecting that the owner, operator, or agent in charge of the farm has performed an annual review and verification of the farm's continued eligibility for the qualified exemption. We calculate that there are a total of 3,285 farms that will incur the costs of recordkeeping associated with demonstrating qualified exempt status. Therefore, it is estimated that one recordkeeper on each of 3,285 farms will spend an average of 0.5 hours per year on recordkeeping related to documenting eligibility for the

qualified exemption. Therefore, $3,285 \text{ recordkeepers} \times 0.5 \text{ average hours per recordkeeper} = 1,643 \text{ hours}$ to meet the requirements of § 112.7(b).

Training records

Section 112.30(b)(1) requires the establishment and maintenance of records of training documenting required training of personnel, including the date of training, topics covered, and the persons(s) trained. We calculate that there are a total of 24,420 farms ($37,404 \text{ total farms} \times 0.65 \text{ not currently keeping training records}$) that will incur the costs of worker training recordkeeping. Therefore, it is estimated that one recordkeeper on each of 24,420 farms will spend an average of 7.25 hours per year on recordkeeping related to training requirements (recording and maintaining the dates and topics of training, and person(s) trained) of this final rule. Therefore, $24,420 \text{ recordkeepers} \times 7.25 \text{ average hours per recordkeeper} = 177,045 \text{ hours}$ to meet the requirements of § 112.30(b)(1).

Water testing

Water Testing for Zero Detectable Generic E. coli. Section 112.46(c) requires testing untreated groundwater for the purposes that are subject to the requirements of § 112.44(a). We calculate there are a total of 26,038 farms (all farms with activities during and after harvest, and sprout farms using untreated ground water for growing sprouts) that will incur these costs. Therefore, it is estimated that two recordkeepers on each of 26,038 farms will spend an average of 0.66 hours per year on testing water for zero detectable generic E. coli of this final rule. Therefore, $26,038 \text{ farms} \times 2 \text{ recordkeepers} \times 0.66 \text{ average hours per recordkeeper} = 34,371 \text{ hours}$ to meet the requirements of §§ 112.44(a) and 112.46(c).

Testing for GM of 126 CFU/100 mL and STV of 410 CFU/100 mL Generic E. coli. –
Untreated Surface Water Used For Direct Application Irrigation of Non-Sprout Covered

Produce. Section 112.46(b) requires testing each such source of water used for the purposes that are subject to the requirements of § 112.44(b). We calculate that there are a total of 12,554 farms (all irrigated farms using surface water less the percentage estimated on public water sources) that will incur these costs. Therefore, it is estimated that 6.29 recordkeepers on each of 12,554 farms will spend an average of 0.92 hours per year on Testing for GM of 126 CFU / 100 mL and STV of 410 CFU / 100 mL Generic E. coli – Untreated Surface Water Used For Direct Application Irrigation of Non-Sprout Covered Produce of this final rule. Therefore, 12,554 farms × 6.29 recordkeepers × 0.92 average hours per recordkeeper = 72,648 hours to meet the requirements of §§ 112.44(b) and 112.46(b).

Testing for GM of 126 CFU / 100 mL and STV of 410 CFU / 100 mL Generic E. coli – Untreated Ground Water Used For Direct Application Irrigation of Non-Sprout Covered Produce. Section 112.46(b) requires testing each such source of water used for the purposes that are subject to the requirements of § 112.44(b). We calculate that there are a total of 9,471 farms (all irrigated farms using ground water less the percentage estimated on public water sources) that will incur these costs. Therefore, it is estimated that 1.4 recordkeepers on each of 9,471 farms will spend an average of 0.92 hours per year on Testing for GM of 126 CFU / 100 mL and STV of 410 CFU / 100 mL Generic E. coli – Untreated Ground Water Used For Direct Application Irrigation of Non-Sprout Covered Produce of this final rule. Therefore, 9,471 farms × 1.4 recordkeepers × 0.92 average hours per recordkeeper = 12,198 hours to meet the requirements of §§ 112.44(b) and 112.46(b).

Section 112.45 requires water testing as part of certain options for corrective steps when the water quality requirements of §§ 112.41 or 112.44 are not met (see §§ 112.45(a)(1)(i) and 112.45(b)(2)). We calculate approximately one percent of all irrigated farms will need to conduct

these tests; therefore 298 farms ($29,763 \times 1$ percent) will incur these costs. Therefore, it is estimated that 1 recordkeeper on each of the 298 farms will spend an average of 0.33 hours per year on these actions taken when requirements in subpart E are not met. Therefore, $298 \text{ farms} \times 1 \text{ recordkeeper} \times 0.33 \text{ average hours per recordkeeper} = 98 \text{ hours}$ to meet the requirements of § 112.45.

Recordkeeping related to water

Section 112.50(b)(1) requires the establishment and maintenance of records of the Findings of Water System Inspections. We calculate that there are 34,369 (all covered farms not currently keeping these records) that will incur the costs of water inspection recordkeeping. Therefore, it is estimated that 4 recordkeepers on each of 34,369 farms will spend an average of 0.8 hours per year on recordkeeping related to the Findings of Water System Inspections. Therefore, $34,369 \text{ farms} \times 4 \text{ recordkeepers} \times 0.8 \text{ average hours per recordkeeper} = 110,066 \text{ hours}$ to meet the requirement of § 112.50(b)(1).

Section 112.50(b)(2) requires the establishment and maintenance of Records of Testing for 0 Detectable Generic E. coli. We calculate that 26,038 farms (see testing discussion) will incur the costs of recordkeeping of testing for 0 detectable generic E. coli. Therefore, it is estimated that 2 recordkeepers on each of the 26,038 farms will spend an average of 0.33 hours per year on recordkeeping related to Records of Testing for 0 Detectable Generic E. coli. Therefore, $26,038 \text{ farms} \times 2 \text{ recordkeepers} \times 0.33 \text{ average hours per recordkeeper} = 17,185 \text{ hours}$ to meet the requirements of § 112.50(b)(2).

Section 112.50(b)(2) requires the establishment and maintenance of Records of Testing for GM of 126 CFU / 100 mL and STV of 410 CFU / 100 mL Generic E. coli for Untreated Surface Water Used for Direct Application Irrigation of Non-Sprout Covered Produce. We

calculate that 12,554 farms (see previous testing discussion) will incur the costs of establishing these records. Therefore, it is estimated that 6.29 recordkeepers on each of the 12,554 farms will spend an average of 0.08 hours per year on this recordkeeping. Therefore, $12,554 \text{ farms} \times 6.29 \text{ recordkeepers} \times 0.08 \text{ average hours per recordkeeper} = 6,317 \text{ hours}$ to meet the requirements of § 112.50(b)(2). As noted in response to Comment 229, we are exploring the development of an online tool to allow covered farms to derive their GM and STV values and appropriate time intervals between last irrigation and harvest using the 0.5 log per day die-off rate, based on input of sample data, such that farms would not need to perform the necessary calculations themselves. We expect such a tool to reduce the recordkeeping burden associated with testing of untreated surface and untreated ground water (§§ 112.46(b) and 112.50(b)(2)) and time intervals applied between last irrigation and harvest (§§ 112.45(b)(1) and 112.50(b)(6)). Moreover, FDA will not be collecting, storing, or otherwise using any water testing sample data that farms enter into the online tool to calculate the GM and STV values and develop or update their microbial water quality profiles.

Section 112.50(b)(2) also requires the establishment and maintenance of Records of Testing for GM of 126 CFU / 100 mL and STV of 410 CFU / 100 mL Generic E. coli for Untreated Ground Water Used for Direct Application Irrigation of Non-Sprout Covered Produce. We calculate that 9,471 farms (see previous testing discussion) will incur the costs of establishing these records. Therefore, it is estimated that 1.4 recordkeepers on each of the 9,471 farms will spend an average of 0.08 hours per year on this recordkeeping. Therefore, $9,471 \text{ farms} \times 1.4 \text{ recordkeepers} \times 0.08 \text{ average hours per recordkeeper} = 1,061 \text{ hours}$ to meet the requirements of § 112.50(b)(2). As noted previously, we expect development of an online tool to

reduce the recordkeeping burden associated with testing of untreated surface and untreated ground water required under §§ 112.46(b) and 112.50(b)(2).

Section 112.50(b)(4) requires Documentation of Results of Monitoring Water Treatment under § 112.43(b). We calculate that 5,547 farms (the proportion of covered farms that do not use municipal water sources and who are not able to use other options to otherwise meet quality criteria) will incur the costs of documentation of monitoring water treatment. Therefore, it is estimated that 1 recordkeeper on each of the 5,547 farms will spend an average of 0.98 hours per year on recordkeeping related to Monitoring Water Treatment. Therefore, $5,547 \text{ farms} \times 1 \text{ recordkeeper} \times 0.98 \text{ average hours per recordkeeper} = 5,436 \text{ hours}$ to meet the requirements of § 112.50(b)(4).

Section 112.50(b)(6) requires documentation of any corrective actions taken in accordance with § 112.45. Further, where time intervals or (calculated) log reductions are applied in accordance with § 112.45(b)(1)(i) and/or (b)(1)(ii), such documentation must include the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities such as the dates of last irrigation and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing. We calculate that 14,643 farms will incur the costs of documentation of any corrective actions taken in accordance with § 112.45, including any time intervals or calculated log reductions applied. Therefore, it is estimated that 1 recordkeeper on each of the 14,643 farms will spend an average of 0.5 hours per year on recordkeeping related to corrective actions applied. Therefore, $14,643 \text{ farms} \times 1 \text{ recordkeeper} \times 0.5 \text{ average hours per recordkeeper} = 7,322 \text{ hours}$ to meet the requirements of § 112.50(b)(6). As noted previously, we expect development

of an online tool to reduce the recordkeeping burden associated with time intervals applied between last irrigation and harvest as required under §§ 112.45(b)(1) and 112.50(b)(6).

Section 112.50(b)(7) requires annual documentation of the results or certificates of compliance from a Public Water System required under § 112.46(a)(1) or (a)(2), if applicable. We calculate that 9,108 farms (the number of farms using public water systems such as municipal water sources) will incur the costs of getting this annual documentation from their public water systems. Therefore, it is estimated that 1 recordkeeper on each of the 9,108 farms will spend an average of 0.33 hours per year on recordkeeping related to Documentation from Public Water Systems. Therefore, $9,108 \text{ farms} \times 1 \text{ recordkeeper} \times 0.33 \text{ average hours per recordkeeper} = 3,005 \text{ hours}$ to meet the requirements of § 112.50(b)(7).

Recordkeeping related to biological soil amendments of animal origin

Section 112.60(b) of this rule specifies the records that covered produce farms must establish and keep regarding biological soil amendments of animal origin.

For treated soil amendments acquired from a third party, § 112.60(b)(1) requires documentation, at least annually, that certain criteria have been met, namely that: (1) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and (2) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin. It is estimated that, for any covered produce farm already using treated biological soil amendments from a third party, this requirement does not represent a new recordkeeping burden. Furthermore, to account for the possibility that this may still be a new recordkeeping burden for farms using soil amendments acquired from a third party, it is estimated that this requirement will be a new

recordkeeping burden for an additional 10 percent of remaining covered farms ($35,029 \times 0.10 = 3,503$) Therefore, for the purposes of this analysis, it is estimated that one recordkeeper for each of a maximum of 3,503 farms will spend 0.25 hour annually to meet this requirement, estimated to consist of the act of acquiring and maintaining documentation. Therefore, $3,503 \text{ recordkeepers} \times 0.25 \text{ hour} = 876 \text{ annual hours}$.

Section 112.60(b)(2) of this rule requires covered farms to document, for a treated biological soil amendment of animal origin produced by the covered farm, documentation that process controls (for example, time, temperature, and turnings) were achieved. NASS data do not exist that would make it possible to estimate how many covered farms would choose to produce treated biological soil amendments of animal origin for use on their own farms. However, using the USDA's 1999 Fruit and Vegetable Survey (Ref. 260), it is estimated that 15 percent of farms that claim to use manure also claim that the manure is composted on farm. Furthermore, using data from NASS, the RIA estimates that a total of 2,802 covered produce farms use manure (either as a component of stabilized compost or raw). For the purposes of this analysis, we assume, as an upper bound, that 420 covered farms ($2,802 \times 0.15 = 420$) choose to produce treated biological soil amendments of animal origin for their own farms, and that one recordkeeper for each of the 420 farms will spend 0.5 hour annually on this requirement, estimated to consist of recording confirmation of process control achievement. Therefore, $420 \text{ recordkeepers} \times 0.5 \text{ hour} = 210 \text{ annual hours}$.

Recordkeeping related to cleaning and sanitation

Section 112.140(b)(1) requires establishment and maintenance of records related to cleaning and sanitation, including cleaning worker tools and machinery. We calculate that 16,061 very small farms (farms that are not currently cleaning and sanitizing tools plus 50

percent of farms that are currently cleaning and sanitizing tools) will incur the costs of recordkeeping related to cleaning and sanitizing worker tools. Therefore, it is estimated that 1 recordkeeper on each of the 16,061 very small farms will spend an average of 8 hours per year on recordkeeping related to cleaning and sanitizing worker tools. Therefore, 16,061 very small farms \times 1 recordkeeper \times 8 average hours per recordkeeper = 128,485 hours to meet the requirements of § 112.140(b)(1). We calculate that 8,635 small and large farms (farms that are not currently cleaning and sanitizing tools plus 50 percent of farms that are currently cleaning and sanitizing tools) will incur the costs of recordkeeping related to cleaning and sanitizing worker tools. Therefore, it is estimated that 1 recordkeeper on each of the 8,635 small and large farms will spend an average of 25 hours per year on recordkeeping related to cleaning and sanitizing worker tools. Therefore, 8,635 small and large farms \times 1 recordkeeper \times 25 average hours per recordkeeper = 215,871 hours to meet the requirements of § 112.140(b)(1).

Section 112.140(b)(1) also requires establishment and maintenance of records related to the cleaning and sanitizing machinery. We calculate that 13,156 very small farms (farms that are not currently cleaning and sanitizing machinery plus 50 percent of farms that are currently cleaning and sanitizing machinery) will incur the costs of recordkeeping related to cleaning and sanitizing machinery. Therefore, it is estimated that 1 recordkeeper on each of the 13,156 very small farms will spend an average of 8 hours per year on recordkeeping related to cleaning and sanitizing machinery. Therefore, 13,156 very small farms \times 1 recordkeeper \times 8 average hours per recordkeeper = 105,248 hours to meet the requirements of § 112.140(b)(1). We calculate that 7,073 small and large farms (farms that are not currently cleaning and sanitizing machinery plus 50 percent of farms that are currently cleaning and sanitizing machinery) will incur the costs of recordkeeping related to cleaning and sanitizing machinery. Therefore, it is estimated that 1

recordkeeper on each of the 7,073 small and large farms will spend an average of 25 hours per year on recordkeeping related to cleaning and sanitizing machinery. Therefore, 7,073 small and large farms \times 1 recordkeeper \times 25 average hours per farm = 176,831 hours to meet the requirements of § 112.140(b)(1).

Testing requirements related to sprouts

Sections 112.144(b) and (c), and 112.147 requires testing spent sprout irrigation water from each production batch of sprouts, or if such testing is not practicable, each production batch of sprouts at the in-process stage for certain pathogens, and § 112.150(b)(4) requires recordkeeping related to those tests. This burden is estimated to vary across farm size. It is estimated that the burden associated with testing is an average of 0.5 hour per test. This time burden is estimated to include collecting and preparing the sample. We estimate that 33 very small sprout farms produce 3,710 batches, 27 small sprout farms produce 2,976 batches, and 68 large sprout farms produce 33,623 batches. Each farm will have one recordkeeper for each test. Small and very small farms will average 125 (50×2.5 one each for E. coli and Salmonella and 0.5 to reflect the uncertainty associated with applicability of testing requirements for additional pathogens) tests per farm; large farms will average 558 (223×2.5) tests.

It is estimated that a total of 4,163 batches of sprouts will be tested annually for E. coli and Salmonella and, if certain criteria are met, emerging pathogens across 33 very small farms. Therefore, 4,163 tests \times 0.5 hour per test = 2,081 annual hours for very small farms to comply with §§ 112.144(b) and (c) and 112.147. It is estimated that a total of 3,375 batches of sprouts will be tested annually across 27 small farms. Therefore 3,375 tests \times 0.5 hour per test = 1,688 annual hours for small farms to comply with §§ 112.144(b) and (c) and 112.147. It is estimated that 37,882 batches of sprouts will be tested annually across 68 large farms. Therefore, 37,882

test \times 0.5 hour per = 18,941 annual hours for large farms to comply with §§ 112.144(b) and (c) and 112.147.

Sections 112.144(a) and 112.145 require testing the sprout growing, harvesting, packing, and holding environment for Listeria spp. or L. monocytogenes, and § 112.150(b)(4) requires recordkeeping related to those tests. This burden is estimated to vary across farm size. It is estimated that the burden associated with testing is 0.15 hour to collect and prepare each sample. We expect that all firms will sample on a monthly basis; it is also expected that the number of samples will vary with the size of the farm. We expect very small farms to average five samples for each test; small farms to average ten samples per test; and large farms to average 15 samples. More samples are expected as the size of the farm increases because we estimate that the number and location of sampling sites, including appropriate food-contact surfaces and non-food-contact surfaces of equipment and other surfaces would increase as the farm size increases. It is estimated that one recordkeeper from each of the farms will be responsible for collecting samples. Therefore, to comply with the requirements of §§ 112.144(a) and 112.145, 33 very small farms will incur a total of 300 hours of burden annually (33 farms \times 5 samples \times 12 annual tests \times 0.15 hour per sample); 27 small farms will incur a total of 486 hours annually, (27 farms \times 10 samples \times 12 annual tests \times 0.15 hour per sample); and 68 large farms will incur a total of 1,835 hours (68 farms \times 15 samples \times 12 annual tests \times 0.15 hour per sample).

Recordkeeping requirements related to sprouts

Section 112.150(b)(1) requires documentation of treatment of seeds or beans or documentation of previous seed treatment by a third party. This burden is expected to vary across farms; however, this documentation burden is estimated to be 0.2 hour per activity, estimated to consist of the time needed to record the treatment of seeds or beans. It is estimated that one

recordkeeper per very small farm will document this activity 50 times annually. Therefore, 33 very small farms \times 50 records = 1,665 records \times 0.2 hours per record = 333 hours for very small farms to comply with § 112.150(b)(1). It is estimated that one recordkeeper per small farm will document this activity 50 times annually. Therefore, 27 small farms \times 50 records = 1,350 records \times 0.2 hours per record = 270 hours for small farms to comply with § 112.150(b)(1). It is estimated that one recordkeeper per large farm will document this activity about 223 times annually. Therefore, 68 large farms \times 223 records = 15,153 records \times 0.2 hours per record = 3,031 hours for large farms to comply with § 112.150(b)(1).

Section 112.150(b)(2) requires sprout operations to establish and keep a written environmental monitoring plan in accordance with § 112.145. It is estimated that there is a one-time burden to establish this record (that is, determining the information needed to be included in the sampling plan and developing a template for the plan) and an annual burden to maintain this record (such as updating or making needed changes to the plan). For annual burdens, it is estimated that each record will require one recordkeeper to work 0.15 hour to maintain the environmental monitoring plan (such as updating or making needed changes to the plan), across all farm sizes. For 46 very small farms, it is estimated that one record will be generated annually. Therefore, 46 records \times 0.15 hour per record = 7 total annual hours for very small farms to comply with § 112.150(b)(2). For 37 small farms, it is estimated that 37 total records will be generated annually. Therefore, 37 records \times 0.15 hour per record = 6 total annual hours for small farms to comply with § 112.150(b)(2). For 94 large farms, it is estimated that 94 total records will be generated annually. Therefore, 94 records \times 0.15 hour per record = 14 total annual hours for very small farms to comply with § 112.150(b)(2).

Section 112.150(b)(3) requires the documentation of the written sampling plan for each production batch of sprouts in accordance with § 112.147(a). It is estimated that there is a one-time burden to establish this record (that is, determining the information needed to be included in the sampling plan and developing a template for the plan) and an annual burden to maintain this record (such as updating or making needed changes to the plan). For each of 177 sprout farms, it is estimated that there will be an annual burden of 1 hour per farm to update and make needed changes to the plans. Therefore, $177 \text{ sprout farms} \times 1 \text{ hour} = 177 \text{ annual hours}$ for sprout farms to comply with § 112.150(b)(3).

Section 112.150(b)(4) requires records of all testing conducted in accordance with the requirements of § 112.144 for sprouting operations. To comply with this, records of testing for E. coli O157:H7 and Salmonella spp. and any pathogen meeting the criteria in § 112.144(c) will be kept, and it is estimated that each such record will represent a burden of 0.15 hour, estimated as the time needed to record the results of the tests, but the number of records will vary across farm sizes. For 33 very small sprouting operations testing for E. coli O157:H7 and Salmonella and other pathogens as applicable, it is estimated that 2,498 total records will be generated annually (or an average of 50.13 per firm $\times 1.5$ to account for the uncertainty associated with applicability of testing requirements for additional pathogens). Therefore, $2,498 \times 0.15 = 375$ annual hours for very small sprouting operations to comply with § 112.150(b)(4). For 27 small sprouting operations it is estimated that 2,025 total records will be generated annually (or an average of about 49.6 per sprouting operation $\times 1.5$ to account for the uncertainty associated with applicability of testing requirements for additional pathogens). Therefore, $2,025 \text{ records} \times 0.15 \text{ hour per record} = 304$ annual hours for small sprouting operations to comply with § 112.150(b)(4) with respect to testing for E. coli O157:H7 and Salmonella and other pathogens as

applicable. For 68 large sprouting operations it is estimated that 22,689 total records will be generated annually (or an average of about 222.6 per sprouting operation \times 1.5 to account for the uncertainty associated with applicability of testing requirements for additional pathogens). Therefore, 22,689 records \times 0.15 hour per record = 3,403 annual hours for large sprouting operations to comply with § 112.150(b)(4) with respect to testing for E. coli O157:H7 and Salmonella, and other pathogens as applicable.

Section 112.150(b)(4) requires records of all testing conducted in accordance with the requirements of §§ 112.144 and 112.145 for sprouting operations. To comply with this, records of testing for Listeria spp. or L. monocytogenes will be kept, and it is estimated that each such record will represent a burden of 0.17 hour, estimated as the time needed to record the results of the tests, but the number of records will vary across sprouting operation sizes. For 33 very small sprouting operations, it is estimated that a total of 1,998 records will be kept annually (or an average of 60 per sprouting operation) with respect to testing for Listeria spp. or L. monocytogenes. Therefore, 1,998 records \times 0.17 hour per record = 340 total annual hours for small sprouting operations to comply with § 112.150(b)(4) with respect to testing for Listeria spp. or L. monocytogenes. For 27 small farms, it is estimated that a total of 3,240 records will be kept annually (or an average of 120 per sprouting operation). Therefore, 3,240 records \times 0.17 hour per record = 551 total annual hours for small farms to comply with § 112.150(b)(4) with respect to testing for Listeria spp. or L. monocytogenes. For 68 large sprouting operations, it is estimated that a total of 12,231 records will be kept annually (or an average of 180 per sprouting operation). Therefore, 12,231 records \times 0.17 hour per record = 2,079 total annual hours for large sprouting operations to comply with § 112.150(b)(4) with respect to testing for Listeria spp. or L. monocytogenes.

Section 112.150(b)(6) requires records of corrective actions conducted in accordance with the requirements of §§ 112.142(b)(2), 112.146, and 112.148 for sprouting operations. It is estimated that all sprouting operations may collectively perform approximately 285 corrective actions annually. For each of 285 sprout operations, it is estimated that there will be an annual burden of 0.5 hour per operation to make the required record documenting these corrective actions. Therefore, 285 sprout farms × 0.5 hour = 143 annual hours for sprout farms to comply with § 112.150(b)(6).

Commercial processing exemption recordkeeping

Under § 112.2(b)(4), farms relying on the commercial processing exemption must establish and maintain records of their required disclosures to customers regarding produce that has not been commercially processed and the annual written assurances obtained from customers regarding such commercial processing. It is estimated that § 112.2(b)(4) represents a recordkeeping requirement for 4,568 entities (4,153 farms that only grow produce exempt from the rule due to commercial processing, who would otherwise be subject to the rule × an additional 10 percent to account for covered farms relying on this exemption for only some of their produce, and other entities that will be required to make these records). We estimate that it will take approximately 5 minutes to make these records each year. Therefore, 4,568 entities × 0.08 hour per entity = 365 annual hours to comply with § 112.2(b)(4).

Table 32.-- Estimated Annual Recordkeeping Burden

One-Time Hourly Burden						
21 CFR	No. Of Recordkeepers	No. of Records	Total Records	Average Hourly Burden	Total Hours	Operating Costs in millions (related to testing burdens)
Agricultural Water—Documentation of Scientific Data						
112.50(b)(3)	5,547	1	5,547	0.5	2,773	

112.50(b)(5)	3,661	2	7,322	0.5	3,661	
112.50(b)(8); 112.49(a)	8,757	1	8,757	0.5	4,379	
112.50(b)(8); 112.49(b)	3,661	1	3,661	0.5	1,830	
112.50(b)(8); 112.49(c)	2,511	1	2,511	0.5	1,255	
112.50(b)(8); 112.49(d)	2,511	1	2,511	0.5	1,255	
112.50(b)(9)	1	1	1	5.0	5	
Sprouts-Establishment of Environmental Monitoring Plan						
112.150(b)(2), Very Small Farms	46	1	46	7.0	321	
112.150(b)(2), Small farms	37	1	37	12.0	446	
112.150(b)(2), Large farms	94	1	94	17.0	1,592	
Sprouts-Establishment of Sampling Plan						
112.150(b)(3)	177	1	177	8.0	1,414	
Sprouts – Documentation of Scientific Data						
112.150(b)(5)	1	1	1	5.0	5	
112.150(b)(5); 112.144(c)	177	2	353	2.0	707	
Variances						
112.173	7	1	7	120.0	840	
Total One-Time Hourly Burden					20,484	N/A
Annual Hourly Burden						
21 CFR	No. of Recordkeepers	No of Records	Total Annual Records	Avg. Hourly Burden	Total Hours	Operating Costs (in millions)
Qualified Exempt Farms – Documenting Eligibility for Exemption						
112.7(b)	3,285	1	3,285	0.5	1,643	
Training						
112.30(b)(1)	24,420	1	24,420	7.25	177,045	
Testing Requirements for Agricultural Water						
Records of Testing for 0 Detectable Generic <u>E. coli</u>						
112.44(a), 112.46(c)	26,038	2	52,077	0.7	34,371	\$2.48

Testing for GM of 126 CFU / 100 mL and STV of 410 CFU / 100 mL Generic <u>E. coli</u> – Untreated Surface Water Used For Direct Application Irrigation of Non-Sprout Covered Produce						
112.44(b), 112.46(b)	12,554	6.29	78,965	0.92	72,647	\$5.24
Testing for GM of 126 CFU / 100 mL and STV of 410 CFU / 100 mL Generic <u>E. coli</u> – Untreated Ground Water Used For Direct Application Irrigation of Non-Sprout Covered Produce						
112.44(b), 112.46(b)	9,471	1	13,259	0.9	12,198	\$0.88
Records of Analytical Test Results as Part of Corrective Steps						
112.45	298	1	298	0.33	98	
Recordkeeping Related to Agricultural Water						
Findings of Water System Inspection						
112.50(b)(1)	34,396	4	137,583	0.8	110,066	
Records of Testing for 0 Detectable Generic <u>E. coli</u>						
112.50(b)(2)	26,038	2	52,077	0.33	17,185	
Records of Testing for GM of 126 CFU / 100 mL and STV of 410 CFU / 100 mL Generic <u>E. coli</u> – Untreated Surface Water Used For Direct Application Irrigation of Non-Sprout Covered Produce						
112.50(b)(2)	12,554	6.29	78,965	0.08	6,317	
Records of Testing for GM of 126 CFU / 100 mL and STV of 410 CFU / 100 mL Generic <u>E. coli</u> – Untreated Ground Water Used For Direct Application Irrigation of Non-Sprout Covered Produce						
112.50(b)(2)	9,471	1	13,259	0.08	1,061	
Documentation of Monitoring Water Treatment						
112.50(b)(4)	5,547	1	5,547	0.98	5,436	

Documentation of corrective actions applied						
112.50(b)(6)	14,643	1	14,643	0.5	7,322	
Documentation from Public Water Systems						
112.50(b)(7)	9,108	1	9,108	0.33	3,005	
Recordkeeping Related to Soil Amendments						
112.60(b)(1)	3,503	1	3,503	0.25	876	
112.60(b)(2)	420	1	420	0.50	210	
Recordkeeping Related to Cleaning and Sanitation						
112.140(b)(1) Cleaning worker tools, very small farms	16,061	1	16,061	8.0	128,485	
112.140(b)(1) Cleaning worker tools, small and large farms	8,635	1	8,635	25.0	215,871	
112.140(b)(1) Cleaning machinery, very small farms	13,156	1	13,156	8.0	105,248	
112.140(b)(1) Cleaning machinery, small and large farms	7,073	1	7,073	25.0	176,831	
Testing Requirements for Sprouts						
Testing for <u>E. coli</u> and <u>Salmonella</u> and additional pathogens as applicable						
112.144(b) and (c), 112.147, very small farms	33	125	4,163	0.50	2,081	\$0.15
112.144(b) and (c), 112.147, small farms	27	125	3,375	0.50	1,688	\$0.12
112.144(b) and (c), 112.147, large farms	68	558	37,882	0.50	18,941	\$1.37
Testing for <u>Listeria</u> spp. or <u>L. monocytogenes</u>						
112.144(a), 112.145, very small farms	33	60	1,998	0.15	300	\$0.02
112.144(a), 112.145, small farms	27	120	3,240	0.15	486	\$0.04
112.144(a), 112.145, large farms	68	180	12,231	0.15	1,835	\$0.13
Recordkeeping Related to Sprouts						
Documentation of Treatment of Seeds or Beans						
112.150(b)(1), very small farms	33	50	1,665	0.20	333	
112.150(b)(1), small farms	27	50	1,350	0.20	270	
112.150(b)(1), large farms	68	223	15,153	0.20	3,031	
Environmental Monitoring Plan - Updating						
112.150(b)(2), very small farms	46	1	46	0.15	7	
112.150(b)(2), small farms	37	1	37	0.15	6	
112.150(b)(2), large farms	94	1	94	0.15	14	

Sampling Plan - Updating						
112.150(b)(3)	177	1	177	1.00	177	
Records of Testing for <u>E.coli</u> and <u>Salmonella</u> and additional pathogens as applicable						
112.150(b)(4), very small farms	33	75	2,498	0.15	375	
112.150(b)(4), small farms	27	75	2,025	0.15	304	
112.150(b)(4), large farms	68	334	22,689	0.15	3,403	
Records of Testing for <u>Listeria</u> spp. or <u>L. monocytogenes</u>						
112.150(b)(4), very small farms	33	60	1,998	0.17	340	
112.150(b)(4), small farms	27	120	3,240	0.17	551	
112.150(b)(4), large farms	68	180	12,231	0.17	2,079	
Records of corrective actions						
112.150(b)(6)	285	1	285	0.50	143	
Commercial processing exemption recordkeeping						
Records of disclosures to customers and annual written assurances obtained from customers						
112.2(b)(4)	4568	1	4,568	0.08	365	
Annual Hourly Burden					1,112,641	
Operating Costs						\$10.42

Third-Party Disclosure Burden

Under § 112.6(b) certain qualified exempt farms (those that would otherwise be covered by the rule but that meet the criteria in § 112.5) must comply with certain food labeling or disclosure requirements. A total of 21,666 non-sprout farms are estimated to be eligible for the qualified exemption in § 112.5. After subtracting the number of farms that are not covered by the rule because they have annual monetary value of produce sold of \$25,000 or less, 3,285 farms remain that must comply with § 112.6(b). It is estimated that it will take the farm operator approximately 5 minutes to buy and prepare one poster board. It is also estimated that the operator will buy posters bi-weekly. The total annual time required to buy and prepare a poster

board is 24 hours $[(60 \text{ minutes} \times 24)/60]$. Therefore, $3,285 \text{ farms} \times 24 \text{ annual hours} = 78,840$ annual hours for these farms to comply with the requirement of § 112.6(b).

It is estimated that farms with other marketing channels will provide their name and complete business address on an invoice or receipt that accompanies their product. We estimate that a total of 3,083 farms will incur a cost to comply with this provision. It is estimated that it will take a farm operator 5 minutes (0.08 hour) to change this template for new invoices, and that this is a one-time burden. Therefore, $3,083 \times 0.08 \text{ hour} = \text{about } 247$ hours to comply with § 112.6(b).

Under § 112.31(b)(2), covered farms are required to instruct personnel to notify their supervisor(s) if they have, or if there is a reasonable possibility that they have an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea). The number of farms that will need to implement this disclosure is based on the estimated number of farms that are not currently implementing the requirements imposed by the rule in the RIA. It is estimated that one worker from each of 29,175 farms will spend 5 minutes annually to comply with § 112.31(b)(2), which will consist of the employer giving verbal instructions to employees. Therefore, $29,175 \times 5 \text{ minutes} = 2,334$ hours to comply with § 112.31(b)(2).

Under § 112.33(a), covered farms must make visitors aware of policies and procedures to protect covered produce and food-contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures. It is estimated that farms with voluntary food safety programs in place will already have practices aligned with this provision; therefore no burden is estimated for those farms. After subtracting these farms, it is estimated that § 112.33(a) represents a third-party disclosure requirement for

35,556 farms. We estimate that it will take 8 hours annually for the operator to inform visitors of the farm policies, including showing them where the restrooms are, and to take reasonable steps to ensure their compliance, such as monitoring visitors to ensure they are following the policies and procedures. Therefore, $35,556 \text{ farms} \times 8 \text{ hours per farm} = 284,448$ annual hours to comply with § 112.33(a).

Under § 112.2(b)(2), farms must disclose in documents accompanying produce that is eligible for the commercial processing exemption that the food is “not processed to adequately reduce the presence of microorganisms of public health significance.” It is estimated that § 112.2(b)(2) represents a third-party disclosure requirement for 4,568 entities (4,153 farms that only grow produce exempt from the rule due to commercial processing, who would otherwise be subject to the rule \times an additional 10 percent to account for covered farms relying on this exemption for only some of their produce, and other entities that will be required to make these disclosures). We estimate that it will take 0.08 hours to provide this statement, and the statement will occur on average about 26 times per year (or once a week for half of the year). Therefore, $4,568 \text{ entities} \times 0.08 \text{ hours per entity} \times 26 \text{ shipments} = 9,502$ annual hours to comply with § 112.2(b)(2).

Under § 112.2(b)(3), farms relying on the commercial processing exemption must receive certain annual documentation from their buyers ensuring that the relevant produce will receive the required processing. It is estimated that § 112.2(b)(3) represents a third-party disclosure requirement for 4,568 entities (the same entities described previously regarding § 112.2(b)(2)). We estimate that it will take 1 hour to provide this documentation each year. Therefore, $4,568 \text{ entities} \times 1 \text{ hour per entity} = 4,568$ annual hours to comply with § 112.2(b)(3).

Under § 112.142(b)(2), with certain limited exceptions, if a sprouting operation knows or has reason to believe that a lot of seeds or beans may be contaminated with a pathogen, the sprouting operation must report that information to the seed grower, distributor, supplier, or other entity from whom the sprouting operation received the seeds or beans. We estimate that this requirement will apply to only a small percentage of sprouting operations; therefore this requirement represents a burden to 13 sprouting operations (128 × 10 percent). We estimate that it will take 1 hour to provide this documentation each year. Therefore, 13 sprouting operations × 1 hour per sprouting operations = 13 annual hours to comply with § 112.2(b)(3).

Table 33.-- Estimated Third-Party Disclosure Burden

One Time Third-Party Disclosure Burden					
21 CFR Section (Or FDA Form #)	No. of Respondents	No. of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
112.6(b) Documentation	3,083	1	3,083	0.08	247
Total One-Time Burden					247
Annual Third-Party Disclosure Burden					
21 CFR Section (Or FDA Form #)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
112.6(b) Posting signage	3,285	24	78,840	1	78,840
112.31(b)(2)	29,175	1	29,175	0.08	2,334
112.33(a)	35,556	1	35,556	8	284,448
112.2(b)(2)	4,568	26	118,776	0.08	9,502
112.2(b)(3)	4,568	1	4,568	1	4,568
112.142(b)(2)	13	1	13	1	13
Total annual burden hours					379,705

XXIX. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, FDA has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XXX. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. These references are also available electronically at <http://www.regulations.gov>. We have verified the Web site addresses, but we are not responsible for any subsequent changes to Web sites after this document publishes in the Federal Register.

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List of Subjects

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 112

Foods, Fruits and vegetables, Incorporation by reference, Packaging and containers, Recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 11, 16, and 112 are amended as follows:

PART 11--ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

1. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

2. In § 11.1, add paragraph (k) to read as follows:

§ 11.1 Scope.

* * * * *

(k) This part does not apply to records required to be established or maintained by part 112 of this chapter. Records that satisfy the requirements of part 112 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

* * * * *

PART 16--REGULATORY HEARING BEFORE THE FOOD AND DRUG
ADMINISTRATION

3. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28
U.S.C. 2112; 42 U.S.C. 201-262, 263b, 364.

4. Amend § 16.1 by:

- a. In paragraph (b)(1), adding an entry in numerical order.
- b. In paragraph (b)(2), adding an entry in numerical order.

The additions read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(1) * * *

Section 419(c)(2)(D) of the Federal Food, Drug, and Cosmetic Act relating to the
modification or revocation of a variance from the requirements of section 419 (see part 112,
subpart P of this chapter).

* * * * *

(2) * * *

§§ 112.201 through 112.213, (see part 112, subpart R of this chapter), relating to
withdrawal of a qualified exemption.

* * * * *

5. Add part 112 to read as follows:

PART 112--STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND
HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

Subpart A--General Provisions

Sec.

112.1 What food is covered by this part?

112.2 What produce is not covered by this part?

112.3 What definitions apply to this part?

112.4 Which farms are subject to the requirements of this part?

112.5 Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?

112.6 What modified requirements apply to me if my farm is eligible for a qualified exemption in accordance with § 112.5?

112.7 What records must I establish and keep if my farm is eligible for a qualified exemption in accordance with § 112.5?

Subpart B--General Requirements

112.11 What general requirements apply to persons who are subject to this part?

112.12 Are there any alternatives to the requirements established in this part?

Subpart C--Personnel Qualifications and Training

112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces?

112.22 What minimum requirements apply for training personnel who conduct a covered activity?

112.23 What requirements apply regarding supervisors?

112.30 Under this subpart, what requirements apply regarding records?

Subpart D--Health and Hygiene

112.31 What measures must I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?

112.32 What hygienic practices must personnel use?

112.33 What measures must I take to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance?

Subpart E--Agricultural Water

112.41 What requirements apply to the quality of agricultural water?

112.42 What requirements apply to my agricultural water sources, water distribution system, and pooling of water?

112.43 What requirements apply to treating agricultural water?

112.44 What specific microbial quality criteria apply to agricultural water used for certain intended uses?

112.45 What measures must I take if my agricultural water does not meet the requirements of § 112.41 or § 112.44?

112.46 How often must I test agricultural water that is subject to the requirements of § 112.44?

112.47 Who must perform the tests required under § 112.46 and what methods must be used?

112.48 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?

112.49 What alternatives may I establish and use in lieu of the requirements of this subpart?

112.50 Under this subpart, what requirements apply regarding records?

Subpart F--Biological Soil Amendments of Animal Origin and Human Waste

112.51 What requirements apply for determining the status of a biological soil amendment of animal origin?

112.52 How must I handle, convey, and store biological soil amendments of animal origin?

112.53 What prohibitions apply regarding use of human waste?

112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?

112.55 What microbial standards apply to the treatment processes in § 112.54?

112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?

112.60 Under this subpart, what requirements apply regarding records?

Subpart G--H [Reserved]

Subpart I--Domesticated and Wild Animals

112.81 How do the requirements of this subpart apply to areas where covered activities take place?

112.83 What requirements apply regarding grazing animals, working animals, and animal intrusion?

112.84 Does this regulation require covered farms to take actions that would constitute a “taking” of threatened or endangered species; to take measures to exclude animals from outdoor growing areas; or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages?

Subpart J--[Reserved]

Subpart K--Growing, Harvesting, Packing, and Holding Activities

112.111 What measures must I take if I grow, harvest, pack or hold both covered and excluded produce?

112.112 What measures must I take immediately prior to and during harvest activities?

112.113 How must I handle harvested covered produce during covered activities?

112.114 What requirements apply to dropped covered produce?

112.115 What measures must I take when packaging covered produce?

112.116 What measures must I take when using food-packing (including food packaging) material?

Subpart L--Equipment, Tools, Buildings, and Sanitation

112.121 What equipment and tools are subject to the requirements of this subpart?

112.122 What buildings are subject to the requirements of this subpart?

112.123 What requirements apply regarding equipment and tools subject to this subpart?

112.124 What requirements apply to instruments and controls used to measure, regulate, or record?

112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?

112.126 What requirements apply to my buildings?

112.127 What requirements apply regarding domesticated animals in and around a fully-enclosed building?

112.128 What requirements apply regarding pest control in buildings?

112.129 What requirements apply to toilet facilities?

112.130 What requirements apply for hand-washing facilities?

112.131 What must I do to control and dispose of sewage?

112.132 What must I do to control and dispose of trash, litter, and waste in areas used for covered activities?

112.133 What requirements apply to plumbing?

112.134 What must I do to control animal excreta and litter from domesticated animals that are under my control?

112.140 Under this subpart, what requirements apply regarding records?

Subpart M--Sprouts

112.141 What commodities are subject to this subpart?

112.142 What requirements apply to seeds or beans used to grow sprouts?

112.143 What measures must I take for growing, harvesting, packing, and holding sprouts?

112.144 What testing must I do during growing, harvesting, packing, and holding sprouts?

112.145 What requirements apply to testing the environment for Listeria species or L. monocytogenes?

112.146 What actions must I take if the growing, harvesting, packing, or holding environment tests positive for Listeria species or L. monocytogenes?

112.147 What must I do to collect and test samples of spent sprout irrigation water or sprouts for pathogens?

112.148 What actions must I take if the samples of spent sprout irrigation water or sprouts test positive for a pathogen?

112.150 Under this subpart, what requirements apply regarding records?

Subpart N--Analytical Methods

112.151 What methods must I use to test the quality of water to satisfy the requirements of § 112.46?

112.152 What methods must I use to test the growing, harvesting, packing, and holding environment for Listeria species or L. monocytogenes to satisfy the requirements of § 112.144(a)?

§ 112.153 What methods must I use to test spent sprout irrigation water (or sprouts) from each production batch of sprouts for pathogens to satisfy the requirements of § 112.144(b) and (c)?

Subpart O--Records

112.161 What general requirements apply to records required under this part?

112.162 Where must I store records?

112.163 May I use existing records to satisfy the requirements of this part?

112.164 How long must I keep records?

112.165 What formats are acceptable for the records I keep?

112.166 What requirements apply for making records available and accessible to FDA?

112.167 Can records that I provide to FDA be disclosed to persons outside of FDA?

Subpart P--Variances

112.171 Who may request a variance from the requirements of this part?

112.172 How may a State, tribe, or foreign country request a variance from one or more requirements of this part?

112.173 What must be included in the Statement of Grounds in a petition requesting a variance?

112.174 What information submitted in a petition requesting a variance or submitted in comments on such a petition are publicly available?

112.175 Who responds to a petition requesting a variance?

112.176 What process applies to a petition requesting a variance?

112.177 Can an approved variance apply to any person other than those identified in the petition requesting that variance?

112.178 Under what circumstances may FDA deny a petition requesting a variance?

112.179 When does a variance approved by FDA become effective?

112.180 Under what circumstances may FDA modify or revoke an approved variance?

112.181 What procedures apply if FDA determines that an approved variance should be modified or revoked?

112.182 What are the permissible types of variances that may be granted?

Subpart Q--Compliance and Enforcement

112.192 What is the applicability and status of this part?

112.193 What are the provisions for coordination of education and enforcement?

Subpart R--Withdrawal of Qualified Exemption

112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?

112.202 What procedure will FDA use to withdraw an exemption?

112.203 What information must FDA include in an order to withdraw a qualified exemption?

112.204 What must I do if I receive an order to withdraw a qualified exemption applicable to my farm?

112.205 Can I appeal or request a hearing on an order to withdraw a qualified exemption applicable to my farm?

112.206 What is the procedure for submitting an appeal?

112.207 What is the procedure for requesting an informal hearing?

112.208 What requirements are applicable to an informal hearing?

112.209 Who is the presiding officer for an appeal and for an informal hearing?

112.210 What is the timeframe for issuing a decision on an appeal?

112.211 When is an order to withdraw a qualified exemption applicable to a farm revoked?

112.213 If my qualified exemption is withdrawn, under what circumstances would FDA reinstate my qualified exemption?

Authority: 21 U.S.C. 321, 331, 342, 350h, 371; 42 U.S.C. 243, 264, 271.

Subpart A--General Provisions

§ 112.1 What food is covered by this part?

(a) Unless it is excluded from this part under § 112.2, food that is produce within the meaning of this part and that is a raw agricultural commodity (RAC) is covered by this part. This includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(b) For the purpose of this part and subject to the exemptions and qualified exemptions therein, covered produce includes all of the following:

(1) Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives,

cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams; and

(2) Mixes of intact fruits and vegetables (such as fruit baskets).

§ 112.2 What produce is not covered by this part?

(a) The following produce is not covered by this part:

(1) Produce that is rarely consumed raw, specifically the produce on the following exhaustive list: asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

(2) Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management; and

(3) Produce that is not a raw agricultural commodity.

(b) Produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (2), and (3) of this section) under the following conditions:

(1) The produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of part 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products; and

(2) You must disclose in documents accompanying the produce, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance;” and

(3) You must either:

(i) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from the customer that performs the commercial processing described in paragraph (b)(1) of this section that the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance; or

(ii) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from your customer that an entity in the distribution chain subsequent to the customer will perform commercial processing described in paragraph (b)(1) of this section and that the customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and

(B) Will only sell to another entity that agrees, in writing, it will either:

(1) Follow procedures (identified in a written assurance) that adequately reduce the presence of microorganisms of public health significance; or

(2) Obtain a similar written assurance from its customer that the produce will receive commercial processing described in paragraph (b)(1) of this section, and that there will be disclosure in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and

(4) You must establish and maintain documentation of your compliance with applicable requirements in paragraphs (b)(2) and (3) in accordance with the requirements of subpart O of this part, including:

(i) Documents containing disclosures required under paragraph (b)(2) of this section; and

(ii) Annual written assurances obtained from customers required under paragraph (b)(3) of this section; and

(5) The requirements of this subpart and subpart Q of this part apply to such produce; and

(6) An entity that provides a written assurance under § 112.2(b)(3)(i) or (ii) must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 112.3 What definitions apply to this part?

(a) The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part.

(b) For the purpose of this part, the following definitions of very small business and small business also apply:

(1) Very small business. For the purpose of this part, your farm is a very small business if it is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than \$250,000.

(2) Small business. For the purpose of this part, your farm is a small business if it is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than \$500,000; and your farm is not a very small business as provided in paragraph (b)(1) of this section.

(c) For the purpose of this part, the following definitions also apply:

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Adequately reduce microorganisms of public health significance means reduce the presence of such microorganisms to an extent sufficient to prevent illness.

Agricultural tea means a water extract of biological materials (such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase.

Agricultural teas are held for longer than one hour before application. Agricultural teas are soil amendments for the purposes of this rule.

Agricultural tea additive means a nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.

Agricultural water means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

Animal excreta means solid or liquid animal waste.

Application interval means the time interval between application of an agricultural input (such as a biological soil amendment of animal origin) to a growing area and harvest of covered produce from the growing area where the agricultural input was applied.

Biological soil amendment means any soil amendment containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination.

Biological soil amendment of animal origin means a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination. The term “biological soil amendment of animal origin” does not include any form of human waste.

Composting means a process to produce stabilized compost in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated

period of time (for example, 3 days) at a designated temperature (for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions.

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of “farm” as defined in this chapter. Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in § 112.2(b) are also covered activities. This part does not apply to activities of a facility that are subject to part 110 of this chapter.

Covered produce means produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term “covered produce” refers to the harvestable or harvested part of the crop.

Curing means the final stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. Curing may or may not involve insulation, depending on environmental conditions.

Direct water application method means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food contact surfaces during use of the water.

Farm means:

(i) Primary Production Farm. A Primary Production Farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the

growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:

(A) Pack or hold raw agricultural commodities;

(B) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (i)(C)(2)(i) of this definition; and

(C) Manufacture/process food, provided that:

(1) All food used in such activities is consumed on that farm or another farm under the same management; or

(2) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(i) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(ii) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(iii) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(ii) Secondary Activities Farm. A Secondary Activities Farm is an operation, not located on a Primary Production Farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the Primary Production Farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the Secondary Activities Farm owns, or jointly owns, a majority interest in the Secondary Activities Farm. A Secondary Activities Farm may also conduct those additional activities allowed on a Primary Production Farm in paragraphs (i)(B) and (C) of this definition.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes seeds and beans used to grow sprouts.

Food contact surfaces means those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food contact surfaces” includes food contact surfaces of equipment and tools used during harvest, packing and holding.

Ground water means the supply of fresh water found beneath the Earth’s surface, usually in aquifers, which supply wells and springs. Ground water does not include any water that meets the definition of surface water.

Growth media means material that acts as a substrate during the growth of covered produce (such as mushrooms and some sprouts) that contains, may contain, or consists of components that may include any animal waste (such as stabilized compost, manure, non-fecal animal byproducts or table waste).

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from

the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard means any biological agent that has the potential to cause illness or injury in the absence of its control.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Known or reasonably foreseeable hazard means a biological hazard that is known to be, or has the potential to be, associated with the farm or the food.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Manure means animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. The term “undesirable microorganisms” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm

mixed-type facility,” which is an establishment that is a farm, but that also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and, when required, to produce an accurate record of the observation or measurement.

Non-fecal animal byproduct means solid waste (other than manure) that is animal in origin (such as meat, fat, dairy products, eggs, carcasses, blood meal, bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal) and is generated by commercial, institutional, or agricultural operations.

Packing means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pest means any objectionable animals or insects, including birds, rodents, flies, and larvae.

Pre-consumer vegetative waste means solid waste that is purely vegetative in origin, not considered yard trash, and derived from commercial, institutional, or agricultural operations without coming in contact with animal products, byproducts or manure or with an end user (consumer). Pre-consumer vegetative waste includes material generated by farms, packing houses, canning operations, wholesale distribution centers and grocery stores; products that have

been removed from their packaging (such as out-of-date juice, vegetables, condiments, and bread); and associated packaging that is vegetative in origin (such as paper or corn-starch based products). Pre-consumer vegetative waste does not include table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, or any waste generated by restaurants.

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

Production batch of sprouts means all sprouts that are started at the same time in a single growing unit (e.g., a single drum or bin, or a single rack of trays that are connected to each

other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown in a single growing unit).

Qualified end-user, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227) that is located:

- (i) In the same State or the same Indian reservation as the farm that produced the food; or
- (ii) Not more than 275 miles from such farm.

Raw agricultural commodity (RAC) means “raw agricultural commodity” as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Sewage sludge biosolids means the solid or semi-solid residue generated during the treatment of domestic sewage in a treatment works within the meaning of the definition of “sewage sludge” in 40 CFR 503.9(w).

Soil amendment means any chemical, biological, or physical material (such as elemental fertilizers, stabilized compost, manure, non-fecal animal byproducts, peat moss, perlite, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea and yard trimmings) intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water. The term soil amendment also includes growth media that serve as the entire substrate during the growth of covered produce (such as mushrooms and some sprouts).

Spent sprout irrigation water means water that has been used in the growing of sprouts.

Stabilized compost means a stabilized (i.e., finished) biological soil amendment produced through a controlled composting process.

Static composting means a process to produce stabilized compost in which air is introduced into biological material (in a pile (or row) that may or may not be covered with insulating material, or in an enclosed vessel) by a mechanism that does not include turning. Examples of structural features for introducing air include embedded perforated pipes and a constructed permanent base that includes aeration slots. Examples of mechanisms for introducing air include passive diffusion and mechanical means (such as blowers that suction air from the composting material or blow air into the composting material using positive pressure).

Surface water means all water open to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors that are directly influenced by surface water.

Table waste means any post-consumer food waste, irrespective of whether the source material is animal or vegetative in origin, derived from individuals, institutions, restaurants, retail operations, or other sources where the food has been served to a consumer.

Turned composting means a process to produce stabilized compost in which air is introduced into biological material (in a pile, row, or enclosed vessel) by turning on a regular basis. Turning is the process of mechanically mixing biological material that is undergoing a composting process with the specific intention of moving the outer, cooler sections of the material being composted to the inner, hotter sections.

Visitor means any person (other than personnel) who enters your covered farm with your permission.

Water distribution system means a system to carry water from its primary source to its point of use, including pipes, sprinklers, irrigation canals, pumps, valves, storage tanks, reservoirs, meters, and fittings.

We means the U.S. Food and Drug Administration (FDA).

Yard trimmings means purely vegetative matter resulting from landscaping maintenance or land clearing operations, including materials such as tree and shrub trimmings, grass clippings, palm fronds, trees, tree stumps, untreated lumber, untreated wooden pallets, and associated rocks and soils.

You, for purposes of this part, means the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of this part.

§ 112.4 Which farms are subject to the requirements of this part?

(a) Except as provided in paragraph (b) of this section, a farm or farm mixed-type facility with an average annual monetary value of produce (as “produce” is defined in § 112.3(c)) sold during the previous 3-year period of more than \$25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment, is a “covered farm” subject to this part. Covered farms subject to this part must comply with all applicable requirements of this part when conducting a covered activity on covered produce.

(b) A farm is not a covered farm if it satisfies the requirements in § 112.5 and we have not withdrawn the farm’s exemption in accordance with the requirements of subpart R of this part.

§ 112.5 Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?

(a) A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if:

(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in § 112.3(c)) the farm sold directly to qualified end-users (as defined in § 112.3(c)) during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and

(2) The average annual monetary value of all food (as defined in § 112.3(c)) the farm sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

(b) For the purpose of determining whether the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

§ 112.6 What modified requirements apply to me if my farm is eligible for a qualified exemption in accordance with § 112.5?

(a) If your farm is eligible for a qualified exemption in accordance with § 112.5, you are subject to the requirements of:

- (1) This subpart (General Provisions);
- (2) Subpart O of this part (Records);
- (3) Subpart Q of this part (Compliance and Enforcement); and
- (4) Subpart R of this part (Withdrawal of Qualified Exemption).

(b) In addition, you are subject to the following modified requirements:

(1) When a food packaging label is required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act or its implementing regulations, you

must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown.

(2) When a food packaging label is not required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice.

(3) The complete business address that you must include in accordance with the requirements of paragraph (b)(1) or (2) of this section must include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms.

§ 112.7 What records must I establish and keep if my farm is eligible for a qualified exemption in accordance with § 112.5?

If your farm is eligible for a qualified exemption in accordance with § 112.5:

(a) You must establish and keep records required under this provision in accordance with the requirements of subpart O of this part, except that the requirement in § 112.161(a)(4) for a signature or initial of the person performing the activity is not required for sales receipts kept in the normal course of business. Such receipts must be dated as required under § 112.161(a)(4).

(b) You must establish and keep adequate records necessary to demonstrate that your farm satisfies the criteria for a qualified exemption that are described in § 112.5, including a written record reflecting that you have performed an annual review and verification of your farm's continued eligibility for the qualified exemption.

Subpart B--General Requirements

§ 112.11 What general requirements apply to persons who are subject to this part?

You must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act on account of such hazards.

§ 112.12 Are there any alternatives to the requirements established in this part?

(a) You may establish alternatives to certain specific requirements of subpart E of this part, as specified in § 112.49, provided that you satisfy the requirements of paragraphs (b) and (c) of this section.

(b) You may establish and use an alternative to any of the requirements specified in paragraph (a) of this section, provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part, and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in light of your covered produce, practices, and conditions.

(c) Scientific data and information used to support an alternative to a requirement specified in paragraph (a) of this section may be developed by you, available in the scientific literature, or available to you through a third party. You must establish and maintain documentation of the scientific data and information on which you rely in accordance with the

requirements of subpart O of this part. You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative under this section.

Subpart C--Personnel Qualifications and Training

§ 112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces?

All of the following requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces:

(a) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive adequate training, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually.

(b) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must have a combination of education, training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with this part.

(c) Training must be conducted in a manner that is easily understood by personnel being trained.

(d) Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in subparts C through O of this part.

§ 112.22 What minimum requirements apply for training personnel who conduct a covered activity?

(a) At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities must receive training that includes all of the following:

(1) Principles of food hygiene and food safety;

(2) The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food contact surfaces with microorganisms of public health significance; and

(3) The standards established by FDA in subparts C through O of this part that are applicable to the employee's job responsibilities.

(b) Persons who conduct harvest activities for covered produce must also receive training that includes all of the following:

(1) Recognizing covered produce that must not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards;

(2) Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce with known or reasonably foreseeable hazards; and

(3) Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person's job responsibilities.

(c) At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.

§ 112.23 What requirements apply regarding supervisors?

You must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of this part.

§ 112.30 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the persons(s) trained.

Subpart D--Health and Hygiene

§ 112.31 What measures must I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?

(a) You must take measures to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance from any person with an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea).

(b) The measures you must take to satisfy the requirements of paragraph (a) of this section must include all of the following measures:

(1) Excluding any person from working in any operations that may result in contamination of covered produce or food contact surfaces with microorganisms of public health significance when the person (by medical examination, the person's acknowledgement, or observation) is shown to have, or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health; and

(2) Instructing personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have an applicable health condition.

§ 112.32 What hygienic practices must personnel use?

(a) Personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to the extent necessary to protect against such contamination.

(b) The hygienic practices that personnel use to satisfy the requirements of paragraph (a) of this section when handling (contacting) covered produce or food contact surfaces during a covered activity must include all of the following practices:

(1) Maintaining adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces;

(2) Avoiding contact with animals other than working animals, and taking appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals;

(3) Washing hands thoroughly, including scrubbing with soap (or other effective surfactant) and running water that satisfies the requirements of § 112.44(a) (as applicable) for water used to wash hands, and drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices:

(i) Before starting work;

(ii) Before putting on gloves;

(iii) After using the toilet;

(iv) Upon return to the work station after any break or other absence from the work station;

(v) As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and

(vi) At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards;

(4) If you choose to use gloves in handling covered produce or food contact surfaces, maintaining gloves in an intact and sanitary condition and replacing such gloves when no longer able to do so;

(5) Removing or covering hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand; and

(6) Not eating, chewing gum, or using tobacco products in an area used for a covered activity (however, drinking beverages is permitted in designated areas).

§ 112.33 What measures must I take to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance?

(a) You must make visitors aware of policies and procedures to protect covered produce and food contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures.

(b) You must make toilet and hand-washing facilities accessible to visitors.

Subpart E--Agricultural Water

§ 112.41 What requirements apply to the quality of agricultural water?

All agricultural water must be safe and of adequate sanitary quality for its intended use.

§ 112.42 What requirements apply to my agricultural water sources, water distribution system, and pooling of water?

(a) At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems, to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following:

(1) The nature of each agricultural water source (for example, ground water or surface water);

(2) The extent of your control over each agricultural water source;

(3) The degree of protection of each agricultural water source;

(4) Use of adjacent and nearby land; and

(5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.

(b) You must adequately maintain all agricultural water distribution systems to the extent they are under your control as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.

(c) You must adequately maintain all agricultural water sources to the extent they are under your control (such as wells). Such maintenance includes regularly inspecting each source to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; correcting any

significant deficiencies (e.g., repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections); and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.

(d) As necessary and appropriate, you must implement measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards as a result of contact of covered produce with pooled water. For example, such measures may include using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method.

§ 112.43 What requirements apply to treating agricultural water?

(a) When agricultural water is treated in accordance with § 112.45:

(1) Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in § 112.44, as applicable.

(2) You must deliver any treatment of agricultural water in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.

(b) You must monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.

§ 112.44 What specific microbial quality criteria apply to agricultural water used for certain intended uses?

(a) When you use agricultural water for any one or more of these following purposes, you must ensure there is no detectable generic Escherichia coli (E. coli) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes:

(1) Used as sprout irrigation water;

(2) Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities;

(3) Used to contact food contact surfaces, or to make ice that will contact food contact surfaces; and

(4) Used for washing hands during and after harvest activities.

(b) When you use agricultural water during growing activities for covered produce (other than sprouts) using a direct water application method, the following criteria apply (unless you establish and use alternative criteria in accordance with § 112.49):

(1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic E. coli per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and

(2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic E. coli per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).

§ 112.45 What measures must I take if my agricultural water does not meet the requirements of § 112.41 or § 112.44?

(a) If you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use as required under § 112.41 and/or if your agricultural water does not meet the microbial quality criterion for the specified purposes as required under § 112.44(a), you must immediately discontinue that use(s), and before you may use the water source and/or distribution system again for the intended use(s), you must either:

(1) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and, as applicable, adequately ensure that your agricultural water meets the microbial quality criterion in § 112.44(a); or

(2) Treat the water in accordance with the requirements of § 112.43.

(b) If you have determined that your agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required under § 112.44(b), as soon as practicable and no later than the following year, you must discontinue that use, unless you either:

(1) Apply a time interval(s) (in days) and/or a (calculated) log reduction by:

(i) Applying a time interval between last irrigation and harvest using either:

(A) A microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of your geometric mean (GM) and statistical threshold value (STV) to meet the microbial quality

criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), but no greater than a maximum time interval of 4 consecutive days; or

(B) An alternative microbial die-off rate and any accompanying maximum time interval, in accordance with § 112.49; and/or

(ii) Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a (calculated) log reduction using appropriate microbial removal rates during activities such as commercial washing, to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), and any accompanying maximum time interval or log reduction, provided you have adequate supporting scientific data and information;

(2) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and adequately ensure that your agricultural water meets the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable); or

(3) Treat the water in accordance with the requirements of § 112.43.

§ 112.46 How often must I test agricultural water that is subject to the requirements of § 112.44?

(a) There is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when:

(1) You receive water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State (as defined in 40 CFR

141.2) approved to administer the SDWA public water supply program, and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement;

(2) You receive water from a public water supply that furnishes water that meets the microbial quality requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or

(3) You treat water in accordance with the requirements of § 112.43.

(b) Except as provided in paragraph (a) of this section, you must take the following steps for each source of water used for purposes that are subject to the requirements of § 112.44(b):

(1) Conduct an initial survey to develop a microbial water quality profile of the agricultural water source.

(i) The initial survey must be conducted:

(A) For an untreated surface water source, by taking a minimum total of 20 samples of agricultural water (or an alternative testing frequency that you establish and use, in accordance with § 112.49) over a minimum period of 2 years, but not greater than 4 years.

(B) For an untreated ground water source, by taking a minimum total of four samples of agricultural water during the growing season or over a period of 1 year.

(ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest. The microbial water quality profile initially consists of the geometric mean (GM) and the statistical threshold value (STV) of generic Escherichia coli (E. coli) (colony forming units (CFU) per 100 milliliter (mL)) calculated using this data set. You must determine the appropriate way(s) in which the water may be used based on your microbial water quality profile in accordance with § 112.45(b).

(iii) You must update the microbial water quality profile annually as required under paragraph (b)(2) of this section, and otherwise required under paragraph (b)(3) of this section.

(2) Conduct an annual survey to update the microbial water quality profile of your agricultural water.

(i) After the initial survey described in paragraph (b)(1)(i) of this section, you must test the water annually to update your existing microbial water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. You must analyze:

(A) For an untreated surface water source, a minimum number of five samples per year (or an alternative testing frequency that you establish and use, in accordance with § 112.49).

(B) For an untreated ground water source, a minimum of one sample per year.

(ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest.

(iii) To update the microbial water quality profile, you must calculate revised GM and STV values using your current annual survey data, combined with your most recent initial or annual survey data from within the previous 4 years, to make up a rolling data set of:

(A) At least 20 samples for untreated surface water sources; and

(B) At least 4 samples for untreated ground water sources.

(iv) You must modify your water use, as appropriate, based on the revised GM and STV values in your updated microbial water quality profile in accordance with § 112.45(b).

(3) If you have determined or have reason to believe that your microbial water quality profile no longer represents the quality of your water (for example, if there are significant changes in adjacent land use that are reasonably likely to adversely affect the quality of your

water source), you must develop a new microbial water quality profile reflective of the time period at which you believe your microbial water quality profile changed.

(i) To develop a new microbial water quality profile, you must calculate new GM and STV values using your current annual survey data (if taken after the time of the change), combined with new data, to make up a data set of:

(A) At least 20 samples for untreated surface water sources; and

(B) At least 4 samples for untreated ground water sources.

(ii) You must modify your water use based on the new GM and STV values in your new microbial water quality profile in accordance with § 112.45(b).

(c) If you use untreated ground water for the purposes that are subject to the requirements of § 112.44(a), you must initially test the microbial quality of each source of the untreated ground water at least four times during the growing season or over a period of 1 year, using a minimum total of four samples collected to be representative of the intended use(s). Based on these results, you must determine whether the water can be used for that purpose, in accordance with § 112.45(a). If your four initial sample results meet the microbial quality criteria of § 112.44(a), you may test once annually thereafter, using a minimum of one sample collected to be representative of the intended use(s). You must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criteria in § 112.44(a).

§ 112.47 Who must perform the tests required under § 112.46 and what methods must be used?

(a) You may meet the requirements related to agricultural water testing required under § 112.46 using:

(1) Test results from your agricultural water source(s) performed by you, or by a person or entity acting on your behalf; or

(2) Data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s) and all other applicable requirements of this part are met.

(b) Agricultural water samples must be aseptically collected and tested using a method as set forth in § 112.151.

§ 112.48 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?

(a) You must manage the water as necessary, including by establishing and following water-change schedules for re-circulated water, to maintain its safety and adequate sanitary quality and minimize the potential for contamination of covered produce and food contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce).

(b) You must visually monitor the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for buildup of organic material (such as soil and plant debris).

(c) You must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.

§ 112.49 What alternatives may I establish and use in lieu of the requirements of this subpart?

Provided you satisfy the requirements of § 112.12, you may establish and use one or more of the following alternatives:

(a) An alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, in lieu of the microbial quality criteria in § 112.44(b);

(b) An alternative microbial die-off rate and an accompanying maximum time interval, in lieu of the microbial die-off rate and maximum time interval in § 112.45(b)(1)(i);

(c) An alternative minimum number of samples used in the initial survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(1)(i)(A); and

(d) An alternative minimum number of samples used in the annual survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(2)(i)(A).

§ 112.50 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep the following records:

(1) The findings of the inspection of your agricultural water system in accordance with the requirements of § 112.42(a);

(2) Documentation of the results of all analytical tests conducted on agricultural water for purposes of compliance with this subpart;

(3) Scientific data or information you rely on to support the adequacy of a method used to satisfy the requirements of § 112.43(a)(1) and (2);

(4) Documentation of the results of water treatment monitoring under § 112.43(b);

(5) Scientific data or information you rely on to support the microbial die-off or removal rate(s) that you used to determine the time interval (in days) between harvest and end of storage,

including other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic Escherichia coli (E. coli), in accordance with § 112.45(b)(1)(ii);

(6) Documentation of actions you take in accordance with § 112.45. With respect to any time interval or (calculated) log reduction applied in accordance with § 112.45(b)(1)(i) and/or (ii), such documentation must include the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities such as the dates of last irrigation and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing);

(7) Annual documentation of the results or certificates of compliance from a public water system required under § 112.46(a)(1) or (2), if applicable;

(8) Scientific data or information you rely on to support any alternative that you establish and use in accordance with § 112.49; and

(9) Any analytical methods you use in lieu of the method that is incorporated by reference in § 112.151(a).

Subpart F--Biological Soil Amendments of Animal Origin and Human Waste

§ 112.51 What requirements apply for determining the status of a biological soil amendment of animal origin?

(a) A biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54, or, in the case of an agricultural tea, the biological materials of animal origin used to make the tea have been so processed, the water used to make the tea is

not untreated surface water, and the water used to make the tea has no detectable generic Escherichia coli (E. coli) in 100 milliliters (mL) of water.

(b) A biological soil amendment of animal origin is untreated if it:

(1) Has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials of animal origin used to make the tea have not been so processed, or the water used to make the tea is untreated surface water, or the water used to make the tea has detectable generic E. coli in 100 mL of water;

(2) Has become contaminated after treatment;

(3) Has been recombined with an untreated biological soil amendment of animal origin;

(4) Is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness; or

(5) Is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.

§ 112.52 How must I handle, convey, and store biological soil amendments of animal origin?

(a) You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments. Agricultural teas that are biological soil amendments of animal origin may be used in water distribution systems provided that all other requirements of this rule are met.

(b) You must handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin.

(c) You must handle, convey, and store any biological soil amendment of animal origin that you know or have reason to believe may have become contaminated as if it was untreated.

§ 112.53 What prohibitions apply regarding use of human waste?

You may not use human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.

§ 112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?

Each of the following treatment processes are acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce, provided that the resulting biological soil amendments are applied in accordance with the applicable requirements of

§ 112.56:

(a) A scientifically valid controlled physical process (e.g., thermal), chemical process (e.g., high alkaline pH), biological process (e.g., composting), or a combination of scientifically valid controlled physical, chemical and/or biological processes that has been validated to satisfy the microbial standard in § 112.55(a) for Listeria monocytogenes (L. monocytogenes), Salmonella species, and E. coli O157:H7; or

(b) A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, and/or biological processes, that has been validated to satisfy the microbial standard in § 112.55(b) for Salmonella species and fecal coliforms. Examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in § 112.55(b) include:

(1) Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 consecutive days and is followed by adequate curing; and

(2) Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.

§ 112.55 What microbial standards apply to the treatment processes in § 112.54?

The following microbial standards apply to the treatment processes in § 112.54 as set forth in that section.

(a) For L. monocytogenes, Salmonella species, and E. coli O157:H7, the relevant standards in the table in this paragraph (a); or

For the microorganism—	The microbial standard is—
(1) <u>L. monocytogenes</u>	Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or milliliter, if liquid is being sampled) analytical portion.
(2) <u>Salmonella</u> species	Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or milliliter, if liquid is being sampled) of total solids.
(3) <u>E. coli</u> O157:H7	Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion.

(b) Salmonella species are not detected using a method that can detect three MPN Salmonella species per 4 grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).

§ 112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?

(a) You must apply the biological soil amendments of animal origin specified in the first column of the table in this paragraph (a) in accordance with the application requirements

specified in the second column of the table in this paragraph (a) and the minimum application intervals specified in the third column of the table in this paragraph (a).

If the biological soil amendment of animal origin is--	Then the biological soil amendment of animal origin must be applied--	And then the minimum application interval is--
(1)(i) Untreated	In a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application	[Reserved]
(ii) Untreated	In a manner that does not contact covered produce during or after application	0 days
(2) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, and/or biological processes, in accordance with the requirements of § 112.54(b) to meet the microbial standard in § 112.55(b).	In a manner that minimizes the potential for contact with covered produce during and after application	0 days
(3) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, or biological processes, in accordance with the requirements of § 112.54(a) to meet the microbial standard in § 112.55(a).	In any manner (i.e., no restrictions)	0 days

(b) [Reserved]

§ 112.60 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) For any biological soil amendment of animal origin you use, you must establish and keep the following records:

(1) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) at least annually that:

- (i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and
- (ii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin; and

(2) For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature, and turnings) were achieved.

Subpart G--H [Reserved]

Subpart I--Domesticated and Wild Animals

§ 112.81 How do the requirements of this subpart apply to areas where covered activities take place?

(a) The requirements of this subpart apply when a covered activity takes place in an outdoor area or a partially- enclosed building and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce.

(b) The requirements of this subpart do not apply:

(1) When a covered activity takes place in a fully- enclosed building; or

(2) To fish used in aquaculture operations.

§ 112.83 What requirements apply regarding grazing animals, working animals, and animal intrusion?

(a) You must take the steps set forth in paragraph (b) of this section if under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce.

(b) You must:

(1) Assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience); and

(2) If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.

§ 112.84 Does this regulation require covered farms to take actions that would constitute a “taking” of threatened or endangered species; to take measures to exclude animals from outdoor growing areas; or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages?

No. Nothing in this regulation authorizes the “taking” of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531-1544) (i.e., to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

Subpart J--[Reserved]

Subpart K--Growing, Harvesting, Packing, and Holding Activities

§ 112.111 What measures must I take if I grow, harvest, pack or hold both covered and excluded produce?

If you grow, harvest, pack or hold produce that is not covered in this part (i.e., excluded produce in accordance with § 112.2) and also conduct such activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with this part, you must take measures during these covered activities, as applicable, to:

(a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and

(b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce.

§ 112.112 What measures must I take immediately prior to and during harvest activities?

You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. At a minimum, identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used.

§ 112.113 How must I handle harvested covered produce during covered activities?

You must handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards--for example, by avoiding, to the degree practicable, contact of cut surfaces of harvested produce with soil.

§ 112.114 What requirements apply to dropped covered produce?

You must not distribute dropped covered produce. Dropped covered produce is covered produce that drops to the ground before harvest. Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds).

§ 112.115 What measures must I take when packaging covered produce?

You must package covered produce in a manner that prevents the formation of Clostridium botulinum toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms).

§ 112.116 What measures must I take when using food-packing (including food packaging) material?

(a) You must use food-packing material that is adequate for its intended use, which includes being:

- (1) Cleanable or designed for single use; and
- (2) Unlikely to support growth or transfer of bacteria.

(b) If you reuse food-packing material, you must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.

Subpart L--Equipment, Tools, Buildings, and Sanitation

§ 112.121 What equipment and tools are subject to the requirements of this subpart?

Equipment and tools subject to the requirements of this subpart are those that are intended to, or likely to, contact covered produce; and those instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of microorganisms of

public health significance. Examples include knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce).

§ 112.122 What buildings are subject to the requirements of this subpart?

Buildings subject to the requirements of this subpart include:

- (a) Any fully- or partially-enclosed building used for covered activities, including minimal structures that have a roof but do not have any walls; and
- (b) Storage sheds, buildings, or other structures used to store food contact surfaces (such as harvest containers and food-packing materials).

§ 112.123 What general requirements apply regarding equipment and tools subject to this subpart?

All of the following requirements apply regarding equipment and tools subject to this subpart:

- (a) You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and
- (b) Equipment and tools must be:
 - (1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces; and
 - (2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests.

(c) Seams on food contact surfaces of equipment and tools that you use must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.

(d)(1) You must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.

(2) You must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.

(e) If you use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, you must do so in a manner that minimizes the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards.

§ 112.124 What requirements apply to instruments and controls used to measure, regulate, or record?

Instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be:

- (a) Accurate and precise as necessary and appropriate in keeping with their purpose;
- (b) Adequately maintained; and
- (c) Adequate in number for their designated uses.

§ 112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?

Equipment that is subject to this subpart that you use to transport covered produce must be:

- (a) Adequately clean before use in transporting covered produce; and
- (b) Adequate for use in transporting covered produce.

§ 112.126 What requirements apply to my buildings?

(a) All of the following requirements apply regarding buildings:

(1) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards.

Buildings must:

(i) Provide sufficient space for placement of equipment and storage of materials;

(ii) Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means;

and

(2) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.

(b) You must implement measures to prevent contamination of your covered produce and food contact surfaces in your buildings, as appropriate, considering the potential for such contamination through:

- (1) Floors, walls, ceilings, fixtures, ducts, or pipes; and

(2) Drip or condensate.

§ 112.127 What requirements apply regarding domesticated animals in and around a fully-enclosed building?

(a) You must take reasonable precautions to prevent contamination of covered produce, food contact surfaces, and food-packing materials in fully-enclosed buildings with known or reasonably foreseeable hazards from domesticated animals by:

(1) Excluding domesticated animals from fully-enclosed buildings where covered produce, food contact surfaces, or food-packing material is exposed; or

(2) Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted on covered produce by location, time, or partition.

(b) Guard or guide dogs may be allowed in some areas of a fully enclosed building if the presence of the dogs is unlikely to result in contamination of produce, food contact surfaces, or food-packing materials.

§ 112.128 What requirements apply regarding pest control in buildings?

(a) You must take those measures reasonably necessary to protect covered produce, food contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate.

(b) For fully-enclosed buildings, you must take measures to exclude pests from your buildings.

(c) For partially-enclosed buildings, you must take measures to prevent pests from becoming established in your buildings (such as by use of screens or by monitoring for the presence of pests and removing them when present).

§ 112.129 What requirements apply to toilet facilities?

All of the following requirements apply to toilet facilities:

(a) You must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities.

(b) Your toilet facilities must be designed, located, and maintained to:

(1) Prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste;

(2) Be directly accessible for servicing, be serviced and cleaned at a frequency sufficient to ensure suitability of use, and be kept supplied with toilet paper; and

(3) Provide for the sanitary disposal of waste and toilet paper.

(c) During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands.

§ 112.130 What requirements apply for hand-washing facilities?

All of the following requirements apply to hand-washing facilities:

(a) You must provide personnel with adequate, readily accessible hand-washing facilities during growing activities that take place in a fully-enclosed building, and during covered harvest, packing, or holding activities.

(b) Your hand-washing facilities must be furnished with:

(1) Soap (or other effective surfactant);

(2) Running water that satisfies the requirements of § 112.44(a) for water used to wash hands; and

(3) Adequate drying devices (such as single service towels, sanitary towel service, or electric hand dryers).

(c) You must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a hand-washing facility and take appropriate measures to prevent waste water from a hand-washing facility from contaminating covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(d) You may not use antiseptic hand rubs as a substitute for soap (or other effective surfactant) and water.

§ 112.131 What must I do to control and dispose of sewage?

All of the following requirements apply for the control and disposal of sewage:

(a) You must dispose of sewage into an adequate sewage or septic system or through other adequate means.

(b) You must maintain sewage and septic systems in a manner that prevents contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(c) You must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of covered produce, and prevents or minimizes contamination of food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

(d) After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, you must take appropriate steps to ensure that sewage and

septic systems continue to operate in a manner that does not contaminate covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

§ 112.132 What must I do to control and dispose of trash, litter, and waste in areas used for covered activities?

All of the following requirements apply to the control and disposal of trash, litter, and waste in areas used for covered activities:

(a) You must convey, store, and dispose of trash, litter and waste to:

(1) Minimize the potential for trash, litter, or waste to attract or harbor pests; and

(2) Protect against contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(b) You must adequately operate systems for waste treatment and disposal so that they do not constitute a potential source of contamination in areas used for a covered activity.

§ 112.133 What requirements apply to plumbing?

The plumbing must be of an adequate size and design and be adequately installed and maintained to:

(a) Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or for hand-washing and toilet facilities;

(b) Properly convey sewage and liquid disposable waste;

(c) Avoid being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or agricultural water sources; and

(d) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for a covered activity, for sanitary operations, or for use in hand-washing facilities.

§ 112.134 What must I do to control animal excreta and litter from domesticated animals that are under my control?

(a) If you have domesticated animals, to prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems with animal waste, you must:

- (1) Adequately control their excreta and litter; and
 - (2) Maintain a system for control of animal excreta and litter.
- (b) [Reserved]

§ 112.140 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep documentation of the date and method of cleaning and sanitizing of equipment subject to this subpart used in:

- (1) Growing operations for sprouts; and
- (2) Covered harvesting, packing, or holding activities.

Subpart M--Sprouts

§ 112.141 What commodities are subject to this subpart?

The requirements of this subpart apply to growing, harvesting, packing, and holding of all sprouts, except soil- or substrate-grown sprouts harvested without their roots.

§ 112.142 What requirements apply to seeds or beans used to grow sprouts?

In addition to the requirements of this part, all of the following requirements apply to seeds or beans used to grow sprouts.

(a) You must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you will use for sprouting.

(b) Except as provided in paragraph (c) of this section, if you know or have reason to believe that a lot of seeds or beans may be contaminated with a pathogen (either because it has been associated with foodborne illness; or based on microbial test results, including a positive finding of a pathogen in tests required under § 112.144(b)), you must:

(1) Discontinue use of all seeds or beans from that lot for sprout production and ensure that sprouts grown from that lot of seeds or beans do not enter commerce; and

(2) Report the information (association with illness and/or findings of microbial testing) to the seed grower, distributor, supplier, or other entity from whom you received the seeds or beans.

(c) If your reason to believe that a lot of seeds or beans may be contaminated was based only on microbial test results:

(1) You are not required to take the steps set forth in paragraph (b)(1) of this section if you treat your lot of seeds or beans with a process that is reasonably certain to achieve destruction or elimination in the seeds or beans of the most resistant microorganisms of public health significance that are likely to occur in the seeds or beans; or

(2) You are not required to take the steps set forth in paragraphs (b)(1) and (2) of this section if you later reasonably determine, through appropriate followup actions, that the lot of seeds or beans is not the source of contamination (e.g., the lot of seeds or beans is not the source of a pathogen found in spent sprout irrigation water or sprouts).

(d) You must visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards.

(e) You must either:

(1) Treat seeds or beans that will be used to grow sprouts using a scientifically valid method to reduce microorganisms of public health significance; or

(2) Rely on prior treatment of seeds or beans conducted by a grower, distributor, or supplier of the seeds or beans (whether to fulfill this requirement completely or for the purpose of considering such prior treatment when applying appropriate additional treatment of the seeds or beans at the covered farm immediately before sprouting), provided that you obtain documentation (such as a Certificate of Conformance) from the grower, distributor, or supplier that:

(i) The prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance; and

(ii) The treated seeds or beans were handled and packaged following the treatment in a manner that minimizes the potential for contamination.

§ 112.143 What measures must I take for growing, harvesting, packing, and holding sprouts?

You must take all of the following measures for growing, harvesting, packing, and holding sprouts:

(a) You must grow, harvest, pack, and hold sprouts in a fully-enclosed building.

(b) Any food contact surfaces you use to grow, harvest, pack, or hold sprouts must be cleaned and sanitized before contact with sprouts or seeds or beans used to grow sprouts.

(c) You must conduct testing during growing, harvesting, packing, and holding sprouts, as specified in § 112.144.

(d) You must establish and implement a written environmental monitoring plan as specified in § 112.145.

(e) You must take certain actions if you detect Listeria species or L. monocytogenes in the growing, harvesting, packing, or holding environment, as specified in § 112.146.

(f) You must establish and implement a written sampling plan to test spent sprout irrigation water or sprouts for pathogens as specified in § 112.147.

(g) You must take certain actions if the samples of spent sprout irrigation water or sprouts test positive for a pathogen as specified in § 112.148.

§ 112.144 What testing must I do during growing, harvesting, packing, and holding sprouts?

All of the following testing must be done during growing, harvesting, packing, and holding sprouts:

(a) You must test the growing, harvesting, packing, and holding environment for Listeria species or L. monocytogenes in accordance with the requirements of § 112.145.

(b) You must either:

(1) Test spent sprout irrigation water from each production batch of sprouts for E. coli O157:H7, Salmonella species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of § 112.147; or

(2) If testing spent sprout irrigation water is not practicable (for example, soil-grown sprouts harvested with roots or for hydroponically grown sprouts that use very little water), test each production batch of sprouts at the in-process stage (i.e., while sprouts are still growing) for E. coli O157:H7, Salmonella species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of § 112.147.

(c) In addition to E. coli O157:H7 and Salmonella species, you must conduct tests as provided in paragraph (b) of this section for additional pathogens when the following conditions are met:

(1) Testing for the pathogen is reasonably necessary to minimize the risk of serious adverse health consequences or death from use of, or exposure to, sprouts; and

(2) A scientifically valid test method for the pathogen is available to detect the pathogen in spent sprout irrigation water (or sprouts).

§ 112.145 What requirements apply to testing the environment for Listeria species or L. monocytogenes?

All of the following testing requirements apply for the growing, harvesting, packing, and holding environment for Listeria species or L. monocytogenes.

(a) You must establish and implement a written environmental monitoring plan that is designed to identify L. monocytogenes if it is present in the growing, harvesting, packing, or holding environment.

(b) Your written environmental monitoring plan must be directed to sampling and testing for either Listeria species or L. monocytogenes.

(c) Your written environmental monitoring plan must include a sampling plan that specifies:

(1) What you will test collected samples for (i.e., Listeria species or L. monocytogenes);

(2) How often you will collect environmental samples, which must be no less than monthly, and at what point during production you will collect the samples; and

(3) Sample collection sites; the number and location of sampling sites must be sufficient to determine whether measures are effective and must include appropriate food contact surfaces

and non-food-contact surfaces of equipment, and other surfaces within the growing, harvesting, packing, and holding environment.

(d) You must aseptically collect environmental samples and test them for Listeria species or L. monocytogenes using a method as set forth in § 112.152.

(e) Your written environmental monitoring plan must include a corrective action plan that, at a minimum, requires you to take the actions in § 112.146, and details when and how you will accomplish those actions, if the growing, harvesting, packing, or holding environment tests positive for Listeria species or L. monocytogenes.

§ 112.146 What actions must I take if the growing, harvesting, packing, or holding environment tests positive for Listeria species or L. monocytogenes?

You must, at a minimum, take the following actions if you detect Listeria species or L. monocytogenes in the growing, harvesting, packing, or holding environment:

(a) Conduct additional testing of surfaces and areas surrounding the area where Listeria species or L. monocytogenes was detected to evaluate the extent of the problem, including the potential for Listeria species or L. monocytogenes to have become established in a niche;

(b) Clean and sanitize the affected surfaces and surrounding areas;

(c) Conduct additional sampling and testing to determine whether the Listeria species or L. monocytogenes has been eliminated;

(d) Conduct finished product testing when appropriate;

(e) Perform any other actions necessary to prevent recurrence of the contamination; and

(f) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into commerce.

§ 112.147 What must I do to collect and test samples of spent sprout irrigation water or sprouts for pathogens?

All of the following requirements apply for collecting and testing samples of spent sprout irrigation water or sprouts for pathogens as required in § 112.144(b):

(a) You must establish and implement a written sampling plan that identifies the number and location of samples (of spent sprout irrigation water or sprouts) to be collected for each production batch of sprouts to ensure that the collected samples are representative of the production batch when testing for contamination.

(b) In accordance with the written sampling plan required under paragraph (a) of this section, you must aseptically collect samples of spent sprout irrigation water or sprouts, and test the collected samples for pathogens using a method as set forth in § 112.153. You must not allow the production batch of sprouts to enter into commerce unless the results of the testing of spent sprout irrigation water or sprouts are negative for E. coli O157:H7, Salmonella species, and, if applicable, a pathogen meeting the criteria in § 112.144(c).

(c) Your written sampling plan must include a corrective action plan that at a minimum, requires you to take the actions in § 112.148, and details when and how you will accomplish those actions, if the samples of spent sprout irrigation water or sprouts test positive for E. coli O157:H7, Salmonella species, or a pathogen meeting the criteria in § 112.144(c).

§ 112.148 What actions must I take if the samples of spent sprout irrigation water or sprouts test positive for a pathogen?

You must, at a minimum, take the following actions if the samples of spent sprout irrigation water or sprouts test positive for E. coli O157:H7, Salmonella species, or a pathogen meeting the criteria in § 112.144(c):

(a) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into commerce;

(b) Take the steps required in § 112.142(b) with respect to the lot of seeds or beans used to grow the affected production batch of sprouts (except as allowed under § 112.142(c));

(c) Clean and sanitize the affected surfaces and surrounding areas; and

(d) Perform any other actions necessary to prevent reoccurrence of the contamination.

§ 112.150 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep the following records:

(1) Documentation of your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm; or alternatively, documentation (such as a Certificate of Conformance) from your seed supplier that seeds or beans are treated to reduce microorganisms of public health significance and are appropriately handled and packaged following the treatment, in accordance with the requirements of § 112.142(e);

(2) Your written environmental monitoring plan in accordance with the requirements of § 112.145;

(3) Your written sampling plan for each production batch of sprouts in accordance with the requirements of § 112.147(a) and (c);

(4) Documentation of the results of all analytical tests conducted for purposes of compliance with this subpart;

(5) Any analytical methods you use in lieu of the methods that are incorporated by reference in §§ 112.152 and 112.153; and

(6) Documentation of actions you take in accordance with §§ 112.142(b) and (c), 112.146, and 112.148.

Subpart N--Analytical Methods

§ 112.151 What methods must I use to test the quality of water to satisfy the requirements of § 112.46?

You must test the quality of water using:

(a) The method of analysis published by the U.S. Environmental Protection Agency (EPA), “Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA-821-R-09-007,” December, 2009. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from EPA, Office of Water (4303T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. You may inspect a copy at FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html; or

(b)(1) A scientifically valid method that is at least equivalent to the method of analysis in § 112.151(a) in accuracy, precision, and sensitivity; or

(2) For any other indicator of fecal contamination you may test for pursuant to § 112.49(a), a scientifically valid method.

§ 112.152 What methods must I use to test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* to satisfy the requirements of § 112.144(a)?

You must test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* using:

(a) The method of analysis described in “Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples,” Version 1, October 2015, U.S. Food and Drug Administration. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy from, and/or inspect a copy at, the Division of Produce Safety, Center for Food Safety and Applied Nutrition (CFSAN), U.S. Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1600; FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039; <http://www.fda.gov/fsma>; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html; or

(b) A scientifically valid method that is at least equivalent to the method of analysis in § 112.152(a) in accuracy, precision, and sensitivity.

§ 112.153 What methods must I use to test spent sprout irrigation water (or sprouts) from each production batch of sprouts for pathogens to satisfy the requirements of § 112.144(b) and (c)?

You must test spent sprout irrigation water (or sprouts) from each production batch for pathogens using:

(a) For *E. coli* O157:H7, *Salmonella* species:

(1) The method of analysis described in “Testing Methodologies for E. coli O157:H7 and Salmonella species in Spent Sprout Irrigation Water (or Sprouts),” Version 1, October 2015, U.S. Food and Drug Administration. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy from, and/or inspect a copy at, the Division of Produce Safety, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1600; FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039; <http://www.fda.gov/fsma>; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html; or

(2) A scientifically valid method that is at least equivalent to the method of analysis in § 112.153(a)(1) in accuracy, precision, and sensitivity; and

(b) For any other pathogen(s) meeting the criteria in § 112.144(c), a scientifically valid method.

Subpart O--Records

§ 112.161 What general requirements apply to records required under this part?

(a) Except as otherwise specified, all records required under this part must:

(1) Include, as applicable:

(i) The name and location of your farm;

(ii) Actual values and observations obtained during monitoring;

(iii) An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record;

(iv) The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and

(v) The date and time of the activity documented;

(2) Be created at the time an activity is performed or observed;

(3) Be accurate, legible, and indelible; and

(4) Be dated, and signed or initialed by the person who performed the activity documented.

(b) Records required under §§ 112.7(b), 112.30(b)(2), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

§ 112.162 Where must I store records?

(a) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.

(b) Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm.

§ 112.163 May I use existing records to satisfy the requirements of this part?

(a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this part. Existing records may be

supplemented as necessary to include all of the required information and satisfy the requirements of this part.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

§ 112.164 How long must I keep records?

(a)(1) You must keep records required by this part for at least 2 years past the date the record was created.

(2) Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with §§ 112.5 and 112.7, must be retained as long as necessary to support the farm's status during the applicable calendar year.

(b) Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued.

§ 112.165 What formats are acceptable for the records I keep?

You must keep records as:

(a) Original records;

(b) True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or

(c) Electronic records. Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 112.166 What requirements apply for making records available and accessible to FDA?

(a) You must have all records required under this part readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying.

(b) If you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, you must provide the records to FDA in a format in which they are accessible and legible.

(c) If your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request.

§ 112.167 Can records that I provide to FDA be disclosed to persons outside of FDA?

Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.

Subpart P--Variances

§ 112.171 Who may request a variance from the requirements of this part?

A State, Federally-recognized tribe (or “tribe”), or a foreign country from which food is imported into the United States may request a variance from one or more requirements of this part, where the State, tribe, or foreign country determines that:

(a) The variance is necessary in light of local growing conditions; and

(b) The procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.172 How may a State, tribe, or foreign country request a variance from one or more requirements of this part?

To request a variance from one or more requirements of this part, the competent authority (i.e., the regulatory authority for food safety) for a State, tribe, or a foreign country must submit a petition under § 10.30 of this chapter.

§ 112.173 What must be included in the Statement of Grounds in a petition requesting a variance?

In addition to the requirements set forth in § 10.30 of this chapter, the Statement of Grounds in a petition requesting a variance must:

(a) Provide a statement that the applicable State, tribe, or foreign country has determined that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act and to provide the same level of public health protection as the requirements of this part;

(b) Describe with particularity the variance requested, including the persons to whom the variance would apply and the provision(s) of this part to which the variance would apply;

(c) Present information demonstrating that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of this part.

§ 112.174 What information submitted in a petition requesting a variance or submitted in comments on such a petition are publicly available?

We will presume that information submitted in a petition requesting a variance and comments submitted on such a petition, including a request that a variance be applied to its similarly situated persons, does not contain information exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with this request.

§ 112.175 Who responds to a petition requesting a variance?

The Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN), or the Director, Office of Compliance, CFSAN, responds to a request for a variance.

§ 112.176 What process applies to a petition requesting a variance?

(a) In general, the procedures set forth in § 10.30 of this chapter govern our response to a petition requesting a variance.

(b) Under § 10.30(h)(3) of this chapter, we will publish a notice in the Federal Register, requesting information and views on a filed petition, including information and views from persons who could be affected by the variance if the petition were to be granted (e.g., because their farm is covered by the petition or as a person similarly situated to persons covered by the petition).

(c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing and will also make public a notice on FDA's Web site announcing our decision to either grant or deny the petition.

(1) If we grant the petition, either in whole or in part, we will specify the persons to whom the variance applies and the provision(s) of this part to which the variance applies.

(2) If we deny the petition (including partial denials), our written response to the petitioner and our public notice announcing our decision to deny the petition will explain the reason(s) for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of filed petitions requesting variances, including the status of each petition (for example, pending, granted, or denied).

§ 112.177 Can an approved variance apply to any person other than those identified in the petition requesting that variance?

(a) A State, tribe, or a foreign country that believes that a variance requested by a petition submitted by another State, tribe, or foreign country should also apply to similarly situated persons in its jurisdiction may request that the variance be applied to its similarly situated persons by submitting comments in accordance with § 10.30 of this chapter. These comments must include the information required in § 112.173. If FDA determines that these comments should instead be treated as a separate request for a variance, FDA will notify the State, tribe, or foreign country that submitted these comments that a separate request must be submitted in accordance with §§ 112.172 and 112.173.

(b) If we grant a petition requesting a variance, in whole or in part, we may specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition.

(c) If we specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition, we will inform the applicable State, tribe, or foreign country where the similarly situated persons are located of our decision in writing and will publish a notice on our Web site announcing our decision to apply the variance to similarly situated persons in that particular location.

§ 112.178 Under what circumstances may FDA deny a petition requesting a variance?

We may deny a variance request if it does not provide the information required under § 112.173 (including the requirements of § 10.30 of this chapter), or if we determine that the variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.179 When does a variance approved by FDA become effective?

A variance approved by FDA becomes effective on the date of our written decision on the petition.

§ 112.180 Under what circumstances may FDA modify or revoke an approved variance?

We may modify or revoke a variance if we determine that such variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.181 What procedures apply if FDA determines that an approved variance should be modified or revoked?

(a) We will provide the following notifications:

(1) We will notify a State, tribe, or a foreign country directly, in writing at the address identified in its petition, if we determine that a variance granted in response to its petition should be modified or revoked. Our direct, written notification will provide the State, tribe, or foreign country with an opportunity to request an informal hearing under part 16 of this chapter.

(2) We will publish a notice of our determination that a variance should be modified or revoked in the Federal Register. This notice will establish a public docket so that interested parties may submit written comments on our determination.

(3) When applicable, we will:

(i) Notify in writing any States, tribes, or foreign countries where a variance applies to similarly situated persons of our determination that the variance should be modified or revoked;

(ii) Provide those States, tribes, or foreign countries with an opportunity to request an informal hearing under part 16 of this chapter; and

(iii) Include in the Federal Register notice described in paragraph (a)(2) of this section public notification of our decision to modify or revoke the variance granted to States, tribes, or foreign countries in which similarly situated persons are located.

(b) We will consider submissions from affected States, tribes, or foreign countries and from other interested parties as follows:

(1) We will consider requests for hearings by affected States, tribes, or foreign countries under part 16 of this chapter.

(i) If FDA grants a hearing, we will provide the State, tribe, or foreign country with an opportunity to make an oral submission. We will provide notice on our Web site of the hearing, including the time, date, and place of the hearing.

(ii) If more than one State, tribe, or foreign country requests an informal hearing under part 16 of this chapter about our determination that a particular variance should be modified or revoked, we may consolidate such requests (for example, into a single hearing).

(2) We will consider written submissions submitted to the public docket from interested parties.

(c) We will provide notice of our final decision as follows:

(1) On the basis of the administrative record, FDA will issue a written decision, as provided for under part 16 of this chapter.

(2) We will publish a notice of our decision in the Federal Register. The effective date of the decision will be the date of publication of the notice.

§ 112.182 What are the permissible types of variances that may be granted?

A variance(s) may be requested for one or more requirements in subparts A through O of this part. Examples of permissible types of variances include:

(a) Variance from the microbial quality criteria when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method, established in § 112.44(b);

(b) Variance from the microbial die-off rate that is used to determine the time interval between last irrigation and harvest, and/or the accompanying maximum time interval, established in § 112.45(b)(1)(i); and

(c) Variance from the approach or frequency for testing water used for purposes that are subject to the requirements of § 112.44(b), established in § 112.46(b).

Subpart Q--Compliance and Enforcement

§ 112.192 What is the applicability and status of this part?

(a) The failure to comply with the requirements of this part, issued under section 419 of the Federal Food, Drug, and Cosmetic Act, is a prohibited act under section 301(vv) of the Federal Food, Drug, and Cosmetic Act.

(b) The criteria and definitions in this part apply in determining whether a food is:

(1) Adulterated within the meaning of:

(i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been grown, harvested, packed, or held under such conditions that it is unfit for food; or

(ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

or

(2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

§ 112.193 What are the provisions for coordination of education and enforcement?

Under section 419(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act, FDA coordinates education and enforcement activities by State, territorial, tribal, and local officials by helping develop education, training, and enforcement approaches.

Subpart R--Withdrawal of Qualified Exemption

§ 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?

(a) We may withdraw your qualified exemption under § 112.5:

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or

(2) If we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm.

(b) Before FDA issues an order to withdraw your qualified exemption, FDA:

(1) May consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and

(3) Must consider the actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption.

§ 112.202 What procedure will FDA use to withdraw an exemption?

(a) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 112.203 What information must FDA include in an order to withdraw a qualified exemption?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 must include the following information:

(a) The date of the order;

(b) The name, address and location of the farm;

(c) A brief, general statement of the reasons for the order, including information relevant to one or both of the following circumstances that leads FDA to issue the order:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or

(2) Conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm.

(d) A statement that the farm must either:

(1) Comply with subparts B through O of this part on the date that is 120 calendar days from the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 112.206.

(e) A statement that a farm may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 112.213;

(f) The text of section 419(f) of the Federal Food, Drug, and Cosmetic Act and of this subpart;

(g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 112.208;

(h) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the farm is located (or for foreign farms, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(i) The name and the title of the FDA representative who approved the order.

§ 112.204 What must I do if I receive an order to withdraw a qualified exemption applicable to my farm?

The owner, operator, or agent in charge of a farm that receives an order to withdraw a qualified exemption applicable to that farm under § 112.5 must either:

(a) Comply with applicable requirements of this part within 120 calendar days of the date from receipt of the order or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(b) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 112.206.

§ 112.205 Can I appeal or request a hearing on an order to withdraw a qualified exemption applicable to my farm?

(a) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(b) If the owner, operator, or agent in charge of the farm appeals the order, and FDA confirms the order:

(1) The owner, operator, or agent in charge of the farm must comply with applicable requirements of this part within 120 calendar days from the date of receipt of the order, or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and

(2) The owner, operator, or agent in charge of the farm is no longer subject to the modified requirements in §§ 112.6 and 112.7.

§ 112.206 What is the procedure for submitting an appeal?

(a) To appeal an order to withdraw a qualified exemption applicable to a farm under § 112.5, the owner, operator, or agent in charge of the farm must:

(1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center

for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 15 calendar days of the date of receipt of the order; and

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the farm relies.

(b) In a written appeal of the order withdrawing an exemption provided under § 112.5, the owner, operator, or agent in charge of the farm may include a written request for an informal hearing as provided in § 112.207.

§ 112.207 What is the procedure for requesting an informal hearing?

(a) If the owner, operator, or agent in charge of the farm appeals the order, the owner, operator, or agent in charge of the farm:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 112.206 within 15 calendar days of the date of receipt of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, a written notice of the determination will be given to the owner, operator, or agent in charge of the farm explaining the reason for the denial.

§ 112.208 What requirements are applicable to an informal hearing?

If the owner, operator, or agent in charge of the farm requests an informal hearing, and FDA grants the request:

(a) The hearing will be held within 15 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the farm and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under § 112.5, rather than the notice under § 16.22(a) of this chapter, provides notice of the opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 112.209, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 112.208(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (2), (3), and (5) of this chapter and 112.208(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 112.209 Who is the presiding officer for an appeal and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 112.210 What is the timeframe for issuing a decision on an appeal?

(a) If the owner, operator, or agent in charge of a farm appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If the owner, operator, or agent in charge of a farm appeals the order and requests an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 112.208(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 112.211 When is an order to withdraw a qualified exemption applicable to a farm revoked?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 is revoked if:

(a) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) The owner, operator, or agent in charge of the farm appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

(d) Confirmation of a withdrawal order by the presiding officer is considered a final Agency action for purposes of 5 U.S.C. 702.

§ 112.213 If my qualified exemption is withdrawn, under what circumstances would FDA reinstate my qualified exemption?

(a) If the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) determines that the farm has adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) will, on his own initiative or at the request of a farm, reinstate the qualified exemption.

(b) You may ask FDA to reinstate a qualified exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(2) Present, in writing, data and information to demonstrate that you have adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced and harvested at your farm, such that continued withdrawal of the exemption is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

(c) If your qualified exemption was withdrawn under § 112.201(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the

outbreak is not directly linked to your farm, FDA will reinstate your qualified exemption under § 112.5, and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your qualified exemption was withdrawn under § 112.201(a)(1) and (2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified exemption under § 112.5, in accordance with the requirements of paragraph (b) of this section.

Dated: October 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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