Draft Environmental Impact Statement (EIS) for the

PROPOSED RULE:

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

January 12, 2015

Abstract

Draft Environmental Impact Statement

Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

U.S. Food and Drug Administration

The Food Safety Modernization Act of 2011 (FSMA) directs FDA to build a new food safety system based on the public health principle of comprehensive prevention, an enhanced focus on risk-based resource allocation, and partnership across the public and private sectors to minimize food and feed hazards from farm to table. As such, FSMA gives FDA the public health mandate to establish standards for the adoption of modern food safety prevention practices by those who grow, process, transport, and store food. Through FSMA, FDA has proposed seven rules for stakeholders (food producers, suppliers, distributors) to follow in the supply chain that would protect public health by promoting safe, sanitary standards that, when implemented, would minimize or prevent food safety hazards. One of the Proposed Rules: *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (Produce Safety Proposed Rule or PS PR) is the subject of this Draft Environmental Impact Statement (EIS).

The purpose of proposing this rule is to minimize the risk of serious adverse health consequences or death, including those actions 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.

FDA announced its intent to prepare an EIS and began the EIS scoping period in August 2013. This EIS, prepared in accordance with the National Environmental Policy Act and developed by the FDA in cooperation with the U.S. Department of Agriculture, assesses the environmental (including human) and related socioeconomic impacts based on "potentially significant provisions" of the PS PR, and alternatives to the provisions that were considered. The No Action Alternative is also assessed in this EIS as a basis for comparison, to determine the environmental impacts associated with existing conditions (current practices, laws, and procedures) if the PS PR were not implemented. FDA is seeking public comment on the conclusions reached in this EIS.

To comment on this Draft EIS, please use one of the following methods:

Regular Mail:
Dockets Management Branch (HFA-305)
Docket No. FDA-2014-N-2244
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD USA 20852
Internet:
FDA's Division of Dockets Management at
http://www.regulations.gov

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Executive Summary

The U.S. Food and Drug Administration (FDA), an Operating Division within the U.S. Department of Health and Human Services (HHS), is responsible for protecting public health by ensuring the safety and security of human and veterinary drugs, biological products, medical devices, tobacco, foods, cosmetics, and products that emit radiation (FDA, 2013a). In compliance with the Congressional mandate contained within the FDA Food Safety Modernization Act (FSMA), the FDA is proposing to implement a final rule aimed at minimizing the risk of contamination of fresh produce during growing, harvesting, packing, and/or holding of fresh produce for human consumption. This proposal is based on FDA's analysis and conclusions that the final rule and the provisions contained therein will be beneficial to human health by reducing the incidence of foodborne illness.

Congress specifically mandated through FSMA that " . . . the Secretary [of HHS, and by delegation, FDA], in coordination with the Secretary of Agriculture and representatives of State departments of agriculture (including with regard to the national organic program established under the Organic Foods Production Act of 1990), and in consultation with the Secretary of Homeland Security, shall publish a notice of proposed rulemaking to establish 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 raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death" (section 419(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. § 350h(a)(1)(A)). Further, FSMA mandates that "the Secretary [of HHS, and by delegation, FDA] . . . adopt a final regulation to provide for minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks" (section 419(b)(1) of FFDCA (21 U.S.C. § 350h(b)(1))).

ES.1 Purpose and Need

The purpose of establishing requirements for the growing, harvesting, packing, and holding of produce for human consumption is to minimize the risk of serious adverse health consequences or death, including those requirements 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.

Each year foodborne diseases result in an estimated 48 million people (1 in 6 Americans) within the U.S. becoming ill, 128,000 hospitalizations, and 3,000 deaths, according to recent data from the Centers for Disease Control and Prevention (CDC) (CDC, 2014a). This is a significant burden to public health that is largely preventable. The estimated annual costs of foodborne illnesses attributable to produce is $1.865 billion (FDA, 2014b).

According to CDC's FoodNet data, for the period from 2000 through 2008, more than 6.5 million illnesses and/or hospitalizations, and nearly 800 deaths occurred from contaminated produce. The estimated number of annual foodborne illnesses attributable to produce that would be covered by the rule, based on FDA 2013 estimates, is 2,703,144 cases (FDA, 2013b).

Congress recognizes the unique challenges faced by FDA in the area of food safety in the 21st century and, in 2011, enacted FSMA to meet those challenges. FSMA directs FDA to build a new food safety system based on the public health principle of comprehensive prevention, an enhanced focus on risk-based resource allocation, and partnership across the public and private sectors to minimize food and feed hazards from farm to table (FDA, 2012b). As such, FSMA gives FDA the public health mandate to establish standards for the adoption of modern food safety prevention practices by those who grow, process, transport, and store food. FSMA also provides FDA the authorities and oversight tools aimed at providing solid assurances that those practices are being carried out by the food industry on a consistent, on-going basis (FDA, 2014a).

ES.2 Background on the proposed rule

In determining the scope of the proposed rule, FDA found that although there is the potential for chemical, physical, or radiological contamination of produce, rarely do the chemical and physical hazards associated with produce suggest a risk of serious adverse health consequences or death for individuals that would consume the product; FDA also found that the presence of radiological hazards in foods is a rare event and that consumer exposure to harmful levels of radionuclide hazards, outside of catastrophic events, is very low (Beru, 2012; FDA, 2011a; UNSCEAR, 2008). Therefore, the agency is not proposing specific standards for these hazards in the Produce Safety Proposed Rule (PS PR) (see 78 Fed. Reg. 3504 at 3524). Conversely, FDA's analysis of available foodborne illness outbreak data document 131 outbreaks associated with contaminated produce between 1996 and 2010 that caused more than 14,000 illnesses and 34 deaths. Therefore, the PS PR focuses on setting enforceable standards that are reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards and provide reasonable assurances that produce is not adulterated on account of these hazards.

As part of the rulemaking process, FDA conducted a draft qualitative assessment of risk (QAR) associated with growing, harvesting, packing, and holding of produce (hereinafter referred to as the Draft Qualitative Assessment of Risk or Draft QAR) (FDA, 2013c). The Draft QAR provides a scientific evaluation of potential adverse health effects resulting from human exposure to hazards in produce, with a focus on public health risk associated with on-farm microbial contamination of produce. The Draft QAR includes (1) Hazard Identification, (2) Hazard Characterization, (3) Exposure Assessment, and (4) Risk Characterization. This document helped to inform FDA on the risk management decisions the Congressional mandate directs FDA to make, in part, by focusing on those biological hazards that present a risk of serious adverse health consequences or death to the consumer (FDA, 2013c).

Produce commodities are susceptible to exposure to biological hazards before, during, and after harvest. Although the likelihood of exposure to such hazards varies by commodity and by other factors such as cultivation and production systems, the supply chain infrastructure, and environmental considerations, the sources of potential contamination during growing, harvesting, packing, and holding are common across commodities (FDA, 2013c).

Over the years, FDA has obtained information that provides insight regarding the routes of contamination during growing, harvesting, packing, and holding produce safely on farms. Based on findings of the Draft QAR; observations during inspections, investigations, surveillance activities; and other available information, FDA grouped the possible routes of contamination into five pathways: water, soil amendments, animals, worker health and hygiene, and equipment and buildings (FDA, 2013c).

FDA has tentatively concluded it is appropriate to use a regulatory framework based on practices, procedures, and processes associated with growing, harvesting, packing, and holding of all covered produce.[1] FDA considered and rejected the option to develop a framework that, based solely on a history of outbreaks or illnesses associated with specific commodities, would be applicable to individual commodities or classes of commodities. FDA's reasoning for adopting an integrated approach focusing on practices and procedures (e.g., that are linked to common, on-farm routes of contamination), rather than a commodity-specific approach, is discussed in Chapter 1.6 of the EIS.

On January 4, 2013, FDA released for public comment a proposed rule to establish minimum science-based *Standards for Growing, Harvesting, Packing, and Holding Produce for Human Consumption*. This rule is one of seven proposed rulemakings that lays the cornerstone of the prevention-based, modern food safety system that is needed to help protect human health from foodborne illness. FDA published this proposed rule in the Federal Register on January 16, 2013 ("the 2013 proposed rule"), for codification in 21 CFR Part 112 (78 Fed. Reg. 3504). On March 20, 2013, FDA issued a notice to correct technical errors and errors in reference numbers cited in the 2013 proposed rule (78 Fed. Reg. 17155). Subsequent to the publication of the 2013 proposed rule, extensive information received in public comments led to significant changes in FDA's thinking. As a result, on September 29, 2014, FDA issued a supplemental notice of proposed rulemaking ("the supplemental proposed rule"), amending certain specific provisions of the 2013 proposed rule (79 Fed. Reg. 58434). Taken together, these publications constitute FDA's proposed standards for the PS PR. FDA is currently reviewing public comments to develop a Produce Safety Final Rule.

The 2013 proposed rule was accompanied by a categorical exclusion under 21 CFR 25.30(j). Subsequent to the publication of the 2013 proposed rule and after reviewing public comments to the proposed rule, FDA reconsidered the application of the categorical exclusion and determined that the preparation of an EIS was necessary. FDA published a notice of its intent to prepare an EIS, and notice opening the EIS scoping period, in the Federal Register on August 19, 2013 (78

[1] Covered produce is produce that would be subject to the requirements of the proposed 21 CFR Part 112 in accordance with §§ 112.1 and 112.2 and refers to the harvestable or harvested part of the crop.

Fed. Reg. 50358). On April 4, 2014, FDA held a public scoping meeting to provide public attendees and interested parties with background on the 2013 proposed rule, to identify those provisions that may significantly affect the quality of the human environment, to identify alternatives FDA should consider, and to further request public comment.

FDA has considered the comments received in response to scoping process and the 2013 proposed rule, while developing this draft EIS, including the scope of the analysis, the alternatives to be considered, and potentially affected portions of the environment, as described below.

ES.3 Scope of the EIS

FDA is proposing under the PS PR to implement standards for the growing, harvesting, packing, and holding of produce commodities, with some exceptions. Produce commodities not exempt from nor otherwise out of scope of the rule are considered “covered produce.” The provisions of the PS PR, if finalized, would apply to both domestically grown and imported produce. FDA intends to evaluate its obligations under Executive Order (EO) 12114, “Environmental Effects Abroad of Major Federal Actions,” related to this action in a document that is separate from this EIS. The scope of this EIS includes the conterminous United States, as well as Alaska and Hawaii. In addition, areas outside the 50 states examined in this EIS include Puerto Rico, U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands) (hereinafter “EIS geographical areas”) (see Chapter 1.9 for full the scope of the EIS).

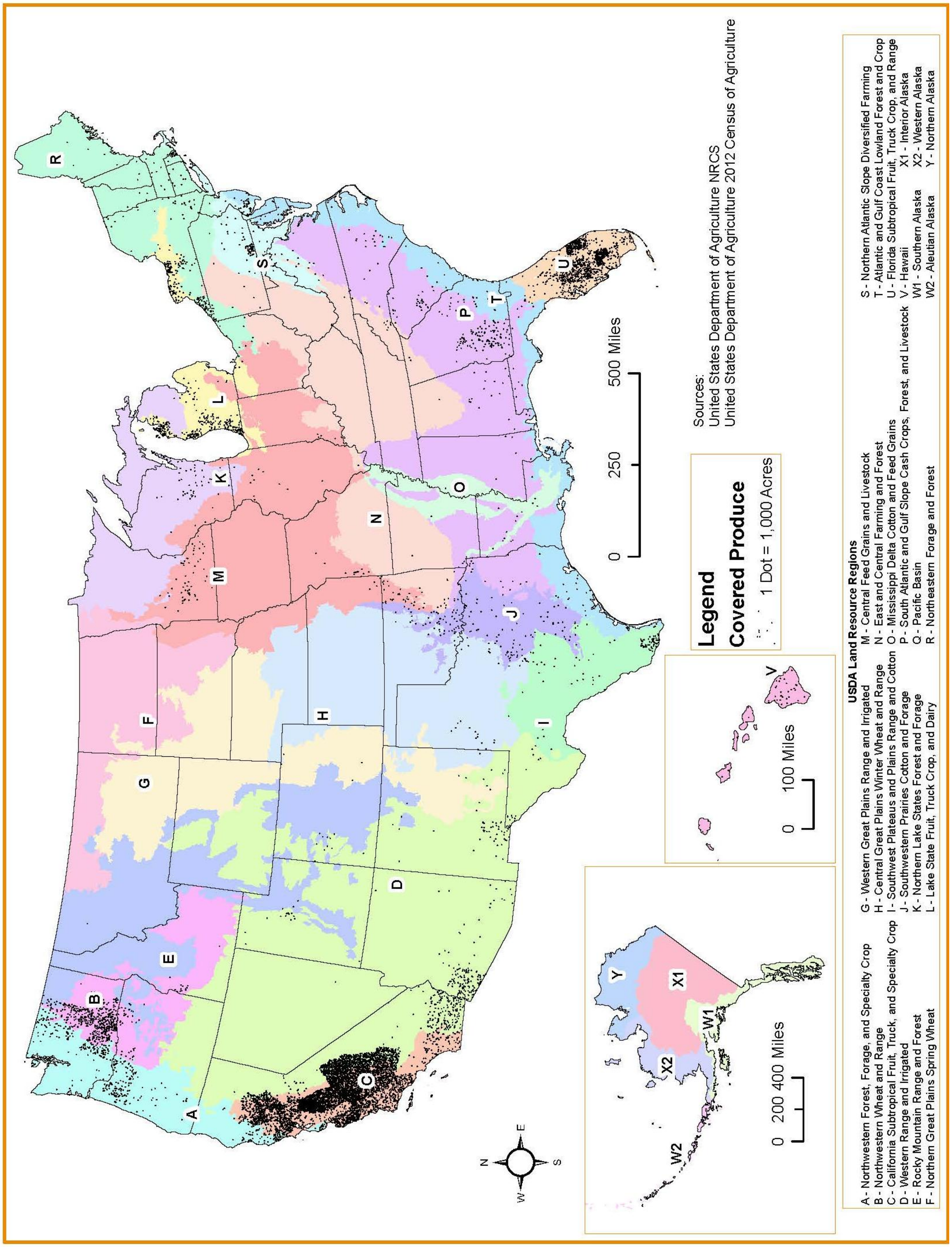
A major source for information on where produce commodities are grown domestically is compiled through USDA National Agriculture Statistics Service (NASS) Census of Agriculture surveys, which are conducted nationally every five years. Using USDA NASS 2012 survey data that was published in 2014 (cited as USDA NASS, 2014a), FDA prepared a map showing where in the U.S. covered produce is grown (see Figure ES-1). Figure ES-1, which also appears in chapter 1.7 as Figure 1.7-4, serves as a foundation for FDA’s analysis within this EIS.

Using this map as a foundation, FDA is able to better compare the relationship between where covered produce is grown and physical resources, such as surface water, groundwater, wildlife and other resources that are presented in Chapter 3 of the EIS, and the impact that covered activities have on these resources, discussed in Chapter 4 of the EIS. The regions depicted in Figure ES-1 are based upon 27 Land Resource Regions that were previously identified by the USDA Natural Resources Conservation Service (NRCS). The USDA NRCS subdivided the country into these regions because they share similar soils, climate, and vegetation or crop types (USDA NRCS, 2006).

Of note, Figure ES-1 illustrates that high densities of covered produce are grown within Regions B, C, D, L, and U; however, other regions are important as they relate to different resource components studied in the EIS. Produce acreage on the map is represented by dots on the map with each dot representing 1,000 acres of cropland.

With respect to the EIS geographical areas, USDA NASS 2012 survey data were available only for Puerto Rico. In addition, a review of 2007 NASS survey data revealed that with a possible few exceptions (individual farms), most farms in the EIS geographical areas would be excluded from the rule because the estimated average annual revenue reported for produce sales was below the proposed $25,000 threshold for produce farms, and therefore, these farms would be excluded from the PS PR (proposed 21 CFR 112.3(c)). As a result, of the EIS geographical areas, only Puerto Rico is included within the analysis of this EIS. Puerto Rico is not shown in Figure ES-1; however, FDA did include farms in Puerto Rico in the Regulatory Impacts Analysis (RIA) (FDA, 2013b), so estimates of total number of covered farms, acreage and cost, include Puerto Rico.

Figure ES- 1. Regions where covered produce in the U.S. is grown



Implementation of the final rule with respect to this EIS would focus on a sub-set of farming operations found within the geographical scope (see Figure ES-1) because the final rule would not affect all businesses that grow produce; rather, the provisions of any final rule would affect the subset of those businesses which grow covered produce with sales above the proposed $25,000 threshold (see subpart A, proposed §§ 112.1 – 112.6).

FDA proposes several size classifications of businesses in relation to the PS PR. One of them is the *de minimis* threshold in total annual sales of produce ($25,000) below which farms would be exempt. The other size thresholds (Small and Very Small Business and All Other Farms) determine when farms would be required to comply with the provisions, if finalized. Other thresholds are considered in the alternatives for subpart A. Background information on the size thresholds of businesses to be excluded and covered by the PS PR is found in detail in Chapter 2.1, subpart A.

While information is available on the size of farms, the data does not identify the location of farms of specific sizes. As such, it is not possible to identify regions where there may be more small and very small farms. Farm operations in general often affect resources that are contained within larger, regional areas, such as water quality/quantity and air quality, among others. Environmental resources and farm operations may be subject to both Federal and State requirements. For these reasons, the analysis of this EIS focuses on the state, regional, and national level of analysis. As such, the potential environmental consequences of management decisions that farmers may take in order to comply with the rule are assessed on a national, regional, and wherever possible state level.

Management decisions and impact analysis

FDA, in coordination with USDA, identified the reasonably foreseeable actions, or management decisions, that businesses potentially affected by any final rule might take in order to come into compliance with, or to potentially avoid being subject to, the alternatives under consideration for inclusion in the final rule. Management decisions were considered reasonably foreseeable if they were in compliance with existing laws and regulations, if they would allow for compliance with the alternatives being considered, if the technology to make such decisions is currently available or is in development, and if such decisions have been considered for the stated purpose. Management decisions that would only be suitable options for some covered produce were included, even if not a viable option for all covered produce. In response to the 2013 proposed rule and the supplemental proposed rule, FDA received numerous comments, including from industry, some of which provided information on the steps that covered farms would need to take to be in compliance with the rule, if finalized. FDA is currently completing its review of all comments received. Management decisions that were implied in these comments were considered in this EIS. It is expected that farms would use one or a combination of these measures depending upon their individual conditions. These management decisions formulate the basis upon which FDA assesses potential environmental impacts in Chapter 4 of the EIS.

ES.4 Alternatives evaluated in the EIS

The EIS assesses the environmental (including human) and related socioeconomic impacts for those provisions of the PS PR that FDA has determined may significantly affect the quality of the human environment (hereinafter referred to as "potentially significant provisions"), the determination of which was based on public and agency comments prior to and during the EIS scoping period, and alternatives to those provisions. It also assesses the No Action Alternative, which is made up of baseline agricultural practices, regulations, and industry programs, as well as background environmental conditions discussed in Chapter 3 of the EIS. By doing so, FDA assesses the current, ongoing environmental impacts related to the growing, harvesting, packing, and holding (i.e., the No Action Alternative) of what would otherwise be "covered produce" in the PS PR, if FDA were not to finalize the PS PR.

FDA determined that the PS PR contains four potentially significant provisions that, if finalized, may significantly affect the quality of the human environment: (Subpart A) General provisions (under which all provisions would apply if the farm is covered under subpart A); (Subpart E) Standards directed to agricultural water; (Subpart F) Standards directed to biological soil amendments (BSAs) of animal origin and human waste; and (Subpart I) Standards directed to domesticated and wild animals (21 CFR proposed Part 112, as amended in the supplemental proposed rule).

Potentially significant provisions and their alternatives for analysis in the EIS

(Subpart E) Standards directed to agricultural water (proposed §§ 112.41 to 112.50)

Additional information on subpart E, along with baseline agricultural conditions is found in Chapter 2.1 of the EIS. Alternatives considered for detailed evaluation in the EIS are as follows:

I. As proposed, i.e., a statistical threshold value (STV) not exceeding 410 CFU of generic *E. coli* per 100 ml of water and a GM not exceeding 126 CFU of generic *E. coli* per 100 ml of water, along with options to achieve this microbial quality standard by applying either a time interval between last irrigation and harvest using a microbial die-off rate of 0.5 log per day and/or a time interval between harvest and end of storage using an appropriate microbial die-off or removal rates, including during activities such as commercial washing.

This Draft EIS analyzes the following three additional alternatives related to the microbial quality standard for agricultural water:

II. A microbial quality standard of no more than 235 CFU (or MPN, as appropriate) generic *E. coli* per 100 ml for any single sample or a rolling GM (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 ml of water, as originally proposed in the 2013 proposed rule;

III. As proposed (i.e., Alternative I), but with an additional criterion establishing a maximum generic *E. coli* threshold; and

IV. For each of the options above, consider the environmental impacts of two different interpretations of the definition of "direct water application method" in § 112.3(c): (1) to include root crops that are drip irrigated; and (2) to exclude root crops that are drip irrigated.

(Subpart F) Standards directed to biological soil amendments of animal origin and human waste (proposed §§ 112.51 to 112.60)

Additional information on subpart F, along with baseline agricultural conditions is found in Chapter 2.1 of the EIS. FDA considered alternatives for untreated (raw) BSAs of animal origin and treated (composted or processed) BSAs of animal origin. The alternatives considered for detailed evaluation in the EIS are as follows:

<u>Untreated BSAs of animal origin</u>

FDA considered comments that it received on the PS PR and during the EIS scoping period with respect to the 9-month minimum application interval (Alternative I) for use of raw manure in proposed § 112.56(a)(1)(i). As a result, FDA is proposing to remove the minimum application interval in proposed § 112.56(a)(1)(i) and defer its decision on an appropriate minimum application interval until it pursues certain actions, including a robust research agenda, risk assessment, and efforts to support compost infrastructure development, in concert with USDA and other stakeholders. With respect to this EIS, FDA determined it is still appropriate to evaluate the potential environmental impacts from implementing proposed § 112.56(a)(1)(i) (as well as alternatives identified in this Chapter) as FDA does still intend to finalize this provision to establish an appropriate minimum application interval at a future point in time.

This Draft EIS analyzes the following five alternatives related to untreated BSAs of animal origin:

I. If the BSA of animal origin is untreated and is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, then the minimum application interval (i.e., time between application and harvest) must be nine months (§ 112.56(a)(1)(i), as originally proposed in the 2013 proposed rule).

II. If the BSA of animal origin is untreated and is applied in a manner that does not contact covered produce during and after application, then the minimum application interval (i.e., time between application and harvest) must be zero days.

III. The U.S. Department of Agriculture (USDA) organic regulations application intervals for the use of raw manure as a soil amendment (i.e., 90 days and 120 days before harvest) depending on whether the edible portion of the crop contacts the soil (as specified in 7 CFR 205.203(c)(1)).

IV. If the BSA of animal origin is untreated and is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, then the minimum application interval (i.e., time between application and harvest) must be six months.

V. If the BSA of animal origin is untreated and is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, then the minimum application interval (i.e., time between application and harvest) must be 12 months.

Treated BSAs of animal origin

I. As amended, proposed § 112.56(a)(4)(i)) would establish that if the BSA of animal origin is treated by a composting process in accordance with the requirements FDA proposed in § 112.54(c) to meet the microbial standard proposed in § 112.55(b), and is applied in a manner that minimizes the potential for contact with covered produce during and after application, then the minimum application interval (i.e., time between application and harvest) is zero days.

This Draft EIS analyzes the following two additional alternatives related to treated BSAs of animal origin:

II. If the BSA of animal origin is treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b), then the BSA of animal origin must be applied in a manner that minimizes the potential for contact with covered produce during and after application, and then the minimum application interval is 45 days.

III. If the BSA of animal origin is treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b), then the BSA of animal origin must be applied in a manner that minimizes the potential for contact with covered produce during and after application, and then the minimum application interval is 90 days.

(Subpart I) Standards directed to domesticated and wild animals (proposed §§ 112.81 to 112.84)

Additional information on subpart I, along with baseline agricultural conditions, is found in Chapter 2.1 of the EIS. The alternatives considered for detailed evaluation in the EIS are as follows:

Domesticated animal grazing

I. At a minimum, if animals are allowed to graze or are used as working animals in fields where covered produce is grown, and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, the grower must take the following measures: (a) An adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed to ensure the safety of the harvested crop; and (b) If working animals are used in a growing area where a crop has been planted, measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce.

In addition, proposed § 112.84 would explicitly state that proposed 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.

This Draft EIS analyzes the following two additional alternatives related to domesticated animal grazing:

II. As an alternative, FDA is proposing that if animals are allowed to graze or are used as working animals in fields where covered produce is grown and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, the grower must employ minimum waiting period of 9 months between the time grazing or working animals are present in areas where covered produce is grown and the time such produce is harvested from such growing areas, and measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce.

This alternative is consistent with the provisions for the use of raw (untreated) manure as a BSA of animal origin, described in § 112.56(a)(1)(i) as it was proposed in the 2013 proposed rule. FDA's new provision regarding the protection of habitat and species protected under the ESA in proposed § 112.84 would be carried forward to this alternative.

III. If animals are allowed to graze or are used as working animals in fields where covered produce is grown and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, the grower must employ minimum waiting period of 90 days and 120 days before harvest, depending upon whether the edible portion of the crop contacts the soil (as specified in 7 CFR 205.203(c)(1)).

This alternative is consistent with USDA's organic regulation application intervals for the use of raw manure as a soil amendment. FDA's new provision regarding the protection of habitat and species protected under the ESA in proposed § 112.84 would be carried forward to this alternative.

Wild animal intrusion

I. FDA proposed that if under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, the grower must monitor those areas that are used for a covered activity for evidence of animal intrusion: (1) As needed during the growing season based on: (i) The covered produce; and, (ii) The grower's observations and experience; and, (2) Immediately prior to harvest.

If animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction via grazing, occurs, the grower must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 (proposed § 112.83(a) and (b)).[2]

This Draft EIS analyzes the following alternative related to wild animal intrusion:

FDA would continue to carry forward the additional provision that the produce safety regulation does not authorize or require covered farms to take actions that would constitute "taking" of threatened and endangered species (proposed § 112.84).

II. If there is a reasonable probability that animal intrusion will contaminate covered produce, under this alternative FDA would require that the grower monitor these areas as needed during the growing season, based on the covered produce being grown and the grower's observations and experiences (proposed § 112.83(a)(1)(i) and (ii)), and immediately prior to harvest (proposed § 112.83(a)(2)). If animal intrusion is reasonably likely to occur, the grower must take measures to exclude animals from fields where covered produce is grown.

In addition, proposed § 112.84 would explicitly state that proposed 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, although it would not include the statement that the measure does not require measures to exclude animals from outdoor growing areas, or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages

[2] Prior to the publication of the 2013 proposed rule, there were a few instances in which a foodborne illness outbreak resulted in growers taking extreme measures to exclude wildlife from their crops that resulted in substantial environmental impacts to wetland habitat. Upon the publication of the 2013 proposed rule, some members of industry expressed concern of a repeat of this or similar action taken on a nationwide scale. FDA, in the supplemental proposed rule, added provision § 112.84, which directly addresses actions related to the authority of the Endangered Species Act (16 U.S.C. 1531–1544). Therefore, 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 A) General Provisions (proposed § 112.1 – 112.6)

Additional information on subpart A is found in Chapter 2.1 of the EIS. The alternatives considered for detailed evaluation in the EIS are as follows:

I. A farm or farm mixed-type facility with an average annual monetary value of produce (as defined in proposed 21 CFR 112.3(c)) sold during the previous 3-year period of more than $25,000 (on a rolling basis) is a "covered farm" subject to part 112, and a ''covered farm'' subject to this part must comply with all applicable requirements of this part when conducting a covered activity on "covered produce" (proposed 21 CFR 112.4, as amended by the supplemental proposed rule).

This Draft EIS analyzes the following three additional alternatives related to the general provisions:

II. Farms with $50,000 or less of annual value of food sold would be excluded from coverage of the PS PR. FDA estimated within its 2013 RIA that approximately 11,958 fewer farms would be covered by the rule if this sales threshold were selected (FDA, 2013b).

III. Farms with $100,000 or less of annual value of food sold would be excluded from coverage. FDA originally estimated that at this threshold, 20,071 fewer farms would be covered by the PS PR.

IV. Farms with $25,000 or less of annual value of "covered produce" sold would be excluded from coverage. There are no estimates available to distinguish between farms at this threshold selling total produce as compared to only covered produce.

Provisions and alternatives that were considered but dismissed from detailed analysis

FDA also proposes in the PS PR preferred alternatives for proposed standards that are primarily administrative in nature, or that do not result in significant environmental impacts on the human environment. For purposes of this EIS, FDA considers how these standards will contribute to the review of the "Socioeconomics and Environmental Justice" resource component when combined with other alternatives as part of analysis of the (subpart A) general provisions (Chapter 4.7 of the EIS) and the overall cumulative impact analysis (Chapter 5 of the EIS). The proposed preferred alternatives for standards that are dismissed from detailed analysis include subparts C, D, K, L, M, N, O, P, Q, and R (discussed in greater detail in Chapter 2.2 of the EIS).

There are also alternatives FDA identified early in the scoping process that did not meet the purpose and need of the proposed action, or that were not feasible for reasons associated with cost. These are potential alternatives that were eliminated from further review (discussed in greater detail in Chapter 2.2 of the EIS).

ES.5 Affected Environment

As described in ES.3, the data and information concerning current farming practices for covered produce and the environmental impacts of such practices vary for each resource. FDA based the selection of resource components to be assessed in this EIS on comments raised by the public, and resources that may be affected by the rule based on management decisions that a farmer may make. As such, the resource components that FDA assessed as part of its impact analysis include Water Resources; Soils; Waste Generation, Disposal, and Resource Use; Biological and Ecological Resources; Air Quality; Socioeconomics and Environmental Justice; and Human Health and Safety.

ES.6 Environmental Impacts

Environmental consequences associated with implementing the potentially significant provisions of the final rule are analyzed in Chapter 4 of the EIS. The analysis includes the alternatives for each potentially significant provision, and the possible management decisions that could be enacted by farm operators, screened against the purpose and need of the PS PR. A summary of the impacts associated with each alternative for the potentially significant provisions is presented below. The region letters presented in the following environmental impacts discussions refer to the regions presented in Figure ES-1.

Subpart E – Standards Directed to Agricultural Water

Alternative I. Preferred: As Proposed. Geometric Mean ≤ 126 CFU generic *E. coli*/100ml and STV ≤ 410 CFU/100ml with added flexibility for microbial die-off and/or removal

- The flexibility in meeting the proposed water quality standard is likely to mitigate the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added microbial die-off and/or removal.
- Disinfectants may be useful for reducing hazards that may cause foodborne illnesses; however, many of these disinfectants may form harmful byproducts. EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. As long as the pesticides are handled and applied according to label directions, no significant adverse impacts would result. Such adverse effects may be limited because a high number of growers in key growing regions, such as California, Arizona, and Florida, participate in marketing agreements that have more stringent numeric water quality standards than what FDA has proposed and are already using water that would be in compliance with the proposed standard, if finalized.
- It is not likely that a farmer will change the water source or cease growing covered produce because, among the regions that are potentially most affected (B, C, D, I, J, and U), many farmers have entered into marketing agreements that establish numeric water quality standards that are the same as, or are more stringent than, those proposed in the PS PR. In addition, reactions and verbal comments from some industry and trade groups that FDA received on the supplemental proposed rule suggest that the new proposed provisions for

microbial die-off and/or removal to achieve the proposed microbial quality standard considerably reduce the perceived need to change water source in order to comply with Alternative I (and similarly Alternative III), compared to Alternative II. Any action that may lead to increases in groundwater drawdown, would be considered a significant environmental impact.

- There may be additional costs from those projected in FDA's Regulatory Impact Analysis (FDA, 2013b and 2014b) if farmers add a post-harvest mechanism (e.g., FDA-approved wash or rinse) to achieve microbial die-off and/or removal, which could potentially result in additional socioeconomic impacts.

Overall, there would be an expected added public health benefit from an estimated 522,083 foodborne illnesses prevented (FDA, 2013b) from this provision.

Alternative II: GM of no more than 126 CFU (or MPN)/100 mL and a single sample maximum of 235 CFU (or MPN) generic *E. coli* /100 ml single sample or a Geometric Mean of no more than 126 CFU (or MPN)/100 ml

The adverse environmental impacts and beneficial public health benefits that may apply under Alternative I would also apply under this alternative; however, due to the more stringent requirements for this alternative, the following environmental impacts may occur in addition to those discussed under Alternative I:

- Under this alternative, switching water source is expected to be the preferred management decision. As compared to Alternative I, this alternative would not have the added flexibility for microbial die-off and/or removal; therefore, farmers would be more likely to decide to switch water sources, particularly away from surface waters to a cleaner source. If the cleanest available source is groundwater, then existing significant adverse conditions (i.e., water drawdown, potential subsidence, and the related continued degradation of water quality) may continue to be exacerbated but to a greater degree than Alternative I, because the water quality requirements would be more stringent under this alternative and more farms are likely to switch to a groundwater source in numbers that may considerably influence groundwater resources. These impacts are expected to be limited to localized regions and are not expected to be widespread. The regions most likely to be affected are B, C, D, I, J, and U. These regions may also experience irreversible effects to soils. Therefore, these impacts under Alternative II related to lowering the water table, deteriorating water quality, and land subsidence, are considered significant adverse.
- Native American Tribes may be disproportionately impacted as groundwater drawdown could have potential environmental impacts including socioeconomic impacts related to access to water on reservations, particularly in regions B and J. Such impacts would be considered significant adverse if there is a reduction in a Tribe's access to water.
- Capital costs related to any switch of water source may be especially burdensome for very small businesses.
- Treating any source to remove harmful pathogens would have an added public health benefit by reducing the potential for foodborne illnesses.

- There would also be greater potential for the use of chemical treatments to bring water into compliance under this alternative relative to Alternative I. With respect to chemical treatments, this alternative is anticipated to have more adverse environmental consequences than Alternative I, but not to a significant level because as previously stated all pesticides must be registered by EPA and must be found to not generally cause unreasonable adverse effects on the environment. However, without the added flexibility for die-off that is afforded under Alternatives I or III, regions that potentially require a higher level of chemical treatment include A, B, C, L, R, T, and U. Long-term, sustained treatment of water sources may result in adverse, but not significant impacts to water quality due to the potential for THMs to be formed and also result in no significant adverse long-term effects to biological/ecological resources and air quality from chemical treatments. These impacts are not anticipated to be significant because the effects may be reversible.
- The use of more chemicals to treat water sources may also result in slightly higher costs for growers, but not to a significant level.
- The risk of adverse impacts to human health relating to the increased use of chemicals would not be significant and may be mitigated as long as labeling requirements are followed, as the FIFRA registration process considers risk to human health and establishes handling processes that are appropriate to minimize such risks. The possibility of potential impacts from THMs to be formed may occur in regions that may require the highest treatments (see above), but because transport of such toxins is not well known, these impacts cannot be well defined. Overall reductions in foodborne illnesses are expected to be comparable under Alternative I and II.

Alternative III: As proposed (i.e., Alternative I), with an additional criterion establishing a maximum generic *E. coli* threshold

- Compared to Alternative I, there is a slightly higher likelihood that more farmers may select to chemically treat water sources or switch water sources altogether because there may be circumstances when the pathogen level would exceed the established threshold and steps allowing for die-off would not be sufficient to be in compliance with the rule. However, the reduced water testing and the less stringent standard means that fewer farms would be expected to make these management decisions as compared to Alternative II.
- Any economic effects of treating contaminated water sources may be considered long-term because while treatments need not be applied throughout the growing period, the overall quality of the water source is a long-term issue and treatments may need to be applied during every growing season.
- The beneficial environmental impacts to health would likely be higher than Alternative I and lower than Alternative II.
- Similar to what is addressed above, the use of pesticides is found to not generally cause unreasonable adverse effects to the environment, so long as such products are handled in accordance with their labeling requirements. Adverse impacts to human health related to handling such substances and treating poor water quality is also considered not significant.
- As compared to Alternative I, establishing a maximum threshold for generic E. coli may cause some growers in a region where the water quality is poorest to potentially shift from growing

covered produce, but not to the degree that may occur under Alternative II. These potential shifts are mitigated by the fact that existing marketing agreements in the most impacted regions already operate with more stringent numeric water quality standards, and also account for more than 80 percent of the growers of produce that would be covered by the rule.

Alternative IV: Alternatives for direct water application method. This alternative would have similar but slightly greater adverse environmental impacts when compared to Alternatives I, II, and III due to the inclusion of root crops, which crops are excluded for Alternatives I, II, and III.

Subpart F: Standards directed to BSAs of animal origin and human waste

Untreated BSAs of animal origin

Alternative I: As Previously Proposed-Decision Deferred. Untreated BSAs of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 9 months.

- Although the available data do not allow for a determination of which farms nationwide use untreated BSAs of animal origin, an analysis of the regional locations of livestock and poultry operations in relation to our regions can be made. Covered produce growers located in regions A, B, C, D, J, M, L, P, S, U and V are located in proximity to livestock and/or poultry operations, which could provide a source of available BSAs of animal origin.
- Given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period.
- If farmers switch to treated manure and the nitrogen availability of the treated manures is unknown or difficult to predict, then regular testing would be required to allow farmers to properly apply manure to meet agronomic needs and environmental goals. With proper management, no impact to soil health will occur. In addition, treatment will require additional storage time, which presents more opportunity for partially processed manure to impact surface and groundwater; however, common best management practices, such as State nutrient management programs, may mitigate these impacts. If the storage of manure occurs at a facility that operates under an NPDES permit, as long as the facility is managed in accordance with permit requirements, potential adverse impacts are not anticipated.
- The production and transport of chemical fertilizers is not expected to have a significant adverse impact on energy use and air quality because the resource use is not expected to change significantly as compared to current conditions.
- The improper use of chemical fertilizers may also have an adverse impact on surface and groundwater; however, given the small number of farms that use untreated BSAs of animal origin (estimated at 820 covered farms, or 2.3 percent of covered farms nationally) that could possibly switch to chemical fertilizers as a result of this provision, the impact would be minimal and not significantly adverse. In addition, proper nutrient management would likely

avoid excess use of chemical fertilizers that would further reduce the minimal impacts that may occur from their use.

- The use of chemical fertilizers could cause moderate adverse environmental impacts to soils. These impacts are not expected to be significant because the effects are reversible and may be mitigated given the growing trend away from chemical fertilizers to practices such as green manuring.
- If growers choose to comply with the 9-month interval instead of changing the soil amendment type or application method, a minimal (not significant) impact is expected to result from the growing regime or from a reduction in the number of crops a farmer may harvest due to the small number of farms nationwide that would be impacted. There may be some reduction in farm income if farms need to set aside land or build structures to store the untreated BSAs of animal origin. The amount of produce may be reduced due to a reduced number of harvests per year based on a 9-month waiting period. This may cause an increase in the price of certain produce if supply is reduced and demand is high. However, this impact is expected to be mitigated by market forces, as other growers—regionally, locally, and internationally—would fill any gaps in supply. Similar effects would be expected if growers stop growing covered produce, and regional produce commodity prices may increase resulting from a decrease in produce grown in any particular region; however, demand for a certain produce commodity would likely eventually be met by other growers in the region, growers in other regions (commodity and environment specific), or international suppliers.
- According to FDA estimates (2013b, 2014b), the number of illnesses that would be prevented from finalizing a BSAs of animal origin provision is 244,917; of these potentially preventable illnesses, 156, 299 would result from the 9-month application interval, with a total health cost benefit of an estimated $14.46 million.

Alternative II: Untreated BSAs of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 0 days.

- This alternative is similar to the existing condition but with the need to apply in a manner that does not contact covered produce.
- If a farmer is allowed to use an interval of 0 days between the application of raw manure and harvest, there is no regulatory need to treat raw manure. Therefore, changes in the type of soil amendment used or crop grown are not anticipated as a result of this management decision. Complying with the 0-day waiting period would require a change in application method for those farms that currently surface treat BSAs of animal origin.
- Changing the application method to prevent the contact of raw manure with a covered produce crop will potentially require the acquisition of additional equipment. This would require the outlay of funds for the purchase of new equipment and its ongoing maintenance, causing a potential minimal adverse impact (not significant).
- Beneficial environmental impacts to human health would occur as a result of implementing this alternative but would be minimal, and therefore not significant, as compared to the Alternative I.

<u>Alternative III</u>: U.S. Department of Agriculture's organic program application intervals for the use of raw manure as a soil amendment, i.e., 90 days and 120 days before harvest, depending on whether the edible portion of the crop contacts the soil (as specified in 7 CFR 205.203(c)(1)).

- With the exception of the short season crops (listed in Table 3.4-5 of the EIS) with growing-to-harvest cycles of 45 days or less, most crops have a growing cycle of about three to four months. For such crops, no changes would be required to management practices in order to comply with this application interval. Additionally, farmers currently in the USDA organic program have adapted their growing practices to be in compliance with this alternative, if finalized. If a certified organic grower chooses to treat raw manure, the grower would be limited in the choices for treatment in order to maintain its organic status. The small percentage of covered farms which utilize untreated BSAs, as well as the high likelihood that such farms are certified organic growers, indicates that few farms would need to change practices in order to comply with this application interval. No significant impacts are associated with any management decision under this Alternative.
- Other farms that may be associated with marketing agreements that have more stringent application intervals may continue to observe their established standards if they are more stringent than what FDA proposes.
- Limited public health benefits may occur over the present conditions for farms that may be using a zero-day application rate. The switch to a longer application rate to harvest interval may result in more (unquantified) foodborne illnesses prevented over Alternative II, but still fewer than what is estimated for Alternative I.

<u>Alternative IV</u>: Untreated BSAs of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 6 months

- As with Alternative I, given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period. Likewise, the improper use of chemical fertilizers may have an adverse impact on surface and groundwater; however, proper nutrient management, e.g. proper storage, nutrient management plans, and careful selection of application methods, would limit any adverse impact so as not to be significant.
- If farmers switch to treated manure and the nitrogen availability of the treated manures is unknown or difficult to predict, then regular testing would be required. While the current factors may be adequate for general estimating of typical manure nitrogen availability, more precise estimates of nitrogen availability based on compositional analyses are needed to guide producers toward economical and environmentally benign application rates when using treated manures. With proper management, no impact to soil health would occur.
- The use of chemical fertilizers could cause moderate adverse environmental impacts to soils. These impacts are not expected to be significant because the effects are reversible and may be mitigated given the growing trend away from chemical fertilizers to practices such as green manuring. The production and transport of chemical fertilizers may have a limited adverse

impact on energy use and air quality because the resource use is not expected to change significantly as compared to current conditions.

- Changing the application method to prevent the contact of raw manure with a covered produce crop may require the acquisition of additional equipment, which would equate to a one-time outlay of funds for the purchase of new equipment and its ongoing maintenance, and thereby cause a potential minimal (not significant) adverse environmental impact related to the socioeconomic resource component.
- Similar to Alternative I, if growers chose to switch to a non-covered crop, regional produce commodity prices may increase resulting from a decrease in produce grown in any particular region; however, demand for a certain produce commodity may eventually be met by other growers in the region, growers in other regions (commodity and environment specific), or international suppliers.
- This alternative may result in improved public health benefits over Alternative II or III but less than Alternatives I or V, due to the longer application to harvest interval.

Alternative V: Untreated BSAs of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 12 months

- As with Alternatives I and IV, given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period. Switching to treated material would reduce the interval between application of the treated manure and harvest to 0 days, rather than the interval of 12 months for the use of raw manure.
- Impacts under Alternative V is substantially similar as what is described under Alternatives I and IV.
- This alternative may result in improved public health benefits over all other alternatives due to the longer application to harvest interval. Several marketing agreements already observe a similar minimum application interval.

Treated BSAs of animal origin

Alternative I. Preferred: As proposed. Minimum application interval of 0 days.

- This is similar to the current baseline conditions. No impacts would be associated with this alternative and corresponding management decisions. The use of chemical fertilizers in place of treated BSAs of animal origin as a nutrient source is unlikely to occur under this alternative because the alternative does not restrict the timing of the use of BSAs, but contains the requirement that the treated BSAs of animal origin be applied in a manner that does not contact covered produce.

Alternative II: Minimum application interval of 45 days.

- With the exception of the short season crops (listed in Table 3.4-6 of the EIS) with growing-to-harvest cycles of 45 days or less, most crops have a growing cycle of about three to four months. Therefore, for most crops an application interval of 45 days would not require any changes in the soil amendment type in order to comply with the requisite waiting period. No significant impacts would be associated with this alternative and corresponding management decisions.

Alternative III: Minimum application interval of 90 days.

- As discussed under Alternative II, most crops have a growing cycle of about three to four months. Therefore, an application interval of 90 days would not require any changes in the soil amendment type in order to comply with the requisite waiting period. No significant impacts would be associated with this alternative and corresponding management decisions.

Subpart I: Standards directed to domesticated and wild animals

Grazing

Alternative I. Preferred: Adequate waiting period.

- Given that only approximately 2,829 dual- or multi-purpose farms raise livestock or poultry, and grow produce (and some smaller subset of this number grows covered produce), the overall regional and nationwide potential environmental impacts from a provision that could affect grazing operations, in general, is minimal. This provision is expected to affect between 1.5 and 8 percent of growers of covered produce.
- Any measures taken to permanently exclude domestic animals (although not required by the rule) from covered produce would not have significant environmental impacts relative to a waiting period for harvesting covered produce. Although there may be some measures such as fencing (not required by the rule) that farmers without fencing now may establish to exclude domesticated animals, any potential environmental impacts are not expected to be significant. The more likely management decision would be to factor in the crop and region in which crops are grown to allow for consideration of late growing seasons and other factors when determining when to remove the animal from the field at some time during the planting to harvest interval. Unlike Alternatives II and III, this Alternative provides flexibility for farmers to make the decision on an appropriate time interval, based on the farm's operation.
- Because such dual-purpose operations are mostly anticipated to have confined grazing or other areas for livestock already, removing the animal from fields where covered produce may be grown, relative to a planting/harvest interval, is not anticipated to result in long-term impacts to either the produce field or to the field(s) where the animal is confined.
- Any measure taken to reduce the hazard from pathogen transport to produce is expected to result in beneficial impacts to human health; however, relative to a permanent exclusionary measure, a management decision to include an adequate waiting period before using a field

for growing covered produce may not have the same level of human health benefits (foodborne illnesses prevented) compared to creating a barrier to animal entry and grazing entirely.

Alternative II: Waiting period of 9 months.

- As compared to Alternatives I and III, there are no substantially different impacts that can be estimated at a regional or national level because of the few farms to which this would apply.

Alternative III: Waiting period of 90/120 days.

- As compared to Alternatives I and II, there are no substantially different impacts that can be estimated at a regional or national level because of the few farms to which this would apply.

Animal Intrusion

Alternative I. Preferred: Evaluate whether produce can be harvested safely.

- Under Alternative I, there would be no significant adverse impacts expected with respect to any specific resource component.
- Evaluating whether produce can be harvested safely and, as appropriate, not harvesting a field or part of a field that is reasonably believed to be contaminated from wildlife intrusion would have no environmental impacts to water resources, waste generation, disposal, and resource use, and air quality. There may be minimal, non-significant beneficial environmental impacts observed to wildlife species as a result of added short-term cover and forage area from not harvesting part of the field and to soils from nutrients that would be reincorporated into the soils and improve soil health.
- Based on the cost-benefit analysis and consideration of costs in considering this alternative, the costs to monitor species and loss of revenue from unharvested contaminated crops are expected to be low. This is because monitoring is not expected to occur daily (estimated monitoring to occur three times per production season) and because it is unlikely that a farmer would choose to not harvest a whole field (it is more likely that the farmer would not harvest only that smaller portion of the crop that is contaminated).
- In terms of reducing pathogens, impacts are expected to be beneficial.

Alternative II: Measures to exclude wildlife.

- As compared to Alternative I, environmental impacts would be greater.
- Measures to exclude wildlife (including measures to clear land to facilitate monitoring) may involve the use of herbicides, rodenticides, or other materials that may have short-term toxic effects to water resources; biological resources and ecosystems directly adjacent to the farm; and soils. These impacts may be mitigated through proper use and handling in accordance with labeling requirements. This is because EPA, in cooperation with States, carefully regulates these chemicals to ensure they do not pose an unreasonable risk to human health or

the environment. EPA requires manufacturers to conduct extensive testing in order to identify any potential risks, and EPA carefully reviews these data provided by manufacturers before the product may be registered for use. Therefore, as long as users apply herbicides (or similar chemicals) in accordance with the EPA and manufacturers' requirements, FDA does not anticipate long-term adverse effects associated with these products. Therefore, the overall environmental impacts would be short-term and not significant. Mitigation measures that may be employed to reduce any other potential adverse effects that may otherwise be significant may include preparing pest management plans.

- Hunting and trapping may be accomplished in accordance with State and local regulations that would mitigate any potentially significant environmental impact, as such regulations factor in species population before determining the number of permits that can be issued without adversely impacting the species population.
- Under this Alternative, proposed § 112.84 could also state that Part 112 does not require covered farms to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.
- Costs under Alternative II would be higher than what would be expected under Alternative I, which could result in greater socioeconomic impacts.
- In terms of reducing pathogens, impacts are expected to be beneficial. However, if chemicals are used in exclusion measures and if they are not handled in accordance with labeling requirements, these impacts could be minimal but adverse, particularly with regard to worker health and safety.

Subpart A: General Provisions (Scope of Coverage of the Proposed Rule); includes impacts related to the cumulative effects of each proposed standard assessed together

The impact analysis for this subpart takes into consideration the impacts for the potentially significant provisions (subparts E, F, and I above, and assessed in greater detail in Chapters 4.1 through 4.7 of the EIS, as well as the overall cost of implementing all provisions of the PS PR, if finalized. These provisions were assessed together (cumulatively, *per se*) because the management decisions that farmers may take if they are covered by the proposed rule under proposed subpart A relate directly to the management decisions that the farmer may take when considering how best to manage their operations with respect to potentially significant provisions of the rule: agricultural water (subpart E), BSAs of animal origin (subpart F), and/or domesticated and wild animals (subpart I), as well as the costs of complying with the standards that were dismissed from detailed analysis (subparts B, C, D, K, L, M, N, O, P, Q, and R).[3]

For the purpose of this evaluation, the comparison of environmental impacts is accomplished by considering the preferred alternative of each potentially significant provision. (Note: For untreated BSAs of animal origin, where FDA has signaled its intent to defer finalization of a

[3] FDA did not conduct an analysis of subpart B, which is a provision of proposed Part 112, because in order to comply with subpart B a business would need to submit a variance in accordance with subpart P and conduct recordkeeping activities in accordance with subpart O. FDA assessed the potential impacts of subparts P and O in Chapter 2.2 of the EIS.

standard, there is no "preferred alternative" and the 9-month standard proposed in the 2013 proposed rule is used as a conservative assumption.) This comparison is demonstrated by resource component, presented below, and the resulting analysis compares these results with the potential outcomes from selecting one of the alternatives FDA considered under subpart A, which is determined by business size class.

Water Resources –

- Significant current and ongoing adverse impacts such as reduced water availability, water-table declines, soil subsidence and increased costs for finding and maintaining access to water, resulting from groundwater withdrawals are presently experienced in regions B, C, D, I, J, and U. These impacts represent the current condition, absent of any final rule, and are the result of many factors that include agricultural practices nationwide, development, and other factors unrelated to FDA's proposed action. Any action (personal, Federal, State, local, etc.) in these regions that would cause a farmer or any entity to draw from groundwater instead of surface water could exacerbate the current environmental conditions, generally. Under such conditions, individuals on Native American reservations in regions B and J may be disproportionately adversely impacted as a result of continued groundwater drawdown. We consider impacts from actions that result in groundwater drawdown to be significant in regions where current conditions for groundwater depletion have significant environmental impact. However, such impacts are best considered under the cumulative effects section, Chapter 5, and are not expected to occur as a result of this rule (see the following bullets).
- The flexibility in meeting the proposed water quality standard is likely to mitigate the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added microbial die-off and/or removal.
- It is not likely that a farmer will change the water source or cease growing covered produce because among the regions that are potentially most affected (B, C, D, I, J, and U), many farmers have entered into marketing agreements that are the same as, or operate under more stringent numeric water quality standards than, those proposed in the PS PR. In addition, reactions and verbal comments from some industry and trade groups that FDA received on the supplemental proposed rule suggest that the new proposed provisions for microbial die-off and/or removal to achieve the proposed microbial quality standard considerably reduce the perceived need to change water source in order to comply with Alternative I. Any action that may lead to increases in groundwater drawdown, would be considered a significant environmental impact.
- The majority of the 285 covered sprouting operations draw from municipal water already. Only minimal adverse, local and not significant impacts may occur from water treatment effluent, and no nationwide or regional impacts are anticipated to water availability from those few operations that may connect to municipal water supplies.
- With respect to water quality and impacts considered under subpart F (untreated), a switch to treatment (composting) will require additional storage time, which presents more opportunity for partially processed manure to impact surface and groundwater. Such impacts may be mitigated through best management practices or adherence to the facility's NPDES permit (where applicable); therefore, potential adverse impacts are not anticipated. Under a decision to switch to chemical fertilizers, any improper use may have an adverse impact on surface and

groundwater; however, given the small number of farms that use untreated BSAs of animal origin that could possibly switch to chemical fertilizers (820 covered farms, or 2.3 percent of covered farms nationally), the impact would not be significant, and adverse impacts may further be mitigated through proper nutrient management.

Biological and Ecological Resources–

- Adverse effects to biological and ecological resources relevant to groundwater drawdown are not expected (discussed above). However, potential adverse effects may occur from the use of disinfectants to treat poor quality water in certain areas (as follows). Disinfectants may be useful for reducing hazards that may cause foodborne illnesses; however, many of these disinfectants may form harmful byproducts. EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. As long as the pesticides are handled and applied according to label directions, no significant adverse impacts would result. Any adverse effects may be limited because a high number of growers in key growing regions, such as California, Arizona, and Florida, participate in marketing agreements that have more stringent numeric water quality standards than what FDA has proposed and are already using water that would be in compliance with the proposed standard.
- With respect to subpart I (wildlife intrusion), any measures taken to exclude wildlife (including measures to clear land to facilitate monitoring) may involve the use of herbicides, rodenticides, or other materials that may have short-term toxic effects to water resources; biological resources and ecosystems directly adjacent to the farm; and soils. These impacts may be mitigated through proper use and handling in accordance with labeling requirements (discussed above). Therefore, the overall environmental impacts would be short-term, and not significant. Mitigation measures that may be employed to reduce any other potential adverse effects that may otherwise be significant may include preparing pest management plans. However, proposed § 112.84 does not require covered farms to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. The preferred alternative and more likely management decision that a farmer may make is to monitor their fields and evaluate whether produce can be harvested safely. As discussed above, any unharvested portions of the field may provide non-significant beneficial impacts to wildlife species as a result of added short-term cover and forage area.
- Hunting and trapping may be accomplished in accordance with State and local regulations that would mitigate any potential significant environmental impact, as such regulations factor in species population before determining the number of permits that can be issued without adversely impacting the species population.

Soils–

- With respect to soil health and impacts related to subpart F (untreated – presently deferred, see Waste Generation below), farmers that switch to treated material may require additional testing to predict nitrogen availability and meet agronomic needs and environmental goals, but with proper management, no impact to soils are expected. A switch 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 such as through green manuring

Waste Generation, Disposal and Resource Use–

- Approximately 12.5 percent of produce farms use BSAs of animal origin, and of those only roughly 18.5 percent use untreated (raw) manure (this is 820 farms nationally, or 2.3 percent of the covered produce farms), and 10.2 percent of covered produce farms use treated BSAs of animal origin (this is 3,618 covered farms nationally). Therefore, a relatively small number of farms nationwide are expected to be impacted by any provision of the rule relating to BSAs of animal origin, if finalized.
- (Untreated) As discussed above, given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period. Treatment (composting) will require additional storage; however, given the small number of farms that may be affected nationwide (820 or 2.3 percent of covered farms), this is not expected to result in a significant impact.
- (Treated) The proposed condition would be similar to the existing condition. No impacts would be associated with this alternative and corresponding management decisions. The use of chemical fertilizers in place of treated BSAs of animal origin as a nutrient source is unlikely to occur under this alternative because the alternative does not restrict the timing of the use of BSAs of animal origin, but would impose a requirement to apply in a manner that does not contact covered produce.

Air Quality and Greenhouse Gases-

- There are minimal adverse environmental impacts (not significant) associated with air quality and greenhouse gases.

Socioeconomic and Environmental Justice –

Major cost summary

Estimates prepared by FDA in the 2014 supplemental regulatory impact analysis put the total cost of implementing the provisions of the PS PR at $386.23 million nationwide for businesses with an average annual monetary value of produce sold during the previous three-year period of more than $25,000 (FDA, 2014b).

Cost-and related environmental impacts

- The average projected per-farm cost of complying with the provisions of the PS PR, if finalized, is approximately $11,000, though this estimate is much lower (i.e., approximately $4,500) for very small farms. Small and very small farms may not be able to afford the added cost burden of complying with the provisions of the PS PR, if finalized. It is anticipated that these farms, if they are not able to qualify for an exemption to reduce the cost of compliance, would be the most likely to make management decisions that would result in them not being subject to the provisions of the PS PR, if finalized.
- As discussed under Chapter 4.2, based on the comments FDA has received to date, FDA does not expect farmers to decide to cease growing covered produce as a preferred management decision except in select instances which are often driven by outside pressures, such as a program run by the state of California that pays farmers to keep land fallow in order to divert

water to the cities. This is not a re-zoning of the land per se; rather, that land is essentially reserved for future alternative agricultural uses.

- If non-covered produce or other agricultural crops that are not produce are grown, requirements to maintain certain water quality conditions would be dependent on any existing state regulations or industry marketing agreements. The type of crop a farmer may select to grow would also be dependent upon the region's climate, soils, water availability, and may involve a decision whether the existing farm's equipment and infrastructure would be sufficient, or would need to be updated, modified, or bought to accommodate a new type of crop.
- Under certain conditions, where very small farms are involved and costs may be a larger factor, some farms may decide to stop growing crops altogether. However, this scenario would be most likely for very small farms as well as livestock operations that grow small amounts of covered produce (although many such diversified farming-livestock operations would likely be excluded based on the new proposed monetary threshold for excluded farms applied to sales of produce only rather than sales of food). There are no data to suggest under what conditions specifically such a management decision may occur, and there are no data available to quantify or qualify any related indirect impacts.
- Also related to subpart E, there may be additional costs from those projected in FDA's Regulatory Impact Analysis (FDA, 2013b and 2014b) if farmers add a post-harvest mechanism (e.g., FDA-approved wash or rinse) to achieve microbial die-off and/or removal, which could potentially result in additional socioeconomic impacts.
- Under subpart F, the production and transport of chemical fertilizers is not expected to have a significant adverse impact on energy use and air quality because the resource use is not expected to change significantly as compared to current conditions.
- Also under subpart F, since it is unlikely that growers will observe the waiting period (discussed above), any costs associated with storing untreated BSAs of animal origin for longer requisite time periods would be unnecessary.

Environmental justice –

- **Minority groups:** As discussed in Chapters 1.9, 3.7, and 4.1 of the EIS, Environmental Justice impacts related to the PS PR are assessed for minority principal operators and minority farmworkers. This is because of the limited amount of data that is available from USDA NASS surveys and the U.S. Department of Labor. Although potential cost impacts could be felt by consumers, without more definitive information regarding specific management decisions that might be taken in response to the PS PR, if finalized, it is unreasonable to project impacts on such groups. Therefore, for the purposes of this EIS, the discussion of potential socioeconomic impacts is limited to principal farm operators and farmworkers (where information is available.

  Relevant to this EIS, when considering the thresholds established in Chapter 3.7.3 of the EIS for identifying potential impacts to minority principal operators, regions that are important for identifying potential impacts to minority principal operators are regions A, B, C, D, W, and V. Of these regions, regions B and C are major produce growing regions (see Chapter 1.7 of the EIS). Information for minority farmworkers is provided below.

- **Principal operators:** Like all principal operators, minority principal operators would need to make management decisions regarding whether to comply with the provisions of any final rule or to cease growing covered produce. As noted above, very small farms are more likely than larger farms to decide to stop growing covered produce altogether if the farm manages livestock operations that also grow small amounts of covered produce. Based upon the "meaningfully greater" threshold FDA established for minority populations of principal operators potentially affected by the rule, regions where minority principal operators manage very small farms that are more likely to make a management decision to cease growing covered produce are regions A, B, C, D, W, and V. FDA has no data to suggest under what conditions specifically such a management decision may occur, and there are no data available to quantify or qualify any related indirect impacts.

- **Minority farmworkers:** Based on the limited information on farmworkers reported by the U.S. Department of Labor through surveys taken by that agency (see Chapter 3.7.3 of the EIS), regions where there are potentially populations of minority farmworkers that may be impacted by the rule, if finalized, include regions C, D, I, and J. Costs incurred by farms of all sizes may result in the farm either increasing the costs of their produce for consumers, or may involve the farm principal operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. FDA has no data to determine where in the nation, or under what specific circumstances may occur as such decisions are highly specific to the individual farm; however, with respect to the scope of this EIS, regions were such actions may adversely disproportionately affect minority farmworkers due to employment-related impacts, include regions C, D, I and J.

- **Native American operators:** Of all farms that are operated by Native American principal operators, whether located on or off reservations, 5.5 percent report growing vegetables, 2.4 percent report growing fruits and tree nuts, and 15 percent report growing combination crops. There may be farms that produce crops in multiple of these categories, and these categories include both covered and non-covered crops. Therefore, based on a very conservative estimate, no more than 22.9 percent of farms—the sum of these three categories—that are operated by Native American principal operators may be growing covered produce (USDA NASS, 2014a). Based on USDA NASS data (2014a), 78 percent of all Native American farms sell less than $10,000 in total sales, annually, meaning that, at most, 22 percent of farms with a Native American principal operator would be covered farms under the PS PR, if finalized. If it is assumed that these trends are consistent across all commodities, this means that, at most, 5 percent of farms with a Native American principal operator would be covered by the rule (22 percent of 22.9 percent is approximately 5 percent). Moreover, farms that sell less than $25,000 annually in produce—not $10,000—are not covered by the PS PR. An additional 14 percent of farms with a Native American principal operator sell less than $49,999, meaning there is a reasonable likelihood that additional farms with a Native American principal operator would not be covered by the PS PR, if finalized. It is not possible to estimate what percent of farms lie between $10,000 and $49,999 average annual sales. An additional 5 percent of Native American operated farms have less than $249,999 in total sales.

Despite the low number of total Native American owners/operators who may be covered by the rule, there is a potential that added operating costs associated with the rule would impact a disproportionate number of Native American farmers compared to farmers as a whole, given that the average income for a farm for which a Native American is the principal operator is 30 percent lower than a farm for which the principal operator is not a Native American (per the 2007 Agricultural census). The average reported agricultural product sales for Native American operated farms is $40,331, compared to an average of $134,807 for all farms. The average potential per farm cost of approximately $4,500 for very small farms could be disproportionally burdensome for farms with a Native American principal operator, as this cost would comprise approximately 11 percent of average annual sales, compared to 8 percent of the average annual sales of all farms.[4] However, the potential impacts for very small and small farms may be entirely mitigated to the extent these farms are eligible for a qualified exemption. It is assumed that large farms would be able to absorb any additional costs of complying with the provisions of the PS PR.

- **Low-income operators:** As discussed in chapter 3.7.3 of the EIS, this class includes any persons whose median household income is at or below the HHS poverty guidelines. The poverty threshold for a family of four in 2012 was set at $23,050. According to the ERS's data sheet, Principal Farm Operator Household Finances by ERS Farm Typology, in 2012, median farm operator household income, an average of the farm and off-farm household incomes of residence farms, intermediate farms, and commercial farms, was $68,298.[5] This exceeds both median U.S. household income, and the HHS poverty thresholds for all HHS poverty thresholds. While there may be low-income principal operators that may be adversely impacted by the costs associated with the rule, we cannot identify a low-income population on a national or regional level.

- **Low-income farmworkers:** As discussed under minority farmworkers, impacts may involve the farm principal operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. FDA has no data to determine where in the nation, or under what specific circumstances may occur as such decisions are highly specific to the individual farm. Based on data provided by the U.S. Department of Labor (information reported for California) (DOL, 2000 and 2005), region C has populations of low-income farmworkers that may be disproportionately impacted by the rule. Note that other regions may experience similar impacts, but there is not enough data available to understand which regions may specifically be impacted.

[4] $4,500 divided by $40,331 equates to approximately 11 percent.
[5] There is limited data for principal farm operator income other than on a national level.

Human Health–

Foodborne illnesses prevented

- FDA estimates, in the 2014 Regulatory Impact Analysis to the PS PR, that the number of foodborne illnesses prevented when considering the rule as proposed, all provisions, is 1.57 million, annually (FDA, 2014b). This represents a significant beneficial outcome to human health.

Human health impacts

- Under subpart E, EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. As long as the pesticides are handled and applied according to manufacturers' instructions, no significant adverse impacts to human health would result.
- Under subpart F, the production and transport of chemical fertilizers is not expected to have adverse impacts to air quality, and therefore, adverse impacts are not expected to principal operator or farmworker health.

Alternatives Analysis under subpart A

By applying the potential environmental impacts from each of the potential management decisions (comply with the rule or switch to non-covered crops), FDA is able to identify the potential environmental and related socioeconomic impacts to each of the alternatives that were first identified in Section ES.3 (and Chapter 2.1 of the EIS, subpart A). A comparison of potential impacts is provided below and summarized in Table ES-1.

Table ES-1. Comparison of potential impacts by alternative for subpart A

		≤ $25,000 * total produce excluded Alternative I	≤ $50,000** Food, excluded Alternative II	≤ $100,000** Food, excluded Alternative III	≤ $25,000 covered produce excluded Alternative IV
Comply with the rule	Covered Farms	35,503	28,253	20,140	Slightly fewer than Alternative I
	Excluded Farms	130,204	161.384	169,497	Slightly greater than Alternative I
	Environmental impacts (Chapters 4.1 – 4.7)	Greater than baseline	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Economic impacts (domestic costs annually)	$540.49 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Domestic benefits (health-related cost savings)	$930 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Public health benefits (foodborne illnesses prevented annually)	1.57 million	Less than Alternative I (less foodborne illnesses prevented)	Less than Alternative II (less foodborne illnesses prevented)	Slightly fewer than Alternative I (less foodborne illness prevented)
Switch to non-covered crop	Covered Farms	Less than 35,503	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Excluded Farms	Greater than 130,204	Greater than Alternative I	Greater than Alternative II	Slightly greater than Alternative I
	Environmental impacts (Chapters 4.1 – 4.7)	Less impacts compared with complying	Less impacts compared with Alternative I	Less impacts compared with Alternative II	Slightly fewer than Alternative I
	Economic impacts (domestic costs annually)	Less than $540.49 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Domestic benefits (health-related cost savings)	Less than $930 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Public health benefits (foodborne illnesses prevented annually)	Less than 1.57 million	Less than Alternative I (less foodborne illnesses prevented)	Less than Alternative II (less foodborne illnesses prevented)	Slightly fewer than Alternative I (less foodborne illness prevented)

*As updated in the Supplemental RIA, published September 2014.
**The associated estimates are found within the 2013 RIA (FDA, 2013b).

Under the Preferred Alternative (Alternative I) more farms would be covered than if the average annual monetary value threshold for exclusion of farms were higher (as in Alternatives II and III) or if the threshold was changed to include sales of covered produce only (as in Alternative IV).

For any alternative the expected environmental outcome may be as follows:

- Significant current and ongoing adverse impacts such as reduced water availability, water-table declines, soil subsidence and increased costs for finding and maintaining access to water, resulting from groundwater withdrawals, are presently experienced in regions B, C, D, I, J, and U, and represent the current condition, absent of any final rule. Any action in these regions that would cause a farmer or any entity to draw from groundwater instead of surface water could exacerbate the current environmental conditions, generally. Under such conditions, individuals on Native American reservations in regions B and J may be disproportionately adversely impacted as a result of continued groundwater drawdown. However, such impacts are best considered under the cumulative effects section, Chapter 5, and are not expected to occur as a result of this rule (see the following bullets).

- The flexibility in meeting the proposed water quality standard is likely to mitigate the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added microbial die-off and/or removal.
- Moreover, reactions and verbal comments from industry and trade groups that FDA has received so far on the supplemental proposed rule suggest that the new proposed provisions for microbial die-off and/or removal to achieve the proposed water quality standard considerably reduce the perceived need to change water source in order to comply with Alternative I under subpart E. In addition, many farmers have entered into marketing agreements that are the same as, or operate under more stringent numeric water quality standards than those proposed in the PS PR.
- Other environmental impacts nationwide are expected to be not significant, with the exception of human health and safety where there would be significant beneficial outcome to human health.

Therefore, given this analysis, FDA expects the PS PR, if finalized as proposed, would have significant adverse environmental impacts on groundwater and soil resources that are reviewed within the scope of this EIS.

For any alternative where fewer farms are covered by the rule (fewer than Alternative I – Preferred Alternative), the potential outcomes may be as follows:

- The expected annual economic impacts nationwide would decrease, but the expected per-farm costs are anticipated to remain the same as Alternative I.
- The expected environmental impacts, both adverse and beneficial, would decrease nationwide, but not to the extent that would reduce any already significant impacts to a less than significant level.
- The expected number of foodborne illnesses prevented would decrease, which means fewer public health benefits would be experienced.

ES.7 Cumulative Impacts

Similar to the comparison of direct and indirect impacts conducted in Chapter 4.7 of the EIS, and discussed in ES.6 above, the cumulative effects analysis was conducted for alternatives under subpart A because, if a farm is covered under subpart A, then the other provisions of the rule apply.

The potential environmental impacts are associated with the likely management decisions a farmer may make. The summary of potential direct and indirect environmental impacts is subdivided by resource component (e.g., water resources, air quality, etc.). This cumulative impacts analysis looks at those resource components and assesses them together with programs and actions that occur within the same time scope of the proposed rule (see Chapters 5.3 and 5.4 of the EIS). Chapter 5.5 provides a full assessment of the potential "cumulative impact" on the environment that results from the incremental impact of FDA's proposed action when added to other past, present, and reasonably foreseeable future actions that are discussed in Chapters 5.3 and 5.4. Therefore, the potential environmental impacts that are summarized below, in some cases, may be more severe than the impacts that were assessed in Chapter 4.7 of the EIS and that are carried into ES.6 (above). Likewise, certain agency and/or industry actions may have beneficial effects, and thus may reduce the potential severity of a potential environmental impact. For more detail on these potential cumulative impacts please refer to Chapter 5.5 of the EIS.

By and large, the added cumulative effects of past, present and reasonably foreseeable actions are not anticipated to substantively raise the significance of potential direct and indirect impacts on the human environment, based on the full analysis conducted in Chapter 5 of the EIS; the possible exception is related to groundwater drawdown (discussed in more detail in Chapter 5.5 of the EIS, and summarized below). Therefore, Table ES-1 above is fairly representative, on a qualitative basis, of the potential cumulative impacts expected if the PS PR is implemented.

For any alternative where fewer farms would be covered by the rule (see Table ES-1, Alternatives II, III, and IV), the potential cumulative environmental, socioeconomic, and public health impacts would be less than what may occur under Alternative I.

Water Resources - Overall, the potential impacts nationwide are expected to be somewhat commensurate with the direct and indirect effects and, therefore, significant. These impacts may vary by region, State, or locality, and are not quantifiable. The potential exception is related to groundwater withdrawal; significant adverse long-term impacts to water availability and soils (related to the irreversible impacts from land subsidence) may continue to occur in regions B, C, D, I, J, and U as a result of excessive groundwater use. These significant effects are the result of the current condition and projected ongoing impacts related to water use throughout the U.S., and are anticipated to occur even if a final rule were not enacted. Individuals on Native American reservations in regions B and J may be disproportionately adversely impacted as a result of continued groundwater drawdown and reduced access to water on reservations.

The problem of downstream degradation of water quality by salts, agrochemicals, and toxic leachates is a serious environmental problem. Regions that grow covered produce and that are already experiencing high exceedances in state surface water quality levels based on CWA Section 303(d) requirements (33 U.S.C § 1313(d)) (compare Figure 3.1-15 in Chapter 3.1.3.9 to Figure 1.7-4 in Chapter 1.7), and groundwater quality impairments (primarily from coliform bacteria) include regions A, B, C, L, R, T, and U (compare Figures 3.1-16 and 3.1-17 in Chapter 3.1.3.9 to Figure 1.7-4).[6]

[6] Regions A, B, C, L, R, T, and U represent the majority of the east and west coast states.

Biological and Ecological Resources - Because FDA does not anticipate significant impacts to biological and ecological resources as a result of the rule, and due to the prevalence of mitigation through private and public conservation, the potential cumulative environmental effects may be considered as not significant.

Soils - Relative to soil quality and subpart F, when one considers that more farms use treated manure versus untreated, and also considering the growing trends in use of green manuring and other best management practices, FDA expects that the cumulative effects nationwide related to soil health and BSAs of animal origin are not expected to be significant. Potential impacts related to land subsidence is addressed under Water Resources, above.

Waste Generation, Disposal, and Resource Use – Waste generation, disposal and resource use is not expected to be adversely affected to a significant degree.

Air Quality and Greenhouse Gases - With respect to air quality, given the very low number of farming operations that may be affected by the PS PR, the incremental effects expected from the finalizing a rule is expected to not be significant.

Socioeconomics and Environmental Justice - The costs of the rule may be easily absorbed by large farms, even considering added other economic influences. Small and very small farms may be more adversely affected by such costs; however, these farms may be eligible for qualified exemptions, which would effectively mitigate costs of the rule. There are no data to suggest under what conditions specifically certain management decisions (discussed above) may occur, and there are no data available to quantify or qualify any related cumulative impacts. Other added costs not estimated by FDA in the Regulatory Impact Analysis (FDA, 2014b) potentially may include the costs associated with implementing a post-harvest mechanism.

Minority principal operators

Principal operators for very small farms are more likely than principal operators of larger farms to make management decisions to stop growing crops altogether if the farm manages livestock operations that also grow small amounts of covered produce, although many such diversified farming-livestock operations would likely be excluded based on the new proposed monetary threshold for excluded farms applied to sales of produce only rather than sales of food. FDA has no data to suggest under what conditions specifically such a management decision may occur, and there are no data available to quantify or qualify any related indirect impacts. Given that on a nationwide basis, an estimated 35,503 farms would be covered by the rule, and some portion of that number would be eligible for qualified exemptions (in the very small and small farm categories), the anticipated incremental, cumulative economic impact to minority principal operators covered by the rule may be considered adverse, but because of the management decisions that are available to these farms, such impacts would not be considered to be significant. As noted above, potentially adverse impacts to minority principal operators are more likely to occur in regions A, B, C, D, W and V.

Minority farmworkers

As discussed above and in Chapters 3.7.3 and 4.7 of the EIS, costs incurred by farms of all sizes may result in the farm either increasing the costs of their produce for consumers, or may involve the farm primary operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. FDA has no data to determine where in the nation or under what specific circumstances such impacts may occur, as such decisions are highly specific to the individual farm. Regions were such actions may adversely disproportionately affect minority farm workers include regions C, D, I, and J. Regions where such actions may adversely disproportionally affect low-income farmworkers include region C.

Native American operators

At most, 5 percent of farms with a Native American principal operator would be covered by the rule. Despite this relatively low number of total Native American owners/operators who may be covered by the rule, there is a potential that added operating costs associated with the rule would impact a disproportionate number of Native American farmers compared to farmers as a whole, given that the average sales for a farm with a Native American principal operator is 30 percent lower than a farm with a non-Native American principal operator farm (per the 2007 Agricultural census). The average reported agricultural product sales for Native American operated farms is $40,331, compared to an average of $134,807 for all farms. The average potential per farm cost of approximately $4,500 could be disproportionally burdensome for Native American operated farms as it would comprise approximately 11 percent of their average annual sales, compared to 8 percent of the average annual sales of all farms. However, the potential impacts for very small and small farms may be entirely mitigated to the extent these farms are eligible for a qualified exemption; therefore, potential incremental cumulative impacts may also be mitigated and would not be considered significant. It is assumed that large farms would be able to absorb any additional costs of complying with the provisions of the PS PR.

As discussed in Chapter 4.7 of the EIS, and the discussion above related to water availability, individuals on Native American reservations in regions B and J may be disproportionately adversely impacted as a result of continued groundwater drawdown. These conditions are a result of current and projected ongoing impacts related to water use throughout the U.S., and are anticipated to occur even if a final rule were not enacted.

For any alternative where fewer farms would be covered by the rule (Alternatives II, III, and IV) the potential cumulative environmental, socioeconomic, and public health impacts would be less than what may occur under Alternative I.

- The expected annual economic impacts nationwide would decrease but the expected per farm costs are anticipated to remain the same as Alternative I.
- The expected environmental impacts, both adverse and beneficial, would decrease nationwide, but not to the extent that would reduce any already significant impacts to a less than significant level.
- The expected number of foodborne illnesses prevented would decrease, which means fewer public health benefits would be experienced.

ES.8 Mitigation

Many of the potential impacts may be mitigated through management decisions made by farm operators. Mitigation of potentially adverse environmental impacts may also be achieved, for example, through the proper use and handling of pesticides and other resource treatment technologies, and through any State's applicable permitting process.

Lastly, the final rule does not authorize or permit unlawful behavior associated with the use or management of natural resources. Federal and State environmental laws will remain unaffected by implementation of the final rule.

ES.9 Decision to be Made

FDA will consider public and agency comment received during the Draft EIS public comment period. The Draft EIS will be followed by a Final EIS. FDA will evaluate the potential alternatives and the environmental impacts of each, including related socioeconomic and human health effects, as presented in the Final EIS before finalizing the PS PR. This evaluation will be reflected in a Record of Decision (ROD). The ROD will be available to the public, and signed no earlier than 30 days following publication of the Final EIS.

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1.0 Introduction, Purpose, and Need

1.1 Introduction

The United States (U.S.) Food and Drug Administration (FDA), which is an Operating Division within the U.S. Department of Health and Human Services (HHS), is responsible for protecting public health by assuring the safety and security of human and veterinary drugs, biological products, medical devices, tobacco, foods, cosmetics, and products that emit radiation (FDA, 2013a).

Globalization[1], advancements in science and technology, and shifts in consumer expectations continually drive changes throughout human and animal food systems, which often results in unforeseen challenges to public health and consumer protection. While some of these shifts may have added benefit to consumers (e.g., increased choice or selection of foods, food availability, and in some cases lower prices), FDA reports that foodborne illnesses continue to have a substantial impact on public health with an estimated 48 million illnesses occurring annually (78 Fed. Reg. 3504 at 3506, January 16, 2013).

Congress recognizes the unique challenges faced by FDA in the area of food safety in the 21st century and, in 2011, enacted the Food Safety Modernization Act (FSMA) to meet those challenges. FSMA directs FDA to build a new food safety system based on the public health principle of comprehensive prevention, an enhanced focus on risk-based resource allocation, and partnership across the public and private sectors to minimize food and feed hazards from farm to table (FDA, 2012b). As such, FSMA gives FDA the public health mandate to establish standards for the adoption of modern food safety prevention practices by those who grow, process, transport, and store food; FSMA also provides FDA the authorities and oversight tools aimed at providing solid assurances that those practices are being carried out by the food industry on a consistent, on-going basis (FDA, 2014a).

Congress specifically mandated through FSMA that " . . . the Secretary [of HHS, and by delegation, FDA], in coordination with the Secretary of Agriculture and representatives of State departments of agriculture (including with regard to the national organic program established under the Organic Foods Production Act of 1990), and in consultation with the Secretary of Homeland Security, shall publish a notice of proposed rulemaking to establish 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 raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death" (section 419(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S. Code (U.S.C.) § 350h(a)(1)(A)). Further, FSMA mandates that " . . . the Secretary [of HHS, and by delegation, FDA] . . . adopt a final regulation to provide for minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known

[1] More than $2 trillion worth of FDA-regulated products are manufactured in more than 300,000 foreign facilities in over 150 countries. The United States imports approximately 50 percent of its fresh fruit and 20 percent of fresh vegetables (FDA, 2012a).

safety risks, which may include a history of foodborne illness outbreaks" (section 419(b)(1) of FFDCA (21 U.S.C. § 350h(b)(1))).

On January 4, 2013, FDA released for public comment a proposed rule to establish minimum science-based *Standards for Growing, Harvesting, Packing, and Holding Produce for Human Consumption*. This rule is one of seven proposed rulemakings that lays the cornerstone of the prevention-based, modern food safety system that is needed to help protect human health from foodborne illness associated with the consumption of contaminated produce. FDA published this proposed rule in the *Federal Register* on January 16, 2013 ("the 2013 proposed rule") for codification in the Code of Federal Regulations (CFR) at 21 CFR Part 112 (78 Fed. Reg. 3504). On March 20, 2013, FDA issued a notice to correct technical errors and errors in reference numbers cited in the 2013 proposed rule (78 Fed. Reg. 17155, March 20, 2013). Subsequent to the publication of the 2013 proposed rule, extensive information received in public comments led to significant changes in FDA's thinking. As a result, on September 29, 2014, FDA issued a supplemental notice of proposed rulemaking ("the supplemental proposed rule"), amending certain specific provisions of the 2013 proposed rule (79 Fed. Reg. 58434, September 29, 2014). Taken together, these publications constitute FDA's proposed standards for the growing, harvesting, packing, and holding of produce for human consumption ("the Produce Safety Proposed Rule" (PS PR)). FDA is currently reviewing public comments to develop a final Produce Safety rule.

1.2 National Environmental Policy Act

The National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. § 4321 et seq.), directs that all agencies of the Federal Government include a detailed statement on the environmental impact of a major Federal action significantly affecting the quality of the human environment. The President's Council on Environmental Quality (CEQ) published regulations implementing the procedural provisions of NEPA in 40 CFR Parts 1500-1508. An "Environmental Impact Statement" (EIS) is the detailed written statement required by section 102(2)(C) of NEPA (40 CFR 1508.11). Subsequent to the publication of the CEQ regulations, FDA published regulations in 21 CFR Part 25 governing compliance with NEPA, to supplement the procedural provisions established by CEQ. Under 21 CFR 25.22, FDA determined that there are no categories of FDA actions that routinely significantly affect the quality of the human environment that would ordinarily require the preparation of an EIS. FDA further defined, in 21 CFR Part 25, subpart C, specific classes of actions that are ordinarily categorically excluded from the need to prepare an EIS.

The 2013 proposed rule was accompanied by a categorical exclusion under 21 CFR 25.30(j). Subsequent to the publication of the 2013 proposed rule, however, FDA reconsidered the application of the categorical exclusion after reviewing public comments to the proposed rule and determined that the preparation of an EIS was necessary. FDA published a notice of its intent to prepare an EIS, and notice of the EIS scoping period, in the *Federal Register* on August 19, 2013 (78 Fed. Reg. 50358, August 19, 2013). On April 4, 2014, FDA held a public scoping meeting to provide public attendees and interested parties with background on the 2013 proposed rule, to identify those provisions that may significantly affect the quality of the human environment, to identify alternatives FDA is considering, and to further request public comment. Chapter 1.7

provides more detail on the public meeting as well as other public outreach activities FDA has undertaken with regard to FSMA.

This EIS was prepared in accordance with CEQ regulations, 40 CFR Parts 1500-1508, and FDA regulations, 21 CFR Part 25. The scope of the PS PR is broad;[2] therefore, this EIS examines potential *broad* direct, indirect, and cumulative impacts to the human environment, and includes the conterminous (enclosed within one common boundary) U.S., Alaska and Hawaii. In addition, areas outside these states examined in this EIS include Puerto Rico, U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands) (hereinafter "EIS geographical areas") (see Chapter 1.9 for full the scope of the EIS).

The EIS assesses the environmental (including human) and related socioeconomic impacts for those provisions that FDA has determined may significantly affect the quality of the human environment (hereinafter referred to as "potentially significant provisions"), and alternatives to those provisions. It also assesses the No Action Alternative, which is made up of baseline agricultural practices, regulations, and industry programs, as well as background environmental conditions discussed in Chapter 3. By doing so, FDA assesses the current, ongoing environmental impacts related to the growing, harvesting, packing, and holding of what would otherwise be "covered produce" in the PS PR, if FDA were not to finalize the PS PR.

1.3 Organization of the EIS

This EIS is organized by chapters. The major issues and topics of each chapter are summarized below:

Chapter 1, Purpose, Need, and Scope. This chapter identifies FDA's purpose for the PS PR, and outlines the public health need for this proposed action including the goals and objectives for meeting the stated need. This chapter also summarizes scoping activities FDA conducted prior to, and since, publishing the 2013 proposed rule, in addition to comments received during the proposed rule comment period and the official public scoping period of the EIS. This chapter further identifies the scope of the EIS and discusses those issues that FDA has eliminated from detailed study in accordance with 40 CFR 1501.7.

Chapter 2, Description of the Proposed Action and Alternatives. This chapter presents a discussion of FDA's proposed requirements, focusing on the provisions that FDA identified during scoping that may significantly impact the quality of the human environment. This chapter also presents alternatives to implementing each such provision, as proposed.

Chapter 3, Affected Environment. This chapter describes the background environmental conditions with respect to environmental resource components assessed in this EIS. Resource components to be addressed include: 1) water resources, 2) biological and ecological resources, 3) soils, 4) waste generation, disposal, and resource use, 5) air quality and greenhouse gases, 6) cultural and tribal resources, 7) socioeconomics and environmental justice, and 8) human health and safety.

[2] The PS PR applies to covered produce that is introduced or delivered for introduction into interstate commerce.

Chapter 4, Environmental Consequences. This chapter provides the methodologies and criteria by which potential environmental impacts are assessed. It also includes an assessment of the potential direct and indirect environmental impacts that may result from the PS PR, if finalized, as well as alternatives considered for potentially significant provisions.

Chapter 5, Cumulative Impacts. This chapter provides an assessment of potential environmental impacts that may result from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions.

Chapter 6, Potential Irreversible and Irretrievable Commitment of Resources. This chapter is related to the use of non-renewable resources and the potential impact that the use (or depletion) of these resources would have on future generations. Irreversible effects primarily result from the use or destruction of a specific resource that cannot be replaced within a reasonable time frame, such as fossil fuels.

Chapter 7, Potential Unavoidable Adverse Impacts. This chapter relates to the review of any significant unavoidable impacts for which either no mitigation or only partial mitigation is feasible.

Chapter 8, Natural Resources Conservation Service (NRCS) Conservation Support. This chapter describes the non-regulatory conservation support available through the U.S. Department of Agriculture (USDA) Natural Resources Conservation Service.

Chapter 9, References. This chapter includes the studies, data, policies, and resources used to prepare the EIS.

Chapter 10, Acronyms. This chapter defines the acronyms used throughout this document.

Chapter 11, Glossary. This chapter defines the terms used in the document.

Chapter 12, Preparers and Reviewers. This chapter includes a list of contributors, and in accordance with 40 CFR § 1502.17 includes a description of qualifications that include position/title, education, experience, and expertise.

1.4 Purpose and Need of the Proposed Action

Purpose

The purpose of establishing requirements for the growing, harvesting, packing, and holding of produce for human consumption is to 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.

Need

Each year foodborne diseases result in an estimated 48 million people (one in six Americans) within the U.S. becoming ill, 128,000 hospitalizations, and 3,000 deaths, according to recent data from the Centers for Disease Control and Prevention (CDC) (CDC, 2014a). This is a significant burden to public health that is largely preventable. The estimated annual cost of foodborne illnesses attributable to produce is $1.865 billion (FDA, 2014b).

Pathogens (harmful disease-causing microbes) that cause many foodborne illnesses are tracked through food safety surveillance systems such as the Foodborne Diseases Active Surveillance Network (FoodNet), which is managed by the CDC (CDC, 2014b).[3] At present, public health surveillance systems and investigation networks are frequently unable to identify specific farms that may be associated with outbreaks linked to produce. Through extensive epidemiological investigations and interviews, the CDC has identified foods that are most associated with foodborne illnesses. According to CDC's FoodNet data, for the period from 2000 through 2008, more than 6.5 million illnesses and/or hospitalizations, and nearly 800 deaths occurred from contaminated produce during that period. The estimated number of annual foodborne illnesses attributable to produce that would be covered by the rule (Chapter 1.5), based on FDA 2013 estimates, is 2,703,144 cases (FDA, 2013b).

While it is true that most foodborne illnesses originate from raw foods of animal origin (*i.e.*, raw meat and poultry, raw eggs, unpasteurized milk, and raw shellfish), fruits and vegetables consumed raw are also of particular concern. Washing raw produce may minimize or decrease pathogen contamination, but it may not completely eliminate pathogenic contamination.[4] Based on CDC's foodborne illness investigations, and in data the agency has compiled in FoodNet, CDC published on its Food Safety Web site that food contaminated with pathogens that cause human illness can be traced to several factors, which include but are not limited to the following (CDC, 2014c) [5]:

- Food processing under unsanitary conditions, including contaminated food or equipment touching food contact surfaces where clean food is prepared, processed, or packaged;
- Food that is washed or irrigated with water that is contaminated with animal manure or human sewage, or that comes into contact with contaminated animal manure or human sewage; and,
- Food that is in contact with infected humans who handle food (humans that are ill or who have unwashed hands).

Measures that can be taken to reduce the spread of harmful pathogens include the use of clean water to irrigate, process, and package food; the treatment of raw manure (biological soil amendments) through a process that is scientifically proven to decrease or eliminate pathogens, or

[3] FoodNet reports released annually document the changes in the number of people sickened in the U.S. from foodborne infections, as confirmed through laboratory tests. More information may be found at http://www.cdc.gov/foodnet/.

[4] CDC food safety statistics and information may be found at http://www.cdc.gov/foodsafety/facts.html.

[5] Other factors that are not listed here are related more specifically to foodborne illness linked to contaminated meat products (e.g., beef, poultry, and fish).

through the application of untreated biological soil amendments in a way that minimizes pathogen transport; the promotion of proper hygienic worker training; the use of clean equipment, tools, or surfaces that may contact produce or food contact surfaces; and the promotion of proper hand-washing and hygienic decisions. Through training, reporting, and the use of best management practices, many hazards associated with microorganisms of public health concern can be controlled to reduce illnesses.

Rulemaking considerations that support the purpose and need for the proposed action

FDA considered the following factors that are relevant to the provisions that are addressed in this EIS (see below where FDA describes the provisions of the rule addressed in this EIS):

- Develop science-based minimum standards to minimize the risk of serious adverse health consequences or death (section 419(a)(1)(A) of the FFDCA (21 U.S.C. § 350h(a)(1)(A));
- Provide sufficient flexibility for different sizes of operations (section 419(a)(3)(A) of the FFDCA (21 U.S.C. § 350h(a)(3)(A));
- Consider existing conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies (section 419(a)(3)(D) of the FFDCA (21 U.S.C. § 350h(a)(3)(D)); and,
- Avoid conflicts and duplication with the requirements set by the National Organic Program (NOP) (section 419(a)(3)(E) of the FFDCA (21 U.S.C. § 350h(a)(3)(E)).

Develop science-based minimum standards to minimize serious adverse health consequences or death

FDA has determined it must establish science-based minimum standards to ensure the safe growing, harvesting, packing, and holding of fruits, vegetables, and mixes/categories of fruits and vegetables that are raw agricultural commodities, to minimize the risk of serious adverse health consequences or death (section 419(a)(1)(A) of the FFDCA).

FDA has identified the following science-based minimum standards and provisions with respect to growing, harvesting, packing, and holding of produce for human consumption, as discussed in greater detail in the 2013 proposed rule and the supplemental proposed rule:

1) (Subpart C) Standards directed to personnel qualifications and training (proposed §§ 112.21 to 112.30). Proposed subpart C would establish requirements for the qualifications and training for personnel who handle (contact) covered produce[6] or food contact surfaces,[7] or who are engaged in the supervision thereof. Having personnel follow proper food hygiene practices, including personal health and hygiene, can reduce the potential for on-farm contamination of covered produce. Educating personnel who conduct covered

[6] Covered produce is produce that would be subject to the requirements of the proposed §§ 112.1 and 112.2 and refers to the harvestable or harvested part of the crop.

[7] Food contact surfaces are surfaces that contact human food, including equipment and tools used during harvesting, packing, and holding. See Chapter 11-1 for a full definition of the term.

activities in which they contact covered produce and supervisors about food hygiene, food safety, and the risks to produce safety associated with foodborne illnesses and inadequate personal hygiene is a simple step that can be taken to reduce the likelihood of pathogens being spread from or by personnel to covered produce.

2) (Subpart D) Standards directed to health and hygiene (proposed §§ 112.31 to 112.33). Proposed subpart D would establish hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance.

3) (Subpart E) Standards directed to agricultural water (proposed §§ 112.41 to 112.50, as amended in the supplemental proposed rule §§ 112.44(c), 112.44(d), and 112.50(b)). Proposed subpart E would establish requirements applicable to agricultural water, including measures to be taken with respect to agricultural water sources, water distribution system, and pooling of water; requirements related to the treatment of agricultural water, when appropriate; requirements for testing of agricultural water, frequency of testing, and actions that can be taken based on test results; and measures to be taken for water used during harvest, packing, and holding activities.

4) (Subpart F) Standards directed to biological soil amendments (BSAs) of animal origin and human waste (proposed §§ 112.51 to 112.60, as amended in the supplemental proposed rule (79 Fed. Reg. 58434). Proposed subpart F would establish standards directed to treated and untreated BSAs of animal origin and human waste. These standards include requirements applicable for determining the status of a BSA of animal origin; procedures for handling, conveying, and storing BSAs of animal origin; provisions regarding the use of human waste in growing covered produce; acceptable treatment processes for BSAs of animal origin applied in the growing of covered produce; microbial standards applicable to treatment processes; application requirements and minimum application intervals; requirements specific to agricultural teas.

5) (Subpart I) Standards directed to domesticated and wild animals (proposed §§ 112.81 to 112.84, as amended in the supplemental proposed rule. PS PR subpart I includes standards that would be directed to the potential for biological hazards from animal excreta to be deposited by a covered farm's 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 the regulated entity conducts a covered activity on covered produce. Proposed subpart I would not be directed to the potential for biological hazards from manure that may be used as a soil amendment.

6) (Subpart K) Standards directed to growing, harvesting, packing, and holding activities (proposed §§ 112.111 to 112.116). Proposed subpart K would establish measures to take if a covered farm grows, harvests, packs, or holds both covered produce and excluded produce; measures to take during harvest activities; how to handle harvested produce

during covered activities; requirements applying to dropped "covered" produce; packing covered produce; and associated food packing materials.

7) (Subpart L) Standards directed to equipment, tools, buildings, and sanitation (proposed §§ 112.121 to 112.140). Proposed subpart L would establish standards related to equipment, tools, and buildings that are used in relation to covered produce, covered activities, and transportation of covered produce; instruments and controls use to measure, regulate, or record covered produce or covered activities; construction requirements for buildings, including separating domesticated animals from buildings or areas where covered produce is grown, handled, packed, or stored; pest control; toilet facilities; hand-washing; sewage and plumbing; trash and litter; the control of animal excreta; and recordkeeping.

8) (Subpart M) Standards directed to sprouts (proposed §§ 112.141 to 112.150). Proposed subpart M would establish requirements, including those applicable to seeds or beans used to grow sprouts; measures to be taken for growing, harvesting, packing, and holding sprouts; testing requirements for the environment for Listeria species or *L. monocytogenes* and follow-up actions for positive findings; and collection and testing of samples of spent sprout irrigation water and sprouts.

9) (Subpart N) Analytical methods (proposed §§ 112.151 to 112.152). Proposed subpart N would specify methods of analysis for testing the quality of water and the growing environment for sprouts, as would be required under proposed subparts E and M if these provisions were finalized as proposed.

10) (Subpart O) Requirements applying to records that must be established and kept (proposed §§ 112.161 to 112.167). Proposed subpart O would establish the general requirements applicable to documentation and records that would need to be established and maintained under proposed Part 112, if finalized as proposed.

11) (Subpart P) Variances (proposed §§ 112.171 to 112.182). Proposed subpart P would establish the process by which variances from one or more requirements of proposed Part 112 may be requested by a State or foreign government. This subpart details the information that would need to accompany such requests, and lists the procedures and circumstances under which FDA may grant or deny such requests and modify or revoke such variances. As proposed, variances approved by FDA would be limited to the requirements of proposed Part 112 specified by FDA and would have no effect on the application of other provisions of the FFDCA.

12) (Subpart Q) Compliance and enforcement (proposed §§ 112.191 to 112.193). Proposed subpart Q would establish the overarching provisions related to compliance and enforcement activities.

13) (Subpart R) Withdrawal of qualified exemption (proposed §§ 112.201 to 112.213, as amended in the supplemental proposed rule, and including new provisions §§ 112.201(b)(1), 112.201(b)(2), and 112.201(b)(3)). Proposed subpart R establishes 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 § 112.5 and circumstances under which FDA would reinstate a qualified exemption that is withdrawn.[8]

Provide sufficient flexibility for different sizes of operations

As proposed, the PS PR would reduce the burden on small farms as compared to larger farms, in part through the use of exemptions. Certain small farms would be eligible for a qualified exemption based on average monetary value of produce sold and direct sales to qualified end users (proposed § 112.5). The proposed rule additionally would provide all farms flexibility to use alternative practices, processes, and procedures for certain specified requirements, provided the farm has 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.

Consider existing conservation and environmental practice standards and policies established by Federal agencies

FDA has determined that the final rule shall not conflict with policies set forth by Federal agencies; for example, the Endangered Species Act (ESA) of 1973 established by the U.S. Fish and Wildlife Service (USFWS) or the Clean Water Act (CWA) of 1977 established by the U.S. Environmental Protection Agency (EPA). Rather, the rule should be used together with existing practices and regulations that promote environmental conservation. As such, FDA has invited USDA, EPA, and USFWS to provide technical assistance to FDA during the rulemaking and NEPA process (discussed in greater detail in Chapter 1.7, Scoping – Agency Involvement, Consultation, and Cooperation). In addition, this EIS assesses the potential environmental impacts associated with potentially significant provisions based on existing regulations, agency guidance, and industry practices.

Avoid conflicts and duplication with the requirements set by the National Organic Program

The NOP comes under the direction of the USDA's Agricultural Marketing Service (AMS). The final rule establishing the program and the corresponding USDA organic regulations are codified in 7 CFR Part 205. According to 7 CFR § 205.600, the program is responsible for developing national standards for organically produced agricultural products, including the National List of Allowed and Prohibited Substances (hereinafter, "National List") which identifies substances that may or may not be used in organic production and handling operations. The program's other roles include accrediting certifying agents to certify organic producers/handlers as well as investigating and/or taking action on regulatory violation complaints. The Organic Food Production Act of 1990 authorizes the establishment of the National Organic Standards Board (NOSB), a Federal advisory committee to assist in the development of standards for substances to be used in organic production and advises the Secretary of Agriculture on any other aspects of the program (7 U.S.C. 6518(a)). Generally speaking, most farms that wish to claim its products are "organic" are required by law to be certified in accordance with the organic regulations.

[8] Additional information on qualified exemptions is found within this EIS at Chapter 2.1, subpart A.

USDA organic regulations that apply to agricultural water and BSAs of animal origin

Agricultural Water

Water Quality: USDA organic regulations do not contain specific requirements for water that is used in organic agricultural production. However, certifying agents (who inspect and assess farming operations for compliance with USDA organic regulations) are authorized to collect and test water samples to verify that prohibited substances are not being applied through this means (7 CFR § 205.403(c)(3)). Most organic farmers default to reliance on state or local water quality standards, World Health Organization (WHO) guidelines, or Good Agricultural Practice (GAP) manuals.[9]

Water Treatment: It is important to refer back to FDA's definition of agricultural water stated above and to note that FDA has not proposed any specific mechanism to bring water into compliance with the proposed water quality criteria. With respect to contaminated agricultural water (except irrigation water), EPA has registered various chemical treatment options that are currently available for farmers to treat agricultural water for harvesting, holding, and packing activities; albeit fewer options are available for organic farmers who are restricted by the National List (*See* USDA organic regulations' Allowed Substances, at 7 CFR § 205.601). In order for organic farmers to remain in the NOP, any EPA-registered pesticide that could be used to treat contaminated agricultural water would need to be an allowed substance on the National List, which adheres to strict environmental criteria. As the NOP already allows for the use of specific chemical treatments, and has the ability to expand the list of Allowed Substances at its discretion, no direct conflicts with FDA's PS PR are expected.

Manure

With respect to BSAs, a summary of USDA organic regulations is provided below.

Untreated: USDA organic regulations require a 120-day or 90-day application interval for untreated manure depending on whether the edible portion of a product does or does not have direct contact with the soil in which the manure is used (7 CFR § 205.203).

It should be noted that the preamble to the final rule establishing USDA organic regulations (65 Fed. Reg. 80548, December 21, 2000) (section on Crop Production: Changes Requested but not Made), when discussing the use of raw manure as a potential food safety concern, states that the standard in its rule is "not a public health standard" and that a comprehensive risk assessment of the safety of applying raw manure to human food crops was not undertaken when developing the standard. Rather, the standard was intended to be consistent with the organic industry practices at that time, and based on NOSB recommendations for organic food crop production. The preamble further states that, "Should additional research

[9] GAP manuals are often prepared through partnerships between farm stewardship groups and cooperative extension offices/facilities to help small, diversified farms manage potential food safety risks while meeting the standards set in USDA's GAP/GHP certification program.

or Federal regulation regarding food safety requirements for applying raw manure emerge, AMS will ensure that organic production practice standards are revised to reflect the most up-to-date food safety standard."

Treated: USDA organic regulations do not require any application interval for composted manure. They do specify criteria for composting plant and animal materials, including time, temperature, and carbon to nitrogen ratio (C:N) (7 CFR § 205.203(c)(2), see also National Organic Program Guidance 5021 – Compost and Vermicompost in Organic Crop Production).

1.5 Potential hazards considered

In determining the scope of the proposed rule, FDA found that although there is the potential for chemical, physical, or radiological contamination of produce, rarely do the chemical and physical hazards associated with produce suggest a risk of serious adverse health consequences or death for individuals that would consume the product; FDA also found that the presence of radiological hazards in foods is a rare event and that consumer exposure to harmful levels of radionuclide hazards, outside of catastrophic events, is very low (Beru, 2012; FDA, 2011a; UNSCEAR, 2008). Therefore, the agency is not proposing specific standards for these hazards in the PS PR (see 78 Fed. Reg. 3504 at 3524). Conversely, FDA's analysis of available foodborne illness outbreak data document 131 outbreaks associated with contaminated produce between 1996 and 2010 that caused more than 14,000 illnesses and 34 deaths. Therefore, the PS PR focuses on setting enforceable standards that are reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards and providing reasonable assurances that produce is not adulterated on account of these hazards.

1.6 Produce covered by the proposed rule

The CDC, in partnership with State and local health agencies has had foodborne illness surveillance systems in place for decades. Surveillance methods, programs, and partnerships are discussed extensively on CDC's Foodborne Illness Surveillance, Response, and Data Systems Web page.[10] Food commodities associated with pathogens that cause foodborne illnesses change frequently, and while pathogens are not specific to particular foods, trends presented in publicly available data from CDC show that certain raw agricultural commodities, which are not commercially processed prior to human consumption, present the greatest potential risk to spreading certain pathogens.

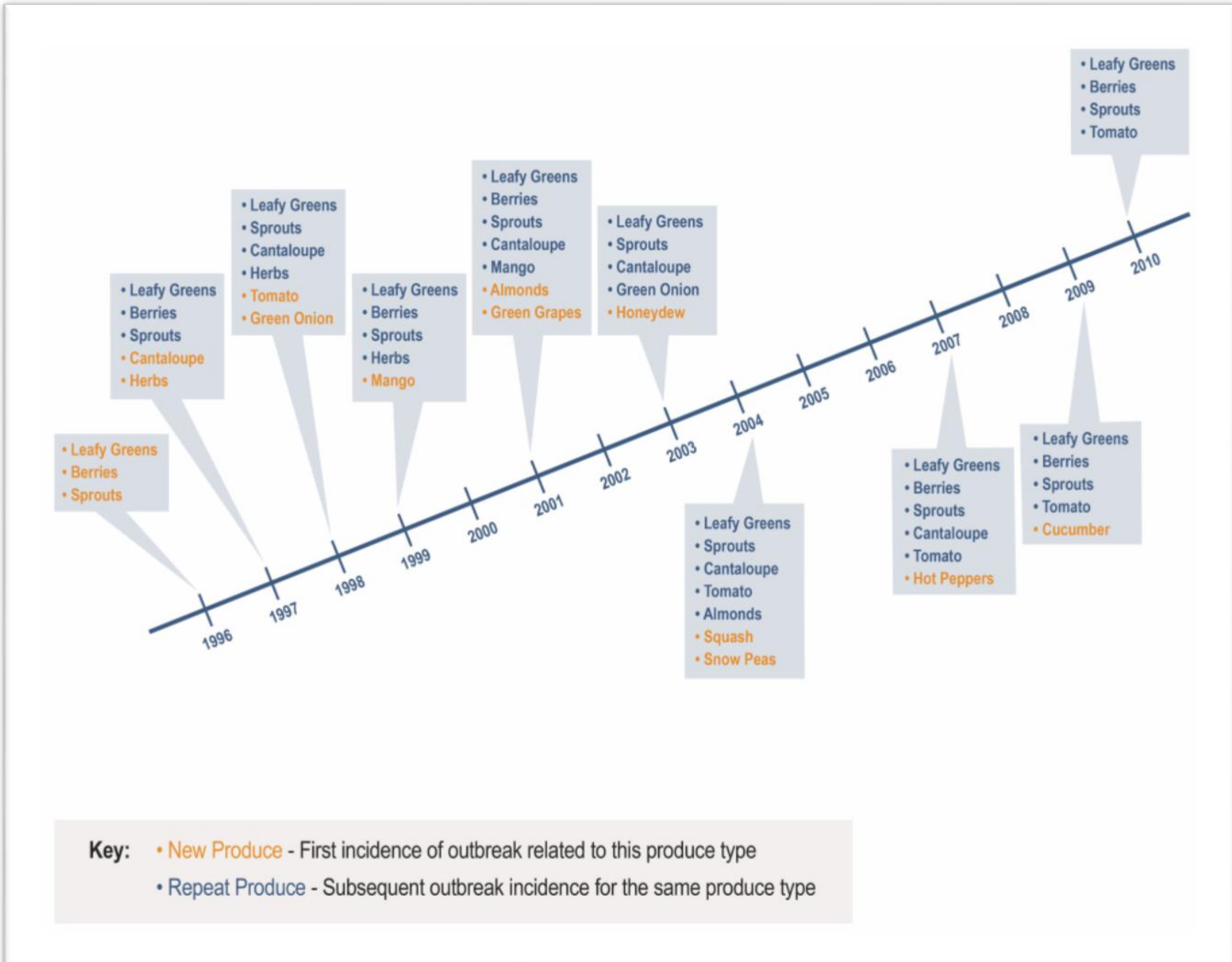
Food is a vehicle by which pathogens may be transported to humans. The ultimate source of harmful pathogens, however, is typically from the production environment, and more specifically enteric (from the gut or intestines) pathogens from the feces of wild animals; domesticated animals; or humans (Food and Agriculture Organization of the United Nations (FAO)/WHO, 2008). Pathogens from the animal and human gut may contaminate water, soils, equipment, food-contact surfaces, packing materials, and the food itself. A 2008 FAO/WHO study further indicated

[10] CDC Foodborne Illness Surveillance, Response, and Data Systems Web page: http://www.cdc.gov/foodborneburden/surveillance-systems.html

that contamination may occur from animals entering the fields where food is grown (animal intrusion), from livestock production (including manure production), as well as from water, aerosols, and dust contaminated with fecal material containing pathogens. Climate, topography, hydrology, and weather all may contribute to the extent that food commodities become contaminated. Flooding of fields may also introduce hazards to produce, as does poor hygienic practices or conditions.

It has been sufficiently demonstrated by CDC, State and local departments of agriculture, and WHO that the practices associated with growing, harvesting, handling, packing, and holding food commodities that are normally eaten raw (i.e., not cooked or commercially processed prior to human consumption) are of primary concern, and these practices may be mitigated in ways to reduce the risk of pathogen contamination. Figure 1.6-1 provides a snapshot in time beginning in 1996 (CDC surveillance of outbreaks began much earlier), which shows certain produce commodities associated with pathogen outbreaks, and how many distinct commodities are linked to outbreaks.

Figure 1.6-1. Timeline showing produce commodities associated with past outbreaks



As discussed in the 2013 proposed rule, FDA has tentatively concluded to use a regulatory framework based on practices, procedures, and processes associated with growing, harvesting, packing, and holding of all covered produce. FDA considered and rejected the option to develop 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. FDA explained that because foodborne illness outbreaks have regularly been associated with commodities that have previously not been linked to outbreaks, this approach carries the risk of failing to prevent future 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 FDA needs to focus to minimize current and future risk of illness. FDA further noted that relevant references on the subject of produce safety, as well as FDA's qualitative assessment of risk, identify common on-farm routes of contamination, such as personnel training, health, and hygiene; domestic and wild animals; BSAs of animal origin; agricultural water; and equipment and buildings. Procedures, processes and practices in each of these on-farm routes of contamination have the potential to introduce biological hazards into or onto any covered produce. Therefore, FDA proposed an integrated approach to prescribe standards for each of these on-farm routes of contamination (see 78 Fed. Reg. 3504 at 3524-3529).

Produce, meaning any fruit or vegetable (including specific mixes or categories of fruits and vegetables) grown for human consumption, and including mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs, would be covered under the PS PR, if finalized. Under proposed § 112.1, FDA provided a list of commodities intended simply to provide examples of produce commonly consumed in the U.S. that would be included within the scope of the regulation. In its proposal, FDA identified three types of produce that would not be covered by the rule (see proposed § 112.2(a)). First, proposed § 112.2(a)(1) would provide an exclusion for produce that is rarely consumed raw. FDA proposed to establish an exhaustive list of specific fruits and vegetables that would be exempt from the rule (see Table 1.6-1). FDA explained that because these listed fruits and vegetables are almost always consumed only after being cooked, which is a kill-step that adequately reduces the presence of microorganisms of public health significance, these listed produce would be excluded from the requirements of the rule. Second, FDA proposed to exempt produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same ownership (proposed § 112.2(a)(2)). Third, FDA proposed to exclude produce that is not a raw agricultural commodity from this proposed rule. For example, this would exclude "fresh-cut" produce (proposed § 112.2(a)(3)).

Table 1.6-1. List of specific fruits and vegetables that would be exempt from the PS PR

List of specific fruits and vegetables that would be exempt from the rule			
- Arrowhead	- Collard greens	- Lima beans	- Rutabaga
- Arrowroot	- Crabapples	- Okra	- Sugarbeet
- Artichokes	- Cranberries	- Parsnips	- Sweet corn
- Asparagus	- Eggplant	- Peanuts	- Sweet potatoes
- Beets	- Figs	- Pinto beans	- Taro
- Black-eyed peas	- Ginger root	- Plantains	- Turnips
- Bok choy	- Kale	- Potatoes	- Water chestnuts
- Brussels sprouts	- Kidney beans	- Pumpkin	- Winter squash (acorn and butternut squash)
- Chick peas	- Lentils	- Rhubarb	- Yams

In addition to these three exemptions, FDA proposed to allow covered produce, which receives commercial processing that adequately reduces the presence of microorganisms of public health significance, to be eligible for an exemption from the requirements of the rule (proposed § 112.2(b)). FDA tentatively concluded that such commercial processing significantly minimizes the risk of serious adverse health consequences or death associated with biological hazards for such produce, such that the produce can be considered to be low risk and the imposition of the requirements of the PS PR is not warranted (see 78 Fed. Reg. 3504 at 3535-3539).

Table 1.6-2 provides examples of raw agricultural commodities that are not rarely consumed raw, and due to their growing, harvesting, packing, and holding conditions, may present a high risk of pathogen contamination to humans.

Table 1.6-2. Examples of produce* covered by the Produce Safety Proposed Rule

List of produce that would be covered by the PS PR (proposed 21 CFR 112.1)				
- Almonds	- Carrots	- Green Beans	- Nectarine	- Spinach
- Apples	- Cauliflower	- Guava	- Onions	- Sprouts (such as alfalfa and mung bean)
- Apricots	- Celery	- Herbs (such as basil, chives, cilantro, mint, and parsley)	- Papaya	
- Aprium	- Cherries		- Passion Fruit	
- Asian Pear	- Citrus (such as clementine, grapefruit, lemons, limes, mandarin oranges, tangerines, tangors, and uniq fruit)		- Peaches	- Strawberries
- Avocados			- Pears	- Summer Squash (such as patty pan, yellow, and zucchini)
- Babaco		- Honeydew	- Peas	
- Bamboo Shoots		- Kiwi Fruit	- Peppers (such as bell and hot)	
- Bananas		- Lettuce		
- Belgian Endive		- Mangos	- Pineapple	- Tomatoes
- Blackberries	- Cucumbers	- Other Melons (such as canary, Crenshaw, and Persian)	- Plums	- Walnuts
- Blueberries	- Curley Endive		- Plumcot	- Watercress
- Broccoli	- Garlic		- Radish	- Watermelon
- Cabbage	- Grapes		- Raspberries	
- Cantaloupe		- Mushrooms	- Red Currant	
- Carambola			- Scallions	
			- Snow Peas	

* Including mixes of intact fruits and vegetables

1.7 Exposure to pathogens

Pathogens Responsible for Foodborne Illness Related to Covered Produce

Bacteria play an important role in maintaining life by decomposing organic matter, contributing to the carbon and nitrogen cycles, providing protection from diseases, and digesting food. Many bacteria are present as part of the natural human body flora and are mostly benign (not harmful), usually acting to competitively inhibit colonization by harmful microbes. Bacteria not naturally present in the body can be transported by a variety of mechanisms through direct or indirect contact with primary and secondary sources.

Harmful, disease-causing microbes are called “pathogens.” Four major microbial pathogens (shiga toxin-producing *E. coli* (STEC) O157, *Listeria monocytogenes*, Norovirus, and *Salmonella*) account for the majority of the foodborne illnesses for which a precise cause is often not determined (Newell et al., 2010). While all of the pathogens have been associated with contaminated food, ingestion of contaminated water, contact with infected animals, and unsanitary surfaces also serve as exposure pathways. Within the agricultural industry, these sources and modes of transport may include irrigation water, manure, soils, humans, and pests.

If able to bypass the defense mechanisms of a host (e.g., skin, immune system, etc.), bacteria may be able to establish a parasitic relationship. Some bacteria are capable of this under the right conditions but are otherwise harmless (i.e., opportunistic pathogens). Other bacteria have evolved to specifically overcome host defense mechanisms in order to establish a parasitic relationship; these are collectively referred to as bacterial pathogens. *Escherichia coli*, *Listeria monocytogenes*, *Salmonella*, and Norovirus outbreaks on produce have led to numerous deaths in the U.S. in the last several years, and all pathogens listed in Table 1.7-1 have been responsible for foodborne illnesses and hospitalizations (Scallan et al., 2011). Table 1.7-1 lists the major pathogens responsible for foodborne illness in the U.S. and includes the mode of pathogen transmission.

Table 1.7-1. Major pathogens (on produce) responsible for foodborne illness

Microorganism Name	Type	Transmission
E. coli	Bacteria	Contaminated food Consumption of unpasteurized (raw) milk Consumption of water that has not been disinfected Contact with cattle, or contact with the feces of infected people
Listeria monocytogenes	Bacteria	Contaminated food
Norovirus	Virus	Contaminated food Contaminated liquids Hard surfaces Contact with infected person
Salmonella	Bacteria	Contaminated food Contaminated water Contact with infected animals

The produce commodity group (which includes beans, fruits, vegetables covered under the proposed rule) attributed to 66 percent of viral, 32 percent of bacterial, 25 percent of chemical, and 30 percent of parasitic foodborne illnesses from 1998-2008 (Painter et al., 2013). Leafy vegetables accounted for a greater proportion of foodborne illnesses than the land animal or aquatic animal commodity groups for the following microorganisms: enterotoxogenic *E. coli*, STEC, *Salmonella*, and Norovirus. Additionally, more foodborne illnesses were attributed to leafy vegetables (22 percent) than to any other commodity group. Painter's study further found that foodborne illnesses associated with leafy vegetables were the second most frequent cause of hospitalizations at 14 percent, and during the time period cited. "Previous studies have shown that produce containing foods were the source for approximately half of Norovirus outbreaks with an identified simple food vehicle during 2001–2008 and the second most frequent food source for *E. coli* O157 outbreaks during 1982–2002." (Painter et al., 2013) Outbreaks of STEC infections transmitted by spinach and lettuce, and *Salmonella* infections transmitted by tomatoes, mangos, sprouts, and peppers heighten concerns about contamination of produce that is consumed raw.

<u>Transport of Pathogens in an Agricultural Setting</u>

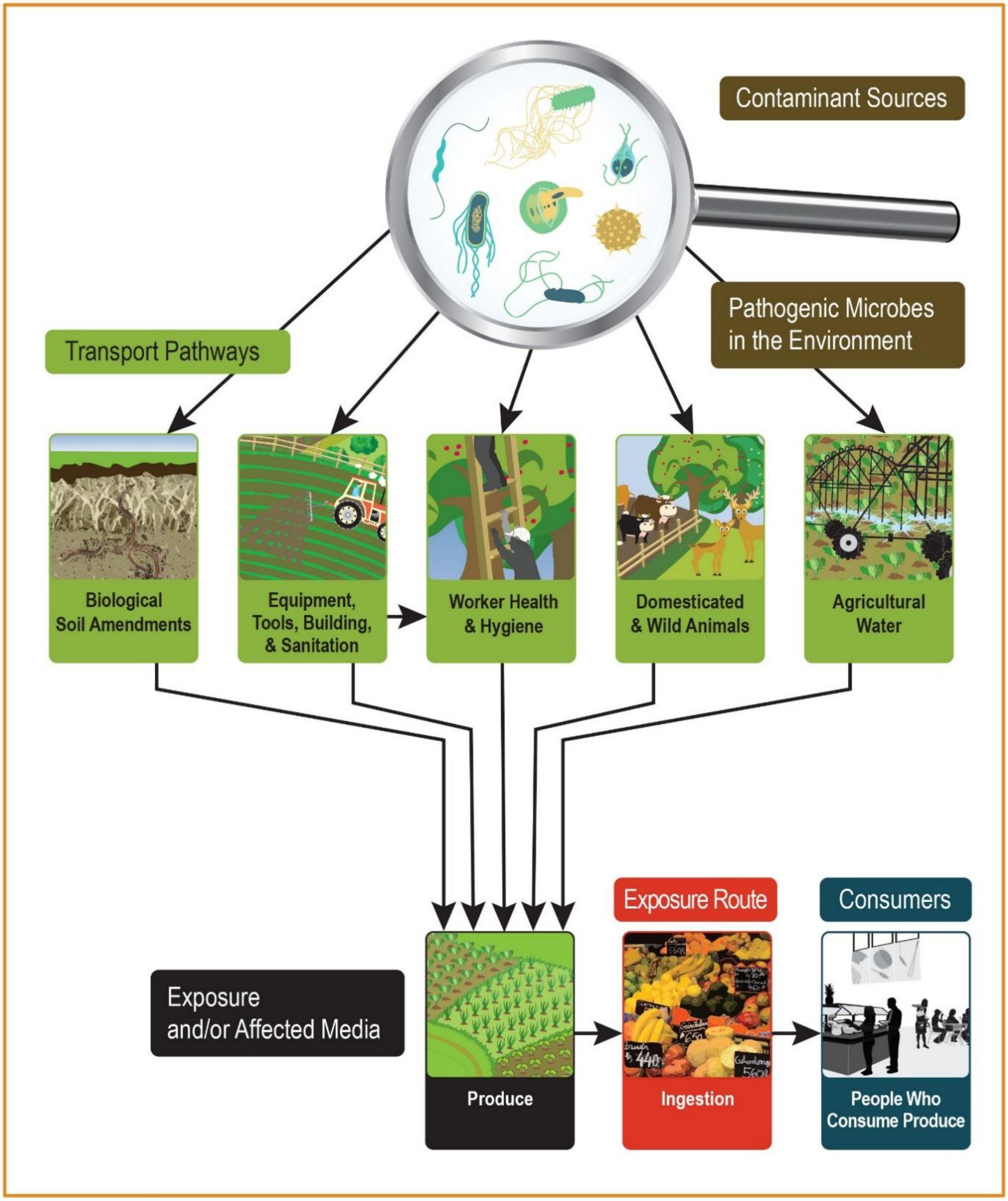
FDA conducted a qualitative assessment of risk associated with growing, harvesting, packing, and holding of produce and published a Draft report on the findings of this assessment as part of the supporting material to the 2013 proposed rule (2013c) (hereinafter referred to as the Draft

Qualitative Assessment of Risk or Draft QAR). The Draft QAR provides a scientific evaluation of potential adverse health effects resulting from human exposure to hazards in produce, with a focus on public health risk associated with on-farm microbial contamination of produce. The Draft QAR includes (1) Hazard Identification, (2) Hazard Characterization, (3) Exposure Assessment, and (4) Risk Characterization. This document helped to inform FDA on the risk management decisions the Congressional mandate directs FDA to make, in part, by focusing on those biological hazards that present a risk of serious adverse health consequences or death to the consumer.

Produce commodities are susceptible to exposure to biological hazards before, during, and after harvest. Although the likelihood of exposure to such hazards varies by commodity and by other factors such as cultivation and production systems, the supply chain infrastructure, and environmental considerations, the sources of potential contamination during growing, harvesting, packing, and holding are common across commodities (FDA, 2013c).

Over the years, FDA has obtained information that provides insight regarding the routes of contamination during growing, harvesting, packing, and holding produce safely on farms. Based on findings of the Draft QAR; observations during inspections, investigations, surveillance activities; and other available information, FDA grouped the possible routes of contamination into five pathways: Water, Soil amendments, Animals, Worker health and hygiene, and Equipment and buildings (FDA, 2013c). These pathways are depicted in Figure 1.7-1 along with exposure routes that begin with the produce commodity and end with consumers.

Figure 1.7-1. Contaminant sources and pathogenic modes of transport through the agricultural environment.



FDA estimates that 2.7 million foodborne illnesses are attributable to produce that would be covered by the rule (FDA, 2013b), and that the number of foodborne illnesses potentially prevented once a rule is finalized is estimated at 1.57 million.[11] This equates to an approximate $930 million saved annually in foodborne illness-related expenditures (benefit). The potential cost of compliance with the rule annually for all affected farms is estimated at $529.62 million (FDA, 2014b).

The Wild Farm Alliance (WFA), with substantial technical input from University of California, Davis (UC Davis), USDA, and the Community Alliance with Family Farmers (CAFF) prepared a detailed graphic (Figure 1.7-2) to better illustrate factors that affect pathogen survival in a farm-ecology setting, as well as to highlight co-management techniques that can help improve food safety.[12]

Figure 1.7-2 depicts several modes of pathogen transport that can be related to most agricultural operations relevant to the PS PR. The illustration key for this graphic is included with this EIS as Appendix A. For the purposes of this EIS, the concept of co-management[13] is important in promoting stewardship on the farm, including protecting water and soil quality and conserving wildlife and ecosystem habitat, while balancing food safety and farm productivity goals. Figure 1.7-2 demonstrates co-management techniques that may be employed alongside pathogen vectors.

Important pathogen vectors that highlight the significance of food safety concerns include contaminated animal waste that may in-turn contaminate water sources or fields through direct or indirect application, and animal intrusion vectors.

Human vectors that are not shown on this graphic include poor hygiene, poor sanitizing practices and poor packaging practices.

There are many different types of farms, each filling an important role in our nation's food supply chain. The traditional sense of the farm is that it is a source of animal commodities (e.g., beef, pork, fish, or poultry), wheat or grains, or produce. But this would be an oversimplification of what farms yield and the many important benefits that farms have to the local, regional, and national economy. Just as important as what a farm produces, is how the land on a farm is used. Farm land and how it is managed has an impact on the local ecology and environment, in addition to its social and economic impact locally and regionally.

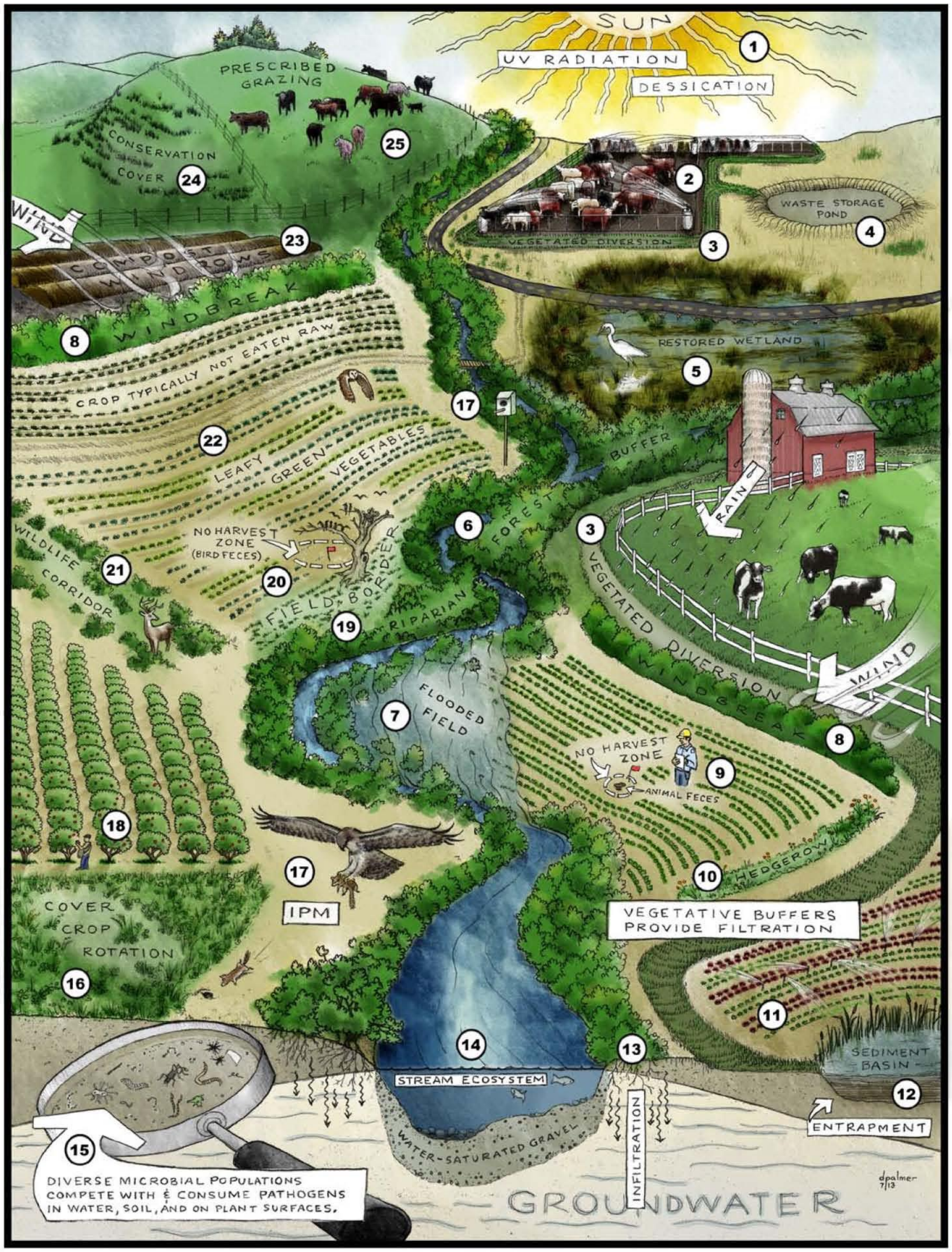
[11] Estimate adjusted for changes made in the supplemental proposed rule. Specifically this number does not include the deferred standard for untreated BSAs of animal origin.

[12] The *Healthy, Diverse Ecosystems Help Keep Pathogens in Check* graphic, including *A Farmer's Guide to Food Safety and Conservation*, may be found at http://wildfarmalliance.org/resources/FS_Facts_Tip_FAQ.htm.

[13] Co-management strategies balance food safety concerns with environmental and farm management concerns. The USDA NRCS or local count extension agents offer information and best practices for co-management techniques.

Figure 1.7-2. Basic factors that affect the survival and movement of foodborne pathogens in an agricultural setting

Healthy Diverse Ecosystems Help to Keep Pathogens in Check



Not to Scale

Excerpted From: A Farmer's Guide to Food Safety and Conservation published by WFA and CAFF, Oct. 2013

Farm-to-Table Supply Chain

Produce grown in the U.S. originates from farms of all sizes that operate on a local, regional, or national scale. The geographical area that a farm serves depends on factors such as, but not limited to, food production and processing capabilities, the distribution network, food commodity marketing, price of the food commodity, and demand for the food commodity.[14] Growers may not rely solely on their own marketing and distribution system in order to get their food to consumers.[15] Food distribution centers, for example, may purchase food commodities from several growers in a particular area and then process, package, re-brand, and sell those foods together to consumers. Food distribution centers, therefore, may have input in terms of the quality of food products grown and how consistently the food commodities make it to the market, which in turn means that *how* food is grown and harvested may be part of a planning process that involves more than just the farmer (USDA AMS, 2012; USDA AMS, 2013a).[16]

There is a wide variety of produce supply chains that move food commodities to the market places where consumers shop.[17] The example of the food distribution center is valuable in that it demonstrates one model of how food makes it to consumers other than what is commonly perceived as direct sales from farms to consumers, restaurants, or to supermarkets. The opportunities that farmers have to market their food commodities to consumers continue to improve. One result of this more diverse food supply chain is that a greater variety of food is now offered to consumers from a greater variety of growers. Figure 1.7-3 shows the percentage of farms by farm size (in terms of annual revenue), during the years 2008 to 2009, which participate local food sales to consumers. According to these data, which are provided from USDA's Agricultural Resources Management Survey (conducted annually), "small" farms (i.e., those with local food sales of up to $49,999)[18] make up approximately 79 percent of the participants in local sales but earn ten percent of the total sales. In contrast, under the USDA definition of large farm, large farms make up approximately three percent of the total participants in local sales and earn an estimated 56 percent of the total sales (USDA, 2013).

What this information emphasizes is that farms of all sizes contribute agricultural commodities to local markets, including farms or businesses that also contribute their food commodities to regional or national markets. While this trend is important on many levels to our economy and to farm productivity, it further underscores the need for a reliable food safety system.

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[14] USDA operates the Agricultural Marketing Service, which supports domestic production and provides an outlet for surplus food commodities to reach consumers through an approved vendor network all over the nation.

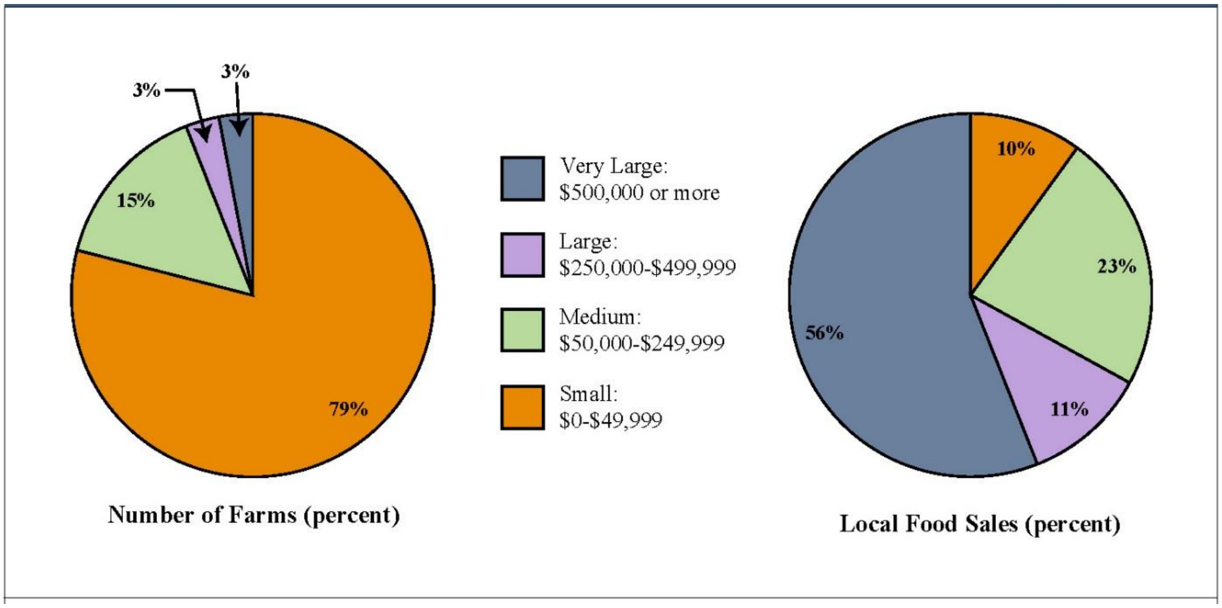
[15] Consumer groups may be made up of individuals, institutions such as schools, restaurants, supermarkets, or others.

[16] More information on the food supply chain may be found at http://www.ams.usda.gov.

[17] USDA works with industry partners to improve farm access to supply chains and regional markets. More information may be found in *Building Regional Produce Supply Chains* (FarmsReach, 2012), and online at www.ers.usda.gov.

[18] Note that the definition of small farms in terms of annual revenue, as used by USDA in this example, is different than the definition of small farm by average annual revenue used by FDA in the PS PR and in this EIS.

Figure 1.7-3. Farms engaged in and the value of local food sales, 2008-2009 average



Source: USDA Agricultural Resources Management Survey 2008-2009 (USDA, 2013)

Where covered produce is grown

USDA NRCS developed and maintains a map (as shown in Figure 1.7-4) illustrating 27 Land Resource Regions and Major Land Resource Areas for the U.S. (referred to as "regions" throughout the EIS). The combination of geology, soils, and climate form the foundation for where food is produced. The USDA NRCS subdivided the country into these regions because they share similar soils, climate, and vegetation or crop types (USDA NRCS, 2006).

Figure 1.7-4 serves as a foundation for FDA's analysis within this EIS. The map includes the locations where produce that would be covered by the rule is grown. Data inputs for the map are from USDA's National Agricultural Statistics Service (NASS) 2012 Agricultural Census data (USDA NASS, 2014a).[19] Using this map as a foundation, FDA is able to better compare the relationship between resource components studied in this EIS (e.g., soils and air quality) with common resources such as where BSAs of animal origin are produced, and the availability and quality of water that may be used for irrigation. Of note, Figure 1.7-4 illustrates that high densities of covered produce are grown within Regions B, C, D, L, and U; however, other regions are important as they compare to different resource components studied in the EIS. Produce acreage on the map is represented by dots on the map with each dot representing 1,000 acres of cropland.

[19] More information on the Census of Agriculture may be found at www.agcensus.usda.gov.

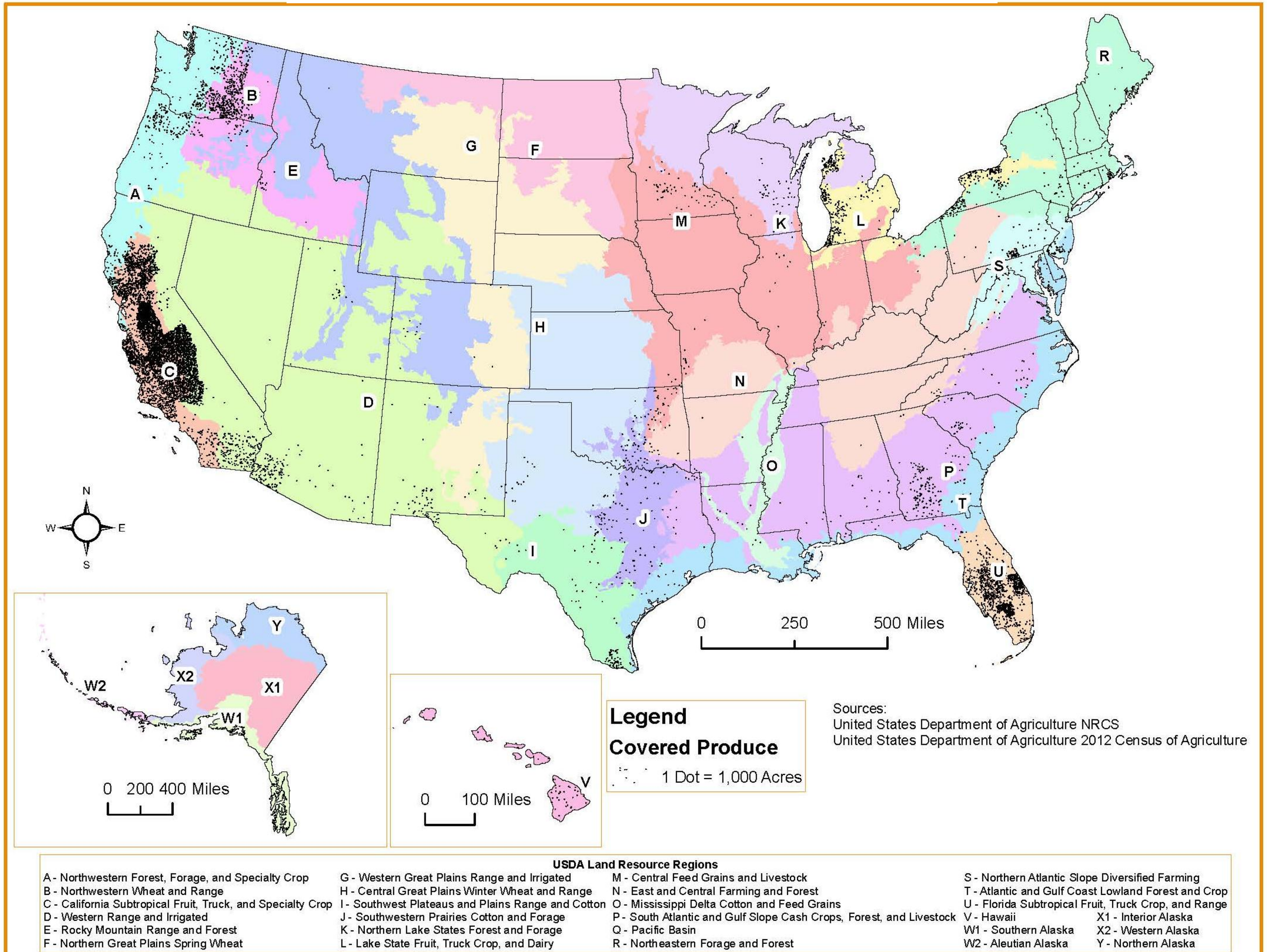


Figure 1.7-4. Regions where covered produce in the U.S. is grown

Agricultural management techniques related to the PS PR

Irrigation

Irrigation is the artificial application of water (as opposed to natural rainwater) to land or soil, which is used to support the growing of agricultural commodities (crops). Irrigation systems are used across the world to help augment growing conditions and improve crop yield. Some irrigation systems draw from surface water supplies, and some draw from subsurface sources (groundwater or aquifers) (see Chapter 3.1 Water Resources). Irrigation water may be applied to crops at the soil surface, or at or near the root zone (subsurface). Water quality, including the level and persistence of contaminants or pathogens present in water, is dependent upon many factors that are discussed in Chapter 3 of this EIS. It is generally accepted that water quality is better from subsurface sources (groundwater) as compared to surface water. More information on water quality, sources, water source interactions, and contaminants is presented in Chapter 3.1. In addition, Appendix B offers details on water irrigation systems and applications, and treatment options related to poor water quality conditions.

Biological Soil Amendments

Biological Soil Amendments include organic material such as BSAs of animal origin (e.g., humus, manure, non-fecal animal byproducts such as bone meal or blood meal) and biosolids, which constitute the organic solid product of wastewater treatment processes or sewage sludge; or BSAs of vegetative origin, which includes, but is not limited to, table scraps and yard trimmings. Chapter 3.4 discusses BSAs in greater detail. Appendix C of this document provides an introduction on the application of animal manure, manure management guidance and common handling systems, as well as the methods and timing for manure application, which is helpful to understanding the basis of potential environmental impacts.

1.8 FSMA stakeholder engagement

FDA has participated in an unprecedented level of outreach to producers throughout the U.S. in an effort to hear directly from those who may be most affected by the PS PR.

Since the January 2013 release of the PS PR, FDA has conducted extensive outreach, including conducting more than 100 presentations to industry and consumer groups, farmers, State and local officials, international officials, and the research community. Included in this number are three FDA-sponsored public meetings (District of Columbia; Chicago, Illinois; and Portland, Oregon); six sponsored State meetings (North Carolina, Georgia, Michigan, Ohio, and two in California); numerous other listening sessions accomplished through webinars or in person with stakeholder groups; meetings in Europe with the European Union, the World Trade Organization, and the Global Food Safety Initiative; two extensive U.S. regional farm tours in the Pacific Northwest and in New England; as well as farm tours in Mexico to discuss the combination of the FSMA rules FDA has proposed that, if finalized, would help ensure the safety of both domestic and imported foods. Outreach efforts by the Office of Foods and Veterinary Medicine (OFVM) and program headquarters staff have been complemented by the outreach of FDA's field and foreign offices, which have also been actively conducting outreach in the various regions where FDA has postings.

Senior FDA staff visited more than 20 farms in 13 States and interfaced with hundreds of stakeholders at various meetings across the country to develop the proposed rule. Many of these meetings included senior officials from the USDA as well as State commissioners of agriculture.

As part of FDA's outreach effort, FDA personnel routinely engaged with the National Association of State Departments of Agriculture, the Produce Marketing Association, United Fresh Produce Association, the National Sustainable Agriculture Coalition, the Organic Trade Association as well as with national and regional producer and farm organizations including Western Growers, the American Farm Bureau, the Ohio Produce Growers and Marketers Association and a number of regional produce and fruit and vegetable associations such as the Florida Fruit and Vegetable Association and the California Citrus Growers. FDA personnel also routinely engaged other significant FDA foods stakeholders on produce issues, such as the Safe Food Coalition, the Grocery Manufactures Association, and the Food Marketing Institute.

In addition, two produce-related alliances were established: the Produce Safety Alliance (PSA) and the Sprout Safety Alliance. The PSA is a collaborative project between Cornell University, USDA, and FDA. The overarching objective of this project is to provide the produce industry and associated groups with training and educational opportunities related to current best practices and guidance, as well as technical assistance on the PS PR. The Sprouts Safety Alliance was created in cooperation with the Illinois Institute of Technology's Institute for Food Safety and Health to assist sprout producers in identifying and implementing best practices in the safe production of sprouts.

Finally, FDA posts all information relevant to the PS PR on the FDA FSMA webpage. This webpage includes information specific to farmers such as a produce safety resources toolkit, summary information on produce provisions, an extensive set of questions and answers, as well as blogs, interviews, speeches and PowerPoint presentations on the Produce Safety Rule. The information posted on the FDA FSMA website is shared through a list serve that has over 20,000 subscribers.

Issues raised during public and agency scoping

In addition to the outreach effort described above, FDA sought comment from the public on a number of environmental issues in the form of questions that were inserted in the 2013 proposed rule. The agency has evaluated the information and input received in response to the PS PR to determine further actions, as appropriate, when developing this EIS.

Through public involvement, FDA determined a range of issues including potentially significant issues to be addressed in the EIS. This section provides an overview of the scoping process FDA used, including timing, as well as summarizing comments FDA received during the scoping period, and during the scoping meeting.

Scoping – Public Notification

On August 19, 2013, FDA initiated the EIS process by publishing a *Notice of Intent (NOI) to Prepare an Environmental Impact Statement for the Proposed Rule* in the *Federal Register* (78 Fed. Reg. 50358). The NOI provided general information on the 2013 proposed rule and announced the beginning of the scoping process, the period during which FDA and the public collaborate to identify issues to be addressed in the EIS. Specifically, the NOI invited the public to submit comments for FDA's consideration during the preparation of the EIS and to aid FDA with determining the need to hold any public scoping meetings. FDA stated that it would receive such comments until the closing date, November 22, 2013.

Subsequently, FDA announced a comment period extension for the EIS on the PS PR that extended the comment period to March 15, 2014 (78 Fed. Reg. 69006, November 18, 2013). The extension was provided to allow interested parties more time to provide comments on the scope and significance of issues that FDA should consider in the EIS. The extension was also granted to allow FDA additional time to hold, as appropriate, one or more public scoping meetings.

On March 11, 2014, FDA announced a public scoping meeting on the EIS for April 4, 2014, in College Park, Maryland, and a second comment period extension for the EIS that extended the comment period from March 15, 2014, to April 18, 2014 (79 Fed. Reg. 13593, March 11, 2014). Accordingly, the comment period for the scope of the EIS ended on April 18, 2014. In addition to providing information on the proposed rule, the March 11, 2014, *Federal Register* publication announcing the public scoping meeting included a summary (based on FDA's preliminary review of comments, currently available information, and further analysis of the proposed rule) of those provisions of the proposed rule that may significantly affect the quality of the human environment, and a range of potential alternatives for each provision for consideration in the EIS. FDA requested public comment on specific issues, alternatives, mitigation measures, or other information FDA should include for further analysis in the EIS.

Scoping – Public Outreach and Involvement

During the full scoping period for the EIS on the proposed rule (August 19, 2013, through April 18, 2014), FDA provided numerous ways that the public could participate in the EIS process. For example, the above-mentioned notices in the *Federal Register* provided instructions for submitting comments electronically online via the Federal eRulemaking Portal at http://www.regulations.gov or by mail/hand delivery/courier (for paper or CD-ROM submissions).

The public scoping meeting was held on April 4, 2014, at the Harvey W. Wiley Federal Building Auditorium in College Park, Maryland, from 1 p.m. – 5 p.m. (EST). Public participants had the option of attending the meeting in person or via an interactive live webcast, a recording of which was made available after the meeting.[20] The scoping meeting included a session that allowed individuals to review posters describing the issues under consideration for the EIS. During the

[20] The full transcripts and recording of the meeting are available at the following Web address: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm388369.htm

poster session, FDA staff was on hand to answer questions and discuss poster content. The meeting included a presentation by FDA on the background of the PS PR and the scoping process, an overview of the NEPA process, proposed alternatives for provisions of the proposed rule that may significantly impact the quality of the human environment, and how the public may submit comment on the scope of the EIS. The scoping meeting also had an open microphone session where attendees were offered opportunities to provide comments, followed by a question and answer (Q&A) session between the audience and FDA officials. A court reporter was also available on-site throughout the entire meeting to transcribe oral comments.

There were 150 participants in the public scoping meeting on April 4, 2014: 43 attended in person, and 107 participated in the meeting via the live webcast. Of the on-site participants, five (5) individuals provided public comments during the open microphone session. Table 1.8-1 provides the breakdown of the number of FDA and public participants, and their respective venues (on site or via webcast).

Table 1.8-1. April 4, 2014 public scoping meeting participants

FDA and Public Participants	Number of Participants
Total Participants	**150**
FDA, on-site	23
FDA, via Webcast	10
Public, on-site	20
Public, via Webcast	97

FDA has received more than 17,000 comments to the rulemaking docket, to date. This includes comments received on the 2013 proposed rule as well as comments received to date on the scope of the EIS. In the 2013 proposed rule, FDA stated that it was seeking comments on the potential environmental effects as part of the public comment period for the PS PR, including specific comments regarding agricultural water, BSAs of animal origin, and wildlife. FDA stated, in the August 19, 2013, EIS NOI, that these comments are still relevant to the environmental analysis. Consequently, FDA reviewed these comments on the 2013 proposed rule along with comments received as part of the EIS scoping process, in addition to other data and information, to determine the specific issues and alternatives FDA should include for analysis in the EIS.

Each of the notices in the *Federal Register* provided instructions for interested persons or agencies on how to access the PS PR rulemaking docket to read background documents or comments received. FDA is currently reviewing all public comments for the purpose of developing a final rule.

Scoping – Agency Involvement, Consultation, and Cooperation

Pursuant to 40 CFR 1501.7(a)(1), as the lead agency, FDA is required to "invite the participation of affected Federal, State, and local agencies, any affected Indian tribe, the proponent of the action, and other interested persons (including those who might not be in accord with the action on environmental grounds)."

According to 40 CFR 1508.5, a "cooperating agency" is "any Federal agency other than a lead agency which has jurisdiction by law or special expertise with respect to any environmental impact involved in a proposal (or a reasonable alternative) for legislation or other major Federal action significantly affecting the quality of the human environment." In August of 2013, FDA sent letters to EPA, USDA, and the USFWS requesting their participation as cooperating agencies in the preparation of the EIS. At this time, FDA also sent letters to the State Departments of Agriculture inviting their comments to the docket and leaving them the opportunity to request cooperating agency status, although not issuing a formal invitation.

USDA has agreed to be an official cooperating agency. Within USDA, FDA has consulted with USDA AMS, which oversees the organic program; and NRCS, which develops and maintains the National Conservation Practice Standards. In addition, EPA is answering questions from FDA on an as-requested basis and has responded to requests for formal opinions on various topics of the PS PR. USFWS has also agreed to work with FDA through other appropriate channels, specifically with regards to the ESA. Having these agencies involved helps ensure that environmental and conservation standards and policies established by these agencies are appropriately considered in developing the EIS for the PS PR.

For a summary of tribal outreach on the EIS for the PS PR as well as information on which tribes, so far, have specifically requested consultation with FDA, please see the Tribal Outreach section directly following Table 1.8-2 below.

Scoping – Summary of Comments

Comments received with respect to the PS PR and during the EIS scoping period were generally grouped by resource component assessed for environmental impact analysis. Table 1.8-2 summarizes the comments raised by the public from the oral statements and written comments received and generally identifies the sections of this Draft EIS where we considered these comments. These comments provide a general summary of comments submitted that relate to the scope of the EIS. It is important to note that FDA has addressed some of the concerns of these comments by amending some specific provisions and proposing new provisions within the supplemental proposed rule.

Table 1.8-2. Summary of comments identified for inclusion in the scope of the EIS

	Comments/Issues	Sections of EIS where comments are considered in evaluating environmental impacts
Water Resources	Concern that the proposed rule would create a preference for synthetic fertilizers which would increase groundwater nitrate which could cause future environmental effects such as eutrophication downstream. Increased use of synthetic fertilizers can cause agricultural runoff and pollution.	Potential impacts are addressed in Chapter 4.3, subpart F
	Concern that the proposed rule creates a preference for farmers to use groundwater, municipal water, and/or public water. Switching to municipal water could place an increased demand on already-stressed municipal water supplies. Switching from surface water to groundwater/municipal/public water could put significant pressure on water supplies and aquatic ecosystems. Using municipal water could decrease minimum flows, thereby harming aquatic life.	Potential impacts are addressed in Chapter 4.2, subpart E
	Concern over treatment residue from chemicals used to treat surface water. Encourage FDA to look at which chemicals farmers will likely use to treat surface water. Residue from treatment could impact water resources and aquatic animals because of agricultural runoff and leachate containing chemically treated irrigation water. Tailwater resulting from using treated irrigation water may negatively impact aquatic life.	Potential impacts are addressed in Chapter 4.2, subpart E
	EPA's 1986 Recreational Water Standard is not flexible/risk-based enough because it applies regardless of risk, climate, location, farming system, or water system. In many parts of the country, surface water cannot meet this standard without chemical water treatment. The proposed rule creates a preference for chemical water treatment.	Per the supplemental proposed rule, the EIS addresses added flexibility in Chapter 2.1.
	Need to examine unique irrigation challenges that exist in various parts of the country.	Chapter 1.9 addresses the EIS scope; potential impacts are found in Chapter 4.2 subpart E; and Appendix B discusses irrigation practices.
Biological and Ecological Resources	Concern over impacts on non-target wildlife from methods used to control pests and wildlife such as habitat removal, fencing, and poison. Special concern over harming migratory birds and threatened and endangered species. Food safety and conservation should be co-managed.	Chapter 2.1 subpart I, Chapter 4.5 subpart I.
	To avoid the proposed rule's animal monitoring requirements, farmers may take actions such as habitat destruction and clearing farm borders.	Per the supplemental, FDA has codified its thinking on this issue in Chapter 2.1 subpart I, and Chapter 4.

	Comments/Issues	Sections of EIS where comments are considered in evaluating environmental impacts
Soils	Adopt soil treatment regulations (relative to BSAs) that align with USDA organic regulations.	BSAs of animal origin, relative to potential future regulation and interaction with USDA's organic regulations are addressed in Chapter 1.4, Chapter 2.1 subpart F, and Chapter 4.3 subpart F
	Unspecified concerns about the natural biological integrity of the soil (soil quality) as a result of changes in BSA practices.	Chapter 4.3 and 4.4 subpart F
	Manure management rules could impact manure use. Animal waste (manure) returns nutrients to the soil contributing to healthy soil life.	Chapter 4.3 subpart F
Waste Generation, Disposal, and Resource Use	Proposed rule does not address Concentrated Animal Feeding Operations (CAFOs), use of which could increase due to restrictions on animal grazing and result in increased raw manure generation and subsequent impacts to soil and water quality.	Chapter 3.4 and Chapter 4.3 subpart F
	Concern over application intervals in some parts of the country being longer than the growing season, resulting in a switch to non-produce crops or lower yields for crops produced in those areas.	Chapter 4.3 and 4.4 subpart F
	Concern that the proposed rule could deter farmers from using manure causing stockpiles to form.	Chapter 4.3 subpart F
	Concern that the proposed rule creates a preference for farmers to use synthetic fertilizers and result in increased environmental exposures, as opposed to biological soil amendments.	Chapter 4.3 and 4.4 subpart F
Air Quality	Concern about impacts on air quality from water purification processes.	Chapter 4.2 subpart E
	Concern over impacts on energy usage to treat and/or store water: Increased energy could involve emissions affecting farmers' ability to meet Clean Air Act/Greenhouse gas reduction standards.	Chapter 4.2 subpart E
	Concern that the proposed rule creates a preference for synthetic fertilizers over biological soil amendments—could lead to additional emissions and energy expenditure to produce the synthetics. Synthetic fertilizers can cause air impacts due to the formation and release of the greenhouse gas nitrous oxide (N_2O) when there are of high concentration of soluble nitrogen present in the soil.	Chapter 4.3 and 4.4 subpart E
	Concern over increased transportation emissions to get rid of untreated animal waste and/or import synthetic fertilizers or treated amendments.	Chapter 4.3 subpart F
	Concern over anaerobic decay of large concentrations of wastes (both raw manure and composting).	Chapter 4.3 subpart E
Cultural Resources	Concern over the end/decline of farming as a way of life. Concern that the proposed rule will discourage traditional agricultural practices and/or the growing of traditional cultural crops.	Chapter 3.6.1

	Comments/Issues	Sections of EIS where comments are considered in evaluating environmental impacts
Socioeconomics & Environmental Justice (including Tribal Resources)	Concern about environmental impacts stemming from small farms going out of business due to costs associated with complying with the proposed rule.	Chapter 4.2 and 4.7
	With many tribes being located in arid regions, tribes have expressed concern that the proposed rule's water quality standards could cause an increase in groundwater demand and exacerbate water rights concerns.	Chapter 4.2 subpart E
	Concern about tribes' access to local produce, especially in light of the prevalence of significant medical conditions among tribal populations.	Chapter 4 subpart E as it relates to all disadvantaged or low income populations.
	Concern that the proposed rule, in aggregate, may have a disproportionate impact on minority, low-income, and the socially disadvantaged.	Chapter 4
	Concern that the proposed rule creates incentives for mono-culture and conventional farming over diversified farms.	Chapter 4.2 subpart E
	Concern that proposed rule will raise prices of locally grown food causing consumers with lower incomes to be unable to afford them.	Chapter 4.2 subpart E
Human Health and Safety	Concern over access to fresh/local/organic food because the proposed rule could create a preference for factory/commercial/mass-produced food farms that use genetically modified organisms (GMOs) or CAFOs.	Chapter 4.2 subpart E
	Several supportive comments on provisions that improve measures to protect public health.	Chapter 4
	Concern that the proposed rule does not go far enough to protect public health. This is demonstrated by the fact that some existing industry market agreements have more stringent standards with respect to BSAs than do the provisions of the PS PR.	Chapter 4

Scoping – Tribal Outreach

The FDA has been in consultation with several interested Native American Tribes since the invitation for consultation was sent in August 2013. A timeline showing the record of outreach and communication between FDA and interested tribal parties by HHS Regions is included in Appendix D (HHS, 2014). Chapter 3.7 provides a greater discussion of the affected environment for Native American Tribes. A full list of all 566 Federally recognized tribes can be found in the *Federal Register* at 79 Fed. Reg. 4748, January 29, 2014.

1.9 Scope of the EIS

As discussed in Chapter 1.5, FDA determined that microbiological hazards pose the greatest risk of serious adverse health consequences or death.

FDA subsequently prepared its Draft QAR associated with growing, harvesting, packing, and holding of produce. In particular, the Draft QAR was intended to address various risk management questions related to biological hazards of concern in fresh produce that can lead to serious adverse health consequences or death, potential routes of contamination, and the likelihood of contamination and likelihood of illness attributable to consumption among various types of produce commodities. The findings of the Draft QAR informed FDA's regulatory approach and several proposed provisions (see Chapter 1.4 for proposed provisions).[21]

FDA determined that the PS PR contains four potentially significant provisions (defined in Chapter 1.2) that, if finalized, may significantly affect the quality of the human environment: (Subpart A) General provisions; (Subpart E) Standards directed to agricultural water; (Subpart F) Standards directed to BSAs of animal origin and human waste; and (Subpart I) Standards directed to domesticated and wild animals (21 CFR proposed Part 112, as amended in the supplemental proposed rule).

There are management decisions related to compliance with these potentially significant provisions that a grower may make that may result in environmental effects that may significantly impact the human environment, and include effects which may be later in time or farther removed in distance, but are still reasonably foreseeable (40 CFR 1508.8). For example, if agricultural water is unsafe for use, then the grower may make a management decision that may include treating the water source, changing the irrigation mechanism, changing the water source, ceasing to grow covered produce, or adding a post-harvest rinse to account for microbial removal. Chapter 4 addresses the potential effects of the potentially significant provisions along with proposed alternatives. Alternatives for each such provision are identified in Chapter 2.1. FDA also recognizes that proposed provisions of the PS PR, taken together and taken with other reasonably foreseeable Federal or State actions, may result in significant cumulative effects. These potential cumulative effects are addressed in Chapter 5.

Management decisions that a grower may take if the rule is finalized would rely on a broad number of factors, including, but not limited to, availability of clean "safe" water or an alternative safe water supply, and the costs associated with accessing the water; availability and costs associated with soil amendments; the extent to which grazing animals or wildlife may contaminate covered produce; climate and weather; soil quality conditions; topography; demand and prices for certain agricultural commodities; and the type of crop being grown. These conditions vary widely across the nation and often are specific to the location of the farm and the grower. The crops, soil conditions, water supplies, and management techniques used on one farm may not be the same conditions found on a neighboring farm or other farms in the same county. Therefore, it is not feasible for an EIS to assess individual (site-specific) potential environmental impacts. This makes it necessary for FDA to identify a reasonable geographic scope within which to identify baseline agricultural conditions and background environmental conditions (see Chapter 1.2) and to conduct an impact analysis (Chapter 4).

With respect to Environmental Justice impacts related to the PS PR, FDA considers potential impacts to minority principal farm operators and farmworkers in Chapter 3.7.3. USDA NASS survey data provides information on principal operators of farms. Limited data is available for

[21] A summary of the Draft QAR is found in Section IV(A) of the 2013 proposed rule (78 Fed. Reg. 3504 at 3522).

farmworkers; however, there is no data specifically reported for farmworkers on produce farms. The U.S. Department of Labor reports some data on farmworkers in terms of ethnicity and income; however, State-level data are reported only for California and no other State. Potential impacts to farm worker employment may be dependent upon multiple factors including (but not limited to) average annual farm income, estimates for crop yield, and commodity prices. Increases in farm operating costs may also impact farm worker employment. It should be noted that farmworker employment can be highly seasonal (USDA ERS, 2014a). Increases in farm operating costs may result in adverse impacts to farmworkers, but such costs may also be transferred to consumers. Although potential cost impacts could be felt by consumers, without more definitive information regarding specific management decisions that might be taken in response to the PS PR, if finalized, it is unreasonable to project impacts on such groups. Therefore, for purposes of this EIS, the discussion of potential socioeconomic impacts is limited to principal farm operators and farm workers (where information is available). The background information for principal operators and farmworkers that fall within this resource component is in Chapter 3.7 Socioeconomics and Environmental Justice.

Geographical scope

As discussed in Chapter 1.6, FDA proposes to cover produce commodities, with some exemptions, within the scope of the PS PR. These produce are considered "covered produce." Covered produce grown within the U.S. is shown on Figure 1.7-4. The scope of this EIS includes the borders of the conterminous U.S., and also includes Alaska, Hawaii, and the EIS geographical areas.

Conterminous U.S., Alaska and Hawaii

Most information important for conducting an impact analysis is reasonably accessible for the 50 states. There are more data available for certain States, such as California, where more than 80 percent of produce that would be covered by the rule is grown. Wherever possible, potential impacts are discussed by State, but impacts are generally assessed by region or nationwide. A major source for information on where produce commodities are grown is compiled through USDA NASS 2012 surveys (see Chapter 1.7).

As described in Chapter 3, the data and information concerning current farming practices for covered produce and the environmental impacts of such practices vary for each resource component. For example, Chapter 3.1 Water Resources draws on information on water contamination published in nationwide databases that are managed by the U.S. Geological Survey (USGS) and EPA; however, the information, which is contributed by States, is not consistently reported. For most resource components, background environmental conditions and data are available to help establish the foundation for potential environmental impacts with respect to the proposed action for covered produce, by region. For certain resource components (certain aspects of water resources and socioeconomics and environmental justice) there is enough data available to determine environmental impacts by State. However, there are no data to determine environmental impacts of current farming practices for covered produce at the local level within a State.

EIS Geographical Areas

Less data is available for the EIS geographical areas (Puerto Rico, U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands) than for the 50 states. The 2012 Census of Agriculture did not include data on any geographic area except for Puerto Rico. FDA included Puerto Rico within its estimates for covered farms in the Regulatory Impact Analysis (FDA, 2013b and 2014b), so estimates throughout the EIS of the total number of covered farms, acreage and cost, include Puerto Rico. For this EIS, FDA reviewed the 2007 USDA NASS survey data for American Samoa, Guam, Northern Mariana Islands, and the U.S. Virgin Islands as USDA did not publish surveyed data for these regions in 2012 (USDA NASS, 2011; USDA NASS, 2009c,d,e)[22]:

- Guam: there are 104 total farms with an average farm size of 9.6 acres per farm. The average estimated revenue for fruit commodity farms was reported at about $7,000; and the average estimated annual revenue of fruit and vegetable farms was reported at just over $18,000 per farm.
- American Samoa: There are 5,840 total farms. The average annual revenue for fruit, nut, and vegetable crops is less than $10,000 and sales are generally reported as $500 or more.
- Northern Mariana Islands: there are 256 total farms. Produce farms reported an average of less than three acres per farm with average annual estimated revenue of less than $6,000 per farm.
- U.S. Virgin Islands: There are 219 total farms reporting an average of 27 acres per farm. The estimated average annual revenue of produce farms is less than $4,000 per farm.

Because the estimated average annual revenue reported for the EIS geographical areas listed above is below the proposed $25,000 threshold for produce farms that would be excluded from the PS PR (proposed 21 CFR 112.3(c)), with a possible few exceptions within each geographical area, most farms within these areas would be excluded from the rule. In addition, limited other environmental background information (not related specifically to agriculture) is available for water quality and air quality for some of these areas. Therefore, because most farms within these areas may be excluded from the rule, and because there is a lack of related environmental background information, no EIS geographical area except Puerto Rico is included within the analysis of this EIS.

International Growers

A portion of the covered produce consumed domestically is grown in foreign countries. The provisions of the PS PR, if finalized, would apply to both domestic and imported produce. FDA intends to evaluate its obligations with Executive Order (EO) 12114, "Environmental Effects Abroad of Major Federal Actions," related to this action in a document that is separate from this EIS.

[22] The type of data available by U.S. Territory varied based on what was reported. The total number of farms reported here by Territory includes produce and non-produce farms.

Time scope

This section establishes a timeframe within which reasonably foreseeable effects (impacts) from implementation of a final rule may occur. The provisions of the PS PR, if finalized, would occur in accordance with proposed compliance dates, as follows:[23]

- Very small businesses, those with more than $25,000 but no more than $250,000 in annual produce sales, would have four years after the rule's effective date to comply with most provisions;
- Small businesses, those with more than $250,000 but no more than $500,000 in produce sales, would have three years after the rule's effective date to comply with most provisions;
- All other farms would have two years after the effective date to comply with most provisions; and,
- The compliance dates for water quality standards and related testing and recordkeeping provisions would be an additional two years beyond the compliance dates listed above for very small, small, and all other farms.

Additional corresponding pressures on agricultural producers

The U.S. Census of Agriculture reports that 914.5 million acres of land in the U.S., including Puerto Rico, were farmed in 2012. The amount of land farmed has declined in every agricultural census since 1982, when 986.8 million acres of land were farmed. Since 1982, farmland acreage has declined 7.3 percent overall. Analysis of trends between 1997 and 2002 and between 2002 and 2007 shows a decrease in the amount of land farmed of 1.7 percent within each five-year period. Analysis of the trend between 2007 and 2012 shows a decelerating rate (compared to the rates from 1997 to 2007) of decrease in the amount of land farmed of 0.8 percent (USDA NASS, 1982 to 2012 surveys). Additionally, trend analysis as demonstrated in Chapter 3.7 shows that the average age of principal operators (farmers) is increasing, and fewer people are entering the profession, which presents an overall ongoing decline in farming. It is unclear what the current land that was previously used for farming is currently being used for: for example, whether the land is currently in reserve (left to go fallow, or unused to avoid surplus production), whether the land has been transferred to residential development, whether the land is being managed in some other way, or a combination of these or other factors.

Climate change is anticipated to have a continued impact on farming and food security. The recent report released by the Intergovernmental Panel on Climate Change (IPCC) demonstrates that some regions within our geographical scope may continue to experience drought conditions, precipitation variability and temperature extremes, particularly in semi-arid regions (West) of North America (IPPC, 2014). Even despite climate change, the trends associated with drought conditions, particularly in Western states, has resulted in conditions that include but are not limited to a rise in water prices, shifts in commodities that make more money (e.g., almonds), adapting or switching irrigation systems and sources in response to low-rainfall conditions, decline in agricultural-related employment, and preserving water resources (water banking) to improve water

[23] Information on compliance dates is found on FDA's Web site: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm

conservation. A recent study by University of California, Davis shows that as many as 17,100 jobs have been lost in California, state-wide, related to drought conditions (Howitt et al., 2014). The University also reports that California farms (not just farms growing produce that would be covered by the rule) have abandoned or let go fallow up to 500,000 acres of agricultural land this year; simultaneously, more growers are switching to drip irrigation systems as a means to reduce water use.

Pests and disease continue to burden farms, crop yields, and the ability of the grower to efficiently and sustainably farm the land. For example, the recent “orange greening” scourge in Florida has affected nearly every orange grove in the State, which directly impacts crop yields and subsequently, prices of commodities (USDA ARS, 2014).

Growers of produce adapt to changing conditions in the market and the environment. The changing agricultural landscape has contributed to an overall decline in domestic agricultural production, as well as a decline in principal operators. Irrespective of any final rule, current trends in the decline of domestic agricultural production are anticipated to continue, although would be expected to level out at some point in time. Several programs exist today to help farmers incorporate food safety into their growing practices, and adapt to economic conditions, drought and other climate effects, pests and disease, and other pressures. This includes a network of partnerships between farmers and Government and industry; some of these examples include the following:

- FDA for a hundred years has had the responsibility to prevent foods from being contaminated and to set standards for labeling foods to help people know what they are buying and to choose healthy diets. In 1998, FDA issued its “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” (hereinafter referred to as the “1998 Guide” or “FDA’s 1998 Guide”) (FDA, 1998).[24] In 2002, the New Jersey Department of Agriculture petitioned USDA AMS to implement an audit-based program to verify conformance with the 1998 Guide. This led to the creation of USDA AMS’s GAP and Good Handling Practices (GHP) audit verification program, known collectively as the GAP&GHP program (USDA AMS, 2006). Subsequently, as a result of the prevalence of foodborne illnesses linked to sprouts, FDA published *Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds* (1999). FDA has further published commodity-specific food safety guidelines for the melon supply chain, leafy greens, and fresh tomatoes (discussed in Chapter 2). Additional discussion on FDA guidance to industry is provided in Chapter 2.1.
- USDA has long been a partner with farmers to provide leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on sound public policy, the best available science, and efficient management (USDA, 2014). USDA continues to help farmers overcome challenges such as drought and climate change, food safety (though GAP&GHP Program Audits), grants and loans, and education, to name a few. Through AMS, USDA helps farmers by creating marketing opportunities to ensure the availability of food and agricultural products for consumers in domestic and export

[24] Since the document was issued as guidance and not as a regulation, it does not have the force and effect of law and therefore does not contain enforceable requirements (FDA, 1998).

markets. Through NRCS, USDA provides farmers with financial and technical assistance to voluntarily put conservation on the ground (an example is the NRCS Conservation Practices Program that is discussed in Chapter 8).

- Forty-five States require that certain farmers develop and adhere to Nutrient Management Plans (NMPs) as discussed in Chapter 3.4 that help to manage nutrient runoff to water resources.
- Universities, such as land grant universities, that receive special designation and Federal support to conduct research on current challenges and help Government and the agricultural community find innovative solutions to overcome those challenges.
- State and industry marketing agreements have formed, in part, to collaboratively sell products while verifying compliance (among its membership) with food safety measures.

FDA acknowledges that there may be direct, indirect, and cumulative effects on the human environment, of varying significance, if a final rule is enacted. Moreover, these consequences may affect growers of produce that would be covered by the rule in various ways: some adverse, some beneficial. These effects are addressed in Chapter 4 and take into account the baseline agricultural conditions and background environmental conditions farmers face presently and how these effects are mitigated to the extent practicable through agency and industry partnerships. Also addressed is added flexibility within the agricultural water provision (subpart E) that FDA proposed in the supplemental proposed rule.

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2.0 Description of the Proposed Action and Alternatives

2.1 Proposed Action and Alternatives

In the PS PR, FDA proposed several science-based minimum standards for the safe production and harvesting of produce. This chapter discusses in detail potentially significant provisions (the determination of which was based on public and agency comments prior to- and during the EIS scoping period, see Chapter 1.2) and, therefore, included within the scope of the EIS. This chapter also discusses those provisions which FDA determined would not result in significant environmental impact and, therefore, eliminated from further review. For those potentially significant provisions, FDA identifies the preferred alternative and discusses other alternatives to the preferred alternative, including a no action alternative. FDA also addresses those alternatives that were considered but eliminated from detailed environmental analysis. Finally, FDA, in coordination with USDA, identified the reasonably foreseeable actions, or management decisions, that businesses potentially affected by any final rule might take in order to come into compliance with, or to potentially avoid being subject to, the alternatives under consideration for inclusion in the final rule. Management decisions were considered reasonably foreseeable if they were in compliance with existing laws and regulations, if they would allow for compliance with the alternatives being considered, if the technology is currently available, or is in development and has been considered for the stated purpose. Management decisions that would only be suitable options for some covered produce were included, even if not a viable option for all covered produce. As part of the comment period on the 2013 proposed rule, FDA received comments from industry detailing the steps that would be needed to be in compliance with the rule. Management decisions that were implied in these comments were considered. It is expected that farms would use one or a combination of these measures depending upon their individual conditions.

For each potentially significant provision discussed below, some information on baseline agricultural practices is provided in order to add context for existing industry practices, agency guidance, or regulatory conditions that growers of covered farms may already rely on to incorporate some level of food safety into their business. In some cases industry guidance may be more stringent than what FDA is proposing in the PS PR. Therefore, for farms that presently comply with such programs and practices, some of the potential impacts that are anticipated if a rule is finalized may be mitigated based on existing programs and practices.

Examples of Federal, State and industry guidance

As discussed in Chapter 1.9, USDA’s GAP&GHP audit program offers voluntary independent audits of produce that are focused on best agricultural practices to verify that fruits and vegetables are produced, packed, handled, and stored in the safest manner possible to minimize risks of microbial contamination. The audits confirm adherence to FDA’s recommendations made in its 1998 *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, as well as other industry-recognized food safety practices (USDA AMS, 2013b).

It is important to note that while the GAP&GHP audit program remains popular, some farms use private audit companies. Audits conducted by USDA AMS and private third-party auditors both check to see if the farm is following FDA's 1998 Guide and documenting its activities; however, third-party auditors tended to have varying criteria for their audits (GAPcertification.com, 2014).

The USDA AMS, along with other third-party auditors, are in the process of switching over to the "Produce GAPs Harmonized Food Safety Standard," an industry-wide initiative effort that began in June 2009 to standardize the various audits so that farmers receive simply one audit by any credible third party that is acceptable to all buyers, thereby reducing confusion and the need for farmers to undergo multiple audits (United Fresh Produce Association, 2014). In 2011, USDA AMS incorporated the Produce GAPs Harmonized Food Safety Standard into its GAP audit program and is currently USDA AMS's preferred audit (USDA AMS, 2013c).

In June 2009, while the Produce GAPs Harmonized Food Safety Standard initiative was underway, USDA AMS received a petition for rulemaking and request for public hearing to establish a national marketing agreement for leafy green vegetables resulting in the "Proposed National Marketing Agreement Regulating Leafy Green Vegetables," published in the *Federal Register* on April 29, 2011 (76 Fed. Reg. 24292, April 29, 2011).

Prior to this petition for a national marketing agreement, members of the California leafy green vegetable industry had already initiated their own State marketing agreement. A similar program was implemented in Arizona in 2007. Both the California and Arizona marketing agreements were established in response to the September 2006 multi-State *E. coli* outbreak linked to fresh spinach, which resulted in the largest recall to date of fresh leafy green vegetables (see 76 Fed. Reg. 24292). While entering into such State/industry-specific marketing agreements are voluntary, the requirements of these agreements are mandatory for all signatories to such agreement in the respective State (76 Fed. Reg. 24292).

Table 2.1-1 provides examples of such marketing agreements and guidance to industry related to proposed FDA potentially significant provisions. While many of these examples are State/industry-specific marketing agreements, USDA AMS provides oversight services for the commodity-specific audits required under these marketing agreements (USDA AMS, 2013d). Similar to marketing agreements, farmers can also voluntarily become members of State/industry specific GAP programs in which all members agree to comply with their program's documented standards.

In addition to the marketing agreements and programs listed in Table 2.1-1, the table also lists an example of a required (non-voluntary) State-specific food safety program (Florida tomato industry), as well as FDA's draft commodity specific guidance for melons; tomatoes; and leafy greens, all of which have not yet been issued in final form (78 Fed. Reg. 3504 at 3510).

Table 2.1-1. Examples of Federal, State, and industry specific guidance, programs, and marketing agreements related to FDA potentially significant provisions

Marketing agreements and Industry Guidance	Water Standards	Manure Standards	Domesticated and Wild Animal Grazing/Intrusion Standards
California Leafy Greens Marketing Agreement (CA LGMA)[a] And Arizona Leafy Greens Marketing Agreement (AZ LGMA)[b]	Pre-harvest Water (edible portions of crop are contacted by water, e.g. overhead irrigation, pesticide/fungicide applications): analyze for generic *E. coli*; acceptable level is no more than 126 Most Probable Number (MPN)/100 milliliter (ml) (geometric mean (GM) of five samples) AND no more than 235 MPN/100 ml (all single samples) Pre-harvest Water (edible portions of crop are NOT contacted by water, e.g. furrow or drip irrigation, dust abatement water): analyze for generic *E. coli*; acceptable level is no more than 126 MPN/100 ml (GM of five samples) AND no more than 576 MPN/100 ml (all single samples) Postharvest Water (direct product contact, e.g. re-hydration, core in field, etc.): analyze for generic *E. coli*; acceptable level is negative or below detection limit (DL)/100 ml OR >1 ppm free Chlorine (pH 6.5 - 7.5) or > 650 milliVolts Oxidation Reduction Potential (ORP) (pH 6.5 - 7.5) after contact	Raw: do not use in edible crop production; for previously treated fields, a 1-year waiting period shall be observed before planting any variety of leafy green crops Treated (Composted): if microbe levels are below corresponding action level numbers, then an application time interval of at least 45 days before harvest must be observed Treated (Heated): for non-validated process, observe application time interval of at least 45 days before harvest; for validated process, no application time interval is required	Allows growers to assess the animal risk they feel most threatens to contaminate their crops and determine the best ways to mitigate that risk; allows growers to access the risk to subsequent crop production or production acreage that has experienced recent postharvest grazing by domesticated animals and take appropriate corrective action (as outlined in the marketing agreement)
Mushroom Good Agricultural Practices Program (MGAP)[c]	Water used for irrigation should meet EPA microbial standards for drinking water	Receive and store materials in a manner that avoids the potential for cross-contamination between mushrooms and an unpasteurized substrate	Exclusion of pests (including insects, rodents, and birds) in fully-enclosed mushroom growing buildings

Marketing agreements and Industry Guidance	Water Standards	Manure Standards	Domesticated and Wild Animal Grazing/Intrusion Standards
Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, Edition 2.0 (national, voluntary guidelines)[d], and Tomato Food Safety Audit Protocol[e]	Irrigation water must meet the standard for EPA's standard for *E. coli* in recreational waters (foliar application at the time of harvest must meet microbial standards for potable water); water used for washing tomatoes after harvest must meet microbial standards for potable water in 40 CFR Part 141.63	Only properly composted manure is allowed for use in tomato fields and greenhouses	Domestic animals and livestock must be excluded from tomato fields during growing and harvesting seasons; wild animals cannot be excluded but shall be minimized to the degree possible by methods identified by wildlife experts
Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons[f]	Ensure water is of sufficient microbial quality for intended purpose; monitor water disinfectant levels to ensure disinfectant is at sufficient levels to reduce potential risk of contamination	Evaluate soil amendments when melons directly contact soil	Monitor and reduce (to the extent possible) domestic animal, wildlife, and insect activity in melon production areas
Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens[g]	Ensure water is of appropriate microbial quality for intended use; test water source regularly	Recommendation to refrain from use of raw manure with any leafy greens crop; maximize the time interval between soil amendment application and time to harvest	Evaluate the risk to crop production on production acreage that has experienced recent postharvest grazing of domesticated animals; monitor and minimize domestic animal and wildlife activity in fields and production areas
Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes[h]	Utilize appropriate water treatment methods and identify alternative water sources, if necessary, to ensure water quality is sufficient for intended use; establish and follow corrective actions if water testing indicates a potential problem	Recommendation to refrain from use of raw manure on tomato crop; maximize the time interval between soil amendment application and time to harvest	Recommend that domestic animals and livestock be excluded from tomato fields and measures be taken to minimize wildlife presence using methods identified by wildlife experts

[a] Source: CA LGMA, 2013
[b] Source: AZ LGMA, 2013
[c] Source: Penn State University (Penn State) and the American Mushroom Institute (AMI), 2010
[d] Source: Florida Department of Agriculture and Consumer Services (DACS), 2012
[e] Source: North American Tomato Trade Work Group (NATWWG) and United Fresh Produce Association (United Fresh), 2008
[f] Source: FDA, 2009a
[g] Source: FDA, 2009b
[h] Source: FDA, 2009c

While all of the Federal, State, and industry guidance, programs, and commodity-specific marketing agreement examples in the above table are still active, the proposed "National Marketing Agreement Regulating Leafy Green Vegetables" proceedings were terminated in December 5, 2013 due to USDA AMS's decision that FDA's ongoing rulemaking, including the PS PR, may affect fundamental aspects of the proposed National Leafy Green Vegetable Marketing Agreement Program (78 Fed. Reg. 73111, December 5, 2013).

Proposed actions and alternatives

This section specifically addresses the potentially significant provisions for which FDA determined may significantly affect the quality of the human environment. For each provision (subparts E, F, I, and A), FDA provides a brief discussion or definition of the provision; information on baseline agricultural conditions that adds context for the existing industry practices, agency guidance, or regulatory conditions that growers of covered farms may operate within; and FDA identifies the preferred alternative and discusses other alternatives to the preferred alternative, including a no action alternative as well as lists the management decisions that may be applicable to those alternatives.

(Subpart E) Standards directed to agricultural water (proposed §§ 112.41 to 112.50)

Agricultural water for the purposes of this document is defined 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. Agricultural water includes 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).

The definition of agricultural water does not include indirect water application methods used during growing activities (i.e., water that is not intended to, or is not likely to, contact produce that is covered by the rule or food-contact surfaces), such as furrow irrigation of fruit-bearing trees (where the harvested portion does not contact subsurface irrigation water, or the soil).

Baseline agricultural conditions

There are no Federal regulations presently in place to regulate agricultural water quality with respect to minimizing food safety hazards. There are some regional or State water suppliers' (e.g., irrigation districts, acequia associations) or growers' associations' standards for agricultural water (including surface contact irrigation with covered crops, indirect irrigation (drip/furrow), or processing, holding, or cooling waters). Participation in these programs tends to be voluntary, with some exceptions, but such programs provide benefits by increasing growers' selling potential and market exposure, which makes participation attractive for many growers.[25] Appendix B offers discussion on irrigation systems specifically.

[25] An example of a mandatory State program is the Tomato Good Agricultural Practices program (T-GAPs), which is mandatory for tomato growers in Florida and relate to field and greenhouse production. See Table 2.1-1.

In its Draft QAR (2013c), FDA concluded that the following practices or pathways for pathogenic transport, relative to agricultural water, are important causes of contamination of produce:

- Agricultural water can be a source of contamination of produce.
- Public Drinking Water Systems (domestically regulated by EPA) have the lowest relative likelihood of contamination due to existing standards and routine analytical testing.
- Groundwater has the potential to pose a public health risk, despite the regulation of many U.S. public wells.
- There is a significant likelihood that U.S. surface waters will contain human pathogens, and surface waters pose the highest potential for contamination and the greatest variability in quality of the agricultural water sources.
- Susceptibility to runoff significantly increases the variability of surface water quality.
- Water that is applied directly to the harvestable portion of the plant is more likely to contaminate produce than water applied by indirect methods that are not intended to, or not likely to, contact produce.
- Proximity of the harvestable portion of produce to water is a factor in the likelihood of contamination during indirect application.
- Timing of water application in produce production before consumption is an important factor in determining likelihood of contamination.
- Commodity type (growth characteristics, e.g., near to ground) and surface properties (e.g., porosity) affect the probability and degree of contamination.
- Microbial quality of source waters, method of application, and timing of application are key determinants in assessing relative likelihood of contamination attributable to agricultural water use practices.

Proposed action and alternatives related to agricultural water

In the *Federal Register* notice announcing a public meeting on scoping of the EIS (79 Fed. Reg. 13593, March 11, 2014; hereinafter referred to as “the Public Scoping *Federal Register* notice”) and the corresponding public meeting held on April 4, 2014, FDA discussed potential alternatives to provisions proposed in FDA’s 2013 proposed rule. For the purposes of those discussions, FDA listed the following proposed provision and potential alternatives related to the microbial quality standard for agricultural water that is used in a direct application method during growing or produce (other than sprouts):

Provision proposed by FDA per the 2013 proposed rule

Proposed § 112.44(c) (in relevant part), in the 2013 proposed rule, reads as follows:

"When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method you must test the quality of water in accordance with one of the appropriate analytical methods in subpart N. If you find that there is more than 235 colony forming units (CFU) (or MPN, as appropriate) generic *E. coli* per 100 ml for any single sample or a rolling GM (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 ml of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in this paragraph."

Proposed § 112.3(c), to which no modifications have been proposed since the 2013 proposed rule, defines "direct water application method" as 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.

Potential Alternatives (identified in the Public Scoping Federal Register notice)

1. No action;

2. As proposed, i.e., no more than 235 CFU (or MPN, as appropriate) generic *E. coli* per 100 ml for any single sample or a rolling GM (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 ml of water;

3. No detectable generic *E. coli* per 100 ml;

4. A flexible water quality standard that allows for adjustment to a specified microbial quality standard based on mitigation steps that occur after application of agricultural water and prior to consumption. For example, WHO recommends a minimum microbial quality for water of 1,000 CFU generic *E. coli* per 100 ml for water used on root crops that are eaten raw, and 10,000 CFU generic *E. coli* per 100 ml for water used on leaf crops, which is dependent upon a 2-log reduction due to die-off between last irrigation and consumption (includes die-off in the field and during distribution) and a 1-log reduction attributed to washing prior to consumption (WHO and UNEP, 2006)[26]; and

5. For each of the options above, consider the environmental impacts of two different interpretations of the definition of "direct water application method" in § 112.3(c): (1) to include root crops that are drip irrigated and (2) to exclude root crops that are drip irrigated.

[26] The term "log" refers to logarithm, which has many applications in mathematics, but in this definition refers to exponentially reducing the measured amount per 100 milliliters (ml) that a pathogen persists in any particular media (water, soil, surface of produce, etc.).

Supplemental proposed rule

In the supplemental proposed rule, FDA amended proposed § 112.44(c) to update the microbial quality standard for water that is used during growing of produce (other than sprouts) using a direct application method in a way that is consistent with EPA's current recreational water standard (i.e., a GM of samples not to exceed 126 CFU of generic *E. coli* per 100 ml of water and (when applicable) a statistical threshold value of samples not to exceed 410 CFU of generic *E. coli* per 100 ml of water) (79 Fed. Reg. 58434 at 58471). In addition, FDA proposed two new provisions within proposed § 112.44(c) (i.e., § 112.44(c)(1) and (c)(2)) to incorporate additional flexibility and provided means to achieve the amended proposed microbial quality standard (described under Alternative I, Preferred Alternative, below).

Potential alternatives (analyzed in this EIS) [27]

This Draft EIS analyzes the following provision in the supplemental proposed rule (proposed § 112.44(c)) as the preferred alternative in the draft EIS related to the microbial quality standard for agricultural water when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method:

1. As proposed, i.e., a statistical threshold value (STV) not exceeding 410 CFU of generic *E. coli* per 100 ml of water and a GM not exceeding 126 CFU of generic *E. coli* per 100 ml of water, along with options to achieve the standard by applying either a time interval between last irrigation and harvest using a microbial die-off rate of 0.5 log per day and/or a time interval between harvest and end of storage using an appropriate microbial die-off or removal rates, including during activities such as commercial washing.[28]

This Draft EIS analyzes the following three additional alternatives related to the microbial quality standard for agricultural water:

[27] We have included an overarching potential alternative for "No Action" that is presented at the end of this chapter and, therefore, a separate "No Action" alternative to the proposed microbial standard is not necessary. We have also eliminated the "No detectable generic *E. coli* per 100 ml" alternative from the list of potential alternatives considered in this Draft EIS because we do not believe it is a realistic option at this time.

[28] This proposed action reflects previous Alternative 4 identified in the Public Scoping *Federal Register* notice and in documents discussed at the public meeting, i.e., a flexible water quality standard that allows for adjustment to the specified microbial quality standard based on mitigation steps that occur after application of agricultural water and prior to consumption. Therefore, we have eliminated previous Alternative 4 from the current list of potential alternatives analyzed in this Draft EIS.

2. A microbial quality standard of no more than 235 CFU (or MPN, as appropriate) generic *E. coli* per 100 ml for any single sample or a rolling GM (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 ml of water, as originally proposed in the 2013 proposed rule;

3. As proposed (i.e., Alternative I), but with an additional criterion establishing a maximum generic *E. coli* threshold[29]; and

4. For each of the options above, consider the environmental impacts of two different interpretations of the definition of "direct water application method" in § 112.3(c): (1) to include root crops that are drip irrigated; and (2) to exclude root crops that are drip irrigated.

Alternative I. As proposed (preferred alternative, proposed § 112.44(c), as amended)

When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method, the grower must test the quality of water in accordance with one of the appropriate analytical methods in subpart N (§§ 112.151 – 112.152) to develop and verify the water quality profile of the water source as described in § 112.45(b)(1). Using the water quality profile as described in § 112.45(b)(1), if (when applicable) the estimate of the STV of samples exceeds 410 CFU of generic *E. coli* per 100 ml of water, or if the GM of samples exceeds 126 CFU of generic *E. coli* per 100 ml of water, the grower must either:

(1) Apply a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day (or an alternative microbial die-off rate consistent with paragraph (d)(2) of this section) to achieve a (calculated) log reduction of the GM of generic *E. coli* level to 126 CFU or less per 100 ml and (when applicable) of the STV to 410 CFU or less per 100 ml, or an alternative microbial standard consistent with paragraph (d)(1); or

(2) Apply a time interval (in days) between harvest and end of storage 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 to achieve a (calculated) log reduction of the GM of generic *E. coli* level to 126 CFU or less per 100 ml and (when applicable) of the STV to 410 CFU or less per 100 ml (or an alternative microbial standard consistent with paragraph (d)(1) of this section), provided there is adequate supporting scientific data and

[29] In the supplemental proposed rule, FDA acknowledged that, under FDA's proposed approach, there would be no maximum threshold for a baseline of generic *E. coli* above which the agricultural water would be precluded from use in direct application during growing such that a covered farm would not be able to apply an appropriate time interval between last irrigation and harvest or between harvest and end of storage. FDA asked for public comment on whether FDA should establish a maximum level of *E. coli* (GM and/or STV) 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. Given FDA's request for public comment on this issue, it is reasonable to consider FDA's proposed action accompanied by a maximum generic *E. coli* threshold as a potential alternative to the agency's proposed action. Therefore, we are including this new potential Alternative 3.

information. The grower may apply this time interval in addition to the time interval in accordance with paragraph (c)(1) of this section; or

(3) Immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in this paragraph. Before the grower may use the water source and/or distribution system again for the uses described in this paragraph, they must either reinspect the entire agricultural water system under their 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 retest the water to determine if those changes were effective; or treat the water in accordance with the requirements of § 112.43.

As proposed, FDA defines "direct water application method" (§ 112.3(c)) as 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.

In the 2014 supplemental proposed rule, FDA also amended proposed § 112.45, resulting in a tiered approach to testing untreated surface water and untreated groundwater. The proposed approach would 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 ultimately reduce the required frequency of testing. Proposed § 112.45 would also establish specific sampling frequencies for untreated surface water and untreated groundwater sources.

Alternative II. Originally proposed. 235 CFU per 100 ml (more restrictive)

When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method the grower must test the quality of water in accordance with one of the appropriate analytical methods in subpart N (§§ 112.151 – 112.152). If there is more than 235 CFU (or MPN, as appropriate) generic *E. coli* per 100 ml for any single sample or a GM (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 ml of water, the grower must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described [in § 112.44(c)].

As proposed, FDA defines "direct water application method" (§ 112.3(c)) as 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.

The conditions set forth under Alternative I, including conditions for log die-off of pathogens and for the tiered approach to water testing requirements would not apply to this alternative.

Alternative III. As proposed, but establishing a maximum generic E. coli threshold (more restrictive)

As proposed (i.e., Alternative I), but with an additional criterion establishing a maximum generic *E. coli* threshold. In the supplemental proposed rule, FDA requested public comment on any potential maximum threshold.

Alternative IV. Direct water application method

For each of the alternatives above, FDA is considering the environmental impacts of two different interpretations of the definition of "direct water application method" as defined in proposed § 112.3(c): (1) to include root crops that are drip irrigated; and (2) to exclude root crops that are drip irrigated.

In the 2013 proposed rule, FDA proposed to define "direct water application method" as 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 (proposed § 112.3). FDA received public comments on this proposed definition requesting clarification on whether drip irrigation on root crops, such as onions and carrots, would be considered a direct water application method, as proposed. FDA is currently considering comments received on this issue. Because it is reasonably foreseeable that the final definition of "direct water application method" may explicitly include or exclude root crops, we are considering the environmental impacts of an alternative to include, and an alternative to exclude, root crops that are drip irrigated in the context of any final definition of "direct water application method."

As discussed at the beginning of this section, FDA proposed to define agricultural water (see above) as water that 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 (e.g., overhead), water used for preparing crop sprays and water used for growing sprouts) and in harvesting, packing and holding activities. For example, generally, water used for drip or furrow irrigation in apple orchards would not be considered agricultural water because the water is unlikely to contact the harvestable portion of the crop.

Basically, if water used on the farm is going to (or is reasonably likely to) contact a produce that is covered by the PS PR, that water is subject to provisions of the water standard. Water that does not have the potential to come in contact with produce covered by this rule is considered indirect water and is not subject to this rule.

Appendix B discusses in more detail various types of irrigation methods, including direct irrigation methods commonly used throughout the United States.

Management decisions

Table 2.1-2 lists a set of management decisions that a grower could reasonably be expected to make if the PS PR were finalized using one of the four alternatives presented. For each alternative

FDA and USDA determined that are some basic, common, management decisions that a grower may consider in order to meet the requirements of subpart E: Use chemical treatment, change irrigation mechanism, change water source, or stop growing covered produce. Such decisions would be based upon a variety of factors (e.g., crop type, soil conditions, environmental conditions, costs, to name a few). Given the added flexibility FDA proposed in the 2014 supplemental proposed rule (Alternative I), it is reasonably foreseeable that a grower may decide that none of the aforementioned management decisions are applicable to their decision making process, and therefore, may instead determine that a mechanism to account for pathogenic die-off is a more reasonable option.

Table 2.1-2. Management decisions, by alternative proposed under subpart E

Alternative I. As Proposed. GM ≤ 126 CFU generic *E. coli*/100 ml and STV ≤ 410 CFU/100 ml	**Alternative II.** 235 CFU (or MPN) generic *E. coli* /100 ml single sample or a GM of no more than 126 CFU (or MPN)/100 ml	**Alternative III.** As proposed (i.e., Alternative 1), with an additional criterion establishing a maximum generic *E. coli* threshold	**Alternative IV.** Alternatives for direct water application method
Use chemical treatment	Use chemical treatment	Use chemical treatment	Use chemical treatment
Change irrigation mechanism	Change irrigation mechanism	Change irrigation mechanism	Change irrigation mechanism
Change water source	Change water source	Change water source	Change water source
Stop growing covered produce	Stop growing covered produce	Stop growing covered produce	Stop growing covered produce
Add mechanism to account for die-off			

(Subpart F) Standards directed to biological soil amendments of animal origin and human waste (proposed §§ 112.51 to 112.60)

FDA defines biological soil amendments (BSAs) as 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. BSAs of animal origin consist, 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. The term ‘‘biological soil amendment of animal origin’’ does not include any form of human waste (§ 112.3).

Chapter 3.5 Waste Generation, Disposal, and Resource Use, discusses raw (untreated) and treated manure (compost); where these BSAs are produced in relation to covered produce operations; the prevalence of use of BSAs in agriculture; and the benefits and problems of applying these BSAs. Additional information on BSAs is provided in Appendix C.

FDA considered comments that it received on the PS PR and during the EIS scoping period with respect to the 9-month minimum application interval for use of raw manure in proposed

§ 112.56(a)(1)(i). As a result, FDA is proposing to remove the minimum application interval in proposed § 112.56(a)(1)(i) and defer its decision on an appropriate minimum application interval until it pursues certain actions, including a robust research agenda, risk assessment, and efforts to support compost infrastructure development, in concert with USDA and other stakeholders. With respect to this EIS, FDA determined it is still appropriate to evaluate the potential environmental impacts from implementing proposed § 112.56(a)(1)(i) (as well as alternatives identified in this Chapter) as it does still intend to finalize a provision at a future point in time. Such analysis has value in order to establish or improve upon the methodology for identifying environmental consequences, costs, and risks associated with implementing the proposed action or one of its alternatives in the future, at a time when FDA has completed its research, risk assessment, and public outreach. Including the analysis further allows FDA to evaluate the cumulative potential impacts of the final action. At that time, it may be necessary to either update the Record of Decision (ROD), or prepare a NEPA re-evaluation or supplemental statement in accordance with 40 CFR § 1502.9(c), based on FDA's findings.

In addition, the agency proposed amendments to § 112.56(a)(4)(i) to establish that if the BSA of animal origin is treated by a composting process and is applied in a manner that minimizes the potential for contact with covered produce during and after application, then the minimum application interval (i.e., time between application and harvest) is 0 days.

Baseline agricultural conditions

In its Draft QAR (2013c), FDA concluded that the following agricultural practices or pathways for pathogenic transport, relative to soil amendment use, are important causes of contamination of produce:

- Soil amendments can be a source of contamination of produce.
- BSAs of animal origin have a greater likelihood of containing human pathogens than do chemical or physical soil amendments or those BSAs that do not contain animal waste (e.g., plant-based soil amendments).
- Animal waste subject to treatment, such as chemical and physical treatments and composting, has relatively lower levels of human pathogens than untreated animal waste.
- Composting is less likely than controlled chemical or physical treatments to fully eliminate human pathogens from animal waste.
- Incompletely treated, or re-contaminated, BSAs of animal origin may also contain human pathogens.
- Human pathogens in untreated or composted BSAs of animal origin, once introduced to the growing environment, will eventually die off, but the rate of die-off is dependent upon a number of environmental, regional, and other agro-ecological factors.
- Treatments, such as chemical and physical treatments and composting, can effectively reduce the levels of human pathogens in animal waste.
- Among application methods, application of soil amendments in a manner in which they contact the harvestable portion of the crop presents the greatest likelihood of contamination, especially when applied close to harvest.

Based on FDA 2014 estimates in the supplemental Analysis of Economic Impacts (also known as the Supplemental Preliminary Regulatory Impact Analysis (PRIA)), 35,503 farms, or 1.70 percent of 2,109,303 total U.S. farms, would be covered by the PS PR, which represents an estimated 18.7 percent of all produce-growing farms (FDA, 2014b). According to 2013 estimates.[30] 4,438 covered farms used BSAs (Table 2.1-3). Not all BSAs are of animal origin; some organic farms use green manure.[31] Of the 4,438 covered farms using BSAs, approximately 821 farms used untreated BSAs (raw manure). The remainder of covered farms may use chemical fertilizers already on the market to augment soil quality with nutrients such as nitrogen (N), phosphorus (P), and potassium (K), which promote plant growth.

Table 2.1-3. Covered domestic farms using treated and untreated BSAs

	Very small	Small	Large	Total
Covered farms that use manure	2,748	562	1,128	**4,438**
[a] Livestock and produce farms	1,819	354	656	**2,829**
Estimated number of farms using untreated (raw) manure	337	66	121	524
Estimated number of farms using treated manure	1,483	289	534	2,306
[b] Organic produce farms using green manure or BSAs of animal origin	402	55	131	**588**
Estimated organic farms using untreated manure	74	10	24	109
Estimated other farms using BSAs of animal origin	527	153	342	**1,021**
Estimated farms using untreated manure	97	28	63	188

[a] Source: USDA NASS 2007 Survey (2012 survey data not available at the time of estimates) (USDA NASS, 2009a)

[b] Source: USDA NASS 2007 National Organic Survey (2012 survey data not available at the time of estimates) (USDA NASS, 2010)

Note: the bolded numbers in the "Total" column represents the reported total numbers for those categories (covered farms, livestock and produce farms, organic produce farms, and other farms).

According to 2013 estimates, there were 4,473,575 total produce acres (FDA, 2013b); of these, 81 percent are managed by large farms, 9 percent were small farms, and approximately 10 percent were very small farms. The 4,438 covered farms have an associated 549,437 produce acres and 573,016 manure acres.[32] Of produce acres, approximately 70,134, or 12.8 percent, used untreated

[30] Because the 2013 estimates used a definition of $25,000 average annual monetary value of total "food" and the present estimates use average annual monetary value of "produce," there are now fewer covered farms. Overall 2013 and 2014 estimates are mostly comparable, but also that fewer covered farms use BSAs.

[31] Green manure is a crop that is grown then plowed into the soil or otherwise left to decompose for the purpose of soil improvement (e.g., clover, rye or soybeans). Green manure would not be regulated by the final rule.

[32] In order to determine a conservative estimate for the amount of produce acres to which untreated manure is applied, FDA reviewed responses from farmers to USDA NASS Surveys. Where farms reported that they grew produce commodities, FDA calculated the amount of produce acres where the farms responded raw manure was applied. In instances where farms reported more manured acres then all produce acres, FDA determined that those farms also

BSAs of animal origin.[33] Table 2.1-4 shows the total produce acres, total produce and manured acres of covered farms that use BSAs, and breaks down these farms into three categories: livestock and produce farms, organic produce farms using green manure or BSAs of animal origin, and other farms using BSAs.

Table 2.1-4. Covered farms and associated produce acres (including manured acres)

	Very small	Small	Large	Total
Total produce acres	447,342	389,610	3,636,623	**4,473,575**
Percentage produce acres by size	10%	9%	81%	**100%**
Covered farms that use manure	2,748	562	1,128	**4,438**
Total number of produce acres	56,441	52,114	440,882	**549,437**
Total number of manure acres	112,987	67,622	392,407	**573,016**
[a] Livestock and produce farms	1,819	354	656	**2,829**
Estimated manured produce acres (treated and untreated totals)	29,036	23,882	118,556	171,474
Estimated number of untreated (raw) manure acres	4,065	3,344	16,598	24,006
Estimated number of treated (composted) manure acres	24,971	20,539	101,958	147,468
[b] Organic produce farms using green manure or BSAs of animal origin	402	55	131	**588**
Estimated number of manured produce acres	5,385	4,489	56,542	66,416
Estimated organic produce acres using untreated manure	754	629	7,916	9,298
Estimated other farms using BSAs of animal origin	527	153	342	**1,021**
Estimated number of remaining manured acres	22,020	23,742	217,310	263,072
Estimated number of remaining untreated manured acres	3,083	3,324	30,423	36,830

[a] Source: USDA NASS 2007 Survey (2012 survey data not available at the time of analysis) (USDA NASS, 2009a)
[b] Source: USDA NASS 2007 National Organic Survey (2012 survey data not available at the time of analysis) (USDA NASS, 2010)

Chapter 3.4.2 provides an overview of existing regulations that govern the use or application of BSAs of animal origin. Similar to agricultural water, there are some growers' associations' standards that are currently in place. Many of these programs are voluntary. Table 2.1-1 provides some examples of such agreements and their associated guidelines for applying BSAs.

grew non-covered commodities and that the farm also applied manure to those crops. If the amount of manured acres totaled more than the amount of produce acres, FDA estimated that manure was applied to all produce acres. There are no data to verify this estimate.

[33] 70,134 was calculated by totaling the amount of estimated manured produce acres as shown in Table 2.1-4 whereas livestock and produce farms applied untreated manure to 24,006 produce acres, organic produce farms applied untreated manure to 9,298 produce acres, and other farms applied untreated manure to 36,830 produce acres.

Untreated: Alternative I. Nine months (Originally proposed as § 112.56(a)(1)(i)- Decision Deferred)

As proposed in the 2013 proposed rule: If the BSA of animal origin is untreated and is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, then the minimum application interval (i.e., time between application and harvest) must be nine months (proposed § 112.56(a)(1)(i)).

As described in the 2013 proposed rule and in the conclusions of the Draft QAR, soil amendments can be a source of contamination to produce and BSAs of animal origin have a greater likelihood of containing human pathogens than do chemical or physical soil amendments or those that do not contain animal waste. FDA also noted that human pathogens in untreated or composted BSAs, once introduced to the growing environment, will eventually die-off, but the rate of die-off is dependent upon a number of environmental, regional, and other agro-ecological factors (see 78 Fed. Reg. 3504 at 3523), which is subject to continued study.

As noted above, in the supplemental proposed rule, FDA proposed to remove the originally proposed 9-month minimum application interval and deferred its decision on an appropriate time interval until FDA pursues certain actions. In the absence of a current FDA-proposed minimum application interval, there is no "preferred alternative" for untreated BSA of animal origin in this EIS. However, for purposes of evaluating impacts, we use the 9-month minimum application interval as a potential alternative against which other potential alternatives are compared. See also Chapter 2.4 for additional discussion of this issue.

Untreated: Alternative II. Zero days (less restrictive)

If the BSA of animal origin is untreated and is applied in a manner that does not contact covered produce during and after application, then the minimum application interval (i.e., time between application and harvest) must be zero days.

This alternative is considered to be closer to baseline conditions for growers that do not presently participate in USDA's organic program or that do not voluntarily participate in marketing agreements (examples listed in Table 2.1-1), and therefore may apply untreated BSAs of animal origin without restriction.

Untreated: Alternative III. Application interval consistent with Organic Regulations (less restrictive)

The USDA organic regulations specify application intervals for the use of raw manure as a soil amendment (i.e., 90 days and 120 days before harvest) depending on whether the edible portion of the crop contacts the soil (as specified in 7 CFR 205.203(c)(1)).

Untreated: Alternative IV. Application interval of 6 months (less restrictive)

If the BSA of animal origin is untreated and is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, then the minimum application interval (i.e., time between application and harvest) must be six months.

Untreated: Alternative V. Application interval of 12 months (more restrictive)

If the BSA of animal origin is untreated and is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, then the minimum application interval (i.e., time between application and harvest) must be 12 months.

Treated: Alternative I. Application interval of zero days (Preferred alternative, as proposed (proposed § 112.56(a)(4)(i))

As amended, proposed § 112.56(a)(4)(i)) would establish that if the BSA of animal origin is treated by a composting process in accordance with the requirements FDA proposed in § 112.54(c) to meet the microbial standard proposed in § 112.55(b), and is applied in a manner that minimizes the potential for contact with covered produce during and after application, then the minimum application interval (i.e., time between application and harvest) is zero days.

Treated: Alternative II. Application interval of 45 days

If the BSA of animal origin is treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b), then the BSA of animal origin must be applied in a manner that minimizes the potential for contact with covered produce during and after application, and then the minimum application interval is 45 days.

Treated: Alternative III. Application interval of 90 days

If the BSA of animal origin is treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b), then the BSA of animal origin must be applied in a manner that minimizes the potential for contact with covered produce during and after application, and then the minimum application interval is 90 days.

Management decisions

Table 2.1-5 lists a set of management decisions that a grower may make if the PS PR were finalized. The potential environmental impacts of these decisions are addressed in Chapter 4. There are two distinct sets of management decisions that FDA and USDA identified for these alternatives. This is because the potential pathogen load is different in untreated BSAs of animal origin as compared to treated BSAs of animal origin (explained further in Chapter 3.4). Also, *how* and *when* a grower applies untreated versus treated BSAs of animal origin may be different for a variety of factors (including, but not limited to availability, compliance with marketing agreements, industry best practices). Therefore, it is reasonable for a grower to potentially decide to switch to treated BSAs of animal origin if they are presently using untreated material, which is why that management decision is represented only under alternatives considered for untreated BSAs of animal origin.

For all alternatives under treated and untreated BSAs of animal origin, FDA and USDA determined that the most reasonably foreseeable, common management decisions include switching to BSAs of non-animal origin (see Chapter 3.4) or chemical fertilizers, applying the requisite waiting period, or changing the application of BSAs of animal origin to a mode that the material will not contact covered produce during and after application.

Table 2.1-5. Management decisions, by alternative proposed under subpart F

Untreated BSAs					Treated BSAs		
Alternative I. Minimum application interval of 9 months	Alternative II. Minimum application interval of 0 days	Alternative III. Minimum application interval of 90/120 days	Alternative IV. Minimum application interval of 6 months	Alternative IV. Minimum application interval of 12 months	Alternative I. Minimum application interval of 0 days	Alternative II. Minimum application interval of 45 days	Alternative III. Minimum application interval of 90 days
Switch to treated material	Switch to treated material	Switch to treated material	Switch to treated material	Switch to treated material	Use BSAs of non-animal origin or processed	Use BSAs of non-animal origin or processed	Use BSAs of non-animal origin or processed
Use BSAs of non-animal origin	Use BSAs of non-animal origin	Use BSAs of non-animal origin	Use BSAs of non-animal origin	Use BSAs of non-animal origin	Use chemical fertilizers	Use chemical fertilizers	Use chemical fertilizers
Use chemical fertilizers	Use chemical fertilizers	Use chemical fertilizers	Use chemical fertilizers	Use chemical fertilizers	Wait 0 days	Wait 45 days	Wait 90 days
Wait 9 months	Wait 0 days	Wait 90/120 days	Wait 6 months	Wait 12 months	Change application method	Change application method	Change application method
Stop growing covered produce	Stop growing covered produce	Stop growing covered produce	Stop growing covered produce	Stop growing covered produce			
Change application method	Change application method	Change application method	Change application method	Change application method			

(Subpart I) Standards directed to domesticated and wild animals (proposed §§ 112.81 to 112.84)

This subpart draws a distinction between the potential for contamination to occur from domesticated animal excreta (feces) in situations when domesticated animals are permitted to graze or work where covered produce is grown prior to harvest as well as the contamination that may occur from wild animal feces at any time during when covered produce is grown, prior to harvest.

Domesticated animals include livestock, working animals, pets, and domesticated animals from a nearby area (such as livestock from a nearby farm).

Baseline agricultural conditions

In its Draft QAR (2013c), FDA concluded that the following agricultural practices or pathways for pathogenic transport, relative to wild and domesticated animals, important causes of contamination of produce:

- Animals can be a source of contamination to produce.
- Animal excreta pose a high likelihood of contamination of produce.
- Excreta from domesticated animals pose a greater likelihood of contamination of produce than does excreta of wild animals. However, domesticated animals can be expected to be more readily controlled (i.e., kept apart from produce growing, harvesting, and postharvest areas).
- Excreta from wild animals that rarely associate with human activities poses the least likelihood of contamination of produce.
- Human pathogens from animal excreta, once introduced to the growing environment, can be expected to eventually die off; but the rate of die-off is dependent upon a number of environmental, regional, and other agro-ecological factors.

Grazing by domesticated animals may occur under circumstances where working animals are in the fields where covered produce is grown either pre-harvest or during harvest; 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; or, when a covered activity takes place in an outdoor area or a partially enclosed building if, under the circumstances, there is a reasonable probability that animals will contaminate covered produce because it is reasonably likely that such animals will encroach on such areas and deposit excreta on covered produce or food contact surfaces.

The threat from domesticated animal fecal contamination does not occur entirely within the produce field. Contamination may occur from domesticated animal waste that is left uncontrolled and may infiltrate agricultural water systems; therefore, any areas where animal waste or litter is stored must also be kept separate from where covered activities occur. For example, STEC has been shown to be viable in cattle water trough sediments for up to 245 days; in addition, contaminated trough water that has had no known animal contact for six months has been demonstrated to infect cattle (LeJeune et al., 2001). Where such reservoirs of contaminated water may infect animals and may potentially be located in close proximity to covered produce or where covered activities occur, it is evident that pathogen persistence and colonization present risk factors for contamination of covered produce.

In its Draft QAR, FDA found that the number and type of pathogens detected in animal feces varies with the animal species (FDA, 2013c), as addressed below.

The predominant source of STEC from animal feces is cattle, and the predominant source of Salmonella spp. from animal feces is poultry (Cramer, 2006; McSwane and Linton, 1998; WHO and UNEP, 2006). Cattle are also well known carriers of different types of pathogens, including strains of *Salmonella enterica* (non-STEC) pathogenic *E. coli* (Goulet et al., 2012; Todd et al., 2007). Beyond cattle and poultry, other domesticated animals such as sheep, goats, and swine are also common carriers of pathogenic microorganisms (Sadowsky and Whitman, 2011).

Domesticated animals (Franz et al., 2008; Renter and Sargeant, 2002) and pests (e.g., rats) are generally more likely to harbor zoonotic pathogens than are wild animals, due to their closer proximity to and interaction with humans (Nielsen et al., 2004).

Wild animals, including pests, can also act as reservoirs of human pathogens (Fischer et al., 2001; Jay et al., 2007). Pathogenic *E. coli* have been isolated from deer, feral swine, pigeons and seagulls (Fischer et al., 2001; Jay et al., 2007; Nielsen et al., 2004). Dunn et al. reports that the prevalence of STEC infection in white-tailed deer ranges from a level that is undetected to 2.4 percent (2004).

Wild animal intrusion presents hazards from fecal contamination of covered plants directly, or indirectly by contaminating agricultural water or soil. Fecal contamination of plants and watersheds following wild or feral animal intrusion may be considered a risk factor for pre-harvest produce contamination (Jay-Russell, 2013).

As noted in the PS PR, consistent with section 419(a)(1)(A) of the FFDCA (21 U.S.C. § 350h(a)(3)(D)), and in accordance with FSMA, FDA consulted with the USDA NOP and USDA's NRCS, USFWS, and EPA to ensure that environmental and conservation standards and policies established by those agencies were appropriately considered in developing the requirements proposed in subpart I. FDA tentatively concluded that the provisions of proposed subpart I do not conflict with or duplicate the requirements of the NOP.

In addition, in the supplemental proposed rule, FDA proposed to add a new provision § 112.84 to explicitly state that proposed 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 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.

Similar to the standards proposed for agricultural water and BSAs of animal origin, there are some growers' associations' standards that do have guidelines for controlling risk factors related to domesticated and wild animals contaminating crops. Additionally, USDA NRCS Conservation

Practice Standards are often employed by growers to help control pests and to minimize risk of contamination where food is grown and livestock is managed on the same facility.

Grazing: Alternative I. As proposed (preferred alternative, § 112.82)

At a minimum, if animals are allowed to graze or are used as working animals in fields where covered produce is grown, and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, the grower must take the following measures: (a) An adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed to ensure the safety of the harvested crop; and (b) If working animals are used in a growing area where a crop has been planted, measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce.

In addition, proposed § 112.84 would explicitly state that proposed 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 / 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. See the Chapter 4 subsection for *Resource components not included for review in the EIS.*

Grazing: Alternative II. Waiting period of 9 months

As an alternative, FDA is proposing that if animals are allowed to graze or are used as working animals in fields where covered produce is grown and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, the grower must employ minimum waiting period of 9 months between the time grazing or working animals are present in areas where covered produce is grown and the time such produce is harvested from such growing areas, and measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce.

This alternative is consistent with the proposed provisions for the use of raw (untreated) manure as a BSA of animal origin, described in § 112.56(a)(1)(i).

FDA's new provision regarding the protection of habitat and species protected under the ESA would be carried forward to this alternative. However, it would not include the statement that the measure does not require measures to exclude animals from outdoor growing areas.

Grazing: Alternative III. Waiting period of 90 days and 120 days

If animals are allowed to graze or are used as working animals in fields where covered produce is grown and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, the grower must employ minimum waiting period of 90 days and 120 days before harvest, depending upon whether the edible portion of the crop contacts the soil (as specified in 7 CFR 205.203(c)(1)).

This alternative is consistent with USDA's NOP application intervals for the use of raw manure as a soil amendment.

FDA's new provision regarding the protection of habitat and species protected under the ESA would be carried forward to this alternative. However, it would not include the statement that the measure does not require measures to exclude animals from outdoor growing areas.

Animal Intrusion: Alternative I. As proposed (Preferred Alternative, §§ 112.83 and supplemental proposed 112.84)

FDA proposed that if under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, the grower must monitor those areas that are used for a covered activity for evidence of animal intrusion:

(1) As needed during the growing season based on:
(i) The covered produce; and,
(ii) The grower's observations and experience; and,
(2) Immediately prior to harvest.

If animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction via grazing, occurs, the grower must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 (proposed § 112.83(a) and (b)).

Prior to the publication of the 2013 proposed rule, there were a few instances in which a foodborne illness outbreak resulted in growers taking extreme measures to exclude wildlife from their crops (e.g., clear-cutting land adjacent to farm fields), in large part due to food-safety practices imposed by buyers. These measures ultimately resulted in substantial environmental impacts to water quality, riparian (wetland) habitat, and the elimination of wildlife on and near farm land (Lowell et al., 2010). Upon the publication of the 2013 proposed rule, some members of industry expressed concern of a repeat of this or similar action taken on a nationwide scale. Specifically in relation to proposed § 112.83 and in response to concerns raised about potential adverse consequences to habitat as a result of the 2013 proposed rule, FDA, in the supplemental proposed rule added provision § 112.84, which states:

> "Nothing in this regulation authorizes the ''taking''[34] 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

[34]In the Endangered Species Act "take" means "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct" (16 U.S.C. 1532(19)). USFWS has further declared that "harm" includes "significant habitat modification or degradation." (64 Fed. Reg. 60727-31, November 8, 1999) Thus, the habitat as well as the endangered animal is protected from private action.

to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages."

FDA furthered clarified in the preamble to the supplemental proposed rule that growers of produce should also be aware that clearing or manipulation of habitats, including activities affecting water resources, groundwater or natural vegetative cover, can affect species listed as threatened and endangered. The supplemental proposed rule further stated that growers can identify whether any listed species may be present in their area by checking USFWS's Endangered Species Web site and the Information, Planning, and Conservation System Web site; that growers should coordinate with their local USFWS office on any activity that could potentially affect listed species or critical habitat.[35]; and that growers could contact their local USFWS office for any additional information. See Chapter 4 for additional information on this issue.

Animal Intrusion: Alternative II. Animal exclusion

If there is a reasonable probability that animal intrusion will contaminate covered produce, under this alternative FDA would require that the grower monitors these areas as needed during the growing season, based on the covered produce being grown and your observations and experiences (proposed § 112.83(a)(1)(i) and (ii)), and immediately prior to harvest (proposed § 112.83(a)(2)). If animal intrusion is reasonably likely to occur, the grower must take measures to exclude animals from fields where covered produce is grown.

In addition, proposed § 112.84 would explicitly state that proposed 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, although it would not include the statement that the measure does not require measures to exclude animals from outdoor growing areas, or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

Management decisions

Table 2.1-6 lists a set of management decisions that a grower may make if the PS PR were finalized with one of the specified alternatives. The environmental impact of these decisions is addressed in Chapter 4.

The management decisions would be different for grazing operations as compared to the requirements FDA proposes for monitoring and managing animal intrusion. For all alternatives under domesticated animal grazing, FDA and USDA determined that reasonably foreseeable management decisions growers may make include fencing (although it is more likely that fencing may not involve the produce field, rather it involves better managing the fences that may already exist to manage livestock in dual purpose operations); and/or observing an adequate waiting period. Waiting periods include what is believed to be consistent with current practices (immediately prior to or during harvest), waiting nine months (similar to Alternative I under

[35] As defined under the ESA, critical habitat is a specific geographic area(s) that contains features essential for the conservation of a threatened or endangered species and that may require special management and protection (see 16 U.S.C. 1532(5)(A)).

subpart F / Untreated BSAs of animal origin); or waiting 90 or 120 days (consistent with USDA organic regulations for applying raw manure).

For all alternatives under animal intrusion, FDA and USDA determined that reasonably foreseeable management decisions growers may make include that the grower may not harvest the field or part of the field that is contaminated with animal fecal matter; or that the grower may take measures to exclude wildlife. Under normal circumstances this may include hunting or trapping wildlife, but under some unspecified circumstances this may mean to consider fencing the farm field where covered produce is grown.

Table 2.1-6. Management decisions, by alternative proposed under subpart I

Domesticated / Grazing			Animal Intrusion	
Alternative I. Adequate waiting period	**Alternative II. Waiting period of 9 months**	**Alternative III. Waiting period of 90/120 days**	**Alternative I. Not harvest crops that may be contaminated**	**Alternative II. Measures to exclude wildlife**
Fencing	Fencing	Fencing	Do not harvest field or part of field	Do not harvest field or part of field
Adequate waiting period	Adequate waiting period	Adequate waiting period	Measures to exclude wildlife, e.g. fencing, trapping, hunting, poisoning	Measures to exclude wildlife, e.g. fencing, trapping, hunting, poisoning

(Subpart A) General Provisions (proposed § 112.1 – 112.6)

FDA proposes three main size classifications of businesses in relation to the PS PR. The size classifications clarify whether businesses would or would not be subject to the provisions of the PS PR, if finalized. The size classifications of businesses (farms or farm mixed-type facilities) include not covered (excluded), very small businesses, and small businesses (Table 2.1-7). While no specific classification was established, farms that do not fit into these size classifications would be considered “large.”

In the 2013 proposed rule, FDA proposed to apply the Produce Safety regulation only to farms and farm mixed-type facilities with an average annual monetary value of food (as defined under the FFDCA and including seeds and beans used to grow sprouts) sold during the previous 3-year period of more than $25,000 on a rolling basis (proposed § 112.4). FDA also proposed to apply certain monetary value thresholds based on total food sales to define those very small and small businesses that would be eligible for FDA’s proposed extended time periods to comply with the Produce Safety regulation. In proposed § 112.3(b)(1), FDA proposed to define “very small business” to mean a business that would be subject to proposed part 112 and for which, on a rolling basis, the average annual monetary value of food (as defined under the FFDCA and including seeds and beans used to grow sprouts) sold during the previous 3-year period is no more than $250,000. In addition, under proposed § 112.3(b)(2), FDA proposed to define “small business” to mean a business that is subject to proposed part 112 and for which, on a rolling basis, the average annual monetary value of food (as defined under the FFDCA and including seeds and beans used to grow sprouts) sold during the previous 3-year period is no more than $500,000, and which farm is not a "very small business."

In the supplemental proposed rule, FDA proposed amendments to § 112.4 and to the definitions of very small business and small business to apply the monetary value thresholds based on sales of produce (rather than on total food sales). Accordingly, farms or farm mixed-type facilities with an average annual monetary value of produce (as "produce" is defined in § 112.3(c)) sold during the previous 3-year period of $25,000 or less (on a rolling basis) would be excluded from coverage of the Produce Safety regulation. In addition, "very small business" and "small business," which would be subject to the Produce Safety regulation but under extended compliance periods, would be determined based on sales of produce, rather than on total food sales.

Table 2.1-7. Summary of three size-based categories of businesses under the PS PR

Size class of farm/business	Average annual monetary value	Potential Exemptions
Small Business	Above $250,000 and no more than $500,000 in produce sales	Specified extended compliance periods. May qualify for certain exemptions.
Very Small Business	Above $25,000 and no more than $250,000 in produce sales	Specified extended compliance periods. May qualify for certain exemptions.
Not covered	$25,000 or less in produce sales	Excluded from coverage under the PS PR.

In addition, FDA proposed certain criteria for when certain businesses may be eligible for a qualified exemption from provisions of the PS PR and, instead, would be subject to certain specified modified requirements (see proposed §§ 112.5 and 112.6). This distinction is important to some impact-related analyses in Chapter 4. Under the PS PR, in order for farms to be eligible for qualified exemptions, farms would need to meet the following proposed requirements: (i) The farm must have "food" sales averaging less than $500,000 per year during the previous 3-year period preceding the applicable calendar year; and (ii) the farm's sales to qualified end-users must exceed sales to other buyers during that period. A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same State as the farm or not more than 275 miles away.

Farms eligible for a qualified exemption would be largely exempt from the proposed provisions of the PS PR but would be subject to a narrower set of modified requirements. As defined in subpart R, proposed §§ 112.201 to 112.213, FDA would have the authority to withdraw the qualified exemption under certain circumstances and farms would be able to have the exemption re-instated under certain other circumstances.

Alternative I. $25,000 threshold (Preferred Alternative; proposed § 112.4(a))

A farm or farm mixed-type facility[36] with an average annual monetary value of produce (as defined in proposed 21 CFR 112.3(c)) sold during the previous 3-year period of more than $25,000 (on a rolling basis) is a "covered farm" subject to part 112, and a ''covered farm'' subject to this part must comply with all applicable requirements of this part when conducting a covered activity on "covered produce" (proposed 21 CFR 112.4, as amended by the supplemental proposed rule).

Farms with an average annual monetary value of produce sold of $25,000 or less collectively account for 4 percent of covered produce acres,[37] suggesting that they contribute little exposure to the overall produce consumption within the United States (FDA, 2014b). According to 2012 NASS data, there are 2,103,210 total farm operations in the United States, of which approximately nine percent, or 189,637 farms, grow produce (USDA NASS, 2014a). Of the farms that grow produce, nearly 69 percent, or 130,204 farms, have less than $25,000 average annual monetary value of produce sold and would be eligible for a qualified exemption under the PS PR (FDA, 2014b).

Of the 189,637 farms that grow produce, an estimated 18.7 percent, or 35,503 farms, grow covered produce, which represents approximately 1.70 percent of all farms.

FDA further proposed flexibility in complying with any final rule that results from the proposed rule. The proposed effective date for the final rule would be 60 days after the date of publication of the final rule in the *Federal Register*, with staggered compliance dates depending upon the size of the business operations (Table 2.1-8).

Table 2.1-8. Compliance dates for businesses of various sizes if a final rule is implemented

Size class of farm/business	Compliance dates following the Final Rule*	**Total:** includes additional 2 years for compliance with water quality provisions**
Very small businesses	4 years	6 years
Small businesses	3 years	5 years
All other covered businesses	2 years	4 years

* Consistent with section 419(b)(3)(B) of the FFDCA.
** Increased flexibility in accordance with the PS PR

Alternative II. $50,000 threshold

Farms with $50,000 or less of annual value of produce sold would be excluded from coverage of the PS PR. FDA estimated within its 2013 PRIA that approximately 11,958 fewer farms would be covered by the rule if this threshold for annual revenue were selected (FDA, 2013b). These estimates were derived on the basis of the originally proposed § 112.4(a) using the monetary value threshold based on total "food" sales. However, FDA amended this proposed provision in its

[36] A full definition of the term "farm" and "mixed-type facility" is offered in the glossary. See also § 112.3 of the PS PR.
[37] This accounts for roughly 3.1 percent of all produce acres in the U.S.

supplemental proposed rule to apply the monetary threshold based on sales of produce. In the accompanying regulatory impact analysis (FDA, 2014b), FDA determined that regulating on the basis of the average annual monetary value of "produce" sold reduces the burden to small businesses. FDA did not quantify the associated number of covered and excluded farms using the threshold based on produce sales; however, the number of farms eligible for a qualified exemption under a threshold based on total value of produce sold could be no lower than the amount of farms eligible for a qualified exemption based on the total value of food sold.

At the $50,000 threshold, because more farms would potentially be excluded, even fewer foodborne illnesses would be prevented (1.69 million annually based on 2013 estimates) than what would be expected at the $25,000 threshold, and the illness-related expenditures nationwide would increase over what is expected at the $25,000 threshold. The total estimated annual cost for compliance nationwide is estimated at $348 million, which is lower than what is expected when compared to the $25,000 threshold (Alternative I of this provision).

Alternative III. $100,000 threshold

Farms with $100,000 or less of annual value of food sold would be excluded from coverage. FDA originally estimated that at this threshold, 20,071 fewer farms would be covered by the PS PR; potentially even fewer farms would be covered as compared to even Alternative II.

FDA anticipates at this threshold that even fewer illnesses attributable to produce (1.63 million annually) would be prevented as compared to the threshold values of Alternatives I and II. The potential annual illness-related costs would be higher because fewer farms would be covered. However, the total estimated annual compliance costs would be lower ($316 million).

Alternative IV. $25,000 threshold (covered produce only)

Farms with $25,000 or less of annual value of covered produce sold would be excluded from coverage. There are no estimates available to distinguish between farms at this threshold selling total produce as compared to only covered produce. It can be assumed that the number of farms that would be covered would be slightly lower as compared to that of Alternative I; and slightly more farms would be excluded from coverage. Therefore, the amount of potential prevented illnesses and costs to comply with the PS PR would likely be comparable to the slight (unestimated) differences between total produce and covered produce.

Table 2.1-9 provides a summary of estimated costs and benefits for each of the alternatives identified under subpart A.

Table 2.1-9. Summary of alternatives compared under subpart A

	≤ $25,000 total produce (Alternative I)*	≤ $50,000 (Alternative II)**	≤ $100,000 (Alternative III)**	≤ $25,000 covered produce (Alternative IV)
Covered Farms	35,503	28,253	20,140	Slightly fewer than Alternative I
Excluded (non-covered) farms	130,204	161,384	169,497	Slightly greater than Alternative I
Prevented Illnesses (millions)	1.73 **1.57***	1.69	1.63	Slightly fewer than Alternative I
Total domestic benefits (millions)	$930.00	$1,004	$973	Slightly fewer than Alternative I
Total domestic costs (millions)	$386.23	$348	$316	Slightly fewer than Alternative I

*As updated in the Supplemental PRIA, published September 2014. Other estimates are found in the original PRIA, published January 2013.
**These numbers were based on estimates within the 2013 PRIA (FDA, 2013b).

Management decisions

Table 2.1-10 lists a set of management decisions that a grower may make if the PS PR were finalized under each of the alternatives. The environmental impacts of these decisions are addressed in Chapter 4.

For all alternatives, FDA and USDA determined that the most reasonably foreseeable management decision the grower may make would be either to comply with the rule, or to switch to a non-covered crop. FDA acknowledges that complying with the rule would to some extent mean complying with whichever alterative was selected, and further may depend upon the management decision that a grower might make under those alternatives. Because FDA has not yet decided on which alternative to select for those potentially significant provisions identified above, the analysis in Chapter 4 draws a comparison between all alternatives identified for potentially significant provisions and their associated potential management decisions, and summarizes these potential environmental and associated socioeconomic impacts in Chapter 4.7.

Table 2.1-10. Management decisions, by alternative proposed under subpart A

Alternative I. As Proposed. $25,000 or less average annual monetary value of Produce sold are excluded	Alternative II. Farms with $50,000 or less average annual monetary value of Produce sold are excluded	Alternative III. Farms with $100,000 or less average annual monetary value of Produce sold are excluded	Alternative IV. Farms with $25,000 or less average annual monetary value of Covered Produce sold are excluded
Comply with the Rule	Comply with the Rule	Comply with the Rule	Comply with the Rule
Switch to non-covered crops	Switch to non-covered crops	Switch to non-covered crops	Switch to non-covered crops

No Action Alternative

The baseline agricultural conditions as they relate to the potentially significant provisions of the PS PR are discussed in the preceding sections and are summarized within this section. Background environmental conditions by resource component evaluated in this EIS are provided in Chapter 3.

(Subpart A) General Provisions (Scope of the PS PR)

In general, several growers associations exist throughout the country in order to improve market value for their members and to promote sustainable growing conditions and food safety initiatives, which are in their growers' best interest in order to maintain a level of competitiveness with other similar market providers.

Farms of all size classes participate in growers associations and similar market forums. Similarly, farms and businesses of all sizes participate in all types of markets. As previously discussed in Chapter 1.7, local produce markets, while previously dominated by local small farmers, have been trending toward a small amount of large farms owning a greater percentage of the total sales market share. While large farms make up a small percentage of the nation's total farms, large farms operate greater than 81 percent of the total produce growing acreage, and also bear a greater risk of contributing to pathogen transport based upon the higher volume of produce that large farms contribute to the overall market.

(Subpart E) Agricultural Water

Regarding agricultural water, there are no Federal regulations that require a specific microbial standard for maintaining relatively clean water supplies for irrigation purposes, or to ensure that clean water used for other agricultural purposes remains relatively free of harmful pathogens. In 2012, EPA updated its recreational water quality standard to an STV of 410 CFUs per 100 ml water generic *E. coli* and a GM of 126 CFU per 100 ml in any 30-day interval, and there should not be greater than a ten percent excursion frequency of the selected STV magnitude in the same 30-day interval. This standard does not apply to agricultural water quality.

Agricultural water quality standards for produce growers are presently in place across the country. These standards are not uniform in their basic standard values. All States have drinking water quality standards, but few States have standards that specifically address agriculture or that are readily made available on State environmental or State agricultural Web sites.

The USDA GAP&GHP audit program promotes FDA guidance to industry on irrigation water quality, and uses a process to certify and audit farms that are approved under the program to employ water quality standards. The GAP&GHP audit program offers guidance on water quality testing, water use, and surveillance for hazards associated with microbial risk factors; however, specific water quality standards are not established.

Many growers associations provide standards for meeting water quality and work to reduce microbial risk factors. For example, the California Leafy Greens Marketing Initiative established standards for pre-harvest water in requiring California growers to analyze for generic *E. coli*, with acceptable levels not to exceed 126 MPN/100 ml (GM of five samples) AND no more than 235 MPN in 100 ml of water for all single samples. Regarding post-harvest water, the California Leafy Greens Marketing Initiative requires its growers to analyze for generic *E. coli*, with acceptable levels not to exceed 126 MPN in 100 ml (GM of five samples), and no more than 576 MPN in 100 ml of water for all single samples. Table 2-1 provides additional examples of growers' associations' standards.

Water quality conditions nationwide (addressed in Chapter 3.1) are the result of many factors, including geology, hydrogeology, topography, weather and climate; and may be influenced by human activities, animals, and natural processes. Water quality of surface waters generally are thought to be influenced more by contaminant sources than is groundwater, but even groundwater is subject to contamination from surface water bodies and run-off. Groundwater drawn from the same surface geographical location, but from different depths and bedrock layers, will many times vary in the level or concentration of microbes present.

The application of agricultural water for irrigation will vary by such factors as crop being grown, location, climate, and water availability. Therefore, two farms that are adjacent to one another may employ two or more very different modes of irrigation.

(Subpart F) BSAs of animal origin

At present, a very small percentage of farms use untreated BSAs of animal origin on their fields; approximately 12.8 percent of all covered produce growing acres use untreated BSAs of animal origin. Most BSAs of animal origin that are used on covered crops are treated before applying to areas where covered produce is grown, in order to meet market agreements' or growers associations' standards promoting food safety. Although this represents a relatively small percentage of farms, under today's conditions, BSAs of animal origin that are applied raw or applied treated, but that used an inadequate treatment method, still contribute to an estimated 244,917 illnesses annually.

Application intervals

There are varying standards at present guiding the intervals between of application of BSAs of animal origin and harvest of the crop. Some standards are more specific; some are less specific. Many such standards only provide guidance on the time of year of application or the relative quantity of application based on soil and crop nutrient needs (discussed in more detail in Chapter 3.4). Many of these industry or state standards are defined in order to improve crop management and minimize environmental impacts to water quality. Examples of industry or Federal (USDA) application to harvest criteria include national organic regulations, California (and similar) leafy greens marketing agreements, and the tomato food safety audit protocol (see Table 2.1-1).

USDA organic regulations

Roughly three percent of the food sold in the U.S. is USDA Certified Organic. The USDA Economic Research Service (ERS) reports that only one percent of U.S. farms are certified organic (USDA ERS, 2013a). The USDA Certified Organic Program does not require a waiting period for treated BSAs (compost) application before harvest. USDA organic regulations require a waiting period for untreated BSAs of animal origin of 90 days (approximately three months), or 120 days (approximately four months) depending on the height of the edible portion of the crop when growing thereby minimizing contact with the soil surface as a measure of food safety; therefore, the waiting period for untreated BSAs of animal origin is generally three months for trees and bushes and four months for vines, greens, and root crops.

California Leafy Greens Marketing Agreement

When applying raw (untreated) manure to fields where raw manure has been applied previously, a one-year waiting period shall be observed before planting on any variety of leafy green crops. With respect to treated (composted) BSAs, if microbe levels are below corresponding action level numbers, then an application time interval of at least 45 days before harvest must be observed. For BSAs that are heat-treated with a process that requires validation, the grower shall observe an application interval of at least 45 days before harvest; for processes that are previously validated, no application time interval is required.

Tomato food safety audit protocol

Only properly composted (treated) manure is allowed for use in tomato fields and greenhouses, due to the high potential for microbial contamination and transport.

(Subpart I) Domesticated and Wild Animals

State nutrient management guidelines and marketing or growers associations' standards related to fecal contamination from domesticated animal grazing or animal intrusion are not well defined.

Many State NMPs generally offer time-of-year guidelines with respect to grazing and are oriented toward nitrogen contribution to soils (adding nutritive value) and minimizing run-off, rather than incorporating a harvest interval to minimize microbial safety-related hazards. In other words, grazing is managed through many State guidelines as a mode to augment soil conditions. Animal intrusion or pest management is not defined in most State management plans.

USDA organic regulations 7 CFR § 205.239(e) provides that a "producer of an organic livestock operation shall manage livestock manure in a manner that does not contaminate crops, soil, or water by plant nutrients..." Other regulation standards revolve around grazing practices and management. USDA national organic regulations do not address animal intrusion protocols.

2.2 Provisions and alternatives considered but dismissed from detailed analysis

This EIS carries forward for evaluation FDA's proposed action of finalizing provisions of the PS PR, and it takes a hard look at a number of alternatives for potentially significant provisions defined in Chapter 1.2 as those provisions that FDA has determined may significantly affect the quality of the human environment. In determining whether or not an alternative is reasonable, and thus, carried forward for analysis, each identified alternative is evaluated against the stated Purpose and Need (Chapter 1.4). The potentially significant provisions include subpart A, subpart E, subpart F, and subpart I (Chapter 2.1).

FDA also proposes in the PS PR preferred alternatives for proposed standards that include those that do not result in any significant environmental impacts on the human environment. Alternatives that are not significant are identified and eliminated from detailed study (40 CFR 1501.7(a)). The proposed preferred alternatives that are dismissed from detailed analysis include subparts C, D, K, L, M, N, O, P, Q, and R (discussed in greater detail below). For purposes of this Draft EIS, we are considering how these alternatives will contribute to our review of the "Socioeconomics and Environmental Justice" resource component when combined with other alternatives as part of the overall cumulative impact analysis (Chapter 5).

Finally, there are alternatives FDA identified early in the scoping process that did not meet the purpose and need of the proposed action, or that were not feasible for reasons associated with cost. These are potential alternatives that were eliminated from further review (see below).

Proposed Preferred Alternatives (Proposed Standards) dismissed from detailed analysis

FDA has determined that the following alternatives are consistent with the classes of actions found in 21 CFR 25.30(h) and (j), which include Current Good Manufacturing Practice (CGMP) regulations[38]; Hazard Analysis & Critical Control Points (HACCP) regulations[39]; establishment standards[40]; emergency permit control regulations[41]; Good Laboratory Practice (GLP) regulations[42]; and issuance or denial of permits, exemptions, variances, or stays under these regulations, and procedural or administrative regulations. FDA has previously determined that these classes of actions do not have a significant impact on the human environment.

These proposed standards would establish a systematic approach to the identification, assessment of risk, and control of the food safety hazards associated with a particular food production process.

[38] Information on CGMP regulations is found at this FDA Web page: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm090016.htm

[39] Information on HACCP regulations is found at this FDA Web page: http://www.fda.gov/Food/GuidanceRegulation/HACCP/

[40] Information on FDA Establishment Standards is found at this FDA Web page: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=600&showFR=1&subpartNode=21:7.0.1.1.1.2

[41] Information on emergency permit control regulations is found at this FDA Web page: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=108

[42] Information on FDA GLP regulations is found at this Web page: http://www.21cfrpart11.com/files/library/pred_rules/mcdowall_glp_annotate.pdf

Further considerations used when dismissing these proposed standards from further analysis are discussed under the relevant standards.

(Subpart C) Standards directed to personnel qualifications and training for personnel who handle (contact) covered produce or food-contact surfaces (proposed §§ 112.21 to 112.30).

Assuring personnel who operate or work for covered businesses are appropriately trained in safe practices that effectively reduce the risk of contamination of covered produce does not have a significant effect on the human environment. Training is a normal and customary part of employment for all types of professions. It is assumed that new employees would require training, and henceforth may require re-training in order to use new agricultural techniques, equipment, or best practices; therefore, training may occur in order to identify and minimize risks associated with microbial contamination. For many agricultural businesses of all sizes that belong to growers associations or are a part of market agreements that incorporate food safety practices, including growers of sprouts, a certain amount of personnel training may already be required. Generally, the major change as a result of requirements aimed at training and qualification are an increase in recordkeeping and classroom-based training, which would not result in any significant environmental impact. While such training may require travel in some situations such as to attend workshops or bring in consultants with specialized knowledge and training, generally the overwhelming majority of the training will happen on site. The cost of the training, which is part of the overall cost-benefit analysis, is considered in the context of the cumulative impact analysis in Chapter 4.7.

(Subpart D) Standards directed to health and hygiene (proposed §§ 112.31 to 112.33).

Adequate health and hygiene measures are a food safety staple for any business that handles food meant for a human consumer base. While such practices are not uniformly administered or consistently followed in many industries in general, there is a reasonable assumption that measures are needed and can be codified to address good hygienic practices for activities covered under the PS PR. Actions covered under this provision, such as avoiding contact with animals while conducting covered activities, washing hands, using clean, single-service towels to dry hands, and maintaining sanitary conditions are everyday practices that do not result in significant environmental impacts. Many of these practices are also covered in industry guidance or guidelines for producers of covered produce.

(Subpart K) Standards directed to growing, harvesting, packing, and holding activities (proposed §§ 112.111 to 112.116).

Adequate clean and sanitary food contact surfaces on the farm or post-harvest facility are needed to ensure the safe production of produce while achieving microbial hazard reduction. Whether in an agricultural setting, at a market, or in the kitchen of a restaurant, clean, food-contact surfaces and sanitary practices are paramount to minimizing microbial contamination and are necessary to safeguard consumer health. There are ample State health regulations nationwide that require clean, safe, and pest-free environments for where consumer food is handled and prepared.[43] While these State health regulations do not necessarily extend to farms and farm mixed-type facilities, there is ample industry guidance for growers to avoid harvest-related activities for food that may be contaminated with animal feces. Because these actions are associated with common food industry practices that are among the classes of actions which FDA has previously determined do no result in significant environmental impacts, these actions are not expected to result in significant environmental impacts.

(Subpart L) Standards directed to equipment, tools, buildings, and sanitation (proposed §§ 112.121 to 112.140).

Adequate clean and sanitary equipment, tools, containers, buildings and facilities, and vehicles are needed to ensure the safe production of produce meant for consumer consumption, while achieving microbial hazard reduction. Similar food industry practices are required and carried out every day for consumer food establishments such as restaurants and supermarkets, and safe and sanitary conditions for these establishments are regulated primarily by State health regulations. In addition, in the agricultural setting, several voluntary and mandatory marketing agreements (e.g., California Leafy Greens Marketing Agreement, and T-GAPs) require similar standards for their participants. For many produce growers such practices are already normal and customary such that significant changes in industry practices would not be needed and thus, are not expected to result in significant environmental impacts.

(Subpart M) Standards directed to sprouts (§§ 112.141 to 112.150)

FDA estimates that 285 sprout operations may be affected by the rule, nationwide (FDA, 2013b). According to surveys conducted by FDA (2012), approximately 67 percent of sprouting operations use municipal water that is treated for a zero detection limit for enteric viruses in accordance with the Safe Drinking Water Act of 1974 (SDWA, 40 U.S.C. § 300f et seq.), and that further meets the proposed requirement described under § 112.44(a) and §§ 112.45(a)(1) and (2). Water used and discarded by all sprouting facilities is required discharged in accordance with National Pollutant Discharge Elimination System (NPDES) permits. Sprout facilities are believed to currently be largely, if not entirely, located indoors; and FDA's 1999 sprout Guidance to Industry recommends that growing containers be located off of floors and away from walls to reduce the possibility of contamination by rodents, pests, or other animals. Also, sprouting facilities do not operate activities that require a clean air permit in accordance with the Clean Air Act of 1970 (CAA) (42 U.S.C, §7401 et seq.); do not typically use BSAs of animal origin; and generally use only controlled soil types or are hydroponic (soil-free). Furthermore, most sprouting facilities follow FDA's 1999 *Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seed*s, which provides recommendations for reducing the risk of raw sprouts serving as a vehicle for

[43] Where pests are present and where the situation may require pesticides, insecticides, or rodenticides to rid the environment from such pests, EPA registered products are normally available for use. EPA requires an extensive environmental and human health risk review of such products prior to their gaining approval for registration. Such products should be handled in accordance with product labeling requirements to avoid adverse human health or environmental impacts.

foodborne illness. Many of the recommendations in FDA's Guidance for Industry are carried forward in FDA's proposed rule.

Sprouting operations are largely already regulated for water use and disposal or discharge, already rely heavily on existing municipal water sources, and largely follow similar FDA Guidance for Industry recommendations. Thus, the proposed FDA regulations under subpart M are not expected to result in significant environmental impacts on environmental resource components, such as water, soil, or biological and ecological resources.

(Subpart N) Analytical methods (proposed §§ 112.151 to 112.152).

Scientific-based analytical methods to facilitate accurate quality testing for the presence of harmful microbes have been approved or recommended by many agencies (Federal and State) and under specific circumstances and for specific microbes. Certain analytical methods or techniques have proven, over time, to be more accurate than others in identifying if a contamination problem is present. Testing guidelines generally have specific standards and conditions to ensure quality, and to ensure that proper equipment and/or sample disposal techniques are followed. Testing measures are taken every day by Federal, State, and local agencies, industry groups, and private entities for a number of reasons. While there may be an increase in the number of tests performed by covered farms under the requirements that would be established under subpart N, such tests are expected to happen in certified laboratories, which are permitted facilities (must obtain permits for discharges to air, water, and for handling and disposing of hazardous materials in accordance with all applicable Federal, State, and local regulations). Certified laboratories are also audited regularly by EPA-certified State and third party auditors.[44] If the testing method (for *E. coli*) requires the use of hazardous materials, EPA requires the laboratory to comply with the applicable regulations for neutralizing and disposing of the samples and materials used (this is specified in the EPA published document for whichever method the laboratory uses).

Because the testing and disposal process is tightly controlled and regulated, FDA does not reasonably expect activities under subpart N to result in significant environmental impacts. Any potential economic impacts associated with testing requirements are addressed as part of subpart E.

(Subpart O) Requirements applying to records that must be established and kept (proposed §§ 112.161 to 112.167).

Though compliance with the provisions set forth in subpart O of the PS PR could require that farms maintain additional records of their activities, and though there has been some public comment during the EIS scoping process that such recordkeeping may increase the use of paper products

[44] For example, laboratories that analyze drinking water compliance samples for coliform bacteria must be certified by EPA to perform coliform sampling in accordance with 40 CFR § 141.21.

nationwide; FDA does not believe that the use of paper for recordkeeping is needed or would substantially offset the nationwide decline in use of paper products.[45]

Records may also be kept electronically so long as they are retrievable from an onsite location. Furthermore, purchasing and disposing of paper products is not a regulated activity. Paper may be recycled or it may be disposed of in the users' normal trash. Therefore, FDA does not reasonably expect activities under subpart O to result in adverse environmental or social impacts.

(Subpart P) Variances (proposed §§ 112.171 to 112.182).

Variances may be requested by submitting to FDA a citizen petition, using the process described in 21 CFR 10.30, specifically identifying the standard or standards from which the requesting entity is requesting a variance, and identifying the specific growing conditions and science-based procedures or practices that would support a variance. For example, these variances may include variance from the requirements, established in proposed § 112.44(c), when agricultural water is used during growing operations for covered produce (other than sprouts) using a direct water application method; variance from the process conditions, established in § 112.54(c)(1), for static composting; and/or variance from the process conditions, established in § 112.54(c)(2), for turned composting. FDA expects requests for variances to be supported by relevant and scientifically valid information or materials specific to the covered produce or covered activity to support the petitioner's determination that the variance requested is reasonably likely to ensure that the produce is not adulterated and to provide the same level of public health protection as the relevant requirement. This would 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.

Proposed §§ 112.171 to 112.182 set forth the procedures for requesting a variance and FDA's review of such request. Establishing the administrative procedures for variances is the same type of action FDA considered when establishing the categorical exclusion in 21 CFR 25.30(h) concerning the issuance of administrative regulations, including procedures for submission of applications for approval that the agency has determined do not have a significant effect on the human environment. The variance procedures include requirements related to who may request a variance, what must be included in a request, the public availability of the information, who may respond to the request and how, scope of permissible variances, and criteria or procedures for denial, modification, or revocation of a variance. Administrative procedural requirements such as these do not have a significant effect on the human environment. However, an FDA action to grant or deny a particular variance request would be independent from FDA's action to establish the procedural requirement in a final produce safety rule. A decision by FDA to grant or deny a variance request would be a "major Federal action" (as defined in 40 CFR 1508.18). Therefore, FDA would evaluate, independent of any final rule on establishing administrative procedures for variances, its obligations under NEPA for a decision to grant or deny a particular variance request submitted consistent with such required procedures. Therefore, FDA does not need to consider

[45] The U.S. Department of Commerce's Reports on Manufacturers' Shipments, Inventories and Orders (September 2014 and 2013) demonstrate an overall decline in the manufacture and demand for paper products nationwide (paper products are not specified by type).

environmental impacts related to the proposed administrative procedural requirements for variances in the Draft EIS.

(Subpart Q) Compliance and enforcement (proposed §§ 112.191 to 112.193).

Provisions regarding compliance and enforcement are not expected to have a significant impact on the human environment. Considerations relating to the environmental impacts stemming from provisions with which individuals would need to comply under the PS PR, if finalized, are discussed in other sections of this document.

(Subpart R) Withdrawal of qualified exemption (§§ 112.201 to 112.213).

Consistent with section 419(f)(3)(A) of the FFDCA and proposed § 112.201 of the PS PR, FDA may withdraw a qualified exemption applicable to a covered farm under one of two circumstances: (1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the farm that had received a qualified exemption (proposed § 112.201(a)); or (2) if FDA determines that it 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 or held at the farm (proposed § 112.201(b)). However, in these cases, FDA is committed to working with farms directly. Depending on the circumstances, FDA may take a variety of actions, including educating growers and sending warning letters, as well as enforcement actions such as administrative detention, seizure, and injunction, to protect the public health and prevent or mitigate a foodborne illness outbreak. FDA may consider taking such actions prior to or in conjunction with a consideration to withdraw a qualified exemption. To make its intent clear that FDA would consider other actions, as appropriate, before issuing an order to withdraw a qualified exemption, FDA proposed a new provision (proposed § 112.201(b)). In addition, under proposed § 112.213, FDA proposed to provide the process under which FDA would reinstate a qualified exemption that was withdrawn.

Establishing the administrative procedures for the withdrawal or reinstatement of qualified exemptions is the same type of action FDA considered when establishing the categorical exclusion in 21 CFR 25.30(h) concerning the issuance of administrative regulations, including procedures for submission of applications for approval that the agency has determined do not have a significant effect on the human environment.

Potential alternatives that were eliminated from further review

In its Draft QAR, FDA performed an assessment of potential routes of contamination and the likelihood of contamination on farms (FDA, 2013c). FDA evaluated the relative risk for 12 different classes of commodities during growing, harvest, and post-harvest. Contaminated water is a potential route of contamination when directly applied during irrigation, when applied for protection during growing, and when indirectly applied. Soil amendments were another identified route of contamination during the growing process. Workers, animals, and equipment were also identified as potential routes of contamination during growing. FDA identified water, workers, and equipment as potential routes of contamination during harvest; water, workers, equipment, and buildings were identified as potential routes of contamination during postharvest activities. Therefore, all of these routes are being evaluated for standards to reduce the potential for biological contamination and associated risk of foodborne illnesses.

Procedures, processes and practices in each of these on-farm routes of contamination have the potential to introduce biological hazards into or onto any covered produce. Therefore, FDA proposed an integrated approach to prescribe standards for each of these on-farm routes of contamination (see 78 Fed. Reg. 3504 at 3524-3529). These standards are the foundation that FDA uses to establish requirements for the growing, harvesting, packing, and holding of produce for human consumption, in order to 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. This is the purpose of FDA's proposed action (see Chapter 1.2). FDA is mandated by FSMA to perform this action in accordance with FSMA (see Chapter 1.1).

Alternatives or actions that FDA considered that did not meet the purpose of FDA's proposed action, or were unreasonable were eliminated from further review.

FDA considered a number of options and alternatives that were based on industry, agency, and public comment for the proposed rule (see Chapter 1.8), as well as the analysis FDA conducted as part of its Draft QAR (FDA, 2013c) and Regulatory Impact Analysis (FDA, 2013b and 2014b). The options and alternatives FDA considered but eliminated include:

FDA considered but eliminated the following options:

(1) No new regulatory action (FDA, 2013b).

FDA considered under this option, to rely on current guidance such as GAPs guidance and other commodity-specific guidance, voluntary adoption of some or all provisions of the proposed regulation, current or enhanced State and local enforcement activity to bring about a reduction of potential harm from adulterated foods, or the tort system, with litigation or the threat of litigation serving to bring about the goals of the proposed rule.

However, FSMA requires FDA to conduct its rulemaking establishing produce safety standards. Moreover, FDA believes that these methods are unable to fully minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce. The advantage of this option is that there would be no costs to the produce industry, but the disadvantage is that there would also be no benefits (in terms of illnesses prevented).

(2) Exclude commodities not associated with outbreaks, from some or all of the provision of the rule.

As discussed in greater detail in Chapter 1.6, FDA considered and rejected the option to develop 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. Foodborne illness outbreaks have regularly been associated with commodities that have previously not been linked to outbreaks; therefore, this approach carries the risk of failing to prevent future 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 FDA needs to focus to minimize current and future risk of illness. Furthermore, FDA's Draft QAR (2013c) identifies common on-farm routes of contamination, which are not commodity-specific.

(3) Require less-extensive standards (FDA, 2013b).

FDA considered that several of the proposed provisions could be combined to provide a less extensive set of controls than in the rule. Certain prevention measures could be separated and put forth as stand-alone regulations; for example, provisions regarding agricultural water could be issued as a separate proposed rule. The various individual measures would, by themselves, generate lower costs than the integrated program outlined in the proposed rule.

As an alternative, FDA considered that certain provisions could be eliminated altogether, such that eliminating provisions for domesticated and wild animals and BSAs of animal origin would reduce the cost of the proposed rule; however, potential [healthcare related cost] benefits would also be reduced. FDA did not select this alternative because all requirements are important in reducing the level of contamination and human health burden associated with produce. Additionally, the likely reduction in costs from cutting these requirements would probably not outweigh the benefits of preventing foodborne illnesses.

(4) Apply a $10,000 limit to an average annual monetary value of "food" sold during the previous three-year period (FDA, 2013b).

FDA considered under this option to require that farms or farm mixed-type facilities with an average annual monetary value of food sold during the previous three-year period of more than $10,000 would be considered covered farms subject to the proposed rule. Therefore, as described in the Regulatory Impact Analysis (FDA, 2013b) more farms would be required to implement the standards outlined in the proposed rule, many of which were estimated to be very small farms. The result would have been approximately a 16 percent increase in costs to very small farms over the estimates provided in the 2013 proposed rule, but the estimated annual benefits (in terms of healthcare costs avoided) would have been very small compared to the overall cost to farms. FDA has not selected this alternative because the anticipated costs outweigh the potential benefits from eliminating all illnesses associated with these farms.

(5) Apply a $25,000 limit to an average annual monetary value of "food" as the threshold above which farms would be subject to the rule (79 Fed. Reg. 58434 at 58437).

FDA considered that farms with an average annual monetary value of food sold of $25,000 or less collectively account for 1.5 percent of covered produce acres, suggesting that they contribute little exposure to the overall produce consumption. Applying the $25,000 limit to an average annual monetary value of "produce" (rather than food, 2014 supplemental proposed § 112.4(a)) sold would account for an estimated total of 4 percent of covered produce acres and about 3.1 percent of all produce acres in the United States. The amended proposal would remove farms with produce sales of $25,000 or less from coverage, resulting in removal of an additional 2.1 percent of produce acres from coverage.[46] Under this scenario, as with the previous proposed approach, such businesses 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. FDA determined that applying the $25,000 limit to "produce" sales would not adversely affect the level of public health protection that it proposes to accomplish.

(6) With respect to standards directed to agricultural water, no detectible *E. coli* per 100 ml (see Chapter 2.1 subpart E, and 79 Fed. Reg. 13593, March 11, 2014).

FDA considered an alternative to proposed § 112.44(c) (2013 proposed rule, 235 CFUs (or MPN) generic *E. coli* per 100 ml) that would equate to no detectible *E. coli* per 100 ml. Water generally associated with no detectible *E. coli* is municipally treated drinking water. Many farms across the U.S. are not presently connected to such municipal systems due to the rural setting for most agriculture (water treatment plants generally reach to residential and commercial users in suburban and urban settings). In addition, if farms were connected to municipal supplies, it is likely they would not be permitted to draw from those supplies for irrigation due to the very large water demand that irrigation requires (irrigation water demand from surface and groundwater is detailed in Chapter 3.1.3). Furthermore, there presently is no EPA-approved chemical treatment for contaminated water used to control pathogens in water directly applied to produce (EPA, 2014a) (see Chapter 4.2 for a more detailed discussion). Therefore, FDA determined that this alternative is not a reasonable option at this time.

2.3 Incomplete or unavailable information

This section describes the information that was not available for FDA to use to support a more detailed impact analysis. However, in the absence of these data sets described below, the information that is used to assess potential environmental impacts is based upon sound research and publicly available data from State and Federal agencies, and is deemed appropriate to the geographic scope of the EIS.

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[46] After removal of acres as a result of the provisions related to the qualified exemption, produce that is rarely consumed raw, and produce destined for commercial processing that eliminates pathogens of concern.

As discussed in Chapter 1.9 within the geographic scope of the EIS, FDA used USDA NASS survey data to identify the locations of farms that grow covered produce, within the boundaries of the conterminous U.S., Alaska, Hawaii and Puerto Rico.[47] In terms of the geographic scope of the EIS, NASS data only provides information on where produce commodities that are covered under the PS PR are grown. NASS data sets for produce do not specifically relate to the size class of farms that would be covered by the rule, nor does the data relate to farms that are otherwise eligible for qualified exemptions or excluded from coverage altogether. Therefore, FDA could not assess potential environmental impacts based on specific locations of where different sized covered farms operate.

USDA NASS data are available for the locations of livestock and poultry operations in the nation. FDA also relied on a USDA fruit and vegetable survey (USDA NASS, 2001) in order to estimate the prevalence of use of untreated and treated soil amendments and fertilizer with respect to farms that grow produce.[48] However, together, these data sets could not conclusively link the locations of where untreated soil amendments (reported as manure) are generated versus where these products are applied, and in what specific quantity. Such analysis would require extensive market surveys. Therefore, assumptions were made in Chapter 3.4 and in Chapter 4 as to the geographic relationship between soil amendment use and availability of untreated soil amendments. Further, there are no data available that relates geographically where composting of soil amendments occurs with where treated soil amendments are used.

With respect to applying BSAs of animal origin, there are no consistent data available nationwide that specifically identifies the timing for applying untreated or treated soil amendments with respect to the produce commodity's growing and harvest intervals. Factors that influence timing of application include (but are not limited to) the commodity, climate or region, and availability and cost of the soil amendment(s). USDA organic regulations and certain mandatory or voluntary State- or commodity-specific marketing agreements may regulate application to harvest intervals, and to some extent they may regulate how a soil amendment is applied. But the conditions specific to growing seasons, soil amendment availability, and soil amendment application vary too widely by region and commodity to conduct an impact analysis that is commensurate with the scope of this EIS.

No data are available for the locations of dual-purpose operations (farms that grow produce and raise livestock or poultry); therefore, it is presently not possible to inform a detailed analysis for impacts related to domesticated animals and wildlife with respect to covered farms.

EPA water quality data cited in Chapter 3.1 relies extensively on accurate reporting by States and counties. It was evident when reviewing the data sets that many States and counties had not updated or, in some cases even contributed data to EPA's database on a consistent basis. Therefore,

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[47] Note that Puerto Rico, is included within the count for covered farms, and within Chapter 3.7 as socioeconomic information was available for Puerto Rico, but it is not included on EIS maps showing where covered produce is grown.

[48] It should be noted that the USDA fruit and vegetable survey was a one-time survey that provided important statistical information as a foundation for some of FDA's analysis in the Regulatory Impact Analysis (FDA, 2013b); however, because it was a one-time survey, trends in the data cannot be inferred.

the data provided support the evaluation of potential impacts on a regional or national level, but often State or county level information was not consistent enough for further evaluation.

With respect to the air quality impact assessment, data were available by State and county on reportable pollutants (i.e., National Ambient Air Quality Standards (NAAQS)), and FDA used statistics available from EPA on agriculture's contribution to air quality conditions. However, impacts to air quality could only tangentially be assessed based on potential management decisions that a farmer may make in order to comply with the rule. Because specific data are not available on the size classes for farms impacted by the rule, and because there are data limitations beyond the ability to assess national and regional impacts for water quality and BSAs of animal origin; the management decisions that a farmer may make and their potential impacts to air quality are also limited to a national and regional scale.

The Socioeconomic and Environmental Justice evaluation (see background data in Chapter 3.7) relies primarily on U.S. Census block data as well as USDA NASS survey information specific to where covered produce is grown. While NASS data does provide the ethnicity (in most cases) of a farm's principal operator, these data sets do not provide the locations of covered farms by size class related to the principal operator's ethnicity. Therefore, FDA could not distinguish between a principal operator of any particular ethnicity that operates a farm with an average annual revenue of greater than $500,000 compared to a farm with an average annual revenue of less than $25,000 of produce sold. The EIS uses statistical analysis to identify the low-income and minority population percentage within any given State to establish a "meaningfully greater" threshold upon which to base an impact analysis by State and region. This approach is consistent with CEQ guidance, *Environmental Justice Guidance under the National Environmental Policy Act* (CEQ, 1997a). Regarding minority farmworkers, the EIS relies on data from the USDA ERS and the U.S. Department of Labor on farmworker demographics and median income. Very limited data is available for minority farmworkers, as both the USDA ERS and the Department of Labor rely on surveys taken periodically; farmworker employment is often seasonal work and is sometimes filled by non-U.S. Citizens or farmworkers are sometimes brought to the farms by third party contractors; and, in the case of Department of Labor surveys, survey data is only reported for California.

3.0 Affected Environment

This chapter is intended to identify the environmental resource components that may be influenced by the proposed action of implementing the PS PR. Before and as a result of the EIS scoping process, FDA identified seven resource areas for evaluation: 1) water resources 2) biological and ecological resources; 3) soils; 4) waste generation, disposal and resource use; 5) air quality and greenhouse gases (GHGs); 6) cultural resources 7) socioeconomics and environmental justice; and, 8) human health and safety.

This chapter is organized into subchapters that address each of the seven environmental resource components as recognized above. Each resource subchapter provides the following information:

1. Definition of the Resource. Definitions may include the physiological or geographic scope of the resource that is potentially affected, list the relevant existing laws or agencies that have purview over regulating the resource area, and establish the baseline conditions that exist before the PS PR is to be implemented so that the potential impacts may be appropriately measured or estimated in the EIS.

2. Regulatory Oversight. Identifies the existing Federal and State regulations (where applicable) pertaining to each environmental resource component.

3. Current Background Environmental Conditions. Data sources include scientific research; data compiled and presented by FDA or other regulatory agencies (including cooperating agencies); maps or figures developed by such agencies or maps and figures developed by the FDA contractor from data derived from authenticated sources; and tables and graphics that may be used to better describe the resource background conditions.

3.1 Water Resources

3.1.1 Definition of the Resource

Water Resources encompasses the sources of water that are useful to plants, animals, and humans in a particular area. Changes in the environment can affect a hydrologic system's water quality, and the availability of usable water.

Resource use means how the resource is applied to crops in raw form (untreated), processed (chemically or physical filtration) or municipal (treated). The PS PR would regulate agricultural water used on covered commodities on produce farms. It would also regulate water used a) for irrigation during growing, prior to harvest; b) in cooling, packing, holding, and maintaining hydration (crispness/firmness); and, c) in washing produce, as well as water used for cleaning packing and packaging materials and for food contact surfaces. Each of those various uses would incur different water quality standards, measured by indicator bacteria (generic *E. coli* for all agricultural water).

In terms of identifying the background conditions of the resource, this section identifies the following factors:

- regulatory or industry practices that govern the use and protection of the resource;
- the natural environment of the resource;
- physical, chemical and biological anthropogenic stresses placed on the resource; and
- frequency and cause of impairments (current baseline conditions).

3.1.2 Regulatory Oversight

The CWA (33 U.S.C. § 1251 et seq.) is the principle law governing pollution control and water quality. The objective of the CWA is to restore and maintain the chemical, physical and biological integrity of the nation's waters (EPA, 2014b and c). The primary statutes relating to water resources also includes SDWA (42 U.S.C. § 300 et seq.). The SDWA assigns the EPA responsibility and authority to regulate public drinking water supplies by establishing national health-based drinking water standards to protect against both naturally-occurring and man-made contaminants (USDA ERS, 1994).

Section 402 of the CWA requires that municipal, industrial and commercial facilities that discharge into wastewater or stormwater directly from a point source (a pipe, ditch or channel) into a surface water of the U.S. (e.g., a lake, stream, or river) must obtain a permit under the NPDES permit (EPA, 2014d).[1]

Under Section 303(d) of the CWA, States, Territories, and certain tribes are required to develop lists of impaired waters (determined as impaired through testing regiments) (33 U.S.C. 1313(d)). CWA Sections 305(b) and 303(d) deal specifically with water quality assessments and Total Maximum Daily Load (TMDL) development (EPA, 2014e), which is used to develop national water quality criteria as a basis for State water quality standards (Section 305(b) is found at 33 U.S.C. § 1315). Under this regulation, if an operator or facility has a permit to discharge to surface water (e.g., in this case an entity such as a CAFO, sprouting facility, or other permitted agricultural operation that may be discharging to an impaired water body that is on the State's TMDL list) the entity may be held accountable to comply with its permit requirements.

The CWA requires states to designate beneficial uses for all waters and develop water quality standards to protect each use. Beneficial uses include drinking water as well as primary contact recreation, fish consumption and aquatic life support (EPA, 1998a).

Water quality standards are set for maximum acceptable concentrations of pollutants in order to establish acceptable ranges for potential contaminants (USDA ERS, 1994). Water quality standards define (not quantify) conditions and attainable goals for a designated water use. Water quality standards (or criteria) may include; biological (desirable aquatic communities), nutrients (to prevent over-enrichment) and sediment (to avoid adverse effects) (EPA, 2014f).

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[1] Relevant to this EIS, some farm operators, e.g., certain confined animal feeding operations (CAFOs), are also required to obtain and maintain a NPDES permit.

3.1.3 Current Background Conditions

3.1.3.1 Physical Processes and Environmental Setting

Water may be drawn from several different sources, such as groundwater, surface water, rain harvesting, or water storage. Some growers may have reasonable access to quite a few of these resources, while others have trouble obtaining sufficient access to even one source (such as in arid regions). Water availability and access depends upon a number of factors including, but not limited to, geology and hydrogeology, topography, climate and precipitation. It is important for growers to manage their water source effectively to experience a successful crop yield. Surface water and groundwater can both be used for irrigation, and are widely used in some areas to increase yields where natural precipitation is lacking during the growing season.

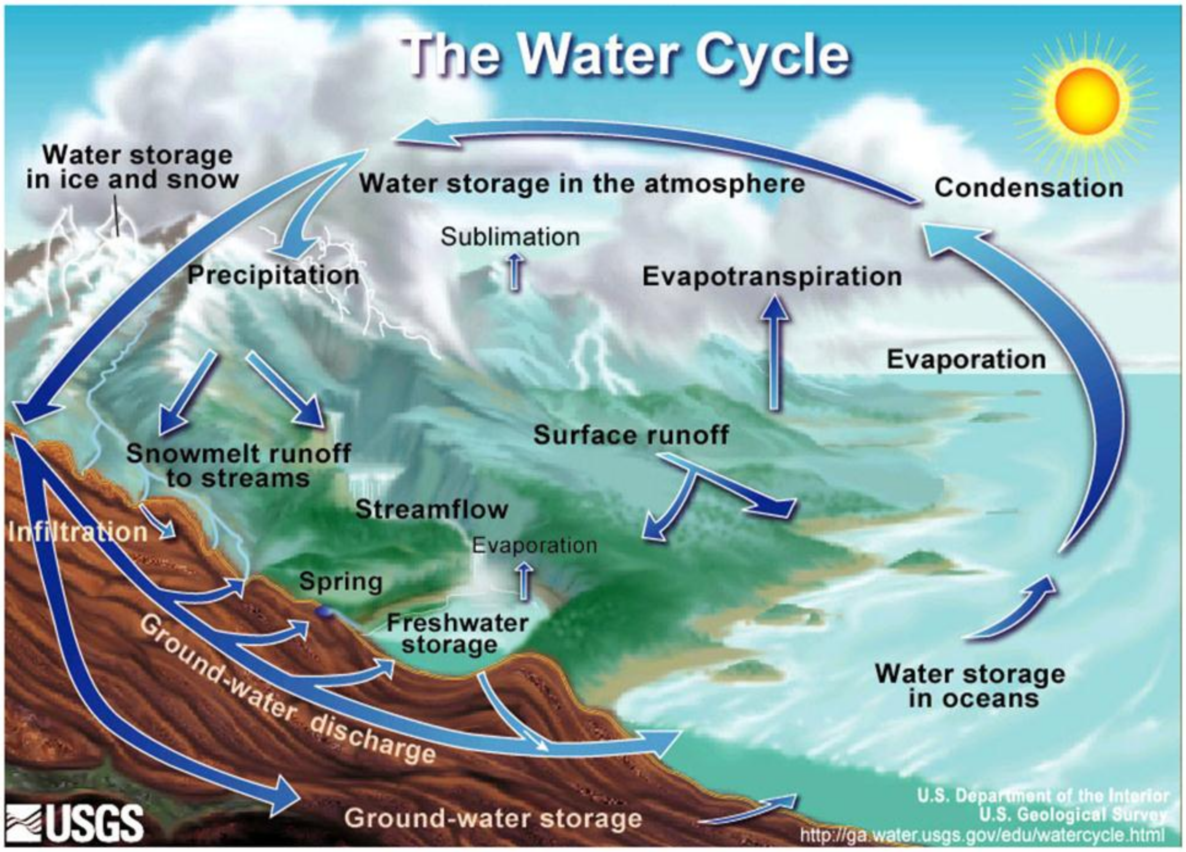
The USGS (2009) reports that surface water has historically been the primary source for irrigation, although trends identified in the 2009 report show an increasing usage of groundwater since the mid-20th Century (USGS, 2009). A 2005 water use summary published by USGS (2009) indicates that during 1950, 77 percent of all irrigation withdrawals were surface water. USGS notes that trends show that surface-water withdrawals comprised only 59 percent of the total. Groundwater withdrawals for irrigation during the early 21st Century were more than three times larger than during the mid-20th Century. About 61.1 million acres were irrigated in 2005 according to USGS. About 30.5 million acres were irrigated with sprinkler systems; 26.6 million acres were irrigated with surface flood systems, 4.05 million acres with micro-irrigation systems; and the national average application rate was 2.35 acre-feet per acre per year. Appendix B of this EIS explains the different types of agricultural irrigation used and describes the irrigation practices and considerations relevant to the produce covered under the PS PR.

Both surface water and groundwater can contain natural ambient innocuous bacteria, as well as enteric organisms indicating fecal material contamination. Water containing enteric organisms can contain pathogens, which are a risk to consumers, and such water used as agricultural water is therefore a concern. The PS PR would seek to limit the potential for harmful pathogens contaminating covered produce through agricultural water, including irrigation water.

3.1.3.2 The Hydrologic Cycle and Interactions of Groundwater and Surface Water

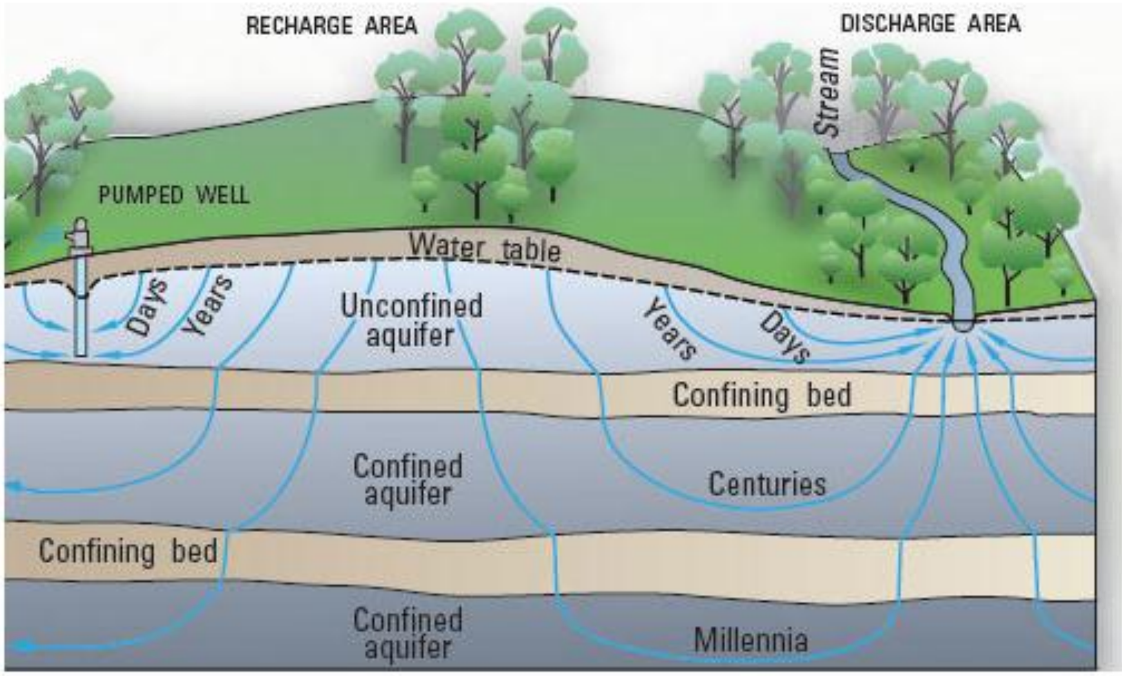
The hydrologic cycle, as explained by the USGS (1998), is the continuous movement of water above, and below the Earth’s surface. Figure 3.1-1 is a simple diagram of the hydrologic cycle, which shows only major transfers of water between continents and oceans. However, there is a great deal of variability that contributes to hydrologic processes. Precipitation is the source of virtually all freshwater in the hydrologic cycle, but its distribution is highly variable (based on climate and other factors). Similarly, evaporation and transpiration return water to the atmosphere nearly everywhere, but evaporation and transpiration rates vary considerably according to climatic conditions. As a result, much of the precipitation never reaches the oceans as surface and subsurface runoff before the water is returned to the atmosphere. The relative magnitudes of the individual components of the hydrologic cycle, such as evapotranspiration, may differ significantly even at small scales, as between an agricultural field and a nearby woodland.

Figure 3.1-1. The hydrologic cycle



As shown in Figure 3.1-2, the direction and speed of groundwater movement is determined by characteristics of aquifers and confining layers of subsurface rocks (which water has a difficult time penetrating) in the ground. Water moving below ground depends on the permeability of soil and bedrock layers, and on the porosity (the amount of open space in the material) of the subsurface rock. If the rock has characteristics that allow water to move relatively freely through it, then groundwater can move greater distances in a number of days. But groundwater can also sink into deep aquifers where it takes thousands of years to move back into the environment, or even go into deep groundwater storage, where it might stay for much longer periods.

Figure 3.1-2. Groundwater flow paths and timeframes (USGS, 1998)



- Unconfined aquifers: In unconfined aquifers, water has simply infiltrated from the surface and saturated the subsurface material. If people drill a well into an unconfined aquifer, they have to install a pump to push water to the surface.

- Confined aquifers: Confined aquifers have layers of rock above and below it that are not very permeable to water. Natural pressure in the aquifer can exist; pressure that can sometimes be enough to push water in a well above the land surface. Not all confined aquifers produce artesian water; however, artesian pressure can force water to the surface with great pressure. (Note: this concept is important when considering potential impacts because if poor surface water quality causes additional groundwater pumping to supply irrigation needs, confined aquifers can become less pressurized and may need to be pumped or pumped from greater depths, which is more expensive.)

3.1.3.3 Surface Water Hydrology

Rivers are major aquatic landscapes for plants and animals. Rivers can help keep aquifers full of water by discharging water downward through their streambeds (USGS, 1998).

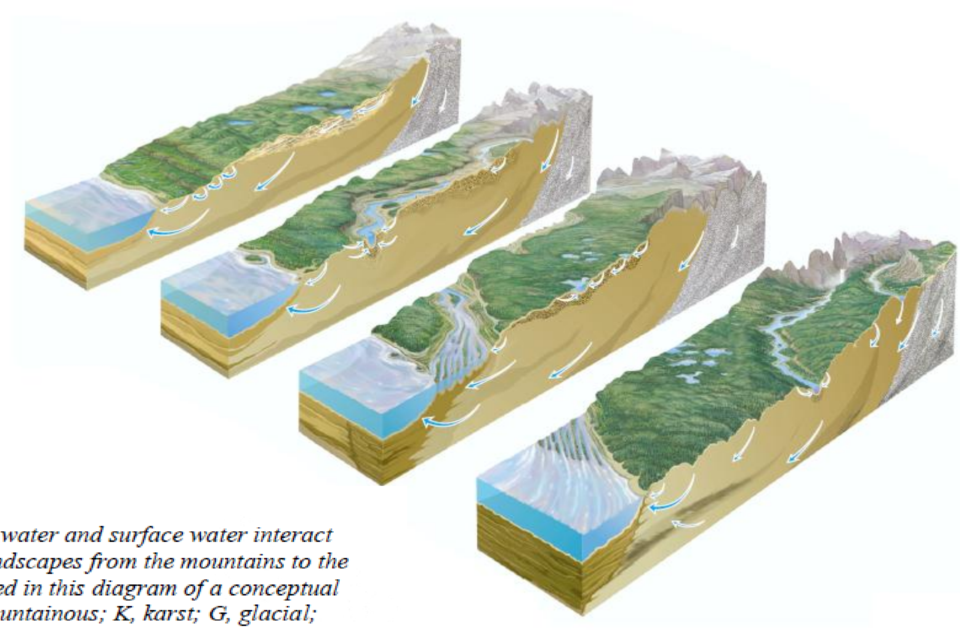
When looking at the location of rivers and the amount of streamflow in rivers, an important concept is the river's "watershed." A watershed encompasses the area of land that contributes to all of the water that falls within that area and is transported to the same place (e.g., a larger water body such as an estuary). Watersheds can be as small as a farm pond or large enough to encompass a water basin. Larger watersheds may contain many smaller watersheds. It depends on the outflow point; all of the land that drains water to the outflow point is the watershed for that outflow location.

3.1.3.4 Surface Water/Groundwater Interactions

Figure 3.1-3 shows how streams interact with groundwater in all types of landscapes. With respect to understanding potential impacts to the availability and quality of water resources it is important to recognize that surface water and groundwater resources are interconnected (USGS, 1998). The interaction takes place in three basic ways: streams gain water from inflow of groundwater through the streambed (gaining stream, Figure 3.1-4), they lose water to groundwater by outflow through the streambed (losing stream, Figure 3.1-5), or they do both, gaining in some reaches and losing in other reaches. For groundwater to discharge into a stream channel, the altitude of the water table in the vicinity of the stream must be higher than the altitude of the stream-water surface. Conversely, for surface water to seep to groundwater, the altitude of the water table in the vicinity of the stream must be lower than the altitude of the stream-water surface.

Losing streams can be connected to the groundwater system by a continuous saturated zone (Figure 3.1-5) or can be disconnected from the groundwater system by an unsaturated zone. Where the stream is disconnected from the groundwater system by an unsaturated zone, the water table may have a discernible mound below the stream (Figure 3.1-6) if the rate of recharge through the streambed and unsaturated zone is greater than the rate of lateral groundwater flow away from the water-table mound. An important feature of streams that are disconnected from groundwater is that pumping of shallow groundwater near the stream does not affect the flow of the stream near the pumped wells. In some environments, streamflow gain or loss can persist; that is, a stream might always gain water from groundwater, or it might always lose water to groundwater. However, in other environments, flow direction can vary a great deal along a stream; some reaches receive groundwater, and other reaches lose water to groundwater.

Figure 3.1-3. Groundwater and surface water interactions in various landscapes (USGS, 1998)



Ground water and surface water interact throughout all landscapes from the mountains to the oceans, as depicted in this diagram of a conceptual landscape. M, mountainous; K, karst; G, glacial; R, riverine (small); V, riverine (large); C, coastal.

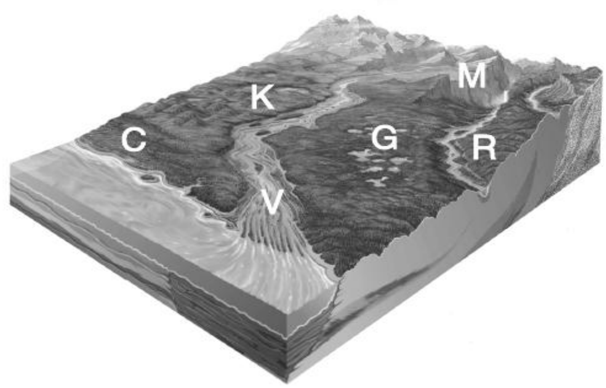


Figure 3.1-4. Gaining streams receive water from the groundwater system (USGS, 1998)

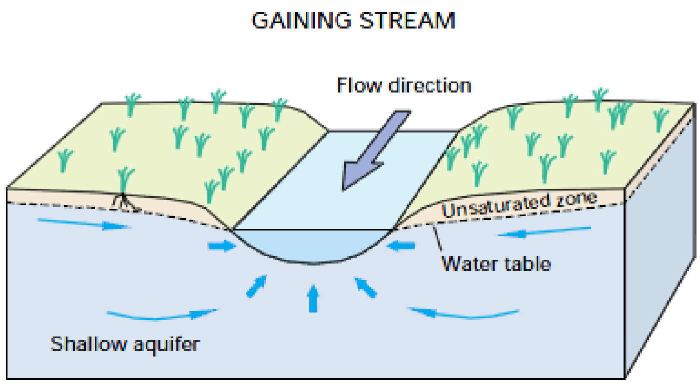


Figure 3.1-5. Losing streams lose water to the groundwater system (USGS, 1998)

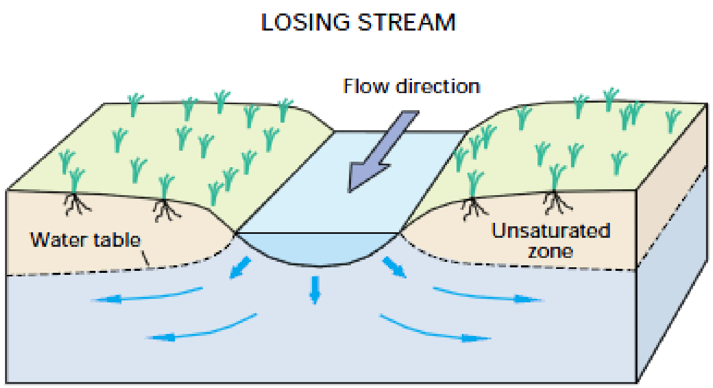
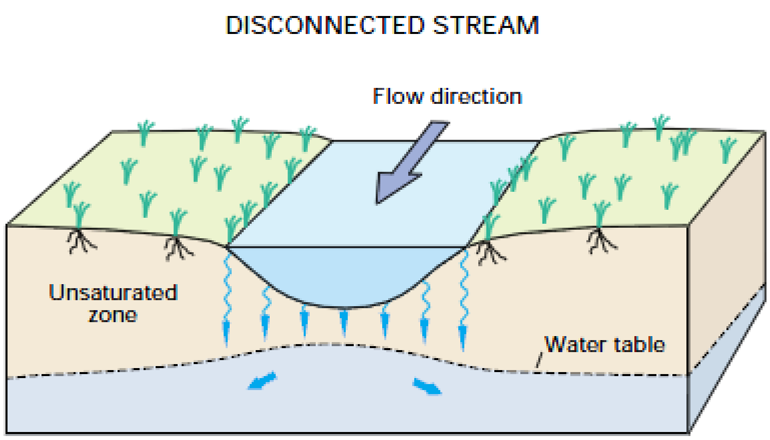


Figure 3.1-6. Disconnected streams are separated from the water table (USGS, 1998)



Changes in streamflow between gaining and losing conditions can also be caused by pumping groundwater near streams. Pumping can intercept groundwater that would otherwise have discharged to a gaining stream, or at higher pumping rates it can induce flow from the stream to the aquifer.

In addition to bank storage, other processes may affect the local exchange of water between streams and adjacent shallow aquifers. As described below, this interchange of water can also lead to the cross contamination of nitrates or pathogens between surface water and groundwater.

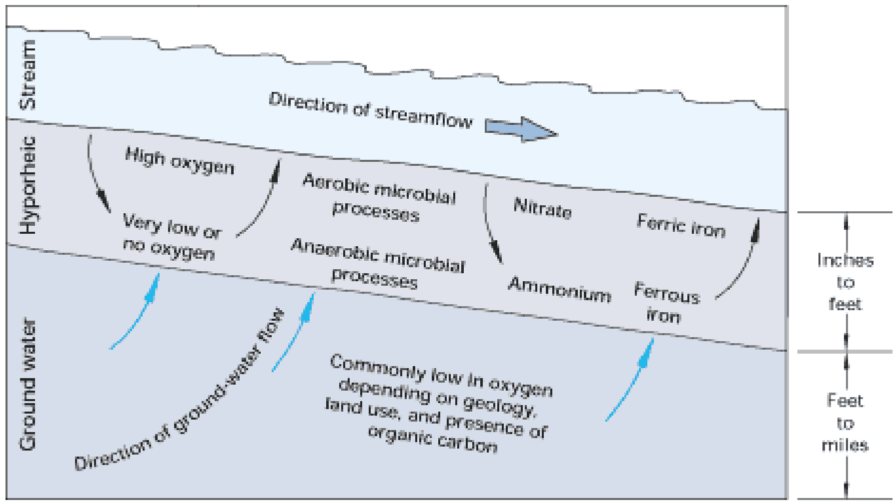
3.1.3.5 Chemical Interactions of Groundwater and Surface Water

As described in USGS (1998), groundwater chemistry and surface water chemistry cannot be dealt with separately where surface and subsurface flow systems interact. The movement of water between groundwater and surface water provides a major pathway for chemical transfer between terrestrial and aquatic systems (Figure 3.1-7). This transfer of chemicals affects the supply of carbon, oxygen, nutrients such as nitrogen and phosphorus, and other chemical constituents that enhance biogeochemical processes on both sides of the interface. This transfer can ultimately affect the biological (e.g., pathogens) and chemical (e.g., nitrates and pesticides) characteristics of aquatic systems downstream.

Many streams are impaired (contaminated); therefore, the need to determine the extent of the chemical reactions that take place in the region beneath and alongside a stream bed, where the mixing of shallow groundwater and surface water[2] is widespread because of the concern that the contaminated stream water will contaminate shallow groundwater. Streams offer good examples of how interconnections between groundwater and surface water affect chemical processes. Rough channel bottoms cause stream water to enter the streambed and to mix with groundwater in the hyporheic zone. This mixing establishes sharp changes in chemical concentrations in the hyporheic zone. A zone of enhanced biogeochemical activity usually develops in shallow groundwater as a result of the flow of oxygen-rich surface water into the subsurface environment, where bacteria and geochemically active sediment coatings are abundant (Figure 3.1-7). This input of oxygen to the streambed stimulates a high level of activity by aerobic (oxygen-using) microorganisms if dissolved oxygen is readily available. It is not uncommon for dissolved oxygen to be completely used up in hyporheic flow paths at some distance into the streambed, where anaerobic microorganisms dominate microbial activity. Anaerobic bacteria can use nitrate, sulfate, or other solutes in place of oxygen for metabolism. The result of these processes is that many solutes are highly reactive in shallow groundwater in the vicinity of streambeds.

[2] This region of mixing is called the hyporheic zone.

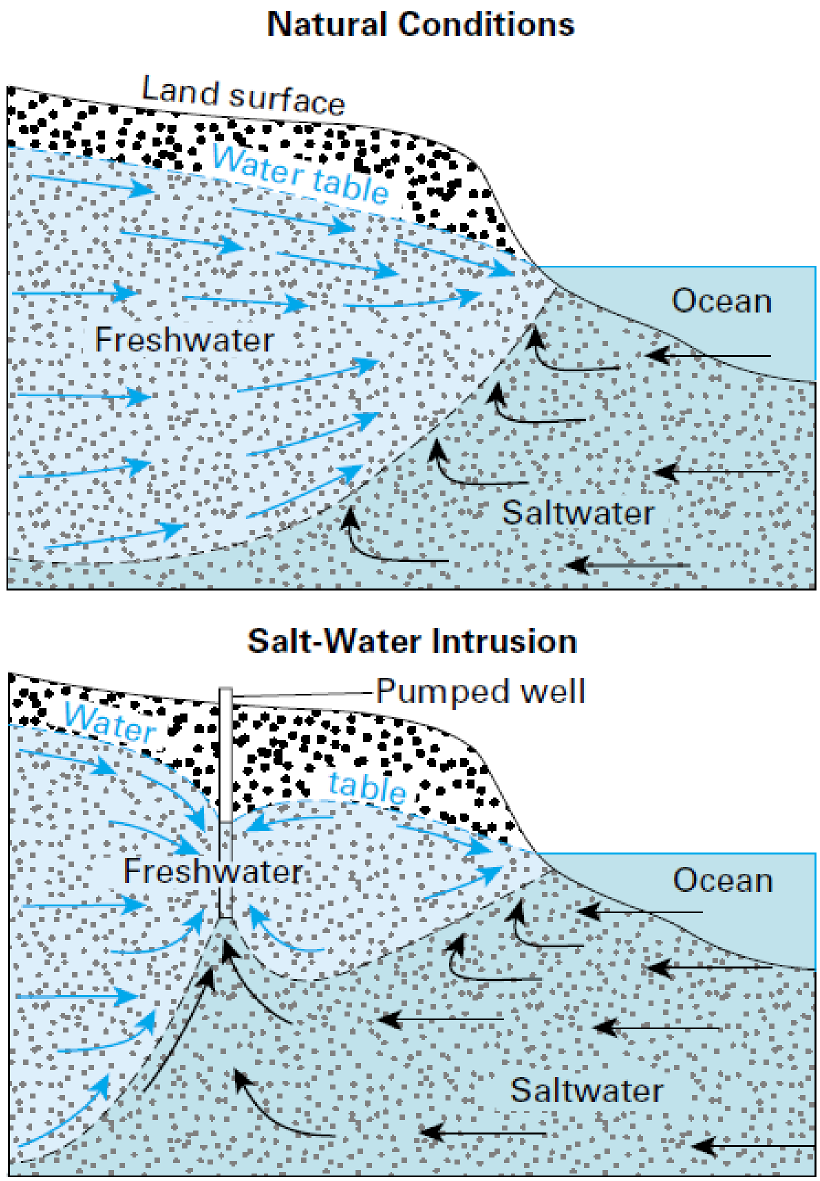
Figure 3.1-7. Processes and chemical transformations that may take place in the hyporheic zone (USGS, 1998)



3.1.3.6 Saltwater Intrusion

In some coastal areas, intensive pumping of fresh groundwater has caused salt water to intrude into fresh-water aquifers (Figure 3.1-8). Since saltwater has high concentrations of dissolved sodium chloride (salt) and other minerals, it can be hazardous to animals or plants in large concentrations (USGS, 2003a).

Figure 3.1-8. How intensive groundwater pumping can cause salt-water intrusion in coastal aquifers. (USGS, 2003a)

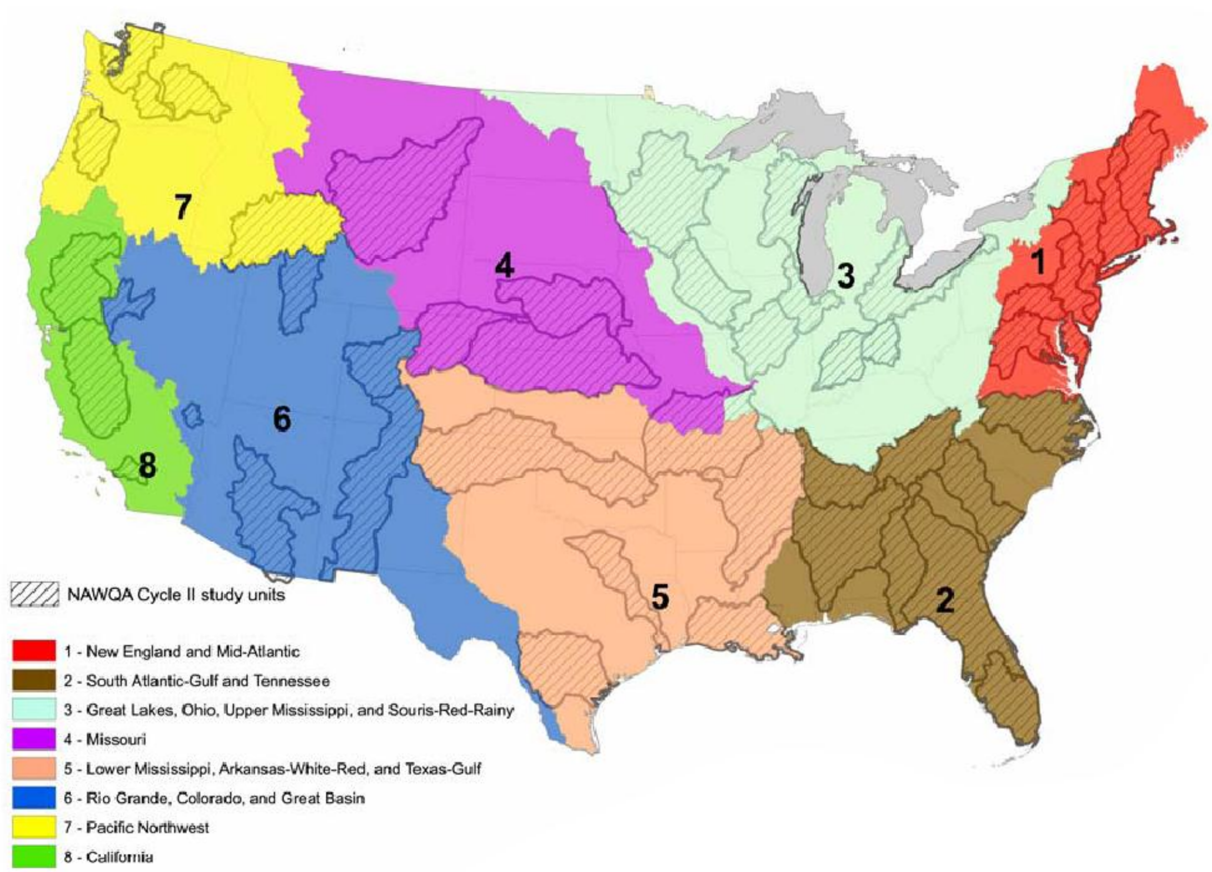


3.1.3.7 National Water-Quality Assessments

In 1991, the U.S. Congress established the National Water-Quality Assessment (NAWQA) Program within the USGS to develop nationally consistent long-term datasets and provide information about the quality of the Nation's streams and groundwater (USGS, 2010). As described by USGS, a major focus of NAWQA is on regional- and national-scale assessments of water-quality and trends in streams and rivers. NAWQA has identified eight large geographical regions (referred to as "major river basins") as the basis for its status and trends assessments.

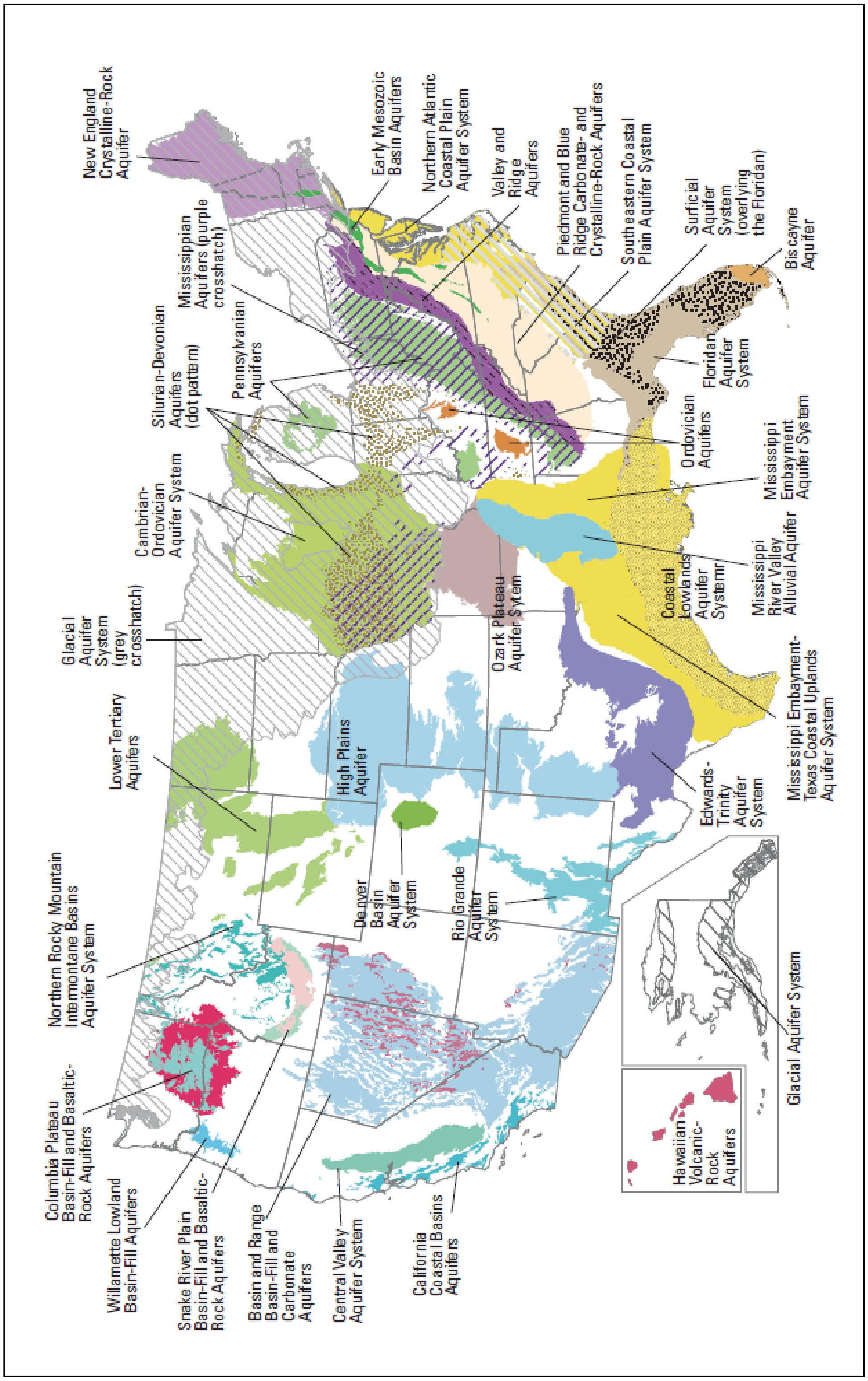
NAWQA assessments build upon previous findings generated from 1992-2001 for streams and rivers in smaller basins (referred to as "Study Units"). Primary goals remain the same: to characterize the status of surface-water quality (stream chemistry and ecology); determine trends at those sites that have been consistently monitored for more than a decade; and build an understanding of how natural features and human activities affect water quality. Figure 3.1-9 illustrates the major U.S. river basins and sets the stage for the discussion of potential water quality impacts in Chapter 4.

Figure 3.1-9. Major river basins defined by NAWQA (USGS, 2006a)



The USGS defines an aquifer as a geologic formation, group of formations, or part of a formation that contains sufficient saturated, permeable material to yield significant quantities of water to streams, wells and springs. (USGS, 2014a). A total of 62 principal aquifers underlie the U.S. (USGS, 2010). For each geographic area, the aquifer shown in Figure 3.1-10 is generally the uppermost principal aquifer. Each principal aquifer is classified as one of six types of permeable geologic material: unconsolidated deposits of sand and gravel, semi-consolidated sand, sandstone, carbonate rocks, interbedded sandstone and carbonate rocks, or basalt and other types of volcanic rock. The aquifer name is also included.

Figure 3.1-10. Location and extent of the principal aquifers in the U.S. as defined by NAWQA (USGS, 2010)

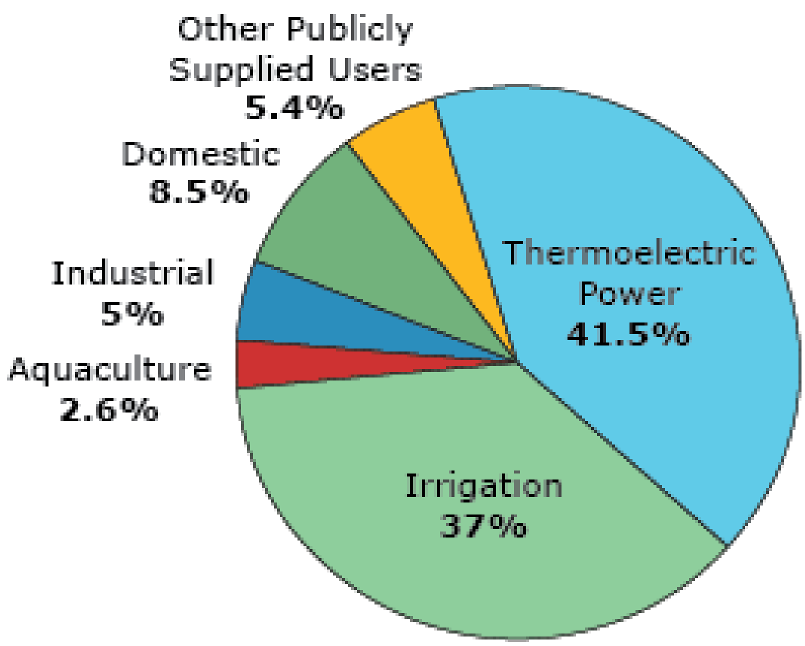


3.1.3.8 Total Water Use in the U.S.

Every five years since 1950, the USGS has published a series of estimated water use reports that include estimates of water withdrawals by State, source of water, and category of use (USGS, 2009). The twelfth report in the series is titled "Estimated use of water in the U.S. in 2005," and is the most recent report available. Unless otherwise cited, the information pertaining to water use in 2005 and presented below was obtained from the USGS report (USGS, 2009).[3]

Figure 3.1-11 shows the percentage of total U.S. water withdrawals by major user group. As of 2005, crop irrigation represented the second highest usage of water; although it should be noted that the figure does not distinguish between covered produce and all crops. Additional supporting information is found in Figure 3.1-12 and Figure 3.1-13.

Figure 3.1-11. Total U.S. withdrawals, 2005 (USGS, 2009)



The geographic distribution of total, surface-water, and groundwater withdrawals is shown in Figure 3.1-12. The total withdrawals for a State are, in part, a function of the size of the State—for example, a large State would have more irrigable land area and larger irrigation withdrawals than a small State if other factors such as climate, soils, and available water supply are the same. In 2005, more surface water than groundwater was withdrawn for all categories except self-supplied domestic, livestock, and mining. Of the 270,000 million gallons per day (MGD) fresh surface water withdrawals, more than one-half were for thermoelectric power, and more than one-fourth were for irrigation. The largest surface water withdrawals were in California, where irrigation was the largest use of fresh surface water.

[3] Report completion and data availability for the 2010 survey is not expected to be available until late 2014.

Nearly two-thirds of the fresh groundwater withdrawals in 2005 were for irrigation, and more than one-half of the groundwater for irrigation was withdrawn in just four States: California, Nebraska, Arkansas, and Texas. Irrigation was the largest use of fresh groundwater in 25 States. Nationwide, groundwater withdrawals for irrigation were about 3.5 times larger than groundwater withdrawals for public supply.

As illustrated in Figure 1.7-4 (Chapter 1.7), roughly over 80 percent of covered farms occur in regions B, C, D, and U, including; central and southern California, southwestern Arizona, south-central Florida and central Washington.

USGS found in 2005 that total irrigation withdrawals were roughly 128,000 MGD, or 144,000 thousand acre-feet per year, and irrigation withdrawals were 37 percent of total freshwater withdrawals and 62 percent of total freshwater withdrawals for all categories excluding thermoelectric power. Surface water accounted for 58 percent of the total irrigation withdrawals. About 61.1 million acres were irrigated in 2005.

About 26.6 million acres were irrigated with surface (flood) systems, 4.05 million acres with microirrigation systems, and 30.5 million acres with sprinkler systems. The national average application rate was 2.35 acre-feet per acre.

The geographic distribution of total, surface-water, and groundwater withdrawals for irrigation is shown in Figure 3.1-13. In 2005, the majority of withdrawals (85 percent) and irrigated acres (74 percent) were in the 17 conterminous Western States. The 17 Western States are located in areas where average annual precipitation typically is less than 20 inches and is insufficient to support crops without supplemental water.[4] Surface water was the primary source of water in the arid West and the Mountain States. California, Idaho, Colorado, and Montana combined accounted for 49 percent of the total irrigation withdrawals and 64 percent of surface-water irrigation withdrawals. Nearly 90 percent of the groundwater used for irrigation was withdrawn in 13 States, and each of these States withdrew more than 1,000 MGD (1,120 thousand acre-feet per year) of groundwater for irrigation in 2005. Among these 13 States, groundwater was the primary source for irrigation in Nebraska, Arkansas, Texas, Kansas, Mississippi, and Missouri.

Total irrigation withdrawals in both Eastern and Western States were smaller in 2005 than in 2000, but because the West accounts for such a large majority of the total, changes in those States have a greater effect on the total. Groundwater withdrawals increased slightly in the East, and surface water withdrawals declined in both the East and West. Total irrigated acres decreased in the West by 4 percent and increased in the East by 5 percent. In the West, acres irrigated by surface irrigation methods declined by 16 percent, and acres irrigated by sprinkler methods increased by 9 percent. Irrigated acres in the East increased for all type of systems; the largest percentage increase was in microirrigation systems.

[4] In accordance to USGS in this context, these Western States refer to all or parts of Arizona, California, Colorado, Idaho, Kansas, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington, and Wyoming.

Total irrigation withdrawals of 128,000 MGD for 2005 were almost 8 percent less than the estimated 139,000 MGD withdrawn during 2000. Surface-water withdrawals of 74,900 MGD in 2005 were 9 percent less than in 2000, when an estimated 82,400 MGD were withdrawn. Groundwater withdrawals of 53,500 MGD in 2005 were about 5 percent less than the 56,600 MGD withdrawn in 2000. Total irrigated acres in 2005 were 2 percent less than 2000. Acres irrigated with surface (flood) irrigation systems declined by 10 percent, from 29.7 million acres in 2000 to 26.6 million acres in 2005. Acres irrigated with sprinkler irrigation systems increased almost 7 percent, from 28.5 million acres in 2000 to 30.5 million acres in 2005.

Five States—California, Nebraska, Texas, Arkansas, and Idaho—accounted for 52 percent of total irrigated acreage. Nebraska, Texas, and California accounted for 41 percent of the irrigated acreage using sprinkler and microirrigation systems. California alone accounted for 65 percent of the irrigated acreage with microirrigation systems. Sprinkler and microirrigation systems combined were associated with more than 56 percent of total irrigated acreage.

Generally, application rates were greatest in the arid West and Mountain States where surface water was the predominant source of water used for irrigation, and surface (flood) application was the predominant method of irrigation. Massachusetts is the exception with the highest application rate in the U.S. (6.9 acre-feet per acre), likely due to water-management practices in the many cranberry bogs in that State. In Arizona and Idaho, application rates exceeded 5 acre-feet per acre. Many States that typically use large quantities of water for irrigation, such as California, Montana, Florida, Kansas, and Nevada, showed declines in application rates in 2005 compared to 2000.

During 2005, livestock withdrawals were an estimated 2,140 MGD, or 2,390 thousand acre-feet per year. Livestock withdrawals were less than one percent of total freshwater withdrawals and one percent of total freshwater withdrawals excluding thermoelectric power. Groundwater was the source for 60 percent of total livestock withdrawals. Estimated total livestock withdrawals for 2005 were eight percent less than in 2000.

The geographic distribution of total, surface water, and groundwater livestock withdrawals in 2005 is shown in Figure 3.1-14. Texas, California, Oklahoma, and North Carolina each used more than 125 MGD for livestock and accounted for 35 percent of total livestock withdrawals in 2005. Texas, North Carolina, Nebraska, California, Iowa, and Kansas each used more than 80 MGD of groundwater for livestock and accounted for 47 percent of groundwater withdrawals for this use. California, Oklahoma, and Texas each used more than 95 MGD of surface water for livestock and accounted for 37 percent of surface-water withdrawals for this use.

Figure 3.1-12. Total surface water and groundwater withdrawals, 2005 (USGS, 2009)

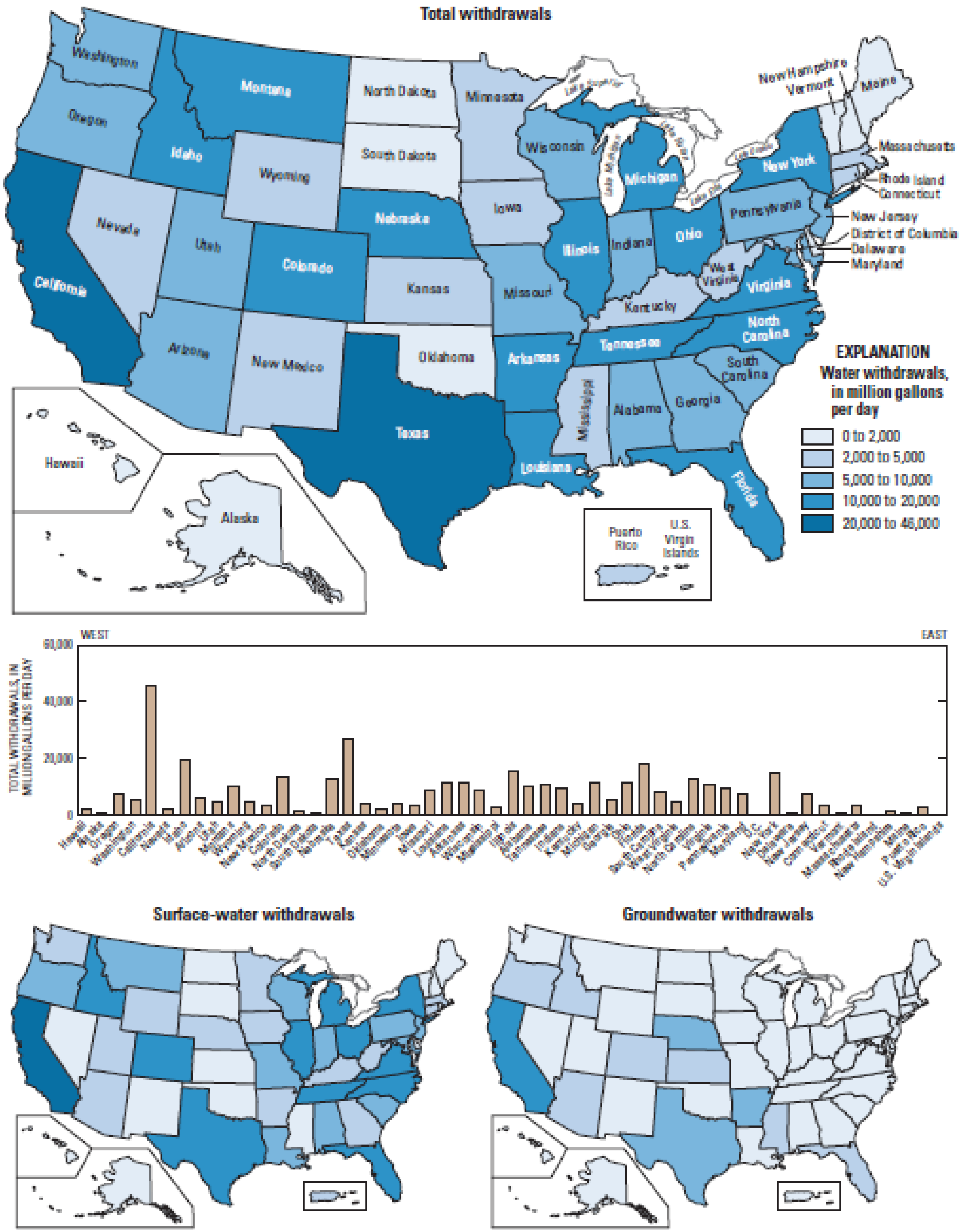


Figure 3.1-13. Irrigation water supply and withdrawals by source and state, 2005 (USGS, 2009)

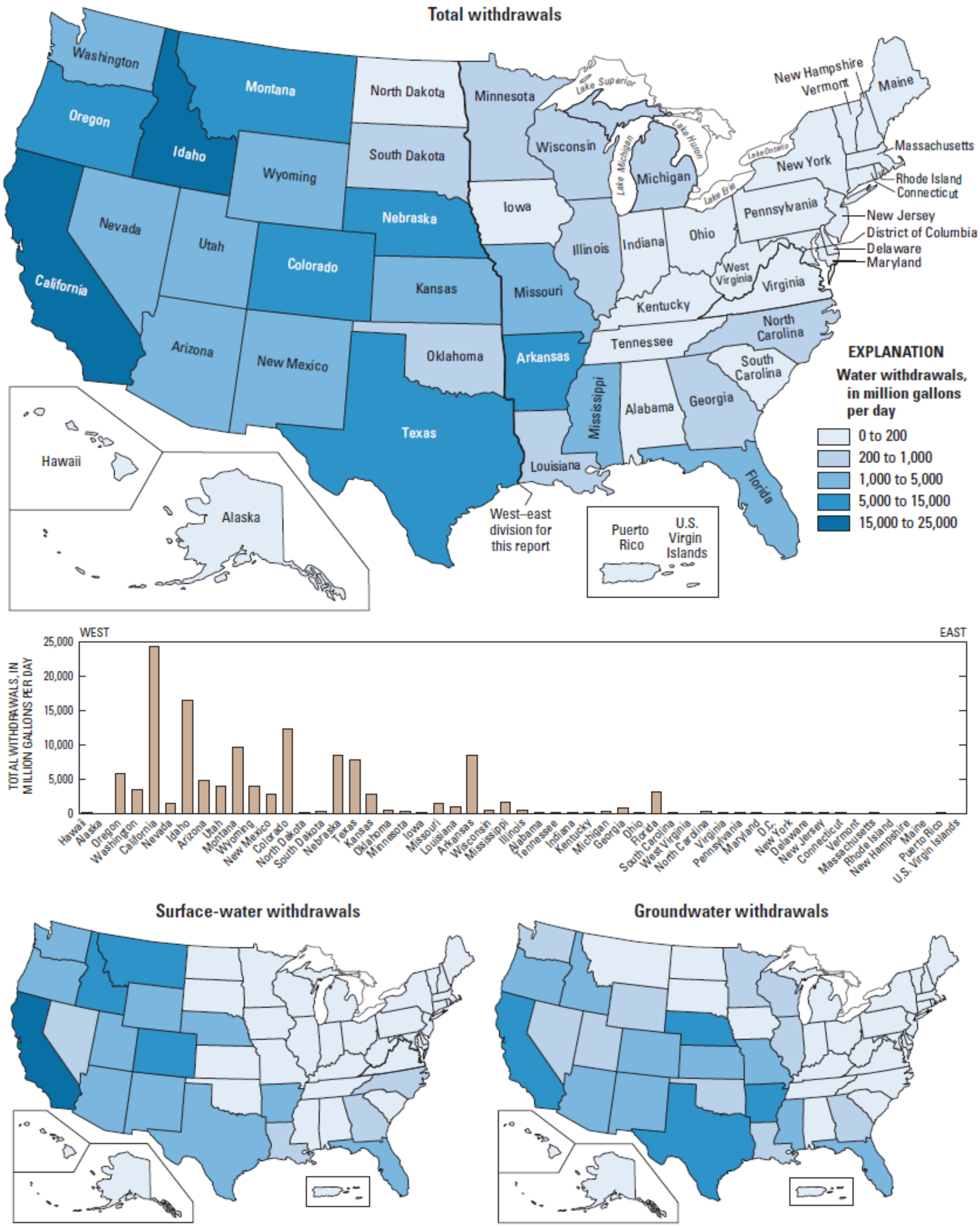
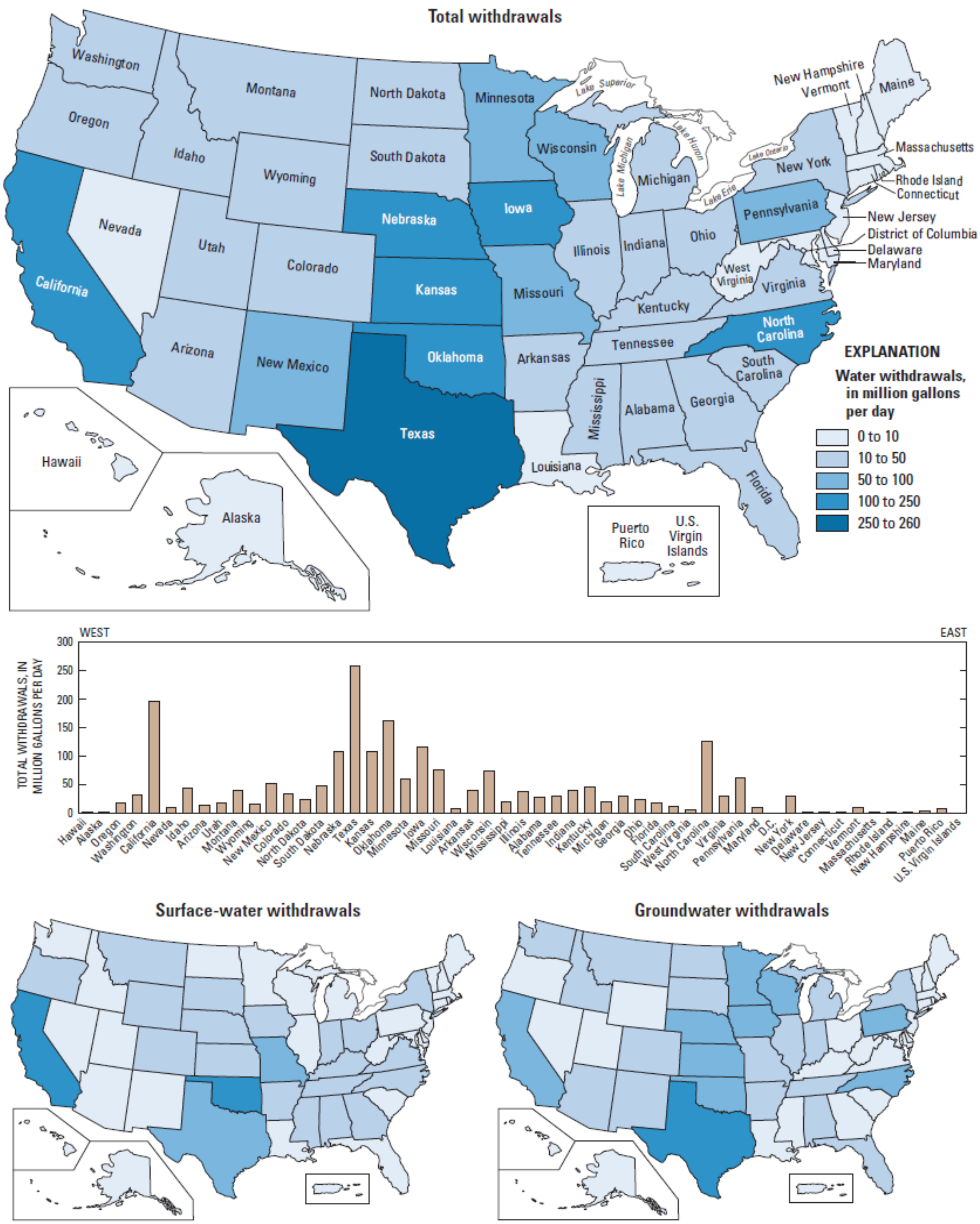


Figure 3.1-14. Livestock water withdrawals by source and state, 2005 (USGS, 2009)



3.1.3.9 Data Sources Used to Establish the Background Environmental Conditions

Surface Water Quality

NAWQA provides an understanding of whether water quality is getting better or worse over time; and how natural features and human activities affect those conditions (USGS, 2010). As discussed by USGS (2010), regional and national assessments are possible because of a consistent study design and uniform methods of data collection and analysis. Monitoring data are integrated with geographic information on hydrological characteristics, land use, and other landscape features in models to extend water-quality understanding to unmonitored areas. Local, State, Tribal, and national stakeholders use NAWQA information to design and implement strategies for managing, protecting, and monitoring water resources.

CWA Geospatial data from EPA's Office of Water Programs, including 303(d) Impaired Waters, 305(b) Assessed Waters and TMDLs are available for download by watershed, State, or to a national extent. Generally, State-level geospatial data represents the most recent data submitted to EPA by states. Table 3.1-1 presents the number of impaired waters listed by state. According to the EPA tabulated data, pathogens are the leading cause of impairment for 303(d) listed waters (Table 3.1-2). The specific reported causes of impairment that make up the selected impairment group and the number of each cause of impairment reported are listed in Table 3.1-3.

Table 3.1-1. Impaired waters listed by state, 2010 (EPA, 2014g)

State	Miles	State	Miles	State	Miles	State	Miles
Alabama	283	Indiana	1,836	New Hampshire	1,449	Tennessee	1,028
Alaska	35	Iowa	480	New Jersey	716	Texas	719
Arizona	91	Kansas	1,372	New Mexico	209	Utah	156
Arkansas	225	Louisiana	236	New York	1,543	Vermont	104
California	1,021	Maine	114	North Carolina	1,130	Virginia	1,523
Colorado	244	Maryland	184	North Dakota	201	Washington	2,420
Connecticut	461	Massachusetts	720	Ohio	267	West Virginia	1,097
Delaware	101	Michigan	2,352	Oklahoma	657	Wisconsin	593
District of Columbia	36	Minnesota	1,144	Oregon	1,397	Wyoming	107
Florida	2,292	Mississippi	229	Pennsylvania	6,957		
Georgia	215	Missouri	257	Puerto Rico	213		
Hawaii	309	Montana	584	Rhode Island	120		
Idaho	741	Nebraska	342	South Carolina	961		
Illinois	1,057	Nevada	215	South Dakota	155		

Table 3.1-2. Causes of water quality impairment and the number of cases for each cause for 303(d) listed waters, 2010 (EPA, 2014g)

Cause	No.	Cause	No.	Cause	No.	Cause	No.
Pathogens	10,783	Temperature	3,134	Other Cause	475	Biotoxins	87
Nutrients	7,686	Turbidity	2,899	Toxic Organics	457	Trash	84
Metals (other than Mercury)	7,229	Pesticides	2,096	Ammonia	408	Noxious Aquatic Plants	83
Organic Enrichment/ Oxygen Depletion	6,720	Salinity/Total Dissolved Solids /Chlorides/ Sulfates	1,931	Toxic Inorganics	378	Cause Unknown - Fish Kills	68
Sediment	6,565	Algal Growth	1,265	Flow Alteration(s)	238	Radiation	52
Polychlorinated Biphenyls (PCBs)	5,806	Cause Unknown	1,147	Oil and Grease	192	Chlorine	52
Mercury	4,802	Habitat Alterations	811	Taste, Color and Odor	142	Nuisance Native Species	4
pH/Acidity/Caustic Conditions	4,341	Dioxins	621	Nuisance Exotic Species	119		
Cause Unknown - Impaired Biota	3,664	Total Toxics	514	Fish Consumption Advisory	101		

Total: 74,954 Cases of Impairment

Table 3.1-3. Specific causes of impairment that make up the national pathogens cause of impairment group, 2010 (EPA, 2014g)

Cause of impairment	Number of cases	Cause of impairment	Number of cases
Fecal coliform	4,452	Indicator bacteria	312
E. coli	3,446	Total coliform	80
Pathogens	814	Coliforms	37
Enterococcus bacteria	589	Bacteria (Oyster waters)	16
Bacteria	464	Bacterial slimes	2
		Sanitary waste	1

The causes for impaired surface water within the States that contain regions B, C, D, L, and U, are summarized in Tables 3.1-4 through 3.1-7. In all of these states pathogens are reported as one of the top three causes of impairment. In addition, the TMDL summary pathogen data tabulated by the EPA (Table 3.1-8) indicates that large numbers of stream and river miles are impaired.

Table 3.1-4. California causes of impairment for 303(d) listed waters, 2010 (EPA, 2014g)

Cause of impairment	Cases	Cause of impairment	Cases	Cause of impairment	Cases
Pathogens	526	Sediment	71	Algal Growth	18
Pesticides	437	Temperature	59	Taste, Color and Odor	13
Metals (other than Mercury)	293	Trash	46	Other Cause	10
Total Toxics	239	Turbidity	46	Flow Alteration(s)	6
Salinity/Total Dissolved Solids/Chlorides/Sulfates	183	Ammonia	42	Biotoxins	6
Nutrients	179	Toxic Organics	40	Habitat Alterations	5
Mercury	160	Toxic Inorganics	37	Oil and Grease	2
Organic Enrichment/Oxygen Depletion	116	Nuisance Exotic Species	30	Fish Consumption Advisory	2
Polychlorinated Biphenyls	116	Dioxins	28	Cause Unknown - Fish Kills	1
pH/Acidity/Caustic Conditions	108	Cause Unknown - Impaired Biota	21		

Total: 2,840 cases of impairment

Table 3.1-5. Washington causes of impairment for 303(d) listed waters, 2010 (EPA, 2014g)

Cause of impairment	Cases	Cause of impairment	Cases	Cause of impairment	Cases
Temperature	988	Toxic Organics	135	Total Toxics	26
Pathogens	954	Metals (other than Mercury)	68	Turbidity	19
Organic Enrichment/ Oxygen Depletion	731	Dioxins	62	Ammonia	14
pH/Acidity/Caustic Conditions	294	Nutrients	50	Cause Unknown - Impaired Biota	13
Pesticides	228	Other Cause	43	Sediment	9
Polychlorinated Biphenyls	146	Mercury	30	Chlorine	3

Total: 3,813 cases of impairment

Table 3.1-6. Florida causes of impairment for 303(d) listed waters. 2010 (EPA, 2014g)

Cause of impairment	Cases	Cause of impairment	Cases	Cause of impairment	Cases
Mercury	1,128	Metals (other than Mercury)	114	Other Cause	17
Organic Enrichment/ Oxygen Depletion	1,049	Cause Unknown - Impaired Biota	37	pH/Acidity/Caustic Conditions	12
Pathogens	608	Turbidity	25	Noxious Aquatic Plants	1
Algal Growth	350	Salinity/Total Dissolved Solids/Chlorides/Sulfates	21	Dioxins	1
Nutrients	263	Ammonia	19	Chlorine	1

Total: 3,646 cases of impairment

Table 3.1-7. Arizona causes of impairment for 303(d) listed waters, 2010 (EPA, 2014g)

Cause of impairment	Cases	Cause of impairment	Cases	Cause of impairment	Cases
Metals (other than Mercury)	37	Ammonia	9	pH/Acidity/Caustic Conditions	5
Pesticides	30	Sediment	8	Toxic Inorganics	3
Pathogens	21	Nutrients	8	Chlorine	2
Mercury	12	Organic Enrichment/ Oxygen Depletion	6	Nuisance Native Species	1

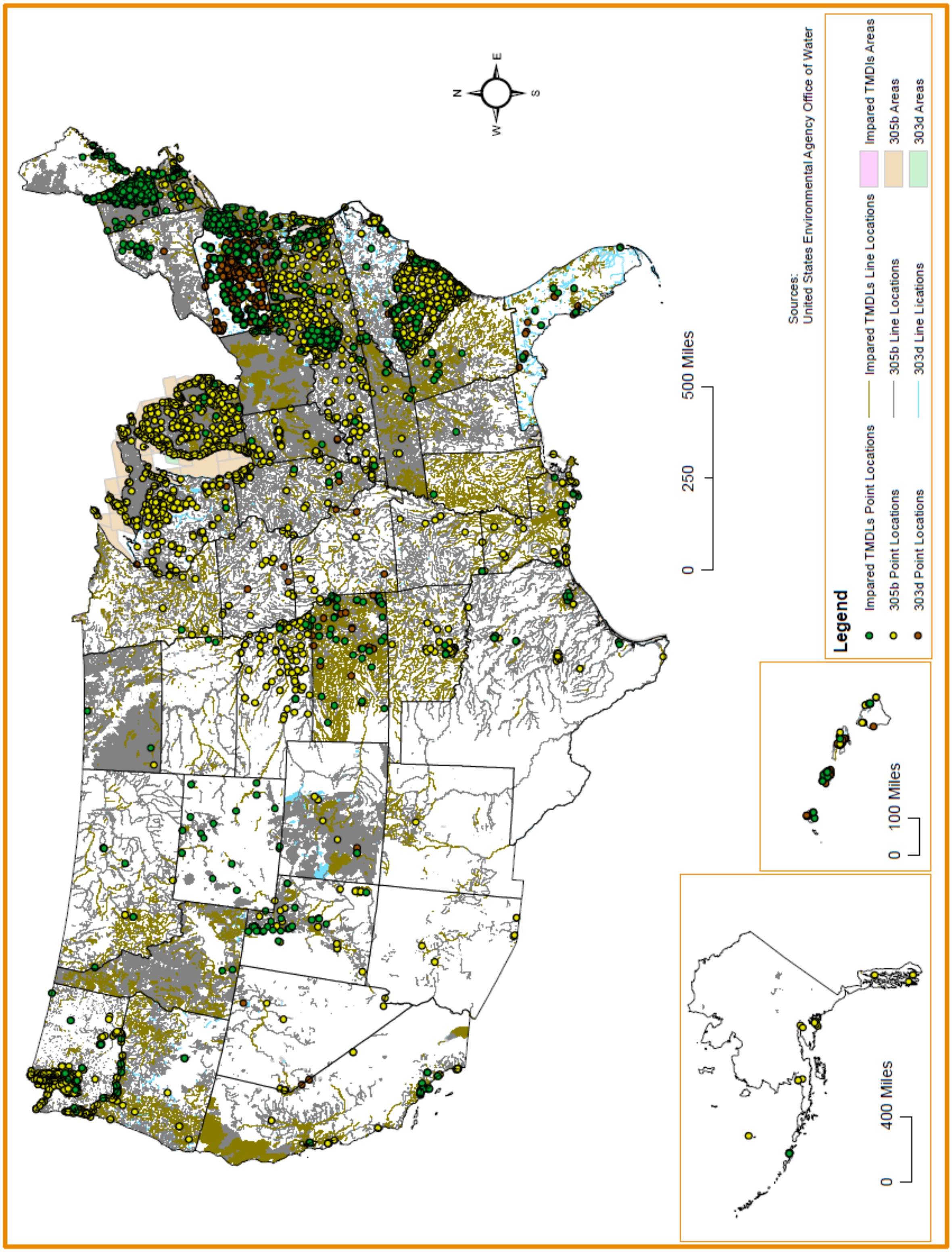
Total: 142 cases of impairment

Table 3.1-8. Nationwide miles of impaired streams (EPA, 2014h)

Cause of Impairment	Rivers and Streams (Miles) Impaired
Bacteria	7,394 mi.
Bacterial slimes	30 mi.
Coliform bacteria	269 mi.
Enterococcus bacteria	10,152 mi.
E. coli bacteria	86,747 mi.
Fecal bacteria	108 mi.
Fecal coliform bacteria	57,562 mi.
Indicator bacteria (only)	942 mi.
Pathogens	4,184 mi.
Total coliform	6,705 mi.
Viruses	6 mi.

Nitrates are often observed in surface and groundwater in agricultural areas. Reported TMDL exceedances are shown in Figure 3.1-15.

Figure 3.1-15. 303(d) Impaired waters due to nitrate exceedances



Groundwater Quality

As described in USGS (2006b), fecal and sewage contamination of water can introduce pathogenic microorganisms into a water resource. Data obtained from the collection of water samples from wells and analyzed for the presence of fecal-indicator microorganisms can be used in multiple ways. Perhaps most importantly, data indicating the presence or absence of fecal-indicator microorganisms in groundwater samples can help determine the suitability of a water resource for different purposes, particularly as a drinking-water or irrigation resource (USGS, 2006b).

As part of NAWQA, USGS collected microbiological data from wells in 22 NAWQA study units during 1993–2004 (Figure 3.1-16) (USGS, 2006b). The wells constituted the sampling networks for three major NAWQA efforts—the major aquifer study, the land-use study, and source-water quality assessments of groundwater used for public supplies. Sixteen principal aquifers were represented by these well networks (Figure 3.1-17). Samples of untreated groundwater were analyzed for concentrations of fecal-indicator bacteria, which included the total-coliform bacteria, fecal-coliform bacteria, and *E. coli*, and for the presence of somatic and male-specific coliphage viruses.

Analyses of the samples showed that coliform bacteria occur relatively frequently—nearly 30 percent of all wells tested positive—and that domestic wells commonly are contaminated by total coliform bacteria, with 33 percent of these wells testing positive (Figure 3.1-18). Coliphage viruses were present in 10 percent or fewer of the wells sampled in the Central Columbia Plateau-Yakima, Georgia-Florida, San Joaquin, and Trinity study units, which represent the Columbia Plateau, Floridan, Central Valley, and Coastal Lowlands principal aquifers, respectively. The frequency of detections and concentrations of total coliform bacteria generally were higher in samples from domestic wells than in samples from public-supply wells; in fractured or porous rock materials (carbonate rocks) than in unconsolidated materials (mixtures of sand, gravel, clay); and in principal aquifers with median depths of sampled wells ranging from 100 to 200 feet than in principal aquifers with median depths of sampled wells less than 100 feet or greater than 200 feet.

The waters most affected by the presence of coliform bacteria were those in the Valley and Ridge, the Floridan, and the Piedmont and Blue Ridge aquifers, where more than 50 percent of the study wells tested positive for these bacteria. The numbers of wells with detections of coliform bacteria were significantly lower for the Glacial Deposits, Stream and River Valley, Columbia Plateau, Basin and Range, High Plains, Southeastern Coastal Plain, and Coastal Lowlands aquifers. Of the 16 principal aquifers sampled, wells in the Valley and Ridge had the highest overall concentrations of total coliforms, with a median of 2 CFU/100 ml. Elevated concentrations of coliform bacteria (greater than 300 CFU/100 ml) also were reported for wells completed in the Mississippian-Pennsylvanian aquifer and the Ordovician aquifer in lower Tennessee.

For the large Major Aquifer Study (MAS) network, the frequency of wells testing positive for total coliform was 82 percent for the Central Valley aquifer (Figure 3.1-18A); however, this high frequency of detection might be a function of the low number of available samples. Detection -frequencies of *E. coli* were highest for MAS wells in the Ordovician aquifer (30 percent), followed by detections in the Central Valley (25 percent) and the Mississippian-Pennsylvanian (19 percent) aquifers (Figure 3.1-18A).

The Piedmont and Blue Ridge, Floridan, Coastal Lowlands, Columbia Plateau, Glacial Deposits, Basin and Range, and Central Valley aquifers, or just less than one-half the 16 aquifers studied since 1993, were the first principal aquifers to be sampled as part of the new Source-Water Quality Assessment (SWQA) network of NAWQA Cycle II. Samples with the highest detection frequencies of total coliforms were collected from Piedmont and Blue Ridge wells (greater than 50 percent) followed by detections in samples from wells completed in the Floridan aquifer (30 percent). Detection frequencies of *E. coli* were low, however, with nondetections reported for all wells in four of the seven aquifers and only one detection in each of the others (Figure 3.1-18B).

Total coliforms were detected in 33 percent of the samples from domestic wells and 16 percent of samples from public supply wells, and *E. coli* were detected in eight and three percent of samples from domestic and public supply wells, respectively (Figure 3.1-19A).

Median concentrations of total coliforms and *E. coli* were at the detection limit of less than one CFU/100 ml for all six classes of water use (Figure 3.1-19B); however, the concentrations in domestic wells were significantly higher (p-value less than 0.05) than concentrations in public-supply wells. In samples from domestic wells, the maximum concentrations of total coliforms and *E. coli* were 1,600 and 1,200 CFU/100 ml, respectively. Maximum concentrations of total coliforms detected in samples from public-supply wells were greater than 80 CFU/100 ml for a well completed in the Floridan aquifer of the Georgia/Florida (GAFL) study unit, and 61 CFU/100 ml for a well completed in the Glacial Deposits aquifer of the High Plains Region Groundwater (HPGW) study unit. More than 75 percent of samples from domestic wells had concentrations of total coliforms of 2 CFU/100 ml or less. In samples from public-supply wells, however, more than 75 percent of concentrations of total coliforms were less than the minimum report level of less than one CFU/100 ml (Figure 3.1-19B).

Figure 3.1-16. Study units of the NAWQA program in which microbiological samples were collected from wells, 1993–2004 (USGS, 2006b).

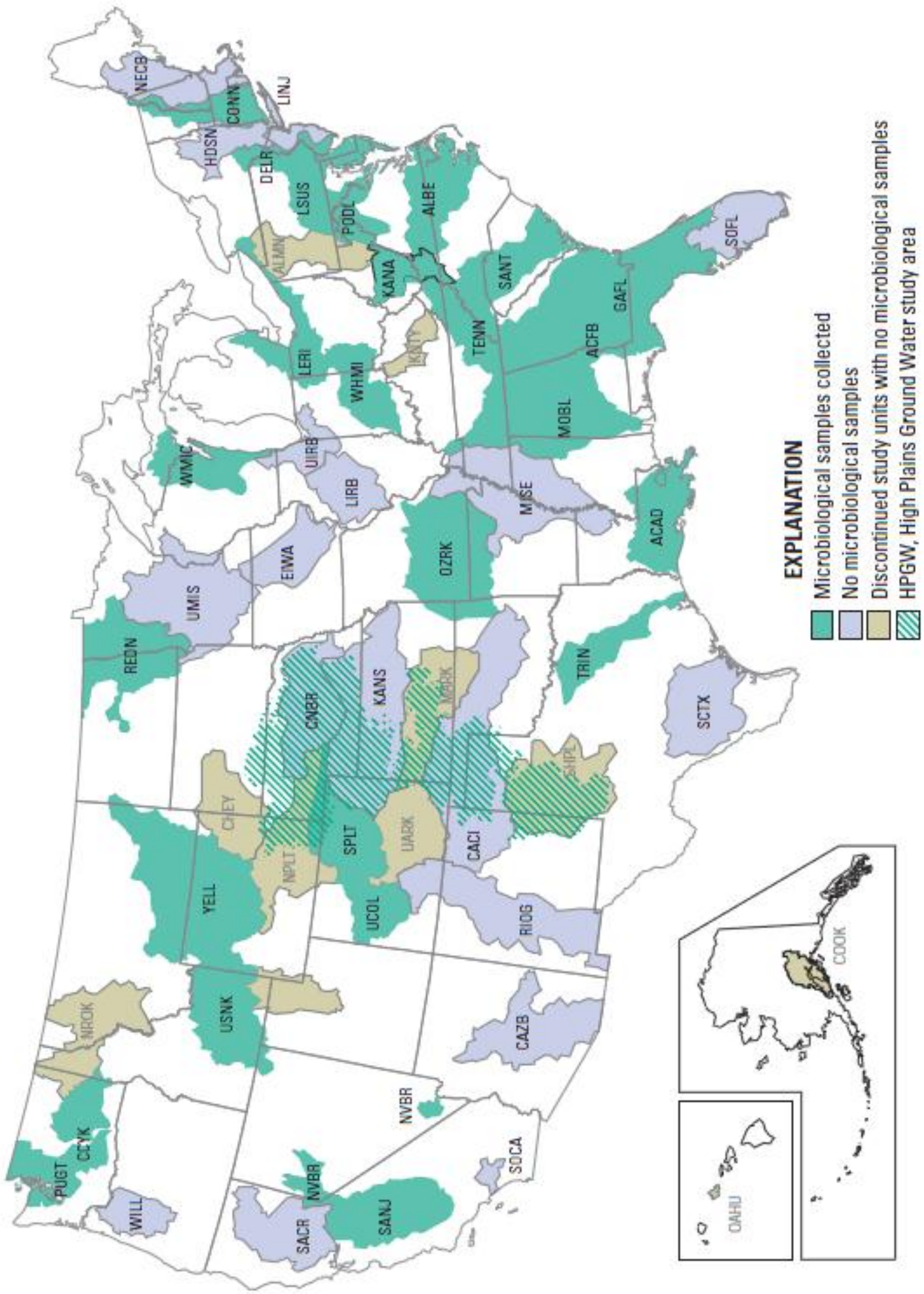


Figure 3.1-17. Locations of wells in principal aquifers that tested positive for fecal-indicator bacteria (A) and wells where fecal-indicator bacteria were not detected in samples collected for the NAWQA program (B), 1993–2004 (USGS, 2006b).

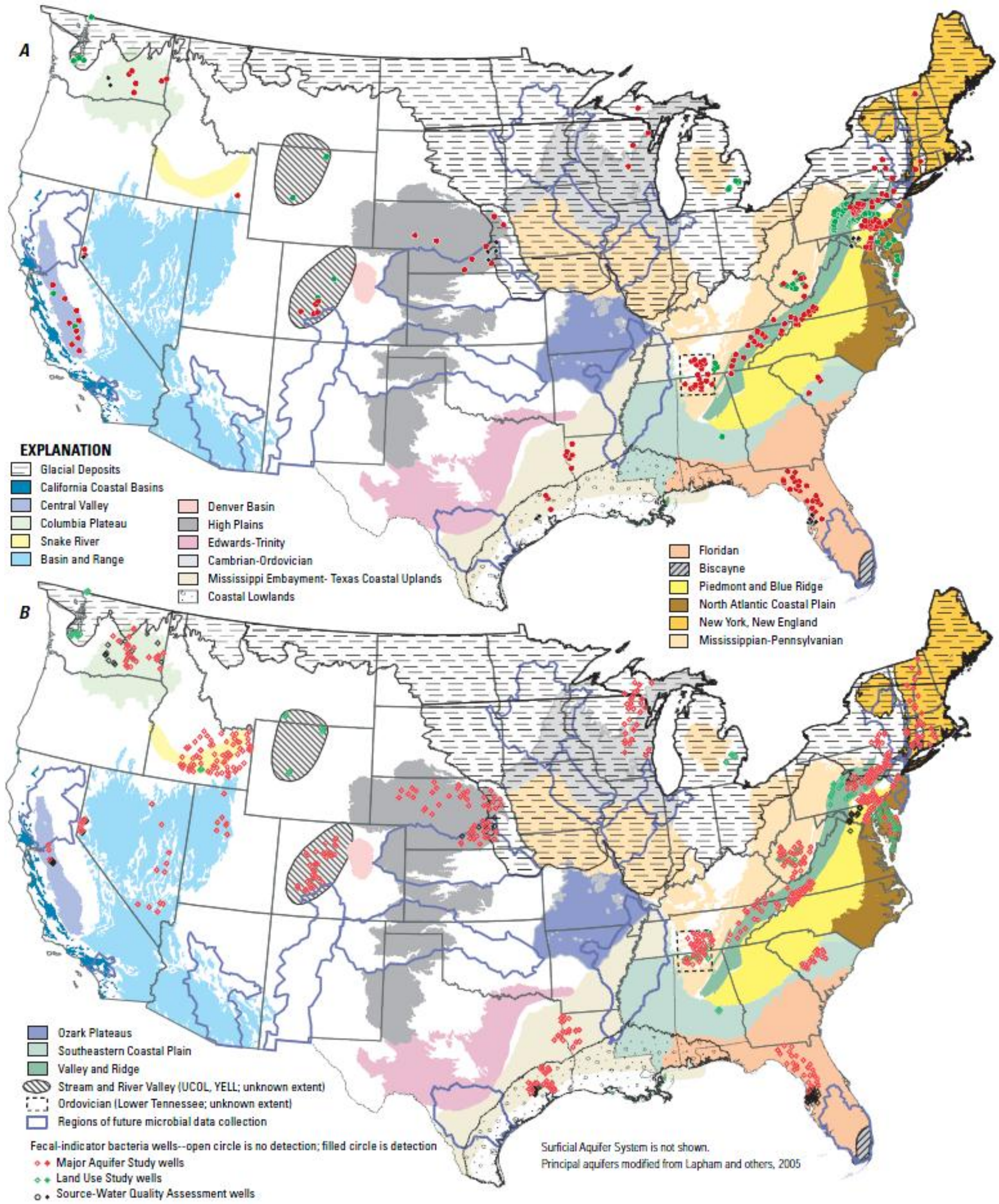


Figure 3.1-18. Percentage of wells testing positive for coliform bacteria (A), and concentrations of coliform bacteria by class of water use (B) in samples collected in MAS and SWQA wells in 22 study units (USGS, 2006b)

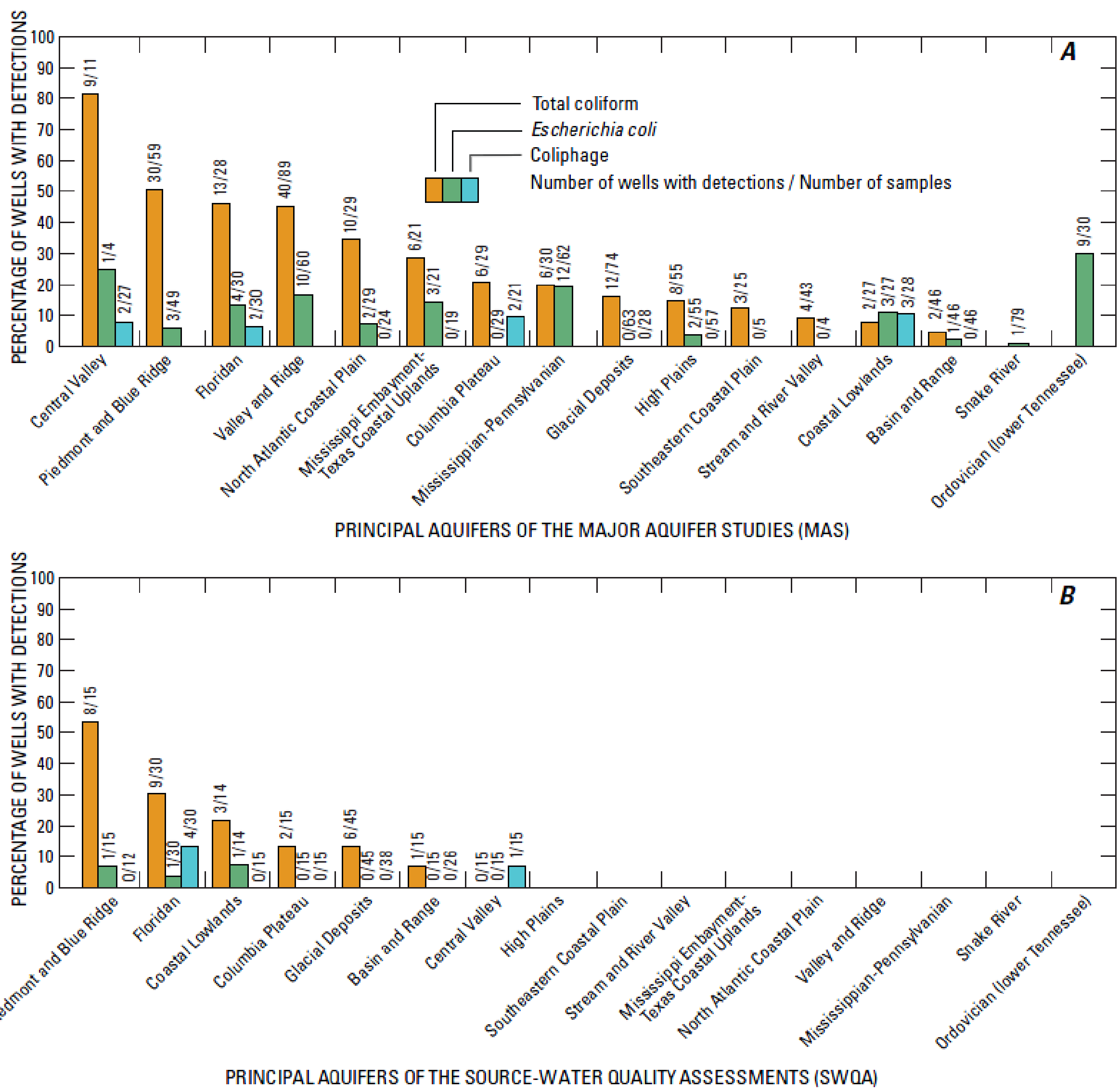
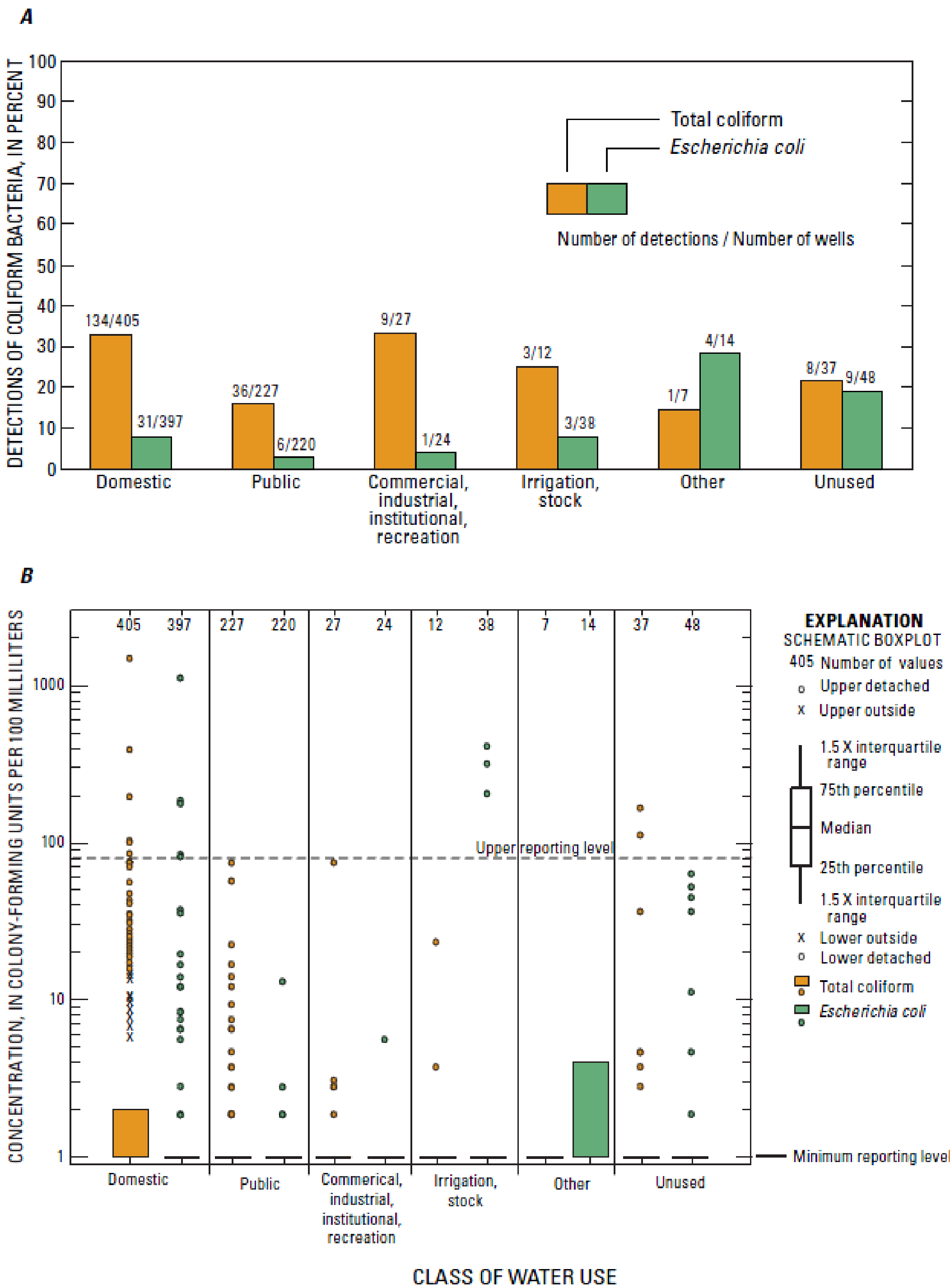


Figure 3.1-19. Percentage of detections of coliform bacteria and coliphage virus in wells sampled as part of the MAS (A) and SWQA (B) for the NAWQA program, 1993–2004 (USGS, 2006b).



3.1.3.10 Sources of Contamination Derived from Treatment of Irrigation Water

Treatment technologies to remove pathogens from irrigation water range from the conventional physical (heat pasteurization and filtration) and chemical (biocides) methods to the more advanced technologies of radiological (UV light) and ozone treatment. Each type of technology has benefits and limitations depending on the method of irrigation. For example, it would not be practicable to filter the large volumes of water associated with most crops grown under surface irrigation practices. They also have the flexibility to be used alone or in conjunction with each other to improve removal efficiencies (e.g., filtration followed by UV light treatment). A primary issue of concern regarding treatment of irrigation water with chemicals is the potential residual effect of the chemicals on beneficial microbial species (referred to as residual disinfection).

Heat Pasteurization is a method by which pathogens are destroyed by elevating the temperature of the water to 203° F for 30 seconds or more. While this method requires input of energy to heat the water, there are no residual disinfection concerns with respect to beneficial microbial species in the soil column.

Filtration is the physical removal of pathogens from the water. Filtration typically begins with a settlement process followed by forcing water through a semi-permeable membrane (or series of membranes) or micron filter media to trap all particulates above a certain size, including pathogens. Filtration requires pumps to force the water through the membranes or micron media filters and is limited by the rate at which large volumes of water can be processed. Passive flow of water through sand or other filter media is also a filtration method, less energy intensive than pumps and membranes. Maintenance required on filtering systems includes period replacement of filter media, pump maintenance and power supply. There are no residual disinfection concerns with respect to beneficial microbial species in the soil column.

Ozone (i.e., triatomic oxygen or O_3) treatment has been effectively used as a disinfectant for drinking water in Europe for the past 100 years (EPA, 1999a). Ozone is a strong oxidizer but does not remain as a component of the treated water due to its rapid decomposition; therefore, there are no concerns regarding residual disinfection of beneficial soil microbes. One drawback of ozonation is the potential oxidization of iron and manganese contained in the irrigation water causing precipitation of hydroxides formed by these elements (e.g., ferric hydroxide and manganese hydroxide). Precipitation of these compounds could result in crop deficiencies of both iron and magnesium.

Ultraviolet light treatment is being effectively utilized for sterilization of irrigation water. Limitations of UV light treatment include the clarity of the water being treated. The more suspended solids in the water column, the less effective the treatment will be. There are no known residual disinfection concerns with UV light treatment.

The use of chemicals, or biocides, is an accepted method of controlling pathogens in agricultural irrigation water. The efficacy of this treatment is dependent on the concentration of pathogens in the source water as well as the concentration of biocides. Residual disinfection of beneficial microbial species in the soil column is a potential concern associated with use of biocides to treat agricultural irrigation water.

The most common chlorine chemicals that are used in agriculture to disinfect bacteria and viruses are sodium hypochlorite, calcium hypochlorite, gaseous chlorine and chlorine dioxide. Trihalomethanes (THMs) are commonly formed when the naturally occurring organics in water react with reactive chlorine producing species such as free chlorine (Cl_2), sodium hypochlorite (NaOCl), or hypochlorous acid (HClO) (Jackman and Hughes, 2009). Under most conditions (except in the presence of unusually high bromide concentrations), chloroform is the THM produced in the highest concentrations during chlorination. THMs, which include chloroform, bromodichloromethane, dibromochloromethane, and bromoform are carcinogenic and are designated by EPA as priority pollutants. Furthermore, in most cases where more than one THM is produced from chlorination, the relative concentrations among the different compounds usually decrease with increasing bromination (chloroform > dichlorobromomethane $\geq$ chlorodibromomethane $\geq$ bromoform) (USGS, 2004).

Chloroform is one of the volatile organic compounds (VOCs) detected most frequently in both ground and surface water (Ivahnenko and Barbash, 2004). Because chloroform is a suspected human carcinogen, its presence in drinking water is a potential human health concern. Liver damage, however, is known to occur at chloroform exposures lower than those required to cause cancer; an observation that has been considered by the EPA as the basis for setting the maximum contaminant level of 80 µg/L for total THMs. Chloroform has been widely detected in national, regional, and local studies of VOCs in ground, surface, source, and drinking waters.

Although much is known about disinfection processes and factors that influence by-product formation, less is known about their fate in the environment. Most groundwater recharge is done with chlorination-disinfected wastewaters. Studies have shown that in surface waters THMs volatilize (USGS, 2002).

The EPA's Toxic Release Inventory (TRI) documents industrial releases of a broad range of anthropogenic compounds to the environment on a nationwide basis. In the U.S., these releases are reported annually and include discharges to surface water, and releases to land. According to the TRI, a total of approximately 1.6 million pounds of chloroform was released by these routes across the Nation in 2001 (USGS, 2004).

Discharges and releases of chloroform to surface water and land, as reported by the TRI, decreased from 1988 to 2001 (Figure 3.1-20 and Figure 3.1-21, respectively). Releases to land, as defined by the EPA, include disposal or burial of chemicals in landfills, application farming (in which the chemical is incorporated into the soil, a practice also known as land treatment), spills, leaks, and leaching from surface impoundments and waste piles (EPA, 1999b).

Releases of chloroform through industrial practices to surface water and land represent approximately 1.2 and 0.5 percent, respectively, of the total releases of anthropogenic chloroform to the environment. As noted earlier, most of the chloroform released to the hydrologic system by human activities is through air emissions.

Figure 3.1-20. Industrial discharges of chloroform to surface water in the U.S. from 1988 through 2001 (USGS, 2004)

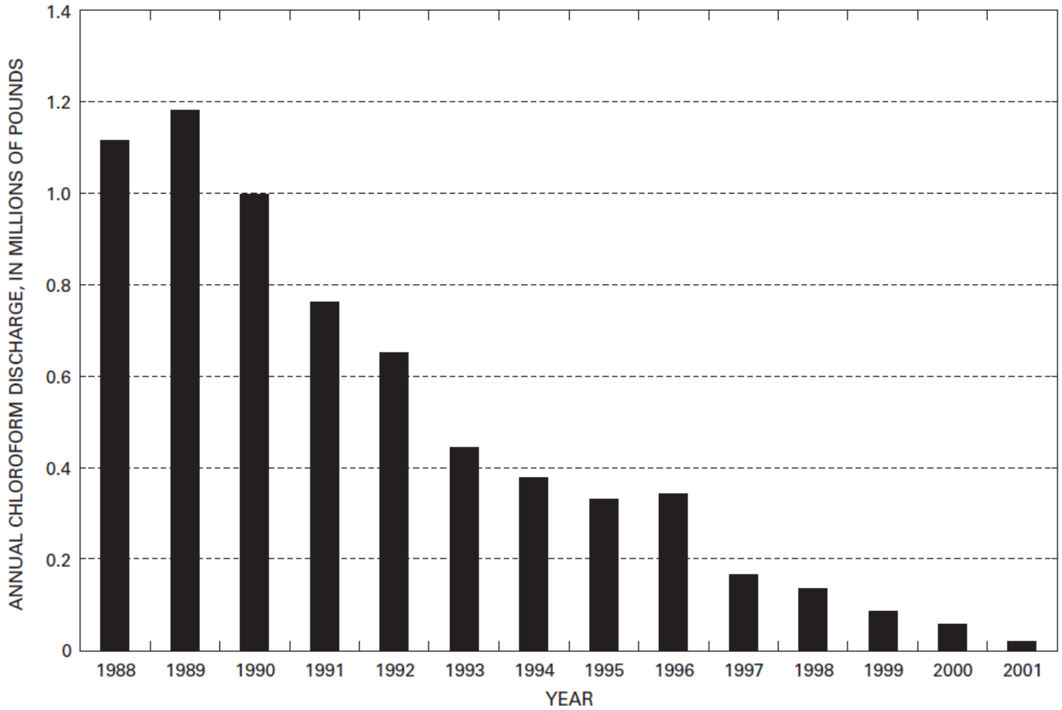
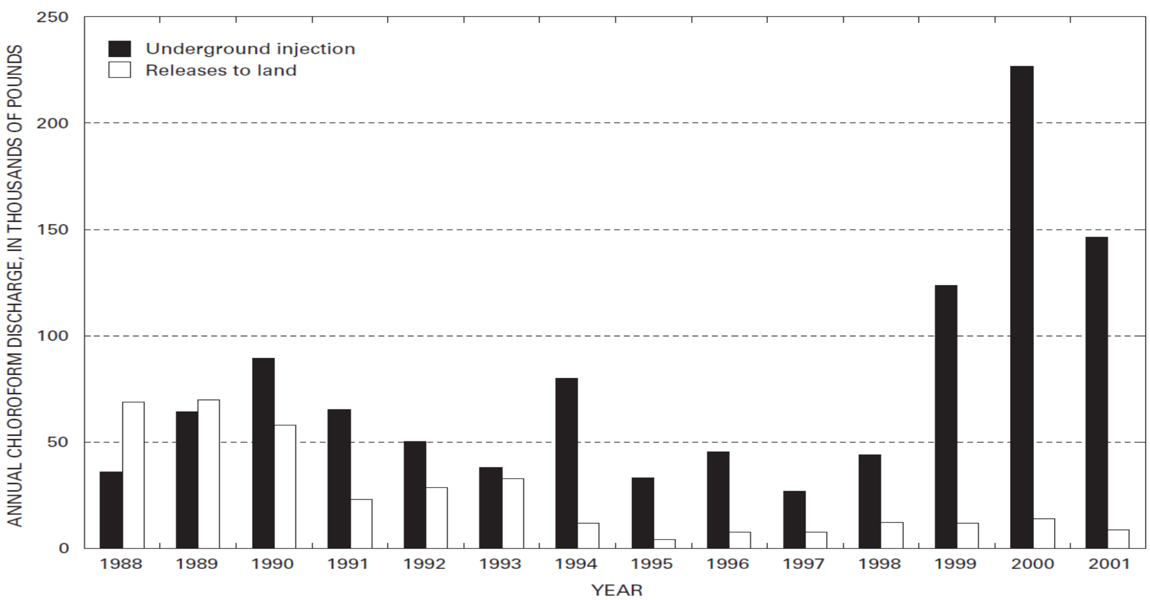


Figure 3.1-21. Industrial discharges of chloroform by underground injection and releases to land in the U.S. from 1988 through 2001 (USGS, 2004)



A national water quality assessment performed by the USGS was designed to provide additional information on the frequency of occurrence, concentration, and temporal variability of THMs in source water used by community water systems (CWSs) (USGS, 2003b). This study found that THMs were detected in 47.8 percent of the CWSs supplied by surface water. Total THM concentrations of the compound, however, were typically less than the Maximum Concentration Limit (MCL).

In the studies that compared land-use settings, frequencies of detection of chloroform were higher beneath urban and residential areas than beneath agricultural or undeveloped areas (Ivahnenko and Barbash, 2004).

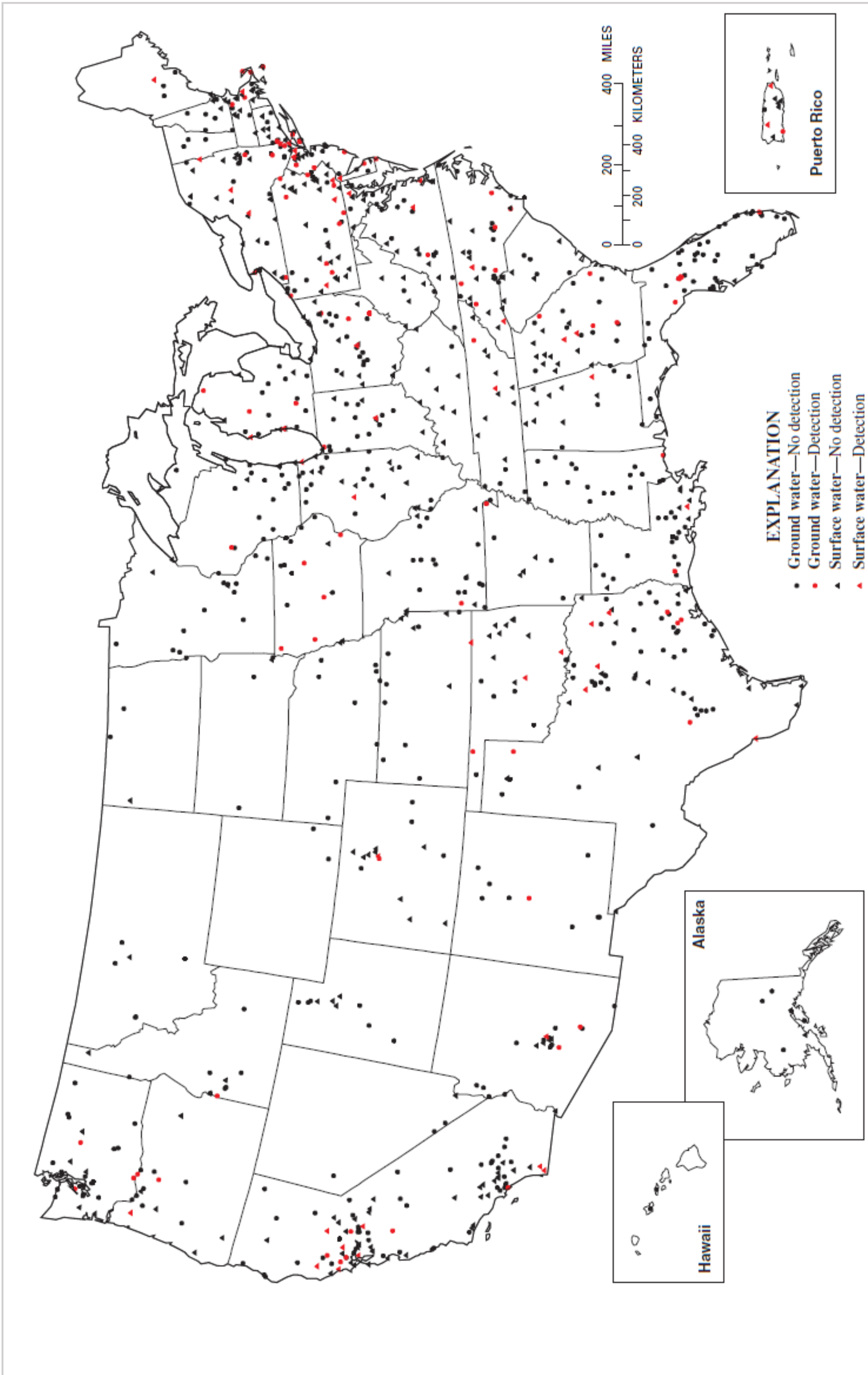
The frequent occurrence of THMs in reservoir source waters was determined to be an artifact of disinfection and the recycling of chlorinated water to these reservoirs. All CWSs with frequent occurrence of THMs served by a reservoir indicated that chlorine was added to waters for various reasons and that the chlorinated water was then released back to, or upstream of, the reservoir or lake that was sampled.

Based on its high volatility, chloroform is expected to be present mostly in the vapor phase following its release to the atmosphere). However, because the compound also is relatively water soluble, some removal of atmospheric chloroform is expected to occur during rainfall events, as demonstrated by the fact that it has been detected in precipitation (USGS, 2004). Since chloroform is relatively volatile it is expected that much of the chloroform in surface waters is likely to volatilize soon after its release.

As might be anticipated from fundamental principles of mass transfer (USGS, 2004), the rate of chloroform volatilization from streams increases with increasing water velocity, as well as with decreasing stream depth. Also in accord with theory is the observation noted previously that chloroform volatilization rates, like the Henry's Law constant, increase with increasing temperature (USGS, 2004).

Figure 3-1.22 summarizes data on chloroform detections in untreated groundwater from a variety of studies ranging in scale from individual urban areas to the entire U.S. (USGS, 2004). For all of the studies listed, chloroform was the VOC detected most frequently in groundwater. However, with the exception of the investigation by Squillace et al. in 1999, all of the sampled groundwater contained Total THM (TTHM) concentrations that were less than the EPA MCL of 80 μg/L for TTHMs (USGS, 2004). Figure 3.1-22 presents data on THM detections in ground and surface water from the national study conducted by S. J. Grady in 2003 (USGS, 2004).

Figure 3.1-22. Detections of total trihalomethanes at or greater than 0.2 micrograms per liter in ground and surface waters sampled for the American Water Works Research Foundation national study (USGS, 2004) .



3.1.3.11 Groundwater Depletion

A shift from surface water resources to pumping groundwater has been shown to stress aquifer(s) and increase groundwater depletion. The USGS has completed a study that evaluates long-term cumulative depletion volumes in 40 separate aquifers by using information from the literature and from new analyses (USGS, 2013). USGS (2013) has calculated depletion using calibrated groundwater models, analytical approaches, or volumetric budget analyses for multiple aquifer systems. Based on these analyses the estimated groundwater depletion in the U.S. during 1900–2008 totals approximately 1,000 cubic kilometers (km^3). Furthermore, USGS (2013) notes that the rate of groundwater depletion has increased markedly since about 1950, with maximum rates occurring during the most recent period (2000–2008) when the depletion rate averaged almost 25 km^3 per year (compared to 9.2 km^3 per year averaged over the 1900–2008 timeframe). The relevance of documenting the areas of groundwater depletion is that these would be the most affected by shifting of irrigation sources from surface water to groundwater. As shown in Figure 3.1-23, there are several geographical areas where large scale groundwater depletion is evident over agricultural areas with a high percentage of the covered farms (Figure 3.1-23). Significant dewatering is evident over the Central, Coachella and Death Valleys of California; Alluvial Basins of Arizona; and the Columbia Plateau in southeastern Washington and northeastern Oregon.

Unless otherwise noted, the summary of groundwater development that follows was provided by L. F. Konikow (USGS, 2013).

The Central Valley of California is a major agricultural area in a large valley with an area of about 52,000 km^2 includes the Sacramento Valley, the San Joaquin Valley, and the Tulare Basin (Figure 3.1-23). Streamflow is an important factor in the water supply of the valley, and is entirely derived from precipitation in the Sierra Nevada to the east and in parts of the Klamath Mountains in the north.

Groundwater development began in the Central Valley around 1880, and by 1913, total annual well pumpage for the Central Valley was about 0.44 km^3. A sharp increase in pumpage was observed during the 1940s and 1950s, and by the 1960s and 1970s averaged about 14.2 km^3/yr. By the 1980s there were approximately 100,000 high-capacity wells in the Central Valley for either irrigation or municipal supply. In the late 1960s, increased importation of surface water caused groundwater pumpage to decline. However, a drought during 1976–77 decreased the availability of surface water, and groundwater pumpage increased to a maximum of 18.5 km^3 in 1977. During Heavy groundwater use in parts of the Central Valley has caused continuous water-level declines. In parts of the San Joaquin Valley and Tulare Basin, water levels had declined nearly 122 m, depleting groundwater from storage and lowering water levels to as much as 30 m below sea level. Long-term water-level records in some wells indicate that water levels were already declining at substantial rates when water levels were first observed as early as the 1930s. The extensive groundwater pumping caused changes to the groundwater flow system, changes in water levels, changes in aquifer storage, and widespread land subsidence in the San Joaquin Valley, which began in the 1920s.

Because of the 2013 drought, Central Valley irrigators face about a one-third reduction or 6.5 million acre feet (maf) in surface water deliveries this growing season, compared with normal years (USGS, 2013). Growers are likely to increase groundwater pumping to replace about 5 maf of this shortage, leaving 1.5 maf or about 7.5 percent of normal irrigation water use in the Central Valley (USGS, 2014b). In 119 years of recorded history, 2013 was the driest calendar year for the State of California (USGS, 2013).

The Southwest alluvial basins include an area of 212,000 km^2 in south-central Arizona and small parts of adjacent States (Figure 3.1-23). Development of water resources was principally for agriculture and was started in the 1860s. Groundwater withdrawals began in the late 1800s, and by 1942, groundwater pumpage totaled 2.1 km^3/yr. Rapid agricultural growth followed, and by 1952, groundwater pumpage was 4.7 km^3/yr. During 1950–80, groundwater pumpage averaged more than 5.9 km^3/yr. The withdrawals greatly exceeded recharge, so large water-level declines resulted, generally in the range of 15 to 140 m, but more than 180 m in places. This also resulted in land subsidence. By 1980, a total of 227 km^3 of groundwater had been withdrawn. More than 50 percent of this volume (113.5 km^3) was removed from aquifer storage.

The Columbia Plateau aquifer system in the northwestern U.S. underlies 131,000 km^2 of southeastern Washington, northeastern Oregon, and northwestern Idaho (Figure 3.1-23). It is a productive agricultural area, and a large quantity of water used in the region is derived from local and imported surface-water sources. Groundwater usage is substantial, however, and the Columbia Plateau aquifer system is the primary source of groundwater in the region. Water levels in localized areas within the Columbia Plateau aquifer system have risen as much as 90 meters due to recharge from surface-water imports in areas of heavy irrigation. Groundwater pumping in areas where surface-water imports are not widely used has led to water-level declines of up to about 90 meters (USGS, 2013). Approximately 80 percent of groundwater withdrawals are used for irrigation purposes, and the remainder is primarily used for municipal and industrial supply.

The major use of water withdrawn in the Columbia Plateau region is for irrigation purposes, and most of the irrigation in the region is supplied by local and imported surface waters. Between 1945 and 1984, about 70 percent of the total water withdrawals were from surface-water sources and that proportion increased to about 74 percent between 1985 and 2007. The water added to the aquifer from percolation of excess irrigation water has significantly expanded the saturated zones in the overburden aquifer and the uppermost permeable basalt unit, which has raised groundwater levels in these areas close to the land surface.

Changes in pump technology and the switch from flood irrigation to sprinkler irrigation greatly increased groundwater use. Nearly 0.22 km3/yr of groundwater was pumped during 1960; nearly 1.2 km3/yr was pumped during 1979. About 1.4 km3/yr was pumped on average between 1984 and 2007.

Water levels rose an average of 12 meters in the overburden aquifer, and water-level rises were as great as 60 meters in areas of heavy irrigation by 1985, though water-rises had stabilized in many areas between the mid-1960s and 1970s. Declines in water levels, however, occurred in much of the deeper basalt units. Water-level records for selected wells showing more recent trends indicate that the rates of change of water levels were often relatively linear from the 1970s through 2000.

In Florida, a thick sequence of carbonate rocks (limestone and dolomites) make up the Floridan aquifer system that underlie all of Florida, southern Georgia, and small parts of adjoining South Carolina and Alabama (USGS, 2003a). In addition to water supply, the Floridan is being used for aquifer storage and recovery systems, in which freshwater is injected into more saline zones of the aquifer and stored for later use. Groundwater withdrawals have resulted in long-term regional water-level declines of more than 10 ft. over broad areas of the flow system (Figure 3.1-24). In these areas groundwater withdrawals have reversed the generally seaward direction of groundwater flow, creating the potential for saltwater intrusion from the Gulf of Mexico or Atlantic Ocean or from deep parts of the aquifer that contain saltwater.

The transition between freshwater and saltwater in the Floridan aquifer system is illustrated by the distribution of chloride in water in the Lower Floridan aquifer (Figure 3.1-25) where much of the Lower Floridan aquifer contains water with chloride concentrations that exceed the 250 milligrams per liter (mg/L) drinking-water limit, which has limited the aquifer's use for water supply.

Figure 3.1-23. Map of the U.S. showing cumulative groundwater depletion, 1900 through 2008, in 40 assessed aquifer systems or subareas. (USGS, 2013)

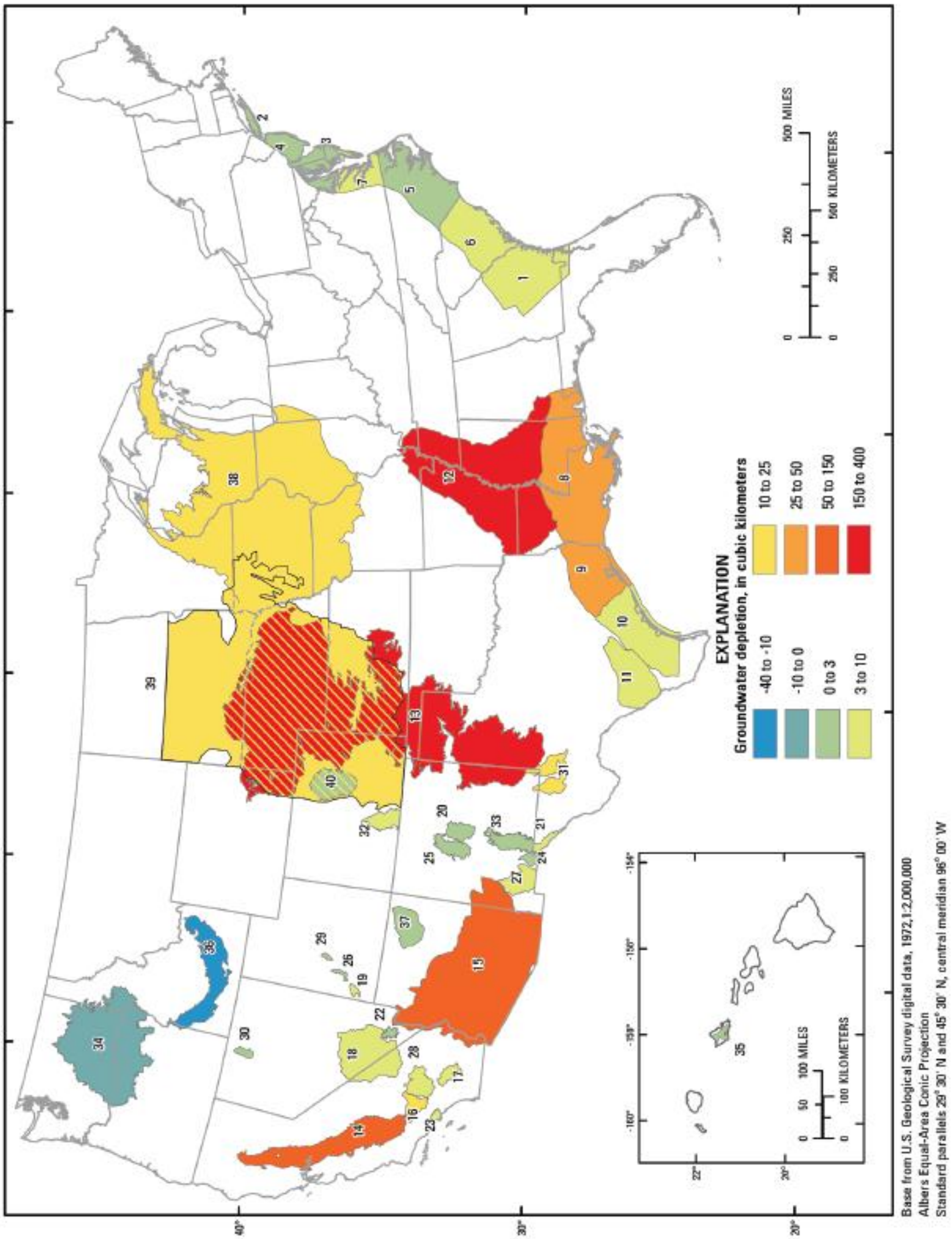


Figure 3.1-24. Areas of large, regional water-level declines in the Floridan aquifer system (USGS, 2003a)

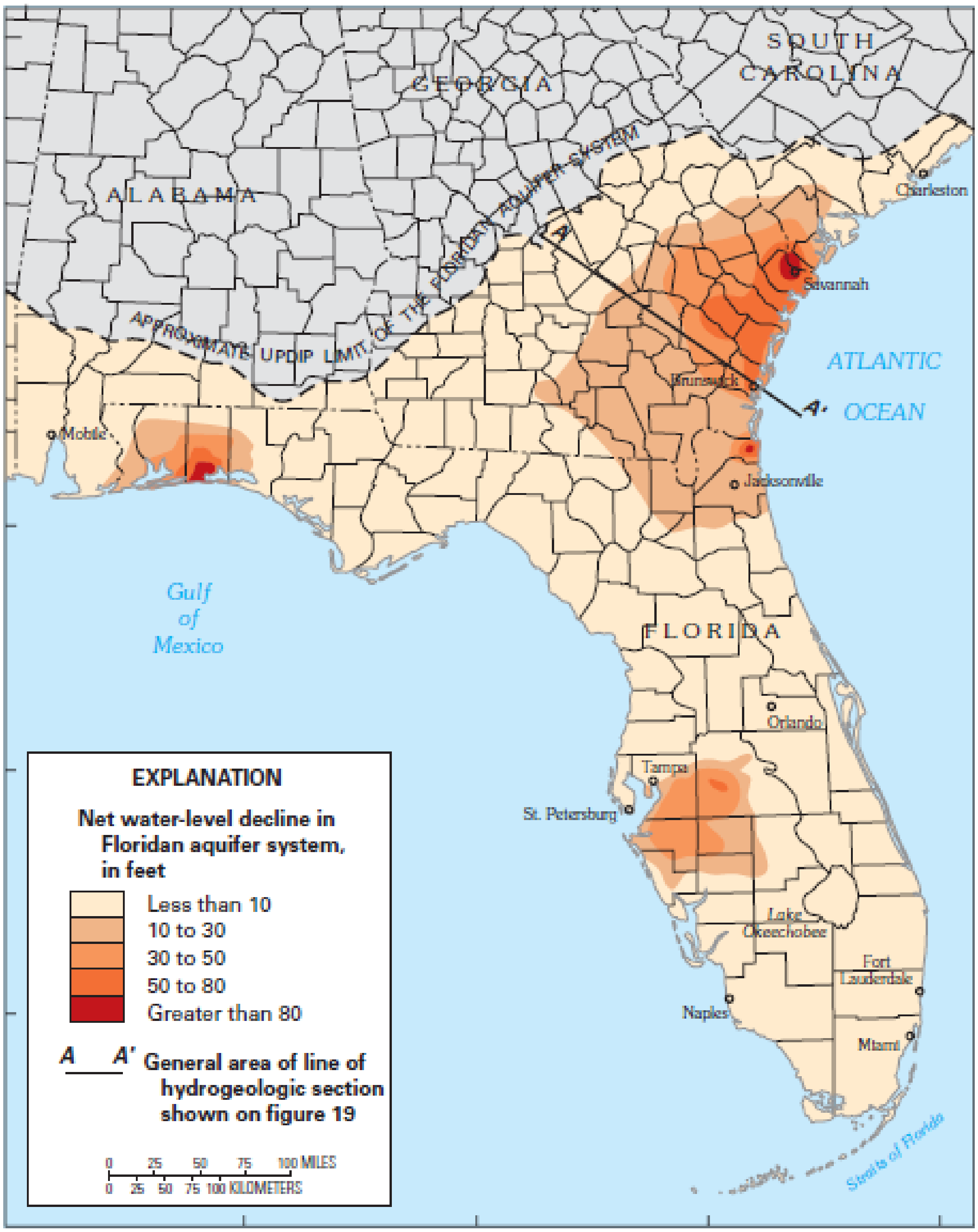
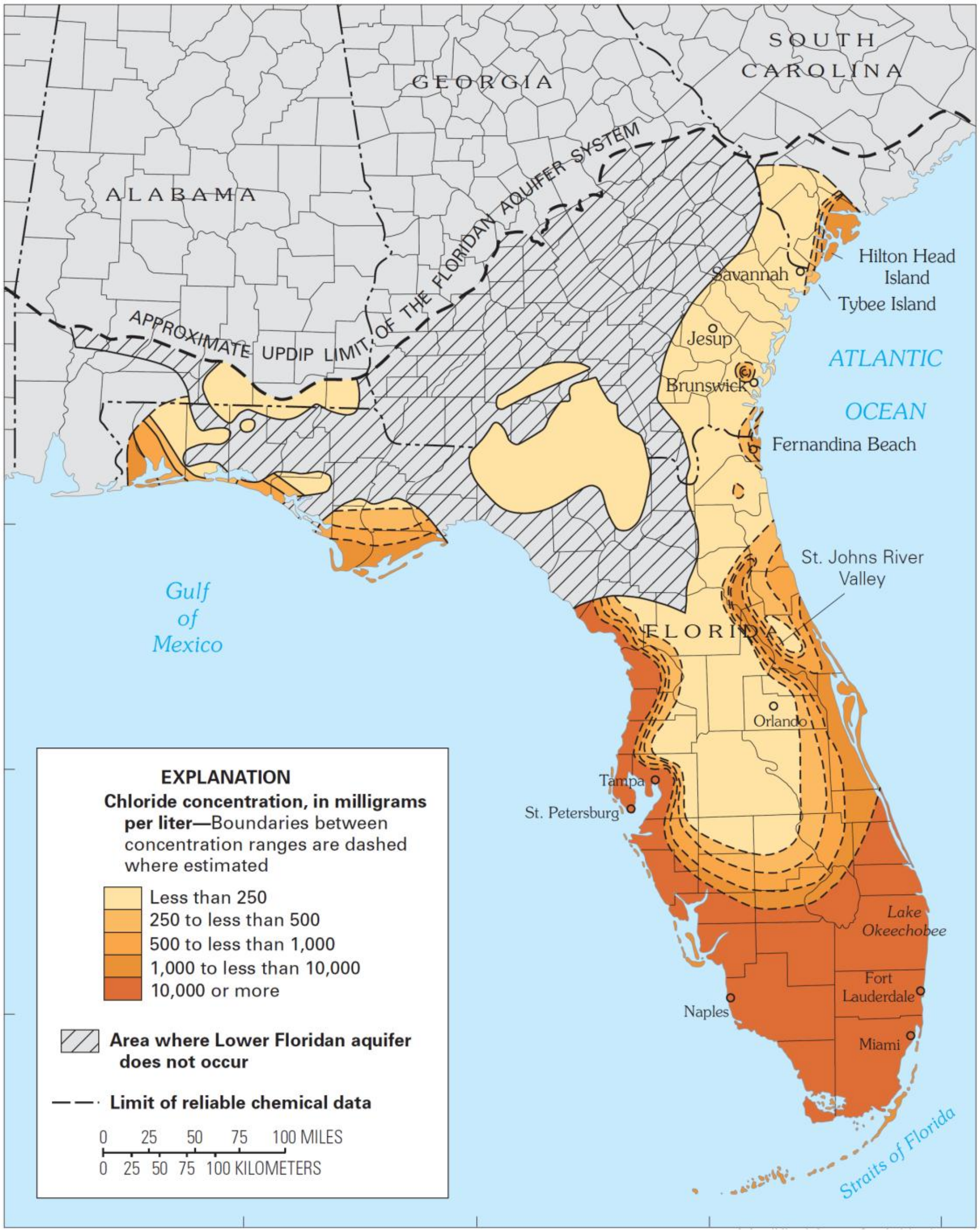


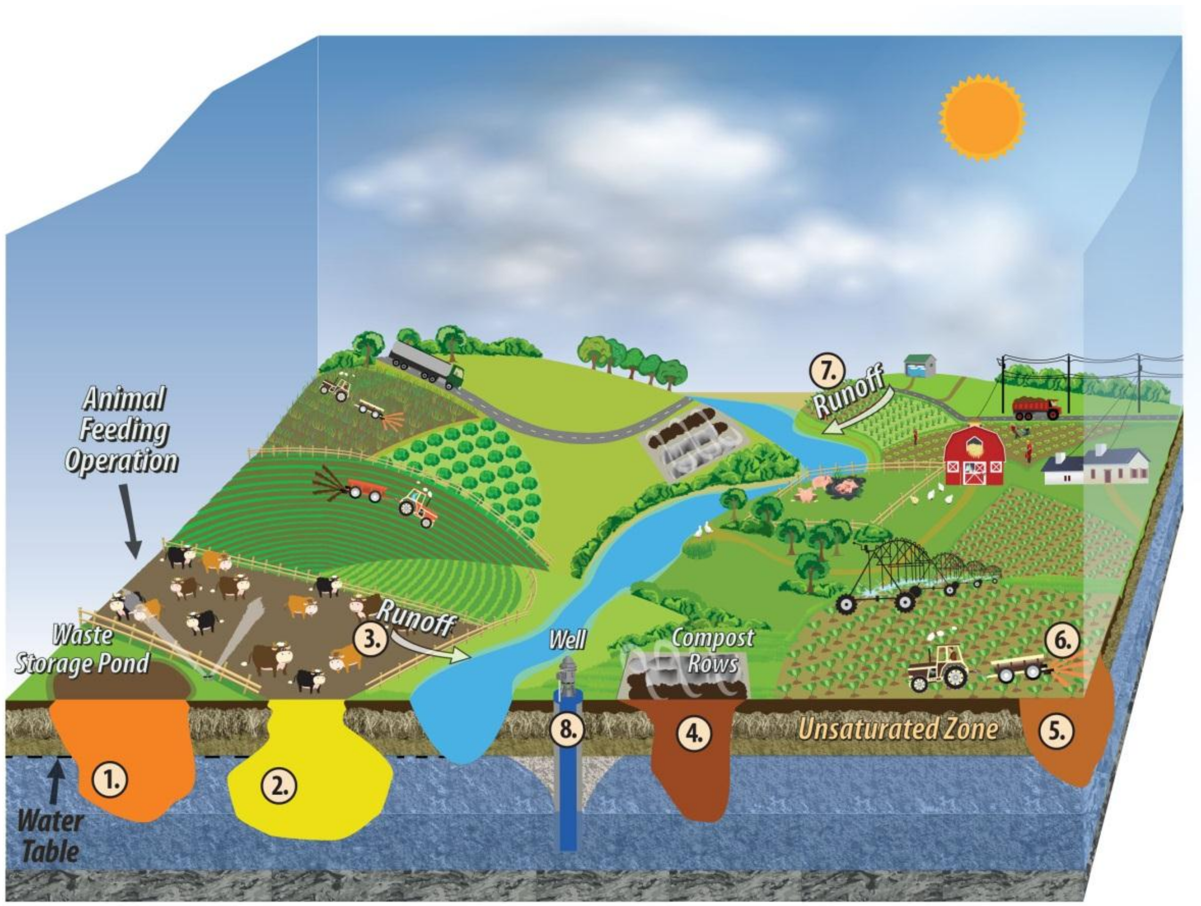
Figure 3.1-25. Chloride concentrations in water from the Lower Floridan aquifer (USGS, 2003a)



<u>Conceptual Site Model</u>

Figure 3.1-26 represents the types of activities on a working produce farm that could affect water resources.

Figure 3.1-26. Conceptual site model for water resources



The Key below contains text that applies to numbered key components of the diagram.

Key to numbered illustrations within Conceptual Site Model (Figure 3.1-26)	
1	● Infiltration from waste storage ponds may lead to groundwater contamination.
2&3	● Wastes concentrated in animal feeding operations may infiltrate to groundwater or be carried in surface water runoff to streams.
4	● Leaching of compost may result in localized sources of groundwater contamination.
5&6	● Fertilizer and pesticides can migrate to groundwater.
7	● Erosion of soil and runoff of fertilizer from cultivated or fallow fields may be a source of surface water contamination.
8	● Groundwater pumping will lower the water table and may lead to reduced stream flow.

3.2 Biological and Ecological Resources

3.2.1 Definition of the Resource

Biological and Ecological Resources include vegetation, terrestrial, avian, and aquatic species, including protected species, within agricultural and allied lands and adjacent "off-farm" areas within the United States. Vegetation includes both native and non-native plant species, such as major agricultural crops, invasive species, and noxious plant species. Wildlife species include both native and non-native species. Wetland resources are also discussed in this section.

Vegetation

Vegetation resources throughout the Nation provide valuable environmental, economic, and recreational functions. Environmental functions include but are not limited to the provision for requisite habitats for wildlife, erosion control and water quality enhancements, and air quality enhancements. The presence of vegetation also provides substantial economic benefits (e.g., lumber) and recreational opportunities in the form of natural areas for hiking, camping, wildlife observation, and hunting.

The vegetation resources most associated with farming operations are generally located adjacent to or abutting the production fields. On a national level, this vegetation is varied and may include hedgerows between production fields, large forested corridors, wet meadows not suited to commercial agriculture, and buffers adjacent to stream channels and lakes.

Non-native vegetation may become a nuisance in certain situations and its presence may have a detrimental effect on the local ecosystem. If vegetation becomes invasive, it changes the vegetated community and possibly no longer provides the life requisites for native wildlife species. The Federal government and many states have enacted laws and regulations addressing the impacts of non-native plant species, including the development of lists of nuisance and invasive plant species. Farming operations by their very nature are often plagued by nuisance and invasive plant species adjacent to and within their production fields.

Wildlife

Wildlife species are important participants in the web of life; fulfilling roles necessary for healthy and successful ecosystems. Many of these species are protected by a patchwork of Federal, State, and local laws designed to manage the overall environmental health and economic sustainability of wildlife resources. Because most wildlife species are mutually reliant and interdependent on other species within the ecosystem, the health of the entire system is important.

Mammals are present in all habitat types throughout the U.S., including agricultural lands. Farm operations and their associated habitats provide shelter, food, water, and breeding opportunities for many species of mammals. Some species have small ranges and may not leave the areas that are actively farmed, while other species have much larger territories and will use farmed areas for just a portion of their life requisites.

There are more than 800 species of birds in the U.S. (Audubon, 2014). These birds have varied sizes of home ranges, dependent on the species. Farms and their adjacent habitats provide shelter, food, water, and nesting for many of these bird species.

Many avian species are protected by various Federal and State laws. The Migratory Bird Treaty Act of 1918 (MBTA, 16 U.S.C. § 703 et seq.) established the Federal prohibition, unless permitted by regulations, to "pursue, hunt, take, capture, kill, attempt to take, capture or kill, possess, offer for sale, sell, offer to purchase, purchase, deliver for shipment, ship, cause to be shipped, deliver for transportation, transport, cause to be transported, carry or cause to be carried, or receive for shipment, transportation, carriage, or export, any migratory bird, and any part, nest, or egg of any such bird" (16 U.S.C. § 703(a)). Non-migratory bird species and their habitats are also protected by various Federal and State laws.

Fish species and other aquatic organisms are present throughout the U.S., including in farm environments. In addition to being a valued part of the food web, many fish and other aquatic species are economically valuable. Amphibians, reptiles, and invertebrate species are also present throughout the U.S., including in farm environments.

<u>Threatened and Endangered Species</u>

Protected species are plants and animals listed (i.e., endangered or threatened) by the Federal government as needing protection because of their population status. The Endangered Species Act of 1973 (ESA, 16 U.S.C. § 1531 et seq.) prohibits the "taking" of threatened or endangered species without a permit. The term "take" means "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct" (16 U.S.C. § 1532(19)).

An endangered species classification is provided to an animal or plant in danger of extinction within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. § 1532(6)). A threatened species classification is provided to any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. § 1532(20)). The number of animal species listed as either endangered or threatened in the U.S. is 671 and the number of plant species listed as either endangered or threatened in the U.S. is 879 (USFWS, 2014a). Table 3.2-1 depicts the number of federally listed threatened and endangered plant and animal species by state.

As discussed in Chapter 4 (subsection for *Resource components not included for review in the EIS),* FDA, in the PS PR, refers growers of produce to the FWS's Endangered Species Web site and the Information, Planning, and Conservation System Web site. FDA further recommends that a grower coordinate with its local FWS office on any activity that could potentially affect listed species or critical habitat (79 Fed. Reg. 58434 at 58464). See Chapter 4 for additional information on this issue.

Table 3.2-1. Federally-listed Plant and Animal Species by State, 2014 (USFWS, 2014b)

State	Total Plants	Total Animals	Total Plants and Animals	State	Total Plants	Total Animals	Total Plants and Animals
Alabama	19	109	128	Montana	3	10	13
Alaska	1	21	22	Nebraska	5	15	20
Arizona	21	45	66	Nevada	10	35	45
Arkansas	6	31	37	New Hampshire	3	13	16
California	188	136	324	New Jersey	7	18	25
Colorado	16	19	35	New Mexico	13	40	53
Connecticut	3	16	19	New York	11	23	34
Delaware	7	15	22	North Carolina	27	42	69
Florida	58	71	129	North Dakota	1	7	8
Georgia	24	54	78	Ohio	6	28	34
Hawaii	368	69	437	Oklahoma	3	20	23
Idaho	4	16	20	Oregon	19	50	69
Illinois	10	32	42	Pennsylvania	6	22	28
Indiana	5	32	37	Rhode Island	3	14	17
Iowa	5	16	21	South Carolina	21	27	48
Kansas	3	18	21	South Dakota	1	10	11
Kentucky	9	44	53	Tennessee	20	83	103
Louisiana	4	29	33	Texas	31	75	106
Maine	3	14	17	Utah	25	18	43
Maryland	10	20	30	Vermont	3	7	10
Massachusetts	5	21	26	Virginia	18	59	77
Michigan	8	16	24	Washington	12	46	58
Minnesota	4	12	16	West Virginia	6	22	28
Mississippi	4	48	52	Wisconsin	7	14	21
Missouri	10	29	39	Wyoming	4	12	16

Figure 3.2-1 and Figure 3.2-2 depict the numerical range of listed plant and animal species that occur by state.

Figure 3.2-1. Map of the U.S. depicting the numerical range of Threatened or Endangered Plant Species by State.

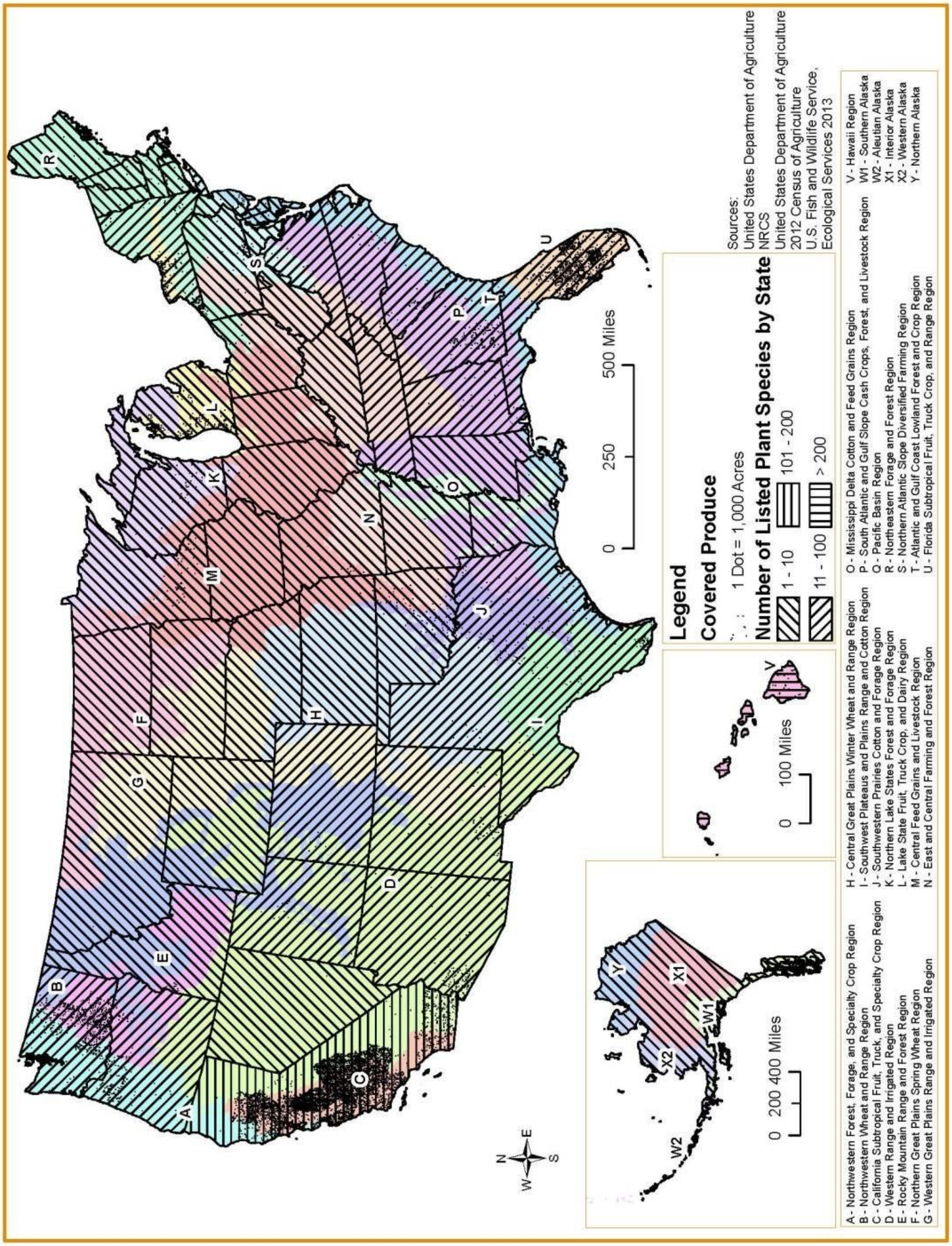
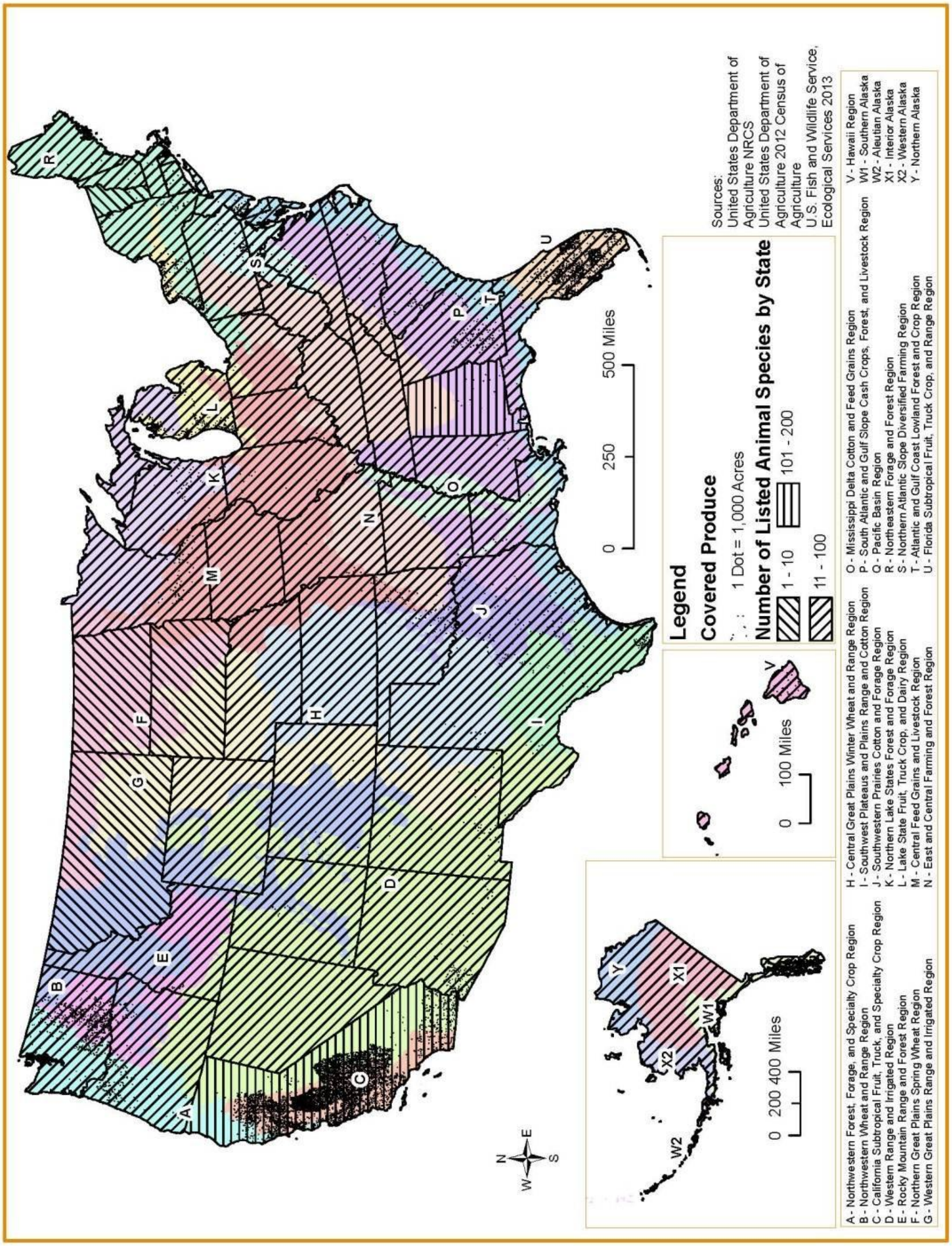


Figure 3.2-2. Map of the U.S. depicting the numerical range of Threatened or Endangered Animal Species by State.



Wetlands

Wetlands are valuable resources that perform many functions, including but not limited to, providing habitat for plants and many forms of wildlife, clean water, and flood protection. Wetlands usually occur at the transition between an aquatic system and a terrestrial system and often have saturated soil for all or most of the growing season. There are many types of wetlands in the U.S., including marshes, swamps, and bogs.

The CWA established the basic structure for regulating discharges of pollutants into the waters of the U.S., including wetlands, and regulating quality standards for surface waters. The CWA requires a permit be obtained prior to impacting a jurisdictional wetland or other water of the U.S. (33 U.S.C. § 1344). Many states also have laws protecting wetland resources.

In 2009, it was estimated that 110.1 million acres of wetlands existed in the Conterminous U.S. (USFWS, 2011). It has been estimated that over 220 million acres of wetlands existed in the Conterminous U.S. in the 1600s, meaning that over 50% of the original wetlands have been drained or converted to other uses between the 1600s and 2009 (EPA, 2013a). Current wetland protection measures have slowed the conversion of wetlands to other land use types (EPA, 2013a).

3.2.2 Regulatory Oversight

Statutory and regulatory requirements at the Federal and State levels are often associated with the use and management of biological and ecological resources. Federal laws include but are not limited to NEPA, the ESA, the MBTA, and the CWA. Federal agencies responsible for the management of biological and ecological resources include, the EPA, USFWS, National Oceanic and Atmospheric Administration/National Marine Fisheries Service (NOAA/NMFS), and the U.S. Army Corps of Engineers (USACE). Each State has its own laws and regulations pertaining to the biological and ecological resources within its borders.

3.2.3 Current Background Conditions

With the exception of federally listed threatened and endangered species, inventories of vegetation and animal species do not exist on a national level. Some State, regional, and local areas throughout the U.S.; maintain lists of flora; however, a comprehensive national database of plant species does not exist. Similarly, animal species data has not been compiled on a national basis. Due to the lack of a comprehensive data set on the presence and distribution of non-listed species, a rigorous analysis of this resource type is not possible.

The National Wetland Inventory, through the USFWS, and several State natural resource agencies maintain inventories of wetland resources throughout the nation. Much of this data is provisional and requires that actual site investigations occur to confirm the presence or absence of wetland resources. In addition, not all wetland resources are jurisdictional (i.e., subject to regulatory control); therefore, any quantities of wetland resources present on a national level, are estimates.

Biological and ecological resources and agricultural water

Biological and ecological resources require water to be available for their sustainability. Water is a life requisite and any change in the quantity or quality of available water may pose a threat to these resources. Once water is used for agricultural purposes, a portion of that water may re-enter the groundwater and surface water ecosystems. The quantity, quality, and fate of the used agricultural water on a local level may be altered from current conditions to a level that changes the interactions of biological and ecological resources with available water supplies.

Biological and ecological resources and biological soil amendments

The use of biological soil amendments in agricultural operations may add nutrients and possibly other contaminants to the ecosystem. If excess nutrients or other contaminants are allowed to enter surface or groundwater, the ecosystem may be altered, favoring one group of organisms over another. However, the addition of organic matter to the soil that typically comes from the use of biological soil amendments generally improves soil health, arability, and tilth, allowing water to soak into the soil and minimizing runoff of agricultural water or precipitation. This improvement in soil quality, and the associated possible reduction in runoff and sedimentation of surface waters, typically contributes to ecosystem health.

Biological and ecological resources and domesticated and wild animals

Agricultural operations are not natural ecosystems (i.e., they are intensively manipulated for the benefit of humans); however, they do provide habitat and other life requisites for many species of plants and animals. The intrusion (grazing) of domesticated and wild animals into farming operations may provide feeding opportunities superior to those found outside of farmed areas, for some species, at specific times of the year.

Sprouts are typically grown in contained facilities away from direct contact with the types of biological and ecological resources discussed in this section. The use of agricultural water for the production of sprouts and the disposal of the water after its use are addressed in other resource discussions.

Biological and ecological resources and businesses covered by the PS PR

The farming operations to be exempted by the PS PR constitute a very small portion of the total farmed acreage of the United States. Therefore, most of the currently farmed acreage will continue to interact with the biological and ecological resources of the nation.

3.3 Soils

3.3.1 Definition of the Resource

A key issue identified for soil resources is maintenance of the natural biological integrity of the soil, which can be interpreted as maintenance of soil health. A primary public concern of agricultural soil health is the reduced use of manure as a nutrient source for soil and the increase use of nitrogen-based synthetic soil amendments. The NRCS in its presentation "Unlock the Secrets in the Soil" (USDA NRCS, 2013a) describes soil health as the continued capacity of the soil to function as a vital living ecosystem that sustains plants, animals and humans. These functions are further identified as follows:

- **Nutrient Cycling** - Soil stores, moderates the release of, and cycles nutrients and other elements. During these biogeochemical processes, analogous to the water cycle, nutrients can be transformed into plant available forms, held in the soil, or even lost to air or water.

- **Water Relations** - Soil can regulate the drainage, flow and storage of water and solutes, which includes nitrogen, phosphorus, pesticides, and other nutrients and compounds dissolved in the water. With proper functioning, soil partitions water for groundwater recharge and for use by plants and soil animals.

- **Biodiversity and Habitat** - Soil supports the growth of a variety of plants, animals, and soil microorganisms, usually by providing a diverse physical, chemical, and biological habitat.

- **Filtering and Buffering** - Soil acts as a filter to protect the quality of water, air, and other resources. Toxic compounds or excess nutrients can be degraded or otherwise made unavailable to plants and animals.

- **Physical Stability and Support** - Soil has the ability to maintain its porous structure to allow passage of air and water, withstand erosive forces, and provide a medium for plant roots. Soils also provide anchoring support for human structures and protect archeological treasures.

3.3.2 Regulatory Oversight

There are few Federal regulations that govern agricultural soil and conservation. The Farmland Protection Policy Act (FPPA) (7 U.S.C. §§ 4201-4209) was enacted in order to protect farms that may be subjected to Federal programs from the unnecessary and possible irreversible conversion of farmland to nonagricultural purposes.[5]

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[5] Note that FDA's proposed rule does not require farms to be converted in any way from their current agricultural use.

3.3.3 Current Background Conditions

The source of basic scientific understanding and information used to develop and support the analysis of soil resources include:

- Databases and research activities from USDA Agriculture Research Service and Western Center for Food Safety at University of California Davis;
- USDA Cooperative Research and Extension Services;
- Research activities from land grant universities (Cornell, Purdue, Michigan State, University of Minnesota etc.); and,
- State-specific guidance documents.

The use of BSAs of animal origin, unless otherwise specified in the form of raw or composted, is regularly applied to agricultural land to improve soil fertility and structure. Manure's fertilizing value is significant in that it supplies all major nutrients (nitrogen (N), phosphorus (P), potassium (K), calcium (Ca), magnesium (Mg), and sulfur (S) necessary for plant growth as well as micronutrients; additionally, degraded soils can be revitalized by adding manure or compost. In addition to prevailing climate and hydrological conditions, studies have determined that the effects of manure and, in particular, the fate of microorganisms on the environment are strongly influenced by the soil conditions. With approximately 4,473,575 acres of vegetable crops harvested for sale (USDA NASS, 2014a) and more than 573,016 vegetable crop acres (USDA NASS, 2014a) that are potentially utilizing all forms of manure for its fertilizing value, understanding the role of soils and the conditions that facilitate the transport of pathogens from the BSA to the food chain is vital. Agricultural disturbances that are recognized as destroying dynamic soil properties include tillage/compaction (physical properties), synthetic fertilizer/misuse of soil amendments (chemical properties) and overgrazing/lack of plant diversity (biological properties) (USDA NRCS, 2013a).

3.3.3.1 Overview of Soil Characteristics and their Influence on Transport of Pathogens

A view of the soil orders map of the U.S. with areas of vegetable production graphically demonstrates the variation of soils across the country at the highest level (Figure 3.3-1). It also shows commonality that exists within regions of the country. The same factors of parent material, organisms, climate, relief and time that determined soil formation are the same factors that are still influencing the soil as a medium and effects how specific soils will affect the survival and movement of microorganisms and subsequently the effectiveness of specific management practices. Therefore, comprehension of these underlying soil forming factors may be important for anticipating the range of conditions that relate to the pathogenic transport in the soils environment.

Commonalities from the soil order level are expressed through the various modeling scales shown in Figure 3.3-2 (core, pedon, hillslope, and watershed). The testing of hypotheses about mechanisms and factors of pathogen transport are performed by taking multiple core soil samples and pedon scale (see illustration on next page), and the results are applied to the model and addressed at the hillslope and watershed scales (Pachepsky et al., 2006).

Figure 3.3-1. Dominant soil orders

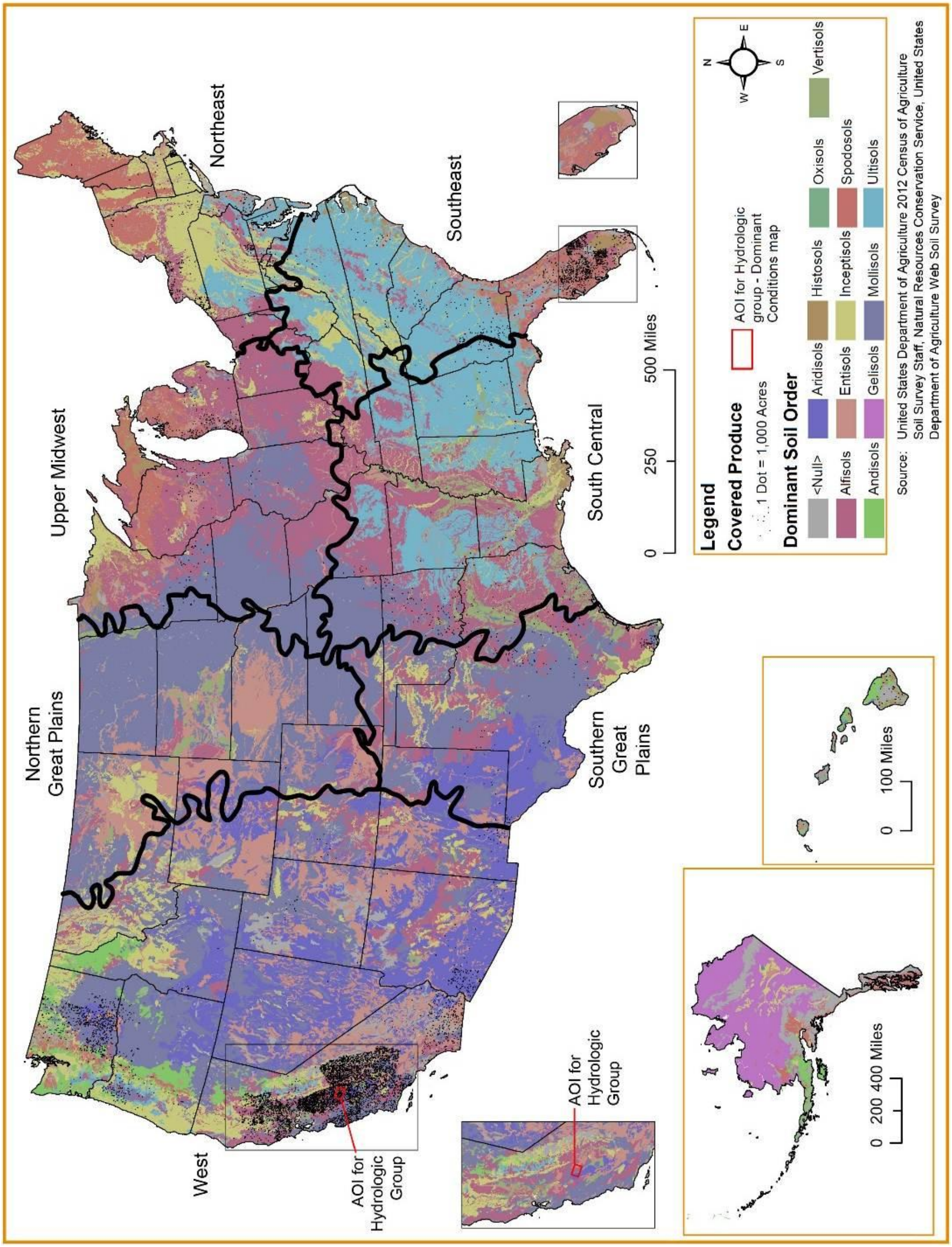


Figure 3.3-2. Scales for modeling manure-borne pathogen transport (Pachepsky et al, 2006)

Figure 3.3-3 demonstrates the information flow in coarse-scale models of manure-borne pathogen transport (Pachepsky et al., 2006) and indicates that pathogen release is very interrelated with soils from soil management to soil properties and is also influenced by vegetation and topography.

Figure 3.3-3. Example of coarse-scale pathogen fate transport model

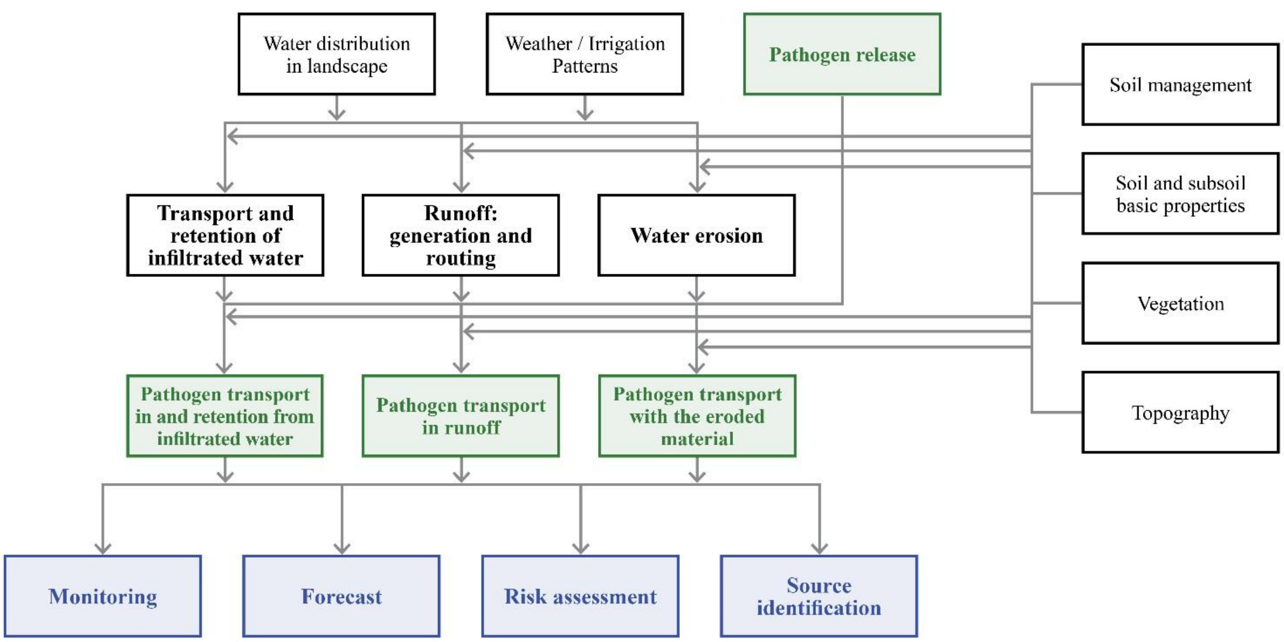


Table 3.3-1 and Table 3.3-2 provide some details of the factors and their effect on the survival and the movement of enteric bacteria and viruses in soil. It demonstrates the variability of factors and indicates the dynamic conditions that influence the process which affects the ability to make broad assumptions. As such these factors are defined as components of studies that are needed to enhance the understanding of the pre-harvest microbial food safety hazard and control measures pertaining to the application of untreated soil amendments (Harris et al., 2012).

Table 3.3-1. Factors affecting survival of enteric bacteria and viruses in soils

	Factor	Comments
Physical and Chemical Nature of Receiving Water	pH	Shorter survival time in acidic soils (pH 3-5) than in alkaline soils
	Soil water content	Longer survival time in wet soils and during times of high rainfall
	Organic matter content	Increased survival and possible growth when sufficient amount of organic matter is present
	Texture and particle size distribution	Finer soils especially clay minerals and humic substances increase water retention by soil, which increases survival time
	Temperature	Longer survival at lower temperature
	Availability of nutrients	Increase survival times
	Adsorption properties	Microorganisms appear to survive better in sorbed state
Atmospheric Conditions	Sunlight	Shorter survival time at the soil surface
	Water (vapor & precipitation	Longer survival time in wet soils and during times of high rainfall
	Temperature	Longer survival at lower temperature
Biological Interaction	Competition from indigenous microflora	In sterile soil, survival is increased
	Antibiotics	Many microorganisms cannot survive in the presence of antibiotics

Source: Abu-Ashour et al. (1993)

Table 3.3-2. Factors affecting movement of enteric bacteria and viruses

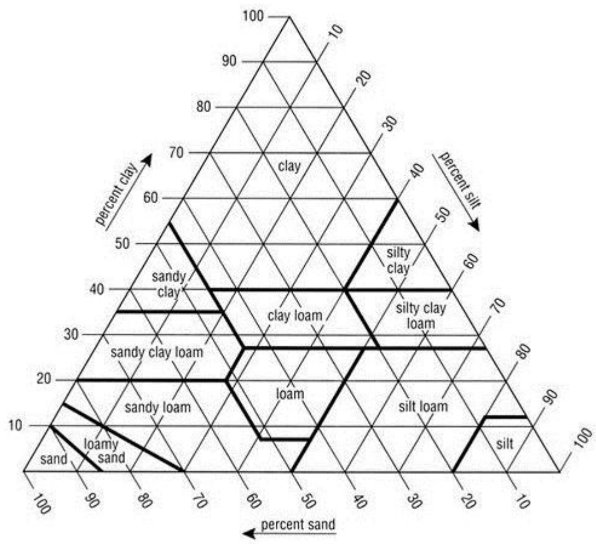
Soil Physical Characteristics	Chemical and Microbial Factors
• Texture • Particle size distribution • Clay type and content • Organic matter type and content • pH • Pore size distribution • Bulk density	• Ionic strength of soil solution • pH of filtrating water • Nature of organic matter in waste effluent solution (concentration and size) • Type of microorganism • Density and dimension of the microorganism
Soil Environment and Chemical Factors	**Application Method**
• Temperature • Soil water content • Soil water flux	• Soil drying between applications • Time of application (winter, spring)

Source: Abu-Ashour et al. (1993)

Influence of Soil Texture

The relative combination of sand, silt, and clay in a soil defines its texture (Figure 3.3-4). Soil texture is important to classify because it determines or influences many other properties, such that medium and fine sands are transported easily through wind processes, and therefore, the wind is a substantial contributor to erosion. Silts and very fine sands easily help to retain or hold water and make it available for plants longer, but these soils are also easily eroded by water. Clay soils have a very low permeability characteristic and therefore, it holds large amounts of plant nutrients; but it may also lead to drainage and tillage problems. (Purdue University, 2014).

Figure 3.3-4. Soil texture classification

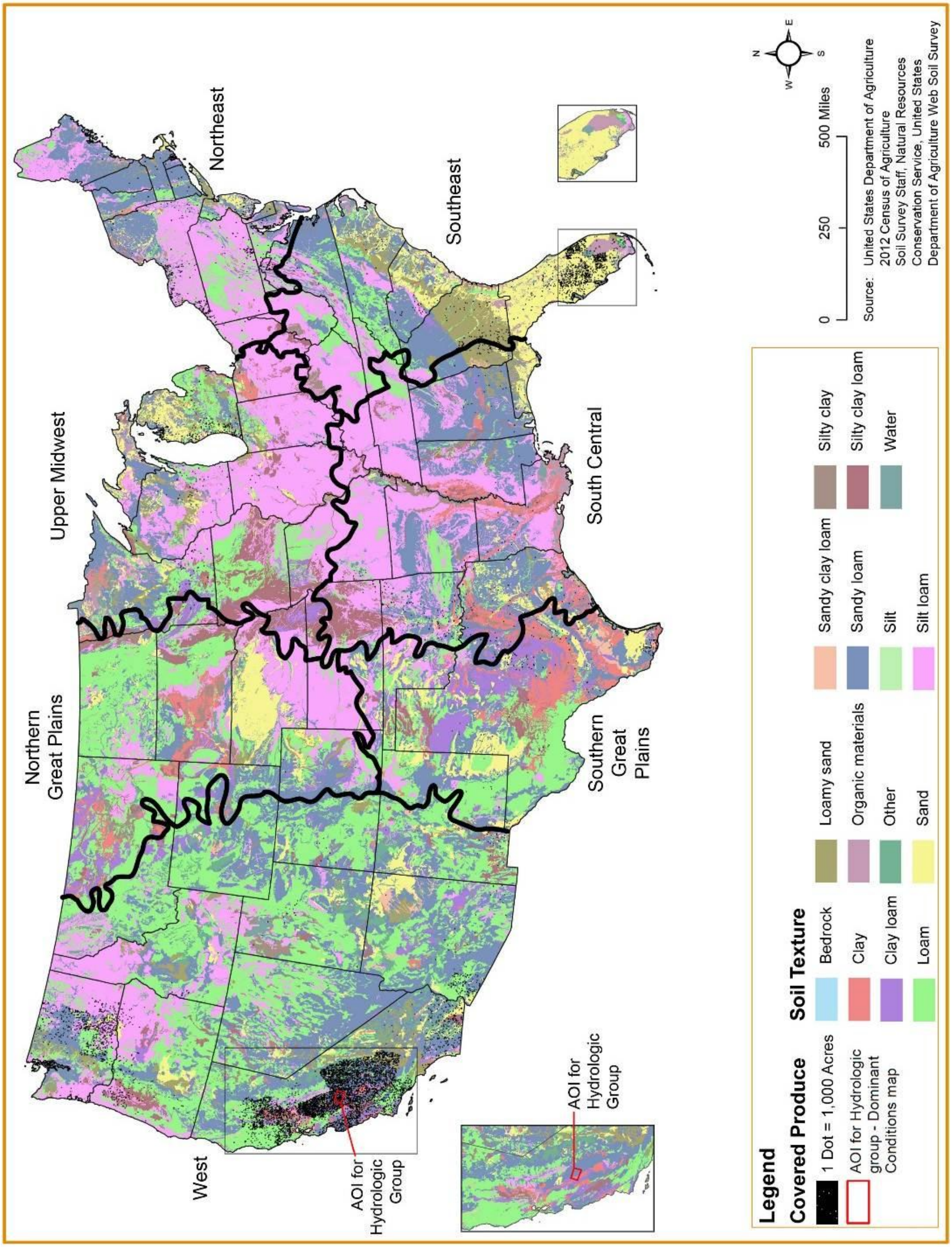


United States Department of Agriculture, NRCS

Texture is also important to microbes in that soil texture plays a role in pathogen transport. Microbes and soil particles can interact to form soil aggregates. These aggregates help to bind soils together and reduce surface soil loses to wind and water erosion. Furthermore, soil texture may influence pathogen survival in that pathogens may absorb to soil particles and are offered a greater degree of protection. Pathogens in the unsaturated (vadose) aerobic zone inactivate more rapidly than in saturated zone because the lack of soil moisture is not conducive to pathogen survival. Also, pathogens in the saturated zone may move more rapidly with water in the soil pore spaces (Cave and Kolsky, 1999). Studies suggest that the single soil property that has the greatest impact on bacterial survival is moisture retention, which is linked to particle distribution and organic matter content (Jamieson et al., 2002).

Figure 3.3-5 shows the distribution of soil textures with the vegetable producing areas throughout the U.S. and the figure illustrates that there are regional commonalities. Dominant textures in the northeast region are silt loam and sandy loam; in the southeast they are dominantly sand, loamy sand and sandy loam; textures in the upper Midwest are dominantly silt loam, silt, sandy loam, silty clay loam; textures in the northwest are dominantly silt loam, silt and sand; and in the west textures are sandy loam, clay, silt clay loam and silt. Studies have shown that moisture is a major factor in determining survival of pathogens and that survival in all types of soil was found to be the greatest in the rainy season (Abu-Ashour et al., 1993). According to Ball (2001), the capacity for soils to hold water is primarily controlled by soil texture and the presence of organic matter in the soils. Soils with smaller particles such as silt and clay, have more surface area than soils with larger sandy particles. The larger surface area of silts and clays allows a soil to hold more water; therefore, there is a higher potential for pathogen survival.

Figure 3.3-5. Soil texture



Soil Drainage Classes

As presented above texture and moisture are interrelated factors that significantly influence the transport of pathogens in the soil. Soils in the U.S. are assigned to drainage classes that provide a guide to the limitation and potential uses of the soil. Achieving a better understanding of the relationship between these parameters and pathogen can provide guidance that is adaptive to regional and local conditions. Figure 3.3-6 illustrates drainage classes within the vegetable producing area in California, which correlates to the dominant soil textures of clay and sandy loam. The drainage classes shown in Figure 3.3-6 are further described in Table 3.3-3.

Figure 3.3-6. Drainage class within vegetable producing area of California

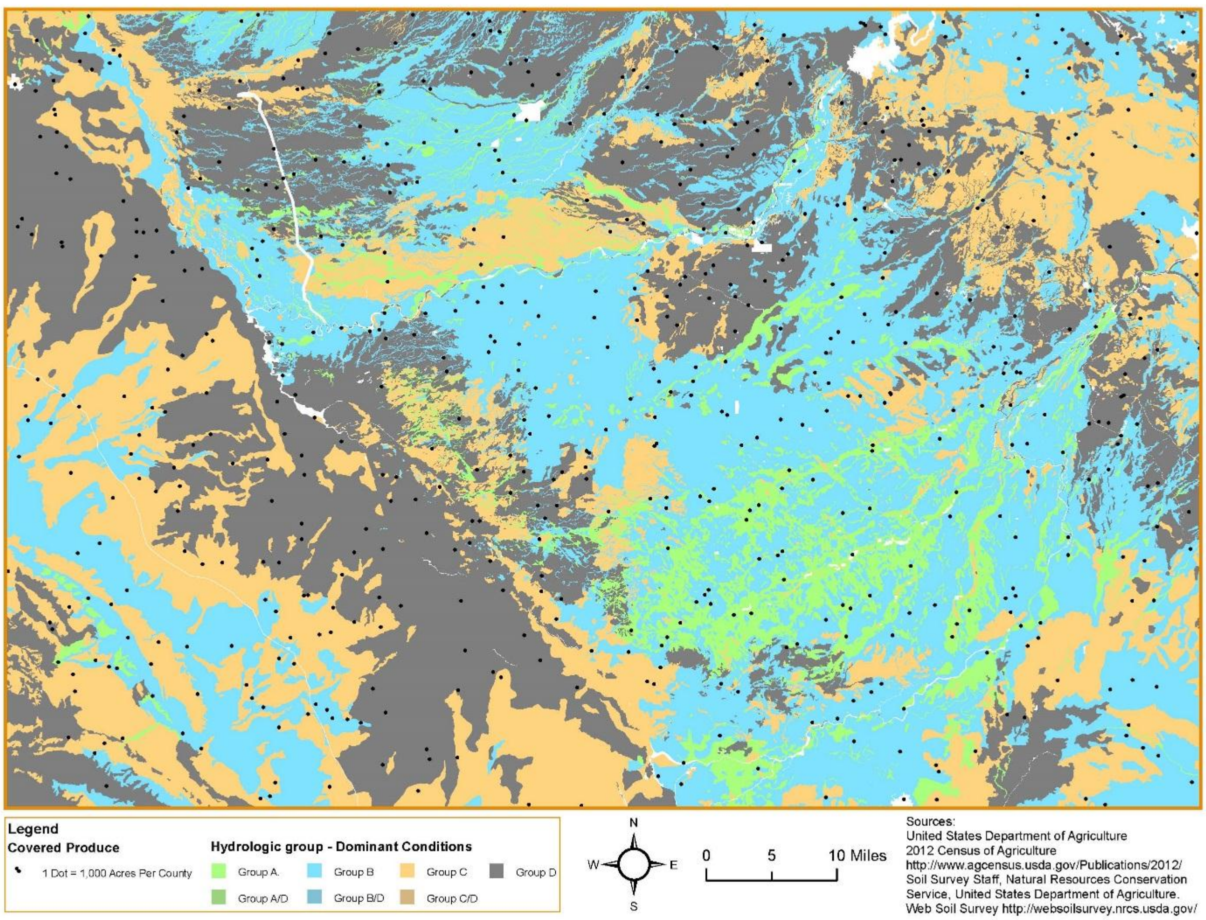


Table 3.3-3. Soil drainage classes

Drainage Classes	Description
Group A	Soils having a high infiltration rate (low runoff potential) when thoroughly wet. These consist mainly of deep, well drained to excessively drained sands or gravelly sands. These soils have a high rate of water transmission.
Group B	Soils having a moderate infiltration rate when thoroughly wet. These consist chiefly of moderately deep or deep, moderately well drained or well drained soils that have moderately fine texture to moderately coarse texture. These soils have a moderate rate of water transmission.
Group C	Soils having a slow infiltration rate when thoroughly wet. These consist chiefly of soils having a layer that impedes the downward movement of water or soils of moderately fine texture or fine texture. These soils have a slow rate of water transmission.
Group D	Soils having a very slow infiltration rate (high runoff potential) when thoroughly wet. These consist chiefly of clays that have a high shrink-swell potential, soils that have a high water table, soils that have a claypan or clay layer at or near the surface, and soils that are shallow over nearly impervious material. These soils have a very slow rate of water transmission.
If a soil is assigned to a dual hydrologic group (A/D, B/D, or C/D), the first letter is for drained areas and the second is for undrained areas. Only the soils that in their natural condition are in group D are assigned to dual classes.	

3.3.3.2 Transport Through Soil

As listed in the tables above there are many factors that influence the fate and transport of pathogens in the soil. However, unlike most chemical pollutants or nutrients such as N and P, a typical bacterial pathogen can be as large as five micrometers long, and would therefore experience difficulty moving between the clay or silt particles of many soils high in clay and silt sized particles. Most pathogens therefore travel across the soil surface in runoff water and infiltrate only partially into the soil pores before being captured in the pore space or by adhering to soil particles. Only in sandy soils is the pore space large enough to provide ample traveling space for bacterial pathogens. Even there, pathogens frequently collide onto grain surfaces where they tend to become permanently attached (eXtension, 2007). Therefore, the extrinsic factors that influence microbial transport through soil are summarized as follows:

- Ease of transport through soil is generally in the order of sand, silt and clay;
- Smaller microbes moves more easily through soils;
- Movement is greater in saturated soil than unsaturated soils;
- Since microbes are generally negatively charged and move with soil solution; and,
- Organic matter can increase pathogen survival through formation of biofilms that allow for re-suspension of pathogens.

Understanding those mechanisms that affect movement and pertinence of these pathogens in soils is not only critical in determining the potential effectiveness of application intervals for BSAs but also for providing the framework for the ability to make reasonable assumptions about the effectiveness of controls applied to different regions, conditions, and practices.

Effects of Soil Temperature

Jiang et al. (2002) reported that STEC survived in manure-amended sandy loam soil for at least two months to over six months (56, 152 and 193 days at 5º, 15º, and 21ºC, respectively). *Salmonella* persisted in hog manure-amended loamy sand and clay soils for more than 180 days during the simulated summer-winter season as compared with less than 160 days in a spring-summer or winter-summer regime (Millner, 2014). Tables 3.3-4 and Table 3.3-5 demonstrate varying reports for pathogen survival and effect of temperature.

Table 3.3-4. Temperature and pathogen persistence

Survival			
Pathogen		**Survival time on crops at 20-30º C**	**Survival time in soil at 20-30º C**
Viruses	Enteroviruses	<60 days, but usually <15	<100 days, but usually <20
Bacteria	Fecal Coliforms	<30 days, but usually <15	<70 days, but usually <20
	Salmonella	<30 days, but usually <15	<70 days, but usually <20
	Vibrio Cholerae	<10 days, but usually <2	<20 days, but usually <10
Protozoa	*Entamoeba Histolytica*	<10 days, but usually <2	<20 days, but usually <10
Helminths	*Ascaris lumbricoides*	60 days, but usually <2	Many months

Source: WHO (1989)

Influence of Microbial Activity

Jiang and Shepherd (2009) summarized studies that revealed that soil with less ambient soil microbial activity allows the extended survival of manure-borne enteric pathogens; directly attributable to less competition from the indigenous soil microflora (FDA, 2001; Jiang et al., 2002). For example the studies they used have shown that pathogenic microbes from contaminated manure survived longer in sterilized soil than in native (unsterilized) soil; (e.g., pathogens detectable for 107 days in unsterilized soil versus 158 days when mixed with sterilized soil) (Jiang et al., 2002). Because nutrient levels vary among different types of soil, then so does the diversity and numbers of indigenous ambient soil microbes. Separate studies cited by Jiang et al. found that the number of STEC increased by approximately 1.5 – 2 logs CFU/g during the first two weeks of manure incorporation, but then declined significantly greater in loamy sand soil than it did in silty clay loam soil (Lau and Ingham (2001) as summarized by Jiang and Shepherd, 2009).

Table 3.3-5. Survival of STEC in manure-amended autoclaved or unautoclaved soil held at different temperatures

Days of survival at storage temperature (0° C) of:				
	Sample	5	15	21
Manure: autoclaved soil	1:10	77*	138	103
	1:25	63	>226	231
	1:50	70	>226	231
	1:100	35	>226	193
Manure: unautoclaved soil	1:10	42	34	103
	1:25	42	152	193
	1:50	56	109	174
	1:100	49	109	131

*Maximum day at which E. coli O157:H7 was detected by either direct plating or enrichment culture methods. (Jiang et. al., 2002)

The Rhizosphere

The rhizosphere is the environment surrounding the root of a plant. The rhizosphere is a complex miniature ecosystem where there are interactions among soil, roots, and microbes. The rhizosphere is rich in organic compounds released by plant roots and also by microorganisms. These organic compounds may affect the survival and growth of enteric bacteria when those microbes are introduced from agricultural water, manure, or other sources. According to Jiang and Shepherd (2009), studies (by Gagliardi and Karns, 2002) have shown that STEC was able to survive for 25 to 47 days in fallow soil, 47 to 96 days in rye roots, and 92 days in alfalfa roots. This demonstrates the enhancing effect provided by the rhizosphere for pathogen survival. They concluded that persistence of enteric pathogens in the rhizosphere is due to interaction among pathogens, ambient soil microorganisms, the soil conditions, and plant roots (Jiang and Shepherd, 2009).

Scientists also found that the amount of spinach contaminated with generic *E. coli* increased if time since planting of spinach was greater than 66 days (Park et al. (2013)). These same scientists concluded that the results suggest that the first cut of spinach crop may be considered less likely to be contaminated than later harvests from the same stand, due to the complex interactions in the rhizosphere.

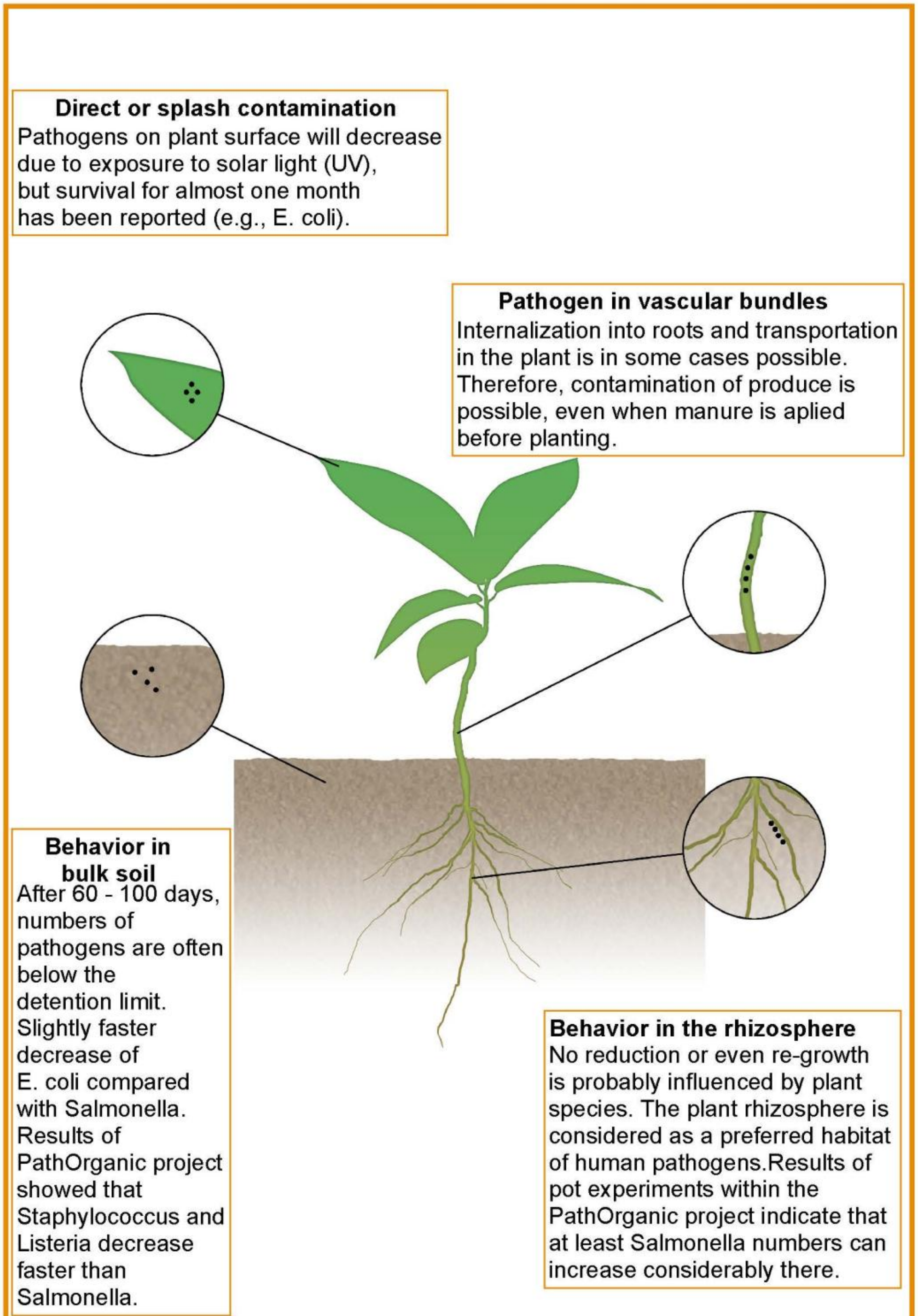
Pathogen, Soil and Plant Interaction

Numerous studies have shown that pathogens can survive on plants and in the soil. When heavy rain or water-gun irrigation occurs, pathogens from the soil surface can be splashed onto the leaves. Pathogens can also be internalized from roots and other openings of the plants, imbedding into plant tissues, and adhering to the roots via soil particles. Growing evidence has demonstrated that enteric and pathogenic bacteria have the ability to colonize plant tissues. Application of raw manure, compost, or irrigation water containing enteric pathogens increases the likelihood of enteric pathogens to inhabit the rhizosphere of plants in the field and to contaminate produce plants. The exact extent to which this pathogen survival proposes a risk has not been established. Figure 3.3-7 summarizes these interactions and qualitative observations. However, studies have established that soil temperature, soil microbial activity, presence of a rhizosphere, types of animal waste, as well as the rate and methods of manure application, all affected the length of time pathogens persisted.

Manure Application Rates and Pathogens

It has been established that competition from indigenous microflora inhibits the survival of manure-borne pathogens (Jiang and Shepherd, 2009). Studies conducted by Lazarovits (2001) demonstrated that organic manure application to soil increased the overall populations of soil microorganisms by up to 1,000 fold (3 logs) and in turn reduced populations of plant pathogens. The intensive application of manure to soil (e.g., one part manure to ten parts soil vs. lesser ratios of manure such as 1:25, 1:50, or 1:100) generally results in greater inactivation of STEC at both 15 and 21°C (when native microflora are active), but not that much at 5°C (Jiang et al., 2002). Jiang and Shepherd further summarized that the application methods used for animal wastes can affect the persistence of manure-borne pathogens. Hutchison et al. (2004) have shown that the populations of *Salmonella*, *L. monocytogenes*, *Campylobacter*, and STEC declined significantly slower in samples with animal waste incorporated into the soil immediately than the populations in samples with the waste left unincorporated on the soil surface. In contrast, another study reported that *Salmonella* survival was significantly longer when hog slurry was surface-spread as compared with results from injected manure (Holley et al., 2006). Results from Gagliardi and Karns (2000) indicated that STEC can travel below the top layers of soil for more than two months after manure application, regardless of disturbed (tilled) or intact (untilled) soil core. These scientific studies concluded that, considering the extended survival of pathogens in manure-amended soil, untreated manure should not be land-applied without adequate treatments to significantly reduce the bacterial populations.

Figure 3.3-7. Soil, plant, and human pathogen interactions



** Image and text reproduced fromTechnical Guide, Manure for Vegetables, FiBL, 2011*

Pathogen Persistence in Manure-Amended Soil

Because there is a slow decline of pathogen populations in manure-amended soil, reducing initial bacterial load is a key factor to reducing the length of pathogen persistence (Jiang and Shepherd, 2009). Fenlon et al. (2000) applied cattle slurry inoculated with minimal amounts of bacteria (e.g., 30 CFU STEC /100 ml) to arable grass plots on a clay loam soil. They could detect STEC only in both the soil and on the grass during the first week after application. In contrast, STEC with very high application rates survived for at least 130 days on manure-amended soil with a grass cover at 18° C (Maule, 1999). Under field conditions, STEC, *Salmonella*, and *Campylobacter* persisted for up to one month, and *L. monocytogenes* for more than one month in both sandy arable and clay loam grassland soil fertilized with livestock manure. Survival times for *Salmonella* were up to ten months (300 days) in soils spread with cattle slurry and eight months (259 days) for soils amended with animal feces (Jones, 1986).

3.3.3.3 Pathogen Delivery to Soils (influence of agriculture)

Manure is a major source of nutrients as well as amendment for improving soil health. The application of manure to farm fields is varied and depends on local conditions and the type of manure that is available. Most of the recommended application methods have been established with the objective of preventing loss of nutrients through volatilization, runoff and leaching and potential pollution of surface and groundwater. Factors that can influence the persistence and survival during the implementation of manure as a fertilizer is the application rate and the manure pathogen load as previously discussed.

Field Application Methods

Manure application guidance provided across the country through extension offices includes minimizing nutrient loss and implementing pollution prevention measures (University of Illinois Extension, 2014a).[6] There are several such guidance steps to take, but a few examples of measures that help to minimize nutrient loss and promote pollution prevention include:

- Use plow-down or disking methods to incorporate manure, otherwise manure left to sit on the soil surface poses the greatest risk of nutrient losses through volatilization and surface runoff.
- Avoid oversaturating soils when applying livestock manure through an irrigation system because the soils may not be permeable enough to absorb the liquids quickly and thus, runoff may occur.
- Knifing manure into the soil is the best way to prevent nutrient loss and protect surface water, and it is the preferred method to incorporate manure in conservation tillage systems because it offers minimal disturbance of crop residue.
- Drag-hose injection eliminates the need to transport manure to the field in a tank, and injecting manure reduces the risk of runoff and odors.

[6] More information may be found at: http://www.thisland.illinois.edu/60ways/60ways_38.html

USDA organic regulations stipulate that the use of manure for soil fertility must not contribute to the contamination of crops, soils, or water (7 CFR § 205.203(c)). In practice, this may equate to applying manure and considering timing (e.g., time of year such that the farmer avoids application on frozen soil), placement (e.g., avoiding application near waterways), and methods (e.g., injection or immediate incorporation).

State-specific Manure Application Guidance

Review of guidance material from around the country showed a consistent recognition of the value of manure as a nutrient resource and the need for strict requirements for handling, specifically for raw manure. Most states recommend proper and thorough composting of manure, incorporation into soil prior to planting and avoidance of top dressing of plants (WCFS, 2014). A summary listing of these resources is provided in Table C-1, in Appendix C. It is noted that fresh manure is the highest pathogen risk, followed by age/stacked manure and correctly composted manure has the lowest risk. The key components of the state guidance include:

- Plan Before Planting
    - Store manure away from areas where fresh produce is grown and handled.
    - If not composted, age manure.
    - Store manure slurry for at least 60 days in summer and 90 days in winter.
    - Actively compost.
- Plan Manure Application Timing Carefully
    - Apply manure in the fall.
    - Avoid harvesting vegetables or fruits until 120 days after manure application (some states recommend 90 days).
    - If the 120-day waiting period is not feasible, apply only properly composted manure (eXtension, 2013).

The acknowledgement of guidance provided by the states that correctly composted manure has the lowest risk of pathogen contamination compared to raw manure as well as decreased nutrient loss and environmental pollution is consistent with the FDA's position that properly composted manure is an effective and safe fertilizer.

Additionally, many states have restrictive nutrient management programs that regulate how much livestock and poultry manure can be applied to fields annually. These programs require that producers consider the development of composting programs, which have been noted to decrease cost and increase beneficial effects, such as increased uniform germination and decreased weed pressure (MidwestBioSystems, 2012). This is already having an impact on how producers handle manure. Understanding the components that should be integrated into existing programs such as Manure Management Planner (MMP), which currently supports 34 States by generating fertilizer recommendations and estimating manure N availability based on each State's Extension and/or NRCS guidelines, and the mechanisms for integration will potentially allow producers to adapt to consideration of pathogen loads in the same manner in which consideration is given to nutrient loading.

3.3.3.4 Assessment of Existing Soil Health (national and regional conditions)

The ability to influence soil health is dependent on having an understanding of how the soil is designed to function and managing it accordingly. The following planning principles have been identified to achieve the goal of the most favorable habitat possible for the soil food web (USDA NRCS, 2013a):

- Minimize disturbance of the soil.
- Maximize diversity of plants in rotation/cover crops to add diversity to soil microorganisms.
- Keep living roots in the soil as much as possible.
- Keep the soil covered at all times with plants and plant residues.

Figures 3.3-8 to 3.3-11 are presented as the best available information to provide a view of existing soil quality, manure production and use of manure as compared with commercial fertilizer. The data was developed for priority cropland acres and as shown some areas of vegetable production were not captured by this data set. However, trends within the regions can be observed and inferred. The soil quality degradation indicator was determined on the basis of the 30-year change in the soil organic carbon (SOC) indicator and the indicator score for the last year of the simulation. The 30-year change in the SOC indicator was calculated as the difference between the SOC indicator score for the first year and the SOC indicator score for the last year in the 30-year simulation. The priority cropland acres with highest potential for soil quality degradation (values that are less than 0) are in the southern regions and California in the west, which are associated with medium and fine textured soil types that are susceptible to erosion.

As stated previously the use of manure is an essential component of enhancing soil quality and the following figure shows the production of livestock manure across the continental U.S. The amount of raw manure utilized on vegetable producing areas could not be determined from the information available. However, it can be inferred that producers are utilizing manure generated within close proximity to production areas. For example, the West region has high correlation of vegetable producing acres and livestock manure production.

Figures 3.3-10 and 3.3-11 (several pages hereafter) show the percentage of nitrogen application utilizing manure N and commercial N. As previously noted, the dataset considered priority croplands and did not capture all covered produce areas. However, review of the maps show a correlation between manure N production and manure N usage associated with the location of covered produce. The locations with the highest manure production and manure N usage include California, Arizona, Washington and Oregon in the west; southern part of Texas, coastal areas of the southeast and the upper Midwest. Application rate in these areas ranged from 75 to over 125 lbs/acre. Conversely, commercial N application rates were lower in these areas with rates of 1 to 25 lbs/acre. Based on figure 3.3-9, 2000+ lbs of manure N is produced per county and with 125+ lbs applied per acre it appears that the manure that is being generated is being utilized and that there is potential capacity to use more considering that one (1) dot of covered produce is equal to 1,000 acres.

Figure 3.3-8. Priority cropland with highest potential for soil quality degradation

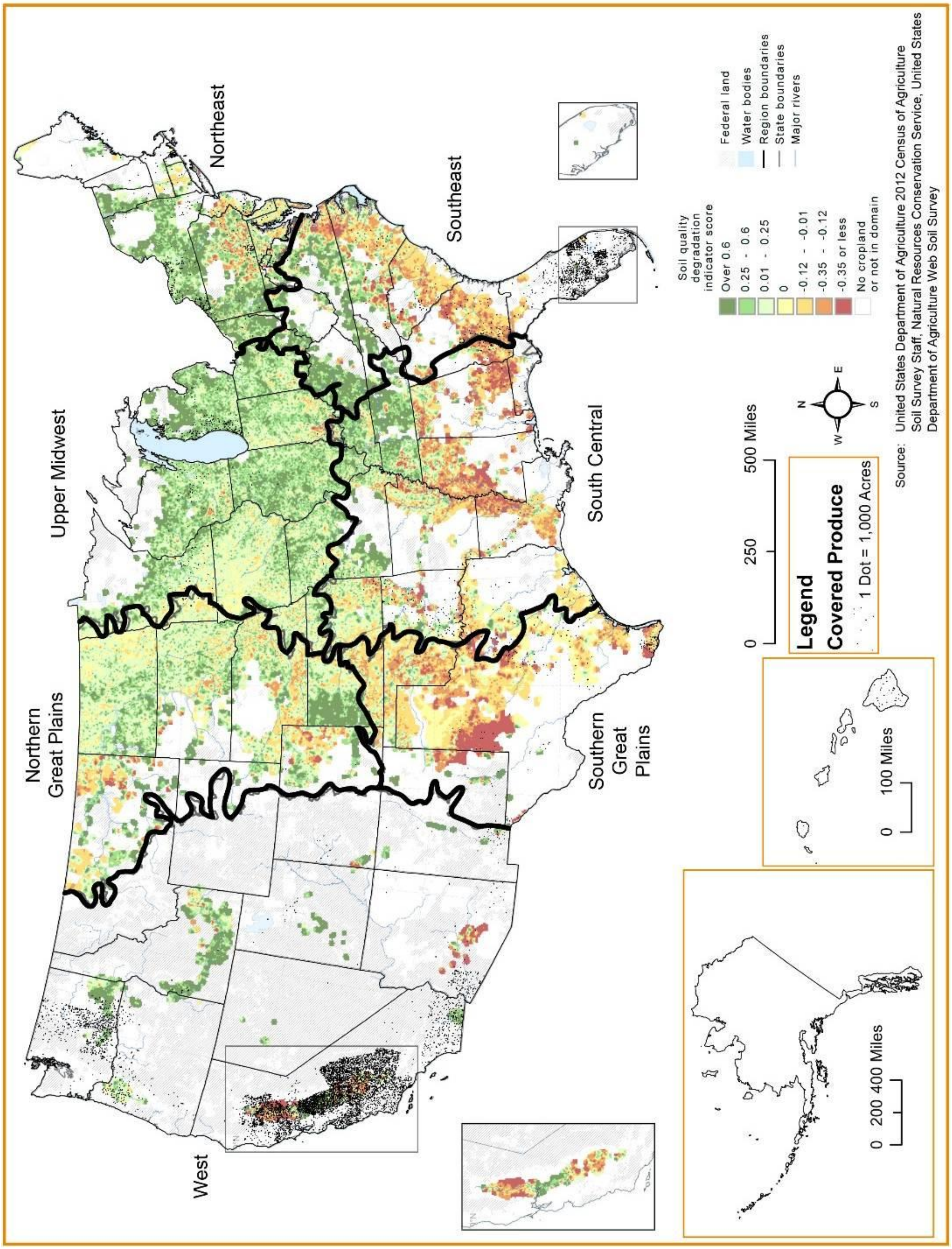


Figure 3.3-9. Estimated manure N production from confined livestock

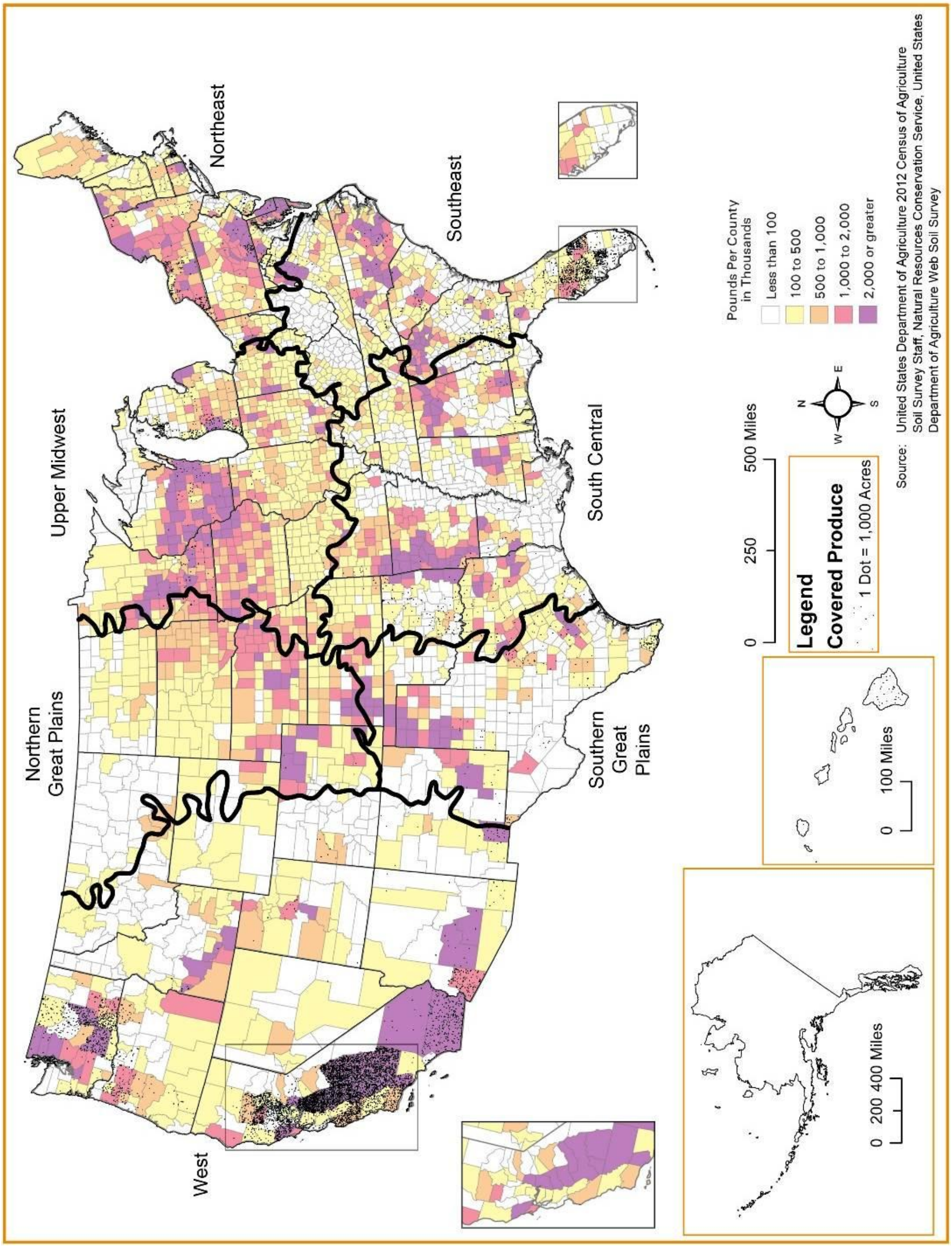


Figure 3.3-10. Average annual commercial N application rates

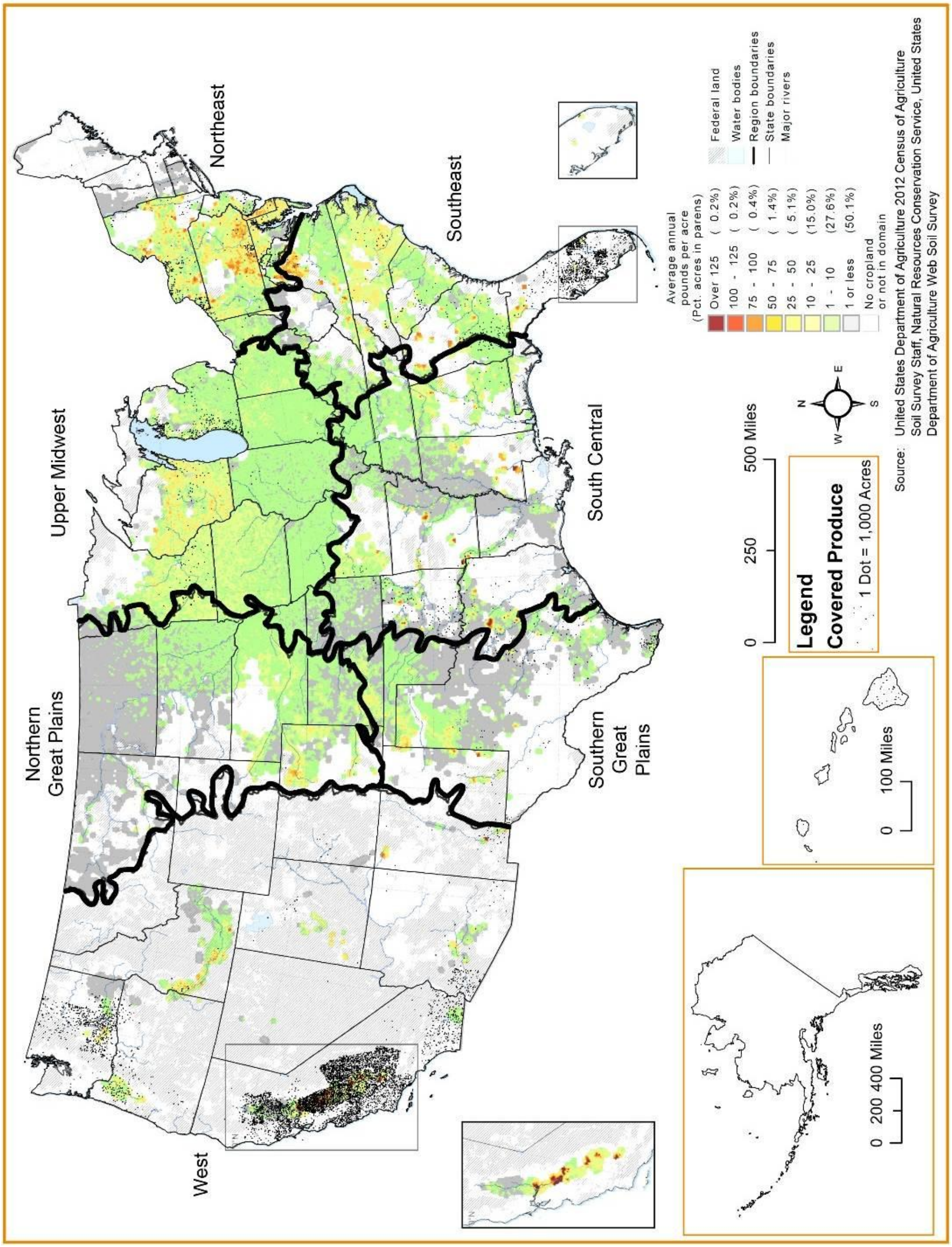
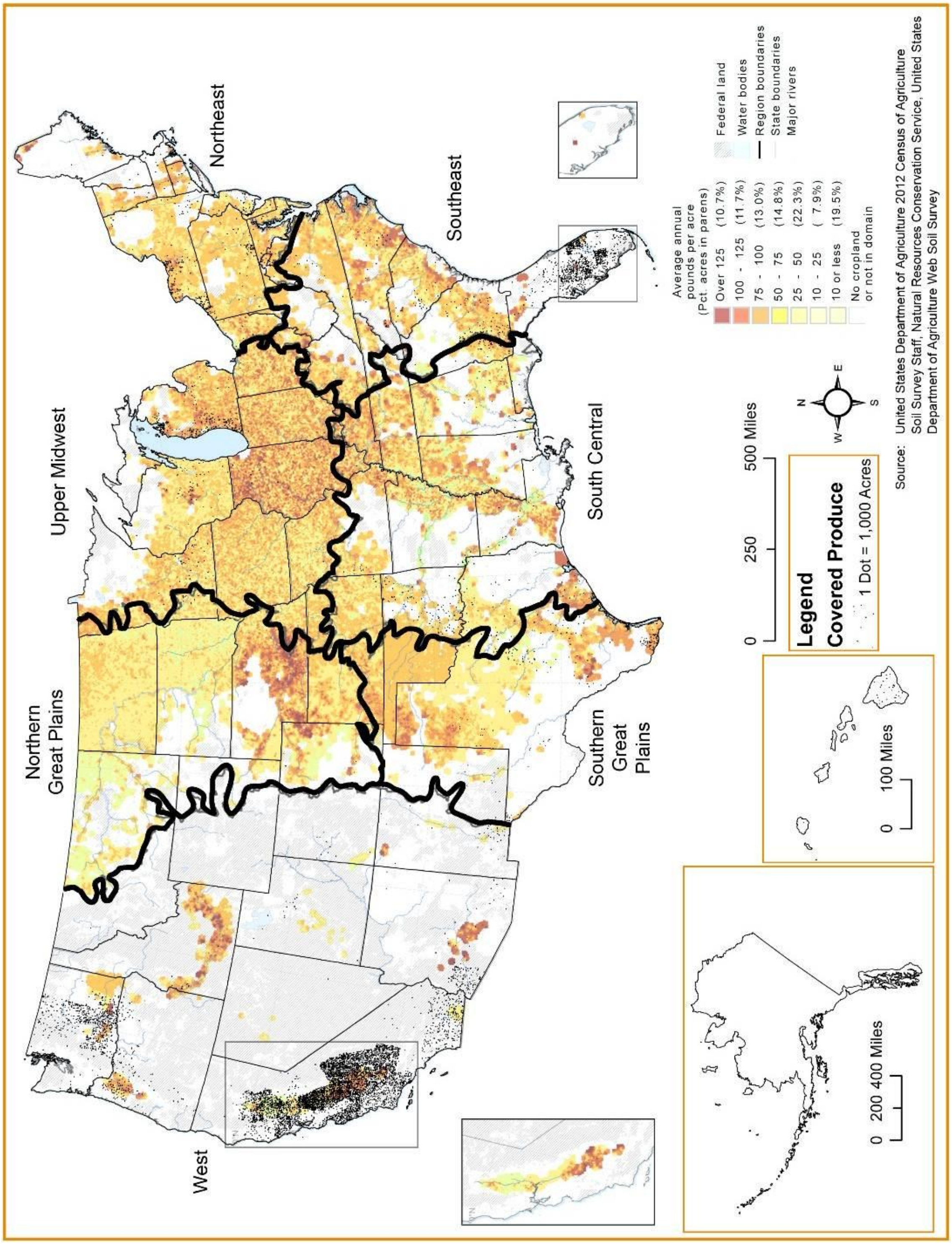


Figure 3.3-11. Average annual manure N application rate

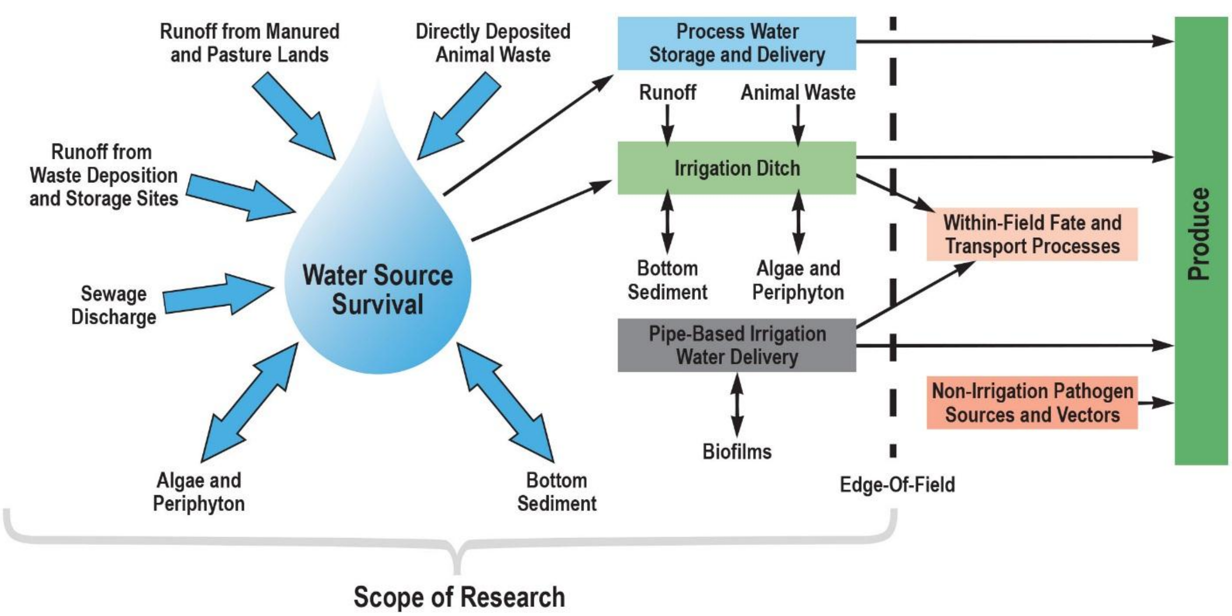


The previous two Figures (3.3-10 and 3.3-11) show that less than 2 percent of priority croplands applied more than 50 lbs. of manure N/acre annually compared with more than 50 percent of priority croplands annually applying more than 50 lbs. of commercial N/acre. While a direct correlation cannot be determine from these data, the data suggest that priority cropland is still significantly utilizing commercial fertilizer, and therefore, manure for use on covered produce is readily available.

3.3.3.5 Soil and Agricultural Water (influence of agriculture)

The presence of pathogenic microorganisms in irrigation waters is considered to be a potentially important factor in the pre-harvest contamination of fresh produce. Figure 3.3-12 demonstrates that pathogens will migrate with water and may be transported via overland flow, infiltrate into the soil followed by through flow, or drainage through soil. The partitioning of water at the soil surface is controlled by the rate of application of water or effluent vs. the soil's infiltration rate. Most infiltrating water is filtered and the microorganisms are trapped in pore throats that restrict passage (straining) and filtration and attachment to solid surfaces (adhesion). These processes which are controlled by soil physical properties such as texture can affect the survival of microorganisms in soil. For instance, it has been documented that straining has a weak effect in sandy soils due to the presence of pore spaces (Buchan and Flury, 2004). While many of the essential pathogen transport processes associated with irrigation are currently not well understood or modeled it is established that irrigation water is a method in which pathogens enter the soil. The following flowchart demonstrates areas of current research to increase understanding of these processes (Pachepsky, 2006).

Figure 3.3-12. Pathogenic transport and survival within overland flow (agricultural water)



Source: Pachepsky et al. (2011)

Soil and Irrigation Methods

There are four primary types of irrigation methods (surface, sprinkler, drip or trickle and subsurface). Soil qualities or characteristics (e.g., soil texture, and slope) along with environmental conditions (e.g., climate including precipitation, water quality and availability) have an impact on the choice of irrigation method that the farmer decides to use. For example, sandy soils allow water to transport through more quickly (i.e., low water storage capacity and high infiltration rate); therefore, these soils require more frequent irrigation water applications. Under these circumstances, sprinkler or drip irrigation are more suitable than surface irrigation. For loam or clay soils all four irrigation methods are suitable, but surface irrigation is what is most commonly used. Clay soils (these are soils that have low infiltration rates) are ideally suited for surface irrigation methods. When a variety of different soil types is found within one area, sprinkler or drip irrigation is what is most commonly used, as it ensures a more even water distribution.

Surface irrigation is used across the country for all types of crops. Sprinkler and drip irrigation, because of their high relative costs (initial capital costs) are mostly used for high value cash crops, such as for certain types of produce and fruit trees. Drip irrigation is more often employed to irrigate individual plants or row crops such as some vegetables and sugarcane.

Furrow irrigation is often suitable for a wide variety of soils and crops, but especially it is used for row crops. (Brouwer et al., 1989)

Drip Irrigation for Vegetable Crop Production

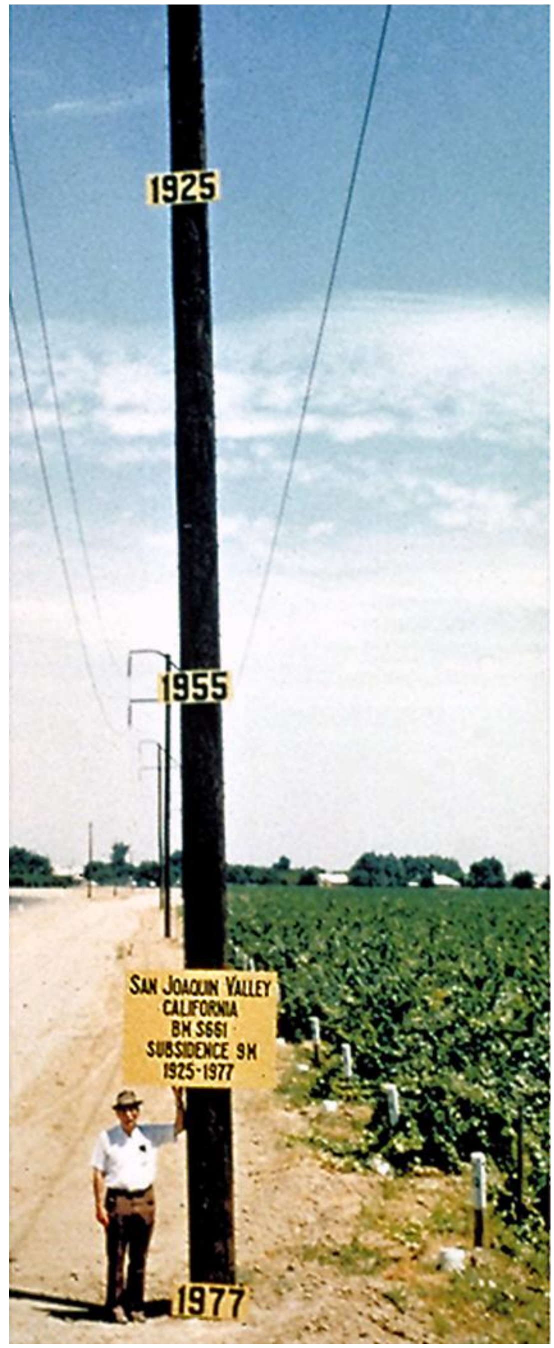
There are two fundamentally different drip irrigation systems for vegetable crop production:

- Temporary surface system that are installed after crop establishment and removed before harvest; and
- Semi-permanent, buried systems that are left in place for multiple crops.

Appropriate fertility management may be profoundly different with the two systems. With a temporary surface system, phosphorus application is typically done before system installation. The wetting is from the top down, pushing soluble nutrients toward the root zone. Because the system is temporary, and conventional tillage is practiced between crops, there is no significant 'mining' of nutrients from a particular region of the soil profile, nor are the effects of maintenance chemicals (acids, for example) spatially concentrated. By contrast, with a semi-permanent, buried system the surface 4-6 inches of soil may (depending on soil characteristics and system depth) often be too dry for active nutrient uptake (Hartz, 2004). Evaporation from the soil surface may move soluble nutrients into this dry zone, beyond the reach of the crop. Since successive crops will draw the bulk of their nutrients from a confined area in the soil, the nutrient status of that area may change substantially over time. Acid-based products applied through the drip system can change pH of the wetted area, potentially affecting micronutrient availability (Hartz, 2004).

More efficient irrigation will reduce N leaching loss, but growers do not always achieve improved efficiency with drip irrigation. Another reason why drip irrigation may increase N fertilizer requirements is that the limited wetted zone reduces the amount of N mineralization from SOM. This is an issue primarily with buried systems, because most N mineralization occurs in the tillage zone, which may remain dry during much of the season. Tillage practices that confine crop residues to the surface few inches of soil, and irrigating a crop with the drip instead of sprinklers, will minimize the availability of N in those residues. Lastly, with buried systems, evaporation from the soil surface over time can deposit a considerable quantity of NO_3-N in the dry surface soil. While this N may be recovered by a subsequent crop, it may be largely beyond the reach of the current crop (Hartz, 2004).

Figure 3.3-13. Example of soil subsidence as a result of aquifer compaction (Photo credit: Dick Ireland, USGS)

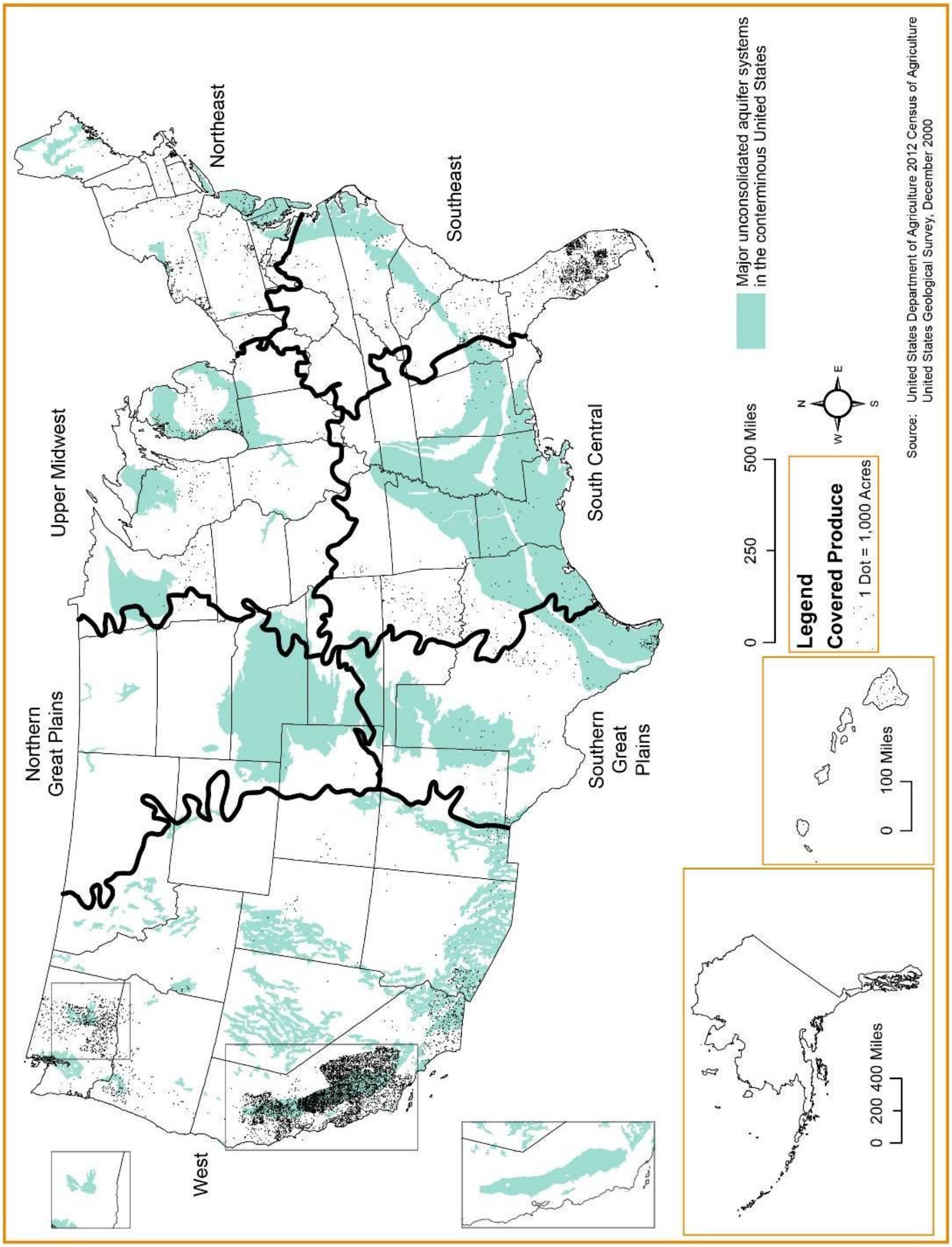


Soil and Groundwater Pumpage

According to USGS, more than 80 percent of the identified subsidence in the nation is a consequence of underground water exploitation, and factors such as increasing residential and commercial development, and continued drawdown of water resources threatens to exacerbate existing land-subsidence problems and initiate new ones. In many areas of the arid Southwest and in more humid areas underlain by soluble rocks such as limestone, gypsum, or salt, land subsidence is an often overlooked environmental consequence of our land- and water-use practices. Figure 3.3-13 is a picture of the San Joaquin Valley Southwest of Mendota in the agricultural area of California (USGS, 2000). Pumping of groundwater for irrigation has caused the land to drop. The past surface elevation is shown by the years on the signs.

Figure 3.3-14 (USGS, 2000) shows the extent of compaction of aquifer systems throughout the U.S. caused by groundwater withdrawals. As the groundwater is pumped out, the aquifer becomes stressed and the soils around it consolidate, which is non-reversible. Thus, the total volume of the silts and clays is reduced, resulting in the lowering of the soil surface. The damage at the surface is much greater if there is differential settlement, or large-scale features, such as sinkholes.

Figure 3.3-14. Areas of subsidence attributed to compaction of aquifer systems



Soil and Chemically Treated Agricultural Water

Chlorine chemicals are very effective against bacteria, viruses and fungi that contaminate water. Four types of chlorine chemicals are commonly used in agriculture: sodium hypochlorite, calcium hypochlorite, gaseous chlorine and chlorine dioxide. Chloride is not adsorbed or held back by soils, and so chlorine compounds move readily with the soil-water and may be taken up by the crop where it accumulates in the leaves (FAO, 1994).

Two of the more popular treatments, though still a very limited practice across the U.S., are injection of calcium hypochlorite or chlorine dioxide. For irrigation of many key crops, the volumes of water being pumped for overhead irrigation, for example, may be in excess of 1,500 gallons per minute. In California and Arizona farms where this is being applied, water quality is generally good and the disinfectant demand is low. Therefore, low doses, 2-5 mg/L (2- 5 parts per million (ppm)) of active ingredient are sufficient. Lower doses of these chemical treatments reduce potential detrimental effects on the crop; however, the concern remains for chronic effects of large-scale use over long periods of time as soil quality may be degraded. Such a result may further also have adverse impacts on wildlife and habitats. In water and soil, sodium and calcium hypochlorite 217 separate into sodium, calcium, hypochlorite ions, and hypochlorous acid molecules. Calcium hypochlorite 218 and sodium hypochlorite are not bioaccumulative (ICF International, 2011).

3.3.3.6 Factors Influencing Soil Health (soil amendments)

Most agricultural lands poorly serve adjacent ecosystems due to the high degree of disturbance, low diversity and high human inputs (e.g., nutrients, pesticides, etc.); therefore, the adjacent ecosystems tend to be of poorer quality. This is evident by comparing forest soil organic matter (SOM) at 4.3 percent while cropland SOM is now 1.6 percent. Nationally more than 50 percent of SOM has been lost in the past 100 years, most since the 1950's (USDA NRCS, 2013a), methods to build and maintain SOM are critical to soil health.

In addition to plant nutrients (N, P, and K), animal manures work to build soil organic matter and improve soil structure. Better soil structure helps to improve water holding capacity, aeration, and friability. In addition, many trace nutrients needed for optimum plant growth are available from manures, which may not be present in commercial fertilizers. When applying animal manure, nutrients are released more slowly and over a longer period of time as compared to most commercial fertilizers (Rowell and Hadad, 2014) as demonstrated in Figure 3-3.15. However, if manure is applied to fields in excess the result is a high P level that discourages plants to develop a healthy mycorrhizal fungi relationship, which then limits the plant's potential to achieve other benefits, such as water and other nutrient exchange. Where there is an overabundance of manure production on a farm, such that the volume of manure that is produced is greater than the farm's potential to "assimilate" the manure's nutrients, there is a potential to create a water quality problem, unless the excess manure is transported to another growing area where it can be properly applied (Gollehon et al., 2001).[7] An example of when manure may be applied in excess

[7] The foremost cause of water quality degradation in the U.S. is from excess loading of N and P into waterbodies.

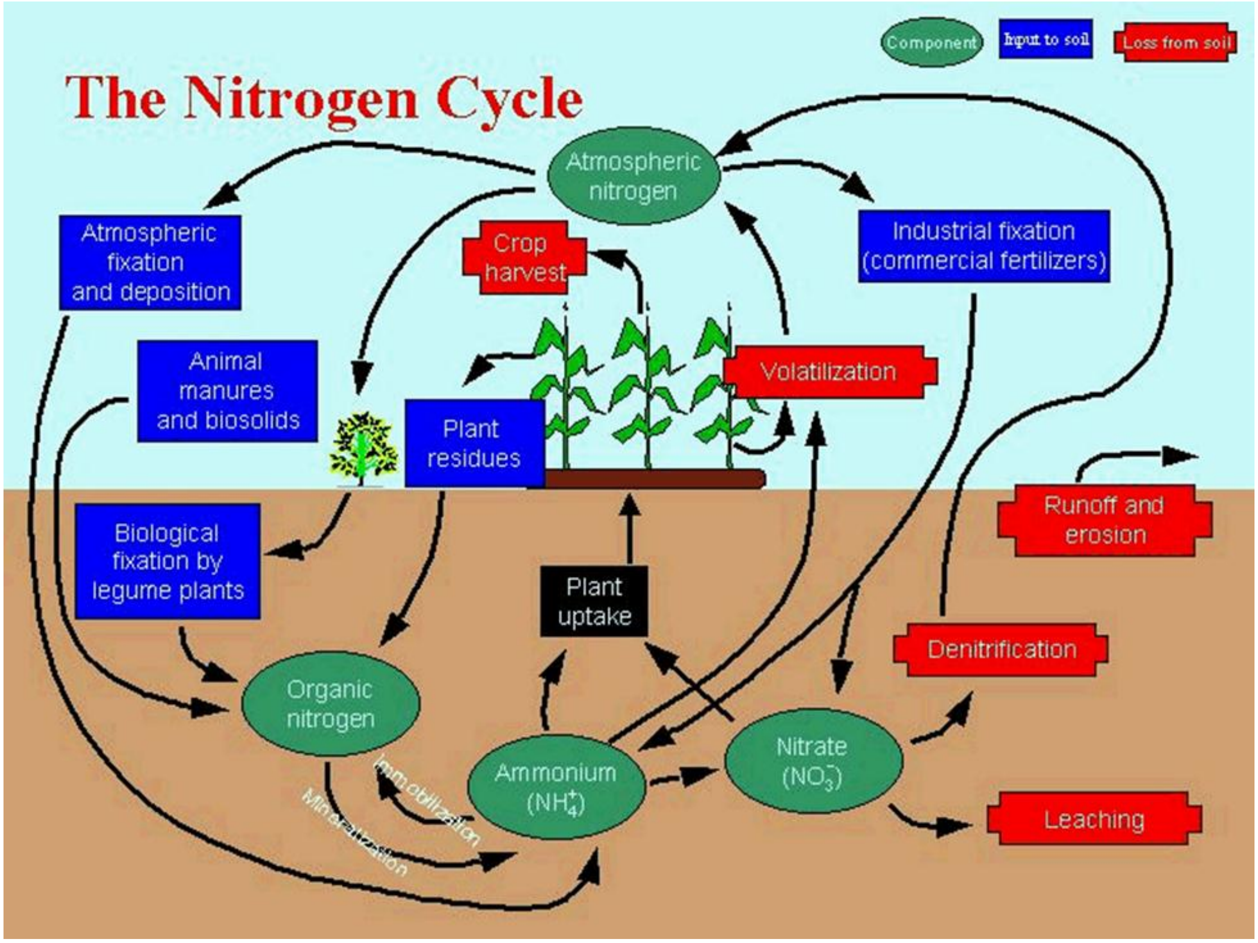
may include when livestock operations do not have sufficient crop production acreage on which to spread manure at agronomic rates. In other words, too much manure may be spread on too few acres to make it efficient for proper plant/crop nutrient uptake. While manure will have more N than P, which is important to understand for nutrient management (see beginning of Chapter 3.3.3.4), the N and P interaction in the environment is also important to consider. Nitrogen is more easily soluble in water than is phosphorus. Therefore, N is more easily transported with water runoff than P. Phosphorus, however, can be mobilized with erodible soils. Both N and P are known to create water quality problems in receiving waters including causing an increase in algal production (as well as overproduction in vascular plants) (Gollehon et al., 2001; EPA, 1998a). The acceleration of algal production and vascular plant biomass in receiving waters due to excess N and P coupled with decomposing organisms in the water will often result in an increase in demand for oxygen, which then depletes the dissolved oxygen in the waterbody. The effect may be fish kills (and death of other aquatic animals), and in some cases harmful algal blooms can endanger human health (EPA, 2012a). This particular process of water quality degradation is called eutrophication. Eutrophication and other water quality problems resulting from excess N and P from agriculture can be managed through proper nutrient management planning (see Chapter 3.4.3.2).

Manure can also contain toxic compounds, which depends upon the food supplements that the cattle or poultry may be fed, and in turn concentrates in the manure. These toxic compounds may also accumulate in the soil where manure is applied (USDA NRCS, 2013a).

The use of commercial fertilizers has significantly increased crop yields; however, it has been determined that it has a detrimental effect to the healthy functioning of soil. Specifically the impact of fertilizer has shown the following effects (USDA NRCS, 2013a):

- Short-circuits the rhizosphere, which is the area adjacent to the root that has the most biological activity taking place such as mineralization (nutrient release) and disease prevention. Excessive fertilizer discourages this area from developing to its full potential.
- Depresses N-fixing bacteria in soil.
- Increases risk of N leaching or denitrification.
- Fertilizer N is applied in one of two forms, NH_4^+ or nitrate, both are inorganic and very water soluble, which can leach or leave the field through surface runoff, and field tile.
- Stimulates bacterial decomposition of SOM.
  - Morrow plots in Illinois have shown that addition of N has led to the loss of 50 percent of the SOM since they began using it in the plot in the 1950.
  - Loss of SOM has been accomplished by stimulating the bacteria throughout the soil profile to decompose organic matter.
- Synthetic fertilizers are salts, which can lead to osmotic shock in plant roots if over applied.

Figure 3.3-15. Transport of organic N (manure) and inorganic N (fertilizer) (Image credit: the Potash and Phosphate Institute)



<u>Raw Manure and Composted Manure</u>

A prime interest with organic amendments is whether or not to compost the manure prior to application. Composting changes both the physical and chemical structure of manure, which has both positive and negative results. Physical changes that occur during composting include: decreased water content, decreased dry matter, decreased volume and increased bulk density. These changes are generally considered advantageous, because smaller mass/volumes are much easier to transport and apply. Composting manure may also serve to eliminate pathogens, parasites, weed seeds and odors, and it has been found to increase disease suppression effects. Composted cattle manure has proven as effective as raw manure in promoting crop yields. However, composting may increase nutrient losses. Manure nitrogen is lost during the composting process through ammonia volatilization, denitrification and leaching, and additionally, much of the plant available nitrogen is immobilized in organic forms. Due to nitrification, compost may contain higher NO_3^- and lower NH_4^+ concentrations than fresh manure. Overall inorganic nitrogen availability, however, is often less in compost than fresh manure and composting may benefit the environment because organic nutrients are less likely to run off to surface waters or to leach to groundwater (Michigan State University Extension, 2012).

Green Manure

"Green manuring" involves the soil incorporation of any field or forage crop while green or soon after flowering, for the purpose of soil improvement and benefits the soil in many ways (Sullivan, 2003). These benefits include the addition of organic matter and improvement to soil structure, it has been reported that "the contribution of organic matter to the soil from a green manure crop is comparable to the addition of nine to 13 tons per acre of farmyard manure or 1.8 to 2.2 tons dry matter per acre" (Sullivan, 2003). The nitrogen fixation capacity of legumes cover crops produces from 40 to 200 lbs. of nitrogen per acre and also crops help recycle other nutrients (P, K, Ca, Mg and S etc.) accumulated by cover crops during a growing season (Sullivan, 2003). Aeration of soil is achieved from extensive rooting action of some cover crops and supports weed suppression. One limitation of cover crops is water consumption especially in areas with less than 30 inches of precipitation per year but the use of native legumes that are adapted to drier conditions can mitigate some of the water needs (Sullivan, 2003). It is also noted that many vegetable rotations can accommodate cover crops. For example, Buckwheat can follow lettuce and still be tilled down in time for fall broccoli. Hairy vetch works well with tomatoes and other warm-season vegetables. The vetch can be killed by flail mowing and tomato sets planted into the mulch (Sullivan, 2003).

3.3.3.7 Soil and Grazing (domesticated and wild animals)

Livestock grazing significantly affects the structure, composition, fertility, chemistry and function of soil in ways that compromise both short and long-term productivity. Grazing changes soil structure by increasing soil compaction. Compaction reduces water and air infiltration into the soil and increases runoff. Grazing dramatically increases the decomposition rate, alters the amount of nutrients stored in soil and lowers pH. Grazing increases short-term soil nutrient availability. Direct comparison of grazed and non-grazed soils generally finds that grazing reduces soil nutrient levels (Roberson, 1996).

3.3.3.8 Soil and Effect of Farm Size

The capacity of the soil to function is not dependent on the size of the farm. The exclusion of farms to be exempted by the PS PR constitutes a very small portion of the total farmed acreage of the United States. Therefore, the vast majority of soil resources will continue to receive the existing management practices.

3.4 Waste Generation, Disposal, and Resource Use

3.4.1 Definition of the resource

With respect to this EIS, waste generation primarily means the animal waste, or excreta (an example of a BSAs of animal origin), that is created during the practices of livestock and poultry production (and animal products) and that is used to amend soil nutrient content in order to promote plant production and increase crop yields. For the purposes of this EIS, the resource also includes processed human waste, which is rarely used for soil amendments, and must be used in accordance with EPA regulations (found in 50 40 CFR Part 503 Subpart D).

Disposal and Resource use means how the resource is applied to crops in raw form (untreated) or composted (treated) or processed (chemically or thermally pasteurized), or how it is otherwise stored prior to use.

In terms of identifying the baseline conditions of the resource, this section identifies the following factors:

- Regulatory or industry practices that govern the use or disposal of the resource;
- How the resource is applied to crops (current baseline conditions);
- Domesticated animal considerations;
- Application to harvest intervals for produce covered by the PS PR; and,
- Transportation related considerations.

3.4.2 Regulatory Oversight

Animal Waste

The USDA organic program is a nationwide program for certified organic producers, including fresh produce. For those certified farms that participate in the USDA organic program, the untreated resource (raw manure) must be applied in accordance with organic regulations (7 CFR 205.203(c)(1) and (2)). These regulations also prescribe application to harvest intervals for raw manure on fields where crops are grown, and they specify methods for composting raw manure in order to treat the resource. Specifically, USDA requires that "[t]he producer [participating in the USDA organic program] ... manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances." (7 CFR 205.203(c)) A comprehensive risk assessment was not conducted by USDA when it established the organic regulations with respect to the safety of applying raw manure to human food crops. The preamble to the organic regulations states, "Should additional research or Federal regulation regarding food safety requirements for applying raw manure emerge, [Agricultural Marketing Service] will ensure that organic production practice standards are revised to reflect the most up-to-date food safety standard." (65 Fed. Reg. 80548, 80567)

State governments in a majority of states (45 states with the exceptions being Alaska, Connecticut, Hawaii, Nevada, and Wyoming) have enacted nutrient management programs that apply some restrictions on manure disposal (University of Missouri Extension, 2008; WCFS, 2014). A mix of State and local agencies, working in series with USDA conservation districts, oversee individual nutrient management plans for farms (including for CAFOs and farms that grow produce that may be covered by the PS PR). These plans, in part, provide application rates for efficient use of the product. Manure is typically managed to avoid over-application of target nutrients (nitrogen or phosphorus) as part of a CWA strategy (as regulated by EPA). Time-of-year restrictions, application procedures including incorporation and setback distances, and other measures are primarily intended to avoid eutrophication of surface water and contamination of groundwater with limiting factor nutrients.

The USDA GAP/GHP program (see Chapter 2.1) also addresses animal manure as soil amendments in a way that helps to minimize microbial food safety hazards. The GAPs program is based on recommendations made in FDA's Guidance to Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (FDA, 1998). Similar practices are applied under produce marketing agreements, which are also voluntary programs that exist for growers across the nation.

Composting

There are many different methods used for composting materials, which depends on the material composition (animal or human waste, vegetable waste, yard scraps, etc.) in order to effectively break down the parent materials for use in whatever application the compost is meant to be applied. There is no one scientifically approved method of composting organic material. The use or storage of compost and raw manure may be regulated by EPA under the CWA when there is the potential to release pollutants such as nitrogen and phosphorus, organic matter, sediments, pathogens, heavy metals, hormones, antibiotics, and ammonia to the environment (40 CFR §§ 122.42 (e)(1)(ix); (e)(2); and (e)(5), and 40 CFR § 412.4(c)(5)). Facilities that may store raw manure and may perform composting operations (e.g., CAFOs) may be required to apply for a NPDES permit (40 CFR §§ 122.42(e)(1)(i) & (e)(5)). Although not all CAFO operations are required to obtain and hold NPDES permits, those that discharge or propose to discharge must comply with terms of such a permit.

3.4.3 Current Background Conditions

Data Sources

The USDA NASS and ERS have been collecting information on agriculture since the early 20th century, and have been collecting information on the prevalence of BSAs use as a soil amendment for over ten years. USDA conducts its Census of Agriculture survey every five years. The data generated from the survey is publicly available on the USDA website, and was used to develop portions of the affected environment for this EIS, specifically data from the 1997, 2002, 2007, and 2012 surveys, where information was available[8].

Other major sources of data used to establish the affected environment for this resource include the USDA NASS Fruit and Vegetable Agricultural Practices survey (USDA NASS, 2001), and the Fertilizer Use and Price statistics (USDA ERS, 2013b).

[8] http://www.nass.usda.gov/Data_and_Statistics/

General Conditions

Although the resource is defined as animal excreta or BSAs of animal origin, soil amendments can include (alone or in combination) the following three general classes: (1) Non-biological elemental soil amendments (e.g., fertilizer); (2) Non-animal biological organic material (e.g., vegetable compost); and (3) BSAs of animal origin, as detailed below. As a general practice, most farms, including farms that would be covered by the PS PR, use a combination of soil amendments to fertilize crop fields.

The USDA survey taken in 1999 (USDA NASS, 2001) was valuable in gathering statistics on numbers of farms and acreage of both fruit and vegetable growers in major producing states, and to gauge the fruit and vegetable industry's respective relative reliance on various soil amendments. USDA organic regulations became effective in 2002; therefore, this survey would include farms that have since achieved organic certification. The criteria used in selecting the targeted fruits and vegetables in the survey were: 1) produce that are included in the top 20 fresh fruit and vegetables consumed in the U.S.; 2) produce with the greatest number of planted acres in the U.S.; and 3) produce that is predominately consumed uncooked. Below are highlights of the survey[9].

- Organic elemental (Non-Biological) fertilizer use:
    - 15% of Fruit Program state farms applied *organic* elemental fertilizer in 1998-1999 (13% of the acreage).
    - 14% of vegetable farms applied *organic* elemental fertilizer in the same time (6% of acres).

- Biosolids (Chemically or Thermally Processed):
    - 1% of fruit farms surveyed applied biosolids (sludge) in Fruit Program states in 1998-1999 (2% of acres).
    - 1% of vegetable farms surveyed applied biosolids in Vegetable Program states in the same time (1% of acres).

- BSAs of animal origin:
    - 5% of fruit farms surveyed applied manure (BSAs of animal origin) in 1998 (6% of both farms and acreage in 1999):
        - 12% of surveyed fruit farms using BSAs of animal origin applied *composted* (treated) manure (21% of acreage); 66% used *aged or not treated* manure; and 23% used *other manure types or were unsure* of treatment methods.
        - 65% used dry broadcast without incorporation; 29% used dry broadcast with incorporation; 5% used liquid broadcast without incorporation.
    - 9% of vegetable farms surveyed applied BSAs of animal origin in 1998 (10% of farms, on 3% of acres in 1999):

[9] Note that the survey did not include statistics on fertilizers considered inorganic; or statistics on organic materials like cover crops. Until the 2012 Census of Agriculture, USDA did not collect information on cover crop practices.

- 41% of surveyed vegetable farms applied composted (treated) manure (55% of acreage); 31% used aged or not treated manure; and 12% used other manure types or were unsure of the treatment methods.

The statistical information (percentage of farms using certain amendment) that were gathered as a result of the survey, were used by FDA in calculating the numbers of covered produce farms and their relative acres that apply various BSAs of animal origin, as published in its *Analysis of Economic Impacts: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (FDA, 2013b).

3.4.3.1 Types of Soil Amendments

1) Non-Biological Elemental Soil Amendments

Non-biological soil amendments can include soil conditioners that help balance pH (relative acidity/alkalinity), provide carbon, and provide macronutrients and micronutrients. Non-biological soil amendments may include:

- Over nineteen pulverized or powdered mineral supplements (e.g. *inter alia*; limestone, dolomite, perlite, vermiculite);
- Humic substances (complex carbon compounds found in soil); or,
- Elemental/chemical fertilizers (defined as a product that contains the major and the secondary macronutrients at measurable levels confirmed by a qualified laboratory).

USDA organic regulations allow certified organic growers to use naturally occurring mineral additives such as soft rock phosphate, sulfate of potash magnesia, sulfate of magnesia, natural organic leonardite (potassium humate), lime/dolomite, and greensand. Specific micronutrients used as soil amendments may also be used by organic growers when soil deficiency is documented by testing (7 CFR §205.601(j)(6)). Other produce growers may add any of these non-biological soil amendments to correct for deficiencies in plant growth needs, detected by soil testing. Elemental/chemical fertilizers are an alternative to the nitrogen, phosphorus, and potassium supplied by manure, and are in fact in widespread use currently in the produce growing industry for balancing crop nutrient needs. Elemental soil amendments can be liquid which is injected, or pellets which are broadcast at planting time or side-dressed during the growing season if necessary for optimal for plant uptake. Although convenient, a major disadvantage of elemental soil amendments can be the variable direct cost of purchasing fertilizer that vary annually, and have increased over time.

Table 3.4-1 below shows a 15-year trend in fertilizer costs adjusted for coverage and corrected for inflation and price indexes. The table demonstrates that costs of fertilizer have increased over this time period; however, use of these fertilizers shows a downward trend over the same time period. This may be attributable to any number of factors including; enrollment in the USDA organic program; increased use of different farming methods such as use of cover crops or green manure; increased use of hybridized crops that improve yields under changing climate conditions; and/or increased use of nutrient management plans.

Table 3.4-1. Farm production expense for fertilizer, lime, and soil conditioners

Year	1997	2002	2007	2012
$1000x Purchase [a]	9,999,752	9,751,400	18,107,194	28,532,713
% Cost increase/ decrease Trend [a]	--	-0.5%/year	+17.1%/year	+11.5%/year
Fertilizer Price Indexes [a]	121	108	216	336
Any fertilizers or chemical expenses reported in numbers of farms[b]	1,463,256	1,376,395	1,288,360	1,187,446

Sources: [a] USDA ERS, 2013b and
[b] USDA NASS: 2014a, 2009a, 2004 (derived from respective 2012, 2007, and 2002 Censuses)

A 1999 survey of fruit and vegetable farms (USDA NASS, 2001) indicated organic fertilizer use comprised 15 percent of the fruit farms and 14 percent of vegetable farms surveyed in principal production states in the year of the survey. In comparison as stated in Chapter 2.1 of this EIS, approximately 12.5 percent of covered produce growers (4,438 farms of 35,503 covered farms) used BSAs in 2007. Fertilizer use therefore slightly exceeds the overall use of BSAs for meeting production nutrient requirements. Reasons for the slightly higher percentage of produce farms using fertilizers despite their higher costs compared to BSAs may include uniformity and predictability of fertilizer. Another contributing factor may be because of organic marketing or participation on a state marketing agreement that stipulates restrictions on usage of BSAs on specified produce crops.

2) Non-Animal Biological Soil Amendments

These soil amendments include decomposed and fresh varieties.

Decomposed plant compost/mulch/detritus may include leaf mold, spent mushroom mulch (depending on its preparation), peat moss, composted yard-trimmings and pre-consumer vegetable matter (provided those contain no table scraps or animal biological components), seaweed/kelp emulsions (containing no fish), and various grain meals like cotton seed meal.

Fresh vegetation material (not decomposed) may include cover crops and crop residue tilled into the soil, and vegetation mulch (e.g., straw, grass-clippings / landscape trimmings, amended peat moss or sawdust).

Non-animal BSAs are typically applied during the off-season by incorporating the material into the soil by disking and harrowing, or direct addition to the furrows during the sowing/planting activity; or applied as mulch after the plants have emerged. Early addition of these materials is necessary for optimal uptake of nutrients by plants because decomposition must occur to allow the nutrients to be available.

3) BSAs of Animal Origin

For purposes of analysis, there are two classifications of BSAs of animal origin: (1) Untreated and (2) Treated. A common untreated BSA of animal origin is manure from livestock or poultry; and a common treated BSA is effectively composted manure. All BSAs of animal origin are derived from animal excreta or animal by-products that present the opportunity for bacteria and other microbes that can include pathogens. The increasing levels of treatment and processing are intended to facilitate reduction in the pathogen loads of the original stock material. Refer to Appendix C of this EIS for a description of BSA management practices. Appendix C also details how these amendments are treated and land-applied to cropland.

Applying both treated and untreated BSAs of animal origin to produce growing areas is not only a nutrient source, but also a way of disposing of what would otherwise be a waste product. Farmers do this according to their own practices, as efficiently as possible; and changes to their practices could alter the efficiency. Manure is collected and can be used beneficially for agricultural purposes such as seed, grain, oil seed, or forage crop production, or for produce growing. Manure is a valuable commodity not only for raising crops but also for land reclamation and for composting for residential/landscaping uses. In certain circumstances, manure generating facilities pay manure brokers to haul manure away; and in most instances this is put to beneficial uses such as fertilizing crops or landscaping, additions to composting facilities including mixed compost (including yard waste and vegetation), for inoculating biogas production in landfills, for land reclamation (e.g., on reclaimed surface mines, or for landfill cover caps), and other uses. In only rare occurrences would manure be treated as "waste", and therefore disposed of, and not as a resource. Such instances might be if the lot is contaminated with parasites or disease requiring actions other than aerobic digestion or composting that would normally destroy or reduce the pathogens.

Table 3.4-2 below shows surveyed fruit and vegetable produce growers' sources of applied manure soil amendments, in terms of percentages of farms and percent of acres in 1999.

Table 3.4-2. Source of applied manure in program states

	Local		Transported
Crop Category/Unit	On-Farm Manure Source	Other Farm Sources of Manure	Commercial Manure Broker Supplier
All Fruit, Farms	37% of farms	16% of farms	47% of farms
All Fruit, Acres	11% of acres	29% of acres	59% of acres
All Vegetables, Farms	24% of farms	29% of farms	47% of farms
All Vegetables, Acres	10% of acres	23% of acres	66% of acres

Source: USDA NASS, 2001

Therefore, it is apparent that slightly more than half of the surveyed produce farms, (but less than the majority of the acreage on fruit and vegetable farms), which generated either on the same operation or on a neighboring operation (within convenient/inexpensive tractor hauling distance). It is also evident that commercial manure brokers supply manure to a large (but not majority) portion of the operators using animal manure and composted manure.

Roughly 8 percent of fruit farms and 6 percent of fruit farm acres; and roughly 9 percent of vegetable farms and 10 percent of vegetable farm acres; use manure (including both untreated and treated/composted BSAs of animal origin) as their nutrient supplement source; but as discussed earlier in this section, more produce growers actually use elemental fertilizer than use BSAs (USDA NASS, 2001). Crop rotation and cover crops are also practices used by produce growers to maintain fertility instead of (or in addition to) using untreated (raw manure) or treated (composted) BSAs of animal origin or fertilizers.

It is also helpful to understand if growers are using solid manure/compost products (e.g., poultry, horse) or slurry (e.g., cattle) and liquid manure (like swine). The largest source nationally of manure on both fruit and vegetables is cattle manure (combining beef and dairy in Table 3.4-3 below indicates 67 percent of fruit and 41% of vegetable growers sourcing their BSAs from cattle farming); followed by poultry manure (20 percent of fruit and 39% of vegetable growers sourcing their manure from poultry farming). Therefore, most manure is a solid (poultry; dried/aged/composted cattle; possibly containing bedding material) or semi-solid / slurry (fresh cattle) manure sources.

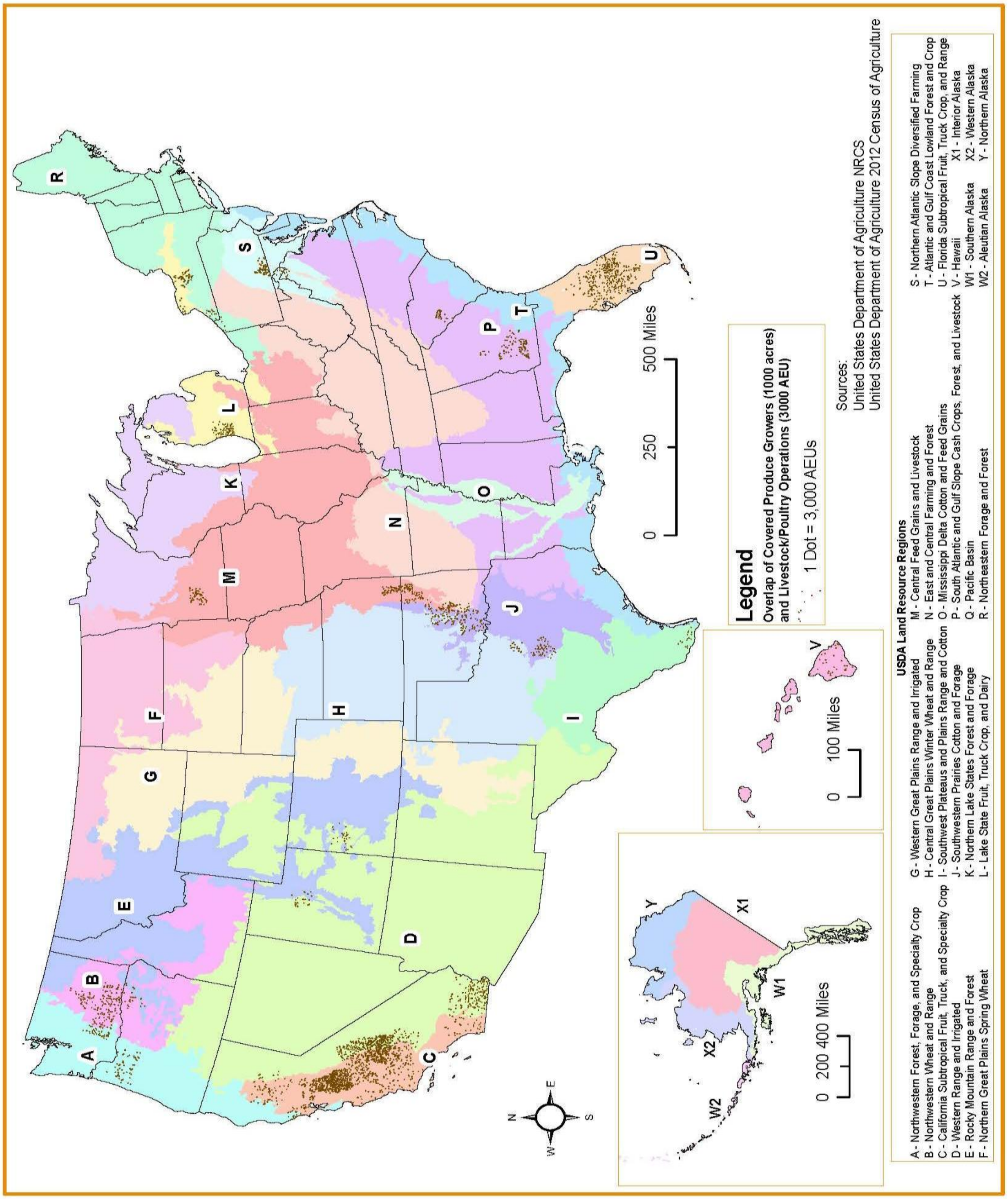
Table 3.4-3. Fruit and vegetable grower agricultural practices; type of manure applied; percentage of acres in program states, 1999

Crop category	Beef Cattle	Dairy Cattle	Swine	Sheep	Poultry	Equine	Other	Total
All Fruit	22	45	0	*	20	*	12	99%
All Vegetables	18	23	(<1)	(<1)	39	9	11	100%

* Insufficient data.
<1 Less than one percent. Sources: USDA NASS, 1999 and 2001

To understand the affected environment in terms of BSAs of animal origin generation, beneficial use and disposal, FDA undertook analysis to ascertain the relative regions where animal agriculture and produce production coincide most. Using the USDA NASS 2012 Census of Agriculture, FDA generated a map correlating the areas of intensive produce growing, with the areas of the most intense livestock and poultry production for purposes of understanding which regions of the U.S. have the greatest potential for using BSAs of animal origin for growing produce (Figure 3.4-1). Other smaller areas are undoubtedly present, but not in widespread concentration where the greatest degree of interrelationship would occur at the scale shown on the map.

Figure 3.4-1. Overlap of most likely areas of covered produce growers (1000 acres) and largest concentrations of livestock/poultry animal operations (3000 AEU)



The most noticeable concentrated areas where both animal production and produce growing occur are shown on Figure 3.4-1 and occur within eleven primary regions identified to be important for covered produce in this EIS; these regions include: A, B, C, D, J, M, L, P, S, U, and V. These eleven regions become the areas where BSAs of animal origin are likely used the most. Therefore these regions represent the largest potential for changes in handling requirements for BSAs, and where the PS PR could have the most effects on both the animal/animal products industry, and the minority portion of produce industry growers whose management practices involve using BSAs of animal origin as a preferred soil amendment.

Below is a synopsis of treated and untreated BSA of animal origin.

Untreated

Untreated BSAs are primarily animal "manure" which contains a number of different organic materials in contact with animals and enteric bacteria stock including potential pathogens. The following organic materials (alone or in combination) are constituents of Untreated BSAs of animal origin.

1. Domesticated animal excreta from poultry, livestock, and other animals, in solid, liquid, semi-solid or slurry forms, which can include either
    - Fresh or raw; or
    - Stacked or aged (kept for a period but not treated by aeration and turning)
2. Non-fecal animal by-products including, *et alia*, [bodily fluids, blood, mortalities, dander (e.g., feathers, fur, etc.), egg shells, and other byproducts of animal housing, slaughter, and rendering]
3. Soiled bedding material, feed
4. Post-consumer table waste (i.e., any food scraps from human food or animal feed, and of any type – either meat or vegetable, raw or cooked)
5. Any non-animal origin biological material contaminated with any of these materials (including special considerations discussed below) and
6. Fish emulsions

Chapter 2.1 identifies the number of farms that would be covered under the PS PR, the number of produce acres, and a breakdown of the number of manured acres. Of the 35,503 estimated farms that would be covered by the PS PR (based in 2014 estimates), approximately 821 farms use raw manure, equating to about 70,134 manured acres. There are no available data that identifies the locations of farms that specifically use untreated (or treated) BSAs aside from the information that may be extrapolated from Figure 3.4-1.

The 2001 NASS survey of fruit and vegetable producers in states (accounting for more than 80 percent of produce growers) reported that on average, 3.2 tons of manure were applied per acre per year on fruit operations; and 3.1 tons per acre per year were applied on vegetable operations (USDA NASS, 2001). The fruit and vegetable survey was conducted in 1999, before the establishment of the National Organic Program in 2002. According to studies conducted by the University of Wisconsin Extension, one Animal Equivalent Unit (AEU) or 1,000 animals (identified as bovine) produces approximately 15 tons of manure per year (UW-Extension, 2014). At those average application rates, one dairy cow produces enough manure for nearly seven acres of crops per year.

The methods and timing of application of BSAs of animal origin are discussed in Appendix C (Manure Memorandum). In general, land application of manure can be via injection of liquid forms, or broadcasting of solid and slurry usually followed by incorporation to minimize volatilization of ammonia nitrogen and for aesthetic principals. Optimization for plant uptake of phosphorus (P) is slow because P (often the limiting element) is not as mobile as nitrogen (N). For this reason, among others, manure is frequently supplemented by side dressing with fertilizers. Also, in part because N compounds in untreated manure could damage the plants, it generally means that untreated BSA materials are applied prior to planting or during planting; not during the growing season. However, if midseason soil testing would indicate deficiencies of nutrients, a grower would need to supplement by topdressing or side dressing with additional macronutrients (N/P/K), generally accomplished with specific elemental, chemical fertilizer to meet the N/P/K plant requirements.

Table 3.4-4 shows the trends in untreated manure use in growing all crops (not just potentially covered crops). Trend data shows that over the last 15 years approximately 72,165 fewer farms are using raw manure. The amount of crop acres where manure is applied decreases slightly.

Table 3.4-4. Trends in use of raw manure (untreated BSAs of Animal Origin) from 1997 to 2012

Year	1997	2002	2007	2012
Total All U.S. Farms Using Manure [b]	No data	347,585	307,073	275,420
Trend in # Total U.S. Farms Using Manure	No data	Not quantifiable	-2.3%/year	-2.1%/year
Total All Farm Manure Acreage [b]	No data	22,749,251	22,096,315	22,070,968
Trend in # Acres Using Manure	No data	Not quantifiable	-0.057%/year	-0.023%/year

Sources: [a] NASS ERS, 2013b and
[b] USDA NASS: 2014a, 2009a, 2004 (derived from respective 2012, 2007, and 2002 Censuses)

Mixed Soil Amendments

Agricultural teas, green manure, pre-consumer vegetable matter, and any other organic matter would also be classified as being an untreated "BSA of animal origin", *if* the producer of these products is using animal manure as the activation/starter medium, or if the product is contaminated or mixed in part or in whole by untreated BSAs of animal origin. Likewise, agricultural teas that use agricultural water that does not meet the microbial standards of the PS PR, or that have incorporated agricultural tea amendments (e.g., addition of molasses to bolster microbial populations) would also be classified as untreated BSAs of animal origin, irrespective of the original feedstock used.

Treated

Any of the above "Untreated" materials of animal origin subjected to physical, thermal, chemical, or biological treatment (such as by the controlled prescribed composting treatment processes described in the PS PR), or a treatment in combination with any of these to eliminate or substantially reduce pathogens to meet proposed microbial reduction standards (proposed §112.55(b)). Examples include pelletized poultry manure, dried blood meal, rendered/steamed bone meal, treated feather meal, or composted manure processed according to the provisions of the PS PR.

This also includes BSAs further treated to reduce pathogens to the more stringent microbiological standards presented in the PS PR (proposed §112.55(a)). For example, the two-phase "pasteurization" process for preparing mushroom mulch.

The storage of BSAs of animal origin, including storage for treatment can contribute to issues such as off-gassing (releasing nitrogen in the form of ammonia) as discussed in the Chapter 3.5 Air Quality, and runoff that can enter surface waters as discussed in Chapter 3.1 Water Resources.

Of the 35,503 estimated farms (based in 2014 estimates) that would be covered by the PS PR, approximately 3,618 farms use treated BSAs of animal origin, equating to about 430,828 produce acres. There are no available data that identify the locations of individual farms that specifically use treated BSAs of animal origin. Therefore, pinpoint locations within general regions of predicted impact shown on Figure 3.4-1 are not possible at this level of analysis. Farms using treated BSAs of animal origin exist outside of the co-location livestock/produce concentration areas as well; and not all of the areas indicated on Figure 3.4-1 would have either individual or community composting facilities for BSAs of animal origin.

3.4.3.2 Domesticated Animal Considerations

Domesticated animals can occur in a growing area for several reasons such as (1) draft or working animals; (2) animals allowed to graze on unharvested portions of produce; or (3) animals introduced for co-management practices (e.g., to control insects). Draft animal use is not typical except on old order (Anabaptist) farms, because the large majority of modern farming uses mechanized machinery. Grazing on unharvested fields would be limited to certain crops suitable for forage, and timed mostly to occur following the growing season. Co-management for insect control is not a common practice. Therefore, given all three of these considerations, it is anticipated that the involvement of domesticated animals would introduce a relatively minor opportunity for involving manure in produce growing areas.

While draft animals were used extensively in farming until the mid-20th Century, engine- or motor-driven mechanized farm machinery has quickly and largely replaced the ox, mule, and horse for plowing and pulling on U.S. farms. The exceptions to this overall trend include Plain Sect agriculture practices (e.g., Amish and Old Order Mennonite, or conservative Anabaptist farmers) and uncommonly encountered farms in similar conventional traditional agrarian communities. Plain Sect farms sometimes contract out their plowing and pulling work, but most communities or congregations are restricted from owning and otherwise using powered machinery. For those who choose to not contract out plowing, planting, and pulling, draft animals (oxen, mules, and horses) are their principal option for cultivating and heavy hauling in fields. Amish communities exist in 30 U.S. states; with the largest communities primarily in Ohio, Pennsylvania, Indiana, Wisconsin, New York, Missouri, and Montana. Mennonite communities are similarly widespread and flourish in the same farming areas as well as California, Illinois, and Kentucky. Due to subdivision of farm inheritance among siblings, in some areas where farm property for expansion of the community is limited, the land available for a farm family to make its living is considerably comparatively small. For example, the average Lancaster County, Pennsylvania farm is 78 acres (Komancheck, 2013); which is not enough land to produce yields sufficient to support farming as a sole income based on grain production. Therefore, specialized farming such as livestock farming and/or growing a high-value crop like tobacco or fresh produce is necessary to maintain suitable returns to make farming a viable sole livelihood for these small family farms.

3.4.3.3 Application to Harvest Intervals

A brief explanation of application (of BSAs of animal origin) to harvest intervals will assist the reader in understanding the potential relationship between application of BSAs of proposed animal origin as proposed under the PS PR and the growth cycle requirements for certain crops covered by the PS PR. Fast-growing produce crops with harvest cycles 45 days or less from planting of seed are few, and include those listed on Table 3.4-5. Most fresh produce crops have full summer planting to harvest cycles, varying over 45 days to under 120 days (Table 3.4-5). While parts of the U.S. only get one crop per year (notably the northeastern regions such as region R as shown on Figure 1.7-4), other parts of the U.S. (notably the subtropical regions including regions B, C, D, and U, can achieve multiple – double- or triple- cropping within one year. Another consideration is that some, produce crops have multiple harvest cycles. That would include perennials or biennials, e.g., caraway, fennel, mints, young sorrel, and strawberry (Dolezal, 1991), which could allow successive harvests in less than 45 days.

BSAs of animal origin may generally be applied pre-planting, or in some cases at the time of planting, or during growing (e.g., side dressing). USDA and state nutrient management regulations recommend against or prohibit application when the ground is frozen; and therefore fall (post season) or spring (pre-planting or during planting) application of are strongly advocated. What is not well documented is if or when BSAs of animal origin are applied between the harvest intervals for crops with shorter seed to harvest durations (Table 3.4-5). It is also possible that a combination of soil amendments may be used during these periods, such as elemental/chemical fertilizers. Because top dressing with manure can damage the plants, side dressing is a more attractive option, and would be done to supplement crop needs if optimal nutrients were not applied prior to planting.

Table 3.4-5. Harvest cycles for example produce

Fresh Produce Commodity Type	Seed to Harvest Cycle Duration	45 Days or Less -- *Fast-growing*	Less than 90 Days (3 mo.) -- *Full-summer*	>90-120 Days (4 mo.) -- *Long-season*
Baby Lettuce/Greens	40 days	✓***		
Bean, Snap	54 days		✓	
Beet	58 days		✓	
Cantaloupe	86 days		✓	
Carrot	68 days		✓	
Cauliflower	70 days		✓	
Celery	105-130 days			✓
Cucumber	57 days		✓	
Endive	95 days			✓
Garden cress	vary 45-70 days		✓	
Garlic	90-100 days		✓	
Kohlrabi	45-60 days		✓	
Lettuces	45 days*	✓		
Melon	110 days			✓
Most herbs	vary by type**, 30 – 60 days	**some**	✓	
Mustard greens	30 days	✓		
Onion, Drying	110 days			✓
Onion, green	60-110 days	(from bulbs)	**Some** (from seed)	✓
Pea, English Garden	60 days		✓	
Pea, Snap or Snow	70 days		✓	
Radish	26 days	✓		
Roquette or Arugula	35 days	✓		
Spinach	45 days ***	✓	✓ (multiple cuts)	
Summer Squash	50 days		✓	
Tomato	80 days		✓	
Turnip	45 days	✓		
Watermelon	73 days		✓	

Source: Dolezal, 1991.
* Head and romaine lettuce mature about 70 days from seeds and 20-35 days from transplants; leaf lettuces at about 45 days from seed.
** Basil 30 days, Chervil 40-60 days, Chinese parsley 40-45 days, Cilantro or Coriander 30-40 days, Dill 25-30 days, Oregano 35 days, Parsley 45-60 days, Sage 35 days, Savory 42 days, Sweet marjoram 40-45 days
*** Successive spinach and greens cuttings occur at more frequent intervals

USDA and Industry Application to Harvest Intervals

In general terms, GAPs recommend avoiding side dressing with raw manure, but instead apply manure and incorporate it prior to planting. In addition, GAPs recommend using treated (composted) material instead of raw or aged manure; and to apply it as early as possible for both maximal plant uptake as well as to avoid contaminating produce with pathogens (FDA, 1998).

USDA organic regulations (7 CFR Part 205) suggest the use of treated (composted) manure instead of untreated manure, however if untreated manure is used, then:

- 90 days between application and harvest are required if the harvested portion of the crop does not contact the soil (e.g., corn or fruit trees); or,
- 120 days between application and harvest if the harvested portion of the crop could contact soil during the growing season (e.g., bush crops, vines, root crops, leafy greens, etc.).

The nature of the difference is such that a farmer complying with the PS PR would still be in compliance with the USDA organic regulations requirements for BSAs.

The California Leafy Greens Marketing Agreement (CA LGMA, 2013) and Arizona LGMA (AZ LGMA, 2013) both have the following restrictions on BSAs of animal origin:

- The grower should not use untreated (raw) manure in edible crop production; and for previously treated fields, a one-year waiting period shall be observed before planting any variety of leafy green crops (the same preclusion or waiting period also applies to California's cantaloupe marketing agreement).
- For treated (composted) manure, if microbe levels are below corresponding action level numbers, then an application time interval of at least 45 days before harvest must be observed.
- For further treated physically processed (heated) products, according to the LGMA guidelines for non-validated process, an observe application time interval of at least 45 days before harvest; or for validated process, no application to harvest interval is required.

The Tomato Food Safety Audit Protocol (NATWWG and United Fresh, 2008) requires that only properly composted manure is allowed for use in tomato fields and greenhouses.

Mushroom Good Agricultural Practices (Penn State and AMI, 2010) currently require that producers receive and store materials in a manner that avoids the potential for cross contamination between mushrooms and an unpasteurized substrate (i.e., require processed BSAs of animal origin, exclusive to untreated or simply treated compost that are not pasteurized).

<u>Relative Risk of Produce Contamination</u>

Together, the combined types of covered produce constitute the single largest category of foodborne illness cases attributed to a single food and over twenty commodities accounted for serious reported outbreaks of disease during the study period from 1996-2010 (FDA, 2013c). FDA's Draft QAR indicates in its exposure assessment that sources of contamination are influenced by input (pathogen load) and survival of pathogens in the environment, and examines the pathways of pathogen transfer. Enteric or gastrointestinal pathogens are generally not considered to be derived outside of a host animal or human source (FDA, 2013c) but can persist in the environment depending on factors including their original input. Animal excreta are considered to have a relatively high potential for harboring zoonotic pathogens such as *Salmonella* species (FDA, 2013c).

Table 3.4-6 illustrates in general terms how different factors related to soil amendments used in growing produce influence the relative likelihood of produce contamination (FDA, 2013c). Much depends on the type(s) of soil amendments added, and the type and degree of treatment the material receives prior to being applied to the growing area soils (FDA, 2013c). In addition, the application method and application timing also influence the likelihood of contamination (FDA, 2013c). Note that non-biological soil amendments are not within the scope of the PS PR, because they present at lower relative risk in terms of biological contamination of fresh produce, no matter if applied prior to or during planting, or as a side dress during the growing season.

Table 3.4-6. Produce contamination from soil amendments

Relative likelihood of produce contamination	Least	←	→	Most
Type of BSAs	Non-Biological	Non-Animal Origin	Animal Origin	Human Waste
And where pathogens exist in the BSA source(s), the likelihood of contamination is a function of pathogen load that is influenced by the following factors:				
Treatment	Pasteurized (heat, chemical, and physical destruction of microbes)	Composted (a.k.a., "Treated")		Untreated/Raw or Aged; Partially Treated; Re-Contaminated
Application Timing	Increased Duration between Application and Harvest Time		Decreased Duration between Application and Harvest Time	
Application Method	No Contact with Harvestable Portion	Effort Made to Minimize Contact		Contact with Harvestable Portion

Source: FDA, 2013c

3.4.3.4 Transportation Related Considerations

There are costs associated with transporting BSAs of animal origin for any distance that could make beneficial reuse uneconomical; therefore, there may be opportunities for technologies that reduce the moisture content of manures to improve efficiency if local disposal becomes an unattractive option. Air quality conditions relative to transportation are addressed in Chapter 3.5.

3.4.3.5 Methods to Analyze Impacts

Summary of Data Collected

Of the approximately 35,503 farms that would be covered by the PS PR, approximately 4,438 farms (12.5 percent) used BSAs (Chapter 2.1). Of the 4,438 covered farms using BSAs, approximately 820 farms used untreated BSAs (raw manure). An estimated 3,618 farms (81.5 percent) use treated BSAs (composted manure). The remainder of covered farms (approximately 87.5 percent) may use chemical fertilizers.

There are eleven regions where BSAs of animal origin are likely used the most; therefore these regions represent the largest potential for changes in handling requirements for BSAs of animal origin: A, B, C, D, J, M, L, P, S, U, and V.

USDA NASS data (2001, 2002, 2007, and 2012) shows a downward trend in the use of both untreated manure and chemical fertilizers (Chapter 3.1.3.1, Table 3.4-1).

While most crops have a seed to harvest interval of approximately four months, intervals for application of BSAs of animal origin to crop harvest vary by Federal (organic regulations) and industry marketing agreements. USDA organic regulations have shorter application to harvest intervals (90/120 days), while some marketing agreements may have application to harvest intervals of up to a year (Chapter 3.4.3.3). FDA found no data to suggest on a consistent basis if and when BSAs of animal origin are applied between the harvest intervals for crops with shorter seed or transplant to harvest durations (between double or triple cropping intervals), or if other soil amendments may be used during these periods, such as chemical fertilizers.

Facilities that may store raw manure and may perform composting operations (e.g., CAFOs) are required to apply for a NPDES permit, if those facilities discharge or propose to discharge. Therefore, if the facilities are operated and maintained in accordance with their permits, under normal circumstances there are processes in place to protect against adverse harm to the environment (effects from run-off). It may be noted that significant rain events, for example, may contribute to unintentional discharges to receiving waters.

The leafy greens industries in California and Arizona implemented marketing agreements in 2007 that impose food safety requirements on participating growers. The CA LGMA covers approximately 99 percent of the volume of leafy greens produced by the State (380 farms), and the AZ LGMA covers approximately 41 farms that would be covered by the PS PR. The AZ LGMA accounts for approximately 85 percent of the leafy greens products consumed in the U.S. and Canada from November to March (FDA, 2013b).

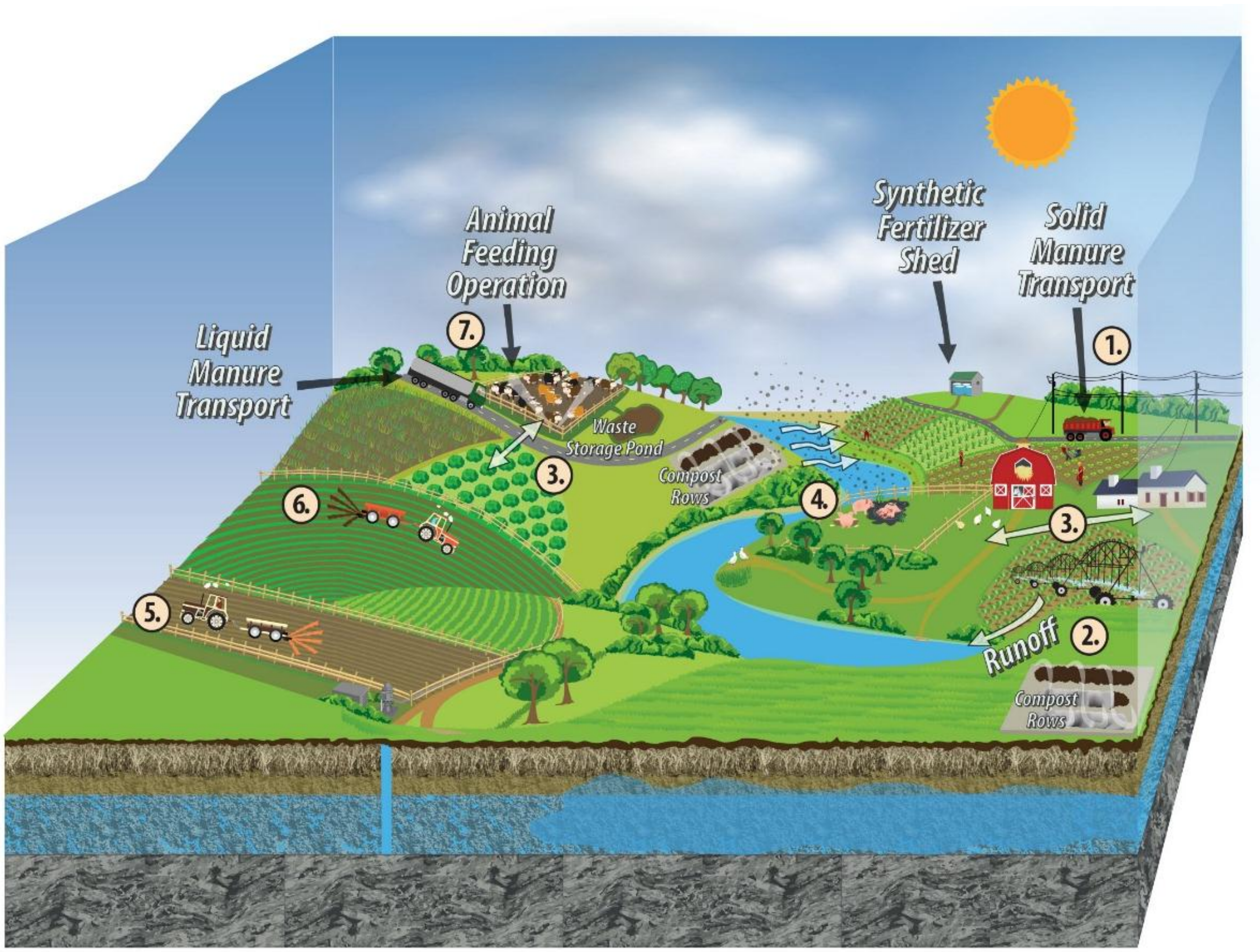
Conceptual Site Model

Figure 3.4-2 illustrates many of the major operations, activities, and processes that contribute to waste generation on working produce farms that may be affected by the PS PR. This graphic summarizes information described within this chapter in order to most comprehensively represent the types of activities that may be affected by the various provisions of the PS PR. The following provides a summary of the major activities that are depicted in Figure 3.4-2:

- **Land Application of Manure**: Application of manure (followed by incorporation) is best done after the harvest (as depicted in the lower illustration), or on cover crops that are plowed under prior to planting (as depicted in the upper illustration).
- **Animal Feeding Operations**: Facilities where manure is generated and collected, for beneficial use onsite and/or offsite.
- **On-Farm and Off-Farm Static Composting Operations**: Facilities where manure is treated to achieve thermal and temporal requirements.
- **Best Management Practices and GAPs**: As outlined below in the Key Components list, the Conceptual Site Model diagram also illustrates measures that can be taken by animal producers and produce growers for environmental and economic benefits.

The Key that follows contains text that applies to numbered key components of the diagram.

Figure 3.4-2. Conceptual site model for animal waste good agricultural practices and conservation measures.



Key to numbered illustrations within Conceptual Site Model (Figure 3.4-2)	
1	● Growers purchasing manure products should obtain a specification sheet from the supplying manure broker for each shipment, and the spec sheet should include information about the method of treatment
2	● Implement practices to avoid potential of contaminating treated manure ● Consider GAPs and conservation measures to minimize leachate from manure storage or treatment areas from contaminating produce growing and handling areas
3	● Manure storage and treatment sites should be situated as far as practicable from fresh produce production and handling areas
4	● Consider barriers or physical containment to secure manure storage or treatment areas where runoff, leaching, or wind spread is a concern
5	● Incorporating manure into soil prior to planting; (applying raw manure or leachate from manure to produce fields during the growing season is not recommended ● Use cover crops (a.k.a., Green Manure) instead of or in addition to BSAs of animal origin applied after harvest (during the off season) to build soil fertility
6	● Maximize time between application of manure to produce production areas, and harvest; or use treated manure instead of raw or aged manure ● USDA Certified Organic standards require application of composted manure (treated according to specific standards including C:N ratio, timing/aeration or turning, temperature minimums); or if untreated / aged manure is used then an application to harvest duration is required (120 days for crops whose edible portion contacts the soil; 90 days for all other crops) (USDA AMS, 2014)
7	● Growers should consult State and local manure handling expertise for specific advice for their region and individual operation; this includes agricultural colleges and cooperative extension service agents with specific expertise ● Domestic animals should be excluded from fresh produce fields, vineyards, and orchards during the growing season (confinement in pens or yards) ● Growers should implement measures to ensure that BSAs of animal origin from adjacent fields or waste storage facilities does not contaminate the produce production areas

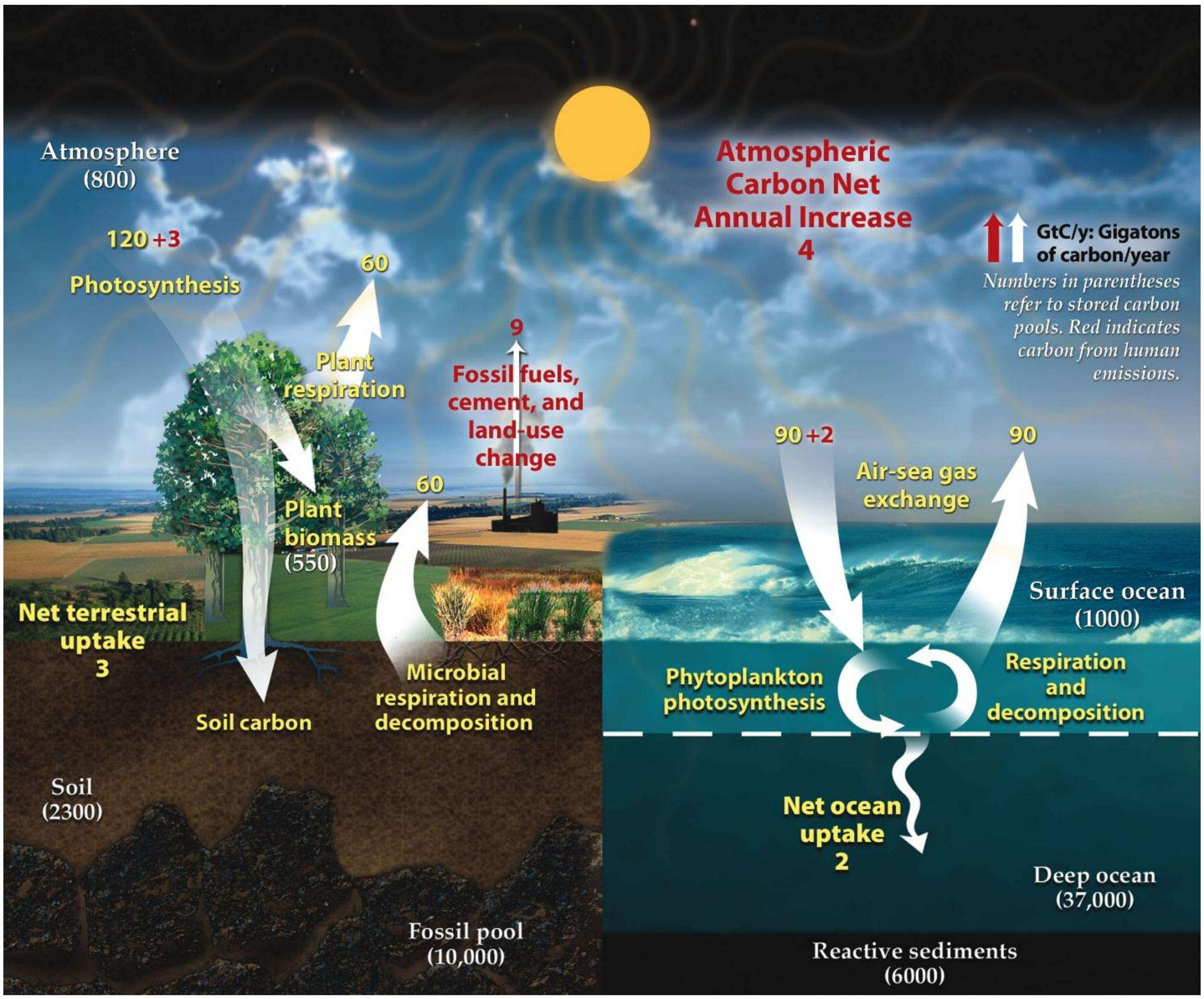
Source for Key text: FDA (1998), except where otherwise indicated.

3.5 Air Quality and Greenhouse Gases

3.5.1 Definition of the Resource

Scientists have become increasingly interested in the impacts of human activities on global temperature and climate change, spurring the EPA to identify carbon dioxide (CO_2), methane (CH_4), and nitrous oxide (N_2O) as the most important long-lived GHGs related to warming temperatures in the atmosphere. Although all of these gases occur naturally in the atmosphere, human activities have significantly increased the concentrations of these gases. Since the beginning of the industrial age in 1750, concentrations of CO_2, CH_4, and N_2O have increased by 38 percent, 143 percent, and 18 percent, respectively (USDA CCPO, 2011).

Figure 3.5-1. Components of the global carbon cycle (DOE, 2013)



The process by which carbon moves between the atmosphere and different reservoirs in the earth is called the carbon cycle. The main reservoirs in which carbon can be stored include the atmosphere, the oceans (in dissolved inorganic carbon and marine biota), the earth's interior, the terrestrial biosphere (living and dead organisms), and sediments including fossil fuels and SOM. The movement of carbon among these reservoirs occurs through a variety of chemical, physical, geological, and biological processes. Major components of the global carbon cycle include: (1) the conversion of atmospheric CO_2 into organic compounds through photosynthesis in plants and phytoplankton; (2) the consumption of carbon and respiration of CO_2 by plants, animals, and microbes; (3) SOM formation; and (4) the return of CO_2 to the atmosphere. Carbon can move quickly within this cycle or may be stored in reservoirs for long periods of time (Denman et al., 2007). Humans can have large effects on the carbon cycle through burning fossil fuels and altering land uses. Figure 3.5-1 illustrates the carbon cycle.

3.5.2 Regulatory Oversight

The Clean Air Act (CAA) (42 U.S.C. § 7401 et seq.) requires EPA to set National Ambient Air Quality Standards (NAAQS) for pollutants considered harmful to public health and the environment. EPA has established NAAQS (40 CFR Part 50) for six criteria pollutants, which include carbon monoxide (CO), lead (Pb), nitrogen dioxide (NO_2), ozone (O_3), sulfur dioxide (SO_2), and particulate matter (PM) between 2.5 and 10 micrometers in diameter (coarse, PM_{10}) or that is less than 2.5 micrometers in diameter (fine, $PM_{2.5}$). Primary NAAQS provide public health protection, while secondary standards protect against welfare effects such as damage to farm crops and vegetation (EPA, 2012b).

The CAA mandates that each state achieve and maintain acceptable levels of the six criteria pollutants. If areas have levels of pollutants that are higher than the acceptable limits set by EPA, then the area is deemed a nonattainment area for the specific pollutant. The CAA requires states to develop a written State Implementation Plan (SIP) that outlines how the state will control air pollution under the CAA (EPA, 2013b). Each SIP consists of regulations, programs, and policies that will aid the state in reducing air pollution in (EPA, 2013b). State and local governments also conduct air quality monitoring and facilities inspections to enforce CAA regulations (EPA, 2014i). Each SIP consists of regulations, programs, and policies that will aid the state in reducing air pollution in nonattainment areas. State and local governments also conduct air quality monitoring and facilities inspections to enforce CAA regulations (EPA, 2014i). Once a nonattainment area meets the standards and redesignation requirements for attainment, EPA designates the area as a "maintenance area" (EPA, 2013b). Therefore, maintenance areas represent areas that used to be in nonattainment but continue to be monitored by the EPA following redesignation to attainment.

3.5.3 Current Background Conditions

Resources Used to Establish Existing Environment for Air Quality

Information and data on criteria air pollutants and GHGs were gathered in order to establish the existing environment at both a national and regional scale. Data from EPA on emissions of criteria air pollutants by source sector were compiled to provide a broad scope of agricultural impacts on air pollution and NAAQS in the United States. In addition, non-attainment area maps were generated in order to illustrate the regions and States that feature the most existing air quality problems. Data related to national and State-level GHG emissions were pulled from two major sources: (1) the EPA *U.S. Greenhouse Gas Emissions and Sinks: 1990-2012* report (EPA 2014k); and (2) the USDA *U.S. Agriculture and Forestry Greenhouse Gas Inventory: 1990-2008* report (USDA CCPO, 2011). Areas of covered farms and associated livestock operations were also overlaid on maps in order to show where air quality resources have the biggest potential to be impacted regionally with regard to the PS PR.

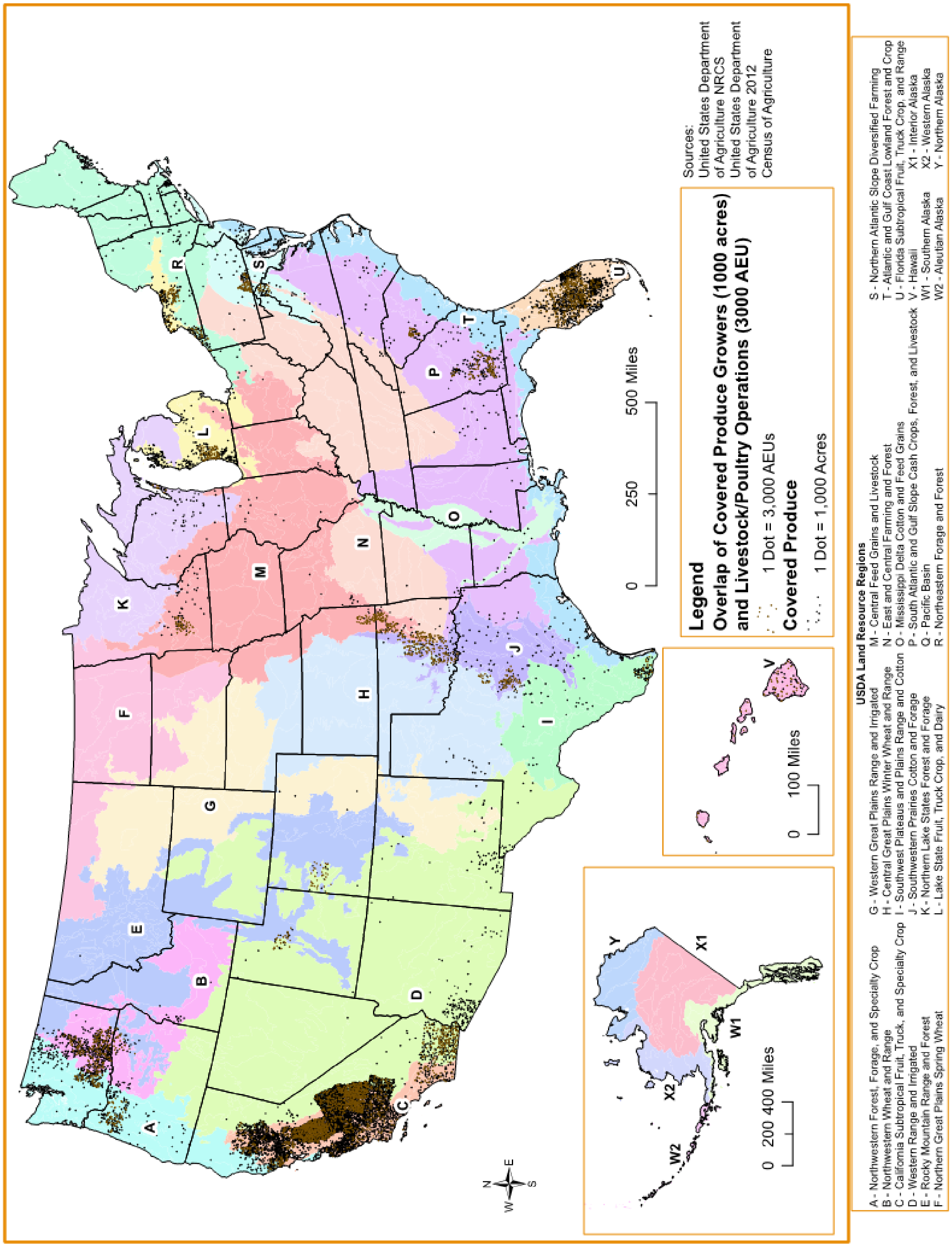
Affected Environment Summary – Covered Farms under the PS PR

Farming operations that are likely to be affected by the PS PR include both cropland and livestock agriculture, both of which contribute to total emissions of air pollutants and GHGs. In order to address potential air quality impacts of the PS PR it is important to understand where covered farms and associated livestock operations are located. Figure 3.5-2 depicts USDA 2012 Census of Agriculture dot-density maps for major concentrations of produce producing areas (concentrations of 1,000 acres of produce), and where large concentrations of livestock and poultry operations (3,000 or more animal equivalent units) overlap with these areas. These data are overlaid on our base map, which can be viewed as a base-map illustrating the states and regions which are most likely to experience the largest impacts to air quality resources from the PS PR. Subsequent maps and figures provided in this section (and later referenced in Chapter 4) will illustrate aspects of existing air quality with the most significant regions affected by the PS PR.

Figure 3.5-2 shows the most important areas of produce production, coupled with the largest areas of farm animal concentrations within covered produce areas. The most noticeable concentrations occur in just four regions, which are listed below in approximate order of largest produce acreage. Importantly, over roughly 80 percent of the covered produce acreage shown in the map occurs within these four regions:

- **Region C –** Subtropical Fruit, Truck Crop, and Specialty Crop (central California)
- **Region D –** Western Range and Irrigated (southern California, southwestern Arizona)
- **Region U –** Florida Subtropical Fruit, Truck Crop, and Range (south-central Florida)
- **Region B –** Northwestern Wheat and Range (central Washington)

Figure 3.5-2. Most likely areas of covered produce growers and overlap with largest concentrations of livestock/poultry operations



Existing Conditions Summary: NAAQS

Of the six criteria pollutants, particulate matter (also known as particle pollution or PM) emissions are most directly associated with agricultural practices. According to data from the EPA, 896,727 tons of $PM_{2.5}$ and 4,502,018 tons of PM_{10} were released in the U.S. in 2011 from agriculture, mostly as a result of crop and livestock dust emissions (EPA, 2014i). Agricultural practices also indirectly contribute to ground-level ozone (O_3) formation through emissions of ozone precursor gases such as nitrogen oxides (NO_x) and volatile organic compounds (VOCs). Direct agricultural practices are not heavily associated with emissions of the remaining criteria pollutants relative to larger sources such as fossil fuel combustion from the transportation and industrial sectors. However, it is important to note that increases in energy use or mobile transport related to the PS PR could lead to increases in emissions of these pollutants.

The existing NAAQS set the amount of pollution allowed in the outdoor air for each criteria pollutant; however, these standards themselves do not establish emission control requirements for any particular industry, including agriculture. In fact, agricultural operations have often been treated differently than other industries with respect to Federal and State laws. Many laws either directly exempt agriculture from regulations or are set up so that farms avoid most of the regulatory impact. With regard to environmental law, regulators have typically focused more attention on larger, more visible sources of pollution (e.g., factories) compared to small farms (Copeland, 2014). It is the responsibly of each state to determine how to reduce a nonattainment area's pollution to meet the NAAQS in their SIP, which must then be approved by EPA. Most agricultural operations are believed to be minor sources of air pollution, and most have not been required to comply with SIP permitting requirements. For individual operations to be required to comply with CAA regulations they typically must meet the definition of a "major source" of regulated pollutants, which can vary by region and whether the source occurs in an existing nonattainment area or not. Most farms do not meet this definition and are therefore exempt from CAA regulations. However, a lack of adequate air quality monitoring data from agricultural operations has often prevented regulators from moving forward with regulations specific to agriculture (Copeland, 2014).

Despite the lack of national-level policies related to agricultural air quality, some states are addressing agricultural emissions of major criteria pollutants (e.g., particulate matter) in their SIP's when the agricultural industry makes up a greater portion of overall emissions. For example, states like California and Arizona, which feature some of the most impaired air quality in the U.S., are addressing PM_{10} from agriculture by incorporating conservation management practices developed with growers and USDA into PM_{10} implementation plans for their nonattainment areas (EPA, 2013c). Air emission permits are now required for many agricultural operations in California, with requirements varying depending on the size of facilities, level of emissions, and attainment status in the area the source is located. However, the lack of sufficiently accurate data on emissions from agricultural activities in general has contributed to resistance from the farming community in implementing laws to regulate agricultural emissions (Copeland, 2014).

Particulate Matter

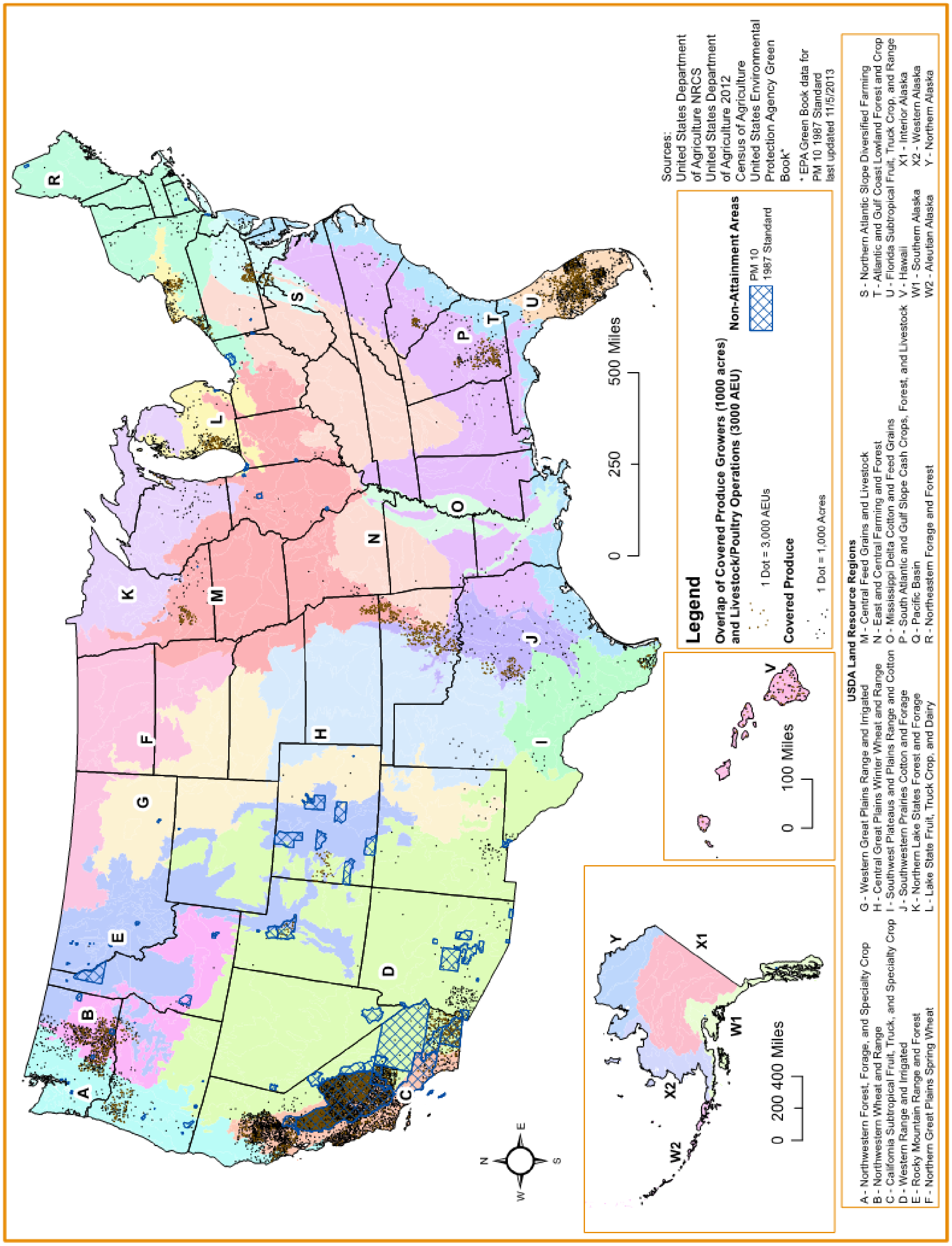
Particulate Matter is a complex mixture of extremely small particles and can be composed of acids, organic chemicals, metals, and soil or dust particles. The EPA regulates particles that are 10 micrometers in diameter or smaller because they can generally pass through the throat and nose and enter the lungs, potentially causing serious health effects such as respiratory and heart diseases and other ailments. Primary particles are emitted from a source, such as smokestacks, fields, unpaved roads, or construction sites. Secondary particles, which make up most of the fine particle pollution in the U.S., form through a variety of chemical reactions in the atmosphere (EPA, 2013d). The majority of states have not required the agricultural industry to establish emission control requirements for PM.

Agriculture is a major contributor to emissions of coarse particulate matter (PM_{10}), which is typically directly emitted to the atmosphere by actions that break up the soil such as road and field travel, tillage operations, animal movement, harvesting, and wind erosion. Fine particulate matter ($PM_{2.5}$) can also be directly emitted to the atmosphere by combustion processes from vehicles and fires. However, a significant portion of fine particulate matter is formed in the atmosphere by chemical reactions with PM precursor gases such as NO_x, VOCs, and ammonia (NH_3). Sources of these precursor gases can include engines, fertilizer application, and animal operations (USDA NRCS, 2012).

The non-attainment areas for PM_{10} and $PM_{2.5}$ (based on EPA Green Book data) are illustrated in Figure 3.5-3 and Figure 3.5-4, respectively (EPA, 2014j). The highest concentrations of particulate matter non-attainment areas that overlap with covered produce operations occur in central and southern California (regions C and D). Estimates of total emissions of PM_{10} and $PM_{2.5}$ in 2011 by source sector are depicted in Figure 3.5-5 and Figure 3.5-6, respectively (EPA, 2014j). The majority of the emissions attributed to agriculture are a result of crop and livestock dust emissions, with minor contributions from livestock waste. However, PM emissions from unpaved roads and fuel combustion are not included in the agriculture source sector; therefore, the total contribution of the agricultural sector to PM emissions is underestimated in these figures.

Ammonia emissions are becoming a greater health concern in the U.S. (Copeland, 2014). Ammonia is produced as a by-product of the microbial decomposition of the organic nitrogen compounds in manure. Therefore, ammonia emissions may result from any area that contains manure, such as open lots, stockpiles, lagoons and pits, and land application areas (EPA, 2004). Ammonia emissions from liquid manure storage structures rapidly adhere to particles in the air, thereby contributing to the formation of ambient particulate matter (Copeland, 2014). Once emitted, ammonia is also re-deposited back to earth in rainfall, which can impair surface waters and harm aquatic life. The EPA estimates that animal agriculture accounts for 50 to 85 percent of total man-made ammonia volatilization in the United States. In the U.S., livestock and poultry production is the largest contributor of ammonia gas emissions, followed by agricultural fertilization (eXtension, 2012a).

Figure 3.5-3. Coarse Particulate Matter (PM_{10}) Non-Attainment Areas (1987 Standard) (EPA 2014j)



Animal Feeding Operations (AFOs), which refer to facilities designed to hold and grow livestock or poultry in a confined area, are becoming more prevalent in the U.S., and PM emissions from these open-lot AFOs are an increasing environmental concern. Very large operations (housing 300 or more cows or equivalent numbers of other species) are defined as Concentrated Animal Feeding Operations, or CAFOs. Of the approximately 238,000 farms that are considered AFOs, roughly 5 percent raise enough animals to be designated as CAFOs (Copeland, 2014). However, organizational shifts in the industry within the past two decades have resulted in larger facilities that are more concentrated in certain regions. Particulate matter has the potential to carry pathogens that could directly lead to human infection or to the contamination of adjacent produce croplands. In addition to human health impacts, fugitive PM (dust) from cattle feedyards and other farms can reduce visibility and carry odors.

On animal lots, the main sources of primary particulate matter are hoof action on uncompacted manure, vehicle traffic on unpaved roads, feed processing, and fossil fuel combustion. These coarser particles generally impact local environmental air pollution. Secondary PM for CAFOs and other animal operations results from gas-phase NH_3 forming fine particles during atmospheric reactions, which tends to impact regional and national air quality. The highest concentrations of fugitive dust from open-lot AFOs come from hoof action or wind scouring of uncompacted manure (eXtension, 2012b). Revisions of regulations from the CWA to better protect surface waters from nutrient-rich runoff from CAFOs can impact air quality. Livestock operators may respond to required nutrient management plans by allowing nitrogen to volatilize into the atmosphere in uncovered lagoons or by applying waste to fields without incorporation into the soil. These practices may reduce runoff of nutrients into surface waters, but they also cause the release of ammonia emissions into the air, thus contributing to particulate matter emissions as well (USDA ERS, 2005).

Figure 3.5-4. Fine Particulate Matter ($PM_{2.5}$) Non-Attainment Areas (2006 Standard) (EPA 2014i)

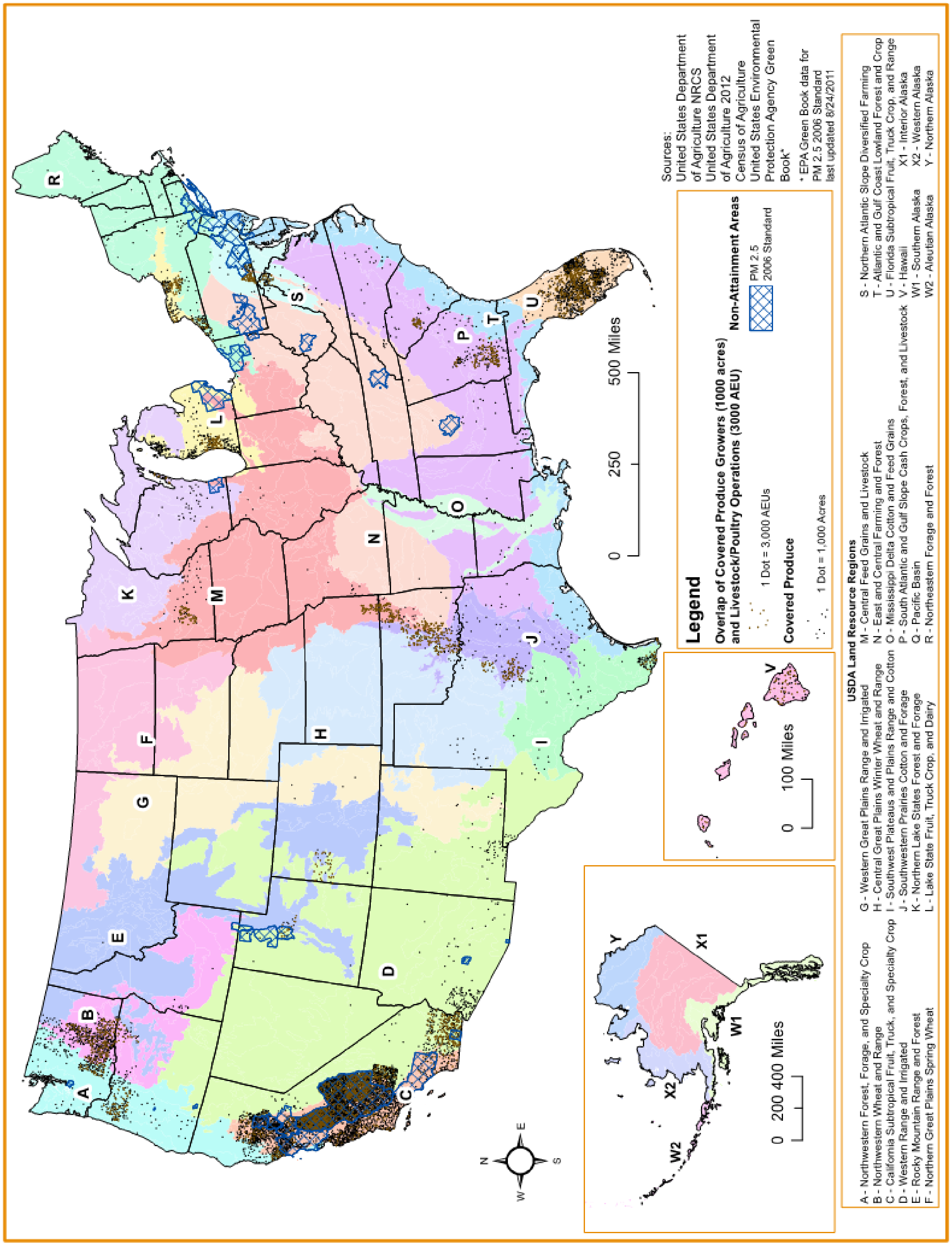


Figure 3.5-5. National PM-10 emissions by source sector in 2011 (EPA, 2014i)

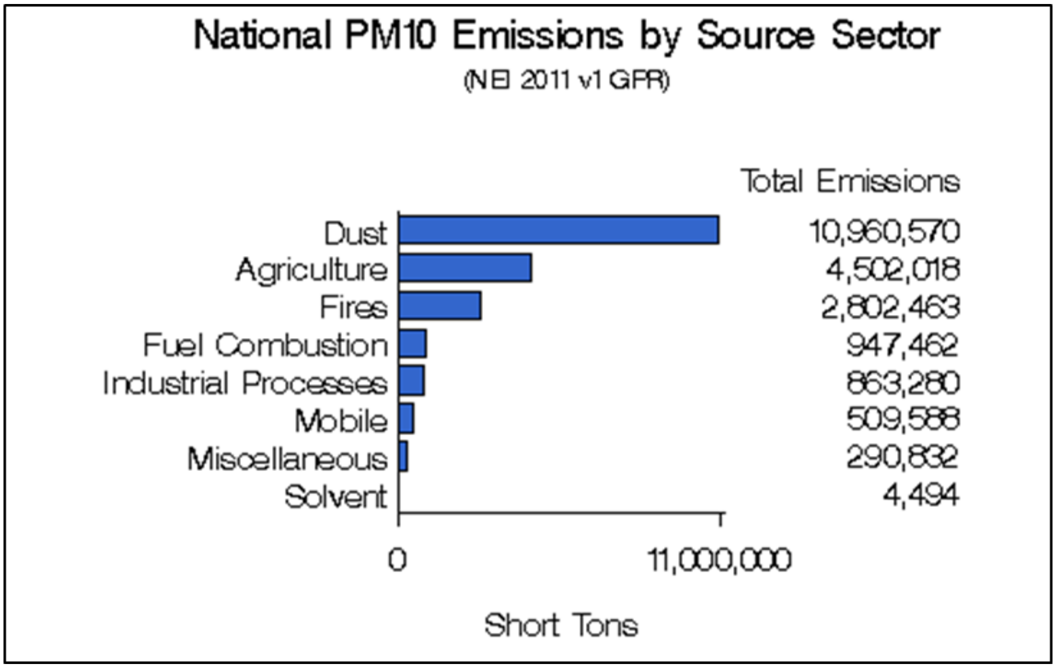
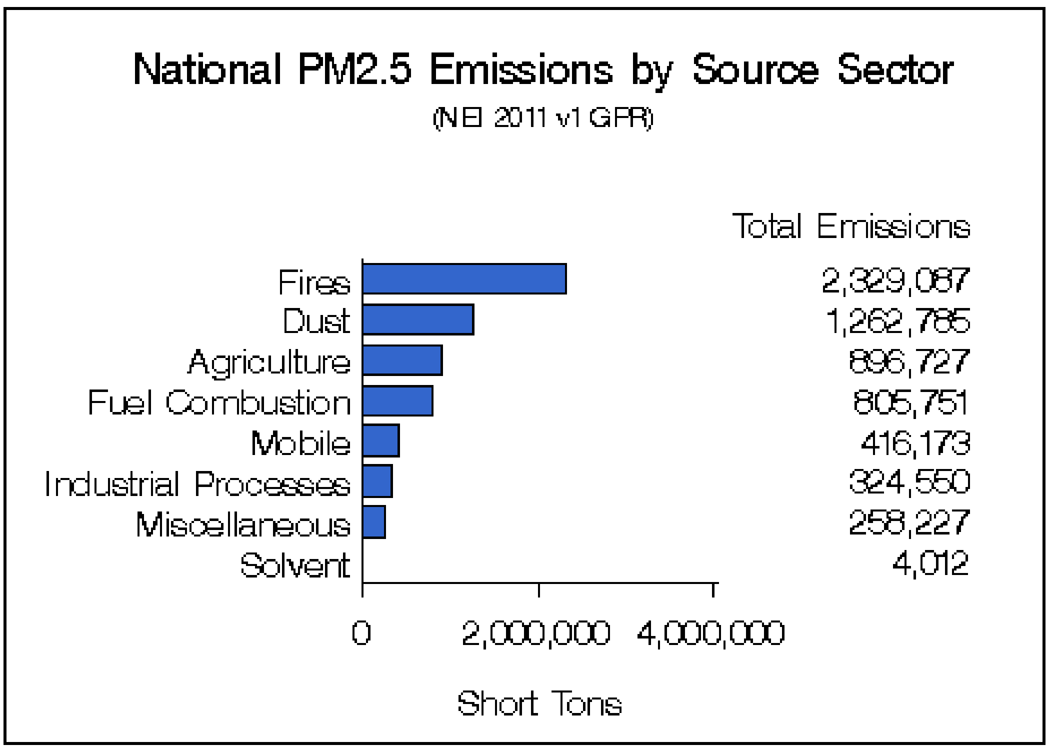


Figure 3.5-6. National PM-2.5 emissions by source sector in 2011 (EPA, 2014i)



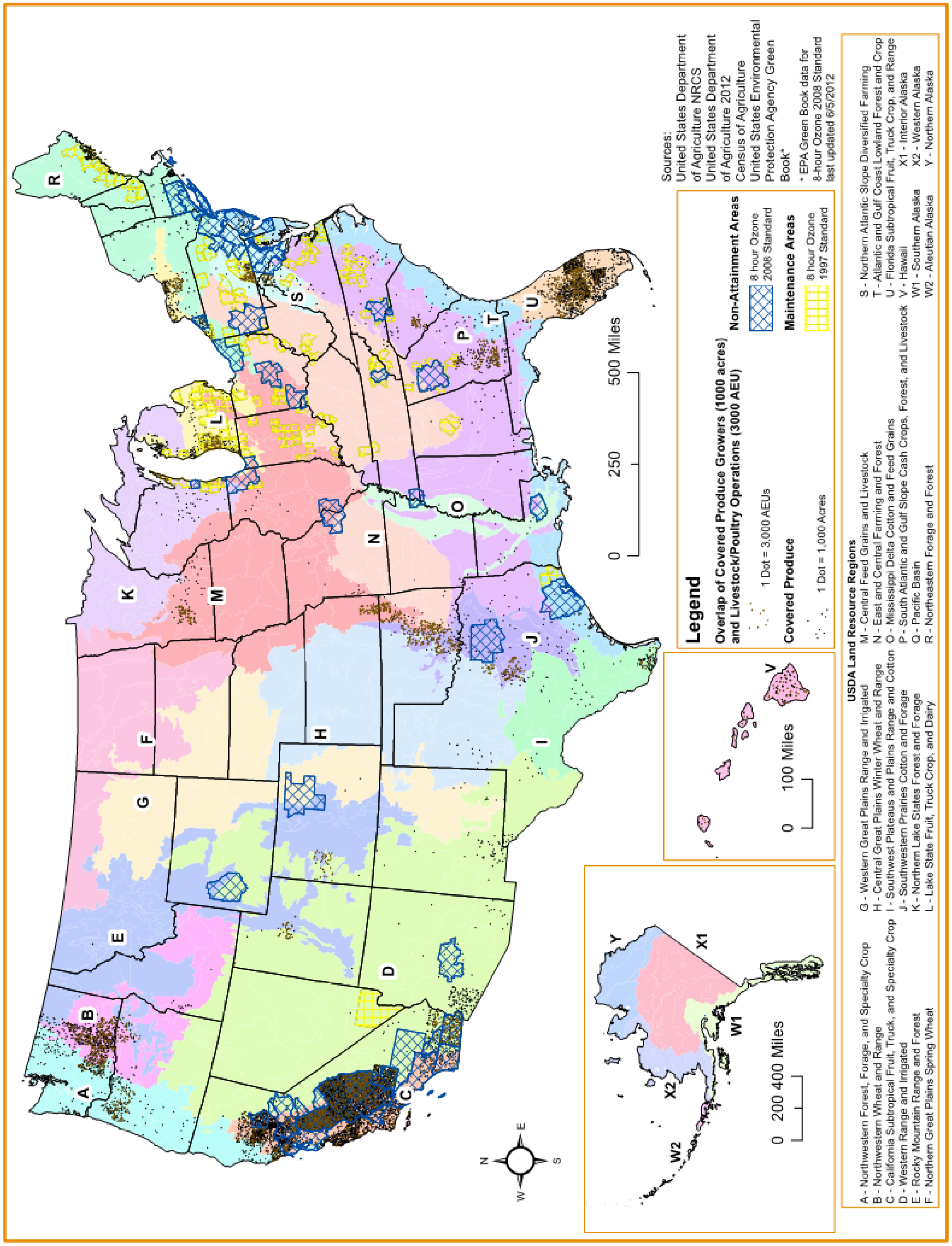
Ground-Level Ozone

Ozone (O_3) occurs in the upper atmosphere, where it shields the Earth from harmful ultraviolet radiation. However, at ground-level ozone acts as an air pollutant and is a main component of urban smog (EPA, 2012c). Ground-level ozone is not directly emitted into the air, but forms through chemical reactions of other pollutants (NO_x and VOCs) in the presence of sunlight. The concentrations of ground-level ozone and other related pollutants tend to be short-lived and spatially variable due to their high reactivity. Ozone concentrations tend to be at their highest on hot sunny days in urban areas, but can also be elevated in rural locations when O_3 is transported long distances by wind (EPA, 2012c). The main sources of NOx formation include soil microbial activity, lightning, biomass burning, and fuel combustion. The major sources of VOC emissions include transportation and industrial processes (EPA, 2012c).

Although they are typically not the primary sources of NO_x and VOCs, emissions of these O_3 precursor gases can result from a variety of agricultural practices and processes, such as manure decomposition, soil processes (nitrification/denitrification), and combustion from farm equipment. In addition to human health impacts, ground-level O_3 can lead to adverse effects on plants and animals and has been documented in contributing to reductions in crop yields by negatively impacting the photosynthetic ability of plants (USDA, 2012b).

Figure 3.5-7 shows the O_3 non-attainment areas based on the current 2008 standard and the maintenance areas associated with the older 1997 standard. These maintenance areas were designated non-attainment under the 1997 standard but have since demonstrated improvements in air quality related to O_3 and are currently in attainment based on the stricter 2008 standard (EPA, 2014j). This map illustrates that, similarly to particulate matter pollution, the majority of the non-attainment areas that coincide with large concentrations of covered farms and livestock operations are located in central and southern California (regions C and D).

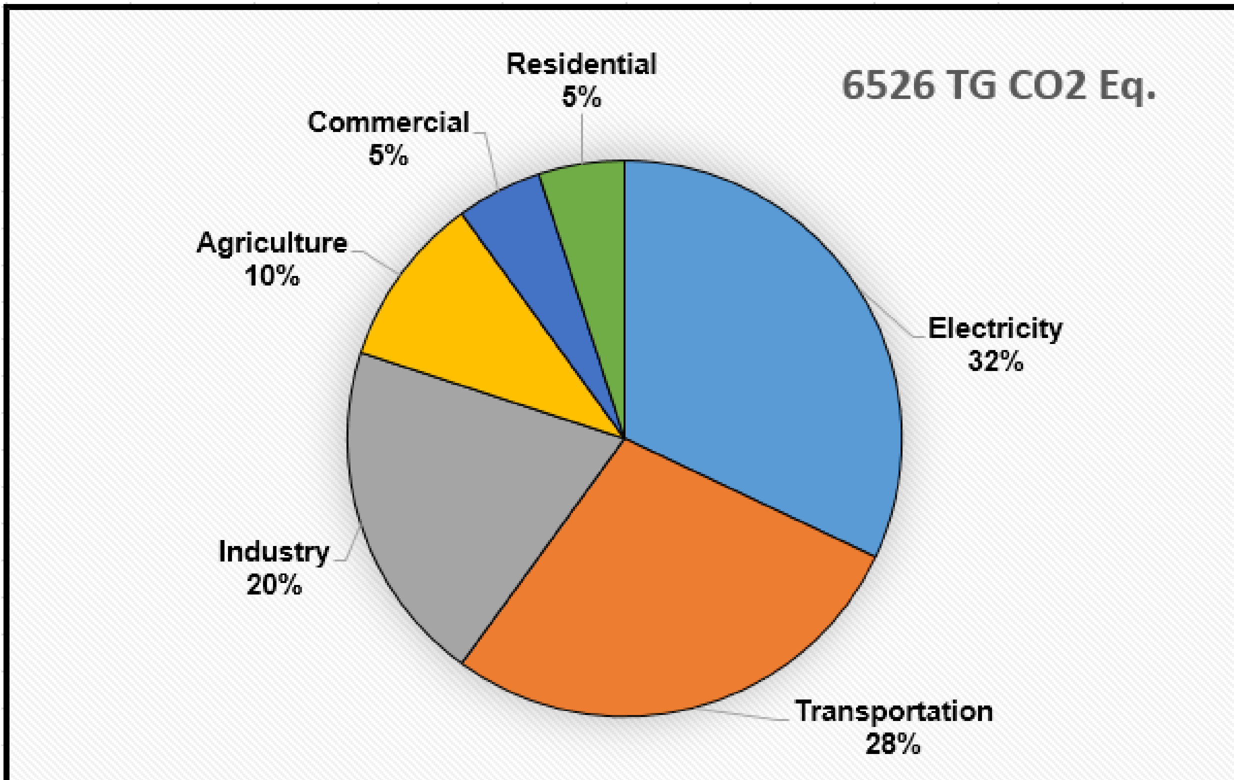
Figure 3.5-7. Ozone Non-Attainment Areas (2008 Standard) and Maintenance Areas (from 1997 Standard) (EPA, 2014j)



Existing Conditions Summary: Major GHSs

Human activities are responsible for a large proportion of the increase in GHGs seen in the atmosphere over the last 150 years. The largest source of anthropogenic greenhouse gas emissions in the U.S. comes from the burning of fossil fuels for electricity, heat, and transportation. Agricultural activities contribute directly to emissions of GHGs through a variety of processes, such as enteric fermentation in domestic livestock, livestock manure management, rice cultivation, agricultural soil management, land use changes, fuel consumption, and field burning of agricultural residues. In 2012, agricultural GHG sources accounted for approximately 10 percent of total U.S. GHG emissions (Figure 3.5-8) (EPA, 2014k). Agricultural activities may serve as sources of GHG emissions or as sinks through carbon sequestration (Table 3.5-1). National policies with regard to greenhouse gas emissions are currently limited, and agriculture has been largely excluded from regulatory and legislative proposals (Copeland, 2014).

Figure 3.5-8. U.S. Greenhouse gas emissions by economic sector, 2012 (EPA, 2014k)



Note: TG CO_2 Eq. = teragrams of carbon dioxide equivalents.

Source: EPA, Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2012, Table ES-7

Table 3.5-1. Agricultural Sector Greenhouse Gas Emissions and Sinks, 2012 (EPA, 2014k)

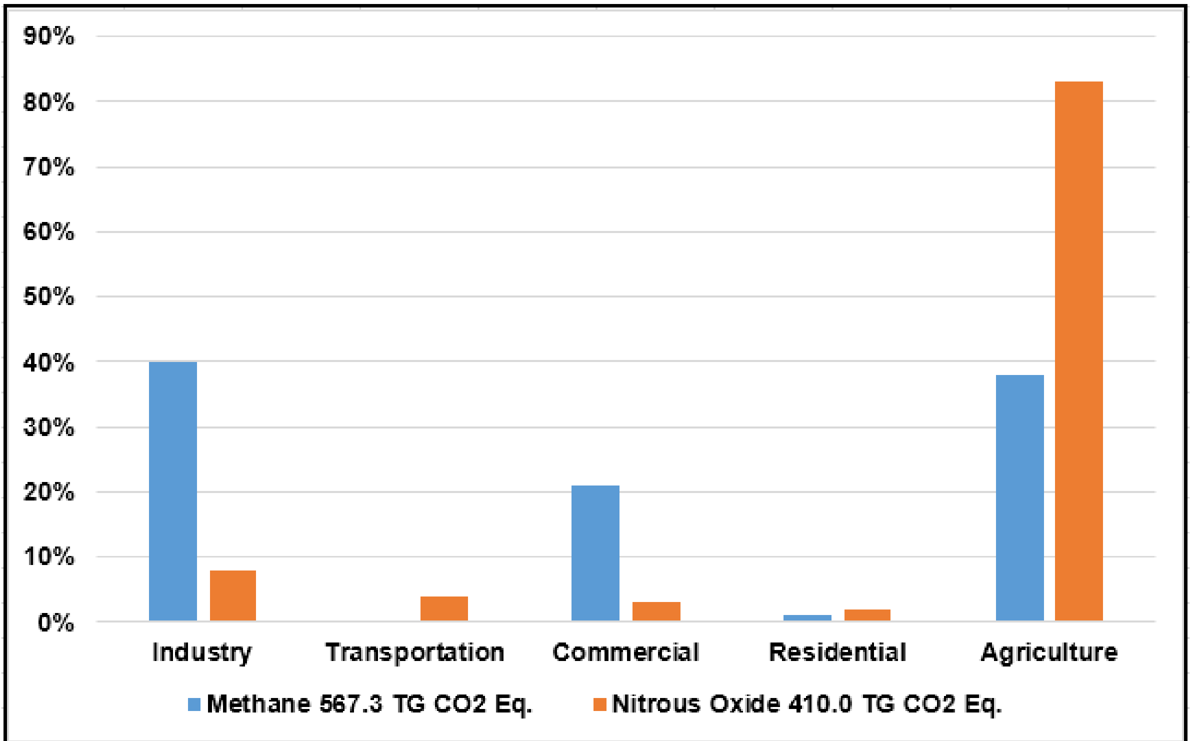
GHG Emissions Source	Tg CO_2 Eq.	Carbon Sink	Tg CO_2 Eq.
Agricultural Soil Management	306.6	Forest Land Remaining Forest	-866.5
Enteric Fermentation	141.0	Settlements Remaining Settlements	-88.4
Manure Management	70.9	Cropland Remaining Cropland	-26.5
Land Converted to Cropland	16.8	Land Converted to Grassland	-8.5
Rice Cultivation	7.4		
Grassland Remaining Grassland	6.7		
Agricultural Equipment	0.6		
Burning of Ag. Residues	0.4		

Source: EPA, Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2012 (April 2014), Tables 6-1, 7-1, 3-13, and 3-14

Fossil fuel combustion is the primary source of anthropogenic CO_2 emissions, with forest clearing, biomass burning, and some non-energy production processes also causing emissions (EPA, 2014k). Although CO_2 accounts for over 80 percent of U.S. GHG emissions, methane and nitrous oxide are the primary GHGs emitted by agricultural activities (USDA CCPO, 2011). Despite being less abundant than CO_2, the more efficient trapping of radiation by methane and the long duration time of nitrous oxide in the atmosphere makes small quantities of these compounds have significant effects on climate change. To address this, the Intergovernmental Panel on Climate Change (IPCC) developed the Global Warming Potential (GWP) concept to compare the ability of a gas to trap heat in the atmosphere relative to CO_2. For example, the comparative climate impacts of one pound of CH_4 or N_2O are approximately 21 and 310 times greater, respectively, relative to one pound of atmospheric CO_2. Estimates of GHG emissions can then be weighted by the GWP to produce a standardized measurement, such as teragrams of carbon dioxide equivalent, or Tg CO_2 Eq. (EPA, 2014k).

Agriculture made up 38 percent of total U.S. CH_4 emissions in 2012 and 83 percent of total N_2O emissions (EPA, 2014k, see Figure 3.5-9). Between 1990 and 2012, methane emissions from agricultural activities increased by 13.6 percent, while N_2O emissions had an overall increase of 9.5 percent. The primary GHG sources for agriculture are N_2O emissions from cropped and grazed soils, CH_4 emissions from ruminant livestock production and rice cultivation, and CH_4 and N_2O emissions from managed livestock waste. Agricultural soil activities such as fertilizer application produced approximately 74.8 percent of N_2O emissions in the U.S. in 2012. Enteric fermentation was the largest source of CH_4 emissions in the U.S. in 2012, at 141.0 Tg CO_2 Eq. Overall, emissions from manure management (includes CH_4 and N_2O) increased 54.7 percent between 1990 and 2012 (EPA, 2014k).

Figure 3.5-9. U.S. Methane and Nitrous Oxide Emissions by Sector in 2012 (EPA, 2014k)



Note: TG CO_2 Eq. = teragrams of carbon dioxide equivalents

Source: EPA, Inventory of Greenhouse Gas Emissions and Sinks: 1990-2012, Table 2-14

Agricultural soil management and manure management are the two largest direct sources of agricultural greenhouse gas emissions most likely to be affected by the PS PR, particularly with regard to standards directed at BSAs of animal origin. Figure 3.5-10 shows the total N_2O emissions by state (note: data unavailable for Alaska) from agricultural soil management (including croplands and grasslands) in 2012, which are highest in areas of intensive agriculture such as Texas, California, and most upper mid-western states (EPA, 2014k). Figure 3.5-11 illustrates the total GHG emissions (CH_4 and N_2O combined) by state from manure management in 2012 (EPA, 2014k). Approximately 51 percent of these emissions can be attributed to just six states (California, Iowa, Texas, North Carolina, Wisconsin, and Minnesota).

According to a 2011 USDA study, crop production (mostly from non-rice soils) contributed close to one third (31 percent) of total GHG emissions from agricultural sources in 2008. The production of livestock represented the majority of total emissions from the agricultural sector, with 28 percent from enteric fermentation, 12 percent from managed livestock waste, and 13 percent from grazed lands. Finally, 14 percent of total emissions were a result of energy use for agricultural activities (USDA CCPO, 2011).

Figure 3.5-10. Total nitrous oxide (N_2O) emissions from agricultural soil management by state in 2012, including emissions from croplands and grasslands (EPA, 2014k)

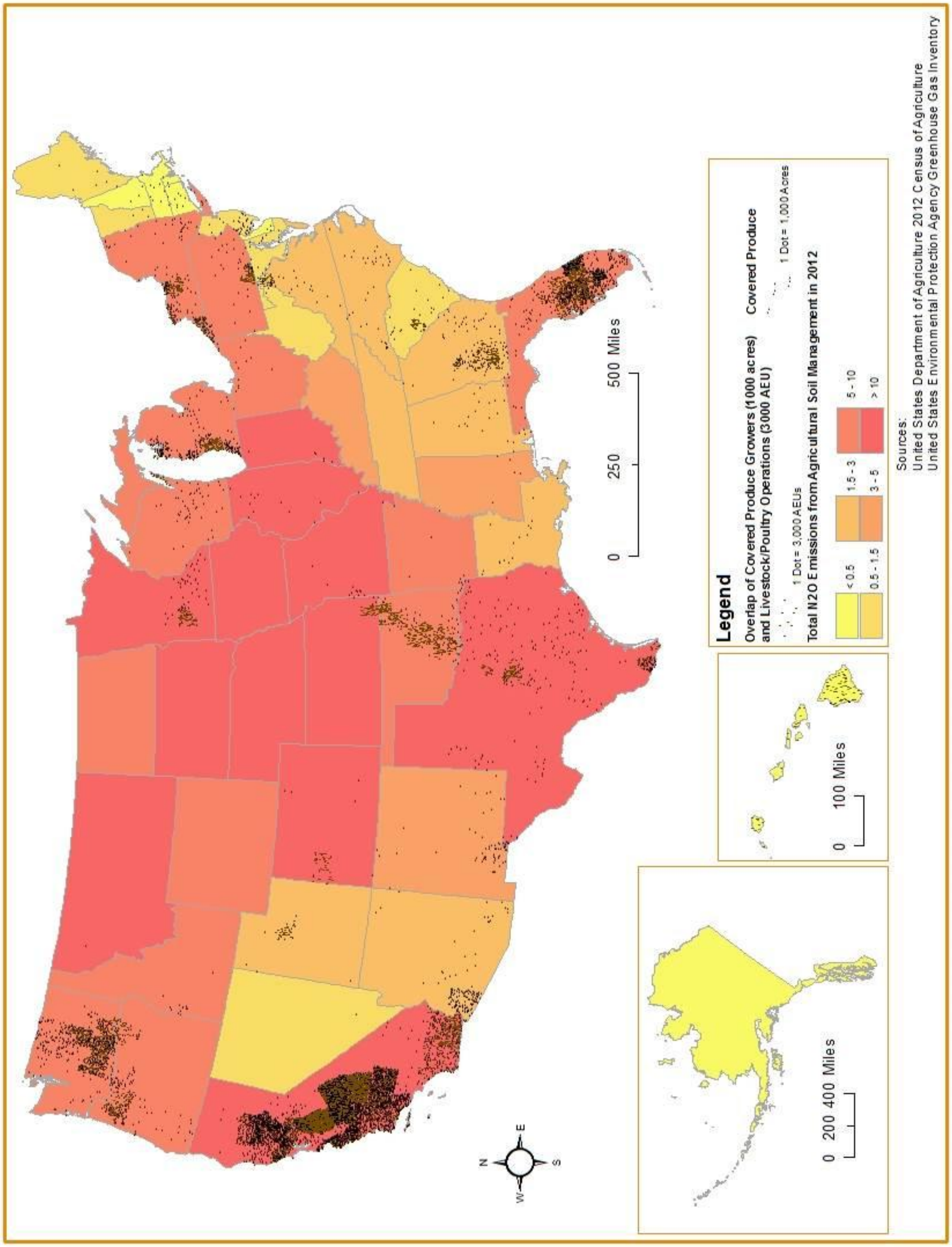
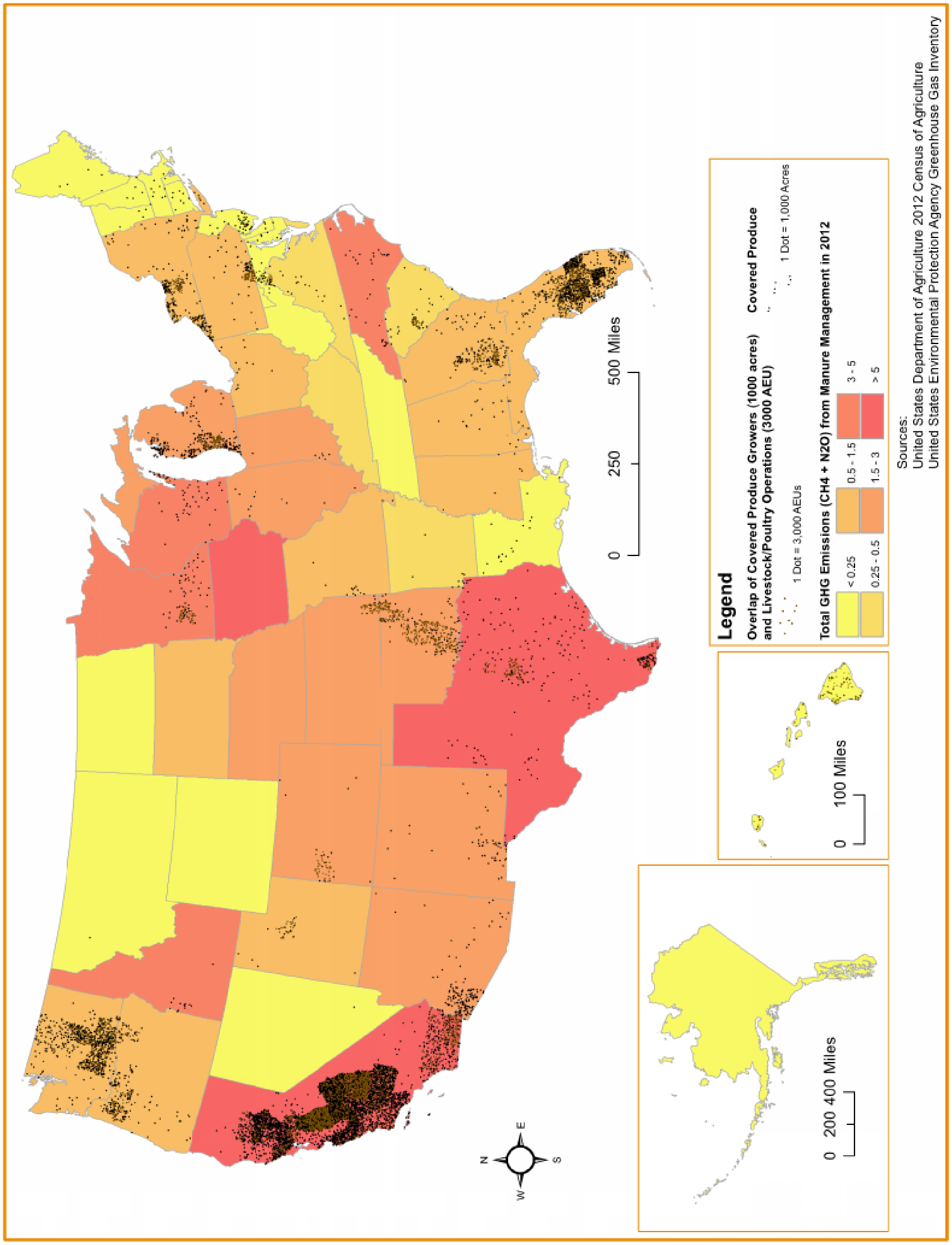


Figure 3.5-11. Total GHG Emissions from manure management by state in 2012, including methane (CH_4) and nitrous oxide (N_2O) emissions (EPA, 2014k)

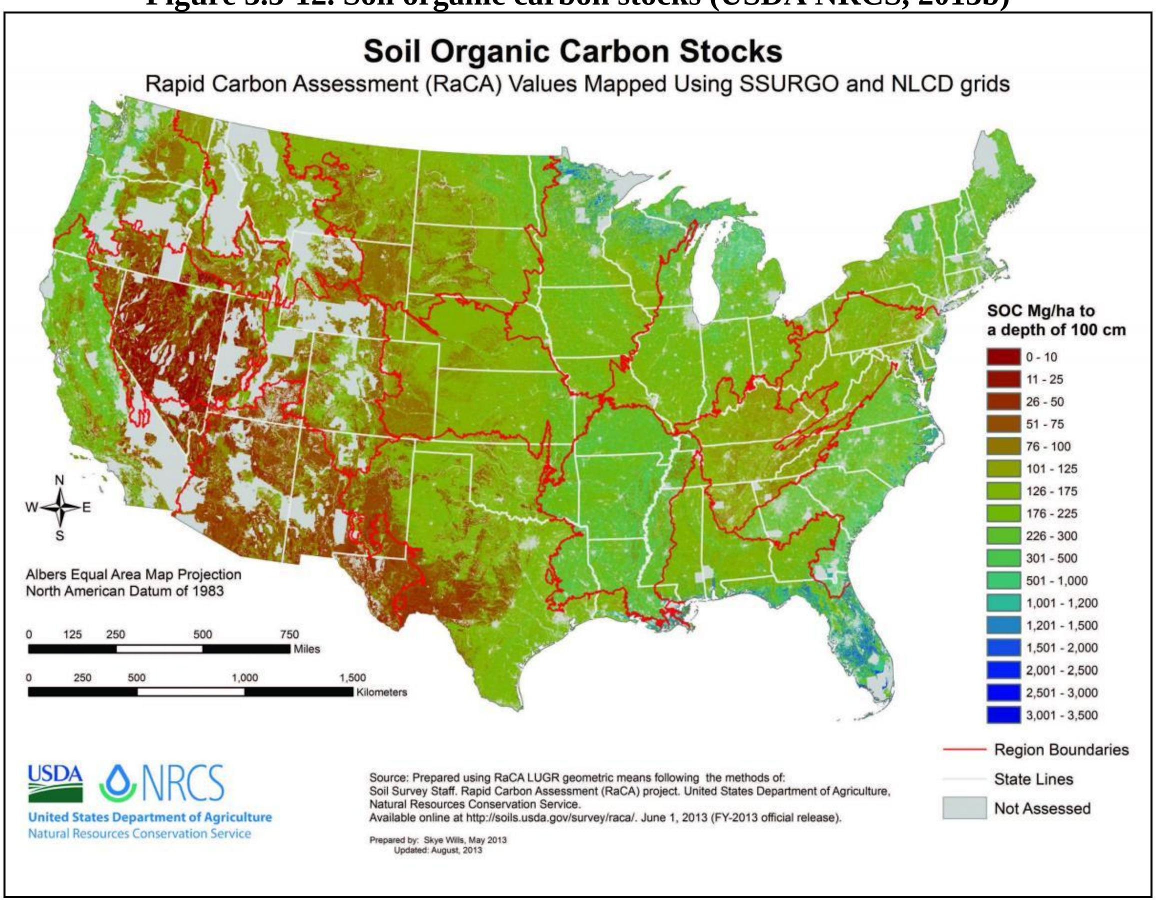


Carbon Sequestration

Soils make up a major part of the global carbon cycle (Figure 3.5-12). Soils have added as much as 55 to 878 billion tons (GT) of carbon to the total atmospheric CO_2. The total soil carbon consists of the SOC and inorganic carbon, estimated to be over 2,250 GT in the top 1 meter depth (Batjes, 1996). The SOC consists of “a mixture of plant and animal residues at various stages of decomposition, of substances synthesized microbiologically and or chemically from the breakdown products, and of the bodies of live microorganisms and small animals.” The SOC includes elemental carbon and carbonates (Li and Feng, 2002).

Although carbon emissions from agricultural activities contribute the enrichment of atmospheric CO_2, carbon sequestration in agricultural soils, through the use of proper management practices, can mitigate this trend. While the soil inorganic carbon contributes approximately 25 percent of the overall soil carbon inventory, agricultural activities have a more profound influence on changes of SOC both in the short and the long term. Increasing SOC content enhances soil quality, reduces soil erosion and degradation, improves surface water quality, and increases soil productivity. Thus, carbon sequestration in soils, (i.e., increasing SOC in agricultural soils through proper management), provides a multitude of environmental benefits. The goals to sequester SOC is to create a win-win situation to improve soil productivity, reduce unnecessary inputs, and promote sustainability (Li and Feng, 2002).

Figure 3.5-12. Soil organic carbon stocks (USDA NRCS, 2013b)



Energy use in agriculture

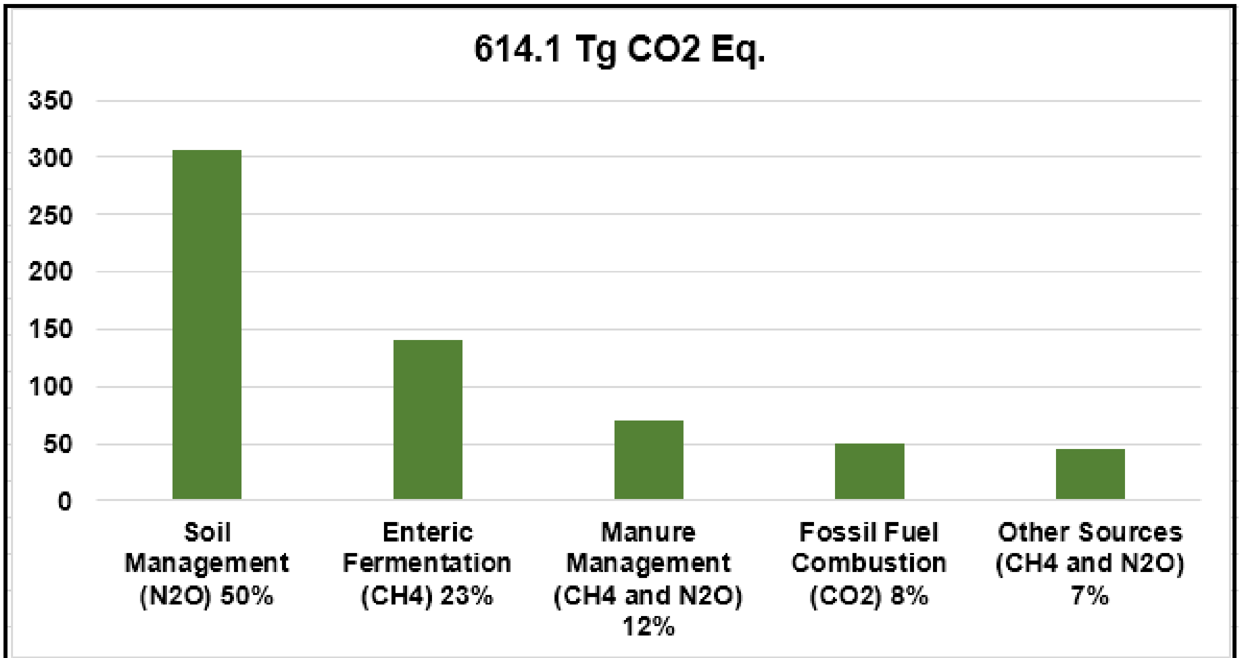
Farm operators rely on a variety of energy sources to perform agricultural practices. How energy is used in agriculture is impacted by many factors including the type of crop or livestock being produced, the size of the farm, and the geographic location. Additionally, temporal variation in energy use can result from changes in weather conditions, energy prices, and total annual production of crops and livestock. Although agricultural energy use does contribute to CO_2 emissions, this source is small relative to the total U.S. CO_2 emissions from energy (USDA CCPO, 2011). Energy use represented approximately 8 percent of the total GHG emissions from the agricultural sector in 2012 (Figure 3.5-13) (EPA, 2014k).

Approximately 0.8 quadrillion btu (British thermal unit) of direct energy was used in agriculture in 2008, resulting in approximately 72 Tg CO_2 Eq. emissions, mostly from electricity use and diesel fuel use (38 percent each) (USDA CCPO, 2011). Energy use for agricultural practices can be categorized as direct or indirect. Direct energy is used for farm operations involved in crop or livestock production, while indirect energy is used to produce synthetic fertilizers and other inputs. Large amounts of diesel fuel, gasoline, and liquefied petroleum (LP) gas are used for field operations during crop production. Most large farms use diesel-fueled vehicles to perform agricultural practices. Gasoline-powered vehicles and equipment, which can include small trucks or older harvesting equipment, tend to be used on smaller farms. The amount and type of energy used in agricultural operations affect overall CO_2 emissions through differences in carbon content and energy efficiency. For example, diesel fuel has a higher carbon content compared to gasoline, but diesel engines are more energy efficient and may still result in lower CO_2 emissions (USDA CCPO, 2011).

Irrigation systems that use pumps to distribute water also use energy. In 2008, approximately 49 million acres of U.S. farmland were irrigated with pumps powered by liquid fuels, natural gas, and electricity (USDA CCPO, 2011). Electricity was the main power source for these pumps, costing $1.5 billion to irrigate about 30 million acres. Diesel fuel was used to power pumps on about 13 million acres and natural gas was used on about 4.7 million acres (USDA NASS, 2009b).

Source categories of emissions from electricity generation include CO_2 from fossil fuel combustion, CO_2 and N_2O emissions from the incineration of waste, and CH_4 and N_2O from stationary sources. Although electricity generation is often analyzed as a major source of GHG emissions, electricity is ultimately consumed in different economic sectors. Electricity-related GHG emissions are mostly distributed among the industrial, transportation, commercial, and residential economic sectors. According to the EPA, in 2012 electricity-related emissions were responsible for approximately 62.2 Tg CO_2 Eq. of the 676.3 Tg CO_2 Eq. total GHG emissions from the agricultural sector. This represents only three percent of the total GHG emissions attributed to the electric power industry in 2012 (EPA, 2014k).

Figure 3.5-13. Greenhouse gas emissions from agriculture by source, 2012 (EPA, 2014k)



Source: EPA, Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2012, Table 2-12

<u>Nitrous Oxide Emissions</u>

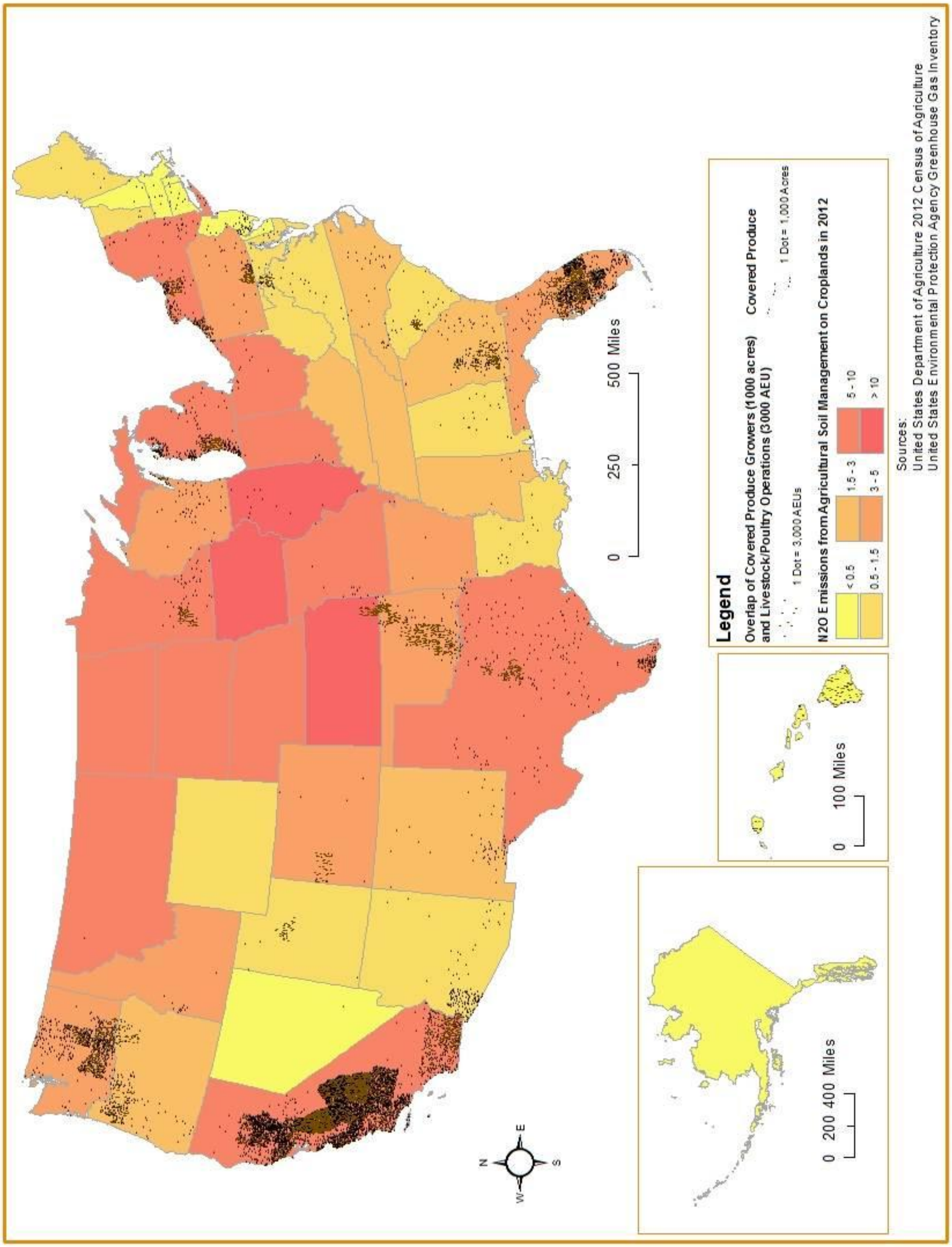
Nitrous oxide emissions can result from a variety of anthropogenic sources including agricultural soils, the use of synthetic and manure fertilizers, manure deposition by livestock, fossil fuel combustion, wastewater treatment, waste incineration, and biomass burning. The agricultural sector is the biggest producer of N_2O emissions in the U.S. (Figure 3.5-13). Agricultural soils accounted for approximately 74.8 percent (306.6 Tg CO_2 Eq.) of U.S. N_2O emissions in 2012 (EPA, 2014k). A major contributor to these emissions is the addition of large amounts of N fertilizers to crops that stimulates the production and direct emission of N_2O (USDA CCPO, 2011). Nitrous oxide emissions can also occur during indirect processes such as the conversion of nitrates in groundwater into N_2O by aquatic denitrification. In 2008, 80 percent of total cropland soil N_2O emissions were direct soil emissions and 20 percent were indirect emissions from nitrate leaching and volatilization (USDA CCPO, 2011).

Nitrous oxide is produced naturally in soils through the microbial processes of nitrification and denitrification. Many agricultural activities increase mineral N availability in soils, ultimately increasing the amount of N_2O emitted. These practices may include fertilization, application of managed livestock manure, production of N-fixing crops, retention of crop residues, and drainage of organic soils in croplands and grasslands. Nitrous oxide emissions can also be impacted by other agricultural soil management activities such as irrigation, drainage, tillage practices, and fallowing of land (EPA, 2014k). When more N is applied than can be used by the plants, either due to the volume or timing of application of manure or fertilizer, the rate of N_2O emissions is increased (USDA CCPO, 2011).

Nitrous oxide emissions from manure management can occur directly through the nitrification and denitrification of the organic N in livestock waste, and indirectly through volatilization or the leaching and runoff of N into groundwater and surface waters (EPA, 2014k). Nitrous oxide emissions from manure management are most likely to occur in dry manure handling systems with aerobic conditions that also contain saturated pockets with anaerobic conditions because both types of reactions are required for direct N_2O emissions to occur. Liquid manure storage systems, which are becoming more prevalent in some industries, can also lead to increased volatilization of N that can escape into the air (Copeland, 2014). In 2012, total N_2O emissions from manure management were estimated at 18.0 Tg CO_2 Eq., an increase of 3.6 Tg CO_2 Eq. over emissions in 1990 (EPA, 2014k).

On average, cropland accounted for approximately 61 percent of total direct N_2O emissions in 2012, while grassland accounted for approximately 39 percent (EPA, 2014k). Nitrous oxide emissions are highly correlated with crop areas and nitrogen inputs. The highest concentrations of N_2O emissions occur in areas of the U.S. where a large portion of land is used for intensive agriculture. Notably, over 90 percent of the land in many counties in the Midwest is intensively cropped. The leading crops for nitrous oxide emissions are corn, soybeans, and hay, largely due to the land area represented by these crops (USDA CCPO, 2011). Direct N_2O emissions tend to be low in the eastern U.S. where a small portion of land is cultivated, and also low in many western areas where rainfall and access to irrigation water are limited (EPA, 2014k). Figure 3.5-14 illustrates the nitrous oxide emissions by state (note: data unavailable for Alaska) from agricultural soil management on croplands in 2012 (EPA, 2014k), over 60 percent of which can be attributed to most upper and central mid-western states, Texas, and California. Direct emissions from grasslands are highest in the central and western U.S. where a high proportion of land features cattle grazing (EPA, 2014k). Non-major crop types resulted in approximately 17 percent of the total N_2O emissions from croplands in 2008. Note that non-major crops (e.g., fruits and vegetables) make up a significant portion of total emissions in some states including California and Florida (USDA CCPO, 2011).

Figure 3.5-14. Nitrous oxide (N_2O) emissions from agricultural soil management on croplands by state in 2012 (EPA, 2014k)



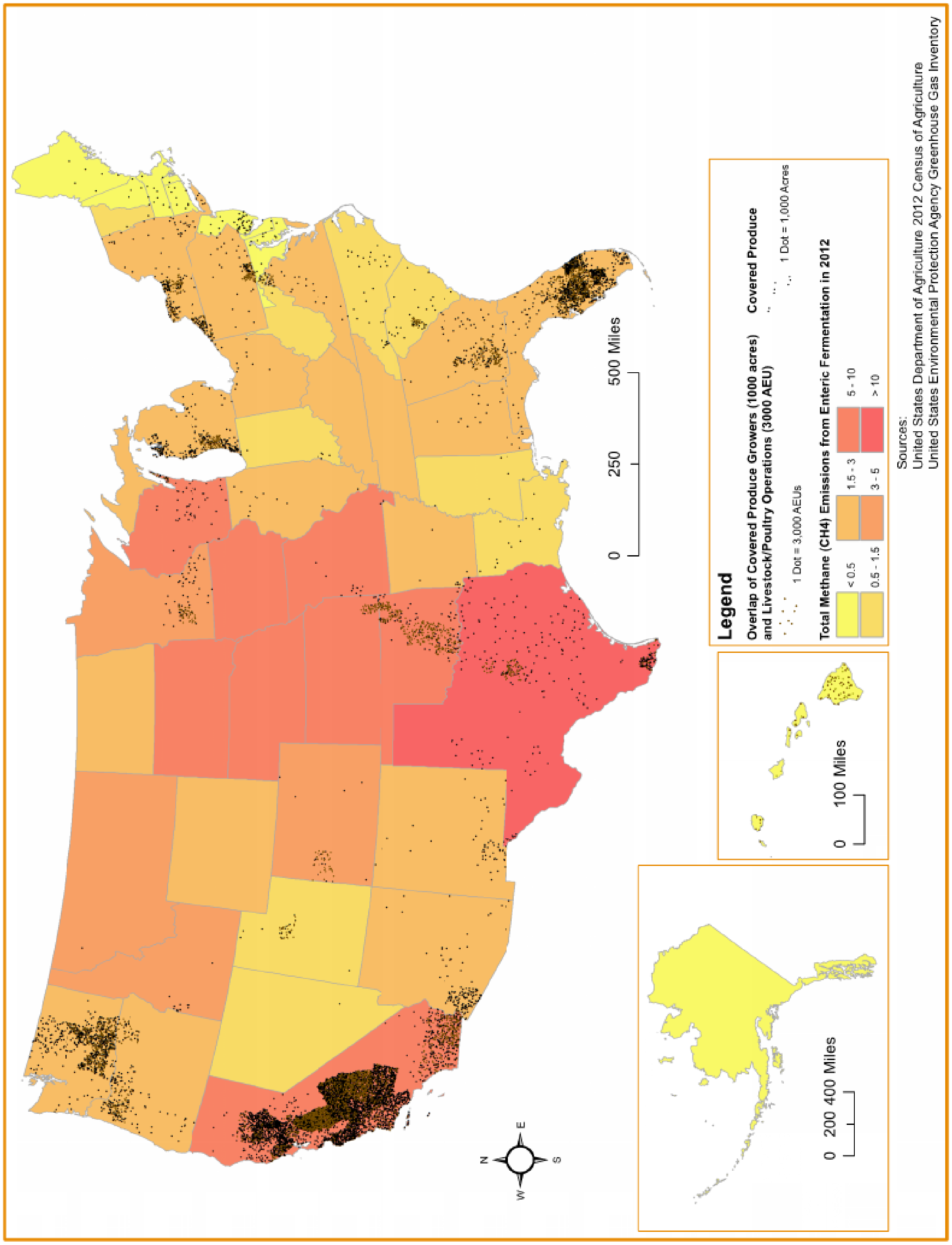
Methane Emissions

Methane is primarily produced through the anaerobic decomposition of organic matter in biological systems. Agricultural processes such as enteric fermentation in animals, decomposition of animal wastes, and wetland rice cultivation are all sources of CH_4 emissions. The decomposition of municipal solid wastes and the production and distribution of some fossil fuels can also result in CH_4 emissions (EPA, 2014k). The IPCC has estimated that slightly more than half of the current CH_4 flux to the atmosphere can be tied to anthropogenic sources (Forster et al., 2007).

Methane is produced as part of normal digestive processes in animals and the microbial fermentation process involved is referred to as enteric fermentation, which represents the largest anthropogenic source of methane emissions in the U.S. Ruminant animals (e.g., cattle, sheep, and goats) are the major emitters of methane due to their unique digestive system, which includes a rumen in which food is broken down by microbial fermentation. Non-ruminant animals (e.g., swine, horses, mules) also contribute to CH_4 emissions but at a much lower rate relative to ruminant livestock. Total livestock methane emissions in 2012 were 141.0 Tg CO_2 Eq. (approximately 25 percent of total CH_4 emissions), with cattle (beef and dairy combined) accounting for 96 percent of these emissions (EPA, 2014k). Not surprisingly, changes in enteric fermentation emissions over time generally follow trends in cattle population sizes.

Figure 3.5-15 illustrates the total CH_4 emissions by state from enteric fermentation in 2012 (EPA, 2014k). Approximately half of the total CH_4 emissions from enteric fermentation in 2012 can be attributed to livestock operations in nine states, including several mid-western states as well as California. It is unlikely that the provisions of the PS PR will cause direct CH_4 emissions from enteric fermentation to change dramatically, as compliance from farmers will relate more to storage and application of manure than to emissions from animal digestion itself. However, Figure 3.5-15 does show which states are dominated by cattle production relative to where concentrations of covered farms are located.

Figure 3.5-15. Total methane (CH_4) emissions from enteric fermentation by state in 2012 (EPA, 2014k)



The treatment, storage, and transportation of livestock manure can produce anthropogenic CH_4 emissions through the anaerobic decomposition of the manure. Methane emissions from manure management have increased by roughly 68 percent since 1990, from 31.5 Tg CO_2 Eq. in 1990 to 52.9 Tg CO_2 Eq. in 2012 (EPA, 2014k). When manure is stored or treated in systems that promote anaerobic conditions (e.g., liquid slurry in tanks, ponds), the decomposition process tends to produce CH_4. Production is greatly reduced when manure is handled as a solid (e.g., in stacks or drylots) or deposited on pasture lands and allowed to decompose aerobically. Overall, land application has been and remains the predominant method for disposing of manure and recycling its nutrient and organic content. For the most part, design objectives for managing manure have focused on odor and dust control, avoidance of direct discharge to surface water, and land application rates to maximize crop yields, largely ignoring minimization of gaseous compounds such as CH_4 (Copeland, 2014).

The majority of managed manure in the U.S. is currently handled as a solid, contributing little CH_4 to overall emissions. However, liquid systems of manure management are becoming more common, particularly in dairy and swine operations. Dairy animal populations have been decreasing overall since 1990. However, dairy populations have increased in some states such as California and New Mexico due to the industry becoming more concentrated with larger facilities, which all tend to use liquid manure systems to manage livestock waste. Manure management practices at smaller operations are also shifting from daily spread to manure managed and stored on site due to new regulations limiting the application of manure nutrients (EPA, 2014k). Livestock waste is termed "unmanaged" when it is deposited directly on grazed lands and not transported (USDA CCPO, 2011).

<u>Agriculture, Air Quality, and the PS PR</u>

The following section briefly discusses how agricultural operations and air quality resources relate to each of the major standards of the PS PR. These discussions will be expanded upon in Chapter 4 (Environmental Consequences). This section also lists the types of pollutants that are expected to be impacted by each of the standards in the PS PR.

- **Agricultural Water Standards:** Agricultural water standards can relate to chemical treatments of agricultural water as well as energy use with regard to water systems (e.g., groundwater pumps). Emissions of CO_2 and criteria air pollutants can result from direct fuel combustion or electricity generation involved in running pumps or other water-transport systems during agricultural operations. In addition, chemical treatments of agricultural water to address pathogens can cause emissions of VOCs.

- **Biological Soil Amendment (BSA) Standards:** Standards directed towards BSAs of animal origin (both untreated and treated) represent the largest potential source of impacts to air quality and GHGs related to the PS PR. The use of BSAs of animal origin (and other soil amendments) primarily involves effects associated with manure management and agricultural soil management practices. The need for storage of greater amounts of manure expected under the standards of the PS PR could result in increases in emissions of windborne PM, O_3 precursor gases, and GHGs (primarily CH_4 but also

N_2O). Changes in agricultural soil management could occur if growers were to switch to other soil amendments. In particular, the greater use of chemical fertilizers could result in increases in N_2O emissions if greater amounts of nitrogen are available in the soil. Finally, any increase in transportation of manure to on or off-site storage or composting facilities could cause increases in emissions of CO_2 and criteria pollutants from fuel combustion, although changes in emissions would be relatively low since trucking of manure would likely occur in localized areas due to economic feasibility.

- **Grazing and Animal Intrusion Standards:** Emissions of PM and major GHGs can occur on grazed lands due to agricultural soil management activities and processes, as well as from animal activities (e.g., enteric fermentation, manure decomposition). However, the standards directed towards grazing and animal intrusion from wild and domesticated animals are not anticipated to have major effects on air quality resources, as overall manure management and agricultural soil management practices would be expected to remain intact. Actions taken by growers to remove or exclude animals from covered produce fields could result in PM and VOC emissions (e.g., switching to chemical pesticides), or emissions of PM and CH_4 from manure being concentrated in certain areas.

- **Sprouts Standards:** The relationship of standards directed towards sprouts to air quality resources is similar to that of agricultural water in general. Emissions of CO_2 and criteria air pollutants can result from direct fuel combustion or electricity generation involved in running pumps or other water-transport systems during agricultural operations. In addition, chemical treatments of agricultural water to address pathogens can cause emissions of VOCs.

- **Scope of the Rule (Businesses Covered):** The overall impacts to air quality resources with regard to the PS PR will result from the combined effects of growers' actions to address the various standards. It is anticipated that these actions will result in larger air quality effects on large farms relative to Small and Very Small farms.

Summary of Impact Assessment Methodology

In the U.S., air quality research in the past half-century has focused largely on NO_x, SO_2, O_3, and PM emissions from the industrial, transportation, and energy sectors (Aneja et al., 2009). There are currently no nationwide monitoring networks in the U.S. to quantify agricultural emissions of GHGs, NO_x, VOCs, or NH_3. Conversely, there is a large network in place to assess atmospheric changes resulting from fossil fuel combustion. Furthermore, researchers have noted large uncertainties in current agricultural air quality modeling as a result of many factors including (1) inaccurate emission inventories; (2) inaccurate meteorological data; (3) lack of detailed information on land use at a fine scale; (4) inadequate model treatments of chemical and physical processes; and (5) a lack of sufficient observations of emissions, concentrations, and deposition for model verification and evaluation (Aneja et al., 2009).

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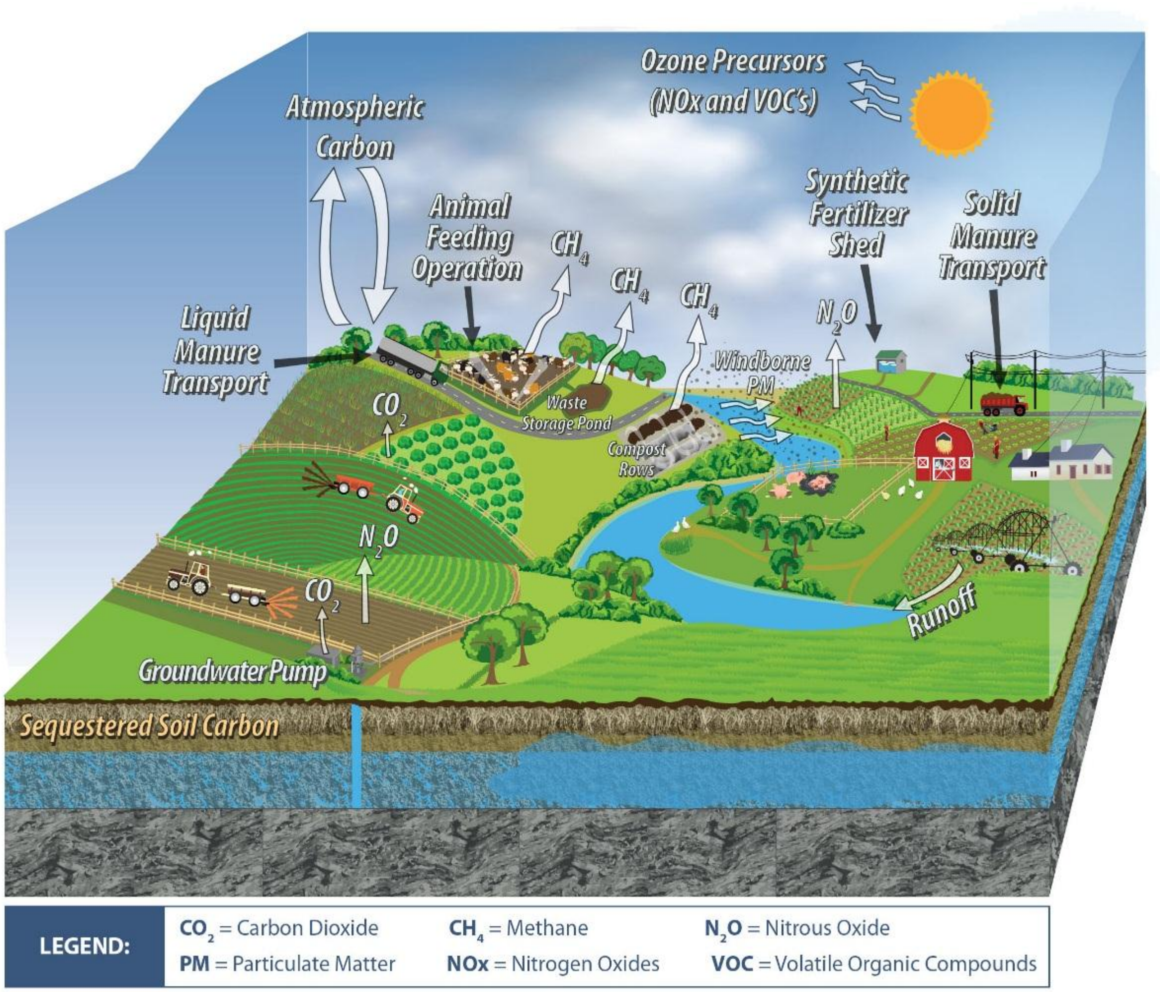
1) Is the proposed alternative likely to cause or contribute to violations of National Ambient Air Quality Standards (NAAQS) of criteria pollutants?
2) Is the proposed alternative likely to cause increases in major greenhouse gas emissions (CO_2, N_2O, and CH_4)?

Data and maps presented in this chapter, such as existing non-attainment areas for criteria air pollutants and state-level emissions of major GHGs, will be referenced to support the major conclusions. However, a detailed quantitative analysis estimating changes in emissions could not be conducted due to a lack of sufficient data regarding emissions of air pollutants and GHGs from agricultural operations, specifically covered farms (Copeland, 2014). In particular, specific information on existing emissions from agricultural soil management and manure management activities from covered farms are lacking. Additionally, data on agricultural emissions of particulate matter typically focus on crop/livestock dust and livestock waste sources. Other major sources of PM emissions, such as un-paved road dust, are categorized separately by EPA and are not classified by source sector (e.g., agricultural operations). Finally, accurate estimates of changes in CO_2 emissions would require data on expected changes in vehicle-miles traveled (due to increased storage and disposal of manure) and energy use (e.g., groundwater pumps).

In 2010, CEQ issued their *Draft NEPA Guidance on Consideration of the Effects of Climate Change and Greenhouse Gas Emissions* (CEQ, 2010), which recommends that any proposed actions that would be reasonably anticipated to cause direct annual emissions of 25,000 metric tons or more of CO_2 Equivalent (CO_2 Eq.) GHG emissions are considered for a quantitative assessment. This indicator is not proposed to be used as a threshold of significant impacts, but rather as a minimum amount of emissions for moving forward with detailed analyses (CEQ, 2010). It is noted that this indicator has been used in rule makings under the CAA, such as EPA's Mandatory Reporting of Greenhouse Gases Final Rule (74 Fed. Reg. 56260, October 30, 2009); however, this rule primarily relates to large stationary emitters (e.g., power plants) and has not been regularly applied to agricultural operations (Copeland, 2014). Although indicator-levels of emissions (such as 25,000 metric tons of CO_2 Eq.) may be useful in impact assessment, they cannot be adequately applied for the PS PR due to a lack of data required for estimating changes in emissions. 3.5-16 illustrates many of the major operations, activities, and processes that contribute to emissions of criteria pollutants and GHGs on working produce farms that may be affected by the PS PR. This graphic summarizes information described within the Air Quality Affected Environment section and includes croplands and livestock operations in order to most comprehensively represent the types of activities that may be affected by the various provisions of the PS PR. This figure will be referred to for illustrative purposes when discussing potential Air Quality impacts in Chapter 4. The following provides a summary of the major air pollutants and the agricultural activities associated with their emissions that are depicted in Figure 3.5-16:

- **Carbon Sequestration:** Carbon can be sequestered in both soils and living plants, which can help mitigate greenhouse gas emissions that end up in the atmospheric carbon pool (Li and Feng, 2002).
- **Methane (CH_4) Emissions:** Enteric fermentation of livestock, such as those in AFOs, is the leading agricultural source of CH_4 emissions. Manure management also results in a significant amount of methane emissions to the atmosphere, both in liquid (e.g., waste storage pond) and solid (e.g., compost rows) management systems (EPA, 2014k).
- **Nitrous oxide (N_2O) Emissions:** Agricultural soil management, which includes the application of manure or synthetic fertilizers to croplands, is the single largest contributor of N_2O emissions in the United States. Manure management processes can also result in releases of nitrous oxide (EPA, 2014k).
- **Ozone (O_3) Formation:** Ozone can form when ozone-precursor gases such NO_x and VOCs react with sunlight. Although they are typically not the primary sources of NO_x and VOCs, emissions of these ozone precursor gases can result from a variety of agricultural practices and processes, such as manure decomposition, soil processes (nitrification/denitrification), and combustion from farm equipment (EPA, 2012c).
- **Particulate Matter (PM) Emissions:** Particulate matter emissions can result from a variety of sources such as vehicle traffic on unpaved roads, field operations (e.g., tractors), animal activity in open lots, and wind erosion of manure or compost piles. In addition, emissions of compounds such as NH_3 from animal activity and manure decomposition can contribute to PM formation (USDA NRCS, 2012).
- **Energy Use:** Carbon dioxide (and other air pollutant) emissions can result from agricultural energy use from sources such as groundwater pumps, irrigation equipment, field operations (e.g., tractors spreading manure/fertilizer), and vehicles transporting manure on or off-site (USDA CCPO, 2011; EPA, 2014k).

Figure 3.5-16. Sources of emissions of air pollutants and GHGs on baseline working produce farm (crops and livestock operations)



3.6 Cultural Resources

3.6.1 Definition of the Resource

Cultural Resources

The Advisory Council on Historic Preservation (ACHP) defines *historic property* as "any prehistoric or historic district, site, building, structure, or object included in, or eligible for inclusion in, the National Register of Historic Places maintained by the Secretary of the Interior. This term includes artifacts, records, and remains that are related to and located within such properties. The term includes properties of traditional religious and cultural importance to an Indian tribe or Native Hawaiian organization and that meet the National Register criteria" (36 CFR § 800.16(l)(1)).

The PS PR primarily pertains to farms (defined by FDA in 79 Fed. Reg. 58434 at 58470-71) and in the glossary (Chapter 11) of this EIS.

Based on the definitions set forth above, with respect to farms, cultural resources are likely to include the historic farmstead (i.e., the farmhouse and associated domestic and agricultural outbuildings) as well as the agricultural lands that were historically associated with the farmstead. Generally, the cultural significance of farms is assessed based on the physical integrity of the farm (i.e., the built structures as well as the extant farmland), and the historical contributions the farms has made to agricultural production in the region.

3.6.2 Regulatory Oversight

Section 106 of the National Historic Preservation Act (NHPA) of 1966 as amended (16 U.S.C. § 470) mandates that Federal agencies consider how their proposed project might have the potential to affect historic or cultural resources. Specifically, the NHPA as amended (16 U.S.C. § 470) states in Section 106:

> "The head of any Federal agency having direct or indirect jurisdiction over a proposed Federal or Federally assisted undertaking in any State and the head of any Federal department or independent agency having authority to license any undertaking shall, prior to the approval of the expenditure of any Federal funds on the undertaking or prior to the issuance of any license, as the case may be, take into account the effect of the undertaking on any district, site, building, structure, or object that is included in or eligible for inclusion in the National Register. The head of any such Federal agency shall afford the Advisory Council on Historic Preservation established under Title II of this Act a reasonable opportunity to comment with regard to such undertaking."

The regulations implementing NHPA, found in 36 CFR 800, states that Federal agencies 1) determine whether activities proposed action constitute "undertakings" that have the potential to cause effects on historic properties; and, 2) if so, to evaluate the effects of such undertakings on such historic resources and consult as appropriate (16 U.S.C. § 470f).

3.6.3 Current Background Conditions

While modifications may need to be made to farm productions in order to comply with the Rule, the PS PR does not constitute an "undertaking" in the scope of Section 106 of the NHPA as there is no expenditure of Federal funds or issuance of any licenses for compliance such that modifications to potential historic resources on farms would be made by individual land owners in order to comply with the PS PR.

As there is no Federal undertaking, Section 106 of the NHPA does not apply to the PS PR. No further evaluation or consideration of potential impacts on historic or cultural resources is necessary. Chapter 4, under the subheader for Resource components not included for review in the EIS, provides additional information on FDA's consideration of cultural resources with respect to EIS impact analysis.

3.7 Socioeconomics and Environmental Justice

3.7.1 Definition of the Resource

Socioeconomics

When an EIS is prepared and socioeconomic and natural or physical environmental effects are interrelated, the EIS must discuss the socioeconomic effects on the human environment. As defined within the CEQ Regulations for Implementing NEPA, the "human environment" comprehensively includes "the natural and physical environment and the relationship of people with that environment" (40 CFR 1508.14). For purposes of the socioeconomics section of this draft EIS, we are considering the following factors: (1) direct or indirect effects interrelated with the environmental impacts of any alternative; (2) consistent with 40 CFR 1502.23, how economic impacts from the cost-benefit analysis might inform on any agency decision making (e.g., economic impacts considered in the proposed rule that would impact how we compare alternatives under 40 CFR 1502.23).

The socioeconomic section of this EIS describes the existing population and demographic trends, including income, employment, and housing conditions, that have been identified within the geographic scope of the EIS (Chapter 1.9). The resources discussed in the sections that follow include general agricultural characteristics associated with the number of farms, acres of primary field crops, and revenues generated from primary field crops, as well as an analysis of rural population trends. The resources identified are essential to the description of the high-level demographic and economic components of the national agricultural operator population and industry.

Socioeconomic information was obtained from the USDA Census, specifically the 2012 dataset (USDA NASS, 2014a). The USDA Census includes a comprehensive summary of agricultural activity, farm operations, and farm operators at the national, state, and county level for "any place from which $1,000 or more of agricultural products were produced and sold, or normally would have been sold, during the census year." To provide for regional comparisons, USDA Report Form Regions, as identified within the 2012 Census of Agriculture, are used in this analysis. Alaska and Hawaii are not included in the USDA's Report Form Regions; in an effort to include these states in the socioeconomic analysis, a new region has been created specifically for this resource component, the Non-Contiguous States Region, as noted in the analysis. This region, in Chapter 4, however, will be related to Alaska and Hawaii's appropriate produce region as identified in Chapter 1.7 (Figure 1.7-4). As discussed in Chapter 1.9, most farms within the EIS geographic areas, except for farms in Puerto Rico, are likely to be excluded from the rule. Further, there is a lack of related environmental background information on farms other than those in the Commonwealth of Puerto Rico. Therefore, the only portion of the EIS geographic areas included within the analysis of this EIS is Puerto Rico.

Data on the characteristics of farming populations include the urban and rural population trends related to movement of the population throughout the United States. Data on these trends were gathered from the USDA Census of Agriculture, the U.S. Census 2010, and the USDA ERS. This section will also describe rural employment trends.

While not considered a minority population with respect to this EIS, farms operating within conventional traditional agrarian communities will allow draft or working animals in their fields during growing or harvest times (see Chapter 3.4.3.2). For these communities, specialized farming such as livestock farming and/or growing a high-value crop like tobacco or fresh produce may be necessary to maintain suitable returns to make farming a viable sole livelihood for these small family farms. If the farmer decides that in order to comply with the rule, working animals may no longer be used and they would have to purchase farming equipment, the associated costs may result in significant adverse effects to members of these communities. These effects are not anticipated. Since fencing is not required by the rule, these farms may rely more heavily on a robust monitoring plan in concert with other measures such as to establish and use horse paths that are segregated from covered produce plantings, and to minimize entry of horses in covered produce plantings, thus minimizing the opportunity for horse excreta to contact covered produce. If such actions were taken the economic impact may be considered low.

Environmental Justice

Executive Order 12898, *Federal Actions to address Environmental Justice in Minority Populations and Low-Income Populations*, signed by President Clinton on February 11, 1994, states that “each Federal agency shall make achieving environmental justice part of its mission by identifying and addressing as appropriate, disproportionality high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low income populations.” (59 Fed. Reg. 7629, February 16, 1994).

This EIS identifies the potential minority and low-income populations that may be affected by the PS PR, if finalized. For the purposes of this EIS, low-income and minority populations, and FDA’s methodology for identifying these populations, are discussed in greater detail in Chapter 3.7.3. Data important for identifying minority and low-income populations potentially affected by the PS PR, if finalized, was also found in the Census of Agriculture (USDA NASS, 2014a). It should be noted that information was not available specific to race as it relates to produce covered by the PS PR; the USDA information does provide data for minority operators by State for general fruits and vegetables.

3.7.2 Regulatory Oversight

Environmental Justice (EJ) guidance under NEPA, as provided by the CEQ (1997a), was established to assist Federal agencies in effectively integrating socioeconomic impacts, including those on minority and low-income populations, into their project development procedures. Additionally, the Department of Health and Human Services (HHS) 2012 Environmental Justice Strategy and Implementation Plan provides strategic elements, strategies, and actions to be undertaken by HHS in order to achieve targeted environmental justice goals.

3.7.3 Current Background Conditions

Nationwide Overview

The U.S. supported a total of 2,109,303 farms in 2012 which were operated by approximately 3.2 million farmers (USDA NASS, 2014a). This represents a decrease of 95,489 farmers from 2007 data (USDA NASS 2009a). Approximately 99.6 percent of the farms are located in the contiguous 48 states. Table 3.7-1 presents the change in farming from 2002 to 2012 throughout the U.S. by region. The West and Non-Contiguous States have seen the greatest increase in farms since 2002 with an approximate ten and thirty percent increase, respectively. Comparatively, marginal growth has been observed in the Plains region, and a decrease in farms has been reported in the Atlantic, Midwest, and South regions, and in Puerto Rico. Table 3.7-1 identifies the states included within each region. These regions, as defined, are carried forward throughout the socioeconomic analysis.

Table 3.7-1. Regional farm distribution and change (2002-2012)

Region		Agricultural Census Year				
		2012	2007	2002	Total Change (2002-2012)	Percent Change (%)
U.S.		2,109,303	2,204,792	2,128,982	-19,679	-0.92
West	Arizona	20,005	15,637	7,294	12,711	174.27
	California	77,857	81,033	79,631	-1,774	-2.23
	Colorado	36,180	37,054	31,369	4,811	15.34
	Idaho	24,816	25,349	25,017	-201	-0.80
	Montana	28,008	29,524	27,870	138	0.50
	Nevada	4,137	3,131	2,989	1,148	38.41
	New Mexico	24,721	20,930	15,170	9,551	62.96
	Oregon	35,439	38,553	40,033	-4,594	-11.48
	Utah	18,027	16,700	15,282	2,745	17.96
	Washington	37,249	39,284	35,939	1,310	3.65
	Wyoming	11,736	11,069	9,422	2,314	24.56
	Regional Total	318,175	318,264	290,016	28,159	9.71
Plains	Kansas	61,773	65,531	64,414	-2,641	-4.10
	Nebraska	49,969	47,712	49,355	614	1.24
	North Dakota	30,961	31,970	30,619	342	1.12
	Oklahoma	80,245	86,565	83,300	-3,055	-3.67
	South Dakota	31,989	31,169	31,736	253	0.80
	Texas	248,809	247,437	228,926	19,883	8.69
	Regional Total	503,746	510,384	488,350	15,396	3.15
South	Alabama	43,223	48,753	45,128	-1,905	-4.22
	Arkansas	45,071	49,346	47,483	-2,412	-5.08
	Florida	47,740	47,463	44,081	3,659	8.30
	Georgia	42,257	47,846	49,311	-7,054	-14.31

Region		Agricultural Census Year				
		2012	2007	2002	Total Change (2002-2012)	Percent Change (%)
	Louisiana	28,093	30,106	27,413	680	2.48
	Mississippi	38,076	41,959	42,186	-4,110	-9.74
	South Carolina	25,266	25,867	24,541	725	2.95
	Regional Total	269,726	291,340	280,143	-10,417	-3.72
Midwest	Illinois	75,087	76,860	73,027	2,060	2.82
	Indiana	58,695	60,938	60,296	-1,601	-2.66
	Iowa	88,637	92,856	90,655	-2,018	-2.23
	Michigan	52,194	56,014	53,315	-1,121	-2.10
	Minnesota	74,542	80,992	80,839	-6,297	-7.79
	Missouri	99,171	107,825	106,767	-7,596	-7.11
	Ohio	75,462	75,861	77,797	-2,335	-3.00
	Wisconsin	69,754	78,463	77,131	-7,377	-9.56
	Regional Total	593,542	629,809	619,827	-26,285	-4.24
Atlantic	Connecticut	5,977	4,916	4,191	1,786	42.62
	Delaware	2,451	2,546	2,391	60	2.51
	Kentucky	77,064	85,260	86,541	-9,477	-10.95
	Maine	8,173	8,136	7,196	977	13.58
	Maryland	12,256	12,834	12,198	58	0.48
	Massachusetts	7,755	7,691	6,075	1,680	27.65
	New Hampshire	4,391	4,166	3,363	1,028	30.57
	New Jersey	9,071	10,327	9,924	-853	-8.60
	New York	35,537	36,352	37,255	-1,718	-4.61
	North Carolina	30,961	52,913	53,930	-3,712	-6.88
	Pennsylvania	59,309	63,163	58,105	1,204	2.07
	Rhode Island	1,243	1,219	858	385	44.87
	Tennessee	68,050	79,280	87,595	-19,545	-22.31
	Vermont	7,338	6,984	6,571	767	11.67
	Virginia	46,030	47,383	47,606	-1,576	-3.31
	West Virginia	21,489	23,618	20,812	677	3.25
	Regional Total	397,095	446,788	444,611	-28,259	-6.36
Non-Contiguous States	Alaska	762	686	609	153	25.12
	Hawaii	7,000	7,521	5,398	1,602	29.68
	Regional Total	7,762	8,207	6,007	1,755	29.22
U.S Geographic Areas	Puerto Rico	13,159	15,745	17,659	-4,500	-25.5

Source: Census of Agriculture 2012, 2007, and 2002 (USDA NASS 2014a, USDA NASS 2009a, and USDA NASS 2004)

The Census of Agriculture provides information for three levels of operators: principal (or primary) operator, second operator, and third operator. The principal operator is responsible for the primary day-to-day operation of the farm. The operator could be an owner, hired manager, cash tenant, share tenant, and/or a partner. If land is rented or worked on shares, the tenant or renter is the operator. Information is collected for up to three operators per farm. In the case of multiple operators, the respondent for the farm identifies who the principal farm operator is during the data collection process. The number of principal operators is used to determine the amount of farms within the United States. Data presented in Table 3.7-2 is reflective of the number of principal operators on a farm. In 2012, 3.2 million farmers operated 2.1 million farms. There has been an approximate three percent decrease in farms and farm operators since the 2007 Census of Agriculture (USDA NASS, 2014a; USDA NASS, 2009a). Table 3.7-2 presents the decline in farming from 2007 to 2012.

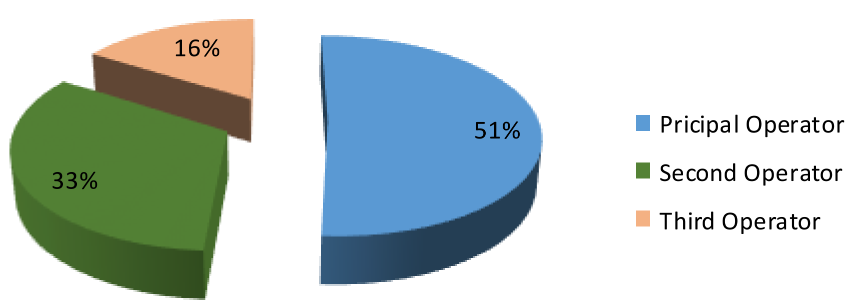
Table 3.7-2. Distribution of farm operators, 2007-2012

Operators	Agricultural Census Year			
	2012	2007	Total Change (2007-2012)	Percent Change (%)
Principal	2,109,303	2,204,792	-95,489	-4.3
Second	928,151	931,670	-3,519	-0.4
Third	142,620	145,072	-2,452	-1.7
Total	3,180,074	3,281,534	-101,460	-3.1

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Figure 3.7-1 presents the U.S. distribution of operator type (USDA NASS, 2014a). These data are the result of the USDA NASS survey data, specifically for 2012, which USDA relies upon to determine the number of farms in the United States.

Figure 3.7-1. Percentage of Operators, 2012



Farm Tenure

The total number of farms has decreased from 2007 to 2012; the amount of land in farms and full ownership (owned and operated by the primary operator) of farms has similarly decreased. Full owners only operated land they owned, while partial owners are defined as persons who operated land they own or rent. The number of farms and total farmland acres by ownership type are described in Table 3.7-3.

Table 3.7-3. Number of farms and total farmland Acres, 2007-2012

	Total	Full Ownership	Partial Ownership	Tenant
Number of Farms 2007	2,204,792	1,522,033	542,192	140,567
Number of Farms 2012	2,109,303	1,428,351	533,070	147,882
Land in Farms 2007 (acres)	922,095,840	343,952,327	496,344,290	81,799,223
Land in Farms 2012 (acres)	914,527,657	336,233,189	491,292,824	87,001,644

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Age of Operators

The trend of increasing operator age, identified in Table 3.7-4, has been observed through previous Censuses of Agriculture. The 2012 Census of Agriculture found the average farm operator age to be 58.3 years, an increase of 8 years from the 1978 Census of Agriculture. The majority of farmers are between the ages of 45 and 64 (51 percent). Farm operators 65 years and older are the second most prevalent (33 percent). There has been a decline in the number of farmers between the ages of 35 to 44 and 45 to 54 according to the 2007 and 2012 Censuses of Agriculture.

Table 3.7-4. Age of operators

Age Range	2012	2007	Percent Change (%)
All Principal Farm Operators			
Under 25 Years	10,714	11,878	-9.8
25 to 34 Years	109,119	106,735	2.2
35 to 44 Years	214,106	268,818	-20.4
45 to 54 Years	466,036	565,401	-17.6
55 to 64 Years	608,052	596,306	1.9
65 to 74 Years	443,571	412,182	7.2
75 Years and Older	257,705	243,472	5.8

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Beginning Farmers[10]

The USDA defines a beginning farmer as an operator with less than 10 years of experience operating a farm as either the sole operator or with others who have operated a farm 10 years or less. The number of beginning farmers has declined significantly since 2007. Table 3.7-5 presents the decline in beginning farmers since 2007. Of the 2.1 million U.S. principal operators in 2012, 25 percent were classified as beginning farmers. Established farmers are defined as those who were on their current operation eleven years or more. Beginning farmers are on average younger than established farmers. The average age of a beginning farmer on their farm for five years or less is 46.9 years old, while the average age of established farmers is 61.4 years (USDA NASS, 2014a). Compared to more experienced farm operators, there is also a higher likelihood of beginning farmers identifying as minorities, working other jobs off the farm, and a lower likelihood that they will state farming as their primary occupation. Farmers on their operations less than five years generally have smaller farms in both acreage and sales. The net gain in sales and acres is smaller for beginning farmers than that of established farmers, and beginning farmers experience higher expense-to-sales ratios. Beginning farmers also received less government payments than established farmers (USDA NASS, 2014a).

Beginning farmers are found across the county, but the top states with principal operators being beginning farmers are Alaska (37%), Rhode Island (33%), Hawaii (33%), Maine (33%), and Florida (31%). The number of beginning farmers growing grain and vegetables has grown since 2007, while there has been a decrease in tobacco and animal farms with beginning farmers as principal operators (USDA NASS, 2014a).

Table 3.7-5. Number of beginning farmers, 2007-2012

Principal Farm Operators	2012	2007	Percent Change (%)
All Beginning Farmers (10 years or less on current operation)	522,058	652,820	-20
5 Years or Less on Current Operation	226,670	291,329	-22
6 to 10 Years on Current Operation	295,388	361,491	-18

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Agricultural Sales

Farm sales within the U.S. have continued to grow, reaching nearly $395 billon in agriculture-related products in 2012. Sales have increased 33 percent from 2007 in each agriculture economic sector. Crop (including fruit and vegetables) and livestock sales accounted for 48 and 19 percent increases, respectively. Crop sales accounted for more than half of all agriculture sales in 2012. Table 3.7-6 presents the 2012 U.S agricultural sales. Thirteen states produced more than $10 billion in agricultural products in 2012 which made up more than 60 percent of the U.S. agricultural sales. These 13 states are presented in Table 3.7-7. California accounted for

[10] These USDA data also include information on ranchers (livestock raising operations) in addition to farmers.

$42.6 billion dollars in sales, and within California, Fresno County had the highest amount with $5 billion in sales of agricultural products (USDA NASS, 2014a).

Table 3.7-6. 2012 U.S. agriculture sales

	2012 ($ billions)	2007 ($ billions)	Percent Change (%)
Crops	212.4	143.7	47.8
Livestock	182.2	153.6	18.7
All Products	394.6	297.2	32.8

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Table 3.7-7. U.S. States in agriculture sales

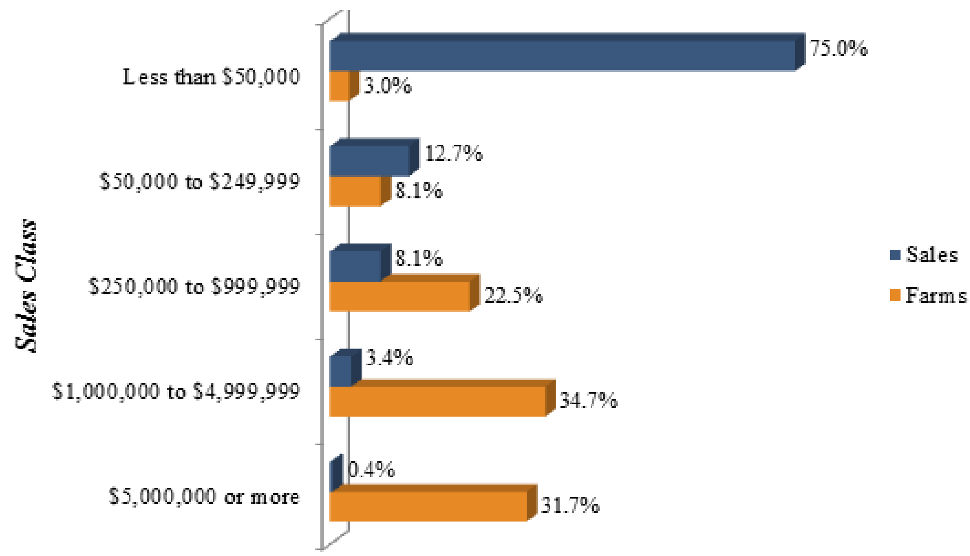
State	2012 ($ billions)	Percent of U.S. Total (%)
California	42.6	10.8
Iowa	30.8	7.8
Texas	25.4	6.4
Nebraska	23.1	5.8
Minnesota	21.3	5.4
Kansas	18.5	4.7
Illinois	17.2	4.4
North Carolina	12.6	3.2
Wisconsin	11.7	3.0
Indiana	11.2	2.8
North Dakota	11.0	2.8
South Dakota	10.2	2.6
Ohio	10.1	2.6

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Farm Size

The majority of farms are small farms, with 75 percent of all farms having sales of less than $50,000. Together, these small farms produce roughly 3 percent of the total value of agricultural products sold. Approximately 95.8 percent of farms have sales of less than $250,000 and account for 33.6 percent of farm sales (USDA NASS, 2014a). Larger farms are not distributed evenly throughout the U.S., with a majority of farms with sales below $50,000 being in located in New England and the Southeast (USDA NASS, 2014a). Figure 3.7-2 shows the distribution of 2012 farm sales by the size of farm. Sales are defined as the gross market value before taxes and production expenses of all agricultural products sold or removed from the place in the year (2012), regardless of who reviewed the payment.

Figure 3.7-2. Share of farms and farm sales, by sales class, 2012



Source: USDA NASS, 2014a

<u>Farm Income</u>

Farm income in addition to agricultural sales includes government payments and earnings from a variety of farm activities. Multiple sources of income are needed to offset farm production expenses. Income through farming is generated from rent, custom work for other farms, forest product sales, recreational services, patronage payments, crop and livestock insurance, and other activities related to agricultural practices. Farm production expenses have continued to increase along with the increase in agricultural sales. The largest expenses related to farm activities are feed, livestock and poultry purchases, fertilizer, labor, and rent for farming property. Government payments have increased nearly 1 percent from 2007, and expenses have increased approximately 36 percent. Government payments to farmers include conservation payments, direct payments, loan deficiency payments, disaster payments, and payments from various government programs (USDA NASS, 2014a). Farm-related income and expenses are described in Table 3.7-8 and Table 3.7-9.

Table 3.7-8. National farm income and expense, 2007-2012

	2012 ($ billions)	2007 ($ billions)	Percent Change (%)
Agricultural Sales	394.6	297.2	32.8
Government Payments	8.1	8.0	0.9
Farm-related Income	18.5	10.5	76.6
Production Expenses	328.9	241.1	36.4
Net Cash Farm Income	92.3	74.6	23.7

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Table 3.7-9. National farm expenses, 2007-2012

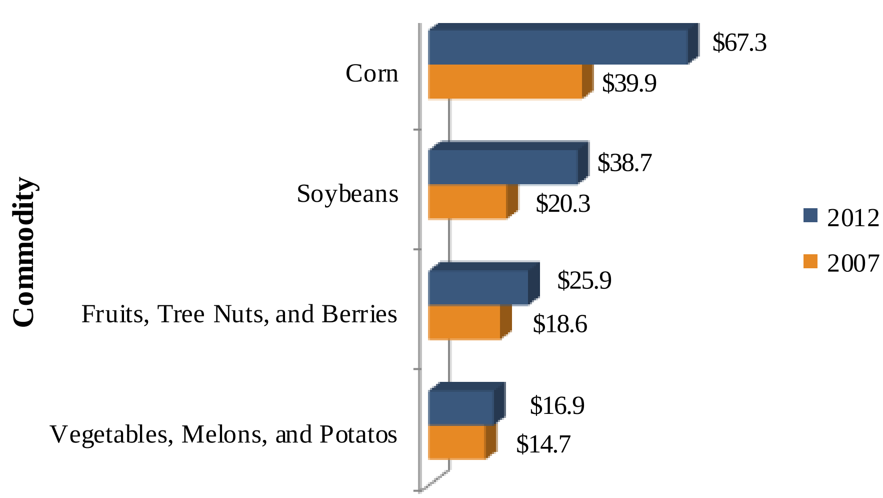
Expenses	2012 ($ billions)	2007 ($ billions)	Percent Change (%)
Feed	75.7	49.1	54.2
Livestock and Poultry Purchases	41.6	38.0	9.4
Fertilizer	28.5	18.1	57.6
Labor	27.0	21.9	23.4
Cash Rent	21.0	13.3	58.2
Seeds	19.5	11.7	66.0
Supplies and Repairs	18.9	15.9	18.7
Gasoline, Fuels, and Oils	16.6	12.9	28.4
Chemicals	16.5	10.1	63.4
Other	63.7	50.1	27.1
Total	328.9	241.1	36.4

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Income from Harvest

The five top grossing commodities in 2012 were cattle, poultry, corn, soybeans and milk. These accounted for 66 percent of the total agricultural sales. Of the crop commodity sales, fruits, tree nuts, berries, vegetables, melons, and potatoes were behind the sales of corn and soybeans, but made increases from 2007 sales. Fruits, tree nuts and berries had sales of nearly $26 billion, and vegetables, melons, and potatoes had sales of approximately $17 billion in 2012 (USDA NASS, 2014a). Figure 3.7-3 presents the 2007 and 2012 sales by commodity sector.

Figure 3.7-3. Top crop commodities by sales, 2007-2012



Source: USDA NASS, 2014a

Value of Harvest

Information related to produce covered by the PS PR is presented below for selected commodities. The farms harvesting the selected crops listed in Table 3.7-10, Table 3.7-11 and Table 3.7-12 make up approximately 15 percent of the total farms listed in the 2012 Agriculture Census.

The vegetable industry is classified by two major end uses: fresh market and processing. Processing is the freezing, canning, and dehydrating of fresh vegetables for consumption. About half of all vegetable production is produced for processing. Most of the vegetable production takes place in California, North Dakota, Idaho, Michigan, Minnesota, Washington and Wisconsin (includes covered and non-covered produce). These areas correspond with regions C, F, E, L, K, M, A, and B which are depicted on Figure 1.7-4 in Chapter 1.7. The Upper Midwest and Pacific States report the largest vegetable acreage for processing (regions: K, L, A, B, and C), while California, Florida, Arizona, Georgia, and New York harvest the largest amount for fresh market consumption (regions: C, U, D, P, T, and R) (USDA ERS, 2014b). More than half of the vegetable production occurs on irrigated land. Vegetable yields continue to grow due to the increase in the use of hybrid varieties and in adoption of precision farming techniques (USDA NASS, 2014a).

During the 2000's fruit and tree nut sales averaged 13 percent of all crop sales, and 6 percent of all farm cash sales. Oranges, grapes, apples and bananas are the most popular fruit; while almonds, walnuts, and pecans are the preferred tree nuts. Output for each has continued to grow due to increased consumption and farming practices. The nation's largest fruit producing states are California, Florida, and Washington (regions: C, U, A and B). California accounts for about half of the harvested fruit acreage (USDA ERS, 2012a). Michigan, New York, Oregon, Pennsylvania, and Texas are other important fruit producing states (regions: L, R, A, B, and R). Fruits are grown for both fresh and processing markets, although more than half of the production is for fresh markets. Processed fruit includes canned, frozen, juice, and dried fruit (USDA ERS, 2012a).

Table 3.7-10. Number of farms harvesting vegetables, 2012

Commodity	2012 Total harvested farms	2012 Farms Harvested for processing	2012 Farms harvested for fresh market
Broccoli	3,636	113	3,580
Cabbage	4,916	228	4,813
Cantaloupe	9,684	31	9,675
Carrots	4,468	304	4,266
Cauliflower	1,330	72	1,295
Celery	488	31	475
Cucumbers	14,183	894	13,571
Curly Endive	109	N/A	109
Garlic	3,408	220	3,306
Herbs (e.g., basil, chives,	2,255	N/A	2,255

Commodity	2012 Total harvested farms	2012 Farms Harvested for processing	2012 Farms harvested for fresh market
cilantro, mint, oregano, parsley)			
Honeydew	534	N/A	534
Lettuce	5,757	N/A	5,757
Onions	8,021	483	7,743
Peas	8,350	2,035	6,546
Peppers (such as bell and hot)	19,519	1,095	18,902
Radish	1,228	34	1,222
Snow Peas	991	86	919
Spinach	1,594	106	1,522
Summer Squash (e.g., patty pan, yellow and zucchini)	14,090	489	13,838
Tomatoes	32,383	2,522	31,047
Watercress	100	N/A	100
Watermelon	12,996	45	12,971

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Table 3.7-11. Number of farms harvesting fruits, nuts, and mushrooms, 2012

Commodity	2012 Total Harvested Farms	2012 Bearing Age Acres Farms	2012 Nonbearing Age Acres Farms
Almonds	7,052	6,285	2,683
Apples	25,129	18,815	12,298
Apricots	2,305	1,654	933
Avocados	7,495	6,919	2,402
Bananas	1,169	970	438
Cherries	10,715	7,660	5,019
Citrus *	13,055	11,886	3,999
Grapes	27,878	23,420	10,092
Guava	399	331	129
Kiwifruit	345	258	131
Mangos	933	800	306
Mushrooms	712	N/A	N/A
Nectarine	1,275	961	509
Papaya	401	339	145
Passion Fruit	153	131	32
Peaches	13,916	9,637	6,895
Pears	10,246	6,631	4,918
Plums	5,888	4,016	2,691
Walnuts	6,656	5,707	2,548

* (e.g., clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unique fruit)
Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Table 3.7-12. Number of farms harvesting berries, 2012

Commodity	2012 Total Harvested Farms	2012 Farms Harvested	2012 Farm Not Harvested
Blackberries	7,291	5,580	2,542
Blueberries	13,432	10,449	4,951
Raspberries	8,052	6,508	2,303
Red Currant	528	363	218
Strawberries	10,388	8,828	2,764

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Table 3.7-13 provides the 2012 value of harvest for covered produce with information available.

Table 3.7-13. Value of selected covered produce

Crop		Crop Unit	2012 Value of Utilized Production ($1,000) Fresh Market	2012 Value of Utilized Production ($1,000) Commercial Processing
Vegetable Covered Crops	Broccoli	cwt	678,619	8,811
	Cabbage	cwt	388,600	-
	Cantaloupe	cwt	325,337	-
	Carrots	cwt	609,548	33,228
	Cauliflower	cwt	235,620	4,144
	Celery[1]	cwt	366,404	
	Cucumbers	cwt	247,957	172,850
	Curly Endive	cwt	(NA)	-
	Garlic[1]	cwt	227,090	-
	Herbs (e.g., basil, chives, mint, cilantro, oregano, parsley)	cwt	(NA)	-
	Honeydew	cwt	69,826	-
	Lettuce (includes head, leaf, and romaine)	cwt	1,871,511	-
	Onions[1]	cwt	944,029	-
	Peas (includes chickpeas, dry edible peas, and wrinkled seed peas)	cwt	294,195	-
	Peppers (e.g., bell and chili) [1]	cwt	802,685	-
	Radish	--	(NA)	-
	Snow Peas (Austrian Winter Peas)	cwt	3,479	-
	Spinach	cwt	223,622	17,055
	Summer Squash (such as patty pan, yellow and zucchini) [1]	cwt	248,725	-

	Crop	Crop Unit	2012 Value of Utilized Production ($1,000) Fresh Market	2012 Value of Utilized Production ($1,000) Commercial Processing
	Tomatoes	tons	863,982	1,010,545
	Watercress	--	(NA)	-
	Watermelon	cwt	520,799	-
Fruits, Nuts and Mushroom Covered Crops	Almonds	Lbs	4,816,860	-
	Apples	Lbs	3,307,635	-
	Apricots	tons	40,879	-
	Avocados	tons	(NA)	-
	Bananas	Lbs	(NA)	-
	Cherries, sweet	tons	843,311	-
	Cherries, tart	Lbs	50,520	-
	Citrus (e.g., clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unique fruit)	boxes	3,712,817	-
	Grapes	tons	5,657,109	
	Green Beans (snap beans)	cwt	323172	191,635
	Guava	Lbs	(NA)	-
	Kiwifruit	tons	(NA)	-
	Mangos	--	(NA)	-
	Mushrooms	Lbs	109,9400	-
	Nectarine	tons	144,906	-
	Papaya	Lbs	(NA)	-
	Passion Fruit	--	(NA)	-
	Peaches	Ton	629,163	-
	Pears	tons	432,988	-
	Pineapple	--	(NA)	-
	Plums	tons	79,940	-
	Walnuts	tons	1,505,910	-
Berries Covered Crops	Blackberries, cultivated (Oregon)	Lbs	44,520	-
	Blueberries (cultivated & wild)	Lbs	850,883	-
	Raspberries (includes Black, Red, and all California)	Lbs	290,024	-
	Red Currant	--	(NA)	-
	Strawberries	cwt	2,408,596	-

[1] Includes processing and fresh market (USDA NASS, 2014b)

Farm Employment

USDA NASS survey data provides information on principal operators of farms. Limited data is available for farmworkers; however, there is no data specifically reported for farmworkers on produce farms. The U.S. Department of Labor reports some data on farmworkers in terms of ethnicity and income; however, State-level data are reported only for California and no other State. Potential impacts to farmworker employment may be dependent upon multiple factors including (but not limited to) average annual farm income, estimates for crop yield, and commodity prices. Increases in farm operating costs may also impact farmworker employment. It should be noted that farmworker employment can be highly seasonal (USDA ERS, 2014a). Increases in farm operating costs may result in adverse impacts to farmworkers, but such costs may also be transferred to consumers. Although potential cost impacts could be felt by consumers, without more definitive information regarding specific management decisions that might be taken in response to the PS PR, if finalized, it is unreasonable to project impacts on such groups. Therefore, for purposes of this EIS, the discussion of potential socioeconomic impacts is limited to principal farm operators and farmworkers (where information is available).

According to the Bureau of Economic Analysis (BEA) data, farm employment is defined as the number of workers engaged in the direct production of agricultural commodities, whether as the sole proprietor, partner or hired laborer. Table 3.7-14 describes the change in farm employment from 2007 to 2012. These data also include various, but not consistent or distinguishable levels of farm operator levels, and not just farmworkers. Therefore, the data presented hereafter may seem somewhat contrary when reporting in terms of numbers of farmworkers. These outcomes depend heavily on the data source, the data collection method, and how and when data are reported. Because these data are collected inconsistently, a comparative analysis is difficult to achieve, and any conclusive analysis cannot be adequately performed.

Table 3.7-14. Farm employment data, 2007-2012

Region	2012	2007	Percent Change (%)
U.S. Total	2,616,000	2,664,000	-1.8
West	572,300	578,022	-1.0
Plains	524,649	534,270	-1.8
South	341,011	353,043	-3.4
Midwest	653,214	669,908	-2.5
Atlantic	511,900	515,497	-0.7
Non-Contiguous States[1]	12,926	13,260	-2.5
Puerto Rico	*	*	*

[1]Includes Alaska and Hawaii
* Data not available
Source: Bureau of Economic Analysis

Hired farmworkers include field crop workers, nursery workers, farm supervisors, and hired farm managers. Hired farmworkers make up less than one percent of the all the U.S. wage and salary workers but are an important part of U.S. agriculture. Farmworkers make up a large part of the costs in labor intensive crops such as fruits, vegetables, and nursery products. Hired farmworkers are one of the most economically disadvantaged groups in the U.S. (USDA ERS, 2014a), especially farm laborers, as discussed the Farmworkers subsection below.

Farmworkers

The USDA periodically conducts research and takes surveys on farm labor issues. According to the most recent farm labor survey (survey taken in 2012), hired farm employment is estimated at 787,000 nationally (USDA ERS, 2014a). Of these 787,000 workers, 64 percent are reported as having U.S. citizenship, and 42 percent are reported as being foreign born. In addition, an estimated 92 percent of farmworkers are reported as being white (race), and 45 percent are reported as Hispanic (ethnicity). Of the 787,000 farmworkers, 56 percent work in crop agriculture (not broken out by specific crops), and 44 percent work in livestock production. Approximately 37 percent of all hired farmworkers are reported to live primarily Arizona, California, Colorado, New Mexico, and Texas.

The U.S. Department of Labor (DOL) also periodically conducts an employment-based, random survey of U.S. crop workers. The purpose of the survey is to assist the Federal Government in conducting occupational injury and health surveillance, estimating the number of farmworkers and their dependents, and to conduct planning. [11] Past surveys conducted in 1997 to 1998, and 2001 to 2002 estimated demographic data in terms of “Non-white race” and “Hispanic Ethnicity.” These surveys also found that in 1997 to 1998 approximately 61 percent of farmworkers were below the U.S. poverty level and reported a median income for an individual as less than $7,500, and less than $10,000 for a family. For survey years 2001 to 2002 approximately 30 percent of farmworkers were below the poverty level and reported a median income range for an individual as $10,000 to $12,499, and a range of $15,000 to $17,499 for a family (DOL, 2000 and 2005). It should be noted that State-level data is only reported for California (region C).

From these data sets, we can extrapolate that regional data on farmworkers is limited, and yet more data is available for regions C, D, I, and J (including California, Arizona, and Texas).[12]

[11] The DOL Web site specifically reports data limitations including that “except for California, the data are not available at the state level.” The Web site is found at: http://www.doleta.gov/agworker/naws.cfm
[12] Colorado and New Mexico do not have high concentrations of covered produce (see Figure 1.7-4).

Environmental Justice

The HHS Mission and Role in Environmental Justice, as identified within HHS's 2012 Environmental Justice Strategy and Implementation Plan, states that "given the persistent, disproportionate burden of environmental hazards on minority and low-income populations and Indian Tribes, HHS will make achieving environmental justice part of its mission by (1) identifying and addressing disproportionately high and adverse human health and environmental effects on minority and low-income populations and Indian Tribes, and (2) encouraging the fair treatment and meaningful involvement of affected parties with the goal of building healthy, resilient communities and reducing the disparities in health and well-being associated with environmental factors."

Minority Populations:
Pursuant to CEQ's Guidance for Federal Agencies on Key Terms in EO 12898 (CEQ, 1997a), and for the purposes of this Technical Report and the associated EIS, minority populations are comprised of members of the following population groups:

- Black or African American: a person having origins in any of the black racial groups of Africa;
- Hispanic or Latino: a person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race;
- Asian American: a person having origins in any of the original peoples of the Far East, Southeast Asia or the Indian subcontinent;
- American Indian or Alaskan Native: a person having origins in any of the original people of North America, South America (including Central America), and who maintains cultural identification through tribal affiliation or community recognition; or,
- Native Hawaiian or Other Pacific Islander: a person having origins in any of the original peoples of Hawaii, Guam, Samoa or other Pacific Islands.

Census of Agriculture data were collected on the racial and ethnic composition of vegetable and melon farmers and on fruit and tree nut farmers for each of the regions and the Non-Contiguous States and Puerto Rico (Table 3.7-15). This approach was taken as it presents the most specific breakdown of crops grown by farmer's racial and ethnic composition available based on data provided by the Census of Agriculture. Specifically, the 2012 Census of Agriculture's Table 60, *Selected Farm Characteristics by Race of Principal Operator: 2012*, sheets 1112 and 1113, were used to determine the number of farms with principals operators who identify as minority operators.

Table 3.7-15. Demographics of principal farm operators

Region	Operators Reporting White	Operators Reporting Black or African American	Operators Reporting Asian	Operators Reporting American Indian or Alaska Native	Operators Reporting Native Hawaiian or Other Pacific Islander	Operators Reporting More Than One Race	Total Minority Principal Operators	Percent Minority Principal Operators
U.S.	121,704	2,674	7,033	3,007	461	1,162	14,337	10.5%
West	54,296	200	4,136	2,441	193	424	7,394	12.0%
Plains	8,478	285	79	235	2	105	706	7.7%
South	18,358	1,539	408	141	31	116	2,235	10.9%
Midwest	14,792	114	436	50	14	71	685	4.4%
Atlantic	24,204	524	241	124	10	151	1,050	4.2%
Non-Contiguous States[1]	1,576	12	1,733	16	211	295	2,267	59.0%
Puerto Rico[2]	12,051	1,023	**	**	**	85	1,108	8.4%

[1]Includes Alaska and Hawaii
Source: 2012 Census of Agriculture (USDA NASS, 2014a)
[2]Data includes all farmers.
* Puerto Rico "More than one race reported" also includes individuals who identified themselves as other in the 2012 Census of Agriculture for Puerto Rico.
** Data not available

In accordance with the CEQ guidance, *Environmental Justice Guidance under the National Environmental Policy Act* (1997), a minority population is found to exist where either (a) the minority population of the affected area exceeds 50 percent of total population or (b) the minority population percentage of the affected area is meaningfully greater than the minority population percentage in the general population or other appropriate unit of geographical analysis. This guidance does not define the specific numerical value or percentage that should be used for determining if the minority or low-income population is "meaningfully greater" than the average in the surrounding jurisdiction. However, it is consistent with the CEQ guidance to set a threshold that is higher than (not equal to) the average of the minority population in the surrounding jurisdiction (in this case, a specific region). For the purposes of this assessment, the population of minority principal operators for each region is deemed to be "meaningfully greater" if it is greater than the value of the country's minority principal operators, plus an additional 10 percent of that value.

The national average of farms with minority principal operators is 10.5%. By applying an additional ten percent of that value (i.e., 1.05%), FDA is able to establish a "meaningfully greater" threshold of 11.6%. Of the regions included within the analysis, we find that both Alaska and Hawaii, and the West region have a minority population of principal operators greater than the 11.6% threshold. Thus, as shown in Table 3.7-15, the Non-Contiguous States (found to be at 59.0 percent) and the West region (found to be at 12 percent) are considered minority populations for the purposes of this analysis. Table 3.7-16 further breaks down the States within the West region. When compared to covered produce regions (Chapter 1.7, Figure 1.7-4), the regions described in this paragraph include regions A, B, C, D, W, and V.

EIS Geographic Areas

Puerto Rico contains 13,159 principal farm operators as indicated by the 2012 Census of Agriculture. Of the just over 13,000 principal farm operators, 8.4% identify themselves as minorities, which is below the 11.6% meaningfully greater threshold (USDA NASS, 2014c). Census data collected for 2012 is not currently available for other EIS geographic areas. The 2007 Census of Agriculture indicated Guam and the Commonwealth of the Northern Mariana Islands have minority principal farmer operator populations with 97.1% and 97.6%, respectively [2007 Census of Agriculture (Guam and Mariana)]. Information related to race was not provided in the 2007 Census of Agriculture for American Samoa and the United States Virgin Islands [2007 Census of Agriculture (AS and USVI)] (USDA NASS, 2009a). Based on Agricultural Census data it is anticipated that the majority of farms in these other EIS geographic areas would be excluded from the provisions of the PS PR, if finalized, as described in Chapter 1.9.

Table 3.7-16. Demographics of principal farm operators in the West

Region		Operators Reporting White	Operators Reporting Black or African American	Operators Reporting Asian	Operators Reporting American Indian or Alaska Native	Operators Reporting Native Hawaiian or Other Pacific Islander	Operators Reporting More Than One Race	Total Minority Operators	Percent of Minority Principal Operators	Covered Produce Growing Regions Within State
West	Arizona	1,059	10	51	1,373	-	9	1,443	57.7%	D
	California	35,339	156	3,668	526	169	278	4,797	12.0%	A, C, D
	Colorado	996	2	15	6	3	10	36	3.5%	D, E, G, H
	Idaho	1,100	-	23	-	-	3	26	2.3%	B, D, E
	Montana	464	-	6	6	-	2	14	2.9%	D, E, F, G
	Nevada	138	-	10	12	-	1	23	14.3%	D
	New Mexico	3,248	15	17	378	-	34	444	12.0%	D, E, G, H
	Oregon	4,697	4	117	21	5	29	176	3.6%	A, B, E
	Utah	840	1	4	40	4	1	50	5.6%	D, E
	Washington	6,364	12	225	79	12	57	385	5.7%	A, B, E
	Wyoming	51	-	-	-	-	-	-	0.0%	D, E, G
	Regional Total	54,296	200	4,136	2,441	193	424	7,394	12.0%	

Source: 2012 Census of Agriculture (USDA NASS, 2014a)

Low-Income Populations:

For the purposes of this EIS low-income persons include any persons whose median household income is at or below the HHS poverty guidelines. While the 2014 HHS poverty threshold data is available, the 2012 dataset is the appropriate data set for a comparison with the 2012 ERS measurement.

Published in the *Federal Register* on January 26, 2012, Table 3.7-17 identifies the 2012 HHS poverty guidelines for the 48 contiguous states and the District of Columbia (77 Fed. Reg. 4034, January 26, 2012):

Table 3.7-17. Poverty guidelines for the 48 Contiguous States and the District of Columbia

Number of Persons in Family/Household	Poverty Threshold[1]
1	$11,170
2	$15,130
3	$19,090
4	$23,050
5	$27,010
6	$30,970
7	$34,930
8	$38,890

Source: U.S. Department of Health and Human Services 2012 Poverty Guidelines (77 Fed. Reg. 4034)

An area is identified as containing a low-income population when the median household income for the area is below the HHS poverty threshold, which was $23,050 for a family of four in 2012 (77 Fed. Reg. 4034). The USDA ERS reports an income measure for farm operator households comparable to the Census Bureau's measure for all U.S. households. According to the ERS's data sheet, *Principal Farm Operator Household Finances by ERS Farm Typology*, in 2012, median farm operator household income, an average of the farm and off-farm household incomes of residence farms, intermediate farms, and commercial farms, was $68,298 (USDA ERS, 2012b). This exceeds both the median U.S. household income and all of the HHS poverty thresholds. Median farm operator household income was not available for the EIS geographic areas.

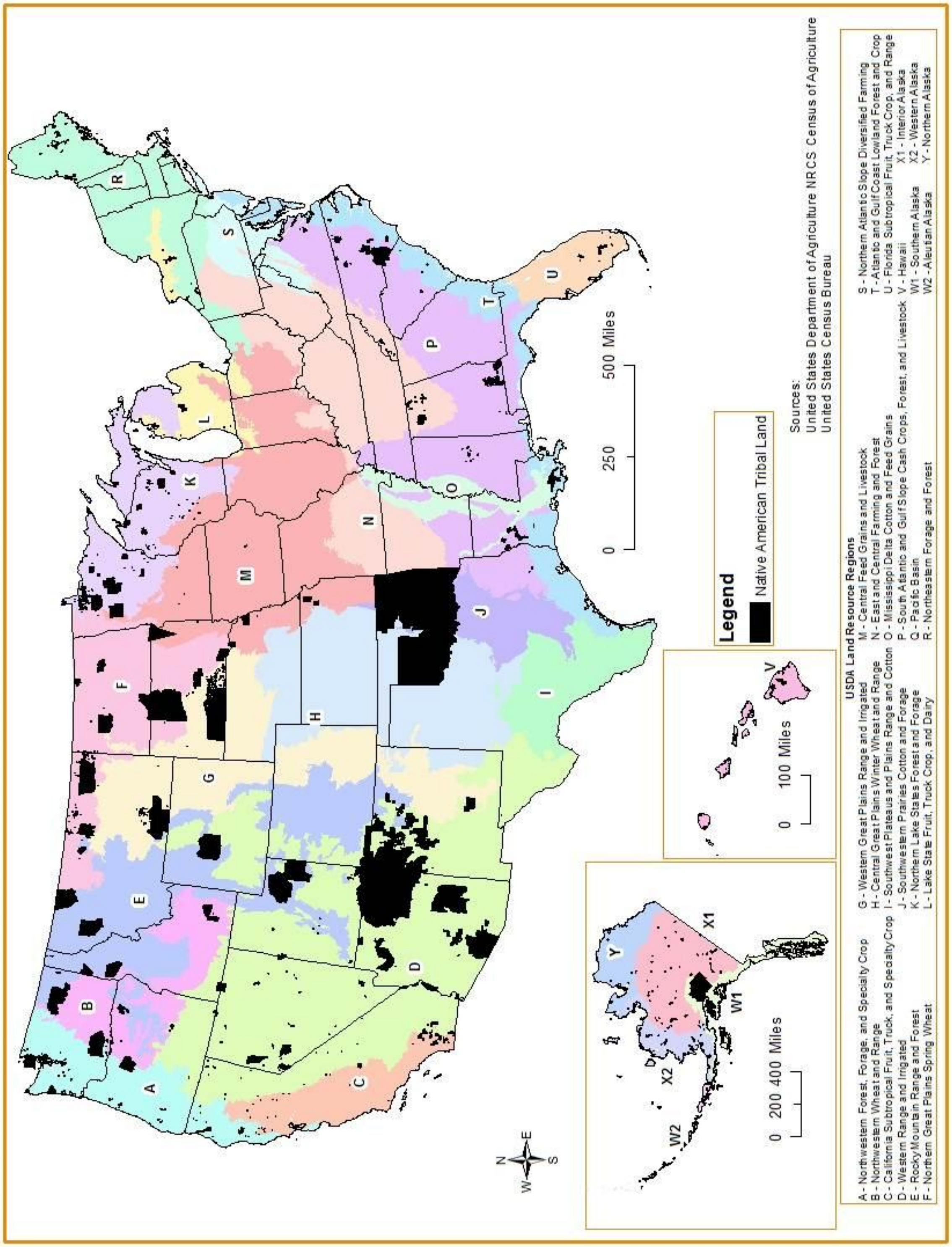
Tribal Resources:

According to the Bureau of Indian Affairs, a *federally recognized tribe* is "an American Indian or Alaska Native tribal entity that is recognized as having a government-to-government relationship with the United States, with the responsibilities, powers, limitations, and obligations attached to that designation, and is eligible for funding and services from the Bureau of Indian Affairs. Furthermore, federally recognized tribes are recognized as possessing certain inherent rights of self-government (i.e., tribal sovereignty) and are entitled to receive certain Federal benefits, services, and protections because of their special relationship with the United States." [13]

There are currently 566 federally recognized tribes located in the United States, with reservations and tribal lands throughout the United States (Figure 3.7-4) each with a wide array of interests and issues which may or may not be relevant or of concern to other tribes. For purposes of the Environmental Justice review, tribal populations are considered part of the total minority population.

[13] http://www.bia.gov/FAQs/index.htm

Figure 3.7-4. Tribal lands in the U.S.



The U.S. works with Indian tribes to address issues concerning Indian tribal self-government, tribal trust resources, and Indian tribal treaty and other rights. Executive Order 13175 requires U.S. Executive Departments and agencies to actively engage in meaningful collaboration and consultation with tribes' officials in the development of Federal policies that have tribal implications.

E.O. Order 13175 and Statutes relevant to tribal resources include:

- Executive Order 13175 and Memorandum (The White House, 2009): Requires executive departments and agencies to engage in regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications.
- The Indian Self-Determination and Education Assistance Act of 1975, as amended (25 U.S.C. § 450 et seq.): Authorized several government agencies (including the HHS) to enter into contracts with Indian tribes and transferred administration controls of the programs under the authorized government agencies to the Indian tribes.
- Tribal Self-Governance Act of 1994 (25 U.S.C. § 458a et seq.): Permits Indian tribes to contract Federal service programs and provides Indian tribes the authority to administer the programs in a manner that will meet the needs of the individual tribal communities.

Tribal Resources

- **Consultation:** The FDA has conducted a number of outreach meetings, webinars, and face-to-face consultations with tribal representatives. The timeline of consultation efforts included in Appendix D illustrate the coordination done to date with tribes regarding the PS PR. This will be updated throughout the EIS process as new meetings occur.

- **Current Baseline Data:** Through tribal coordination and outreach efforts (see Tribal Outreach section in Ch. 1.8 and Appendix D), the FDA has been able to distinguish concerns about the PS PR which are specific to potentially affected tribal organizations. Three key issues were initially identified through consultation with tribes: 1) tribal sovereignty rights; 2) tribal water rights; and 3) potential impacts to traditional farming methods.

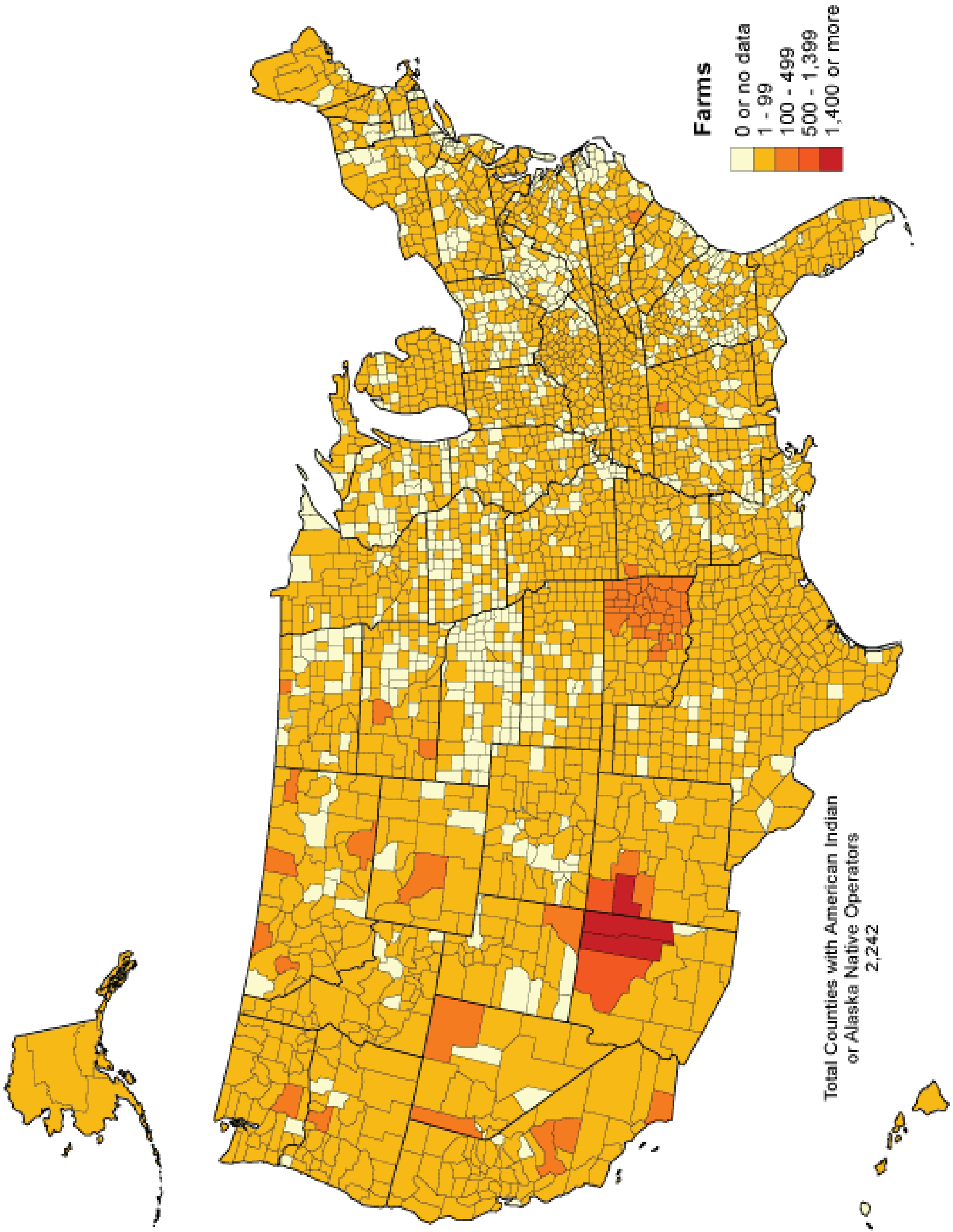
- **Census Data:** Consistent and thorough information on the agricultural operations on tribal lands is lacking. Prior to 1997, each tribal reservation was treated as a single farm, regardless of land ownership and tenancy practices of the individual tribes. Each reservation typically produced a single aggregate report that accounted for all activity on the reservation. In 1997, USDA NASS added a one-page report to the aggregate report, which included the total number of farm or ranch operators on the reservation, a list of counties where the reservation land was located, and the number of operators in each county. The data quality was inconsistent among the field offices—some successfully contacted individual farmers and rangers on reservations, while others gathered only the aggregate information.

In 2002, USDA NASS was encouraged to conduct a more thorough survey of reservation-level data. A pilot project to contact individual farm and ranch operators on tribal reservations was executed in Montana, North Dakota, and South Dakota.

Efforts in the 2007 Census of Agriculture were expanded to include all reservations in all states (USDA NASS, 2009a). The same method was instituted for the 2012 Census of Agriculture. In order to capture a more accurate portrayal of agricultural production on tribal lands, a concerted effort was made to reach every American Indian and Alaska Native farm or ranch operator in the country. However, only a selected number of tribes were identified in the American Indian Reservations reports published for both the 2007 and 2012 Censuses. They were chosen based on approval by tribal officials, the amount of agricultural activity, success of list building activities, and respondent confidentiality.

A general profile of Native American farming practices in the U.S. was published after the 2007 Census of Agriculture was released (an abbreviated demographic profile was published for the 2012 Census). This demographic information, however, profiled the Native American farm operator, rather than farms located on Native American-owned land. Figure 3.7-5 illustrates these findings in 2007.

Figure 3.7-5. Native American Farm owners/operators in the U.S.



While Native American farms are larger in acreage, overall they tend to be smaller in terms of sale of goods (USDA NASS, 2009a). According to information obtained from the 2012 census the following comparisons can be made between Native American farms and all farms (Table 3.7-18):

Table 3.7-18. Comparison of Native American farms with all U.S. farms

Farm Operations	All Farms	American Indian Operated Farms (Both on and off reservation lands)
Average Size of Farms	434 acres	1,021 acres
Average Value of Sales Per Farm	$187,097	$57,081

Source: USDA NASS, 2009a

It is important to note that this is reflective of all farms and all products sold, not just those farms growing covered produce.

According to information obtained from the 2012 Census of Agriculture "...seventy-seven percent of farms with an American Indian principal operator had fewer than 180 acres, and 78 percent had sales of less than $10,000 in 2012" (USDA NASS, 2014a). Table 3.7-19 illustrates the trends in size and sales of farms of those farm operators who are "American Indian Principal Operators" compared to "All Farm Operators":

Table 3.7-19. Farms with American Indian principal operator, by farm size and sales, 2012

Farm Operations		American Indian Operated Farms (percent)	All Farms (percent)
Farm Size	< 50 acres	57	39
	50 to 179 acres	20	30
	180 to 999 acres	15	23
	1,000 acres or more	8	8
	Total	100	100
Farm Sales	< $10,000	78	56
	$10,000 to $49,999	14	19
	$50,000 to $249,999	5	13
	$250,000 to $999,999	2	8
	$1,000,000 or more	1	4
	Total	100	100

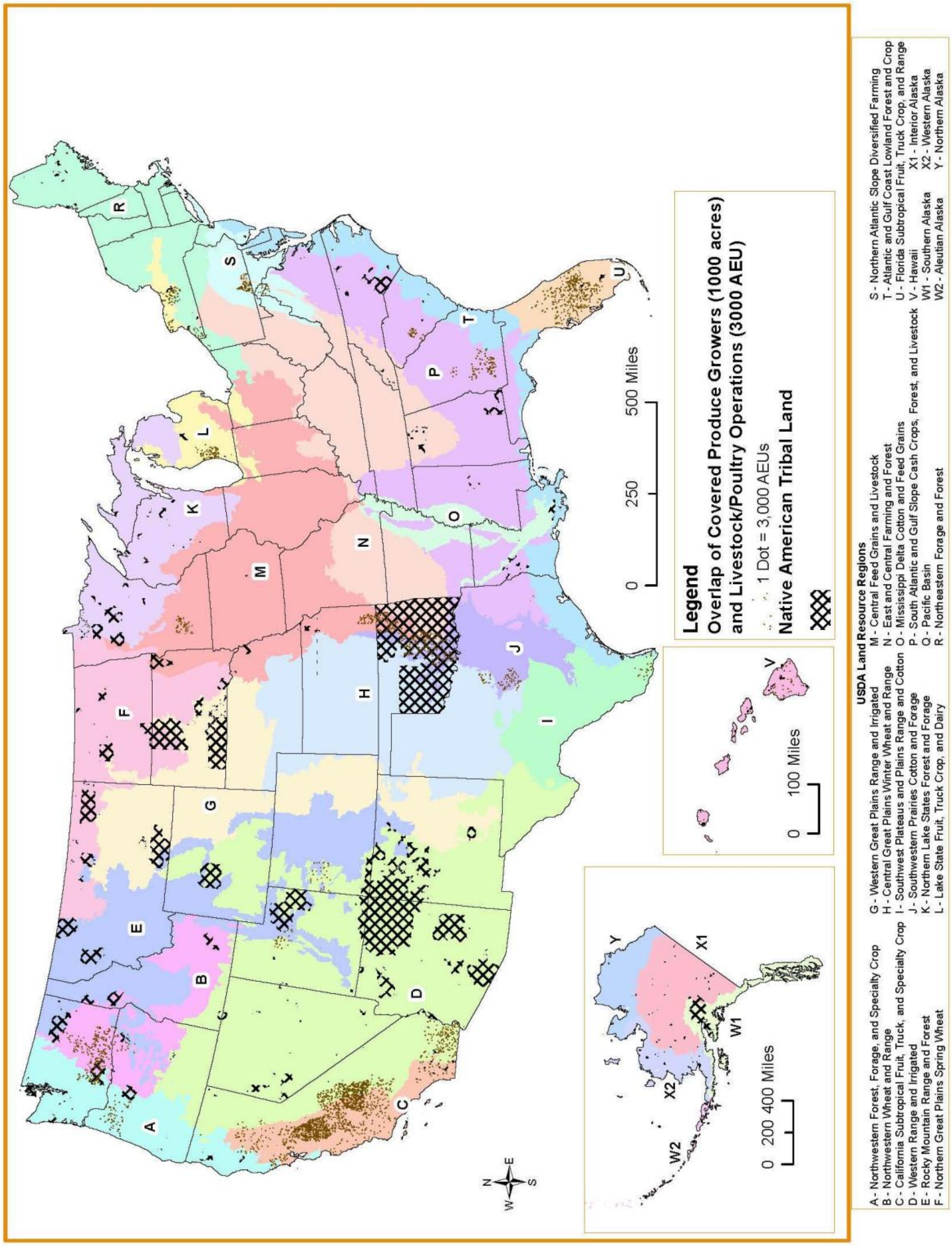
Source: USDA NASS, 2014a

The 2012 Census information also reveals that only 6% of Native American Operated farms grow produce as their principle commodity while another 15% grow some combination of crops as their principle commodity (USDA NASS, 2014a).

Beyond the inconsistencies in data collection from census to census, the breakdown of information provided in the census reports is not detailed enough to show which types of produce are grown by which tribes and thus whether those tribes would be affected by the PS PR. It is unclear whether the crops produced by tribes and tabulated in the census results are those covered by the PS PR. Although state-specific summaries tabulate “Farms with American Indian or Alaska Native Operators,” these summaries track the race/ethnicity of farm operators but do not distinguish whether farms are tribally owned or located on tribal lands. Furthermore, specific census information on individual tribes is not available due to confidentiality laws.

Figure 3.7-6 illustrates tribal lands located throughout the U.S. based on information obtained from the National Atlas of the United States (2014). This information is also useful for analysis although the breakdown of farms on each reservation are not available. To help narrow down regions where tribal lands could be impacted by the PS PR, the map of the tribal reservation lands was overlaid with a map that illustrates areas that have a substantial overlap of livestock and produce production. The resulting map illustrates those areas of the country where tribal lands may have farming operations that are covered by the PS PR. Figure 3.7-6 illustrates these overlaps.

Figure 3.7-6. Native American lands overlaid with areas of covered produce and livestock/poultry operations



Results of this overlay generally indicate three concentrated, though not exclusive, areas in the U.S. where farms on Tribal lands are likely co-located with produce and poultry/livestock operations, these are regions B and J (USDA NASS, 2009a).

To determine whether the PS PR would apply, attempts to identify the produce operations of Tribes in these regions were undertaken. The 2007 Census of Agriculture includes information on 73 Native American reservations; however, those tribes profiled in the census results were chosen based on Tribal approval, amount of agricultural activity, success of list building, and confidentiality. Limited information on livestock and produce production is included in the profiles, but only when providing such information would not inadvertently identify individual farmers in the tribe.

Influence of Agriculture that contributes to the background conditions

The following bullets discuss whether potentially significant provisions were raised as concern to Tribes through the scoping process and through ongoing Tribal consultations.

- **Agricultural Water:** During the EIS scoping period, one commenter raised concern that the rule may result in an increase in groundwater drawdown by agriculture that draws from the same aquifers as Tribes, and that rule potentially may affect Tribes' water sovereign rights. This issue of groundwater drawdown is addressed in Chapters 4.2 and 4.7 of this EIS.

- **Biological Soil Amendments:** There are no data available on the use of BSAs of animal origin by Native American Indian Tribes.

- **Domesticated and Wild Animals (i.e., grazing of domesticated animals and wildlife intrusion):** There are no identified influences from domesticated and wild animals on tribal resources.

- **Businesses Covered by the Rule:** Of all farms that are operated by Native American principal operators, whether located on or off reservations, 5.5 percent report growing vegetables, 2.4 percent report growing fruits and tree nuts, and 15 percent report growing combination crops. There may be farms that produce crops in multiple of these categories, and these categories include both covered and non-covered crops. Therefore, based on a very conservative estimate, no more than 22.9 percent of farms—the sum of these three categories—that are operated by Native American principal operators may be growing covered produce (USDA NASS, 2014a). Based on USDA NASS data (2014a), 78 percent of all Native American farms sell less than $10,000 in total sales, annually, meaning that, at most, 22 percent of farms with a Native American principal operator would be covered farms under the PS PR, if finalized. If it is assumed that these trends are consistent across all commodities, this means that, at most, 5 percent of farms with a Native American principal operator would be covered by the rule (22 percent of 22.9 percent is approximately 5 percent). Moreover, farms that sell less than $25,000 annually in produce—not $10,000—are not covered by the PS PR. An additional 14 percent of farms with a Native American principal operator sell less than $49,999, meaning there is a reasonable likelihood that additional farms with a Native American principal operator would not be covered by the PS PR, if finalized. It is not possible to estimate what percent of farms lie between $10,000 and $49,999 average annual sales. An additional 5 percent of Native American operated farms have less than $249,999 in total sales.

Summary/Conclusions

Based on comments received from Native American and Alaska Native tribes, tribal concerns are focused mainly on sovereignty issues, including tribal water rights, rather than the environmental impacts of the PS PR.

The majority of the environmental issues would affect a tribal entity the same as it would affect any minority property owner.

There is potential for significant environmental impacts to tribal lands based on the water resource impacts identified in Chapter 4 on a regional basis. Geographic regions with moderate to high impacts to water quality will be assessed to determine the presence of tribal agricultural lands and a correlation will be made between the water quality impacts, the presence of tribal agricultural lands and the potential water usage. The sovereignty concerns are outside the scope of this EIS.

3.8 Human Health and Safety

3.8.1 Definition of the Resource

Evaluating Human Health and Safety in an environmental impact assessment offers a unique opportunity to consider the protection and promotion of human health (WHO, 1987). Components of an environmental assessment for human health and safety concerns typically address three key elements including 1) the analysis of the baseline, 2) the prediction of impact, and 3) the assessment of impact (Fehr, 1999).

The driving force behind the focus on biological resources and alternatives is the direct impact on human health and safety (foodborne illness outbreaks). Part of this increased interest is attributed to more frequent reporting of foodborne illness, the acute symptoms associated with infection, and the ability of outbreaks to reach a large number of consumers (Nithya et al., 2014). The primary emphasis of the PS PR is to minimize the risk of serious adverse health consequences or death from consumption of contaminated produce. Food safety has become a major concern and warranted numerous research studies in the last several decades (Nithya et al., 2014). Part of this increased interest is attributed to more frequent reporting of foodborne illness, the acute symptoms associated with infection, and the ability of outbreaks to reach a large number of consumers (Nithya et al., 2014).

The FDA aims to minimize pathogen exposure, in part, through changes in the practices, processes, and procedures related to manure management, agricultural water use, domesticated animal management, and feral wildlife management, used in the growing, harvesting, packing, and holding of produce for human consumption. This section discusses the current risks to humans from pathogens associated with produce, aspects of overall population health that may be impacted by the PS PR, and current practices or methods available to mitigate any adverse human health and safety impacts.

3.8.2 Regulatory Oversight

Up until the passage of FSMA, food safety regulatory oversight was focused on areas shown to be of highest risk for foodborne pathogen contamination, such as processing, food handling, and manufacturing sectors. Currently, there is guidance available on good agricultural practices, generally such as manuals available through the USDA GAP&GHP program, and commodity-specific guidance, available through marketing agreements such as the California and Arizona Leafy Greens Marketing Agreements.

Relevant current regulations that have human health and safety implications include: FFDCA (first introduced in Chapter 1.1), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1996, CAA (Chapter 3.6), CWA and SDWA (Chapter 3.1), the Occupational Safety and Health Act (OSHA) of 1970, and the Agricultural Worker Protection Standard (WPS). Regulations that are not discussed above as a part of another resource area section are described below. This list is focused on Federal regulations and is not meant to be an exhaustive list of all regulations with human health and safety implications.

FFDCA

The FFDCA (21 U.S.C. §301 et seq.), first enacted in 1936, gives the authority to oversee the safety of food, drugs, and cosmetics to the FDA. Relevant to agriculture, the FFDCA provides the authority to set maximum pesticide residue levels on food and animal feed, mandates a primarily health-based standard for setting a maximum residue level, and gives authority to FDA and USDA to monitor and enforce pesticide residues in food (EPA, 2014l).

FIFRA

The FIFRA (7 U.S.C. §136 et seq.) mandates that EPA regulate the use and sale of pesticides to protect human health and preserve the environment. In order to be approved for use, the pesticide must not pose an "unreasonable adverse effect on the environment," which is defined as (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food (EPA, 2014m). Certain pesticides may be applied only by or under the direct supervision of certified pesticide applicators. Certification and training programs are conducted by States, Territories, and Tribes in accordance with national standards.

The Agricultural WPS (40 CFR Part 170) was established to reduce the risk of pesticide poisoning and injury among agricultural workers including those that handle pesticides. 40 CFR 170.1. As such, EPA establishes the Agricultural WPS under the authority of FIFRA (7 U.S.C. 136-136y). The WPS requires that agricultural establishments protect workers from pesticide exposure, train workers about pesticide safety, and provide mitigation measures if exposures were to occur. On February 20, 2014, the EPA proposed changes to WPS to increase protection from pesticide exposure. The proposed changes include: an increase in the frequency and an expansion of mandatory trainings, increased signage for no entry into fields treated with the most hazardous pesticides until residues decline to a safe level, minimum age requirement on pesticide handling, buffer areas surrounding pesticide-treated fields, measures to improve the states' ability to enforce compliance, and making information specific to the pesticide application available to farmworkers (EPA, 2014n).

OSHA

As a result of OSHA (29 U.S.C. §651 et seq.), Congress created the Occupational Safety and Health Administration (OSHA) to ensure safe and healthful working conditions. Farmworkers are exposed to many hazards on the job making agriculture among the most dangerous industries (DOL, 2013). Section 5(a)(1) of OSHA is often referred to as the General Duty Clause. The General Duty Clause (29 USC §654) states that employers should supply employees a workplace free of recognized hazards that are likely to cause death or serious harm and should comply with all OSHA standards, and that employees should also comply with all OSHA standards applicable to their own actions and conduct. Farms are subject to OSHA under 29 CFR Part 1910, Occupational Safety and Health Standards for Agriculture under 29 CFR Part 1928, and the General Duty Clause.[14]

3.8.3 Current Background Conditions

Data Sources

State and local public health authorities investigate foodborne illness outbreaks and report the information to the CDC, which becomes involved in multi-state outbreaks. The CDC provides summary reporting and data in the Foodborne Outbreak Online Database (FOOD) and FoodNet (as discussed in Chapter 1.4) that are available to the public. There is often uncertainty and complexity in the process to determine vehicles and route(s) of contamination of pathogens on contaminated produce.

Once cases of foodborne illness are reported and classified as an outbreak, the vehicle has to be first determined, then traced back through the supply chain in order to identify potential routes and sources of contamination. Contamination could have occurred at many different points in the supply chain from growing, packing, holding, transporting, as well as at retail or by the consumer. In addition, depending on the pathogen, the symptoms of foodborne illness can onset many hours or even up to a week after consuming the contaminated food, which adds to the difficulty of determining the vehicle in an outbreak.

Due to the fact that foodborne illness may not always be reported and that determining the route of contamination is difficult, there is high uncertainty in determining the number of cases (one person getting sick) or number of outbreaks (many people getting sick at the same time) and there is further uncertainty in determining the vehicle of the case or outbreak. Thus, information available on foodborne outbreaks has certain inherent limitations.

General Conditions

Risk from Pathogenic Microbes

Most microorganisms are made up of a single cell and cannot be seen with the naked eye. Small and inconspicuous, they can be found everywhere, and life on the planet could not exist without them. Bacteria play an important role in maintaining human life by decomposing organic matter, contributing to the carbon and nitrogen cycles, providing protection from diseases, and digesting food. Even though ten trillion cells make up the human body, more than ten times that amount of bacterial cells live on and inside the body (Maczulak, 2011). These mostly beneficial microbes, known as the normal body flora, maintain health and prevent colonization by harmful microbes.

Harmful, disease-causing microbes are called "*pathogens*". Four major microbial pathogens (STEC, *Listeria monocytogenes*, Norovirus, and *Salmonella*), account for the majority of the

[14] https://www.osha.gov/dsg/topics/agriculturaloperations/standards.html

foodborne illnesses (Newell et al., 2010) for which a precise route is often not determined. While each four major pathogens have been associated with contaminated food, ingestion of contaminated water, contact with infected animals, and contact with an infected person and unsanitary surfaces also serve as exposure pathways (see Chapter 1.7, Table 1.7-1 and Figure 1.7-1).

Listeria monocytogenes, *Salmonella*, STEC, and Norovirus outbreaks on produce have led to numerous deaths in the U.S. in the last several years (Table 3.8-1). All four pathogens have been responsible for foodborne illnesses and hospitalizations (Scallan et al., 2011).

It is estimated that recent outbreaks have been the cause of over 6.5 million cases resulting in foodborne illness and/or hospitalizations, and nearly 800 people have died (Table 3.8-1). Although the incidence of *Salmonella* infection (15.2 per 100,000 population) was lower in 2013 than in 2010–2012, it remains similar to 2006–2008, and well above the national Healthy People objective (11.4 cases per 100,000 population) (CDC, 2014d).

Table 3.8-1. Foodborne illness outbreaks by pathogen, 2000-2008

Pathogen	Mean Number of Annual Cases of Foodborne Illness[a]	Mean Number of Annual Hospitalizations[a]	Number of Deaths[a]
STEC	63,153	2,138	20
Listeria monocytogenes	1,591	1,455	255
Norovirus*	5,461,731	14,663	149
Salmonella	1,027,561	19,336	378

* = produce is a vehicle of transmission of Norovirus, which can be transmitted by farmworkers involved in harvesting, packing, and packaging fresh produce.
a= Numbers are estimations using data from the years 2000 through 2008, and based on the US population in 2006 (299 million persons). Estimates were derived from statistical models with many inputs, each with some measure of uncertainty (Scallan et al., 2011).

In terms of the number of outbreaks and cases associated with fruits and vegetables, 2009-2010 data show that *Salmonella* were responsible for the greatest number of outbreaks (25) and cases (1,183); followed by Norovirus with 24 outbreaks and 755 cases; and combined instances of *E. coli* O157:H7 and *E. coli* O145 (Sapers and Doyle, 2014). 2007-2008 data for *Listeria monocytogenes* indicate 2 outbreaks and 40 cases associated with fruits and vegetables (Sapers and Doyle, 2014). FDA outbreak surveillance data attributed to biological hazards from a longer period (1996-2010) also indicate that *Salmonella* was the number one ranked organism for outbreaks, hospitalizations, and deaths; followed by STEC as the number two ranked organism (FDA, 2013c). Altogether for the period, bacterial pathogens caused 9,106 illnesses (64 percent of cases linked to outbreaks linked to produce; 650 mean annual cases), 1,189 hospitalizations (87 percent of the hospitalizations linked to biological hazards associated with produce; 85 mean annual hospitalizations), and 24 deaths (89 percent of the deaths linked to biological hazards associated with produce; 1.7 mean annual deaths) (FDA, 2013c).

In FDA's Regulatory Impact Analysis (FDA, 2013b), commodities are split into six categories: herbs, leafy greens, melons, sprouts, tomatoes, and other produce (that includes but is not limited to: berries, peppers, peas, onions, and nuts). Approximately 2.7 million illnesses were attributable to covered produce between 2003 and 2008. As presented in the Draft QAR (FDA, 2013c), the USDA's Microbiological Data Program (MDP) is the largest database of microbiological contamination of produce and is statistically representative of commodities sampled. Table 3.8-2 provides results of over 75,000 samples analyzed for enterohemorrhagic *E. coli* (EHEC), STEC, and *Salmonella*. A positive test result indicates that any one of the three pathogens was detected (FDA, 2013c).

Table 3.8-2. Produce with pathogen contamination

PRIA Commodity Category	Commodity	Number of Samples	Number of Positive Samples	% Positive Samples
Herbs	Cilantro	2510	16	0.64%
	Parsley	1706	8	0.47%
Leafy Greens	Spinach	4433	33	0.74%
	Lettuce	13947	34	0.24%
Melons	Cantaloupe	13264	11	0.08%
Sprouts	Alfalfa Sprouts	7055	12	0.17%
Tomatoes	Tomatoes	19017	6	0.03%
Other Produce	Hot Peppers	1995	6	0.30%
	Green Onions	7342	7	0.10%
	Celery	5478	1	0.02%

Sampling data is from the MDP database for the years 2002 through 2009 and includes produce samples analyzed for EHEC, STEC, and Salmonella.

Overall Population Health

In addition to the reduction of pathogenic contamination of covered produce, the PS PR is expected to impact air quality, water quality and the availability and affordability of fresh produce. These indirect impacts will affect overall population health. See Section 3.5 for current state of air quality and Section 3.1 for the current state of water quality and availability.

Worker Health

Farmworker health is protected by several regulations as detailed in Section 3.8.2. In order for farms to comply with the PS PR, farms may increase use of chemical fertilizer and pesticides.

Due to regulations already in place that protect farmworkers, even if farms increase the use of chemical fertilizer and pesticides, risks to farmworkers are not expected to increase as long as farms stay in compliance with regulations established for the protection of worker health.

Human Health and Safety and the PS PR

Each of the provisions of the PS PR is intended to have a beneficial impact on human health and safety by reducing pathogenic contamination of covered produce. According to the PRIA (FDA, 2014b), the PS PR is expected to prevent an estimated 1.57 million illnesses. See Table 3.8-3 below for likelihood of contamination and expected reduction in illnesses by contamination pathway. As discussed above, the provisions may have unintended impacts to other aspects of overall population health. Potential impacts to overall population health are discussed by provision type below. Estimated illnesses prevented based on farm size (average annual sales), as presented in the 2013 PRIA, is provided in Table 3.8-4.

Table 3.8-3. Reduction in contamination and prevented illnesses by relevant contamination pathways

Contamination Pathway	Likelihood of Contamination*	Efficacy of Proposed Controls	Mean % Reduction in the Risk of Contamination*	Illnesses Attributed to Produce (millions)	Illnesses Prevented (millions)
Agricultural Water – growing and harvest	16%	54%	8.9%	2.7	0.24
Agricultural Water – post harvest	14%	73%	10%		0.28
Biological Soil Amendments	14%	66%	9.1%		0.24
Domesticated and Wild Animals	14%	58 %	8.2%		0.22

Data from the PRIA (FDA, 2013b)

*Worker health and hygiene and equipment, tools, building and sanitation contamination pathways were not considered here but with the consideration of growing and harvest and post-harvest activities, these pathways account for approximately 30% (worker health and hygiene) and 10% (equipment, tools, building, and sanitation) of contamination. With the consideration of proposed controls on all contamination pathways, illnesses attributable to produce are expected to decrease by approximately 65%.

Table 3.8-4. Results of different small size-based farm exclusions

Farm Income (Annual average food sales)	Prevented Illnesses (millions)	Illnesses Not Prevented	Covered Farms Covered Farms	Exempt Farms	Produce Acres not covered
<$25K	1.73	-	40,211	149,426	14%
<$50K	1.69	47,000	28,253	161,384	16%
<$100K	1.63	52,000	20,140	169,497	19%

Data is from the PRIA (FDA, 2013b). In the supplemental proposed rule (79 FR 58434), farm exclusions were modified to include exclusions based on produce sales instead of food sales. Recalculations of all the above scenarios have not been released but estimates, and especially differences between scenarios, are not expected should not change significantly. For example, the percent of produce acres not covered from a $25K value of produce rather than foods is 15 rather than 14 percent.

Recommended Practices Available

Pathogen Reduction Methods

The duration of a foodborne illness outbreak is partially dependent upon the effect of environmental factors on the source of contamination. While high temperatures, sunlight exposure, and unfavorable environmental parameters can be detrimental to foodborne pathogens, many can still persist under a wide range of conditions. For example, *Listeria monocytogenes* can grow and survive outside the host and tolerate a wide range of environmental conditions (higher and lower pH than typically found in the environment, zero to high salinity, and refrigeration temperatures), allowing the pathogen to survive in food processing facilities and a number of food products (Ferreira et al., 2014). Numerous food safety measures have been established to minimize contamination of produce (see next section), however outbreaks continue to occur.

While some of these risks can be minimized, for example through composting or drying manure (Pell, 1997), there has been an increased interest to characterize the mechanisms of microbiological hazards associated with produce outbreaks to help minimize occurrences of illness (Ferreira et al., 2014; Wijands et al., 2014). Research examining where pathogens are most likely to attach to produce have been variable (Kroupitski et al., 2011), although studies demonstrating pathogen survival on different age group of produce have shown persistence of pathogens throughout the growing season (Moyne et al., 2011).

With the pathogen's ability to persist under various conditions, researchers have been developing models to determine the impact of varying modes of handling, packing, and transporting fresh produce on pathogen levels (McKellar and Delaquis, 2011; Pérez Rodríguez et al., 2010; Posada-Izquuiredo et al., 2013; Zeng et al., 2014). Many of these models consider hazard controls (i.e., chlorine washing), retail storage and display, and die-off tied to temperature fluctuations.

Generally due to low cost, chlorine is the most widely used agent for post-harvest treatment of fresh produce (Sapers, 2014). However, chlorine is inactivated when in it comes into contact with organic material and can form unsafe compounds (Al-Nabulsi et al., 2014). Due to potential risk of mutagenicity and carcinogenicity of chlorine and maintenance costs due to corrosivity, additional washing agents and new ways to treat fresh produce have been developed (Sapers, 2014).

Chlorination, UV radiation, heat treatments, and hydrochloric acid (HCl) have long been recommended methods to reduce pathogen presence on seed (Lewis Ivey et al., 2014). However, research has continued to explore other means of controlling microbiological hazards at various stages of growing, harvesting, and post-harvest that can be effective without damaging the product. For example, see food-grade detergents (Keskinene and Annous, 2011), natural antimicrobials (Techathuvanan et al., 2014), rice vinegar (Chang and Fang, 2007), use of epiphytic bacteria (Lopez-Velasco et al., 2010), bacteriophages (Hagens and Loessner, 2010), irradiation (Niemira and Zhang, 2014), pulsed light (Niemira and Zhang, 2014), and sonication (Niemira and Zhang, 2014). New ways to treat irrigation water that are reported include: dielectrophoretic phenomena (Wu and Wu, 2008), mannosylated nanoparticles (Qu et al., 2005), and cold plasma (Critzer et al., 2007; Niemira and Zhang, 2014). Most produce is not expected to have pathogens transmitted by seed, but for sprouts and possibly tomatoes, it is reported that seed sanitizers (Lewis Ivey et al., 2014) may reduce pathogen contamination. The use of antimicrobial chemical substances or other methods used to reduce the presence of microbes in or on produce would likely be subject to both EPA and FDA regulation.

Farm Practices

As stated above, agricultural water, biological soil amendments, domesticated and wild animals, and seeds have the potential to introduce pathogenic microbes and contaminate produce. Currently, there is agency and industry guidance available (see Chapter 2.1) on best practices that help to reduce the risk of pathogen contamination. There are also several commodity-specific marketing agreements that farms in several states may choose to enter (or may be mandatory in some cases, such as for tomatoes grown in Florida). When the guidance is followed and farms opt into voluntary audit programs, the risk of pathogen contamination may be reduced.

Methods to Analyze Impacts

The purpose of the PS PR is to minimize the risk of serious or adverse health consequences and death from consumption of contaminated produce, thereby improving human health and safety. Direct impacts to human health and safety will be focused on reduction of pathogenic outbreaks determined by the amount of covered produce the PS PR may affect. Although reduction in produce-related outbreaks is a focus of the PS PR, overall population health is also important. The PS PR may have unintended, direct and indirect impacts to human health and safety that are unrelated to pathogen reduction, such as potential negative impacts on air or water quality. Thus, these indirect impacts will also be considered in Chapter 4.

4.0 Environmental Impacts

This chapter presents the potential environmental impacts, including human health impacts and related socioeconomic impacts, likely to result from the implementation of FDA's proposed action to establish standards for growing, harvesting, packing, and holding produce for human consumption. Specifically, this chapter analyzes certain FDA proposed requirements (as specified in the 2013 proposed rule and the supplemental proposed rule, taken together) for which FDA determined, if finalized, may significantly affect the quality of the human environment. In addition, this chapter analyzes a range of alternatives to these requirements (as presented in Chapter 2.1), as well as the combined environmental impacts of the proposed rule as a whole, if finalized. To help put potential environmental impacts into context, FDA, in coordination with USDA, identified potential management decisions or actions that businesses affected by any final rule might take in order to come into compliance with, or to potentially avoid being subject to, the requirements (e.g., by changing to non-covered produce commodities or other crops that are not produce and, therefore, would not be subject to the final rule). This chapter also evaluates the environmental impacts from FDA deciding to not implement the PS PR; this is the No Action Alternative.

Organization of Environmental Consequences

This chapter is divided by the potentially significant provisions (as first discussed in Chapter 1.2) that FDA identified that may significantly affect the quality of the human environment, if finalized; these include:

- (Subpart E) Standards Directed to Agricultural Water
- (Subpart F) Standards Directed to Biological Soil Amendments of Animal Origin
    - Subdivided by treated and untreated amendments
- (Subpart I) Standards Directed to Domesticated and Wild Animals
    - Subdivided by domesticated animal grazing and animal intrusion
- All Proposed Standards including (Subpart A) General Provisions (Cumulative Impacts)

Each Subpart in Table 4-1 further contains alternatives that FDA considered for each potentially significant provision; these include:

Table 4-1. Potentially significant provisions and alternatives analyzed for the PS PR

Potentially significant provisions and alternatives		
Subpart E Microbial Standard for Agricultural Water	**Alternative I. Preferred Alternative**	Generic *E.coli*: GM of 126 CFU/100 ml and STV of 410 CFU/100 ml, with additional flexibility for microbial die-off and/or removal (Proposed § 112.44(c))
	Alternative II.	Generic *E.coli*: 235 CFU/100 ml
	Alternative III.	As proposed (i.e., Alternative I), along with an additional criterion establishing a maximum generic *E. coli* threshold
	Alternative IV.	Above three alternatives, including or excluding drip-irrigated root crops

Potentially significant provisions and alternatives		
Subpart F Biological Soil Amendments of Animal Origin	**Untreated: Alt. I.**	9 month application interval of untreated BSAs of animal origin in a manner where there is a reasonable possibility that it will contact covered produce after the application (Originally proposed as § 112.56(a)(1)(i)-Decision Deferred)
	Untreated: Alt. II.	Zero days application interval
	Untreated: Alt. III.	90/120 days application interval
	Untreated: Alt. IV.	6 month application interval
	Untreated: Alt. V.	12 month application interval
	Treated: Alt. I. Preferred Alternative	Zero days application interval (Proposed § 112.56(a)(4)(i))
	Treated: Alt II.	45 days application interval
	Treated: Alt. III	90 days application interval
Subpart I Domesticated and Wild Animals	**Grazing: Alt. I. Preferred Alternative**	Adequate waiting period between grazing and harvest (Proposed §§ 112.82)
	Grazing: Alt. II.	Minimum waiting period of 9 months
	Grazing: Alt. III.	Minimum waiting period of 90/120 days
	Animal Intrusion: Alt I. Preferred Alternative	Monitoring for evidence of animal intrusion immediately prior to harvest and as needed during the growing season (Proposed, §§ 112.83 and supplemental proposed 112.84)
	Animal Intrusion: Alt II.	Measures to exclude wildlife
Subpart A General Provisions	**Alternative I. Preferred Alternative**	$25,000 threshold (all produce), (Proposed §112.4)
	Alternative II.	$50,000 threshold (all produce)
	Alternative III.	$100,000 threshold (all produce)
	Alternative IV.	$25,000 threshold (covered produce only)

The baseline conditions required to analyze the potential environmental impact, as well as many of the management decisions that could be chosen for each provision and its corresponding alternatives tend to overlap significantly. Therefore, relevant background information on baseline conditions is summarized at the start of the analysis for each of the provisions. These summaries are followed by discussions of the potential issues related to the management decisions identified by FDA for the alternatives and the range of potential environmental impacts that are likely. Resource components where no significant effects have been identified are noted and excluded from further analysis in this chapter. Finally, the environmental impacts for each alternative are evaluated with comparison to the baseline and/or other alternatives, as appropriate. In many instances the impact rating, defined below, is the same across several alternatives.

Impact Definitions and Thresholds

The impact ratings defined for this EIS are listed below. Due to the variety of potential impacts, we have established individual threshold levels for each resource component, identifying the threshold upon which an impact is considered to be significant, as presented in Table 4-2. There may be minimal to moderate impacts before reaching the threshold upon which an impact is considered to be significant; such minimal to moderate impacts are not generally considered significant, except with respect to impacts from actions that result in groundwater drawdown in regions where current conditions for groundwater depletion have significant environmental impacts. For purposes of this draft EIS, we consider any additional groundwater depletion in such regions to be a significant environmental impact. Generally, what constitutes such an impact will vary by resource component depending on the potential concern. An example of a change in resource component that would not be significant would be the increase in the chemical load in the environment of a specific chemical when it does not exceed established standards or toxicological thresholds. Whenever possible, we provide additional context regarding where the impacts are likely to be observed geographically (e.g., nationwide, regionally, in specific states). Impact ratings are as follows:

> No Significant Impact: There would be minimal, moderate or no measureable changes to the environment or resource component investigated.[1]
>
> Significant Impact: The impact is readily apparent; the overall impacts may be the result of a deliberate or essential shift in management practices, which may cause an overall substantial beneficial or adverse consequence.

Table 4-2. Impact threshold values by resource component

Resource Analyzed and Impact Threshold(s)		
Water Resources	Significant	• An impact will be considered significant if there would be shifts in sources of irrigation water from surface to groundwater at rates that are sufficient to: • Result in seasonal impacts, where water resources recover to ambient conditions on an annual cycle due to natural flushing of the groundwater and increased stream flows during periods of higher precipitation and snow melt; • Initiate or add to the long-term depletion of the aquifer; • Reduce streamflow of groundwater recharged streams to levels endangering ecological resources; • Cause land subsidence enough to damage infrastructure; and/or,
	Not Significant	• An impact will be considered not significant if enacting the provisions of the proposed rule would not have an adverse or beneficial impact on water resources, or if any adverse impacts associated with the proposed rule, if finalized, could be mitigated to avoid permanent impacts to the resource.

[1] Definition of minimal and moderate are provided in Chapter 11.

Resource Analyzed and Impact Threshold(s)		
Biological and Ecological Resources	Significant	• Impacts to wetlands and other waters of the U.S. would be considered to reach a significant level if impacts could not be mitigated to have minimal or no permanent impacts to the resource.
	Not Significant	• An impact will be considered not significant if enacting the provisions of the proposed rule would not have an adverse or beneficial impact on biological and ecological resources, or any such negative impacts associated with the proposed rule could be mitigated to avoid permanent impacts to the resource.
Soils	Significant	• An impact will be considered significant if the effect on soil resources would change the natural processing of soil functions, and the change would be irreversible.
	Not Significant	• An impact will be considered not significant if the effect on soil resources would have no irreversible change in the processing of soil functions.
Waste Generation, Disposal, and Resource Use	Significant	• An impact will be considered significant if produce growers encounter substantial difficulties in order to adopt practices to comply with the rule (including crop rotation with decreased harvest yields or if the operators would find difficulty in administering available measures to maintain similar yields for a number of years). Likewise, if there are conditions presented that would affect numbers of consumers requiring numbers of operators to adopt needed infrastructure to promote composting and other treatment methods for BSAs of animal origin and if that number of those affected is deemed substantial by FDA, the impacts would be considered significant. • An impact will be considered significant if abandonment of manure or composted manure as a soil amendment would cause widespread problems to the animal raising industry, such as livestock and poultry farmers being forced to pay excessive fees to dispose of excess manure by sending it to a landfill or over-application to their own land (non-covered produce crops and pasture) to the degree it would cause nutrient laden runoff or leachate.
	Not Significant	• An impact will be considered not significant if produce growers encounter minimal or no difficulties in storing, using, or disposing of excess animal waste, or if produce growers encounter minimal or no difficulties in order to adopt practices to comply with the rule (including crop rotation or other measures) while maintaining similar yields.
Air Quality and Greenhouse Gases	Significant	• An impact will be considered significant if particulate matter (PM), carbon monoxide (CO), sulfur dioxide (SO2), ozone (O3), lead (Pb) or nitrogen dioxide (NO2) emissions would contribute to violations of the NAAQS standards and/or increases in GHG emissions that cannot be adequately mitigated for using existing practices.
	Not Significant	• An impact will be considered not significant if it enacting the provisions of the proposed rule would not contribute to violations of the NAAQS standards and that only minimal changes in GHG emissions would occur, and that these changes could be adequately mitigated using existing practices.

Resource Analyzed and Impact Threshold(s)		
Socioeconomics and Environmental Justice,	Significant	• An impact would be considered significant if management decisions result in an increase in costs to principal farm operators that could cause a farm operation to make changes to its farming practices, such as leaving the farm industry entirely. **Tribal Resources** • An impact would be considered significant if it is reasonably foreseeable that changes to the water application methods would reduce a Tribe's access to water.
	Not Significant	• An impact is not considered to be significant impact if it results in minimal or no changes in land use or land management practices.
Human Health and Safety	Significant Adverse	• Adverse impacts will be considered to be significantly adverse when human exposure to chemicals through secondary routes of exposure, e.g. contaminated surface waters, occurs at levels sufficient to result in adverse health effects. • Impacts will also be considered to be significantly adverse when there are readily identifiable increases in worker exposure to pesticides applied to covered farms. • Impacts will also be considered to be significantly adverse if they increase the risk of serious adverse health consequences or death from foodborne illness outbreaks resulting from pathogens
	Significant Beneficial	• Provisions that are likely to minimize the risk of serious adverse health consequences or death from covered produce will have a significantly beneficial impact on human health and safety.
	Not Significant	• An impact will not be significant if it results in minimal or no increases in chemical exposures to workers or the general public.

Each impact threshold will be applied to the analysis provided in this chapter. As previously stated, resource components where no significant effects have been identified are noted and excluded from further analysis.

Resource components not included for review in the EIS

FDA is considering what environmental impacts, by resource component, could be excluded from analysis in this EIS. FDA does not need to consider environmental impacts in this EIS under the following circumstances: 1) where the environmental impact would not be an "effect," within the meaning of 40 CFR 1508.8, of the proposed produce safety rule, if finalized, and therefore not subject to NEPA; or 2) where FDA determines the environmental impact is an "effect" otherwise subject to further review under NEPA, but the impact is not significant. In Chapter 2.2, FDA discussed the provisions that were dismissed from detailed analysis due to the fact that no significant impacts are expected. For each of the following resource components, FDA determined one of these circumstances was met. Therefore, FDA is removing the following from review in this draft EIS:

Cultural Resources: The affected environment and baseline information for Cultural Resources is reported in Chapter 3.6 of this EIS. In regard to the cultural value of farms, the cultural value lies in the historic value of the land and any structures thereon and the lifestyle of the farm. The association of the land with a farm will not change *per se* if the PS PR were finalized, even if management decisions at the individual farm or business level may result in different applications of, for example, agricultural water or soil amendments. Farming as an industry is inherently a progressive endeavor requiring that operators be willing to embrace change (i.e., new technology) in order to remain competitive in a globally changing market. These farms have already been altered in terms of managing agricultural commodities, buildings and machinery; therefore, the additional requirements to changing practices that may necessarily result from any produce safety final rule are in keeping with other changes and modernizations that farms have made over time. Subsistence farmers, and those using more traditional farming methods, are operations that are small in nature and only grow enough food to feed themselves. To the extent such farms have produce sales below $25,000, these types of farms would not be subject to the requirements of the PS PR, if finalized. Overall, the lifestyle of the farm will not change as a result of finalizing the provisions of the PS PR because the changes that may occur will center on modifications due to safety, not in modifications to farming as a way of life.

Land Use: For purposes of the EIS, we use the term "Land Use" to refer to real property classifications that indicate either natural conditions or the types of human activity that occur, or are permitted to occur, on a land parcel. There is no nationally recognized convention or uniform terminology for describing land use categories. Land use is a planning terminology that is used on the local government level, generally in the form of planning or zoning ordinances. As a result, the meanings of land use descriptions and definitions vary among local jurisdictions. Agriculture is often coded or zoned differently from jurisdiction to jurisdiction; therefore, it cannot be examined on a nationwide, regional, or even state-level basis within the scope of this EIS. Furthermore, there are no government plans associated with the proposed action to re-zone or re-classify agricultural lands; it would be highly speculative to assume that if any farm or business loses its ability to operate due to implementation of the proposed action, it would be re-zoned as another land use. It would also be highly speculative to assume how many such businesses may lose their ability to operate, and where. The proposed rule, if finalized, would establish a series of exemptions or modified requirements where certain small entities would be either excluded from coverage based on average monetary value of produce sold (proposed § 112.4), or would be eligible for a qualified exemption based on average monetary value of food sold and direct sales to qualified end users (proposed § 112.5). These exemptions, as well as other management decisions available to the farmer, e.g. switching to a non-covered crop or changing irrigation methods, provide farmers that are most likely to be economically impacted by the rule significant flexibility to avoid the loss of their land which would precede a land use change. For these reasons FDA does not anticipate any land use impacts.

Threatened and Endangered Species: The proposed rule would require a grower of produce to monitor those areas that are used for a covered activity for evidence of animal intrusion and if animal intrusion is evident, to evaluate whether covered produce can be harvested (proposed § 112.83). The proposed requirements do not propose any activity that may result in impacts to threatened or endangered species. In fact, the propose requirements make clear that activity that may impact threatened or endangered species is not authorized by the proposed requirements. Any such activity would be subject to the independent authority and oversight of the USFWS.

NEPA mandates that federal agencies, "to the fullest extent possible," prepare an EIS for "major Federal actions significantly affecting the quality of the human environment." 42 U.S.C. § 4332.

A "Major Federal action" includes "actions with effects that may be major and which are potentially subject to the Federal control and responsibility." 40 CFR 1508.18. The term "Effects" is defined and includes direct and indirect effects "which are caused by the action." 40 CFR 1508.8. However, when the agency is not the legally relevant cause of an effect, the effect is not one the agency is obligated to consider under NEPA (see *Department of Transportation v. Public Citizen*, 541 U.S. 752, 770 (2004) (**"**We hold that where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant 'cause' of the effect.").

In the 2013 proposed rule, FDA proposed, under certain circumstances, to require monitoring of those areas that are used for a covered activity for evidence of animal intrusion, as needed during the growing the season and immediately prior to harvest (proposed § 112.83). If animal intrusion was evident from observation of significant quantities of animals, animal excreta, or crop destruction via grazing, proposed § 112.83 would require one to evaluate whether the covered produce could be harvested in accordance with the requirements of § 112.112 (78 Fed. Reg. 3504 at 3587).

In the supplemental proposed rule, FDA stated that proposed § 112.83 "should not be construed to require the 'taking' of an endangered species, as the term is defined in the Endangered Species Act (ESA) (16 U.S.C. 1532(19)) (i.e., to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct) . . .." (79 Fed. Reg. 58434 at 58463). To address concerns that the Produce Safety regulation may inadvertently promote practices that may adversely affect wildlife and animal habitat, including impacts on threatened or endangered species, we clarified, in proposed § 112.84, that:

> 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.

FDA specifically referred growers of produce to the FWS's Endangered Species Web site and the Information, Planning, and Conservation System Web site (79 Fed. Reg. 58434 at 58464). FDA further recommended that a grower coordinate with its office on any activity that could potentially affect listed species or critical habitat (id.). FDA consulted with USDA's NRCS and the FWS to inform its thinking on this issue (79 Fed. Reg. 58434 at 58463).

To the extent a grower of produce takes an action that may impact a threatened or endangered species, such action would be subject to the independent oversight and authority of the USFWS and not an activity caused by the proposed requirements related to animal intrusion in proposed § 111.83. Consequently, the proposed requirements in § 111.83 would not be the legally relevant "cause" of the effect under NEPA should a grower undertake an action that may impact a threatened or endangered species. Therefore, the impacts would not be an "effect" within the meaning of 40 CFR 1508.8 that FDA would need to analyze in this EIS related to a final produce safety rule. Even if one considered such activity taken by a grower to be an "effect" of FDA's final produce safety rule under NEPA, we would consider the regulatory oversight of the USFWS for such an action to sufficiently mitigate the potential for any significant environmental impact under NEPA. Accordingly, FDA is not considering impacts to threatened or endangered species based on the proposed requirements for produce safety in the context of this EIS.

Distinct from the threatened and endangered species, there may be activities a grower of produce undertakes concerning wildlife generally that may be reasonably foreseeable and for which there may be no local, state, or federal regulatory oversight. Thus, FDA is considering in this draft EIS whether there are any potentially significant environmental impacts to wildlife, generally, as a biological and ecological resource, to the extent the impacts are not mitigated by local, state, and federal oversight.

4.1 No Action: Do Not Implement a Final Rule

The No Action Alternative is assessed as a means for comparison of environmental impacts to the FDA's proposed action and corresponding alternatives. The No Action Alternative is presented in Chapter 2.1. Baseline conditions that are used to assess the No Action Alternative are discussed in Chapter 2.1, throughout Chapter 3, and as part of potential management decisions that are discussed throughout Chapter 4. Important aspects of existing, ongoing, environmental conditions discussed in the No Action Alternative are further assessed as part of the cumulative impacts analysis in Chapter 5. The ongoing conditions, for example, land subsidence and groundwater drawdown, are not the effect of agriculture alone; rather, these effects result from many influences including agricultural production, residential and commercial development, and oil and gas exploration.

FDA does not consider a no action alternative to be a viable alternative. Under the No Action Alternative, FDA would rely on our understanding of current agricultural practices, including agricultural processes implemented based on existing FDA guidance such as FDA's *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* (FDA's GAPs Guide) (FDA, 1998) and draft commodity-specific guidances; voluntary adoption by producers of some or all provisions of the proposed requirements; current or enhanced state and local enforcement activity to bring about a reduction of potential harm from contaminated produce; and risks of financial liability based on the tort system, with litigation or the threat of litigation serving to bring about the goals of the PS PR voluntarily. However, section 105(a) of FSMA (21 U.S.C. 350h(a)) requires FDA to conduct rulemaking establishing minimum science-based produce safety standards.

An estimated 2.7 million cases of domestic foodborne illnesses occur annually that are attributable to produce that would be covered by the PS PR; FDA estimates that approximately $1.88 billion annually is spent on preventing illnesses associated with microbial contamination of covered produce (FDA, 2013b). If the present conditions are to continue, the total annual foodborne illnesses and associated costs are not expected to substantially decrease. Data reported to the U.S. CDC indicate that, between 1973 and 1997, outbreaks of foodborne illness in the United States associated with produce increased both in absolute numbers and in proportion to all reported foodborne outbreaks (Sivapalasingam et al., 2004). Market agreement programs with food safety provisions, and the USDA's GAP program, which verifies conformance with FDA's GAPs Guide have established voluntary measures to help prevent foodborne illness.[2] However, each year, about 48 million Americans (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases, according to estimates from the Centers for Disease Control and Prevention (78 Fed. Reg. 3504). Produce farm participation in marketing agreements and the USDA GAP&GHP program would continue to provide some measure of increased food safety procedures but it would be highly speculative to try to quantify if (or how many) farms may enroll in such programs and the extent to which such participation might change the incidence of foodborne illness.

Under the No Action Alternative, no changes are anticipated with respect to the current practices of how farms/businesses are managed. Restrictions, regulations, or guidelines (e.g., state regulations, state nutrient management plans, or private marketing and cooperative agreements) that are in place now and govern how farms apply certain food safety measures would continue to be implemented as they are today. Examples of such safety measures include controls of irrigation water quality, how and when soil amendments are applied and in what particular quantities, and certain food-safety-related management decisions about how crop harvests are managed and timed.

The current conditions would prevail, with respect to produce production, and are expected to continue into the future. In addition to the continued persistence of human health risks associated with taking no action, farming practices have an impact on other aspects of the environment.

Based on FDA 2014 estimates in the supplemental Preliminary Regulatory Impact Analysis of economic impacts (also known as the supplemental PRIA), 35,503 farms, or 1.70 percent of total U.S. farms, would be covered by the PS PR, which represents an estimated 18.7 percent of all produce-growing farms (FDA, 2014b).

Water Resources- Based upon currently available information, water quality and availability are already experiencing significant adverse effects from agriculture. These issues are addressed in Chapters 1.9 and 3.1.2, and are summarized below. Under current conditions, states that experience the highest total irrigation water supply withdrawals (Figures 3.1-12 and 3.1-13) and that grow the highest concentrations of covered produce are California, Idaho, Texas, Oregon, Arizona, Florida, Washington, and New Mexico; corresponding to regions A, B, C, D, I, J, and U (compare Figure 1.7-4 with Figures 3.1-12 and 3.1-13). These regions account for more than 80 percent of covered produce grown in the U.S. The highest groundwater withdrawals that are currently occurring in States where covered produce is grown are in California, Idaho, Texas, Oregon, Arizona, and Florida (regions A, B, C, D, I, J, and U) (compare Figure 1.7-4 with Figures 3.1-12, 3.1-23 and 3.1-24). In particular, California, Idaho, Texas, and Arizona (regions B, C, D, I and J) are located in areas where average annual precipitation typically is 20 to 30 inches, which rainfall is insufficient to support crops without supplemental water (see Chapter 3.1.3.8). And region U is presently experiencing significant drawdown effects despite a much higher precipitation and aquifer recharge rate as compared to regions B, C, D, I, and J (see

[2] Such programs do not contain enforceable requirements or requirements at the same level of public health protection as would the PS PR, if finalized.

Chapter 3.1.3.11). Therefore, regions important for groundwater drawdown in this EIS are considered to be regions B, C, D, I, J, and U.

Under the No Action Alternative, the risk to water resources would continue as it is today or could potentially get worse during drought conditions when there is less surface water flow to dilute bacterial concentrations. In addition to problems such as desertification, salinization, and erosion that affect irrigated areas, the problem of downstream degradation of water quality by salts, agrochemicals, and toxic leachates is a serious environmental problem. In particular, regions that grow covered produce and that are already experiencing high exceedances in state surface water quality levels based on CWA Section 303(d) requirements (33 U.S.C § 1313(d)) (compare Figure 3.1-15 in Chapter 3.1.3.9 to Figure 1.7-4 in Chapter 1.7), and groundwater quality impairments (primarily from coliform bacteria) include regions A, B, C, L, R, T, and U (compare Figures 3.1-16 and 3.1-17 in Chapter 3.1.3.9 to Figure 1.7-4).[3] Significant current and ongoing adverse impacts such as reduced water availability, water-table declines, soil subsidence and increased costs for finding and maintaining access to water, resulting from groundwater withdrawals are presently experienced in the west and southwest in regions B, C, D, I, J, and in region U (see Chapter 3.1.3.8).

The major impacts on surface and ground waters to which current agricultural practices contribute are described in Table 4-3. Chapter 3.1 provides information showing the location of detection of nutrients, pathogen indicator organisms and pesticide or pesticide breakdown products. While it is known that agriculture in general contributes to these issues, nationwide water quality data presented throughout Chapter 3.1 are not robust enough to provide sufficient information to identify the specific regions within the country where specific environmental impacts are attributable to produce farming. Under the No Action alternative, produce growing practices are expected to continue under the current paradigms.

Table 4-3. General water-related environmental impacts associated with agricultural practices

Agricultural activity	Surface water	Groundwater
Tillage/ ploughing	Sediments carry phosphorus and pesticides adsorbed to sediment particles; reduction of light penetration into the water column; siltation of river beds and loss of habitat, spawning ground, etc.	None
Fertilizing	Runoff of nutrients, especially phosphorus, leading to eutrophication causing taste and odor in public water supply, excess algal growth leading to deoxygenation of water and fish kills.	Leaching of nitrate to groundwater; excessive levels are a threat to public health.
Manure spreading	Carried out as a fertilizer activity; spreading on frozen ground results in high levels of contamination of receiving waters by pathogens, metals, phosphorus and nitrogen leading to eutrophication and potential contamination.	Contamination of groundwater, especially by nitrogen

[3] Regions A, B, C, L, R, T, and U represent the majority of the east and west coast states.

Agricultural activity	Surface water	Groundwater
Pesticides	Runoff of pesticides leads to contamination of surface water and biota; dysfunction of ecological system in surface waters by loss of top predators due to growth inhibition and reproductive failure; public health impacts from eating contaminated fish. Pesticides are carried as dust by wind over very long distances and contaminate aquatic systems thousands of miles away (e.g. tropical/subtropical pesticides found in Arctic mammals).	Some pesticides may leach into groundwater causing human health problems from contaminated wells
Irrigation	Runoff of salts leading to salinization of surface waters; runoff of fertilizers and pesticides to surface waters with ecological damage, bioaccumulation in edible fish species, etc. High levels of trace elements such as selenium can occur with serious ecological damage and potential human health impacts.	Enrichment of groundwater with salts, nutrients (especially nitrate).
Feedlots/ animal corrals	Contamination of surface water with many pathogens (bacteria, viruses, etc.) leading to chronic public health problems. Also contamination by metals contained in urine and feces.	Potential leaching of nitrogen, metals, etc. to groundwater.

Biological and Ecological Resources- The clear cutting of land for agricultural purposes historically has impacted local wildlife and vegetation by appropriating habitat for agricultural purposes. Vegetation types vary by region. Nationally, there are thousands of species of native, non-native, and invasive plants that play important roles in providing habitat and fulfilling life requisites for wildlife species. On a national level, this vegetation is varied and includes hedgerows, large forest corridors, wet meadows not suitable for agriculture, and buffers adjacent to stream channels and lakes. Wildlife species (mammals, birds, fish and other aquatic organisms, amphibians, reptiles, and invertebrates) are important participants in the web of life, fulfilling roles necessary for healthy and successful ecosystems. Many of these species are protected by a patchwork of Federal, State, and local laws designed to manage the overall environmental health and economic sustainability of wildlife resources. Because most wildlife species are mutually reliant and interdependent on other species within the ecosystem, the health of the entire system is important. Crop production not only removes habitat but also has the potential to expose wildlife to diseases present in domesticated animals as well as to animal waste and chemicals that enter the environment as a result of farming practices. Historically, agriculture, through the prior practice of converting wetland to farmland, has also resulted in a net loss of wetlands nationwide due to filling and draining of wetlands. Current laws and the requirement for permits have slowed the conversion of wetlands for other uses such as agriculture and industrial, institutional, or residential development. Wetland permits often include conditions such as mitigation for wetland loss. Mitigations may include replacement or enhancement.

Over the years, conservation measures have been established to help mitigate habitat impacts. The omnibus bills which collectively are generally referred to as Farm Bills, first passed in the 1930s, have helped to mitigate these and other environmental impacts through the establishment of voluntary conservation programs that help to protect wildlife habitat, control soil erosion, and reduce run-off. The Agricultural Act of 2014 (or the 2014 Farm Bill) (Pub.L.No. 113-79, 128 Stat. 649) takes several existing conservation programs, including the wetlands reserve program, which allows the restoration, maintenance and protection of wetlands on private property, and the grasslands reserve program, which enables the restoration of native grasslands, and consolidates them into the Agricultural Conservation Easement Program. Activities covered under the Farm Bill that are aimed at conservation include the Conservation Reserve Program, which pays farmers to set aside marginal land and helps fund activities on these land such as planting of native grasses or establishing erosion control measures; the Conservation Stewardship Program, which rewards the use of environmentally friendly agricultural practices; and the Environmental Quality Incentives Program, which provides technical and financial assistance for the implementing of conservation practices on farms and ranches. Participation in these programs is voluntary.

Soils- Soil provides essential ecosystem services that are critical for life and is the basis of our nation's agroecoystems, which provide us with livestock feed, fiber, food and fuel (SSSA, 2010). However, maintaining healthy soils demands care and effort because farming disrupts the natural soil function. Farming disturbs the natural processes of soil, including that of nutrient cycling (i.e., the release and uptake of nutrients) (FAO, 2005). A major impact of agriculture on soil has been the quality and quantity of soil organic matter (SOM) (see Chapter 3.3.3.6). Specifically, the loss of soil organic carbon (SOC) has been attributed to cultivation with losses of 50 percent being common (see Chapter 3.3.3.4) (University of Minnesota Extension, 2009).

Agricultural practices contribute to the depletion of SOC through deforestation and biomass burning, drainage of wetlands, tillage, crop residue removal, summer fallow, cultivation, and overuse of pesticides and other chemicals. Cropland soils generally store less SOC than grazing land because cropland has greater disturbance from cultivation, a lack of manure being returned to the system, less root biomass, and less biomass returned to the soil surface. This loss of SOC from agricultural soils has resulted from many factors such as climate and soil type, tillage intensity and depth, crop rotation decisions, organic matter inputs, amount of plant residue on surface, soil biological activity, length and time of fallow, and erosion (University of Minnesota Extension, 2009).

Given the declining trend in total agricultural acres, environmental impacts are not projected to exceed those described in Chapter 3.3.

Waste Generation, Disposal, and Resource Use- USDA NASS data (2001, 2002, 2007, and 2012) show a declining trend in the use of untreated BSAs of animal origin and chemical fertilizers (Chapter 3.1.3.1, Table 3.4-1).

This downward trend in the use of chemical fertilizers suggests there is an increasing trend in the use of other, more environmentally beneficial practices, such as the use of green manure or cover crops. This trend could also be the result of more growers complying with State Nutrient Management Plans (see Chapter 3.4.2), which enable growers to use these resources more efficiently.

Although BSAs of animal origin are not the primary source of nutrients applied to covered produce crops, they are an important nutrient source, and there are often close local relationships between manure generating farms (e.g., AFOs and CAFOs), commercial manure brokers/suppliers, and covered produce growers (see Chapter 3.4.3.1).

Farms using the resource

Of the estimated 35,503 farms that would be covered farms as defined in the PS PR, an estimated 4,438 farms (12.5 percent) used BSAs. Of the 4,438 covered farms using BSAs, an estimated 820 farms (18.5 percent (or 2.3 percent of covered farms)) used untreated BSAs (raw manure), while an estimated 3,618 farms (81.5 percent (or 10.2 percent of covered farms)) use treated BSAs (composted manure). The remainder of covered farms (approximately 87.5 percent) may use chemical fertilizers, green manure or cover crops or BSAs of other origin, such as plant or mushroom (see Chapter 2.1, subpart F and Tables 2.1-3 and 2.1-4).

There are eleven regions where BSAs of animal origin are likely to be used the most. These regions represent the largest potential for changes in handling requirements for BSAs of animal origin: A, B, C, D, J, M, L, P, S, U and V (See Figure 3.4-1). The percentage of usage varies by region and locale, and there is no available data regarding where and how BSAs of animal origin are applied within these regions or locales within these regions.

Related infrastructure

Facilities that may store raw manure and that may perform composting operations (e.g., CAFOs) are often required to apply for a NPDES permit (Chapter 3.4.2). Therefore, if the facilities are operated and maintained in accordance with their permits, under normal circumstances there are processes in place to protect against adverse harm to the environment (i.e., effects from run-off). It may be noted that significant rain events, for example, may contribute to unintentional discharges to receiving waters.

Air Quality and Greenhouse Gases- Agriculture is an important source of emissions of air pollutants and greenhouse gases (also written as GHGs). These emissions can affect local and regional air quality (e.g., PM, pathogens) and also contribute to problems caused by GHG emissions on a national or global scale. The most important agricultural emissions in the U.S. include $PM_{2.5}$, PM_{10}, methane, nitrous oxide, and ozone precursor gases. Additionally, agriculture also consumes fossil fuels for farm operations, thus emitting carbon dioxide (CO_2), nitrogen oxides (NO_x), volatile organic carbons (VOCs), and particulates (Aneja et al., 2009).

Of the six criteria air pollutants for which EPA has developed NAAQS, PM emissions are most directly associated with agricultural practices. According to data from the EPA, 896,727 tons of $PM_{2.5}$ and 4,502,018 tons of PM_{10} were released in the U.S. in 2011 from agriculture, mostly as a result of crop and livestock dust emissions (EPA, 2014i). Agriculture is a major contributor to emissions of PM_{10}, which is typically directly emitted to the atmosphere by actions such as tillage operations, harvesting, road travel, animal movement, and wind erosion. Although $PM_{2.5}$ can also be directly emitted, a significant portion of fine particulate matter is formed in the atmosphere by chemical reactions with precursor gases (e.g., NOx, VOCs, ammonia (NH_3)) that may result from engine use, fertilizer application, and animal operations (USDA NRCS, 2012). Agriculture also indirectly contributes to ground-level O_3 formation through emissions of ozone precursor gases (i.e., NOx, VOCs) from a variety of activities including manure decomposition, soil processes (nitrification and denitrification), and combustion from farm equipment (USDA NRCS, 2012).

Agricultural activities contribute directly to emissions of greenhouse gases through a variety of processes. In 2012, agricultural GHG sources accounted for approximately 10 percent of total U.S. GHG emissions (Figure 3.5-8) (EPA, 2014k). Although CO_2 accounts for over 80 percent of U.S. GHG emissions, methane (CH_4) and nitrous oxide (N_2O) are the primary greenhouse gases emitted by agricultural activities (USDA CCPO, 2011). Agriculture made up 38 percent of total U.S. CH_4 emissions in 2012 and 83 percent of total N_2O emissions (see Figure 3.5-9) (EPA 2014k). Between 1990 and 2012, methane emissions from agricultural activities increased by 13.6 percent, while nitrous oxide emissions had an overall increase of 9.5 percent. The primary GHG sources for agriculture include: N_2O emissions from cropped and grazed soils; CH_4 emissions from ruminant livestock production and rice cultivation; and CH_4 and N_2O emissions from managed livestock waste. Agricultural soil activities such as fertilizer application produced approximately 74.8 percent of N_2O emissions in the U.S. in 2012. Enteric fermentation was the largest source of CH_4 emissions in the U.S. in 2012, at 141.0 Tg CO_2 Eq. Overall, emissions from manure management (includes CH_4 and N_2O) increased 54.7 percent between 1990 and 2012 (EPA, 2014k).

Energy use represented approximately 8 percent of the total GHG emissions from the agricultural sector in 2012 (see Figure 3.5-13) (EPA, 2014k). Farm operators rely on a variety of energy sources to perform agricultural practices. For example, large amounts of diesel fuel, gasoline, and liquefied petroleum (LP) gas are used for field operations during crop production (USDA CCPO, 2011). Irrigation systems that use pumps to distribute water also use energy. In 2008, approximately 49 million acres of U.S. farmland were irrigated with pumps powered by liquid fuels, natural gas, and electricity (USDA CCPO, 2011). According to the EPA, 2012 electricity-related emissions were responsible for approximately 62.2 Tg CO_2 Eq. of the 676.3 Tg CO_2 Eq. total GHG emissions from the agricultural sector, representing only three percent of the total GHG emissions attributed to the electric power industry as a whole in 2012 (EPA, 2014k).

Under the No Action alternative, no changes in how farms and associated livestock operations are managed are anticipated. Therefore, current trends to air quality and greenhouse gases resulting from these practices are expected to continue.

Socioeconomics and Environmental Justice- Under the No Action Alternative there would be no added costs to the produce industry (see Chapter 1.9). Industry would continue to operate based on existing practices and could continue to rely on current guidance from FDA and USDA, as well as State and industry standards under marketing agreements. The cost of complying with marketing agreements has already been absorbed by the industry. It is possible that new marketing agreements will be developed or existing marketing agreements revised. However, it is not possible to predict future actions. At this point, FDA has not been made aware of any such development or revision of existing marketing agreements.

There would be no change in socioeconomic impacts associated with the No Action alternative, as current conditions would continue.

Environmental Justice

Minority Groups: As discussed in Chapters 1.9 and 3.7.3, with respect to Environmental Justice impacts related to the PS PR, FDA considers potential impacts to minority principal farm operators and farmworkers. USDA NASS survey data provides information on principal operators of farms. Limited data is available for farmworkers; however, there is no data specifically reported for farmworkers on produce farms. The U.S. Department of Labor reports some data on farmworkers in terms of ethnicity and income; however, State-level data are reported only for California and no other State. In addition, farmworker employment can be highly seasonal (USDA ERS, 2014a). Although potential cost impacts could be felt by consumers, without more definitive information regarding specific management decisions that might be taken in response to the PS PR, if finalized, it is unreasonable to project impacts on such groups. Therefore, for purposes of this EIS, the discussion of potential socioeconomic impacts is limited to principal farm operators and farm workers (where information is available). In the Non-Contiguous States, 59.0 percent of principal farm operators identify themselves as minorities. Under CEQ guidance, *Environmental Justice Guidance under the National Environmental Policy Act* (1997), a minority population is found to exist where the minority population of the affected area exceeds 50 percent of total population. Given that the percent that have identified themselves as minorities exceeds the threshold established in the CEQ guidance, for the purpose of this analysis farm operators in non-contiguous states are considered a minority population. The non-contiguous states are Alaska and Hawaii, which are regions W and V, respectively, for the purpose of the EIS.

Additionally, under CEQ guidance, a minority population is found to exist where the minority population percentage of the affected area is meaningfully greater than the minority population percentage in the greater population or other appropriate unit of geographic analysis. The national average of farms with minority principal operators is 10.5 percent. As described in Chapter 3.7.3, by applying an additional 10 percent to this national average FDA establishes a “meaningfully greater” threshold of approximately 11.6 percent. Of the regions included within the analysis, besides regions W and V, other regions that have a population of minority principal operators greater than the 11.6 percent threshold are regions A, B, C, and D. Thus, the analysis of environmental justice impacts on minority principal operators is limited to regions A, B, C, D, W, and V.

Based on the limited information on farmworkers reported by the U.S. Department of Labor through surveys taken by that agency (see Chapter 3.7.3), regions where there are potentially populations of minority farmworkers that may be impacted by the rule, if finalized, include regions C, D, I, and J. In addition, farmworker income-related information was provided only for region C.

Given that there is no increase is overall cost expected under the No Action alternative, no significant impacts on minority principal farm operators are anticipated under the No Action alternative.

Low-Income: For the purposes of this EIS low-income persons include any persons whose median household income is at or below the HHS poverty guidelines. While the 2014 HHS poverty threshold data is available, the 2012 dataset is the appropriate data set for a comparison with the 2012 ERS measurement. Chapter 3.7, Table 3.7-17 identifies the 2012 HHS poverty guidelines for the 48 contiguous states and the District of Columbia. The 2012 HHS poverty guidelines are also published in 77 Fed. Reg. 4034.

An area is identified as containing a low-income population when the median household income for the area is below the HHS poverty threshold, which was determined to be $23,050 for a family of four in 2012.[4]

There would be no significant impacts associated with the No Action alternative, as current conditions would continue.

Human Health and Safety- FDA has extensively analyzed the current effects of foodborne illness as part of the rulemaking process. Those discussions are summarized in Chapters 1, 2, and 3.8, as well as at the beginning of this section. Assuming current practices continue, FDA anticipates that there would be a significant continued risk to public health under the No Action Alternative.

There are additional adverse impacts associated with agricultural practices in the areas of worker safety as well as secondary exposure to agricultural chemicals (primarily those that enter the water supply through run-off or improper application). These problems occur nationwide. If the agency takes no action, it is possible that additional marketing agreements will be established to try to prevent foodborne illness resulting from pathogen contamination of a specific commodity or group of commodities. Such marketing agreements may establish stringent standards that could increase the use of pesticides, alter BSA application or result in other changes that would result in increased exposure to workers or through secondary routes to the general public. However, as previously stated under this alternative, FDA is not aware of any future marketing agreements that are in development or under revision. Therefore, it would be speculative to try to determine what impacts, if any, would result.

4.2 Subpart E: Standards Directed to Agricultural Water

Water has been shown to be a possible route of pathogen contamination in the field and after harvest. While produce outbreaks citing contaminated water as a suspect vehicle in foodborne disease are plentiful, conclusive evidence is rare (Solomon and Matthews, 2006; WHO and UNEP, 2006) due to time and resource constraints related to field evaluations, collections, and analytical work coupled with the often-transient nature of circumstances leading to contamination. Potential contributing factors cited in produce-associated outbreaks where water was identified as the likely source of contamination include run-off from nearby animal pastures and feed lots, cracked or damaged wells, floods, raw sewage infiltration, and surface waters contaminated with feces (Berger et al., 2010). Studies have demonstrated that pathogens can be transferred from contaminated water to produce (Ijabadeniyim et al., 2011). The presence of bacteria in irrigation surface waters is dynamic, often showing seasonal variation due to changes in temperature, precipitation, and animal carriage rates that may ultimately influence human exposure to waterborne pathogens. For example, one research paper correlated the number and

[4] http://aspe.hhs.gov/poverty/12poverty.shtml

diversity of *Salmonella* serotypes isolated from a mixed use watershed (irrigation, swimming, fishing) in southern Georgia to summer seasonal temperature/rainfall patterns and coincident with salmonellosis case reports (Haley et al., 2009). Pathogen survival rates in water are affected by many of the same parameters affecting survival rates in soil, i.e., UV exposure, temperature, nutrient availability, competition, and pH among others. However, some pathogens (e.g., *Salmonella*) appear to be better adapted for long term aquatic survival than others (e.g., *Shigella*) (McElhany and Pillai, 2011).

Ground water has been historically viewed as less likely to be contaminated with human pathogens than surface water because of the natural filtering capacity of soil and the depth bacteria and pathogens would have to travel to compromise its source. As a general rule, deeper wells filter out more bacteria and pathogens than shallower counterparts given similarly structured soils and other geological properties. However, ground water can be contaminated with pathogens by infusion of wastewater, failed septic tanks, landfill leaks, and improper management of animal wastes. Although wells that are properly constructed and appropriately situated are generally less vulnerable to contamination compared to surface water sources, private wells are an additional concern as routine monitoring and regular treatment are rare (Reynolds et al., 2008). Recent studies have found that (1) 11 percent of U.S. ground water sites from 20 states are reported to have tested positive for *Cryptosporidium*, *Giardia* or both (Moulton-Hancock et al., 2000); and (2) in a 12 year (1991-2002) survey of waterborne diseases, of 183 documented outbreaks associated with drinking water, 76 percent were from a ground water source (Reynolds et al., 2008). Moreover, direct leaching of *E. coli* and *Campylobacter* into shallow ground water sources has been demonstrated (Close et al., 2008). Figure 3.1-17 in Chapter 3.1.3.9 shows the locations of U.S. principal aquifers that tested positive for fecal-indicator bacteria (USGS, 2006b).

In addition to water source and quality, the type of irrigation system or method of use may influence the likelihood of pathogen contamination of produce. For instance, Mitra et al. (2009) showed that *E. coli* O157:H7 survived longer on leaf surfaces of spinach when introduced via water droplets than on roots when introduced by soil infiltration. However, the opposite relationship was demonstrated in the case of *Campylobacter jejuni* in spinach and radish, where survival rates in root systems were significantly higher than on leaves (Brandl et al., 2004). These findings suggest that pathogen survival rates may be dependent not only on mode of introduction (in this case, type of irrigation system), but also on specific pathogen-commodity interactions.

For this reason, Subpart E provides "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 Food Drug and Cosmetic (FD&C) Act." (78 Fed. Reg. 3504 at 3559).

Management decisions

The environmental impacts of standards directed at agricultural water are the result of the management decisions a covered farm makes in order to either comply with the standard or not be subject to the standard. FDA has chosen to take a non-prescriptive approach when establishing standards to allow for, and encourage, scientific advancement in the measures available to comply with the proposed rule.

As discussed at the beginning of Chapter 4, FDA, in coordination with USDA, identified the reasonably foreseeable actions, or management decisions, that businesses potentially affected by any final rule might take in order to come into compliance with, or to potentially avoid being subject to, the proposed action or alternatives under consideration for inclusion in the final rule. Management decisions were considered reasonably foreseeable based on certain considerations, including if such decisions were in compliance with existing laws and regulations, if they would allow for compliance with the alternatives being considered, and/or if the technology is either currently available or in development and has been considered for the stated purpose. Management decisions that would be suitable options for only some covered produce were also included, even if such decisions would not be a viable option for all covered produce. As part of the comment period on the 2013 proposed rule, FDA received extensive comments from industry, many of which provided information on the potential actions that would be needed to comply with the proposed standards. Management decisions that were either explicitly stated or implied in these comments were considered. It is expected that farms would use one or a combination of these decisions depending upon their individual conditions. Under subpart E, FDA and USDA identified the following actions as reasonably foreseeable management decisions in relation to the proposed water requirements or corresponding alternatives: the potential use of chemical treatment of agricultural water sources to comply with the water quality requirements; switching the irrigation method to a non-contact method; switching water sources; switching to agricultural commodities that are not covered by the rule (cease growing covered produce); and adding mechanisms to account for microbial die-off in the field and post-harvest (applies to the Preferred Alternative and Alternative III).

While all reasonably foreseeable alternatives have been identified, FDA is aware that some management decisions will likely be more preferable or potentially more viable to covered farms. In its outreach on the FSMA supplemental proposed rules, FDA is hearing from stakeholders about the likelihood of certain management decisions, given the flexibility added to the proposed requirements for agricultural water sources.[5] In the supplemental proposed rule, FDA added an allowance for consideration of microbial die-off in the field prior to harvest (using a die-off rate of 0.5 log per day) in order to meet the proposed agricultural water standards and an allowance for post-harvest microbial die-off and/or removal techniques, provided there is adequate supporting scientific data and information. Given this added flexibility, it is less likely that operations will need to switch water sources to meet the proposed agricultural water standards.

[5] Transcripts from the November 13, 2014 public meeting on Supplemental Notices of Proposed Rulemaking are found at this FSMA Web page: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm418878.htm

<u>*General background on resources related to the proposed provision*</u>

Water Resources – In order to determine the potential environmental effects of a standard directed to agricultural water, it is important to understand the source of water used for growing covered produce, whether demands on that water are sustainable, and the extent to which that water would be considered impaired for the intended use due to the presence of pathogens which would require measures to bring it into compliance with a standard established by FDA. Water quality and availability are described in Chapters 1.9, 3.1.2 and 4.1. As described in more detail below, both are already experiencing significant adverse effects as a result of agricultural activities and other influences, both those related to covered produce and those related to non-covered produce and other agricultural crops that are not produce commodities. Water quality and availability and their current significance status are viewed on a nationwide basis and are influenced by other factors (e.g., development); the significance of these factors is considered in the cumulative impacts analysis (Chapter 5). Although this EIS cannot assess potential water-related impacts on a localized level, and water quality and availability are variable nationwide, FDA considers impacts from actions that result in groundwater drawdown to have significant impact in regions where current conditions for groundwater depletion have significant environmental impacts Therefore, this chapter assesses the potential for alternatives to contribute to water quality and availability conditions where current conditions have significant impacts, relative to the potential management decision.

<u>Water Sources</u>

The geographic distribution of total, surface-water, and groundwater withdrawals for irrigation is described in Chapter 3.1.3.8 and shown in Figure 3.1-13.

<u>Water Availability</u>

The majority of surface and ground water withdrawals (85 percent) and irrigated acres (74 percent) were in the 17 conterminous Western States (see Chapter 3.3.1.8). The 17 Western States are located in areas where average annual precipitation typically is less than 20 inches and is insufficient to support crops without supplemental water.

Under current conditions, States that are currently experiencing the highest total irrigation water supply withdrawals (Figure 3.1-12) and that grow the highest concentrations of covered produce are California, Idaho, Texas, Oregon, Arizona, Florida, Washington, and New Mexico; corresponding to regions A, B, C, D, I, J, and U (regions for these States shown in Figure 1.7-4). These regions account for more than 80 percent of covered produce grown in the U.S. The highest groundwater withdrawals where covered produce is grown occur in California, Idaho, Texas, Oregon, Arizona, and Florida (regions A, B, C, D, I, J, and U). In particular, the western states of this grouping are located in areas where average annual precipitation typically is 20 to 30 inches, which rainfall is insufficient to support crops without supplemental water; these include California, Idaho, Texas, and Arizona (regions B, C, D, I, and J). Region U is presently experiencing significant drawdown effects despite a much higher precipitation and aquifer recharge rate as compared to regions B, C, D, I, and J (see Chapter 3.1.3.11). Therefore, regions important for groundwater drawdown in this EIS are considered to be regions B, C, D, I, J, and U. As shown in Figures 3.1-23 and 3.1-24, there are several geographical areas where large scale groundwater depletion is evident over agricultural areas with a high concentration of covered farms.

Significant dewatering is presently evident over the Central, Coachella and Death Valleys of California; Alluvial Basins of Arizona; and the Columbia Plateau in southeastern Washington and northeastern Oregon. Because of the 2013 drought, Central Valley irrigators face about a one-third reduction (6.5 million acre feet, or maf) in surface water deliveries this growing season, compared with normal years (USGS, 2013). Growers are likely to increase groundwater pumping to replace about 5.0 maf of this shortage, leaving 1.5 maf or about 7.5 percent of normal irrigation water use in the Central Valley (USGS, 2014b). In 119 years of recorded history, 2013 was the driest calendar year for the state of California (USGS, 2013).

Water quality

Impaired Surface Waters

Information that is obtainable from the EPA database as described in more detail in Chapter 3.1.3.9, which provides data on the type and level of impairment (including impairment by pathogens, as potentially indicated by generic *E. coli*), does not readily support full analysis as it is based on discrete samples, the number of which vary significantly by state, with some states having few, if any available data. As such, these data presented in Chapter 3.1.3.9 may identify some areas of possible pathogen contamination but cannot be considered to be representative of all possible sites. Nonetheless, EPA indicates that based on CWA Section 303(d) (33 U.S.C § 1313(d)) water quality standards set by states (i.e., TMDLs) and based on Section 305(b) (33 U.S.C. § 1315) Reports, there are more than 86,747 miles of streams and rivers impaired by E. coli, 57,562 miles impaired by fecal coliform, 10,152 miles impaired by enterococcus bacteria, 7,349 miles impaired by other bacteria, and 4,184 miles impaired by other pathogens of the more than 3 million square miles of streams in the nation.

Impaired surface waters that are co-located with regions in which covered produce is grown are found mainly in regions A, B, C, L, R, T, and U (compare Figure 3.1-15 with Figure 1.7-4); this corresponds to the West, Northwest, Great Lakes region, Northeast, and Mid-Atlantic moving southward to the Southeast. This indicates regions where there is an increased likelihood that farmers are using waters that may require treatment to be in compliance with the water quality standard FDA decides to finalize.

Impaired Groundwaters

Based upon sampling data from the NAWQA program (USGS, 2014b), supporting groundwater quality analysis, while pathogens are less prevalent in groundwater, they may still be contaminated. The groundwaters most affected by the presence of coliform bacteria were those in the Valley and Ridge, the Floridan, and the Piedmont and Blue Ridge aquifers, where more than 50 percent of the study wells tested positive for the above-noted bacteria. A positive test merely indicates the presence for the bacteria, and not an exceedance of any established water standard. These affected groundwaters are located in regions A, B, C, L, R, S, T, and U (compare Figure 3.1-17 with Figure 1.7-4) (NAWQA program; USGS, 2014b).

Impacts of Standard of Water Resources

The greatest potential for significant impacts on water resources would be expected from management decisions to use chemical or physical treatment to bring agricultural water sources into compliance with any of the alternatives' water requirements, or switch water sources. Industry has already taken steps to improve the quality of the water that is used on some commodities. As discussed in Chapter 2, voluntary (and some mandatory) marketing agreements exist for specific commodities. A component of some of these marketing agreements is standards directed at water quality. In many cases, the voluntary numeric standard is as or more stringent than what is considered in the alternatives (e.g., T-GAPS, CA and AZ LGMA). Some potentially covered farms that may already be complying with these marketing agreements are already using water that is in compliance with the standards that are under consideration. This includes many leafy green producers in California and Arizona and tomato growers in Florida, as cited above and in Chapter 2. Such marketing agreements help to form the background conditions that many farms potentially covered by the rule are already experiencing. The cumulative impacts of the marketing agreements and the proposed rule result are also discussed in greater detail in Chapter 5. In general, the existence of these marketing agreements, particularly in produce growing regions currently experiencing water impacts, minimizes the severity of potential impacts on resource components associated with a final rule, as the number of farms that would need to alter their current management practices is less than the total number of covered farms.

Alternative IV allows for the standards considered under Alternatives I through III to include or exclude drip irrigated root crops. The likelihood that any management decision would be selected for Alternative IV is considered as part of the analysis of Alternatives I through III. However, the severity of a potential impact would vary depending on whether drip irrigated root crops were included or excluded as the total covered acreage would differ.

Use of Chemical Treatment to Bring Agricultural Water Sources into Compliance

Presently, there is no EPA-approved chemical treatment for contaminated water used to irrigate cropland (EPA, 2014a). While there are no pesticide products registered to treat contaminated water used to irrigate cropland, the EPA maintains a list of approximately 50 Registered Antimicrobial Products as Sterilizers. Each of these products received approval under the FIFRA, as Amended in 1996 (40 CFR Parts 152, 156, and 158). Pesticide registrations are specific to the use that was considered as part of the registration process. Therefore, an antimicrobial may only be legally used for the registered use. The compounds on EPA's list of Registered Antimicrobial Products as Sterilizers may not be used to control pathogens in water applied directly to produce. However, farmers who use these antimicrobials consistent with their registered use under FIFRA, e.g., pesticides used to prevent fouling of pipes or for treatment of wells, may see some improvement in their water quality. However, such uses do not correspond to the standards directed at agricultural water, and therefore, would not be a direct or indirect effect of the proposed rule, if finalized. Therefore, FDA is not including an evaluation of environmental impacts from such uses in the context of this draft EIS.

Registration policy documents, disinfectant technical science section documents, product information (including potential hazards related to human health, handling, storage, and environmental or ecological) and registration information may be found at the EPA's Web site.[6]

When considering treatment technologies for contaminated agricultural water to satisfy FDA-established qualitative or quantitative water quality standards in proposed §§ 112.41 and 112.44, water would need to be treated in accordance with proposed §§ 112.43(a) and 112.44(b) and (c). Treatments would need to be applied and monitored to ensure the water is consistently safe. While pesticides are currently the preferred mechanism for treating water, other technology such as UV light, is in development and may be used in the future. All such products would be considered pesticides and would be subject to regulation under FIFRA. EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. Some of these products may be used to treat other types of agricultural water (e.g., may be used to treat the water in lagoons or furrow pits that are drawn from to irrigate crops, or to treat the equipment used to irrigate crop-land).

FDA does not have specific information on the pesticides that would be submitted to EPA for registration for uses to control pathogens in agricultural water applied to produce. However, as described in greater detail in Chapter 3.1, the most commonly used antimicrobials 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 seek FIFRA registration. The primary byproduct of these chemicals are trihalomethanes, or THMs, which are commonly formed when the naturally occurring organics in water come in contact with reactive chlorine producing compounds. Under most conditions (except in the presence of unusually high bromide concentrations), chloroform is the THM produced in the highest concentrations during chlorination.

Chloroform is also one of the VOCs detected most frequently in both ground and surface water (Ivahnenko and Barbash, 2004). A national water quality assessment performed by the USGS was designed to provide additional information on the frequency of occurrence, concentration, and temporal variability of THMs in source water used by community water systems (CWS) (Delzer and Ivahnenko, 2003). This study found that THMs were detected in 47.8 percent of the CWSs supplied by surface water. Total THM concentrations of the compound, however, were typically less than the MCL and therefore, not anticipated to result in significant adverse impacts. In the studies that compared land-use settings, frequencies of detection of chloroform were found to be higher beneath urban and residential areas than beneath agricultural or undeveloped areas (Ivahnenko and Barbash, 2004). As chlorine compounds are frequently used in municipal water systems, the presence of chloroform beneath urban and residential areas, is unlikely to be tied to agricultural use.

USDA organic regulations, codified in 7 CFR Part 205, restricts chemical treatment products to those that are listed on the National List of Allowed and Prohibited Substances (see Chapter 1.4). This limits the pool of available chemical treatment options for growers of covered produce; however, EPA has approved some pesticides that fall into compliance for use under USDA

[6] http://www2.epa.gov/pesticide-registration

organic regulations, under certain circumstances. Regulations specifying these circumstances are detailed under 7 CFR 205.601. In order for organic farmers to remain in the organic program, any EPA-registered pesticide that could be used to treat contaminated agricultural water would need to be an allowed substance on the National List, which adheres to strict environmental criteria.

Regions that would potentially require a higher level of chemical treatment because they already experience high exceedances of surface water quality include regions A, B, C, L, R, T, and U (compare Figures 3.1-16 and 3.1-17 in Chapter 3.1.3.9 to Figure 1.7-4) . While this may result in significant impacts due to the formation of THMs, these impacts are mitigated by the ability of covered farms to choose other management decisions, particularly switching water sources, switching the irrigation method to a non-contact method, or adding mechanisms to account for microbial die-off in the field and post-harvest (Alternative I and III only). As discussed above switching water source is the most likely management decision, although the likelihood varies depending on the alternative. The adoption of this management decision is more likely for Alternative II, than for Alternatives I or III which provide for a mechanism to account for microbial die-off in the field and/or removal, post-harvest.

Switching water source

The public comments that FDA received following the publication of the 2013 proposed rule, made it clear that the stringency of the requirements in Alternative II made a change in water source a viable option for covered farms. Farmers in specific regions, such as the Pacific Northwest, indicated that groundwater may be the most feasible alternative for complying with the standard in Alternative II. Alternatives I and III provide for significantly more flexibility in meeting the water quality standard, including allowing for a microbial die-off and/or removal step(s). Reactions and verbal comments from some in industry and trade groups that FDA received on the supplemental proposed rule suggest that the new proposed provisions for microbial die-off and/or removal to achieve the proposed microbial quality standard considerably reduce the perceived need to change water source in order to comply with Alternative I (and similarly Alternative III), compared to Alternative II. Alternative IV allows for the standards considered under Alternatives I through III to include or exclude drip irrigated root crops.[7]

By and large, groundwater sources are less contaminated than surface water sources (Chapter 3.1); therefore, it is likely that if faced with contaminated irrigation/agricultural water issues to the point where the water may not be treated at all, the grower may switch from surface water to groundwater irrigation. Groundwater depletion is primarily caused by sustained groundwater pumping. Pumping groundwater at a faster rate than it can be recharged can have adverse impacts on the environment and the people who make use of the water.

The geographic distribution of total, surface water, and groundwater withdrawals for irrigation is shown in Chapter 3.1, Figure 3.1-13. Agriculture is a major user of ground and surface water in the United States, accounting for approximately 80 percent of the Nation's consumptive water use and over 90 percent in many Western states. Over the course of the past couple decades, groundwater has become an increasingly important source for irrigation and currently is used in

[7] Public testimony during the November 13, 2014 public meeting can be found at the following FSMA Web page: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm418878.htm

60 percent of the area equipped for irrigation within the United States (Siebert, 2010). The majority of withdrawals (85 percent) and irrigated acres (74 percent) have been in the 17 Western states where average annual precipitation typically is less than 20 inches and is insufficient to support crops without supplemental water. In 2005, approximately 20 percent (82,600 million gallons per day (Mgal/d)) of total national water withdrawals (about 410,000 Mgal/d) came from groundwater sources. More than one-half of the groundwater for irrigation was withdrawn in just four states: California, Nebraska, Arkansas, and Texas. Irrigation represents the largest use of groundwater in 25 states. Nationwide, groundwater withdrawals for irrigation were approximately 3.5 times larger than groundwater withdrawals for public supply (USGS, 2009).

Expansion of groundwater-fed irrigation is attributed to the ubiquity of groundwater, ready access to this resource, minimal infrastructure requirements, and general continuity of supply providing a buffer against droughts (Giordano, 2009).

Total irrigation withdrawals in both Eastern and Western states were smaller in 2005 than in 2000, but because the West accounts for such a large percentage of the total irrigation withdrawals, changes in those states have a greater effect on the total. Groundwater withdrawals increased slightly in the East, and surface-water withdrawals declined in both the East and West. During this period, total irrigated acres decreased in the West by 4 percent and increased in the East by 5 percent. In the West, acres irrigated by surface irrigation methods declined by 16 percent, and acres irrigated by sprinkler methods increased by 9 percent. Irrigated acres in the East increased for all type of systems; the largest percentage increase was in microirrigation systems.

In particular, California, Idaho, Texas, and Arizona (regions B, C, D, I and J) (see Chapter 3.1.3.8) are located in areas where average annual precipitation typically is 20 to 30 inches, where rainfall is insufficient to support crops without supplemental water, and account for more than 80 percent of the covered produce grown in the U.S. Region U is presently experiencing significant drawdown effects despite a much higher precipitation and aquifer recharge rate (see Chapter 3.1.3.11 and Chapter 4.1). Therefore, regions that may experience the highest potential impacts related to groundwater withdrawal include regions B, C, D, I, J, and U. The most severe consequence of replacing surface water irrigation sources with groundwater is that excessive groundwater pumping can lead to lowering the water table, reduction of water in streams and lakes, deterioration of water quality, and land subsidence. These impacts may be disproportionately felt by Native American Tribes as groundwater drawdown could have potential environmental impacts including socioeconomic impacts related to access to water on reservations, particularly in regions B and J (see Figure 3.7-6).[8]

<u>Lowering the water table</u>

Droughts, seasonal variations in rainfall, and pumping affect underground water levels. If a well is pumped at a faster rate than an aquifer is recharged (by precipitation or other underground

[8] When comparing the regions that experience the most significant effects of groundwater drawdown (regions B, C, D, I, J, and U), with the regions where Native American Indian reservations exist and where covered produce are located (see Figure 3.7-6), this comparison shows that regions B and J are where Native American Indian reservations overlap with regions experiencing significant groundwater withdrawals.

flow) water levels in the well can drop, resulting in decreased water availability and deterioration of groundwater quality. Lowering the groundwater table by only a few meters also affects existing users of groundwater, especially at dry times of the year. Springs are fed by groundwater and may dry up if the level falls. Similarly low flows in rivers may be reduced.

Groundwater pumping can alter how water moves between an aquifer and a stream, lake, or wetland by either intercepting groundwater flow that discharges into the surface-water body under natural conditions, or by increasing the rate of water movement from the surface-water body into an aquifer.

Deterioration of water quality

The changing hydrological regime associated with irrigation schemes may alter the capacity of the environment to assimilate water soluble pollution. In particular, reductions in low flows result in increased pollutant concentrations already discharged into the water course either from point sources, such as industry, irrigation drains and urban areas, or from non-point sources, such as agrochemicals leaking into groundwater and soil erosion. Reduced flood flows may remove beneficial flushing, and reservoirs may cause further concentration of pollutants.

All of the water in the ground is not fresh water; much of the very deep groundwater and water below sea level can be saline. Under natural conditions the boundary between the freshwater and saltwater tends to be relatively stable, but groundwater pumping can cause saltwater to migrate inland and upward, resulting in saltwater contamination of the freshwater supply (saltwater intrusion).

Land subsidence

Land subsidence is a gradual settling or sudden sinking of the Earth's surface owing to subsurface movement of earth materials. Excessive groundwater pumping and aquifer depletion can cause land to sink, which can cause permanent loss of groundwater storage in the aquifer system and infrastructure damage (Todd, 1980). Vulnerable areas are those with compressible strata, such as clays and some fine-grained sediments. Any structural change in the soil is often irreversible. The ground level can fall with a lowering of the water table if the soils are organic rather than mineral based. Peats shrink and compact significantly on draining, with consequent lowering of the ground surface by several meters.

Regions that may be most impacted in terms of potential land subsidence, including any additive effects by switching to groundwater sources, include the regions that already experience the highest groundwater withdrawals; these are regions B, C, D, I, J, and U. Any action that may lead to increases in groundwater drawdown within the regions listed here, would be considered a significant environmental impact.

Alternatively, as discussed in Chapter 3.3 drip irrigation has also proven to conserve water effectively, but water infiltration rates vary by soil consistency. Furthermore, pathogen survival and transport from soil surface to the subsurface root zone varies by soil type and the size of pore spaces; but consistent studies have not been performed nationwide on these processes and so little is actually known on potential impacts. As discussed earlier in this subpart, although drip irrigation does increase the potential that uncultivated fields are placed into cultivation thereby increasing water use, the more likely scenario is that drought conditions have already forced farmers to convert much of their irrigation to non-contact. Overall, there are minimal impacts associated with drip irrigation as it relates to water resources.

Switching the irrigation method to a non-contact method

Changes in irrigation method which use non-contact methods is a management decision that is only feasible for specific crops. For crops such as apples where direct application of water can prevent brown spots, switching to non-contact methods is not feasible.

Non-contact irrigation can include certain types of surface irrigation (e.g., furrow) and sub-irrigation methods (e.g., indus basin irrigation system, or IBIS). Each of these systems is discussed in more detail in Appendix B.

Non-contact irrigation allows efficient watering by supplying water where it is needed, at or near the roots of the plants. This approach significantly reduces water percolation through the root zone which in turn leads to decreased runoff from the tail end of gravity irrigated fields, and lower evaporation from the soil; even more advanced flood irrigation systems may be controlled with a system of dikes and levees in extreme flood situations. However, smaller systems are notable exceptions and may contribute to excess runoff. Flood irrigation methods are also often associated with poorer water quality conditions in the tailwater (see discussion in Appendix B).

Overall, most non-contact irrigation provides greater uniformity in the water distribution throughout a field leading to a reduction of moisture stress to plants. Non-contact irrigation also generally allows the precise application of water-carried fertilizers to the roots of the plant, which can considerably increase irrigation efficiency and thereby reduce migration of these chemicals and pesticides into the aquifer. This benefit has been reported by many researchers (Allen, 1993). Furthermore, if irrigation water could be applied to exactly meet the evapotranspiration needs of the crop then it is apparent that less water, and therefore less salts, would be applied. Without excess water and deep percolation, fertilizers and agricultural chemicals would not likely be washed down into the aquifer and groundwater quality would improve.

A conversion to more efficient irrigation technology (e.g., switching from an overhead irrigation method to drip irrigation--see discussion at Chapter 3.3.3.5) can induce a shift away from dry-land crops to irrigated crops, from less water-intensive crops to more water-intensive crops, or from drought-resistant varieties to varieties that require consistent rates of irrigation. Even if the producer does not switch crops, the higher yields made possible through more efficient irrigation technology cause higher rates of evapotranspiration, resulting in less irrigation water being returned to the watershed either as recharge to the aquifer or return flow to surface water sources. For example, in Kansas and other places where the rights system defines an annual limit to the amount of irrigation water that can be used by a producer, water "saved" through increased irrigation efficiency may be used on previously unirrigated land, thus increasing total irrigated acreage (Scheierling, 2004).

Although non-contact irrigation does increase the potential that uncultivated fields are placed into cultivation, thereby increasing water use, the more likely scenario is that since drought conditions have already forced farmers to convert much of their irrigation to non-contact, and any anticipated water-related impacts are not anticipated to be significant because the conditions that may cause such a management decision are persistent.

Add mechanism to account for microbial die-off in the field and post-harvest
A management decision to account for microbial die-off and/or removal post-harvest is only possible for Alternatives I and III. Microbial die-off and removal can be reasonably expected due to natural die-off on the field post irrigation and prior to harvesting of the crop; microbial die-off or removal can occur under certain conditions and/or during extended storage or commercial washing of the produce commodity. Post-harvest steps may also involve the use of some industry-specific antimicrobial direct or indirect food additives that are applied as mechanisms to improve microbial die-off post-harvest; which may also reduce reliance on chemical treatments of contaminated irrigation water supplies or to augment such treatments depending upon the overall quality of the water (the worse the water quality the more treatment options that may need to be employed, pre- and post-harvest).

Since water resources are already stressed over the majority of areas that may be most affected by the PS PR (regions B, C, D, I, J, and U), it is expected that the water application rates have already been largely balanced with the required plant uptake, and although the application rates and durations may change the total volume of water applied to crops is likely to remain fairly constant. Therefore, post-harvest treatment is a viable management decision option that may overall mitigate the potential need for or significant impacts associated with other management decisions reviewed under this alternative.

Among the responsibilities of the FDA is regulation of components of food contact substances. Once known as indirect food additives, FDA now refers to these materials as food contact substances (FCS). An FCS is, “any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food” (21 CFR 170.3(e)(3)). Common types of food contact substances include coatings, plastics, paper, adhesives, as well as colorants, antimicrobials, and antioxidants found in packaging. In an effort to ensure the safe use of these substances, FDA has established a Food Contact Notification (FCN) Program within the Center for Food Safety and Applied Nutrition's (CFSAN) Office of Food Additive Safety. All phases of the product review and approval process for products that undergo review by the FCN Program are described at FDA’s Web page.[9] FCNs are agency actions of a type requiring environmental consideration. After an FCN becomes effective, the agency adds it to the environmental inventory of effective notifications on the internet in compliance with NEPA requirements for public involvement. An inventory of environmental impact decisions, including for antimicrobial products, is found on the agency’s Web site[10]. To date, FDA has not identified any significant impacts related to the use of indirect additives or FCS that would require the preparation of an EIS.

[9] http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ucm064161.htm
[10] http://www.accessdata.fda.gov/scripts/fdcc/?set=ENV-FCN

Post-harvest microbial die-off and/or removal mechanisms do not necessarily mean taking active methods to wash the produce. Allowing for a sufficient interval post application of agricultural water may be sufficient in many situations. Therefore while post-harvest washes are one option, they are not expected to add significant pressures to local water supplies. Further, as the impact of the available FCSs have already been reviewed and found not to result in significant adverse impacts, they are not anticipated to considerably contribute to the degradation of water effluent that may be dispensed to a municipal water collection system or to an individual septic system. Therefore, there are no anticipated adverse impacts to water quality. Significant impacts would not result.

Stop Growing Covered Produce

Based on the comments FDA has received to date, this is not a preferred management decision except in limited instances. Whether farmers stop growing covered produce is dependent upon the alternative use of the land. In California, severe drought conditions have already forced many farmers to let land lay fallow (California Farm Water Coalition (CFWC), 2014; Howitt et al., 2014). In fact, it is widely reported that a shortage of water resources has prompted programs in California that pay farmers to keep land fallow in order to divert water to the cities. This is not a re-zoning of the land *per se*; rather, that land is essentially reserved for future alternative agricultural uses. In other areas of the country where water is more abundant, land formerly used to grow covered produce may be employed to raise livestock or other crops; although, this is not commonly practiced and would require intense capital costs to accomplish.

Therefore, if covered produce is no longer grown and the land is to remain fallow, it most likely would be due to the scarcity of the water, and the overall water use would remain similar since the water would be diverted to other uses.

If non-covered produce or other agricultural crops that are not produce are grown[11], regulation or requirements to maintain certain water quality conditions would be dependent on any existing state regulations or industry marketing agreements, or may not be addressed because potential forms of contamination may be addressed through commercial processing. The type of crop a farmer may select to grow would also be dependent upon the region's climate, soils, water availability, and may involve a decision whether the existing farm's equipment and infrastructure would be sufficient, or would need to be updated, modified, or bought to accommodate a new type of crop.

Under certain conditions, where very small farms are involved and costs may be a larger factor, some farms may decide to stop growing crops altogether. However, this scenario would be most likely for very small farms as well as livestock operations that grow small amounts of covered produce; many such diversified farming-livestock operations would likely be excluded based on the new proposed monetary threshold for excluded farms applied to sales of produce only rather than sales of food. Large operations would likely not cease production of covered produce and would choose another mechanism for addressing standards directed at agricultural water. There

[11] See Chapter 1.6. Produce that are not covered under the PS PR are identified as specific fruits and vegetables that would be exempt from the rule (Table 1.6-1), or produce that is specifically meant for commercial processing using a method that adequately reduces the presence of microorganisms of public health significance.

are no data to suggest under what conditions specifically such a management decision may occur, and there are no data available to quantify or qualify any related indirect impacts.

Any potential impacts on water resources are dependent upon the alternative use of the land. In some cases severe drought conditions have already forced many farmers to let land lay fallow. Under most conditions, a change in the type of agricultural use may not substantially change the water being used for the purposes of farming. Letting a parcel of land go fallow would reduce the pressure on water supply and eliminate water quality regulatory conditions, but either that land may remain fallow until a time when it is needed again, or may transfer to another type of use. Any land management changes are highly speculative and would occur based on local management decisions and personal economic considerations. Overall, there is a low probability that water resources would result in any significant adverse effects under this action/mechanism.

Biological and Ecological Resources – Biological and ecological resources require water to be available for their sustainability. Water is a life requisite and any change in the quantity or quality of available water may pose a threat to biological and ecological resources. Once water is used for agricultural purposes, a portion of that water may re-enter the groundwater and surface water ecosystems. The quantity, quality, and fate of the used agricultural water on a local level may be altered from current conditions to a level that changes the interactions of biological and ecological resources with available water supplies. No significant adverse impacts on biological and ecological resources are identified with the decisions to switch the irrigation method to a non-contact method, cease growing covered produce or practice measures that could allow for microbial die-off. These management decisions may, in select instances, result in beneficial impacts by allowing land to lay fallow, or reduce runoff of nitrogen compounds or other agricultural-related contaminants. The only management decisions that have the potential for significant impacts on biological and ecological resources would be the use of chemical treatment to bring agricultural water sources into compliance with any of the alternatives' water requirements or switching water sources.

Any potential acute toxicity-related impacts would be product-specific and overall any such impacts are anticipated to be minimal providing that any product that is used is handled and disposed of in accordance with labeling requirements.

Use of Chemical Treatment to Bring Agricultural Water Sources into Compliance
Chemicals such as pesticides used for the treatment of agricultural water are not natural to the ecosystem, may be acutely hazardous, and are required to be disposed of properly (EPA, 2014l). If handled or disposed of improperly, and depending upon the chemical composition of the product[12], the effects of such treatments to biological and ecological resources may be experienced at receiving waters downstream of the water source or downstream from tailwater (running off from the field). The persistence of these chemicals in the environment may adversely influence non-target systems (e.g., wetlands and riparian ecology and have further indirect effects to flora and fauna coming into contact with those chemicals, increasing toxicity.

[12] Chemical compounds will break down, volatilize, or decompose differently based on local environmental conditions.

EPA's online Pesticide Registration Manual specifically states, "Pesticides are substances that prevent, destroy, repel, or mitigate a pest. A product's relative toxicity to humans or other non-target organisms does not make it a pesticide. However, the product's toxicity to humans and other organisms is carefully evaluated during EPA's registration evaluation process. When EPA determines that a pesticide product can be registered for use, the Agency has concluded that the use of the pesticide product will not cause unreasonable adverse effects to humans or the environment when applied according to the label directions and restrictions." (EPA, 2014m)[13]

Therefore, providing that any pesticide that is EPA-registered and is handled and applied in accordance with labeling requirements should not result in significant environmental impacts to vegetation, wildlife, and wetland resources. However, such applications may result in short-term minimal to moderate impacts on these resources particularly if applied preceding substantial periods of precipitation which may increase run-off. Such impacts would be intermittent and acute.

Switching water source

Habitats both within and alongside rivers are particularly rich, often supporting a high diversity of species. Changing the source of irrigation water is not anticipated to directly affect the biological and ecological resources of the nation; however, large-scale local or regional depletion of groundwater resources may adversely but not significantly impact wetlands, lakes, and streams and the species that rely on them. Loss of groundwater storage in some cases may drain wetlands and surface waters to the extent that local wildlife populations may not be sustained at their present levels (loss of forage, cover, and breeding opportunities) and lower groundwater levels below the depth that streamside or wetland vegetation needs to survive. The overall effect is a loss of riparian vegetation and wildlife habitat. However, such impacts may be more likely in regions that experience substantial pressure on the aquifer system, such as regions B, C, D, I, J, and U, as compared to other regions in identified in this EIS. It should be noted that regions B, C, D, I, J, and U are regions in which more than 80 percent of covered produce is grown in the United States, and that a high percentage of the growers in these regions already participate in State or industry marketing agreements, some of which (e.g., CA and AZ LGMA, T-GAPs) already meet numeric agricultural water quality standards that are the same as, or more stringent, than what FDA proposes (see Table 2.1-1 in Chapter 2).

The ecology of estuaries is sensitive to the salinity of the water, which may be determined by low stream flows. Saline intrusion into the estuary would also affect fish catches. Saltwater intrusion into freshwater coastal rivers and aquifers is a challenge for water resource managers, and a reduction in water flow caused by water withdrawals (surface and groundwater) can accelerate the landward movement of the freshwater-saltwater interface (see Chapters 3.3.1.6 and 3.3.1.11). Increases in water withdrawals can result in saltwater intrusion, which then may result in impacts to aquatic plants and wildlife.

[13] http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide#toxicity

Vegetation and Wildlife

The natural vegetation and terrestrial, avian and aquatic wildlife that can be found in any region or localized area varies. While the exact vegetative and wildlife make-up depend on a variety of factors, water plays a key role. With respect to the organisms located on or near covered farms, stream corridors adjacent to these and other farm operations help to support the natural vegetation which provides habitat and food for wildlife. Agricultural practices such as irrigation consume water from either surface or groundwater sources, which may limit the availability of water for vegetation and wildlife resources adjacent to or downstream of the farm operation. As described in Chapter 3.1.3.5, there are interactions between surface and ground water. Changes in water source from surface water to groundwater may result in unintended impacts on surface water availability, which organisms rely upon.

A standard directed to agricultural water quality, may also increase the need for impaired waters to be treated in order to be brought into compliance with the standard. This has the potential to increase the chemical contamination of nearby waterways, and potentially impact local vegetation.

Wetlands

Wetlands by definition require water to support hydrophytic vegetation, hydrology, and hydric soils. Changes in water quality and availability have the potential to influence wetland functions and values. Specifically, water withdrawals from agricultural practices may influence water availability and, thus, influence wetland function and value (as a habitat). Generally, wetlands filter contaminants and nutrients from water sources, which have the potential to improve water quality conditions downstream of the wetland.

Soils – Standards directed to agricultural water, are not intended to have direct effects on soils. However, as described in Chapter 3.3.3.4, the USGS has identified that more than 80 percent of the identified subsidence in the nation is a consequence of groundwater exploitation. In many areas of arid western regions and in more humid areas underlain by soluble rocks such as limestone, gypsum, or salt, land subsidence is an often overlooked environmental consequence of land- and water-use practices. Figures 3.1-23 and 3.1-24 show the extent of excessive groundwater pumpage of aquifer systems throughout the U.S. which correlate to areas where land subsidence is most likely to occur. Actions that will increase reliance on groundwater, will potentially also impact soils. As soil can regulate the drainage, flow and storage of water and solutes, which includes nitrogen, phosphorus, pesticides, and other nutrients and compounds dissolved in the water, and as described in Chapter 3.3.3.5, soil plays a role in the removal of pathogens. An impact on soils resulting from groundwater drawdown may result in impacts that are in addition, but related to, irreversible compaction or subsidence, such as reduced ability to partition water for groundwater recharge and for use by plants and soil organisms.

Regions where groundwater withdrawal may have the highest influence on land subsidence, and thus permanent damage to soils, are B, C, D, I, J, and U. As discussed above under water resources, these regions all correspond to covered produce growing regions in the U.S. Therefore, impacts on groundwater resources, where steps are not taken to mitigate the impacts as discussed in Chapter 3.1.3.13, may result in irreversible impacts on soils and corresponding impacts on the ability of those soils to filter nutrients, chemicals and pathogens.

No significant adverse impacts on biological and ecological resources are identified with the decisions to switch the irrigation method to a non-contact method, to cease growing covered produce and to practice measures that could allow for die-off. Changes in irrigation methods would result in beneficial impacts due to improved moisture retainment due to lower soil water evaporation rates and may improve overall soil quality by reducing the erosive effects of wind and rain, and allowing organic material in soils to remain.

Use of Chemical Treatment to Bring Agricultural Water Sources into Compliance
As presented in Chapter 3.3.3.5, chloride is not adsorbed by soils and moves readily with the soil-water; is taken up by the crop; moves in the transpiration stream; and accumulates in the leaves. The chemical reactions that occur when chlorine and organic matter are exposed to each other also produce toxic and carcinogenic by-products. The use of antimicrobials, however, would not be expected to exceed the threshold that would be toxic to crops, as long as labeling requirements are followed for application purposes, and adverse effects to crops from overexposure to chemical treatments should not occur. However, there is concern regarding chronic effects of large-scale and long-term use of such products.

Switching water source
As discussed previously, FDA has received public comment asserting that covered farms consider it more feasible to switch water sources under Alternative II, than under Alternatives I or III. Soil types influence the selection of irrigation methods and irrigation schemes. Many farms use a sprinkler or drip irrigation scheme when the land contains a variety of soil types. The effect of switching from surface sprinkler irrigation to surface furrow irrigation can negatively affect soil structural properties due to over wetting and nutrient availability due to wetting pattern concentrating nutrients in a limited area. A change in water source from surface to groundwater could negatively impact soils by affecting soil structure resulting from aquifer consolidation. Regions that may experience adverse impacts to soil structure through land subsidence, which is not reversible, primarily if Alternative II is finalized, include regions B, C, D, I, J, and U as discussed earlier in this section.

Waste Generation, Disposal, and Resource Use – Standards directed at agricultural water would not result in waste generation or resource use beyond those described above for water. As such there would be no impacts in this resource component for any alternative.

Air Quality and Greenhouse Gases – Standards directed at agricultural water would primarily be expected to impact air quality and greenhouse gas (GHG) emissions if the management decisions result in an increase in energy use (because of the burning of fossil fuels) in order to operate irrigation equipment (e.g., groundwater pumps), and other agricultural equipment associated with post-harvest operations (wash and cooling water). As discussed in Chapter 3.5.3, in 2008, approximately 49 million acres of U.S. farmland were irrigated with pumps powered by liquid fuels, natural gas, and electricity (USDA CCPO, 2011). Electricity was the main power source for these pumps, costing $1.5 billion to irrigate about 30 million acres. Diesel fuel was used to power pumps on about 13 million acres and natural gas was used on about 4.7 million acres (USDA NASS, 2009b).

Although electricity generation is often analyzed as a major source of GHG emissions, electricity is ultimately consumed in different economic sectors. Electricity-related GHG emissions are mostly distributed among the industrial, transportation, commercial, and residential economic sectors. According to the EPA, in 2012 electricity-related emissions were responsible for approximately 62.2 Tg CO_2 Eq. of the 676.3 Tg CO_2 Eq. total GHG emissions from all uses in the agricultural sector. This represents only three percent of the total GHG emissions attributed to the electric power industry in 2012 (EPA, 2014k).

As discussed in Chapter 3.5.3, the primary non-attainment areas for NAAQS in areas where covered produce are prevalent are due to non-attainment for PM_{10}, $PM_{2.5}$ (based on EPA Green Book data) and ozone (based on the current 2008 standard and the maintenance areas associated with the older 1997 standard). These regions are illustrated in Figure 3.5-3, 3.5-4, and 3.5-6 respectively (EPA, 2014i). The highest concentrations of particulate matter and ozone non-attainment areas that overlap with covered produce operations occur in central and southern California (regions C and D).

Standards directed at agricultural water are not expected to result in significant environmental impacts regardless of the management decision that is chosen. Some management decisions may result in minimal impacts as discussed below, but none is expected to be significant because such decisions would not be expected to occur in areas where the contributions along with other emissions would contribute to exceedances of the NAAQS standards and/or increase GHG emissions, which could not be mitigated using existing practices for managing GHG emissions.

Use of Chemical Treatment to Bring Agricultural Water Sources into Compliance

Applying a chemical treatment to contaminated agricultural waters is not anticipated to impact air quality and greenhouse gases on a national scale as there would be no foreseeable measureable change to the air quality environment by adopting this mechanism to comply with the standard.

It is anticipated that there would be minimal localized impacts dealing with chlorine-based chemical products and byproducts in regions where covered produce is heavily concentrated. There is the potential for an increase in localized vehicles-miles-traveled for hauling chemicals to farms. Certain regions in the U.S. that include non-attainment or maintenance areas (e.g., California) would be sensitive to these potential localized impacts on criteria air pollutants (NAAQS), and other federal or state regulations on hazardous air pollutants would apply.

Substances that may be used in crop production, such as, calcium hypochlorite, sodium hypochlorite, and chlorine dioxide, are all synthetic materials not found in nature. Neither calcium hypochlorite nor sodium hypochlorite is persistent in the environment. When released to air, these substances are broken down by sunlight to compounds commonly found in the air. Chlorine dioxide is not persistent in the environment. Chlorine dioxide is a very reactive and breaks down quickly. In air, sunlight rapidly causes chlorine dioxide to break down into chlorine gas and oxygen (USDA AMS, 2011). In water and soil, sodium and calcium hypochlorite separate into sodium, calcium, hypochlorite ions, and hypochlorous acid molecules. Calcium hypochlorite and sodium hypochlorite are not bioaccumulative (USDA AMS, 2011).

Switching the irrigation method to a non-contact method

Switching irrigation methods to non-contact systems can lead to differences in CO_2 and criteria pollutants depending upon the energy source requirement for the irrigation method, although the direction of change may vary depending on the changes in energy use and management practices involved. Any anticipated impacts would be speculative, but may be considered not significant, especially if the management decision results in switching from a sprinkler method where water is broadcast widely to a less energy intensive method.

Switching water source

Changing the normal irrigation method due to contaminated agricultural waters is not anticipated to impact air quality and greenhouse gases on a national scale, as there would be no foreseeable measureable change to the air quality environment by adopting this mechanism to comply with the standard. Based on 2007/2008 statistics, FDA estimates that 18.36 percent (7,440) of affected produce farms use irrigation. It is also estimated that slightly less than half of those produce farms apply irrigation water during the growing season (FDA, 2013b).

There may be localized impacts on CO_2 emissions if there were a potential increase in energy use from pumping by switching the form of irrigation. There could also be a decrease in energy use from switching from a spray/contact irrigation method to a non-contact method where the system is fed by gravity rather than pumping or where there is less demand for energy through electricity or alternative fuels. Finally, changing the irrigation method could lead to reductions in particulate matter emissions due to less soil disturbance, or may increase dust-related particulate matter due to potentially drier soil surfaces. These issues are highly localized and are irrigation method dependent, and may be overall not significant issues.

Socioeconomics and Environmental Justice – Potential socioeconomic impacts that are associated with meeting the requirements for standards directed to agricultural water could stem from economic costs that result from management decisions to comply with the standards. Such decisions could include changing irrigation methods, water source, testing of samples and/or the treatment of water to bring it in to compliance with the rule. These costs are dependent on the chemical treatment technology chosen; the level at which the water source is contaminated; the amount of time the treatment would need to take place; and the type of water source being treated. These variables change the cost for each farm that may be potentially affected. Any related environmental impacts resulting from the cost of implementation are those that would result from management decisions or changes. FDA has proposed and plans to finalize a rule with multiple provisions aimed at a variety of potential routes of contamination of produce for human consumption. The economic cost of an individual provision, based on costs that result from a management decision and associated environmental impacts, would not likely be sufficient to result in changes that could impact the environment. Socioeconomic and environmental justice issues, will be addressed cumulatively (with respect to provisions of the rule) under Chapter 4.7.

Environmental Justice –

In addition to the cumulative discussion in Chapter 4.7, we note that standards directed at agricultural water have the potential to adversely impact a) minority or low income groups if populations are situated in areas that see in increases in secondary routes of exposure to pesticides or other chemicals used to bring water into compliance at concentrations that are sufficient to result in adverse health impacts (note that there is not enough data to establish where such impacts may occur, therefore, potential impacts to minority or low income populations that are not principal farm operators or farmworkers are not assessed (reference Chapters 1.9 and 3.7.3); or b) minority or low income principal operators or farm workers if there is an increase in pesticide use for which they are responsible. As discussed below, there are no impacts anticipated on human health as a result of secondary or worker exposure to pesticides. Therefore, there are also no anticipated significant impacts on minority groups.

Human Health and Safety – As discussed earlier, agricultural water is a source of pathogen contamination for produce. Standards directed at agricultural water are intended to establish "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 Food Drug and Cosmetic (FD&C) Act." (78 Fed. Reg. 3504) Any standard established under this statutory mandate would be expected to have significant beneficial impacts on human health.

In addition to the intended beneficial impacts on human health, there is the potential for adverse impacts on human health related to worker safety, secondary routes of exposure to pesticides, air quality effects which may arise from chemical treatment, changing the irrigation method to non-contact method, changing the water source, and ceasing to grow covered produce.

No adverse impacts on human health would be expected as a result of the decisions to switch the irrigation method to a non-contact method, switch water source, or use post-harvest mechanisms to allow for die-off and/or removal. Some minimal adverse impacts may be associated with the use of chemical treatment to bring agricultural water sources into compliance with any of the alternatives' water requirements, or switch to agricultural commodities that are not covered by the rule (cease growing covered produce). However, all management decisions would be expected to result in significant beneficial impacts on human health based on a reduction in the exposure to potential pathogens. FDA estimated that 240,347 foodborne illnesses attributable to growing/ harvest (g/h) agricultural water and 281,736 foodborne illnesses attributable to postharvest (ph) agricultural water would be prevented through finalizing the requirements of the provision as proposed in the 2013 proposed rule. This equates to an estimated 19.31 percent reduction in the risk of foodborne illness attributable to covered produce (FDA, 2014b).

Use of Chemical Treatment to Bring Agricultural Water Sources into Compliance
Chemical treatment of contaminated agricultural water and its associated health benefits (in reduced illnesses) may be tempered by the potential health-related impacts from chemical contamination of produce, soil, and surface water resources (presenting so called secondary routes of exposure). The chemical treatment of agricultural water to achieve the water quality standard would reduce the potential pathogenic contamination of produce. If approved products are used in accordance with labeling requirements, chemical contamination is not expected to pose a human health risk.

As discussed in Chapter 4.1, FDA does not have specific information on the pesticides that would be submitted to EPA for registration for uses to control pathogens in agricultural water applied to produce. However, as described in greater detail in Chapter 3.1, the most commonly used antimicrobials 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 seek FIFRA registration. Using chlorinated products for chemical treatment could produce unsafe byproducts in the form of THMs when the chlorine comes into contact with organic compounds.

Regions that would potentially require a higher level of chemical treatment because they already experience high exceedances of surface water quality include regions A, B, C, L, R, T, and U (compare Figures 3.1-16 and 3.1-17 in Chapter 3.1.3.9 to Figure 1.7-4). While this may result in significant impacts due to the formation of THMs, these impacts are mitigated by the ability of covered farms to choose other management decisions, particularly switching water sources, switching the irrigation method to a non-contact method, or adding mechanisms to account for microbial die-off in the field and post-harvest.

There is the possible risk of chemical exposure to site workers that may have to handle the chemicals prior to application to agricultural water, but these risks are minimized when using proper handling techniques described by the manufacturer.

Because the treatment of contaminated agricultural water would satisfy the water quality requirement, which minimizes foodborne illnesses, the anticipated impact would be beneficial. The risk of acute chemical exposures to agricultural workers would be minimized by proper product handling; therefore, the risk from chemical exposure would be low. There may be some minimal to moderate adverse risk associated with exposure to harmful byproducts, but there are no data to support the transport of such chemicals through the environment to reach people who would potentially consume these products in drinking water.

Cease growing covered produce

Potential consequences if growers were to switch to non-covered crops (i.e., non-covered produce or agricultural crops that are not produce) or let certain land lay fallow may include growers switching to non-covered crops that require different management practices such as the addition of fertilizer and pesticides, or crops that would be commercially processed. If new crops require additional inputs, water and soils could be adversely impacted. However, if growers were to switch crops to avoid complying with the final rule, they would likely select a crop that would require similar management practices to what they presently employ, in order to reduce the capital costs associated with the switch. However, we would anticipate that only a small number of growers (presently unquantifiable) operating near the margin between very small farms and excluded farms, may make such a management decision to cease growing covered produce altogether.

Conclusions –Ultimately, the finalized standard, in conjunction with the existing water source, local water source availability, and water quality will play a role in influencing the management decisions that are chosen. More stringent numeric standards and those that do not allow for microbial die-off to be accounted for will increase the likelihood of chemical or other treatment of the water or permanent or semi-permanent changes in water source or irrigation method. No management decision is expected to be absolute. Farmers across the nation are expected to select their preferred management decision based on their unique conditions. The ability for farmers in localized regions to select different management decisions will ultimately play a role in mitigating the overall impacts of the rule. The anticipated impacts for each alternative are described and compared below under Alternatives Analysis.

4.2.1 Alternatives Analysis

This section provides a comparison of alternatives that FDA considered under Subpart E, and relates the potential environmental impacts from a grower that may select a particular management decision, as discussed at the beginning of this section.

<u>Alternative I. Preferred</u>

<u>As Proposed. GM ≤ 126 CFU generic *E. coli*/100 ml and STV ≤ 410 CFU/100 ml</u>

This alternative includes adding a mechanism(s) to account for microbial die-off and/or removal, so incorporating practices or measures that result in microbial die-off and/or removal is expected to be the preferred management decision. There would be an anticipated one-time capital cost associated with implementing some of these possible practice or measures, such as a post-wash system, and/or long-term maintenance and product costs; however, these costs are anticipated to be relatively minimal as compared to potential long-term treatment costs, or the capital costs associated with other management decisions assessed.

Beneficial impacts are anticipated to human health as a result of reducing the potential for pathogens to contaminate produce and cause foodborne illness.

If a grower were to choose to use chemical treatment to bring water into compliance, sustained, long-term water treatment may not be required because the added flexibility to account for die-off and/or removal is anticipated to result in few, intermittent impacts that are not significant because these steps may be as simple as allowing sufficient time between final application of agricultural water in the field and harvest, which and are not expected to result in significant increases in demand for water or other resources.

As discussed under water resources above, disinfectants may be useful for reducing hazards that may cause foodborne illnesses; however, many of these disinfectants may form harmful byproducts. EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. Disinfection byproducts are a well-recognized hazard that would be considered as part of the analysis. Therefore, as long as the pesticides are handled and applied according to label directions, no significant adverse impacts would result.

Adverse effects related to the use of chemical treatments, such as pesticides, may be limited because a high number of growers in key growing regions, such as California, Arizona, and Florida, participate in marketing agreements that have more stringent water quality standards than what FDA has proposed and are already using water that would be in compliance with the proposed standard.

Under this alternative, switching water source and ceasing to grow covered produce are not expected to be preferred management decisions. As discussed under the No Action Alternative, while there may be current and on-going significant adverse, long-term impacts from lowering the water table, deteriorating water quality, and land subsidence, each resulting from further groundwater withdrawals, such switches to groundwater are already occurring and causing significant adverse impacts that would be independent of the proposed water standard. Any action that may lead to increases in groundwater drawdown, would be considered a significant environmental impact. Regions that may be most impacted in terms of potential land subsidence, including any additive effects by switching to groundwater sources, include the regions that already experience the highest groundwater withdrawals; these are regions B, C, D, I, J, and U. Due to the added flexibility to account for microbial die-off in the field under Alternative I, coupled with the knowledge that a high amount of potentially affected growers participate in marketing agreements with more stringent numeric water quality standards than what FDA proposes, any potential effects related to Alternative I are not expected to contribute to the current adverse conditions to the extent that would occur under Alternatives II, III or IV.

Alternative II.
GM of no more than 126 CFU (or MPN)/100 mL and a single sample maximum of 235 CFU (or MPN) generic *E. coli* /100 ml single sample or a GM of no more than 126 CFU (or MPN)/100 ml

Under this alternative, switching water source is expected to be the preferred management decision. As compared to Alternative I, this alternative would not have the added flexibility to account for microbial die-off and/or removal; therefore, farmers are more likely to decide to switch water sources, particularly away from surface waters to a cleaner source. If the cleanest available source is groundwater then existing significant adverse conditions (i.e., water drawdown, potential subsidence, and the related continued degradation of water quality) may continue to be exacerbated but to a greater degree than Alternative I, because the water quality requirements would be more stringent under this alternative and more farms are potentially likely to switch to the groundwater source in numbers that may considerably influence groundwater sources. These impacts are expected to be limited to localized regions and are not expected to be widespread. The regions that may be most affected are B, C, D, I, J, and U (as previously identified at the beginning of this section and in Chapter 4.1). These regions may also experience irreversible effects to soils. Therefore, these impacts under Alternative II related to lowering the water table, deteriorating water quality, and land subsidence, are considered significant adverse. Native American Tribes may be disproportionately impacted as groundwater drawdown could have potential environmental impacts including socioeconomic impacts related to access to water on reservations, particularly in regions B and J. Such impacts would be considered significant adverse.

Capital costs related to any switch may be especially burdensome for very small businesses.

Treating any source to remove harmful pathogens would have an added public health benefit by reducing the potential for foodborne illnesses.

Compared to Alternative I, the likelihood of a grower selecting a new water source may be higher due to the lack of added flexibility to account for microbial die-off and/ or removal.

There would also be greater potential for the use of chemical treatments to bring water into compliance under this alternative relative to Alternative I. With respect to chemical treatments, this alternative is anticipated to have more adverse environmental consequences than Alternative I, but not to a significant level because as previously stated all pesticides must be registered by EPA and must be found to not generally cause unreasonable adverse effects on the environment. However, without the added flexibility for die-off that is afforded under Alternatives I or III, regions that potentially require a higher level of chemical treatment include A, B, C, L, R, T, and U (compare Figures 3.1-16 and 3.1-17 in Chapter 3.1.3.9 to Figure 1.7-4). Long-term, sustained treatment of water sources may result in adverse, but not significant impacts to water quality due to the potential for THMs (see Chapter 3.1.3.9) to be formed and also result in no significant adverse long-term effects to biological/ecological resources and air quality from chemical treatments. These impacts are not anticipated to be significant because the effects may be reversible and are not permanent effects.

The use of more chemicals to treat water sources also result in slightly higher costs for growers, but not to a significant level.

The risk of adverse impacts to human health relating to the increased use of chemicals would not be significant and may be mitigated as long as labeling requirements are followed, as the FIFRA registration process considers risk to human health and establishes handling processes that are appropriate to minimize such risks. The possibility of potential impacts from THMs to be formed may occur in regions that may require the highest treatments (see above), but because transport of such toxins is not well known, these impacts cannot be well defined. Overall foodborne illnesses are expected to be reduced compared to Alternative I.

<u>Alternative III.</u>
<u>As proposed (i.e., Alternative I), with an additional criterion establishing a maximum generic *E. coli* threshold</u>

This alternative would be substantially similar to Alternative I, however, the implementation of a threshold may mean that there may be circumstances when a farmer is not be able to account for microbial die-off and/or removal. Such circumstances, however, would be dependent on the numerical criterion of the threshold. Therefore, the likelihood that a farmer may decide to treat water is slightly higher than Alternative I. It is, however, more likely that the farmer would first select to add a post-harvest mitigation step to account for additional die-off.

Any economic effects of treating contaminated water sources may be considered long-term because while treatments need not be applied throughout the growing period, the overall quality of the water source is a long-term issue and treatments may need to be applied during every growing season.

As stated above, all pesticides must be registered by EPA and must be found to not generally cause unreasonable adverse effects on the environment; and, so long as such products are used in accordance with their labeling requirements (the FIFRA registration process considers risks to human health), any adverse environmental and human health impacts related to treating poor water quality may be considered not significant.

As compared to Alternative I, establishing a maximum threshold for generic *E. coli* may cause some growers in a region where the water quality is poorest to potentially shift from growing covered produce, but not to the degree that may occur under Alternative II. These potential shifts are mitigated by the fact that existing marketing agreements in the most impacted regions already operate with more stringent water quality standards, and also account for more than 80 percent of the growers of produce that would be covered by the rule.

Alternative IV.
Alternatives for direct water application method

As previously stated, Alternative IV allows for the standards considered under Alternatives I through III to include or exclude root crops. The analysis of Alternatives I through III, assumes that they exclude root crops. Therefore, the impacts for each of those alternatives would be greater under Alternative IV due to the fact that more crops would be covered under the standards directed at agricultural water.

Chemical treatments may have similar but slightly greater effects compared to Alternatives I, II and III due to the increased types of covered produce, in terms of environmental quality and related costs.

4.3 Subpart F / Untreated: Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste - Untreated Proposed § 112.56(a)(1)(i)

FDA's rationale for proposing Subpart F

It has long been recognized that pathogens can be introduced to fruit and vegetable production systems by the application of manures or sewage sludges as fertilizers (Schlech et al., 1983). Fecal material has been shown to contain human pathogens (Jiang and Shepherd, 2009; Kudva et al., 1998; Pell, 1997; WHO and UNEP, 2006, Zhao et al., 1995), and the use of manure containing soil amendments as an agricultural input increases the likelihood that produce may become contaminated (Jiang and Shepherd, 2009). Soil amendments, partially composted manure, raw manures or teas made from such materials are potentially significant reservoirs of human pathogens.

Proposed Subpart F establishes standards directed to treated and untreated BSAs of animal origin and human waste. These standards include requirements applicable for determining the status of a BSA of animal origin; procedures for handling, conveying, and storing BSAs of animal origin; provisions regarding the use of human waste in growing covered produce; acceptable treatment processes for BSAs of animal origin applied in the growing of covered produce; microbial standards applicable to treatment processes; application requirements and minimum application intervals; requirements specific to agricultural teas; and records requirements (21 CFR Part 112).

Notwithstanding the associated health benefits from implementing the proposed BSA standards, FDA, in the 2014 supplemental proposed rule, proposed removal of the 9-month minimum application interval for use of raw manure in proposed § 112.56(a)(1)(i) (79 Fed. Reg. 58434). FDA is deferring its decision on an appropriate time interval until it pursues certain actions, including a robust research agenda, risk assessment, and efforts to support compost infrastructure development, in concert with the USDA and other stakeholders (79 Fed. Reg. 58434).

Following the completion of the risk assessment and research work, FDA expects 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 establish an appropriate minimum application interval(s).

FDA also acknowledged the comments that pointed out that many growers currently employ the organic program standard of 90 days or 120 days, as specified in 7 CFR 205.203(c)(1), and in the preamble to the supplemental proposed rule stated that such growers will likely continue their current practice to use this standard in organic crop production, even in the absence of an FDA regulation that establishes a food safety standard for minimum application intervals associated with the use of raw manure. In addition, FDA noted that given that the scientific literature demonstrates that the probability of pathogen survival decreases as the length of time between application of raw manure and harvest increases, and that more rapid die-off occurs during the months immediately following application (e.g., 3 to 4 months) as compared to subsequent months (followed by prolonged survival of pathogens at low levels), FDA believes adherence to the organic regulation standard to be a prudent step toward minimizing the likelihood of contamination while the above described research program is ongoing. FDA further indicated that, at this time, the Agency does not intend to take exception to the continuation of this practice.

With respect to this EIS, FDA determined it is still appropriate to evaluate the potential environmental impacts from implementing an application interval under proposed § 112.56(a)(1)(i) (including alternatives identified in Chapter 2.1), because FDA intends to finalize this provision at a future point in time. Such analysis has value in order to establish or improve upon the methodology for identifying environmental consequences, costs, and risks associated with implementing the action that FDA proposed in its 2013 proposed rule or one of its alternatives in the future, at a time when FDA has completed its research, risk assessment, and public outreach. Including the analysis further allows FDA to evaluate the cumulative potential impacts of the final action. At that time, it may be necessary to either update the Record of Decision (ROD), or prepare a NEPA re-evaluation or supplemental statement in accordance with 40 CFR § 1502.9(c), based on FDA's findings.

In terms of conducting the environmental impact analysis described in this document, FDA used available baseline data as provided by USDA's NASS Surveys as presented in Chapter 1.9 and 2.1 Subpart F; and information presented in Chapter 3.4 Waste Generation, Disposal, and Resource Use (as well as related environmental information with respect to water resources (Chapter 3.1), Soils (Chapter 3.3), and Air Quality and GHGs (Chapter 3.5). This information includes where raw manure is generated with respect to produce that would be covered by the PS PR; how raw manure is applied (also discussed in Appendix C); and regulations and industry guidance that govern the use and application rates of raw manure. Other information that was used to support our analysis includes the hazard classification, exposure assessment, and routes of contamination information presented in the draft QAR (FDA, 2013c), and the related economic and foodborne illness discussions presented in the Preliminary Analysis of Economic Impacts (and supplemental) (FDA, 2013b and 2014b). Finally, other sources of information with respect to raw manure and potential pathways of contamination that leads to foodborne illness, came from online information published by CDC (Chapter 1).

The following set of management decisions and alternatives applies to untreated BSAs of animal origin.

Management Decisions

The environmental impacts of standards directed to BSAs of animal origin and human waste - untreated are the result of management decisions a covered farm makes in order to comply with the standard. FDA has chosen to take a non-prescriptive approach when establishing standards under subpart F to allow for, and encourage, scientific advancement in the measures available to comply with the proposed rule.

As discussed under Chapters 4.1 and 4.2, FDA, in coordination with USDA, identified the reasonably foreseeable actions, or management decisions, that businesses potentially affected by any final rule might take in order to come into compliance with, or to potentially avoid being subject to, the alternatives under consideration for inclusion in the final rule. Under subpart F, FDA and USDA identified the following actions: switch to a treated (composted) material; use BSAs of non-animal origin; use chemical fertilizers; comply with the requisite waiting period (applies specifically to each alternative); stop growing covered produce; and, change the application method.

While all reasonably foreseeable alternatives have been identified, FDA is aware that some management decisions will likely be more preferable to covered farms, when a provision on untreated BSAs of animal origin (including an application interval) is finalized. In the interim, as FDA conducts a risk assessment and research to determine the appropriate application interval, it is difficult to identify which management decisions may be more preferable to covered farms. At such time as FDA finalizes a provision for standards directed at untreated BSAs of animal origin, the likelihood of operations taking certain management decisions will be reassessed based on the standard that is being finalized.

General background on resources related to the proposed provision

Much of the baseline information that is presented under this provision refers back to data presented in the No Action alternative (Chapter 4.1) and the baseline data presented in Chapter 3. This section summarizes the relevant baseline data needed to assess the potential environmental impacts for subpart F, specifically proposed § 112.56(a)(1)(i) when finalized to establish an appropriate application interval.

Approximately 12.5 percent of produce farms use BSAs of animal origin, and of those only roughly 18.5 percent use untreated (raw) manure; this equates to approximately 820 farms nationally, or 2.3 percent of the covered produce farms covered by the PS PR (FDA, 2013b). The estimated total acreage of produce farms that apply untreated BSAs of animal origin is 70,134 produce acres or 1.56 percent of total produce acres (FDA, 2013b) (see Chapter 2.1, Table 2.1-4).

Harvest intervals relative to BSAs of animal origin
Few fast-growing produce crops have harvest cycles of 45 days or less from planting of seed; a list of such crops appears in Table 3.4-5. Most fresh produce crops have full summer planting to harvest cycles, varying between 45 days and 120 days. While parts of the U.S. only get one crop per year (notably the northeastern regions such as region R), other parts of the U.S. (notably the subtropical regions C and U) can achieve multiple (i.e., double or triple) cropping within one year. Another consideration is that some produce crops have multiple harvest cycles (e.g., perennials or biennials such as caraway, fennel, mints, young sorrel, and strawberry (Donezal, 1991), which could allow successive harvests in less than 45 days.

While most crops have a seed-to-harvest interval of approximately four months, intervals for application of BSAs of animal origin to crop harvest vary based on the applicability of federal law (i.e., organic regulations) and industry marketing agreements and when none exist or are not chosen to be followed, individual grower's decisions. USDA organic regulations have shorter application to harvest intervals (90/120 days), while some marketing agreements may have application to harvest intervals of up to a year (Chapter 3.4.3.3). FDA found no data regarding whether BSAs of animal origin are commonly applied between the harvest intervals for crops with shorter seed-to-harvest durations (i.e., between double- or triple-cropping intervals), or if other soil amendments, such as chemical fertilizers, may be used during these periods.

Water Resources – Information on water quality and availability is important for establishing potential impacts under this provision.

Standards directed at BSAs of animal origin and human waste are not intended to have a direct impact on water resources. However, indirect effects may occur if as a result of the standards, BSAs are stored or applied in a manner that increases nutrient transport or by altering soil water content.

Produce growing areas of the U.S. are routinely irrigated where natural rainfall does not supply optimal growing conditions, as discussed in Section 3.1 (more than half of vegetable production is from irrigated land). Runoff from precipitation or irrigation tail water (where flood and furrow practices are used) could contain excess nutrients leached or in the form of eroded soil particles, that can enter surface water. The use of BSAs of animal origin over time increases the moisture capacity of soils that in turn would reduce the irrigation requirements of the crops.

Biological soil amendments of animal origin are potential vectors of pathogens harmful to human health. Soil water content is a factor that influences the survival rate of harmful pathogens, (Abu-Ashour et al., 1993). Water soil content is, however but one of many factors that influence pathogen survivability; others include soil physical and chemical properties, and normal atmospheric or climate conditions for the region. Water-soil interaction is discussed in greater detail in Chapter 3.3.

Indiscriminate storage, application or disposal of BSAs of animal origin, irrespective of region, presents the possibility of contamination of both surface waters and of groundwater with harmful pathogens and other contaminants.

Depending upon how and when BSAs of animal origin are incorporated into soils, transport of nutrients and harmful pathogens may increase; for example, if a grower tills the soil after an untreated BSA application there is a reduced chance that runoff will carry nutrients into surface water supplies. Conversely, if untreated BSAs are applied to the soil surface (such as during a fall application) and are not incorporated, there is a higher chance for harmful pathogens along with the nutrients associated with untreated BSAs (e.g., nitrogen) to contaminate surface waters and downstream biological receptors. Pathogen survival, however, is inversely correlated, meaning, incorporated pathogens survive for a longer period, while those present in unincorporated manures die off more rapidly due most likely to exposure to elements (such as desiccation and UV irradiation). The possibility of nutrient loss to runoff and erosion is greater with early fall application or winter application especially where late winter or early spring melt events result in runoff (Heartland Regional Water Coordination Initiative, 2006).

Water resources used for irrigation may have some indirect influence on pathogen survivability as well; for example, where furrow irrigation is involved, even in drier climates (that receive less than 20 inches of rainfall per year), the moisture content of the soils may promote longer pathogen survivability in the soils; however, the filtering qualities of soils may restrict passage of those pathogens to the plant.

Harmful pathogens relative to the rule can persist in livestock and poultry. Regions where CAFOs operate and generate BSAs of animal origin relative to the rule, and relative to where covered produce is grown, include regions A, B, C, D, J, L, M, P, S, U, and V (See Figure 3.4-1).

Forty-five states regulate the application of BSAs of animal origin through Nutrient Management Plans to help protect water quality by requiring proper application rates, thereby reducing the potential for adverse water quality impacts. States that do not require such plans include Alaska, Hawaii, Connecticut, Nevada, and Wyoming.

The wide range of waiting periods represented by the alternatives (0 to 12 months) would increase the likelihood that a management decision would be selected and thus increase the range of potential environmental impacts from the action. The most likely management decision to be chosen in order to comply with Alternative II, i.e., a waiting period of 0 days, would be a change in application methods as the standard would still require that the BSA of animal origin must be applied in a manner that does not contact covered produce during application. The waiting period under Alternative III is identical to those required under the National Organic Program and many farms which use untreated BSAs of animal origin would already be expected to be complying with the National Organic Program standard. Alternatives II and III would establish shorter waiting periods, relative to the originally proposed Alternative I (decision subsequently deferred), would mean that waiting the requisite time period would be more feasible. Alternatives I, IV and V, which would establish longer waiting periods of 9 months, 6 months, and 12 months, respectively, mean that management decisions that would result in switching to BSAs of non-animal origin, treated BSAs or chemical fertilizers would be more attractive to growers. The potential impacts on water resources would depend on both the alternative and the management decision chosen.

As discussed previously, only 12.5 percent of all covered farms use any type of BSAs of animal origin and only 2.3 percent of covered farms use untreated BSAs; most farms are already using chemical fertilizers. Therefore, the potential for increase in the use of chemical fertilizers is limited. When applied properly and given the small percentage of farms that could switch from untreated BSAs, adverse impacts to water resources would not be significant. Although switching to treated manure or BSAs of non-animal origin may have an impact on the crop yield, it is more likely that irrigation requirements are the limiting factor and would remain fairly constant since no additional water is required in the treatment or application process; therefore, as long as nutrient management plans are followed, there would be no impacts to water resources. The potential impacts on water resources, if farmers stop growing covered produce, are dependent upon the new use of the land. Such decisions are made by a farmer and may vary by year, the equipment and farm set-up the farmer has that could be used to manage a new particular crop (without incurring extensive capital costs), and many other factors. It would be speculative to try to assume what these decisions would be.

Comply with requisite waiting period

Increasing the storage time between applications could have an adverse effect on the quality of water resources as the potential for runoff becomes more likely over time, increasing the nutrient loads for nearby surface water sources. A mix of State and local agencies, working in series with USDA conservation districts, oversee individual nutrient management plans for farms (including for CAFOs and farms that grow produce that would be covered by the rule). These plans, in part, provide application rates for efficient use of the product. Manure is typically managed to avoid over-application of target nutrients (nitrogen or phosphorus) as part of a Clean Water Act strategy (CWA is regulated by EPA). Time-of-year restrictions, application procedures including incorporation and setback distances, and other measures are primarily intended to avoid eutrophication of surface water and contamination of groundwater with limiting factor nutrients.

Although the switch to a requisite waiting time may have an impact on which crops are grown, it is likely that irrigation requirements are the limiting factor and would remain fairly constant since no additional water is required, which would likely result in the nine month waiting time having a moderate but not significant adverse impact on water resources due primarily to increases in nutrient runoff.

Change application method

If untreated BSAs of animal origin are injected directly into the soil, there is opportunity for less runoff into nearby waterways. Less runoff means better water quality, and a potential for improved watershed nutrient load into receiving waters. There may be an overall reduction in nutrient load to the ecosystem, which would be a low level beneficial impact on both local and national levels.

Biological and Ecological Resources – These resources are part of a larger ecosystem and are affected by, and help determine, the quality of the natural environment.

Vegetation

BSAs of animal origin are used in farming operations to provide nutrients to agronomic crops. These nutrients, if allowed to interact with non-agronomic plants through direct application or runoff, will affect the growth and health of vegetation adjacent to application sites. Nutrient runoff into surface waters has the potential to cause algal blooms and other unwanted consequences. Algal blooms can result in die-offs in aquatic plant and animal species as well as other algal species due by limiting available sunlight or oxygen. They may also result in the production of toxins that can have adverse impacts on other species.

Wildlife

The application of BSAs of animal origin have indirect impacts on wildlife through the nutrient uptake by vegetation and the resultant growth of this vegetation that provides food and shelter opportunities for wildlife species. The nutrient input to ecological systems may potentially alter the ecosystem, favoring one group of wildlife species over another. Untreated BSAs of animal origin potentially contain pathogens that may adversely affect wildlife species.

Wetlands

The quality of the water entering a wetland system would be adversely impacted if nutrient- or pathogen-laden BSAs of animal origin contaminated surface or groundwater sources. A change in water quality has the potential to impact wetland function and value (as a habitat). Many wetlands have the potential to filter and thereby improve water quality downstream of the wetland.

While nutrient runoff would play a significant role in the potential impacts on biological and ecological resources resulting from standards directed at untreated BSAs, these standards also have the potential to impact biological and ecological resources in other ways.

Switch to treated materials
The scale of a potential change (i.e., increase usage) from untreated to treated BSAs, relative to the current practice is unknown; however, the volume of treated BSAs, relative to current usage (most farms use chemical fertilizers or may be trending toward green manure or other practices) is not expected to increase substantially (only potentially 2.3 percent of all covered farms nationwide could be impacted). Therefore the effect on biological and ecological resources would be expected to be minimal, and not significant relative to baseline conditions. The proper application of treated BSAs would not adversely impact biological or ecological resources differently than the use of untreated BSAs.

Implementation of this management decision is unlikely to have an adverse impact on wildlife resources on a national level.

Due to the application of dried material with reduced moisture content from composting, there is a potential risk of airborne and windblown material to have continued low adverse offsite impacts on receiving water bodies relative to the existing condition. The result of this may potentially contribute to a minimal degradation of overall water quality and may have short term minimal impacts to aquatic organisms. This impact is not expected to reach a level where it would be considered significant due to the relatively low number of farms nationwide that may be impacted (approximately 2.3 percent of all covered farms).

Aquatic organisms, including fish, amphibians, and insects may be adversely impacted by reduced water quality as a result of contaminants contained within air emissions and runoff from treated areas being introduced into surface waters. Increased storage of BSAs of animal origin could potentially lead to increases in off gassing and nutrient run-off as well as a reduction in nutrient availability post application. The effects of nutrient runoff may be mitigated by the requirements of a facility's NPDES permit, where applicable.

Switch to BSAs of non-animal origin

The application of BSAs of non-animal origin would have no impact on vegetation, wildlife on a national level.

If peat is mined to be used as a BSA of non-animal origin, this impact would be considered a permanent high adverse impact to the environment because the extraction rate far exceeds the rate of regrowth. For this reason, peat is usually not considered a renewable resource. Mining peat bogs is also not ideal for wetland habitats as it takes away from a wetland's natural state and degrades the integrity of a wetland. Emissions from both burning and transporting peat are an environmental concern.

Switch to chemical fertilizers

As stated above, the use of chemical nutrients may have a potentially adverse local effect on the environment, including the surrounding waters due to potential runoff if proper precautions are not taken. Excess nutrients from applications of chemical fertilizers in the form of runoff may flow into streams and enter water systems, causing damage to aquatic ecosystems that may include eutrophication and algal blooms. The improper storage of chemical fertilizers may also pose risks to biological and ecological resources, specifically surface and groundwater resources. If proper application and chemical storage precautions are not taken, the use and storage of chemicals may have a potentially adverse effect on the environment, including surrounding waters. However, it is not possible to predict where such impacts may occur, or whether they would represent an increase over those impacts resulting from the use of untreated BSAs of animal origin, as they would be dependent on a variety of factors including soil conditions, application rate, time and method of fertilizer application, and current nutrient levels in surrounding waterways.

Comply with the requisite waiting period

Nutrients or other contaminants associated with the improper storage of BSAs of animal origin may make their way into surface or groundwater resources, indirectly impacting ecosystems on a local level. If excessive amounts of BSAs of animal origin are applied in a single application event (to use up stored BSAs of animal origin) aquatic organisms, including fish, amphibians, and insects may be adversely impacted by reduced water quality as a result of contaminants (nutrients, pathogens, etc.) being introduced into surface waters. Increased storage times could potentially lead to increases in off gassing and nutrient run-off as well as a reduction in nutrient availability. Federal, State, and local laws and regulations concerning the use of soil amendments, will minimize any potential impacts to this resource to a level that is not significant.

Stop growing covered produce
The change from one crop to another may have beneficial impacts on biological and ecological resources. Changing from covered produce to non-covered produce may be beneficial because, similar to crop rotation, changing crops provides for a form of natural pest reduction through diversity. When the same type of crop is grown in the same field repeatedly, pest populations of that crop tend to build up, sometimes to levels that require chemical inputs above those used for past crops. Crop diversity is a part of the preventative pest management program (PMP); therefore switching to a non-covered produce may reduce the amount of chemical inputs, which may have a low beneficial impact on biological and ecological resources.

Change the application method
If untreated BSAs of animal origin are applied directly to the soil surface or injected directly into the soil, there is opportunity for less runoff into nearby waterways. Less runoff means fewer algal blooms, better water quality, and a potential for improved watershed nutrient load into receiving waters. There may be an overall reduction in nutrient load to the ecosystem, which would provide limited beneficial impacts that are not significant on both local and national levels.

Soils – For decades, chemical fertilizers have been an essential component in the production of crops used for food. Use of chemical fertilizers peaked in the early 1980's, and dropped when the largest users (grain growers) lost some market demand for grain. Since that time fertilizer prices have fluctuated, but generally remain consistent with the fluctuation in energy prices. More recently, U.S, farmers have moved toward single-nutrient fertilizers that contain a relatively high level of a certain nutrient needed specifically to enhance a soil quality or crop requirement (USDA ERS, 2013c).

While chemical fertilizers are useful for adding certain depleted nutrients to an agricultural field, if not properly applied, excess chemicals may leach to groundwater, enter tailwaters, or generally run-off into receiving surface waters. Chemical fertilizers also do not promote good soil health, and do not contribute to building healthy soil structure (see Chapter 3.3.3.6 and USDA NRCS, 2013a).

USDA organic regulations limit for certified organic farmers, the use of chemical fertilizers.

The use of BSAs of animal origin is an effective way to improve the nutrient availability, structure, and overall health of agronomic soils. However, the use on produce farms is limited as previously discussed. Where BSAs of animal origin are used, manure application rates are generally determined by an analysis of the available nitrogen of the soil and the nitrogen needs of the crop to be grown, which predominantly may be region-specific due to a number of environmental, climate, geologic, and other factors. Forty-five States require nutrient management plans (see Chapter 3.3 and 3.4) that govern the application rates of untreated manure and other products, the goals include the reduction of erosion and to help States meet TMDL requirements (Chapter 3.1).

The impact of standards directed at untreated BSAs of animal origin will primarily be influenced by the length of the requisite waiting period.

Switch to treated material

Treated manure may reduce the amount of nutrients available for plant uptake, versus untreated manure. It also reduces manure mass and treatment results in less material to transport and apply to cropland. Efficient use of manure as a soil amendment is dependent on the nutrient requirement of the crop and time when the nutrient is needed. About 25 percent of the dry matter from composted cow manure is in the form of ligno-proteins, a marriage of lignins and proteins. As a result, it is very stable, and decomposes slowly (Goldstein, 2001). Therefore, composted manure may also become a soil builder. No significant impacts to soils are anticipated.

Switch to BSAs of non-animal origin

The grower may need to replace nutrient and soil enhancing capacity of BSAs of animal origin by implementing the following strategies: working in a cover crop rotation; use of high-residue crop or perennial sod to add SOM from plant material; consider reducing tillage and the use of bulky organic amendments for both organic matter and plant nutrients; and consider adding nitrogen-based fertilizer with an added source of carbon. As with the use of treated manure, the amendment still requires testing to verify concentrations of nutrients are commensurate with soil requirements or to determine application rate. The use of mitigation strategies and the potential beneficial effect to soil health by implementing these practices, mean that there will be no adverse impacts to soil as a result of implementing this management decision. Although beneficial impacts are expected whether the impact is significant and the level of significance may vary based on the pre-existing condition of the soil treated.

Use of chemical fertilizers

The use of synthetic fertilizers can degrade soil organic matter by accelerating the rate of decomposition.

Any degradation of soil can have a long-term adverse impacts, which may be reversible. Long-term use of synthetic fertilizers may have an adverse impact on soil structure by decreased soil macro aggregates, which may adversely affect the soils' resistance to erosion.

Comply with requisite waiting period

Longer waiting periods such as 6, 9 or 12 months may have a beneficial impact on soil structure because such waiting periods may result in a decreased frequency of disturbances to the soil associated with plowing or turning the soil. The grower can employ strategies to reduce the impact of the waiting period on soil nutrient levels by utilizing treated compost, green manure and cropping rotation, commercial fertilizer, or a combination of all schemes. If the application of chemical fertilizer is the only adaptive strategy utilized, then the potential for adverse effects on soil are increased.

Cease growing covered produce
The impacts on soil resources associated with ceasing to grow covered produce would depend on what crops were grown in its place, if any. It is anticipated that growers would choose alternative crops with similar management practices such that no significant impacts to the soil resource would be anticipated.

Change application method
This management decision is likely regardless of the application interval that is ultimately finalized as the standard in proposed § 112.56(a)(1)(i). Regardless of the application interval, any final regulation (after FDA completes its robust research agenda, risk assessment, and outreach) is anticipated to specify that the untreated BSA must be applied in a manner that does not contact covered produce during application.

Soil structure and quality would continue to be disturbed or decomposed, similar to baseline conditions. The overall effect to soils would remain largely unchanged from present practices; therefore, a minimal but not significant impact to soils would be expected.

Waste Generation, Disposal, and Resource Use – The application of BSAs of animal origin to farm fields provides valuable nutrients and organic matter to the soil, and also provides a mechanism for the beneficial use of manure and other animal derived by-products. Although the available data do not allow for a determination of which farms nationwide use untreated BSAs of animal origin, an analysis of the regional locations of livestock and poultry operations in relation to produce growing regions can be performed (see Chapter 3.4.3.1). Covered produce growers located in regions A, B, C, D, J, M, L, P, S, U and V are located in proximity to livestock and/or poultry operations and therefore sources of available BSAs of animal origin. Many farms and/or CAFOs that generate animal waste are required to comply with NPDES or other permits.

GAPs recommend that raw manure or biosolids application not occur during the growing season, but rather that it occur in fall or in spring prior to planting. GAPs also recommend incorporation of manure or biosolids into the soil to promote competition from ambient soil microbes and facilitate die-off of pathogens and enteric bacteria.

BSAs of animal origin are normally applied before planting, at the time of planting, and/or once the crops are harvested (typically in the fall). The most common method that BSAs of animal origin are incorporated into soils is through plowing or turning the soil in (e.g., disc and harrow), though, an increasing number of growers are employing no-till methods that allow BSAs to incorporate naturally into the soils media (typically in the fall – after harvest).

As discussed in Chapter 3.4, there are some short-season crops (Table 3.4-6) with growing to harvest cycles of 45 days or less; however, most crops have a growing cycle of about three to four months. Growing schedules and nutrient management are normally closely coordinated to ensure soils and plants have the proper amount of nutrients needed to meet projected crop yields.

A majority of BSAs of animal origin are generated either on the same produce farm where they are applied or on a neighboring or nearby farm. Untreated manure is prohibited entirely on certain crops intended for human consumption in some states. In addition, untreated manure is controlled or regulated to a certain extent by some industry growers associations (marketing agreements) and USDA organic regulations, either by disallowing its use entirely for the prior year, or by requiring an application to harvest interval of 3-4 months duration depending on the type of crop. These restrictions are in place to allow natural abatement and pathogen reduction to occur and to prevent raw manure application during the growing season. However, not all growers adhere to those practices, and such practices do not apply to all produce grown but are limited to either organically grown produce or specific commodities.

Switch to treated materials
More farms that would grow produce covered by a final rule already use treated BSAs of animal origin than do farms that use untreated BSAs of animal origin, if they use any BSA at all (most farms use chemical fertilizers or may be trending toward green manure or other practices). Composting (including the various methods to treat waste) is a common practice nationwide; but presently not all composting operations follow specified, scientifically proven GAPs or industry guidelines to ensure the elimination of harmful pathogens. Assuming the treatment process is approved and effective for eliminating harmful pathogens, there would be no impacts associated with waste generation.

If farmers switch to treated BSAs of animal origin and the nitrogen availability is unknown or difficult to predict, then regular testing would be required to allow farmers to properly apply BSAs of animal origin to meet agronomic needs and environmental goals (such as those in nutrient management plans). While the current factors may be adequate for general estimating of typical manure nitrogen availability, more precise estimates of nitrogen availability based on compositional analyses are needed to guide producers toward economical and environmentally benign application rates when using treated manures (University of Wisconsin-Madison, 2014). Chapter 3.3 and 3.4 discusses treated BSAs of animal origin in more detail; and Chapter 4.4 identifies impacts associated with treated BSAs of animal origin.

Switch to BSAs of non-animal origin
BSAs of non-Animal Origin would consist primarily of green manuring. Green manure is a crop that is grown then plowed into the soil or otherwise left to decompose for the purpose of soil improvement (e.g., clover, rye or soybeans). Use of green manure is effective at building soil organic matter. Green manure is discussed in greater depth in Chapter 3.3 Soils. BSAs of non-animal origin may also include decomposed plant compost, mulch, and detritus, peat moss, or other plant-based materials).

On a national basis the change in management practices to include more non-animal natural soil amendments would affect a small number of covered farms (approximately 820 covered farms nationwide) compared to the entire agriculture industry, and result in only slight shifts in overall management practices. Therefore, any potential adverse environmental impacts are not expected to be significant with regard to Waste Generation, Disposal, and Resource Use.

Use chemical fertilizer

On a national basis the change in management practices to include more synthetic fertilizer soil amendments would affect a small number of covered farms compared to the entire agriculture industry, and result in only slight shifts in overall management practices. Therefore, any potential adverse environmental impacts are not expected to be significant with regard to Waste Generation, Disposal, and Resource Use.

Comply with the requisite waiting period

BSAs of animal origin are normally applied before planting, at the time of planting, and/or once the crops are harvested (typically in the fall). The most common method that BSAs of animal origin are incorporated into soils are through plowing or turning the soil in (e.g., disc and harrow),though an increasing number of growers are employing no-till methods that allow BSAs to incorporate naturally into the soils media (typically in the fall – after harvest).

As discussed in Chapter 3.4, there are some short season crops (Table 3.4-6) with growing to harvest cycles of 45 days or less; however, most crops have a growing cycle of about three to four months. Growing schedules and nutrient management are normally closely coordinated to ensure soils and plants have the proper amount of nutrients needed to meet projected crop yields.

The reduced frequency of application under Alternatives I, IV and V would result in increased storage time for BSAs of animal origin prior to their application to farm fields. Storage facilities would need to be constructed where they do not currently exist and managed in a way that prevents nutrients and other contaminants from entering the ecosystem. Facilities that may store raw manure and may perform composting operations (e.g., CAFOs) are often required to apply for a NPDES permit. Therefore, if the facilities are operated and maintained in accordance with their permits (where applicable), under normal circumstances there are processes in place to protect against adverse harm to the environment (effects from run-off). Because a small percentage of covered produce farms currently use untreated BSAs of animal origin, any potential adverse environmental impacts are expected to be minimal and not significant with regard the overall impact to Waste Generation, Disposal, and Resource Use.

Stop growing covered produce

Changing from a covered produce crop to a crop that is not affected by the PS PR would allow the use of BSAs of animal origin, in compliance with other Federal, State, and local laws and regulations. Such restrictions on the use of BSAs of animal origin would alleviate a portion of the need to store and/or treat BSAs of animal origin. Any potential adverse or beneficial environmental impacts are expected to be minimal and not significant with regard to Waste Generation, Disposal, and Resource Use if this management decision were selected. The likelihood that this management decision would be chosen is considered to be slight.

Change application method

Application methods for BSAs of animal origin are discussed in greater detail in Appendix C and in Chapter 3.4. Land application of animal manure is an efficient utilization of BSAs of animal origin because of usually lower costs compared to treatment, and due to the nutrient benefits derived by crops from the manure. The most common land-application methods include surface spreading and subsurface injection. These methods are by-and-large accompanied by soil testing to establish soil fertility levels, testing the BSAs of animal origin for nutrient content, and establishing the proper selection of the application rate and method to ensure not to exceed crop nutrient requirements and to avoid soil and water contamination.

Other forms of manure application include broadcasting, banding, or shallow injection methods. These methods are further described in Appendix C in terms of defining their application method approach and timing.

A change in the application method of BSAs of animal origin is expected to have no impact on Waste Generation, Disposal, and Resource Use as the same quantity of BSAs would be used, just in a different manner.

Air Quality and Greenhouse Gases – As described previously, a relatively small proportion of covered farms is currently using BSA's of animal origin on a small portion (2.3%) of covered farms, where general air quality conditions relate to manure storage and application (especially in terms of odor experienced), which are both short-term and localized conditions (with a possible exception where covered produce and livestock producing manure operations are co-managed – and related to longer-term storage and associated localized air quality conditions).

As illustrated in Figure 3.5-2 (Chapter 3.5), more than 80 percent of covered produce is grown in just five regions: B, C, D, L and U (See Figure 1.7-4). With regard to concentrated areas of covered farms, California currently demonstrates the poorest air quality, with several non-attainment areas for PM_{10}, $PM_{2.5}$, and ground level ozone (see Figures 3.5-3, 3.5-4, and 3.4-7 in Chapter 3.5). Greenhouse gas emissions from cropland agricultural soil management (see Figure 3.4-10 in Chapter 3.4) and manure management (see Figure 3.5-11) are moderate to high in regions B, C, D, and U, and are particularly severe in California.

BSAs of animal origin application practices are often augmented with chemical fertilizers, which also lead to short-term increases in emissions (e.g., N_2O). Transportation of manure further contributes to local, short-term air quality increases in greenhouse gases, PM, and ozone precursor gases.

Many of the management decisions have the potential to influence greenhouse gas emissions as discussed below. The exception is if farmers were to stop growing covered produce, as land management practices related to the application of BSAs of animal origin would likely be similar to the existing condition. When attempting to avoid the need to comply with the provisions of the PS PR, if finalized, growers would likely switch to crops with similar management requirements. Minimal changes in management of agricultural land may result in changes in emissions of criteria pollutants and major greenhouse gases; however, the changes in air quality and GHGs are not anticipated to be significant because farms are expected to switch to crops with similar management requirements such that changes, while potentially noticeable, are not expected to be significant.

Switch to treated material

The potentially greater impacts to air quality as a result of switching from untreated BSA's to treated (composted) material would primarily involve changes in manure management (see

Figure 3.6-11 in Chapter 3.6) and agricultural soil management practices (see Figure 3.6-14) practices.

An increase in the storage of manure (e.g., compost piles) would be expected under this mechanism of complying with the provisions of the PS PR, if finalized, resulting in potential increases of windborne particulate matter, ozone precursor gases and GHG emissions (primarily methane but also nitrous oxide). Changes in GHG emissions from unused manure would vary depending on how this manure is treated or stored. Nitrous oxide emissions can increase due to these changes in agricultural soil management practices. Finally, any increase in transportation of manure to on or off-site storage or composting facilities could cause increases in CO_2 emissions from fuel combustion, although changes in emissions are expected to be relatively minimal and not significant since the transportation of manure would likely occur in localized areas due to the high costs associated with shipping manure long distances. Additionally, farmers may rely on chemical fertilizers or BSAs of non-animal origin to augment their cropland soils due to reduced application of BSAs of animal origin (see below).

Switch to BSAs of non-animal origin

Overall, decomposing plant matter would contribute to SOC and atmospheric CO_2 once released (during tillage or possibly harvest). These contributions, given the relatively small numbers of growers that may switch to this practice on a nationwide scale, will result in no impact to air quality.

An increase in the storage or disposal of manure (including such treatments as the use of compost piles) would be expected as a result of switching to BSAs of non-animal origin; primarily on “dual-purpose” operations from excess manure accumulation, resulting in potential increases of windborne particulate matter, ozone precursor gases and GHG emissions (primarily methane but also nitrous oxide). Changes in greenhouse gas emissions from unused manure would vary depending on how this manure is treated or stored.

Use chemical fertilizers

The major impacts to air quality as a result of switching to chemical fertilizers would involve changes in manure management (see Figure 3.5-11 in Chapter 3.5) and agricultural soil management (see Figure 3.5-14) practices. An increase in the storage or disposal of manure (e.g., compost piles) would be expected under this mechanism, primarily on “dual-purpose” operations from excess manure accumulation, resulting in potential increases of windborne particulate matter, ozone precursor gases and greenhouse gas emissions (primarily methane but also nitrous oxide). This may potentially cause a localized minimal adverse impact on air quality, but such impacts are not expected at a State, regional, or national level. Reliance on chemical fertilizers can lead to increases in N_2O emissions from changes in agricultural soil management practices. Agricultural soil management, including large additions of chemical fertilizers, represents the greatest individual source of agricultural GHG emissions in the U.S. (see Figure 3.5-13).

Comply with requisite waiting period

An increase in the storage of manure would be expected under longer application intervals, potentially resulting in increases in emissions of windborne PM, ozone precursor gases, and GHGs (primarily CH_4 but also N_2O). Changes in GHG emissions from unused manure will vary depending on how manure is treated or stored (short-term or long-term in nature). Some growers may choose to augment their fields with chemical fertilizers due to the nine month application interval, resulting in potential increases in agricultural soil management-related nitrous oxide emissions.

As illustrated in Figure 3.6-2 (Chapter 3.5), more than 80 percent of covered farms occur in just five regions, which are B, C, D, L, and U (See Figure 1.7-4). With regard to concentrated areas of covered farms, California (region C) currently demonstrates the poorest air quality, with several non-attainment areas for PM_{10}, $PM_{2.5}$, and ground level ozone (see Figures 3.5-3, 3.5-4, and 3.5-7 in Chapter 3.6). Greenhouse gas emissions from cropland agricultural soil management (see Figure 3.5-14) and manure management (see Figure 3.6-11) are moderate to high in regions B, C, D, and U, and are particularly severe in California.

To put this regional analysis in perspective, the estimated 35,503 covered farms (covering 4,473,575 acres) represent just 1.70 percent of the total number of U.S. farms and 0.49 percent of total U.S. farm acres (FDA, 2014b). Given the relatively small percentage (2.3%) nationwide of covered farms that presently use untreated BSAs of animal origin, any adverse impacts are expected to be minimal but not significant.

Change application method
Because growers would be switching to an application method that is not likely to contact edible portions of covered produce, manure management practices would likely remain similar to the existing condition. The particular application method employed would depend on the nature of the manure. Solid manure can be applied directly to the soil surface, and better incorporation of the manure into the soil can reduce indirect emissions of N_2O due to volatilization as well as emissions of NH_4, an important precursor of particulate matter generation. Injection of liquid manure beneath the soil surface can also greatly reduce indirect nitrous oxide and ammonia emissions (eXtension 2012a).

Due to the small number of covered farms currently using BSA's of animal origin relative to total U.S. farms, and the fact that these farms would not dramatically change most management practices under this mechanism, it is anticipated that there would be no impact to air quality on a national level. However, changing application methods could result in a minimal beneficial environmental impact that is not significant in regions where covered farms and associated livestock operations are more concentrated (i.e., regions C, D, U, and B (see Figure 3.4-1) due to reductions in particulate matter and nitrous oxide emissions.

Socioeconomics and Environmental Justice – Potential socioeconomic impacts that are associated with meeting the requirements of the provision for BSAs of animal origin could stem from economic costs that result from management decisions to comply with any such final provision (related costs originally estimated at $9.2 million annually). Based on comments received, however, FDA has removed the 9-month application interval related to use of raw manure from the PS PR and deferred its decision until FDA pursues certain actions. See Chapter 2.1 for a detailed discussion of FDA's proposed deferment of this provision. When FDA does choose to finalize this provision, the management decisions and the effects of any decisions on the socioeconomic resource component, would need to be evaluated in the context of the cumulative cost of implementation of all the provisions associated with the PS PR. The economic cost of an individual provision, based on costs that result from a management decision and the associated environmental impacts, would not likely be sufficient to result in changes that could impact the environment. Therefore, socioeconomic and environmental justice issues, are addressed cumulatively under Chapter 4.7. For the purpose of understanding the impact that the finalization of a provision aimed at untreated BSAs of animal origin will have on those impacts, Alternative I will be used in the analysis as a conservative estimate of the potential environmental impacts. Therefore, Alternative I is used as the alternative against which other potential alternatives are compared and cumulative impacts are assessed. At such time as FDA finalizes a provision for standards directed at untreated BSAs of animal origin, the potential impacts will be reassessed based on the standard that is being finalized.

***Human Health and Safety* -** The provisions that would establish a minimum application interval to untreated BSAs are intended to decrease potential pathogen contamination and would have a beneficial impact on human health and safety due to a reduction in exposure to pathogens although the level of significance will be determined by the alternative chosen. The alternatives considered range from 0 days to 12 months for untreated BSAs with a greater time interval leading to a greater reduction in potential pathogen contamination. FDA has indicated its intent to defer finalization of this provision until it pursues certain actions, including a robust research agenda and risk assessment, among other activities. It is too early to know the outcome of this research but it may be possible to identify a waiting period or a combination of requirements inclusive of a waiting period beyond which there is no significant increase in public health benefit.

Switching to treated materials, BSAs of non-animal origin, chemical fertilizers, waiting periods of all length, and changes in application method that avoid direct contact with covered produce are all expected to have a beneficial environmental impact on human health and safety due to a reduction in exposure to pathogens, although the waiting period will determine if the impact is significant or not. Since very few farms (i.e., 2.3% of covered farms or 1.56% of total produce acres) utilize untreated BSAs of animal origin, the impact on human health would be limited to those who consume produce from this limited subset of produce farms. The use of chemical inputs has the potential to create an adverse impact to human health (worker safety in particular); however, any impacts would be mitigated by the requirements for label directions for storage, mixing, and application. Longer application to harvest intervals such as those in Alternatives I, IV and V may result in some portion of farmers reducing the number of crop rotations within a year, which could reduce the amount of produce grown; however, any such reduction would be expected to be mitigated by market forces (i.e., other growers, regionally, locally, and internationally, would fill any gaps in supply).

4.3.1 Alternatives Analysis

This section provides a comparison of alternatives that FDA considered under Subpart F/ Untreated, and relates the potential environmental impacts from a grower that may select a particular management decision, as discussed at the beginning of this section.

Each of these alternatives is expected to have a significant beneficial impact on human health and safety. Despite the limited number of covered farms utilizing raw manure, there are populations who choose to exclusively consume organically grown produce and therefore would be beneficially impacted by the alternatives.

Alternative I.
Minimum application interval of 9 months
Given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period.

If farmers switch to treated manure and the nitrogen availability of the treated manures is unknown or difficult to predict, then regular testing would be required to allow farmers to properly apply manure to meet agronomic needs and environmental goals (such as those in nutrient management plans). While the current factors may be adequate for general estimating of typical manure nitrogen availability, more precise estimates of nitrogen availability based on compositional analyses are needed to guide producers toward economical and environmentally benign application rates when using treated manures (University of Wisconsin-Madison, 2014). The same testing is also required for untreated manure but not for synthetic fertilizers with a known nutrient content. With proper management, no impact to soil health will occur.

The treatment of raw manure will require additional time, possibly creating a need to store manure. The storage of partially processed manure may lead to impacts to surface and groundwater impacts; however, best management practices, can mitigate the potential for these impacts. In addition, if the storage of manure occurs at a facility that operates under a NPDES permit, as long as the facility is managed in accordance with permit requirements potential adverse impacts are not anticipated.

The treatment process will require additional inputs in the form of energy, transportation, and money relative to the use of raw manure.

The improper use of chemical fertilizers may also have an adverse impact on surface and groundwater; however, given the small number of farms that use untreated BSAs of animal origin (estimated at 820 covered farms, or 2.3 percent of covered farms nationally) that could possibly switch to chemical fertilizers the impact would be minimal but not significantly adverse. In addition, proper nutrient management would likely avoid excess use of chemical fertilizers that would further reduce the minimal impacts that may occur from their use.

Chemical fertilizers lack the organic matter that manure otherwise provides, thereby reducing soil structure and health. Therefore, the use of chemical fertilizers could cause moderate adverse environmental impacts to soils. These impacts are not expected to be significant because the effects are reversible, and may be mitigated given the growing trend away from chemical fertilizers to practices such as green manuring.

The production and transport of chemical fertilizers is not expected to have a significant adverse impact on energy use and air quality because the resource use is not expected to change significantly as compared to current conditions given the very small number of covered farms potentially impacted (see Chapter 2.1 subpart F, Chapter 3.4, and Chapter 4.3).

If growers choose to comply with the 9-month interval instead of changing the soil amendment type or application method, a minimal but not significant adverse impact is expected to result from the growing regime or from a reduction in the number of crops a farmer may harvest due to the small number of farms nationwide that would be impacted. There may be some reduction in farm income if farms need to set aside land or build structures to store the untreated BSAs of animal origin. The amount of produce may be reduced due to a reduced number of harvests per year based on a 9-month waiting period. This may cause an increase in the price of certain produce if supply is reduced and demand is high. However, this impact is expected to be mitigated by market forces (i.e., other growers, regionally, locally, and internationally, would fill any gaps in supply. Similar effects would be expected if growers stop growing covered produce, and regional produce commodity prices may increase resulting from a decrease in produce grown in any particular region; however, it is reasonable to predict that demand for a certain produce commodity may eventually be met by other growers in the region, growers in other regions (commodity and environment specific), or international suppliers.

<u>Alternative II.</u>
<u>Minimum application interval of 0 days</u>
This alternative is similar to the baseline condition. Currently there is not a regulated interval for the use of raw manure. However, this alternative would not allow for direct contact with covered produce.

If a farmer is allowed to use an interval of 0 days between the application of raw manure and harvest, there is no regulatory need to treat raw manure, switch to a BSA of non-animal origin or chemical fertilizer or to cease growing covered produce. Therefore, changes in the type of soil amendment used or crop grown are not anticipated as a result of this management decision. Complying with the 0 day waiting period, would require a change in application method for those farms that currently surface apply BSAs of animal origin as they would need to ensure it does not contact the covered produce.

Changing the application method to prevent the contact of raw manure with a covered produce crop will potentially require the acquisition of additional equipment. This will require the outlay of funds for the purchase of new equipment and its ongoing maintenance, causing a potential minimal adverse impact (not significant).

Minimal public health benefits may occur over the present conditions for farms that may be using a zero day application rate.

<u>Alternative III.</u>
<u>Minimum application interval of 90/120 days</u>
With the exception of the short season crops listed in Table 3.4-5 with growing to harvest cycles of 45 days or less; most crops have a growing cycle of about three to four months. For such

crops, no changes would be required to management practices in order to comply with this application interval. Additionally, farmers currently in the USDA organic program have adapted their growing practices to be in compliance with this alternative. If a certified organic grower chooses to treat raw manure, the grower will be limited in the choices for treatment in order to maintain its organic status. The small percentage of covered farms which utilize untreated BSAs, as well as the high likelihood that such farms are certified organic growers, indicates that few farms would need to change practices in order to comply with this application interval. No significant impacts are associated with any management decision under this Alternative.

Other farms that may be associated with marketing agreements that have more stringent application intervals may continue to observe their established standards if they are more stringent than what FDA proposes.

Limited public health benefits may occur over the present conditions for farms that may be using a zero day application rate. The switch to a longer application rate to harvest interval may result in more (unquantified) foodborne illnesses prevented over Alternative II, but still fewer than what is estimated for Alternative I.

Alternative IV.
Minimum application interval of 6 months
As with Alternative I, given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period. Likewise, the improper use of chemical fertilizers may have an adverse impact on surface and groundwater; however, proper nutrient management, e.g. proper storage, nutrient management plans, careful selection of application methods, and use of chemical fertilizers according to label directions will limit any adverse impact so as not to be significant.

If farmers switch to treated manure and the nitrogen availability of the treated manures is unknown or difficult to predict, then regular testing would be required to allow farmers to properly apply manure to meet agronomic needs and environmental goals (such as those in nutrient management plans). While the current factors may be adequate for general estimating of typical manure nitrogen availability, more precise estimates of nitrogen availability based on compositional analyses are needed to guide producers toward economical and environmentally benign application rates when using treated manures (University of Wisconsin-Madison, 2014). The same testing is also required for untreated manure but not for synthetic fertilizers with a known nutrient content. With proper management, no impact to soil health will occur.

Chemical fertilizers lack the organic matter that manure otherwise provides, thereby reducing soil structure and health. Therefore, the use of chemical fertilizers could cause moderate adverse environmental impacts to soils. These impacts are not expected to be significant because the effects are reversible, and may be mitigated given the growing trend away from chemical fertilizers to practices such as green manuring. The production and transport of chemical fertilizers may have a low adverse impact on energy use and air quality because the resource use is not expected to change significantly as compared to current baseline conditions (see Chapter 2.1 subpart F, Chapter 3.4, and Chapter 4.3).

Changing the application method to prevent the contact of raw manure with a covered produce crop may require the acquisition of additional equipment, which would equate to a one-time outlay of funds for the purchase of new equipment and its ongoing maintenance, and thereby cause a potential minimal (not significant) adverse environmental impact related to the socioeconomic resource component.

Similar to Alternative I, if growers chose to switch to a non-covered crop, regional produce commodity prices may increase resulting from a decrease in produce grown in any particular region causing a supply and demand relationship; however, it is reasonable to predict that demand for a certain produce commodity may eventually be met by other growers in the region, growers in other regions (commodity and environment specific), or international suppliers.

This alternative may result in improved public health benefits over Alternative II or III but less than Alternatives I or V, due to the longer application to harvest interval. However, in establishing the regulation in 7 CFR 205.203(c)(1) (reflected in Alternative III), it was acknowledged that the raw manure standard is based on organic crop production practices and is not a public health standard (see 79 FR 58434 at 58459).

Compared to Alternative I, this alternative is expected to have slightly lesser impacts.

<u>Alternative V.</u>
<u>Minimum application interval of 12 months</u>
As with Alternatives I and IV, given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period. Switching to treated material would reduce the interval between application of the treated manure and harvest to 0 days, rather than the interval of 12 months for the use of raw manure. The treatment of raw manure will require additional time, possibly creating a need to store manure. The storage of partially processed manure may lead to impacts to surface and groundwater; however, best management practices, can mitigate the potential for these impacts. The treatment process will require additional inputs in the form of energy, transportation, and money relative to the use of raw manure.

If farmers switch to treated manure and the nitrogen availability of the treated manures is unknown or difficult to predict, then regular testing would be required to allow farmers to properly apply manure to meet agronomic needs and environmental goals (such as those in nutrient management plans). While the current factors may be adequate for general estimating of typical manure nitrogen availability, more precise estimates of nitrogen availability based on compositional analyses are needed to guide producers toward economical and environmentally benign application rates when using treated manures (University of Wisconsin-Madison, 2014). With proper management, no impact to soil health will occur.

The improper use of chemical fertilizers may have an adverse impact on surface and groundwater; however, proper nutrient management e.g., proper storage, nutrient management plans, and careful selection of application methods, will limit any adverse impact so as not to be significant.

Chemical fertilizers lack the organic matter that manure otherwise provides, and therefore may not bolster soils. Therefore, the use of additional chemical fertilizers to treat fields where raw manure was previously utilized could cause moderate, but not significant, adverse environmental impacts to soils. These impacts are not expected to be significant because the effects are reversible, and may be mitigated given the growing trend away from chemical fertilizers to practices such as green manuring. The production and transport of chemical fertilizers may have an adverse impact on energy use and air quality, but not to a significant degree.

Changing the application method to prevent the contact of raw manure with a covered produce crop will potentially require the acquisition of additional equipment. This would require the outlay of funds for the purchase of new equipment and its ongoing maintenance causing a potential minimal (not significant) adverse environmental impact related to the socioeconomic resource component that could result from management decisions taken to comply with this provision.

If growers choose to switch to growing a non-covered crop, regional produce commodity prices may increase resulting from a decrease in produce grown in any particular region causing a potential supply and demand relationship; however, it is reasonable to predict that demand for a certain produce commodity may eventually be met by other growers in the region, growers in other regions (commodity and environment specific), or international suppliers.

Compared to Alternative I, this alternative is expected to have slightly greater, but not significant, environmental impacts.

4.4 Subpart F / Treated: Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste - Treated Proposed §112.56(a)(4)(i)

FDA's rationale for proposing Subpart F

The role that biological soil amendments play in contributing to pathogen presence on produce is discussed in Chapter 4.3. Proposed Subpart F establishes standards directed to treated and untreated BSAs of animal origin and human waste. These standards include requirements applicable for determining the status of a BSA of animal origin; procedures for handling, conveying, and storing BSAs of animal origin; provisions regarding the use of human waste in growing covered produce; acceptable treatment processes for BSAs of animal origin applied in the growing of covered produce; microbial standards applicable to treatment processes; application requirements and minimum application intervals; requirements specific to agricultural teas; and records requirements (21 CFR Part 112).

This set of management decisions and alternatives applies to treated BSAs of animal origin. Many of the facts and considerations discussed in Chapter 4.3 also apply to these standards. The primary difference is that a larger percentage of farms using treated BSAs of animal origin would potentially be impacted by these standards. As discussed in Chapter 2.1, subpart F (Table

2.1-3), approximately 3,618 covered farms use treated manure.[14] This equates to approximately 10.2 percent of covered farms that use treated BSAs of animal origin.

Agencies are directed to devote the "alternatives" section to describing and comparing the alternatives (CEQ 40 Questions, 46 Fed. Reg. 18026, March 23, 1981). Under 40 CFR 1502.2, the EIS must be kept concise and no longer than necessary. For these reasons, discussions from Chapter 4.3, that apply to the management decisions considered reasonably foreseeable under this subpart are not repeated below.

Management Decisions

As discussed under Chapters 4.1 and 4.2, FDA, in coordination with USDA, identified the following actions or mechanisms that a farmer may take in order to either come into compliance with the requirements, or to avoid compliance; these include: use BSAs of non-animal origin; use chemical fertilizers; comply with the requisite waiting period (applies specifically to each alternative); and change the application method.

While all reasonably foreseeable alternatives have been identified, FDA is aware that some management decisions will likely be more preferable to covered farms. Alternative I, the preferred alternative, would establish requirements that are substantially similar to the baseline conditions. Therefore, the most likely management decision is that farmers will elect to comply with the proposed provision § 112.56(a)(4)(i), which specifies a 0-daywaiting period.

General background on resources related to the proposed provision

Much of the baseline information that is presented under this provision refers back to data presented in Chapters 3.4, 4.1 (the No Action alternative), and 4.2. This section summarizes the relevant baseline data needed to assess the potential environmental impacts for Subpart F, proposed §112.56(a)(4)(i).

Water Resources – The prevalence of irrigated acres where treated BSAs of animal origin are applied is expected to be similar to the percentages stated below (under Waste Generation, Disposal, and Resource Use), i.e., a small portion of the overall acreage of (irrigated) covered crops can be expected to have BSAs of animal origin applied, but a majority of those farms would be expected to already use treated manure instead of untreated. Furthermore, an even larger percentage of produce growers use elemental fertilizers instead of BSAs of animal origin. Careful calculation of nutrient application rates, and judicious application methods and timing can reduce the potential for surface and groundwater pollution on irrigated land. The chief concern with composted manure (compared with untreated manure and fertilizer) is the amplification of phosphorus and potassium in complex forms that require extended time for plant uptake; therefore causing greater potential for eroded material from land where compost is applied to cause eutrophication of surface waters. Where operators employ conservation tillage and other practices (e.g., grass waterways, strip cropping, etc.), this concern is reduced. But if

[14] This number is derived from adding the number of livestock and produce farms that use treated manure (2,306) with the number of organic produce farms reporting using green manure or BSAs of animal origin (588 farms minus 109 farms using untreated manure = 479 farms), and other farms (1,021 minus 188 farms using untreated manure = 833 farms). Note that the total of these 3,618 covered farms may be using treated manure or green manure. The data does not differentiate.

conservation measures are removed (as a response to growers creating unvegetated buffer areas for monitoring wildlife intrusion), then compost as a soil amendment has the potential to have an increased effect on surface water.

Biological and Ecological Resources – Composting is known to reduce the prevalence of weed seeds relative to raw manure; which could reduce the amounts of herbicide inputs needed in growing areas. Otherwise, there is little relationship between most forms of terrestrial wildlife on farm crop fields and the application of any sort of soil amendment. As mentioned above under water resources, there is some concern in the absence of conservation measures that compost and chemical fertilizers can upset the balance of limiting nutrients in aquatic systems, leading to biogeochemical oxygen demand and eutrophication ("dead zones") where the problem is prevalent.

Soils – Use of treated manure as a soil amendment (compared to untreated manure) concentrates the amount of nutrients; thus, less land is required for manure application. Composting or digesting manure also reduces manure mass (removes water for example and nitrogen compounds in the form of ammonia off-gassing) and therefore results in less material to transport. The amount of treated BSAs of animal origin needed for production is dependent on the nutrient requirement of the crop and time when the nutrient is needed. Benefits of composted material include (1) improved consistency, (2) lower prevalence of weed seeds, (3) lower loss of nutrients if incorporated immediately, and (4) slower decomposition relative to raw manure, resulting in slower nitrogen release in the soil. Thus, composted manure is one of the best soil building materials (along with green manure cover crops).

Waste Generation, Disposal, and Resource Use – An estimated 4,438 covered produce growing farms (12.5% of all covered farms in total) use BSAs of animal origin. A small majority of BSAs of Animal Origin are generated either on the same farm where they are applied for fertilizing fresh produce, or on a neighboring farm. A large percentage (roughly 47%) of manure products are supplied by commercial manure brokers. Some marketing agreements, and USDA Organic programs have definitions of what is considered treatment (composting) that includes aeration to promote decomposition and thermal reduction of pathogens.

FDA's analysts have estimated that 3,618 covered produce farms use composted manures; by comparison, the number using untreated manure is 820 covered farms (FDA, 2013b). These trends are presented in greater detail in Section 3.4. Given that only a relatively small number (2.3 percent of covered farms or 1.56 percent of covered produce acres), currently use untreated BSAs of animal origin, those farms represent the maximum percent of industry that could be expected to change to treated BSAs of animal origin under this provision. Presently, there are no suggested application to harvest intervals for treated BSAs of animal origin.

Air Quality and Greenhouse Gases – Section 3.5 has maps that illustrate areas of air quality concerns, which do include regions where produce is grown in conjunction with areas where livestock and poultry are raised (e.g., central and southern California and central Florida). Potential effects to air quality and greenhouse gases due to the use of treated BSAs of Animal Origin occur when composting or digesting occur and release ammonia and particulate matter (see Section 3.5). In some states, where the implementation plans indicate a requirement for it, major CAFOs and large composting facilities require stationary source air quality permits, monitoring, and abatement; although there is not a nationwide requirement for all such facilities to be regulated. Presently, (see Section 3.4) more produce growers are already using composted manure than are using untreated manure; which is contrary to the total for all agricultural crops (where untreated manure exceeds compost application in terms of percentages).

Under Alternatives II and III, the potential increased frequency of application of BSAs of animal origin may result in increased air emissions; however, the associated impacts are not expected to be significant because the emissions would be relatively short-term

Socioeconomics and Environmental Justice – Potential socioeconomic impacts that are associated with meeting the requirements for standards directed to treated BSAs of animal origin could stem from economic costs that result from management decisions to comply with the provision, if finalized. Currently, organic farms and dual-purpose farms can manage composted BSAs of animal origin efficiently and effectively in compliance with Federal, State, and local laws and regulations. Dual-purpose farms can also apply untreated or aged manure according to their prescribed state-approved nutrient management plan (if any). The exceptions to this are States with marketing agreement requirements that include several major growing areas (California, Florida, and Arizona) and several major commodities (e.g., leafy greens and tomatoes), where there are currently limitations on application of BSAs of animal origin. Changes anticipated due to possible application to harvest interval restrictions and changes in application methods would include potential for increased costs (storage/treatment or alternative uses for volumes of animal waste; replacement soil amendments; new equipment) and affiliated socioeconomic effects. FDA has proposed and plans to finalize a rule with multiple provisions aimed at a variety of potential routes of contamination of produce for human consumption. The economic cost of an individual provision, based on costs that result from a management decision and the associated environmental impacts, may not be sufficient to result in changes that could impact the environment. Therefore, socioeconomic impacts, will be addressed cumulatively under Chapter 4.7.

Human Health and Safety – Present practices allow for application of treated BSAs of animal origin up until the date of harvest, although such a practice would not be effective at maximizing plant uptake of the nutrients. This situation presents concerns that pathogens could enter the produce through cultured soils contacting the plant or produce, or through direct contact. Also, without hygiene standards, BSAs of animal origin can be transferred to fruit and vegetables if the BSAs of animal origin are present on the soil surface (unincorporated) during harvest operations, as shown on Figure 3.8-1 (Conceptual Site Model / Transport of Pathogen Microbes).

4.4.1 Alternatives Analysis

This section provides a comparison of alternatives that FDA considered under Subpart F/ Treated BSAs of Animal Origin, and relates the potential environmental impacts from a grower that may select a particular management decision, as discussed at the beginning of this section.

Any of these alternatives is expected to have a significant beneficial impact on human health and safety.

Alternative I.
As proposed, Minimum application interval of 0 days
This is similar to the current baseline conditions. No impacts would be associated with this alternative and corresponding management decisions. The use of chemical fertilizers in place of treated BSAs of animal origin as a nutrient source is unlikely to occur under this alternative because the alternative does not restrict the timing of the use of BSA, only the ability for the BSA to contact covered produce.

Alternative II.
Minimum application interval of 45 days
With the exception of the short season crops listed in Table 3.4-6 with growing to harvest cycles of 45 days or less, most crops have a growing cycle of about three to four months. Therefore, for most crops an application interval of 45 days would not require any changes in the soil amendment type in order to comply with the requisite waiting period. No significant impacts would be associated with this alternative and corresponding management decisions.

Alternative III.
Minimum application interval of 90 days
As discussed under Alternative II, most crops have a growing cycle of about three to four months. Therefore, an application interval of 90 days would not require any changes in the soil amendment type in order to comply with the requisite waiting period. No significant impacts would be associated with this alternative and corresponding management decisions.

4.5 Subpart I / Grazing: Standards Directed to Domesticated and Wild Animals Proposed §112.82(a) Grazing

FDA's rationale for proposing Subpart I
Feces from warm-blooded mammals and birds is a major source of many pathogens that may affect the safety of produce (Francis et al., 1999). Animals are a likely source of contamination of produce (e.g., lettuce, peas, spinach) with human pathogens, and have been identified as a likely cause of illness (Campbell et al., 2001; FAO and WHO, 2008; FDA, 1998; FDA, 2011b; Jamieson et al., 2002). Many species of domestic and wild animals are potential carriers of human pathogens, with both the incidence and concentration of human pathogens varying widely depending upon the animal species (Enache et al., 2011; Franz and van Bruggen, 2008; Leifert et al., 2008; Mazzotta, 2001; NACMCF, 2011; Renter and Sargeant, 2002).

The number and type of pathogens detected in animal feces varies with the animal species. For example, the predominant source of pathogenic *E. coli* O157:H7 from animal feces is cattle, and the predominant source of *Salmonella* spp. from animal feces is poultry (Cramer, 2006; McSwane, Rue, and Linton, 1998; WHO and UNEP, 2006). Cattle are also well-known carriers of different types of pathogens, including strains of *Salmonella enterica*, *C. jejuni* and other (non-O157:H7) pathogenic *E. coli* (Goulet et al., 2012; NASPHV, 2011; Todd et al., 2007).

Beyond cattle and poultry, other domesticated animals such as sheep, goats, and swine are also common carriers of pathogenic microorganisms (Sadowsky and Whitman, 2011).

Domesticated animals (Enache et al., 2011; Renter and Sargeant, 2002) and pests (e.g., rats (Nielsen et al., 2004)) are generally more likely to harbor zoonotic pathogens than are wild animals, due to their closer proximity to and interaction with humans. As wild animals interact more with humans or domesticated animals, they are more likely to become carriers of human pathogens (Nielsen et al., 2004).

As proposed, subpart I provides science-based minimum standards that are directed to domesticated and wild animals and 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.

This set of alternatives applies to grazing of domesticated animals. Alternatives directed at wild animals are discussed in Chapter 4.6.

Management decisions

The environmental impacts of standards directed at domesticated animals are the result of the management decisions a covered farm makes in order to comply with the standard. FDA has chosen to take a non-prescriptive approach when establishing the standards in subpart I to allow for, and encourage, scientific advancement in the measures available to comply with the proposed rule.

As discussed in Chapter 4.1 and 4.2, FDA, in coordination with USDA, identified the reasonably foreseeable actions, or management decisions, that businesses potentially affected by any final rule might take in order to come into compliance with alternatives considered under potentially significant provision. Under Subpart I/ Grazing, FDA and USDA identified the following actions or management decisions that a farmer may take once a rule is finalized: fencing or other measures to exclude domesticated animals, and observing an adequate waiting period after grazing and prior to harvest. For purposes of this EIS, we have analyzed both of these identified management decisions. We also expect that farmers will carefully consider any management decision to exclude animals (such as through fencing) in light of our proposed provision § 112.84.

General background on resources related to the proposed provision

Much of the baseline information that is presented under this provision refers back to data presented in the No Action alternative (Chapter 4.1). This section summarizes the relevant baseline data needed to assess the potential environmental impacts for Subpart I, proposed §112.82(a), which establishes the standard related to grazing of domesticated animals.

There are approximately 2,829 dual- and multi-purpose farming operations (raising livestock or poultry and growing produce –inclusive of covered and not-covered or otherwise exempt produce) (USDA NASS, 2014a). The available data are not sufficiently robust to determine which of these dual- and multi-purpose farm operations grow covered produce. An estimated 35,503 farms would be covered by the PS PR (FDA, 2014b). The standard in §112.82(a) would apply to the subset of these operations that grow covered produce, which is between 1.5 and 8% of covered farms with the low end representing the average percent of dual- or multi-purpose farms raising livestock or poultry, and growing produce and the maximum assuming all such dual purpose farms are covered by the PS PR. Although there are no reliable estimates to provide precise numbers of farms that would be affected by this standard, we know the following:

- Only a small subset of these farms ostensibly employ either the practice of grazing in produce fields, and those that do may use the area as forage after the growing season, or between rows for tree crops;
- Relatively few farms use poultry as pest control; and,
- Very few farms in the 21st Century use working animals in their fields, and these farms are concentrated in certain communities with Old Order populations (some Mennonite and most Amish farmers). Therefore, an equally small subset of the 2,829 farms covered produce / animal raising dual or multi-purpose facilities employ working animals.

The potential likelihood of animals to act as vectors of human pathogens is determined by several factors, including but not limited to the type of commodity (as discussed above), and the species of the animal and its association with human or domesticated animal activity or waste (FDA, 2013c). A suitable time period based on these and other relevant factors must be established for the purpose of reducing, via die-off, pathogen levels in the excreta that may be transferred from animals to covered produce. For the purposes of this EIS, we included two waiting periods that provide a sufficiently wide range for the evaluation of potential environmental impacts: (1) 9 months, which aligns with FDA's 2013 proposed application interval for use of untreated manure, and (2) 90/120 days, which is in accordance with the supplemental proposed rule (FDA, 2014a), where FDA eliminated the 9 month proposal and, instead, indicated that it does not intend to take exception to the USDA organic regulation standard for the application of untreated manure (90/120 days, see Chapter 2.1) at this time.

Water Resources – Farming operations that may be relevant to the provision would include CAFOs that also grow covered produce. Such facilities are often required to comply with the requirements of a NPDES permit (Chapter 3.4.1 and 3.4.2); however, these permits would be applicable to the management of waste and not to the farm field. State nutrient management plans do not cover the management of grazing livestock on crop fields.

In general, domesticated animals whether they are allowed to graze in covered fields, are removed from fields for an adequate or specified waiting period, or are fully excluded from fields growing covered produce, would be expected to result in localized soil compaction and thus, increased run-off of nutrients and contaminants into receiving waters, and contributing to (non-point source pollutants) to already poor water quality conditions.

The potential impact to water resources caused by excluding domesticated animals from covered produce, whether for a short or long period of time, would be tied to the fact that animal wastes may be concentrated over smaller areas (pastures or other confined areas), which could lead to greater concentrations of pathogens reaching the water table as well as an increase in direct runoff (from increased soil compaction) to the surface water. For those covered farms that also include livestock operations (to which this would mostly apply), it is important to distinguish that fences to manage livestock are likely already in place and that the farmer would not be building new fencing (see Chapter 2.1 Subpart I, and amended §112.84). The most common grazing activities would occur in dedicated pasture land where perennial grasses grow. Produce fields and livestock management are not typically compatible as livestock if allowed to graze in produce fields would consume much of the commodity.

Since by-and-large, the animals are not used as a primary source to amend the farm field (such as untreated BSAs of animal origin in accordance with subpart F), the amount of animal waste under this provision would be far less in volume than a typical CAFO. Therefore, any adverse environmental impacts on water resources are expected to be minimal and short-term, and therefore, not significant. Since it is likely that dilution would occur at the point of groundwater recharge (Chapter 3.1.3.5), any adverse environmental impacts are expected to be short-term. Moreover, these potential impacts are expected to be minimal, and therefore, not significant.

Fowl such as geese and chickens are sometimes used to graze for insects or remove weeds in fields in lieu of using commercial pesticides. Restricting access to livestock (i.e., poultry) that forage the insects inhabiting the farm field may require the increased use of pesticides. Given that relatively few farms use poultry as pest control in areas where covered crops are grown, any corresponding switch to using insecticide/pesticide would be local and the occurrence would be very low, nationwide. Therefore, any adverse environmental impacts to water quality from the increased use of chemicals on these few fields are expected to be minimal and not significant. If the insecticides are used in accordance with labeling requirements, even any minimal environmental impacts to water quality should be effectively mitigated to a level that is not significant.

Biological and Ecological Resources – As discussed in Chapter 3.2.3, agricultural operations are not natural ecosystems (i.e., they are intensively manipulated for the benefit of humans); however, they do provide habitat and other life requisites for many species of plants and animals. As discussed in soils, below, grazing operations often affect the quality of soils on farms in various ways that may have indirect effects on vegetation, aquatic and terrestrial wildlife, and wetlands. Excluding domesticated animals from fields where produce is grown means that other land would need to be used for grazing, or other animal food sources must be used. Any activities that may have impacts to wetlands must first go through a permitting process irrespective of whether the land is private or public. This process often requires the approval of a Federal agency such as the Corps of Engineers in concert with State approval. As part of the permitting process, if there is a loss of wetlands expected beyond the State's individual thresholds (each state will have different requirements) then mitigation is often required. In addition, FDA has proposed a new provision, § 112.84, that explicitly states that part 112 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. FDA does not believe that these types of actions are needed because of the availability of alternative food sources available for purchase or other land that may be used for grazing.

Fencing is the most obvious measure to exclude domesticated animals from crops whether for a short or long period of time. Because clearing of land would not be required by the proposed rule, if finalized, and because such farms are already likely to have fencing in place to confine animals in general and/or to confine animals from areas where crops are grown, any environmental impacts to vegetation, wildlife, and wetlands are not expected to be significant based on the potentially few farming operations that decide to fence any particular field or livestock. In terms of fencing, FDA is considering potential impacts on the following components:

Vegetation

Herbaceous species would endure a short-term impact due to the swath of land that would be cleared to allow for fencing. Any impact to vegetation is expected to be minimal and not significant, as farmers would likely maintain the exclusion corridors that may already exist surrounding the farmland.

Wildlife

The heightened use of insecticides would generate an escalated level of eco-toxicity to the surrounding habitat; which in-turn may impact target insect species, as well as avian and aquatic or amphibious species. Given the expected low occurrence of decisions to fence farm land, any impacts are expected to be long-term, minimal and not significant. Additionally, reduced access to forage and cover due to the fencing or other exclusion measures may disrupt the existing wildlife corridors of transient terrestrial animal species, but few such disruptions are anticipated because fencing could be ineffective to exclude wildlife from farm fields. The rate of any such disruption would be expected to be lower than the number of facilities that would need to add fences as these corridors are not found on every farm. Any disruption is not expected to be significant. Furthermore, if the insecticides are used in accordance with labeling requirements, even any minimal environmental impacts to water quality should be effectively mitigated to a level that is not significant.

Wetlands

Potential increases of toxicity to water and wetlands, due to the somewhat heightened level of insecticides may result in adverse environmental impacts to aquatic species. The potential adverse effects to aquatic species and wetlands that are located adjacent to a farm field would not be significant if the insecticides are used in accordance with their labeling requirements. This is because EPA, in cooperation with States, carefully regulates these chemicals to ensure they do not pose an unreasonable risk to human health or the environment. EPA requires manufacturers to conduct extensive testing in order to identify any potential risks, and the agency carefully reviews these data provided by manufacturers before the product may be registered for use. Therefore, as long as users apply insecticides in accordance with the EPA and manufacturers requirements, EPA does not anticipate long-term adverse effects associated with these products.

Any impacts that may result in a removal of wetlands would most likely require a permit, subject to permitting by the U.S. Army Corps of Engineers and the State where the wetlands may be impacted. Permit provisions often require mitigation in accordance with State requirements, and therefore, these Federal, State and local permits would mitigate the overall impact to State wetland resources and to the species that habituate them.

Soils – Chapter 3.3.3.7 provides a discussion relative to soils and grazing of domesticated animals. Livestock grazing in fields where covered produce is grown affects the structure, composition, fertility, chemistry and function of soil in ways that compromise both short and long-term productivity. Grazing changes soil structure by increasing soil compaction and by increasing run-off of both nutrients (e.g., nitrogen related compounds including fertilizers (Roberson, 1996). Such impacts are described for primarily bovine operations. Therefore, any environmental impacts on soils associated with a change in practice as a result of the proposed standard, such that poultry or other domesticated animals are not used, are not expected to be significant.

In most cases, covered dual- or multi-purpose operations already have fields that are dedicated pasturelands and would not, under normal conditions, be rotated in for crop land. Any impacts to soils in these areas are most likely already occurring, and therefore, no significant impacts from grazing are expected on soils under any management decision or alternative as a result of the PS PR, if finalized.

Waste Generation, Disposal, and Resource Use - Most grazing, and associated waste generation, occurs in the pens and loafing areas where animals are confined. Such grazing presents little difference in terms of nutritive values for produce-growing areas, with minor added efforts for collection and treatment.

Exclusion of grazing animals on a temporary or permanent basis, would restrict animals to other pastures for extended periods and/or restrict them to confined feedlots. The effect of such exclusion could be more volumes of manure accumulations during the times when animals would otherwise graze. The portion of the standard requiring proper precautions to avoid harvesting contaminated produce for farmers using working animals would only have a minimal, and not significant environmental impact regionally and nationally because the standard is expected to restrict the harvest of only a small amount of produce.

The grazing restriction for exclusion of animals from produce fields on multi-purpose farms to comply with the affiliated standard would have little effect on Waste Generation, Disposal, and Resource Use. The working animal precautions would have no effect on Waste Generation, Disposal, and Resource Use. The environmental impacts of this standard on Waste Generation, Disposal, and Resource Use are expected to restrict the harvest of only a small amount of produce and therefore would be minimal and not significant regionally and nationally.

Air Quality and Greenhouse Gases - There are no data to attribute grazing on fields where covered crops are grown, or grazing in fields in general that addresses air quality. Although the production of methane (a greenhouse gas) would occur as part of grazing, such impacts with respect to covered crops are already occurring and not anticipated to change as a result of the proposed grazing requirements; therefore no environmental impacts from the proposed requirements would be caused by the PS PR, if finalized.

Adding a permanent structure or other measures to exclude domesticated livestock including cattle and fowl, either for a short or long period of time, would have no impact to Air Quality and Greenhouse Gases on a national scale as there would be no foreseeable measureable change to the air quality environment by adopting this mechanism to comply with the standard.

It is anticipated that there would be minimal localized impacts associated with some farms depending on the particular action taken to exclude animals from covered produce crop areas. These impacts could include particulate matter emissions from switching to chemical pesticides and methane and PM emissions from manure storage in concentrated areas. Regions where covered farms are concentrated relative to existing poor air quality conditions may experience minimal environmental impacts where farms switch to chemical pesticides, and methane and PM emissions occur from increased manure storage. Regions where covered farms are concentrated, where such impacts may occur, include regions C, D, U, and B (see Chapter 3.5.3 Figures 3.5-3, 3.5-4, and 3.5-7). However, the number of covered farms for which these changes in current practices is anticipated, is extremely small and changes are not expected to be readily detectable, and therefore, not significant.

Socioeconomics and Environmental Justice – Potential socioeconomic impacts that are associated with meeting the requirements for the grazing standards directed to domesticated and wild animals could stem from economic costs that result from management decisions to comply with the final provision. The associated estimated costs associated with finalizing the rule for this provision are $32.30 million annually for all farms, nationwide. These costs cover both §§ 112.82(a) and 112.83(b) and include developing a monitoring plan and monitoring fields for animal intrusion at various times of year relevant to harvest, and the costs associated with monitoring working animals when in covered fields (FDA, 2014b). FDA has proposed and plans to finalize a rule with multiple provisions aimed at a variety of potential routes of contamination of produce for human consumption. The economic cost of an individual provision, based on costs that result from a management decision and the associated environmental impacts, may not be sufficient to result in changes that could impact the environment. Therefore, socioeconomic and environmental justice issues will be addressed cumulatively under Chapter 4.7.

Environmental Justice

Though environmental justice issues are discussed cumulatively under Chapter 4.7, we note that USDA NASS data do not show whether minority populations relative to this analysis (in regions A, B, C, D, W, and V, or Native American populations) operate dual or multi-purpose farms. Therefore, the likelihood of adverse effects on minority populations is unclear.

Human Health and Safety – Domesticated and wild animals (statistics were taken together) present a likely contamination pathway for produce. FDA estimated that the likelihood of contamination for all covered produce and activities under subpart I is 14.09 percent (FDA, 2013b). In general terms, domesticated animals in growing areas present some hazards from fecal contamination in the instances where domesticated animals are permitted to graze in fields prior to harvest, or working animals are permitted in fields prior to or during harvest. Requiring the farmer to exclude animals for a short or long period of time would reduce potential pathogenic exposure to consumers. If the farmer takes measures, such as fencing, to exclude domesticated animals from the fields, there would be a moderate beneficial environmental impact on human health and safety. No adverse human health effects would be expected.

4.5.1 Alternatives Analysis

This section provides a comparison of alternatives that FDA considered under Subpart I/ Grazing, and relates the potential environmental impacts from a grower that may select a particular management decision, as discussed at the beginning of this section.

Any of these alternatives and management decisions are expected to have a moderate beneficial impact on human health and safety.

Alternative I.
As proposed, Adequate waiting period
Given that only approximately 2,829 dual- or multi-purpose farms raise livestock or poultry, and grow produce (and some smaller subset of this number grows covered produce), the overall regional and nationwide potential environmental impacts from grazing operations, in general, is minimal. For example, if 189,637 farms grow produce (FDA, 2013b), this would represent 1.5 percent of produce farms. As worst, if all of these 2,829 dual- or multi-purpose farms are assumed to grow covered produce it would still represent less than 8% of the 35,503 farms covered by the PS PR.

Although some measures to permanently exclude domestic animals from covered produce, such as fencing, would be permanent, most farms are expected to already have these structures available. Of the farms that do not currently have such fencing, any adverse environmental impacts from farms taking a measure to exclude domestic animals from covered produce are not expected to be significant. The term "adequate waiting period" is not defined by the PS PR. What can be deemed adequate relative to specific in-farm practices such crop rotation or seed to harvest intervals are best performed at the farm-level and not at the level of this EIS. The more likely management decision when determining when to remove the animal from the field at some time during the planting to harvest interval would be to factor in the crop, and region where the crop is grown to allow for consideration of late growing seasons and other factors. Unlike Alternatives II and III, this Alternative provides flexibility for farmers to make the decision on an appropriate time interval, based on the farm's operation.

Because such dual-purpose operations are mostly anticipated to have confined grazing or other areas for livestock already, removing the animal from fields where covered produce may be grown, relative to a planting/harvest interval is not anticipated to result in long-term impacts (other than what is presently experienced) to either the produce field or to the field(s) where the animal is confined.

Any measure taken to reduce the hazard from pathogen transport to produce is expected to result in beneficial impacts to human health; however, relative to a permanent exclusionary measure, a management decision to include an adequate waiting period before using a field for growing covered produce may not have the same level of human health benefits (foodborne illnesses prevented) compared to creating a barrier to animal entry and grazing entirely.

Alternative II.
Waiting period of 9 months
As compared to Alternatives I and III, there are no substantially different impacts that can be estimated at a regional or national level because of the few farms to which this would apply.

Alternative III.
Waiting period of 90/120 days
As compared to Alternatives I and II, there are no substantially different impacts that can be estimated at a regional or national level because of the few farms to which this would apply.

4.6 Subpart I / Animal Intrusion: Standards Directed to Domesticated and Wild Animals Proposed § 112.83(b) Animal Intrusion

FDA's rationale for proposing Subpart I
As discussed in Chapter 4.5, animals are a likely source of contamination of produce (e.g., lettuce, peas, spinach) with human pathogens, and have been identified as a likely cause of illness (Campbell et al., 2001; FAO and WHO, 2010; FDA, 1998; FDA, 2011b; Jamieson et al., 2002). Wild animals, including pests, can also act as reservoirs of human pathogens (Fischer et al., 2001; Jay et al., 2007). Pathogenic *E. coli* have been isolated from deer, feral swine, pigeons and seagulls (Fischer et al., 2001; Jay et al., 2007; Nielsen et al., 2004), and Dunn and colleagues report that the prevalence of *E. coli* O157:H7 infection in white-tailed deer ranges from a level that is undetected to 2.4 percent (Dunn et al., 2004).

As proposed, subpart I provides science-based minimum standards that are directed to domesticated and wild animals and 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.

This set of alternatives applies to animal intrusion.

Management decisions
The environmental impacts of standards directed at domesticated wild animals are the result of the management decisions a covered farm makes in order to comply with the standard. FDA has chosen to take a non-prescriptive approach when establishing the standards in subpart I to allow for, and encourage, scientific advancement in the measures available to comply with the proposed rule.

As discussed in Chapters 4.1 and 4.2, FDA, in coordination with USDA, identified the reasonably foreseeable actions, or management decisions, that businesses potentially affected by any final rule might take in order to come into compliance with the alternatives under consideration for inclusion in the final rule. Under Subpart I/ Animal Intrusion, FDA and USDA identified the following actions or management decisions that a farmer may take with respect to this subpart if the rule were finalized: (1) to avoid harvesting the field or part of the field; or (2) to take measures, such as fencing, to exclude wildlife. For purposes of this EIS, we have analyzed both of these identified management decisions, although we expect that farmers will carefully consider any management decision to exclude wildlife (such as through fencing) in light of proposed provision § 112.84.

General background on resources related to the proposed provision

Much of the baseline information that is presented under this provision refers back to data presented in Chapters 3.2, 4.1 (No Action alternative), and 4.5. This section summarizes the current conditions needed to assess the potential environmental impacts for Subpart I, proposed §112.83(b).

Relative to the PS PR, farms that may be affected include all potentially covered farms nationwide (35,503 farms), and their associated acres, which is 4,473,575 (Chapter 2.1 and FDA, 2014b).

Proposed subpart I would apply when under the circumstances there is a reasonable probability that animals will contaminate covered produce. In such circumstances, proposed subpart I would require monitoring of those areas that are used for a covered activity for evidence of animal intrusion immediately prior to harvest and as needed during the growing season, and if animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction via grazing, occurs, the farm must evaluate whether the covered produce can be harvested safely (21 CFR proposed §§ 112.81 and 112.83). Monitoring wildlife activity at or around covered produce is key to identifying potential hazards.

Water Resources – Wildlife exclusion is anticipated to have no impact on water used for covered produce or water resources in general. Any potential land clearing that involves the application of chemicals to kill herbaceous species, or any type of rodenticide that may be applied adjacent to the farm field, if used in accordance with labeling requirements, would be anticipated to have minimal, but no significant adverse environmental impacts to water quality.

Since the majority of the water use would have already occurred during the growing season not harvesting a field or part of a field would also have no anticipated impacts on water resources as no additional water use would be needed, nor would this process involve any additional pesticide use.

Biological and Ecological Resources - FDA received various comments that expressed the concern that the 2013 proposed rule, if finalized as proposed, would adversely affect wildlife. Comments noted that animal habitat, habitat connectivity, and wildlife populations would be at risk if our proposed provisions related to animal intrusion are perceived by produce growers to mean that less habitat and/or more fencing in the production environment is a necessary management strategy (79 Fed. Reg. 58434 at 58463-58464). With respect to wildlife generally, Part 112 would 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. FDA addresses the scope of the EIS, with regard to threatened and endangered species, at the beginning of Chapter 4.

There are available co-management measures which allow growers to direct wildlife away from fields while still providing adequate habitat. Best management practices may help to mitigate any potential adverse impacts to wildlife, generally, or the environment as they allow growers to direct wildlife away from fields while still providing adequate habitat.

Hunting, trapping, and animal poisoning are other methods that are sometimes used to manage wildlife species at or adjacent to farm fields. Hunting and trapping are often accomplished in accordance with State or County permit requirements and in accordance with State wildlife regulations which factor in species population before determining the number of permits that can be issued without adversely impacting the species survivability.

Vegetation

Herbaceous species would endure a short-term impact due to the swath of land that would be cleared to allow for fencing. Any impact to vegetation is expected to be minimal and not significant, as farmers would likely maintain the exclusion corridors that may already exist surrounding the farmland. However, if all or part of the field is not harvested, a minimal, short-term beneficial impact to vegetation whereby the non-harvested crops are left to be tilled back into the soil may occur due to the additional nutrients being added back into the soil.

Wildlife

Any heightened use of herbicides, rodenticides, or other chemicals that may be used to exclude wildlife may, if not applied properly in accordance with the manufacturer's requirements, contribute to an escalated level of toxic compounds to the surrounding habitat. While such chemicals are generally meant to exclude or kill specific species of wildlife or pests, the toxic components of the chemical may also adversely affect wildlife that were not meant to be harmed. These effects may be experienced by insect species, as well as avian and amphibious species, and aquatic species found in surface waters adjacent to the where they are applied. These conditions may be considered short-term as the chemical components would quickly dissipate or decompose. Because these effects are often considered to be of low toxicity and because the species that may be affected are often resilient to the effects of the chemicals, the overall anticipated impacts are low and adverse (not significant), as long as the chemicals are used in accordance with their labeling requirements. This is because EPA, in cooperation with States, carefully regulates these chemicals to ensure they do not pose an unreasonable risk to human health or the environment. EPA requires manufacturers to conduct extensive testing in order to identify any potential risks, and the agency carefully reviews these data provided by manufacturers before the product may be registered for use. Therefore, as long as users apply these chemicals in accordance with the EPA and manufacturers requirements, EPA does not anticipate significant long-term adverse effects associated with these products.

Additionally, reduced access to forage and cover due to the fencing or other exclusion measures may disrupt the existing wildlife corridors of transient terrestrial animal species, but few such disruptions are anticipated because fencing could be ineffective to exclude wildlife from farm fields. The rate of any such disruption would be expected to be lower than the number of facilities that would need to add fences as these corridors are not found on every farm. Any disruption is not expected to be significant.

If all or part of the field is not harvested, the produce that was unable to be harvested would be accessible for forage and cover for transient species, and there would be a short-term minimal beneficial environmental impact due to the temporary increased availability of food.

Wetlands

Localized use and application of herbicides to maintain monitoring areas or otherwise clear vegetation has the potential to be toxic to wetland plants, which may impact wetland function. If such products are used in accordance with labeling requirements, the anticipated impacts to wetlands adjacent to the farm field may be considered short-term and low adverse. This is because EPA, in cooperation with States, carefully regulates these chemicals to ensure they do not pose an unreasonable risk to human health or the environment. EPA requires manufacturers to conduct extensive testing in order to identify any potential risks, and the agency carefully reviews these data provided by manufacturers before the product may be registered for use. Therefore, as long as users apply herbicides (or similar chemicals) in accordance with the EPA and manufacturers requirements, EPA does not anticipate significant long-term adverse effects associated with these products.

Soils – Overall monitoring for signs of intrusion and determining if the field or part of the field can be harvested could improve the soil since unharvested produce would return nutrients and biomatter, assist in breaking up compaction, prevent erosion, and/or suppress weeds. Minimal beneficial environmental impacts to soils may occur and therefore would not be expected to be significant.

Waste Generation, Disposal, and Resource Use – Wild animal waste is not collected, stored, handled, used, or otherwise disposed of prior to, during, or post-harvest under any circumstances. No impacts on waste generation, disposal or resource use are anticipated as a result of standards directed at animal intrusion.

Air Quality and Greenhouse Gases - There is no direct identified link between air quality and animal intrusion.

Socioeconomics and Environmental Justice – Potential socioeconomic impacts that are associated with meeting the requirements relating to standards directed to domesticated and wild animals could stem from economic costs that result from management decisions to comply with any final provision. There is no consistent nationwide data available on costs associated with managing wildlife around agricultural areas. Costs may be associated with hunting and trapping, or developing techniques to manage or exclude wildlife from crops. Potential socioeconomic and environmental justice issues relating to this provision will be addressed cumulatively under Chapter 4.7.

Human Health and Safety - Excreta from domesticated animals poses a greater likelihood of contamination of produce than does excreta of wild animals; however, domesticated animals can be expected to be more readily controlled (i.e., kept apart from produce growing, harvesting, and postharvest areas). Excreta from wild animals that rarely associate with human activities poses the least likelihood of contamination of produce.

Wild animals, including pests, can also act as reservoirs of human pathogens (Fischer et al., 2001; Jay et al., 2007). Pathogenic *E. coli* have been isolated from deer, feral swine, pigeons and seagulls (Fischer et al., 2001; Jay et al., 2007; and Nielsen et al., 2004), and the prevalence of *E. coli* O157:H7 infection in white-tailed deer ranges from a level that is undetected to 2.4 percent (Dunn et al., 2004) (FDA, 2013c).

Requiring the farmer to evaluate whether or not covered produce should be harvested based on the likelihood of being contaminated by animal intrusion would reduce potential pathogenic exposure to consumers. If the farmer does not harvest the field or part of the field in order to avoid harvesting contaminated covered produce, there would be a moderate beneficial impact on human health and safety. However, this impact would depend on actually observing the contaminant (feces), which may be relatively easy to miss during monitoring or harvest activities, thereby reducing otherwise the beneficial impacts to one that is minimal.

Measures taken to exclude wildlife may also result in a moderate, but not significant, beneficial impact to human health when considered individually; however, when these impacts are added to the overall cumulative impacts of the rule, as discussed in Chapter 4.7, the corresponding reduction in the potential for pathogens to contaminate covered produce and beneficial impacts on human health would be significant. The use of chemicals to exclude wildlife is not expected to result in a significant environmental impact because the use of the product would be subject to EPA oversight and should be used consistent with labeling requirements to avoid any significant adverse impact on worker health and safety.

4.6.1 Alternatives Analysis

This section provides a comparison of alternatives that FDA considered under Subpart I/Animal Intrusion, and relates the potential environmental impacts from a grower that may select a particular management decision, as discussed at the beginning of this section.

Any of these alternatives is expected to have a beneficial impact on human health and safety.

<u>Alternative I.</u>
<u>As proposed, Evaluate whether produce can be harvested safely</u>
Under Alternative I, there would be no significant adverse impacts expected with respect to any specific resource component.

Evaluating whether produce can be harvested safely and, as appropriate, not harvesting a field or part of a field that is reasonably believed to be contaminated from wildlife intrusion would have no environmental impacts to water resources, waste generation, disposal, and resource use, and air quality. There may be minimal, non-significant beneficial environmental impacts observed to wildlife species as a result of added short-term cover and forage area from not harvesting part of the field and to soils from nutrients that would be reincorporated into the soils and improve soil health.

Based on the cost-benefit analysis and consideration of costs in considering this alternative (40 CFR 1502.23), the costs to monitor species, and loss of revenue from unharvested contaminated crops are expected to be low. This is because monitoring is not expected to occur daily (FDA's Regulatory Impact Analysis (2013b) estimated monitoring to occur three times per production season), and because it is unlikely that a farmer would choose to not harvest a whole field (it is more likely that the farmer would not harvest only that smaller portion of the crop that is contaminated).

In terms of reducing pathogens, impacts are expected to be beneficial.

<u>Alternative II.</u>
<u>Measures to exclude wildlife</u>
As compared to Alternative I, environmental impacts would be greater.

Measures to exclude wildlife (including measures to clear land to facilitate monitoring) may involve the use of herbicides, rodenticides, or other materials that may have short-term toxic effects to water resources; biological resources and ecosystems directly adjacent to the farm; and soils. These impacts may be mitigated through proper use and handling in accordance with labeling requirements. This is because EPA, in cooperation with States, carefully regulates these chemicals to ensure they do not pose an unreasonable risk to human health or the environment. EPA requires manufacturers to conduct extensive testing in order to identify any potential risks, and the agency carefully reviews these data provided by manufacturers before the product may be registered for use. Therefore, as long as users apply herbicides (or similar chemicals) in accordance with the EPA and manufacturers requirements, EPA does not anticipate long-term adverse effects associated with these products. Therefore, the overall environmental impacts would be short-term, and not significant. Mitigation measures that may be employed to reduce any other potential adverse effects that may otherwise be significant may include preparing pest management plans that are discussed earlier in this chapter.

Hunting and trapping may be accomplished in accordance with State and local regulations that would mitigate any potential significant environmental impact which factor in species population before determining the number of permits that can be issued without adversely impacting the species survivability.

Under this Alternative, proposed § 112.84 could also state that Part 112 does not require covered farms to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

Costs under Alternative II would be higher than what would be expected under Alternative I.

In terms of reducing pathogens, impacts are expected to be beneficial. However, if chemicals are used in exclusion measures and if they are not handled in accordance with labeling requirements, these impacts could be minimal but adverse particularly with regard to worker health and safety.

4.7 Subpart A: General Provisions (Scope of Coverage of the Proposed Rule); includes impacts related to the cumulative effects of each proposed standard assessed together

FDA's rationale for proposing Subpart A

The PS PR proposes to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce for human consumption, in order to minimize the risk of serious adverse health consequences or death from consumption of contaminated produce. FDA's rationale for establishing these standards is described in detail in Chapter 1.4, with discussions related to the need for potentially significant provisions outlined in Chapters 4.2 through 4.6.

As proposed, subpart A of the proposed regulation contains provisions that establish the scope of, and definitions applicable to, the PS PR, and identifies who would be subject to the requirements of part 112, if finalized. The PS PR would apply to both domestic and imported produce. However, the PS PR would not apply to (1) certain specified produce commodities that are rarely consumed raw; (2) produce that is used for personal or on-farm consumption; (3) produce that is not a raw agricultural commodity; (4) produce that receives commercial processing that adequately reduces the presence of microorganisms (*e.g.* a ''kill step'') as long as certain documentation is kept; (5) produce grown on farms that have an average annual value of produce sold during the previous three-year period of $25,000 or less. The PS PR would also provide a qualified exemption and modified requirements for farms that meet certain requirements specified in the regulation.

Management decisions

Unlike with standards directed at specific potential routes of pathogen introduction, proposed § 112.4 in subpart A of the PS PR establishes the value of produce sold above which a farm growing covered produce would be subject to the provisions of the rule (i.e., covered farms). Covered farms must either comply with the provisions of the rule, including through the use of the management decisions described in Chapters 4.2 through 4.6, or switch to crops that are not covered by the proposed rule.

Complying with the rule would mean that a farmer would have to abide by the provisions of the rule, except where the grower would qualify for certain exclusions from coverage of the rule (such exclusions are discussed briefly above and in more detail in Chapter 2.1). FDA is not evaluating the potential environmental impacts at the local level as part of this EIS; rather it is focused in regional and national environmental impacts. Potential environmental impacts related to specific qualified exemptions would require an analysis of the very small and small farms that may qualify for certain exemptions and information about such farms on a local level across the country.[15] However, farms that are subject to these exemptions would continue to utilize current practices so no significant environmental impacts would be associated with those farms practices and the PS PR. There is economic and foodborne illness related information available for different farm sizes. FDA considers, below, the relationship between the economic cost-benefit

[15] FDA estimated the number of potentially covered farms that may be eligible for a qualified exemption from the rule. This information is presented in the Regulatory Impact Analysis (FDA, 2013b). These exemptions apply to farms based on their eligibility as described in proposed § 112.5.

analysis, including information about foodborne illnesses, and the analyses of unquantified environmental impacts from the PS PR to consider the overall impact of the PS PR.

The impacts associated with a decision to switch to crops exempt from regulation under the PS PR, if finalized, would be substantially similar to the decision to cease growing covered produce assessed in Chapter 4.2; therefore, this related analysis that is presented in Chapter 4.2 is not repeated here, and the reader may refer back to that section of Chapter 4.2 for further detail on FDA's thinking of potential environmental impacts. Whether farmers stop growing covered produce is dependent upon many factors, cost being just one factor. Farmers would consider what other crops they might grow while using the equipment they have in order to avoid purchasing and maintaining new equipment; they might also consider climate, and the types of crops available to them in that region; geology and soil characteristics; topography; availability of water; local and regional consumer markets, and much more.

General background on resources related to the proposed provision

The impact analysis in this chapter takes into consideration the cumulative impacts of all provisions in the PS PR, including impacts related to the economic cost and potential socioeconomic impacts from provisions excluded from further analysis in Chapter 2.2 and the impacts identified in Chapters 4.1 through 4.6. The management decisions that farmers may take if they are covered by the proposed rule under proposed subpart A relate directly to the management decisions that the farmer may take when considering how best to manage their business with respect to potentially significant provisions of the rule: agricultural water (subpart E), BSAs of animal origin (subpart F), and/or domesticated and wild animals (subpart I).

For the purpose of this evaluation, the comparison of environmental impacts is accomplished by considering the Preferred Alternative of each potentially significant provision. For untreated BSAs of animal origin, where FDA has signaled its intent to defer finalization of a standard, the 9-month standard proposed in the 2013 proposed rule is used for purposes of this evaluation. Please note that a comparison of potential environmental impacts by alternative for each potentially significant provision is already accomplished in Chapters 4.2 through 4.7.

FDA proposes three main size classifications of businesses in relation to the PS PR. Within the size classifications are businesses that are not subject to the proposed rule, and businesses that are subject to the proposed rule. The size classifications of businesses (farms or farm mixed-type facilities) include Not Covered (excluded), Very Small Businesses, and Small Businesses. All other covered farms are considered "Large" farms. These size classifications and associated potential exemptions are discussed in Chapter 2.1 (see also Tables 2.1-7 and 2.1-8). There are no data available that identify where these potentially covered farms are located by size class (excluded, very small, small, large). Therefore, potential impacts will continue to be discussed on a nationwide or regional basis.

As discussed in Chapter 2.1, of the 189,637 farms that grow produce, an estimated 18.7 percent, or 35,503 are covered farms, i.e., grow produce that would be covered by the PS PR. Of these 35,503 covered farms, approximately 7,302 would be considered large farms, 4,139 would be small farms, and 24,062 would be very small farms (FDA, 2014b). The geographic locations of covered farms can be found in Figure 1.7-4 in Chapter 1.7. The majority of potentially covered produce is grown in regions B, C, D, L, and U; however, as demonstrated throughout Chapter 4, these and other regions may be impacted by proposed provisions of the PS PR in different and important ways. These differences are summarized as overall potential impacts by potentially significant provision, as presented below.

Subpart E: Standards directed to agricultural water

Table 4-4 presents a summary of potential impacts and comparison of alternatives under subpart E, as discussed in Chapter 4.2.

Table 4-4. Summary and comparison of alternatives under subpart E

Comparison of Alternatives
Alternative I. Preferred: As Proposed. GM ≤ 126 CFU generic E. coli/100ml and STV ≤ 410 CFU/100ml with added flexibility for microbial die-off and/or removal
• The flexibility in meeting the proposed water quality standard is likely to mitigate the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added microbial die-off and/or removal. • Disinfectants may be useful for reducing hazards that may cause foodborne illnesses; however, many of these disinfectants may form harmful byproducts. EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. As long as the pesticides are handled and applied according to label directions, no significant adverse impacts would result. Such adverse effects may be limited because a high number of growers in key growing regions, such as California, Arizona, and Florida, participate in marketing agreements that have more stringent numeric water quality standards than what FDA has proposed and are already using water that would be in compliance with the proposed standard. • It is not likely that a farmer will change the water source or cease growing covered produce because among the regions that are potentially most affected (B, C, D, I, J, and U), many farmers have entered into marketing agreements that are the same as, or operate under more stringent water quality standards than those proposed in the PS PR. In addition, reactions and verbal comments from some industry and trade groups that FDA received on the supplemental proposed rule suggest that the new proposed provisions for microbial die-off and/or removal to achieve the proposed microbial quality standard considerably reduce the perceived need to change water source in order to comply with Alternative I (and similarly Alternative III), compared to Alternative II. Any action that may lead to increases in groundwater drawdown would be considered a significant environmental impact. Regions that may be most impacted in terms of potential land subsidence, including any additive effects by switching to groundwater sources, include the regions that already experience the highest groundwater withdrawals; these are regions B, C, D, I, J, and U. • There may be additional costs from those projected in FDA's Regulatory Impact Analysis (FDA, 2013b and 2014b) if farmers add a post-harvest mechanism (e.g., FDA-approved wash or rinse) to achieve microbial die-off and/or removal, which could potentially result in additional socioeconomic impacts. • Overall, there would be an expected added public health benefit from an estimated 522,083 foodborne illnesses prevented (FDA, 2013b) from the standard itself.
Alternative II: 235 CFU (or MPN) generic E. coli /100 ml single sample or a GM of no more than 126 CFU (or MPN)/100 ml
The adverse environmental impacts and beneficial public health benefits that may apply under Alternative I would also apply under this alternative; however, due to the more stringent requirements for this alternative the following environmental impacts may occur in addition to those discussed under

Alternative I:
• Under this alternative, switching water source is expected to be the preferred management decision. As compared to Alternative I, this alternative would not have the added flexibility for microbial die-off and/or removal; therefore, farmers are more likely to decide to switch water sources, particularly away from surface waters to a cleaner source. If the cleanest available source is groundwater then existing significant adverse conditions (i.e., water drawdown, potential subsidence, and the related continued degradation of water quality) may continue to be exacerbated but to a greater degree than Alternative I, because the water quality requirements would be more stringent under this alternative and more farms are potentially likely to switch to the groundwater source in numbers that may considerably influence groundwater sources. These impacts are expected to be limited to localized regions and are not expected to be widespread. The regions that may be most affected are B, C, D, I, J, and U. These regions may also experience irreversible effects to soils. Therefore, these impacts under Alternative II related to lowering the water table, deteriorating water quality, and land subsidence are considered significant adverse. • Native American Tribes may be disproportionately impacted as groundwater drawdown could have potential environmental impacts including socioeconomic impacts related to access to water on reservations, particularly in regions B and J. Such impacts would be considered significant adverse if there is a reduction in a Tribe's access to water. • Capital costs related to any switch of water source may be especially burdensome for very small businesses. • Treating any water source to remove harmful pathogens would have an added public health benefit by reducing the potential for foodborne illnesses. • There would also be greater potential for the use of chemical treatments to bring water into compliance under this alternative relative to Alternative I. With respect to chemical treatments, this alternative is anticipated to have more adverse environmental consequences than Alternative I, but not to a significant level because as previously stated all pesticides must be registered by EPA and must be found to not generally cause unreasonable adverse effects on the environment. However, without the added flexibility for die-off that is afforded under Alternatives I or III, regions that potentially require a higher level of chemical treatment include A, B, C, L, R, T, and U. Long-term, sustained treatment of water sources may result in adverse, but not significant impacts to water quality due to the potential for THMs to be formed and may also result in non-significant, adverse long-term effects to biological/ecological resources and air quality from chemical treatments. These impacts are not anticipated to be significant because the effects may be reversible and are not permanent effects. • The use of more chemicals to treat water sources also results in slightly higher costs for growers, but not to a significant level. • The risk of adverse impacts to human health relating to the increased use of chemicals would not be significant and may be mitigated as long as labeling requirements are followed, as the FIFRA registration process considers risk to human health and establishes handling processes that are appropriate to minimize such risks. The possibility of potential impacts from THMs to be formed may occur in regions that may require the highest treatments (see above), but because transport of such toxins is not well known, these impacts cannot be well defined. Overall reductions in foodborne illnesses are expected to be comparable under Alternative I and II.
Alternative III: As proposed (i.e., Alternative I), with an additional criterion establishing a maximum generic *E. coli* threshold
• Compared to Alternative I, there is a slightly higher likelihood that more farmers may select to chemically treat water sources or switch water sources altogether because there may be circumstances when the pathogen level would exceed the established threshold and when steps allowing for die-off would not be sufficient to be in compliance with the rule. However, the reduced water testing and the less stringent standard means that fewer farms would be expected to make these management

decisions as compared to Alternative II. • Any costs of treating contaminated water sources may be considered long-term because while treatments need not be applied throughout the growing period, the overall quality of the water source is a long-term issue and treatments may need to be applied during every growing season. • The beneficial environmental impacts to health would likely be higher than Alternative I and lower than Alternative II. • Similar to what is addressed above, the use of pesticides are found to not generally cause unreasonable adverse effects to the environment, so long as such products are handled in accordance with their labeling requirements. Adverse impacts to human health related to handling such substances and treating poor water quality are considered not significant. • As compared to Alternative I, establishing a maximum threshold for generic E. coli may cause some growers in a region where the water quality is poorest to potentially shift from growing covered produce, but not to the degree that may occur under Alternative II. These potential shifts are mitigated by the fact that existing marketing agreements in the most impacted regions already operate with more stringent numeric water quality standards, and also account for more than 80 percent of the growers of produce that would be covered by the rule.
Alternative IV: Alternatives for direct water application method
• This alternative would have similar but slightly greater adverse environmental impacts when compared to Alternatives I, II, and III due to the inclusion of root crops, which crops are excluded for Alternatives I, II, and III.

Subpart F: Standards directed to BSAs of Animal Origin and human waste

Table 4-5 presents a summary of potential impacts and comparison of alternatives under subpart E, as discussed in Chapters 4.3 and 4.4.

Table 4-5 Summary and comparison of alternatives under subpart F

Comparison of Alternatives
Untreated BSAs
Alternative I. As Previously Proposed- Decision Deferred. Untreated BSAs of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 9 months
• Although the available data do not allow for a determination of which farms nationwide use untreated BSAs of animal origin, an analysis of the regional locations of livestock and poultry operations in relation to our regions can be made. Covered produce growers located in regions A, B, C, D, J, M, L, P, S, U and V are located in proximity to livestock and/or poultry operations, which are a source of available BSAs of animal origin. • Given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period. • If farmers switch to treated manure and the nitrogen availability of the treated manures is unknown or difficult to predict, then regular testing would be required to allow farmers to properly apply manure to meet agronomic needs and environmental goals. With proper management, no impact to soil health will occur. In addition, treatment will require additional storage time, which presents more opportunity for partially processed manure to impact surface and groundwater; however, adherence to

common best management practices may mitigate these impacts. If the storage of manure occurs at a facility that operates under an NPDES permit, as long as the facility is managed in accordance with permit requirements, potential adverse impacts are not anticipated. • The production and transport of chemical fertilizers is not expected to have a significant adverse impact on energy use and air quality because the resource use is not expected to change significantly as compared to current conditions. • The improper use of chemical fertilizers may also have an adverse impact on surface and groundwater; however, given the small number of farms that use untreated BSAs of animal origin (estimated at 820 covered farms, or 2.3 percent of covered farms nationally) that could possibly switch to chemical fertilizers the impact would be minimal but not significantly adverse. In addition, proper nutrient management would likely avoid excess use of chemical fertilizers that would further reduce the minimal impacts that may occur from their use. • The use of chemical fertilizers could cause moderate adverse environmental impacts to soils. These impacts are not expected to be significant because the effects are reversible, and may be mitigated given the growing trend away from chemical fertilizers to practices such as green manuring. • If growers choose to comply with the 9-month interval instead of changing the soil amendment type or application method, a minimal (not significant) impact is expected to result from the growing regime or from a reduction in the number of crops a farmer may harvest due to the small number of farms nationwide that would be impacted. There may be some reduction in farm income if farms need to set aside land or build structures to store the untreated BSAs of animal origin. The amount of produce may be reduced due to a reduced number of harvests per year based on a 9-month waiting period. This may cause an increase in the price of certain produce if supply is reduced and demand is high. However, this impact is expected to be mitigated by market forces (i.e., other growers, regionally, locally, and internationally, would fill any gaps in supply). Similar effects would be expected if growers stop growing covered produce, and regional produce commodity prices may increase resulting from a decrease in produce grown in any particular region; however, it is reasonable to predict that demand for a certain produce commodity may eventually be met by other growers in the region, growers in other regions (commodity and environment specific), or international suppliers. • According to FDA estimates (2013b, 2014b), the number of illnesses that would be prevented from finalizing a BSAs of animal origin provision is 244,917; of these illnesses prevented, 156, 299 would result from the 9-month application interval with a total health cost benefit of an estimated $14.46 million.
Alternative II: Untreated BSAs of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 0 days
• This alternative is similar to the existing condition but with the need to apply in a manner that does not contact covered produce. • If a farmer is allowed to use an interval of 0 days between the application of raw manure and harvest, there is no regulatory need to treat raw manure. Therefore, changes in the type of soil amendment used or crop grown are not anticipated as a result of this management decision. Complying with the 0 day waiting period, would require a change in application method for those farms that currently surface treat BSAs of animal origin as they would need to ensure that it does not contact the covered produce. • Changing the application method to prevent the contact of raw manure with a covered produce crop will potentially require the acquisition of additional equipment. This will require the outlay of funds for the purchase of new equipment and its ongoing maintenance, causing a potential minimal adverse impact (not significant). • Beneficial environmental impacts to human health would occur as a result of implementing this alternative but would be minimal, and therefore not significant, as compared to the Alternative I.

Alternative III: U.S. Department of Agriculture's organic program application intervals for the use of raw manure as a soil amendment, i.e., 90 days and 120 days before harvest, depending on whether the edible portion of the crop contacts the soil (as specified in 7 CFR 205.203(c)(1))
• With the exception of the short season crops listed in Table 3.4-5 with growing to harvest cycles of 45 days or less, most crops have a growing cycle of about three to four months. For such crops, no changes would be required to management practices in order to comply with this application interval. Additionally, farmers currently in the USDA organic program have adapted their growing practices to be in compliance with this alternative. If a certified organic grower chooses to treat raw manure, the grower will be limited in the choices for treatment in order to maintain its organic status. The small percentage of covered farms which utilize untreated BSAs, as well as the high likelihood that such farms are certified organic growers, indicates that few farms would need to change practices in order to comply with this application interval. No significant impacts are associated with any management decision under this Alternative. • Other farms that may be associated with marketing agreements that have more stringent application intervals may continue to observe their established standards if they are more stringent than what FDA proposes. • Limited public health benefits may occur over the present conditions for farms that may be using a zero day application rate. The switch to a longer application rate to harvest interval may result in more (unquantified) foodborne illnesses prevented over Alternative II, but still fewer than what is estimated for Alternative I.
Alternative IV: Untreated BSAs of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 6 months
• As with Alternative I, given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period. Likewise, the improper use of chemical fertilizers may have an adverse impact on surface and groundwater; however, proper nutrient management, e.g. proper storage, nutrient management plans, careful selection of application methods, and use of chemical fertilizers according to label directions, will limit any adverse impact so as not to be significant. • If farmers switch to treated manure and the nitrogen availability of the treated manures is unknown or difficult to predict, then regular testing would be required. While the current factors may be adequate for general estimating of typical manure nitrogen availability, more precise estimates of nitrogen availability based on compositional analyses are needed to guide producers toward economical and environmentally benign application rates when using treated manures. With proper management, no impact to soil health will occur. • The use of chemical fertilizers could cause moderate adverse environmental impacts to soils. These impacts are not expected to be significant because the effects are reversible, and may be mitigated given the growing trend away from chemical fertilizers to practices such as green manuring. The production and transport of chemical fertilizers may have a low adverse impact on energy use and air quality because the resource use is not expected to change significantly as compared to current conditions. • Changing the application method to prevent the contact of raw manure with a covered produce crop may require the acquisition of additional equipment, which would equate to a one-time outlay of funds for the purchase of new equipment and its ongoing maintenance, and thereby cause a potential minimal (not significant) adverse environmental impact related to the socioeconomic resource component. • Similar to Alternative I, if growers chose to switch to a non-covered crop, regional produce commodity prices may increase, resulting from a decrease in produce grown in any particular region;

however, demand for a certain produce commodity may eventually be met by other growers in the region, growers in other regions (commodity and environment specific), or international suppliers. • This alternative may result in improved public health benefits over Alternatives II and III but less than Alternatives I or V, due to the longer application to harvest interval. However, in establishing the regulation in 7 CFR 205.203(c)(1) (reflected in Alternative III), it was acknowledged that the raw manure standard is based on organic crop production practices and is not a public health standard (see 79 FR 58434 at 58459).
Alternative V: Untreated BSAs of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 12 months
• As with Alternatives I and IV, given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period. Switching to treated material would reduce the interval between application of the treated manure and harvest to 0 days, rather than the interval of 12 months for the use of raw manure. • Impacts under Alternative V would be substantially similar to those described under Alternatives I and IV. • This alternative may result in improved public health benefits over all other alternatives due to the longer application to harvest interval. Several marketing agreements already observe a similar minimum application interval.
Treated BSAs
Alternative I. Preferred: As proposed. Minimum application interval of 0 days
• This alternative is similar to the current baseline conditions. No impacts would be associated with this alternative and corresponding management decisions. The use of chemical fertilizers in place of treated BSAs of animal origin as a nutrient source is unlikely to occur under this alternative because the alternative does not restrict the timing of the use of BSAs, but contains the requirement that the treated BSAs of animal origin be applied in a manner that does not contact covered produce.
Alternative II: Minimum application interval of 45 days
• With the exception of the short season crops listed in Table 3.4-6 with growing to harvest cycles of 45 days or less, most crops have a growing cycle of about three to four months. Therefore, for most crops, an application interval of 45 days would not require any changes in the soil amendment type in order to comply with the requisite waiting period. No significant environmental impacts would be associated with this alternative and corresponding management decisions.
Alternative III. Minimum application interval of 90 days
• As discussed under Alternative II, most crops have a growing cycle of about three to four months. Therefore, an application interval of 90 days would not require any changes in the soil amendment type in order to comply with the requisite waiting period. No significant environmental impacts would be associated with this alternative and corresponding management decisions.

Subpart I: Standards directed to domesticated and wild animals

Table 4-6 presents a summary of potential impacts and comparison of alternatives under subpart E, as discussed in Chapter 4.5 and 4.6.

Table 4-6. Summary and comparison of alternatives under subpart I

Grazing
Alternative I. Preferred: Adequate waiting period
• Given that only approximately 2,829 dual- or multi-purpose farms both raise livestock or poultry and grow produce (and some smaller subset of this number grows covered produce), the overall regional and nationwide potential environmental impacts from grazing operations would be minimal. This provision is expected to affect between 1.5 and 8 percent of growers of covered produce. • Any measures taken to permanently exclude domestic animals (although not required by the rule) from covered produce would not have significant environmental impacts relative to a waiting period for harvesting covered produce. Although there may be some measures such as fencing (not required by the rule) that farmers without fencing now may establish to exclude domesticated animals, any potential environmental impacts are not expected to be significant. The more likely management decision would be to factor in the crop and region in which the crops are grown to allow for consideration of late growing seasons and other factors when determining when to remove the animal from the field at some time during the planting to harvest interval. Unlike Alternatives II and III, this Alternative provides flexibility for farmers to make the decision on an appropriate time interval, based on the farm's operation. • Because such dual-purpose operations are mostly anticipated to have confined grazing or other areas for livestock already, removing the animal from fields where covered produce may be grown, relative to a planting/harvest interval is not anticipated to result in long-term impacts (other than what is presently experienced) to either the produce field or to the field(s) to which the animal is confined. • Any measure taken to reduce the hazard from pathogen transport to produce is expected to result in beneficial impacts to human health; however, relative to a permanent exclusionary measure, a management decision to include an adequate waiting period before using a field for growing covered produce may not have the same level of human health benefits (foodborne illnesses prevented) compared to creating a barrier to animal entry and grazing entirely.
Alternative II: Waiting period of 9 months
• As compared to Alternatives I and III, there are no substantially different impacts that can be estimated at a regional or national level because of the few farms to which this would apply.
Alternative III: Waiting period of 90/120 days
• As compared to Alternatives I and II, there are no substantially different impacts that can be estimated at a regional or national level because of the few farms to which this would apply.
Animal Intrusion
Alternative I. Preferred: Evaluate whether produce can be harvested safely
• Under Alternative I, there would be no significant adverse impacts expected with respect to any specific resource component. • Evaluating whether produce can be harvested safely and, as appropriate, not harvesting a field or part of a field that is reasonably believed to be contaminated from wildlife intrusion would have no environmental impacts to water resources, waste generation, disposal, and resource use, and air quality. There may be minimal, non-significant beneficial environmental impacts observed to wildlife species as a result of added short-term cover and forage area from not harvesting part of the field and to soils from nutrients that would be reincorporated into the soils and improve soil health.

• Based on the cost-benefit analysis and consideration of costs in considering this alternative, the costs to monitor species, and loss of revenue from unharvested contaminated crops are expected to be low. This is because monitoring is not expected to occur daily (i.e., estimated monitoring to occur three times per production season) and because it is unlikely that a farmer would choose to not harvest a whole field (i.e., it is more likely that the farmer would not harvest only that smaller portion of the crop that is contaminated). • In terms of reducing pathogens, impacts are expected to be beneficial.
Alternative II: Measures to exclude wildlife
• As compared to Alternative I, environmental impacts would be greater. • Measures to exclude wildlife (including measures to clear land to facilitate monitoring) may involve the use of herbicides, rodenticides, or other materials that may have short-term toxic effects to water resources; biological resources and ecosystems directly adjacent to the farm; and soils. These impacts may be mitigated through proper use and handling in accordance with labeling requirements, as EPA, in cooperation with States, carefully regulates these chemicals to ensure they do not pose an unreasonable risk to human health or the environment. EPA requires manufacturers to conduct extensive testing in order to identify any potential risks, and the agency carefully reviews these data provided by manufacturers before the product may be registered for use. Therefore, as long as users apply herbicides (or similar chemicals) in accordance with the EPA and manufacturers' requirements, we do not anticipate long-term adverse effects associated with these products. The overall environmental impacts would be short-term, and not significant. Mitigation measures that may be employed to reduce any other potential adverse effects that may otherwise be significant may include preparing pest management plans that are discussed earlier in this chapter. • Hunting and trapping may be accomplished in accordance with State and local regulations that would mitigate any potentially significant environmental impacts; such regulations factor in species population to determine the number of permits that can be issued without adversely impacting species population. • Under this Alternative, proposed § 112.84 could also state that Part 112 does not require covered farms to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. • Costs under Alternative II would be higher than what would be expected under Alternative I. • In terms of reducing pathogens, impacts are expected to be beneficial. However, if chemicals are used in exclusion measures and if they are not handled in accordance with labeling requirements, these impacts could be minimal but adverse particularly with regard to worker health and safety.

Subpart A: General Provisions (Scope of Coverage of the Proposed Rule); includes impacts related to the cumulative effects of each proposed standard assessed together

Water Resources –

- Significant current and ongoing adverse impacts such as reduced water availability, water-table declines, soil subsidence and increased costs for finding and maintaining access to water, resulting from groundwater withdrawals are presently experienced in regions B, C, D, I, J, and U. These impacts represent the current condition, absent of any final rule, and are the result of many factors that include agricultural practices nationwide, development, and other factors unrelated to FDA's proposed action. Any action (personal, Federal, State, local, etc.) in these regions that would cause a farmer or any entity to draw from groundwater instead of surface water could exacerbate the current environmental conditions, generally. Under such conditions, individuals on Native American reservations in regions B and C may be disproportionately adversely impacted as a result of continued groundwater drawdown. We consider impacts from actions that result in groundwater drawdown to be significant in regions where current conditions for groundwater depletion have significant environmental impact. Such impacts are best considered under the cumulative impacts impacts section, Chapter 5.

- The flexibility in meeting the proposed water quality standard is likely to mitigate the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added microbial die-off or removal.
- It is not likely that a farmer will change the water source or cease growing covered produce because among the regions that are potentially most affected (B, C, D, I, J, and U), many farmers have entered into marketing agreements that establish numeric standards that are the same as, or are more stringent than, those proposed in the PS PR. In addition, reactions and verbal comments from some industry and trade groups that FDA received on the supplemental proposed rule suggest that the new proposed provisions for microbial die-off and/or removal to achieve the proposed microbial quality standard considerably reduce the perceived need to change water source in order to comply with Alternative I. Any action that may lead to increases in groundwater drawdown, would be considered a significant environmental impact. Regions that may be most impacted in terms of potential land subsidence, including any additive effects by switching to groundwater sources, include the regions that already experience the highest groundwater withdrawals; these are regions B, C, D, I, J, and U.
- The majority of the 285 covered sprouting operations draw from municipal water already. Only minimal adverse, local and not significant impacts may occur from water treatment effluent, and no nationwide or regional impacts are anticipated to water availability from those few operations that may connect to municipal water supplies.
- With respect to water quality and impacts considered under subpart F (untreated), a switch to treatment (composting) will require additional storage time, which presents more opportunity for partially processed manure to impact surface and groundwater; but such impacts may be mitigated through best management, or proper adherence to the facility's NPDES permit (where applicable); therefore, potential adverse impacts are not anticipated. Under a decision to switch to chemical fertilizers, any improper use may have an adverse impact on surface and groundwater; however, given the small number of farms that use untreated BSAs of animal origin that could possibly switch to chemical fertilizers (820 covered farms, or 2.3 percent of covered farms nationally) the impact would not be significant, and adverse impacts may further be mitigated through proper nutrient management.

Biological and Ecological Resources–

- Adverse effects to biological and ecological resources relevant to groundwater drawdown are not expected (discussed above). However, potential adverse effects may occur from the use of disinfectants to treat poor quality water in certain areas (as follows). Disinfectants may be useful for reducing hazards that may cause foodborne illnesses; however, many of these disinfectants may form harmful byproducts. EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. As long as the pesticides are handled and applied according to label directions, no significant adverse impacts would result. Such adverse effects may be limited because a high number of growers in key growing regions, such as California, Arizona, and Florida, participate in marketing agreements that have more stringent water quality standards than what FDA has proposed and are already using water that would be in compliance with the proposed standard, if finalized.

- With respect to subpart I (wildlife intrusion), any measures taken to exclude wildlife (including measures to clear land to facilitate monitoring) may involve the use of herbicides, rodenticides, or other materials that may have short-term toxic effects to water resources; biological resources and ecosystems directly adjacent to the farm; and soils. These impacts may be mitigated through proper use and handling in accordance with labeling requirements (discussed above). Therefore, the overall environmental impacts would be short-term, and not significant. Mitigation measures that may be employed to reduce any other potential adverse effects that may otherwise be significant may include preparing pest management plans that are discussed earlier in this chapter. Additionally, proposed § 112.84 does not require covered farms to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. The preferred alternative, and more likely management decision that a farmer may make, is to monitor their fields and evaluate whether produce can be harvested safely. As discussed above, any unharvested portions of the field may provide non-significant beneficial impacts to wildlife species as a result of added short-term cover and forage area.
- Hunting and trapping may be accomplished in accordance with State and local regulations that would mitigate any potential significant environmental impact which factor in species population before determining the number of permits that can be issued without adversely impacting the species survivability.

Soils–

- With respect to soil health and impacts related to subpart F (untreated – presently deferred, see Waste Generation below), farmers that switch to treated material may require additional testing to predict nitrogen availability and meet agronomic needs and environmental goals, but with proper management, no impact to soils are expected. A switch 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 such as through green manuring.

Waste Generation, Disposal and Resource Use–

- Approximately 12.5 percent of produce farms use BSAs of animal origin, and of those that use BSAs of animal origin, only roughly 18.5 percent use untreated manure (this is 820 farms nationally, or 2.3 percent of the covered produce farms), and 10.2 percent of covered produce farms use treated BSAs of animal origin (this is 3,618 covered farms nationally). Therefore, a relatively small number of farms nationwide are expected to be impacted by the rule.
- (Untreated) As discussed above, given the long interval between application and harvest, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period. Treatment (composting) will require additional storage; however, given the small number of farms that may be affected nationwide (820 or 2.3 percent of covered farms), this requirement is not expected to result in a significant impact.
- (Treated) The proposed condition would be similar to the existing condition. No impacts would be associated with this alternative and corresponding management decisions. The use of chemical fertilizers in place of treated BSAs of animal origin as a nutrient source is unlikely to occur under this alternative because the alternative does not restrict the timing of the use of BSAs, but would impose a requirement to apply in a manner that does not contact covered produce.

Air Quality and Greenhouse Gases-

- There are minimal adverse environmental impacts (not significant) associated with air quality and greenhouse gases.

Socioeconomic and Environmental Justice –

Major cost summary

As discussed previously, potential socioeconomic impacts related to the socioeconomic resource component that are associated with meeting the requirements for the provisions of the PS PR, if finalized, could stem from economic costs that result from management decisions to comply with the standards. In addition, FDA would consider estimates prepared by FDA in the 2014 supplemental regulatory impact analysis (2014b) in its consideration of environmental alternatives (see 40 CFR 1502.23). The 2014 economic impact analysis put the total cost of implementing the provisions of the PS PR (2013 proposed rule and supplemental notice, taken together) at $386.23 million nationwide for businesses with an average annual monetary value of produce sold during the previous three-year period of more than $25,000 (FDA, 2014b). Table 4-7 breaks down these costs by provision and by size class of farm.

Table 4-7. Summary of costs for the PS PR (in millions)

Cost Sections	Not Covered	Very Small	Small	Large	Total	Original	Difference
Administrative cost to learn the rule	$11.50	$14.34	$6.09	$7.17	**$39.10**	$36.79	$2.31
Health and Hygiene	$0.00	$23.24	$12.88	$82.06	**$118.17**	$138.21	-$20.04
Agricultural Water	$0.00	$20.29	$4.84	$11.10	**$36.23**	$48.55	-$12.32
BSAs of Animal Origin	$0.00	$0.00	$0.00	$0.00	**$0.00**	$9.20	-$9.20
Domesticated and Wild Animals	$0.00	$8.82	$5.10	$18.38	**$32.30**	$37.78	-$5.48
Growing, harvesting, packing, and holding activities	$0.00	$0.15	$0.08	$0.14	**$0.36**	$0.42	-$0.06
Equipment, tools, buildings, and sanitation	$0.00	$9.73	$7.03	$33.58	**$50.34**	$58.87	-$8.53
Sprouting operations	$0.00	$0.64	$0.61	$5.19	**$6.44**	$7.53	-$1.09
Personnel Qualifications and Training	$0.00	$16.76	$10.98	$50.43	**$78.17**	$91.42	-$13.25
Corrective steps	$0.00	$0.41	$0.19	$0.85	**$1.44**	$2.09	-$0.65
Variances	$0.00	$0.00	$0.01	$0.01	**$0.08**	$0.10	-$0.02
Recordkeeping	$0.00	$13.36	$3.47	$6.76	**$23.59**	$28.60	-$5.01
Total Costs (annual in millions)	$11.50	$107.73	$51.26	$215.73	**$386.23**	$459.56	$73.33
Average Cost per Farm	$88	$4,477	$12,384	$29,545	**$10,996**	$11,430	-$433.65

Source: FDA, 2014b

Notes: Costs presented are annualized over 7 years at 7%. The costs of almost all of these categories have fallen from those originally proposed, due to either reduced requirements or a smaller number of covered farms estimated to incur costs. The sole exception is the total costs to farms not covered by the supplemental proposal. The costs to this group have grown simply because we now estimate there are more farms that would not be covered or would qualify for an exemption; the per-farm costs to this group have not changed.

The average projected per-farm cost of complying with the provisions of the PS PR is approximately $11,000, though this estimate is much lower (i.e., approximately $4,500) for very small farms. Small and very small farms may not be able to afford the added cost burden of complying with the provisions of the PS PR. It is anticipated that these farms, if they are not able to qualify for an exemption to reduce the cost of compliance, would be the most likely to make management decisions that would result in them not being subject to the provisions of the PS PR.

As discussed under Chapter 4.2, based on the comments FDA has received to date, FDA does not expect farmers to decide to cease growing covered produce as a preferred management decision except in select instances which are often driven by outside pressures such as a program run by the state of California that pays farmers to keep land fallow in order to divert water to the cities. This is not a re-zoning of the land; rather, that land is essentially reserved for future alternative agricultural uses.

If non-covered produce or other agricultural crops that are not produce are grown, requirements to maintain certain water quality conditions would be dependent on any existing state regulations or industry marketing agreements. The type of crop a farmer may select to grow would also be dependent upon the region’s climate, soils, water availability, and may involve a decision whether the existing farm’s equipment and infrastructure would be sufficient, or would need to be updated, modified, or bought to accommodate a new type of crop.

Under certain conditions, where very small farms are involved and costs may be a larger factor, some farms may decide to stop growing crops altogether. However, this scenario would be most likely for very small farms as well as livestock operations that grow small amounts of covered produce (although many such diversified farming-livestock operations would likely be excluded based on the new proposed monetary threshold for excluded farms applied to sales of produce only rather than sales of food). There are no data to suggest under what conditions specifically such a management decision may occur, and there are no data available to quantify or qualify any related indirect impacts.

Also related to subpart E, there may be additional costs from those projected in FDA’s Regulatory Impact Analysis (FDA, 2013b and 2014b) if farmers add a post-harvest mechanism (e.g., FDA-approved wash or rinse) to achieve microbial die-off or removal, which could potentially result in additional socioeconomic impacts.

Under subpart F, the production and transport of chemical fertilizers is not expected to have a significant adverse impact on energy use and air quality because the resource use is not expected to change significantly as compared to current conditions.

Also under subpart F, since it is unlikely that growers will observe the waiting period (discussed above) any costs associated with storing untreated BSAs of animal origin for longer requisite time periods would be unnecessary.

Environmental justice –
Minority groups: As discussed in Chapters 1.9, 3.7, and 4.1, Environmental Justice impacts related to the PS PR are assessed for minority principal operators and minority farmworkers. This is because of the limited amount of data that is available from USDA NASS surveys and the U.S. Department of Labor. Although potential cost impacts could be felt by consumers, without more definitive information regarding specific management decisions that might be taken in response to the PS PR, if finalized, it is unreasonable to project impacts on such groups. Therefore, for the purposes of this EIS, the discussion of potential socioeconomic impacts is limited to principal farm operators and farmworkers (where information is available.

When considering the thresholds established in Chapter 3.7 for identifying potential impacts to minority principal operators, regions that are important for identifying potential impacts to minority principal operators are regions A, B, C, D, W, and V. Of these regions, regions B and C are major produce growing regions (see Chapter 1.7). Information for minority farmworkers is provided below.

<u>Principal operators</u>
Like all principal operators, minority principal operators would need to make management decisions regarding whether to comply with the provisions of any final rule or to cease growing covered produce. As noted above, very small farms are more likely than larger farms to decide to stop growing covered produce altogether if the farm manages livestock operations that also grow small amounts of covered produce. Based upon the “meaningfully greater” threshold FDA established for minority populations of principal operators potentially affected by the rule, regions where minority principal operators manage very small farms that are more likely to make a management decision to cease growing covered produce are regions A, B, C, D, W, and V. FDA has no data to suggest under what conditions specifically such a management decision may occur, and there are no data available to quantify or qualify any related indirect impacts.

<u>Minority farmworkers</u>
Based on the limited information on farmworkers reported by the U.S. Department of Labor through surveys taken by that agency (see Chapter 3.7.3), regions where there are potentially populations of minority farmworkers that may be impacted by the rule, if finalized, include regions C, D, I, and J. Costs incurred by farms of all sizes may result in the farm either increasing the costs of their produce for consumers, or may involve the farm principal operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. FDA has no data to determine where in the nation, or under what specific circumstances may occur as such decisions are highly specific to the individual farm; however, with respect to the scope of this EIS, regions were such actions may adversely disproportionately affect minority farmworkers due to employment-related impacts, include regions C, D, I and J.

Native American operators: Of all farms that are operated by Native American principal operators, whether located on or off reservations, 5.5 percent report growing vegetables, 2.4 percent report growing fruits and tree nuts, and 15 percent report growing combination crops. There may be farms that produce crops in multiple of these categories, and these categories include both covered and non-covered crops. Therefore, based on a very conservative estimate, no more than 22.9 percent of farms—the sum of these three categories—that are operated by

Native American principal operators may be growing covered produce (USDA NASS, 2014a). Based on USDA NASS data (2014a), 78 percent of all Native American farms sell less than $10,000 in total sales, annually, meaning that, at most, 22 percent of farms with a Native American principal operator would be covered farms under the PS PR, if finalized. If it is assumed that these trends are consistent across all commodities, this means that, at most, 5 percent of farms with a Native American principal operator would be covered by the rule (22 percent of 22.9 percent is approximately 5 percent). Moreover, farms that sell less than $25,000 annually in produce—not $10,000—are not covered by the PS PR. An additional 14 percent of farms with a Native American principal operator sell less than $49,999, meaning there is a reasonable likelihood that additional farms with a Native American principal operator would not be covered by the PS PR, if finalized. It is not possible to estimate what percent of farms lie between $10,000 and $49,999 average annual sales. An additional 5 percent of Native American operated farms have less than $249,999 in total sales.

Despite the low number of total Native American owners/operators who may be covered by the rule, there is a potential that added operating costs associated with the rule would impact a disproportionate number of Native American farmers compared to farmers as a whole, given that the average income for a farm for which a Native American is the principal operator is 30 percent lower than a farm for which the principal operator is not a Native American (per the 2007 Agricultural census). The average reported agricultural product sales for Native American operated farms is $40,331, compared to an average of $134,807 for all farms. The average potential per farm cost of approximately $4,500 for very small farms could be disproportionally burdensome for farms with a Native American principal operator, as this cost would comprise approximately 11 percent of average annual sales, compared to 8 percent of the average annual sales of all farms.[16] However, the potential impacts for very small and small farms may be entirely mitigated to the extent these farms are eligible for a qualified exemption. It is assumed that large farms would be able to absorb any additional costs of complying with the provisions of the PS PR.

Low-income: As discussed in chapter 3.7.3, this class includes any persons whose median household income is at or below the HHS poverty guidelines. The poverty threshold for a family of four in 2012 was set at $23,050. According to the ERS's data sheet, *Principal Farm Operator Household Finances by ERS Farm Typology*, in 2012, median farm operator household income, an average of the farm and off-farm household incomes of residence farms, intermediate farms, and commercial farms, was $68,298.[17] This exceeds both median U.S. household income, and the HHS poverty thresholds for all HHS poverty thresholds. While there may be low-income principal operators that may be adversely impacted by the costs associated with the rule, we cannot identify a low-income population on a national or regional level.

Low-income farmworkers: As discussed under minority farmworkers, impacts may involve the farm principal operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. FDA has no data to determine where in the nation, or under what specific circumstances may occur as such decisions are highly specific to the

[16] $4,500 divided by $40,331 equates to approximately 11 percent.
[17] There is limited data for principal farm operator income other than on a national level.

individual farm. Based on data provided by the U.S. Department of Labor (information reported for California) (DOL, 2000 and 2005), region C has populations of low-income farmworkers that may be disproportionately impacted by the rule. Note that other regions may experience similar impacts, but there is not enough data available to understand which regions may specifically be impacted.

Human Health–
Foodborne illnesses prevented

FDA estimates, in the 2014 Regulatory Impact Analysis to the PS PR, that the number of foodborne illnesses prevented when considering the rule as proposed, all provisions, is 1.57 million, annually (FDA, 2014b). This represents a significant beneficial outcome to human health.

Human health impacts
Under subpart E, EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. As long as the pesticides are handled and applied according to label directions, no significant adverse impacts to human health would result.

Under subpart F, the production and transport of chemical fertilizers is not expected to have adverse impacts to air quality, and therefore, adverse impacts are not expected to human health.

4.7.1 Alternatives Analysis

By applying the potential environmental impacts from each of the potential management decisions above, we may now identify the potential environmental and related socioeconomic impacts to each of our alternatives that were first identified in Chapter 2.1 Subpart A. A comparison of potential impacts is provided below and summarized in Table 4-8.

Table 4-8. Comparison of potential impacts by alternative for subpart A

		≤ \$25,000 * total produce excluded Alternative I	≤ \$50,000** Food, excluded Alternative II	≤ \$100,000** Food, excluded Alternative III	≤ \$25,000 covered produce excluded Alternative IV
Comply with the rule	Covered Farms	35,503	28,253	20,140	Slightly fewer than Alternative I
Comply with the rule	Excluded Farms	130,204	Greater than Alternative I	Greater than Alternative II	Slightly greater than Alternative I
Comply with the rule	Environmental impacts (Chapters 4.1 – 4.7)	Greater than baseline	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
Comply with the rule	Economic impacts (domestic costs annually)	\$540.49 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
Comply with the rule	Domestic benefits (health-related cost savings)	\$930 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
Comply with the rule	Public health benefits (foodborne illnesses prevented annually)	1.57 million	Less than Alternative I (less foodborne illnesses prevented)	Less than Alternative II (less foodborne illnesses prevented)	Slightly fewer than Alternative I (more foodborne illness prevented)
Switch to non-covered crop	Covered Farms	Less than 35,503	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
Switch to non-covered crop	Excluded Farms	Greater than 130,204	Greater than Alternative I	Greater than Alternative II	Slightly greater than Alternative I
Switch to non-covered crop	Environmental impacts (Chapters 4.1 – 4.7)	Less impacts compared with complying	Less impacts compared with Alternative I	Less impacts compared with Alternative II	Slightly fewer than Alternative I
Switch to non-covered crop	Economic impacts (domestic costs annually)	Less than \$540.49 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
Switch to non-covered crop	Domestic benefits (health-related cost savings)	Less than \$930 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
Switch to non-covered crop	Public health benefits (foodborne illnesses prevented annually)	Less than 1.57 million	Less than Alternative I (less foodborne illnesses prevented)	Less than Alternative II (less foodborne illnesses prevented)	Slightly fewer than Alternative I (more foodborne illness prevented)

**As updated in the Supplemental PRIA, published September 2014.*
***The associated estimates are found within the 2013 PRIA (FDA, 2013b).*

Under the Preferred Alternative (Alternative I) more farms would be covered than if the average annual monetary value threshold for exclusion of farms were higher (as in Alternatives II and III) or if the threshold was changed to covered produce only (as in Alternative IV).

For any alternative the expected environmental outcome may be as follows:

- Significant current and ongoing adverse impacts such as reduced water availability, water-table declines, soil subsidence and increased costs for finding and maintaining access to water, resulting from groundwater withdrawals are presently experienced in regions B, C, D, I, J, and U, and represent the current condition, absent of any final rule. Any action in these regions that would cause a farmer or any entity to draw from groundwater instead of surface water could exacerbate the current environmental conditions, generally. Under such conditions, individuals on Native American reservations in regions B and C may be disproportionately adversely impacted as a result of continued groundwater drawdown. We consider impacts from actions that result in groundwater drawdown to be significant in regions where current conditions for groundwater depletion have significant environmental impact. Such impacts are best considered under the cumulative impacts section, Chapter 5.

- However, such impacts are not expected to occur as a result of this rule based on the flexibility in meeting the proposed water quality standard (see the following bullets).
- The flexibility in meeting the proposed water quality standard is likely to mitigate the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added microbial die-off or removal.
- Moreover, reactions and verbal comments from industry and trade groups that FDA has received so far on the supplemental proposed rule suggest that the new proposed provisions for microbial die-off and/or removal to achieve the proposed water quality standard considerably reduce the perceived need to change water source in order to comply with Alternative I under subpart E. In addition, many farmers have entered into marketing agreements that are the same as, or operate under more stringent numeric water quality standards than those proposed in the PS PR.
- Other environmental impacts nationwide are expected to be not significant, with the exception of human health and safety where there would be significant beneficial outcome to human health.

Therefore, given this analysis, FDA expects the PS PR, if finalized as proposed, would have significant adverse environmental impacts on groundwater and soil resources that are reviewed within the scope of this EIS.

For any alternative where fewer farms are covered by the rule (fewer than Alternative I – Preferred Alternative), the potential outcomes may be as follows:

- The expected annual economic impacts nationwide would decrease but the expected per farm costs are anticipated to remain the same as Alternative I.
- The expected environmental impacts, both adverse and beneficial, would decrease nationwide, but not to the extent that would reduce any already significant impacts to a less than significant level.
- The expected number of foodborne illnesses would decrease, which means fewer public health benefits would be experienced.

<u>Mitigation</u>

Many of the potential impacts discussed above may be mitigated through management decisions made by farm operators. Mitigation of potentially adverse environmental impacts may also be achieved, for example, through the proper use and handling of pesticides and other resource treatment technologies, and through any State’s applicable permitting process.

Lastly, the final rule does not authorize or permit unlawful behavior associated with the use or management of natural resources. Federal and State environmental laws will remain unaffected by implementation of the final rule.

5.0 Cumulative Impacts

5.1 Introduction

The Council on Environmental Quality (CEQ) Regulations for Implementing NEPA require a cumulative impact assessment within the decision making process for proposed major Federal actions (40 CFR §§ 1508.7 and 1508.25(a)(2)). A cumulative impact is defined as "*the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or a person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.*" (40 CFR §1508.7). CEQ's guidance for considering cumulative effects further states that NEPA documents "*should compare the cumulative effects of multiple actions with appropriate national, regional, state, or community goals to determine whether the total effect is significant.*" (CEQ, 1997b).

Chapter 5.2 discusses the methodology used to evaluate potential cumulative impacts as compared with direct and indirect impacts that are addressed in Chapter 4. Chapter 5.2 also identifies Federal and non-Federal actions that are considered in this analysis because those actions may contribute to the aggregate and incremental impact of the proposed action when taken together across the nation and over a certain period of time.

5.2 Methodology for Analyzing Potential Cumulative Impacts

The timeframe for the analysis includes the past; the present; and the reasonably foreseeable future, which includes the compliance dates by which businesses potentially affected by the rule would be required to fulfill the requirements of the final rule. For the purposes of this analysis, FDA is considering the reasonably foreseeable future to extend to approximately six years beyond when any final rule may be issued (this is consistent with the compliance dates discussed in Chapter 2.1, see Table 2.1-8), or 2021.

The geographic scope of the analysis is the same as what is presented in Chapter 1.9; this EIS considered the potential environmental and related socioeconomic and public health impacts to regions within the United States (including all 50 states and the EIS geographical areas, when relevant information was available) (see Figure 1.7-4). Wherever feasible, due to the scale of the proposed action, FDA assesses potential impacts within regions or states. Qualitative information is appropriate because site-specific (measurable/quantitative) information is not practical at a regional or national scale of analysis. Further, the management decisions that a grower may take in order to comply with a final rule would be highly specific to the grower, the location (climate, water availability, soils and nutrient availability, commodity market, etc.), and any industry marketing agreements or local regulations that are being implemented, in addition to those at the Federal and State level; therefore, a number of potential effects are not quantifiable.

FDA used the following steps to analyze potential cumulative impacts for this EIS:

1. Identify Federal, State, or industry standards or practices that both have relevancy to the production of covered produce, and set guidelines that are important to reducing hazards associated with microbial contamination and associated outbreaks of foodborne illness;
2. Identify the participants included in the Federal, State, or industry standards of relevance;
3. Identify potential other environmental, industry, or private actions nationwide that may contribute incremental adverse effects to the proposed action;
4. Identify the similarities and differences in the approach to establishing scientifically valid measures to reduce pathogens on fresh produce to enhance human health, the criteria established to achieve the desired result, and the time of issuance of the various standards.
    a. Examine for similar regulatory or industry programs that place requirements on the same affected community[1];
    b. Examine for complementary program elements that have already established measures similar to the PS PR; and,
    c. Compare to see if the PS PR is more stringent or less stringent than existing standards.

FDA has determined that domestic farms and farm-mixed type facilities that grow covered produce[2] would incur costs as a result of complying with a final rule. In addition, the farmer may make some management decisions in order to come into compliance with, or to potentially avoid being subject to a final rule (management decisions are discussed in more detail in Chapters 1.9, 2.1, and throughout Chapter 4). These management decisions may result in added costs to operate the farm, and potentially may adversely impact the environment. Potential environmental effects may extend throughout a region if enough growers make changes at a local scale to influence a wider geographic area (e.g., groundwater withdrawals). Public health (including low income, minority, and Native American Indian Tribes) may also be affected both adversely and beneficially as a result of the proposed action. It is important to note that this analysis also includes those provisions that were identified as not being “potentially significant provisions”[3] that could result in potential significant impacts to the environment (discussed in Chapter 2.2). Although FDA determined in Chapter 2.2 that these provisions (subparts C, K, L, N, O, P, Q, and R) would not individually reasonably result in adverse environmental consequences, they may have cumulative adverse effects, particularly in terms of decisions made as a result of potential added costs to farms affected by the rule.

The conditions that affect farms nationally are discussed throughout the EIS. Persistent environmental conditions that have changed how agricultural communities operate and that

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[1] For example, there may be more than a hundred different types of State and industry-driven marketing agreements nationwide that may have various requirements related to provisions proposed in the PS PR. FDA looked at a few representative examples (e.g., CA LGMA or T-GAPs) as a means of comparison.

[2] As defined in Chapter 1.6 and 21 CFR proposed §112.1

[3] As potentially significant provisions are defined in Chapter 1.2.

continue to force farmers to adapt to these changing conditions (e.g., types of crops produced, how they irrigate crops, etc.) are discussed at the end of Chapter 1.9. Current baseline conditions that are relevant to specific proposed provisions are discussed in Chapter 2.1. Background environmental conditions (e.g., health of the water, soil, air, and industry practices such as how and where manure is generated) are discussed throughout Chapter 3 and in Appendix B and C. Conditions relative to the No Action Alternative and to certain potential management decisions are discussed throughout Chapter 4. The aggregate of these conditions represent the affected environment, which is also relevant to this cumulative effects analysis.

5.3 Federal and Non-Federal Actions Relevant to the Cumulative Impacts Analysis

5.3.1 Related FSMA Actions

The following FDA NEPA documents were consulted because they directly relate to other FSMA actions. Note that Categorical Exclusions are defined as categories of actions which do not individually or cumulatively have a significant effect on the human environment and, therefore, would not contribute to any potentially significant effects within this cumulative impacts analysis (40 CFR §§ 1500.4(p) and 1508.4).

FSMA Intentional Adulteration Proposed Rule
November 14, 2013 Categorical Exclusion Evaluation (FDA, 2013d): The identified impacts include beneficial impacts to Human Health and Safety, as well as insignificant Ecological and Biological impacts. The proposed rule mentions, but does not require the use of broad mitigation strategies (i.e., fencing) to assist with protection of food from intentional adulteration. As broad mitigation strategies, which serve as foundational actions or procedures that improve a facility's overall defense against intentional contamination caused by acts of terrorism, are already largely in use or would be implemented at largely industrial locations, significant environmental impacts are not expected.

FSMA Sanitary Transportation of Human and Animal Food Proposed Rule (ST PR)
November 22, 2011 Categorical Exclusion Evaluation (FDA, 2011X): No adverse or beneficial impacts were discussed in the evaluation. While beneficial impacts were not specifically addressed in the evaluation, FDA does consider this type of action to be part of a class of actions that will result in beneficial impacts to human health and safety.

FSMA Preventive Controls for Human Food (PC HF PR)
June 21, 2011 (FDA, 2011c) and (Supplemental) August 29, 2014 Categorical Exclusion Evaluation (FDA, 2014c): The PC HF PR requires that the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under Section 402 or misbranded under Section 403(w) of the FFDCA. Significant impacts were not identified, although beneficial impacts on human health would be anticipated.

FSMA Proposed Rule for Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP)

August 25, 2011 Categorical Exclusion Evaluation (FDA, 2011d): The FSVP requires good importing practices for food for humans and animals, requiring hazard analysis and supplier verification. This rule is related to imports, creates no new requirements for produce, and only requires verification that proposed part §112 regulations have been followed.

FSMA Third Party Accreditation

September 1, 2011 Categorical Exclusion Evaluation (FDA, 2011e): This proposed rule would establish a system for the recognition of foreign government agencies or private companies that would accredit third-party auditors of foreign food facilities. These auditors would conduct food safety audits and issue certifications that FDA may use in deciding whether to admit certain imported food into the U.S. that the agency has determined poses a food safety risk.

5.3.2 Other Past, Present, and Reasonably Foreseeable Future Actions

Table 5.3-1 includes other Federal and non-Federal actions that could have affected or could affect growers of covered produce. Table 5.3-1 also lists similar Federal and State/private efforts to manage pathogen transport on fresh produce commodities. In addition, the table includes one major subsidy elimination action related to a high-value crop that could be grown on farms with small tracts of land available. Furthermore, the table includes sustainable conservation practices and measures that work in tandem with efforts between industry and the government to support conservation on the farm and to build a sustainable system where farm production can supportively coincide with wildlife and habitat management efforts. More specific requirements on some of these programs are found in Chapter 2.1, Table 2.1-1.

Table 5.3-1. Comparable Federal and non-Federal actions

Comparable Program	Brief Description	Relevant Standards	Past, Present, and Future Outcomes
FDA Guidance to Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (the GAPs Guide)	Contains voluntary recommendations that growers and packers can take to minimize contamination in their operations, and includes practices associated with the growing, harvesting, packing and holding of fresh produce.	The GAPs Guide provides recommendations for: - Agricultural water - Manure - Worker health & hygiene - Sanitary facilities - Field sanitation - Packing facility sanitation - transportation	Established in 1998, the GAPs Guide is the basis for the USDA AMS GAP&GHP audit program (see Chapter 2.1)

Comparable Program	Brief Description	Relevant Standards	Past, Present, and Future Outcomes
USDA AMS GAP&GHP audit program	Provides voluntary independent audits of produce that are focused on best agricultural practices to verify that fruits and vegetables are produced, packed, handled, and stored in the safest manner possible to minimize risks of microbial contamination	- The GAP&GHP audits verify adherence to the recommendations made in the GAPs Guide and industry recognized food safety practices.	Established in 2006
USDA organic regulations 7 CFR Part 205	National standards for organically-produced agricultural products, restrictions include the national list of allowed and prohibited substances. Includes timing restrictions for using untreated manure, and standards for composting.	- Pre-harvest and post-harvest water standards - Untreated and treated BSAs of animal origin	Has existed since 1990. Participants who agree to adhere to the requirements can market their product as Certified Organic.
USDA-NRCS Conservation Technical and Financial Assistance	Provides the agriculture industry with guidance for applying conservation technology on the land. Standards for those voluntarily applying conservation practices are issued in the National Handbook of Conservation Practices and are updated through notices. [4]	- May be used on a voluntary basis by growers of covered produce.	Has existed since 1990. Protects soil, water, and enhances potential for profitability.
The Fair and Equitable Tobacco Reform Act of 2004	The Tobacco Transition Payment Program (TTPP), also called the "tobacco buy-out," helps tobacco quota holders and producers transition to the free market.	- None (relevancy may include if former tobacco growers switch to growing covered produce, which has historically occurred in States, e.g., Maryland, where the tobacco transition program caused a shift in a small portion of the growing industry).	Payments began in 2005 and end in 2014.

[4] More information on NRCS Conservation Practice Standards may be found at the following Web site: http://www.nrcs.usda.gov/wps/portal/nrcs/detailfull/national/technical/references/?cid=nrcsdev11_001020

Comparable Program	Brief Description	Relevant Standards	Past, Present, and Future Outcomes
Tomato Good Agricultural Practices (T-GAPs) and Best Management Practices Manual (BMP)	Mandatory program in Florida (voluntary elsewhere) for growers of tomatoes, designed to prevent and reduce microbial contamination, and must be followed in the production, handling, packing, distributing, transporting, selling and serving of the product.	- Pre-harvest and post-harvest water standards - Agricultural / irrigation water quality requirements - Worker health & hygiene - Application of manure (raw and composted) - Equipment - Recordkeeping - Pest management and animal exclusion	Florida's program was formed in 2007
Leafy Greens Marketing Agreements	Voluntary program for growers of edible leafy vegetable produce in California and Arizona.	- Pre-harvest and post-harvest water standards - Untreated and treated BSAs of animal origin - Wild Animals	CA LGMA was formed in 2007. AZ LGMA was formed in 2007.
Industry-Wide Food Safety Standards for Fresh Mushroom Growing, Harvesting, and Shipping	Voluntary program for growers of edible fungi throughout the U.S.	- Pre-harvest and post-harvest water standards - Untreated and treated BSAs of animal origin - Wild Animals	Went into effect in 2008.
FDA Draft Guidance for Industry: Guide to minimize food safety hazards of tomatoes	Guidelines provide recommended food safety practices that are intended to minimize the microbiological hazards associated with fresh and fresh-cut tomato products.	- Agricultural water - Untreated and treated manure - Pest management - Worker health & hygiene and training - Recordkeeping - Packing, handling, and holding activities	Issued in 2009
FDA Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons	Recommends practices to minimize the microbial food safety hazards of their products throughout the entire melon supply chain	- Recordkeeping - Equipment cleaning and sanitation - Pest management - Worker health & hygiene and training - Agricultural water	Issued in 2009
FDA Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens	Recommends practices to minimize the microbial food safety hazards of their products throughout the entire leafy greens supply chain	- Recordkeeping - Equipment cleaning and sanitation - Pest management - Worker health & hygiene and training - Agricultural water	Issued in 2009

Comparable Program	Brief Description	Relevant Standards	Past, Present, and Future Outcomes
California cantaloupe program	State-specific, commodity specific voluntary program; includes requirements for a Food Safety Compliance and Implementation Plan, water testing, worker safety, hygiene, and training, and environmental analysis (including animal intrusion and flooding) and documentation of soil amendments.	- Pre-harvest and post-harvest water standards - Untreated and treated BSAs of animal origin - Wild Animals	Went into effect in 2012.
State specific agricultural water quality standards and nutrient management standards	State laws and EPA delegated CWA and SDWA authority.	- Pre-harvest and post-harvest water standards	Varies.
FSMA Preventive Controls for Human Food Proposed Rule (PC HF PR)	Regulates food processing facilities (e.g., food manufacturing facilities and farm mixed-type facilities), and includes: 1) New requirements for hazard analysis and risk-based preventive controls; and, 2) Revisions to existing CGMP requirements.	- Health and Hygiene - Record-Keeping	Anticipated to be finalized in 2015, with compliance dates for very small businesses for up to three years after the rule may be finalized

In addition to Table 5.3-1, there are other non-specific actions and impacts that are occurring nationwide that, when taken together with the FDA's proposed action, could result in cumulative effects to growers of covered produce.

Non-specific actions

Oil and Gas exploration and development. Federal oil and gas lease surface operations are managed by the Bureau of Land Management (BLM) in cooperation with the appropriate Federal surface management agency (Federal land owner) or non-Federal surface owner. The BLM is responsible for ensuring compliance with NEPA for oil and gas exploration on Federal lands nationwide; and in support of its environmental responsibilities, the agency has developed a Gold Book that includes best management practices for minimizing and mitigating adverse environmental impacts. Nevertheless, significant adverse effects to natural resources are documented annually as a result of exploration and development.

Residential and commercial development. The U.S. Department of Housing and Urban Development (HUD) is the Federal agency responsible for national policy and programs that address America's housing needs. HUD reported in September of 2014 (most recent report available) that purchases of new home sales climbed 18.0 percent from a month earlier to a seasonally adjusted annual rate of 504,000 in August. [5]

That National Association of Realtors reported that for the year 2013, new completions (new development) resulted in a net gain of 33 million square feet of office property, and that number is expected to grow by another 46 million square feet for 2014. For Industrial property, there was 115.7 million square feet developed within the first nine months of 2013, and this number is expected to grow another 174 million square feet of new construction in 2014.

While some of this development occurs on previously disturbed land, other development (unspecified) would require clearing vegetation and impacts to surface waters and wetlands.

Groundwater Drawdown. Although this is addressed in Chapter 3.1 and in Chapter 4, the USGS reports that groundwater use has increased markedly since the 1950s (USGS, 2013). There are several geographical areas where large-scale groundwater depletion is evident over agricultural areas with a high percentage of the covered farms (Figure 3.1-23). Significant dewatering is evident over the Central, Coachella and Death Valleys of California; Alluvial Basins of Arizona; and the Columbia Plateau in southeastern Washington and northeastern Oregon. Agricultural uses remain a primary cause of groundwater withdrawals in many regions.

Land subsidence. Although this is addressed in Chapter 3.3 and in Chapter 4, land subsidence will continue to be exacerbated by a number of factors including agriculture and continued commercial and residential development. The USGS reports that land subsidence in the U.S. has directly and adversely impacted more than 17,000 square miles of land/soils in 45 States; this is an area roughly the size of Vermont and New Hampshire combined (USGS, 2000). The principal causes are aquifer system compaction, drainage of organic soils, underground mining, hydrocompaction, natural compaction, sinkholes, and thawing permafrost (National Research Council, 1991). For the purpose of this EIS, and in accordance with USGS reports, land subsidence as a baseline condition is considered an ongoing significant adverse impact.

Climate Change. The Intergovernmental Panel on Climate Change (2014) released a report that highlights the changes in worldwide climate and the impacts on human and natural systems. The changing climate has been indicative of an overall decrease in cold temperature regions, an increase in warm temperature extremes (includes the arid Western U.S.), a projection for more intense weather conditions and extreme precipitation events, to name a few. The report further indicates that rural areas the world over are expected to experience severe impacts related water availability and food security, which in turn is anticipated to directly affect agricultural income. One distinct effect includes a shift in where food crops are grown worldwide.

[5] This represents new construction, there are separate statistics on sales of existing homes.

5.4 Federal and Non-Federal Action Descriptions

This section provides descriptions of the actions listed in Table 5.3-1 as a means of comparing these actions to FDA's proposed action.

FDA Guidance to Industry:
Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables
Draft Guidance: Guide to Minimize Microbial Food Safety Hazards of Tomatoes
Draft Guidance: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens
Draft Guidance: Guide to Minimize Microbial Food Safety Hazards of Melons
And USDA AMS GAP&GHP audit program

As discussed in Chapter 1.9, in 1998, FDA issued its "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" ("Guide" or "FDA's 1998 Guide") (FDA, 1998).[6] In 2002, the New Jersey Department of Agriculture petitioned USDA AMS to implement an audit-based program to verify conformance with the 1998 Guide. This led to the creation of USDA AMS's GAP&GHP audit program (USDA AMS, 2006). The audit program offers voluntary independent audits of produce that are focused on best agricultural practices to verify that fruits and vegetables are produced, packed, handled, and stored in the safest manner possible to minimize risks of microbial contamination. The audits confirm adherence to FDA's recommendations made in its 1998 *Guide* as well as other industry-recognized food safety practices (USDA AMS, 2013b).

As a result of commodity-specific outbreaks of foodborne illnesses, FDA published commodity-specific food safety draft guidelines for the melon supply chain, leafy greens, and fresh tomatoes. The major elements of these draft guidance documents that are relevant to the PS PR are listed in Table 5.3-1. Essentially, these documents have provided growers of fresh produce with preventive measures that farms may take to minimize food safety hazards. Some of these recommendations have been adopted (in whole or part) by industry marketing groups within which participants of the marketing agreements managed by those groups must follow certain food safety guidelines. FDA guidance represents a wholly beneficial influence for food safety throughout much of the fresh produce market.

USDA organic regulations (7 CFR Part 205) – USDA organic regulations, as detailed in Chapter 1.4 and elsewhere throughout the EIS, are a program established for a certain consumer market with the desire to reduce the amount of artificial inputs such as pesticides, herbicides, and artificial fertilizer in foods. The program does not have restrictions on the microbial content of agricultural water, although it does regulate or restrict the chemical additives to such water. The program also places restrictions on certain types of BSAs of animal origin with respect to application to harvest intervals (for untreated manure) based on organic crop production practices.

[6] Since the document was issued as guidance and not as a regulation, it does not have the force and effect of law and therefore does not contain enforceable requirements.

USDA-NRCS Conservation Technical and Financial Assistance – NRCS conservation planning assistance is available (generally through cost-share programs and technical assistance) on a voluntary basis to producers.[7]

Fair and Equitable Tobacco Reform Act of 2004 (FETRA) – A component of the Jobs Creation Act and instituted by USDA by the Tobacco Transitional Payment Program, created a voluntary program to gradually phase out subsidy programs that paid tobacco growers incentives, with payments ending in 2014. Because tobacco farming is a high-value crop, many farms with limited acreage relied on growing it exclusively or as a predominate cash crop. In some tobacco regions, one possible management decision was to cease farming altogether at the beginning of the phase-out program; many regions or States' growers' response was to convert to other high value crops, including produce.

Florida (and other) tomato food safety audit protocol standards and verification – The U.S. Census Bureau reports that roughly 289,000 acres were harvested in the U.S. for fresh tomato production in 2010 (2012). Leading States in tomato production include Florida, California, Georgia, Indiana, Ohio, and Tennessee according to the Statistical Abstract, but many States grow tomatoes primarily for processing. Florida is the top producer of fresh tomatoes in the U.S. (approximately 42 percent by weight), followed by California (approximately 28 percent by weight) (Jones, 2014). The Florida program is mandatory for all tomato growers, however, the other States have voluntary programs, but with similar food safety standards. The Florida Department of Agriculture and Consumer Services (DACS) has published a Tomato Best Practices Manual that includes Tomato Good Agricultural Practices (T-GAPS) and Tomato Best Management Practices (T-BMP)[8]. T-GAP (a mandatory program for Florida tomato growers) requires tomato fields to be located nowhere that drainage or drift from an animal operation or any other source of contamination can be received. Domestic animals and livestock are prohibited from tomato growing fields during the growing season and during harvest. Wild animal intrusion is to be minimized to the degree possible by methods identified by wildlife experts (there were no observed requirements for excluding wild animals). There must be a pest control program environmental review and monitoring review.

In terms of agricultural water, irrigation water for tomato production in Florida must meet the following requirements:

- Water used for irrigation must meet EPA's standard for *E. coli* in recreational waters,[9] which is a standard that is similar to the PS PR, but may be considered more stringent because FDA's proposed numeric standard allows for steps to account for post-irrigation

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[7] Conservation technical and financial assistance, including Conservation Practice Standards, is not a regulatory program and does not have the force and effect of law.
[8] Exemptions from T-GAP and T-BMP are provided for growers selling direct to consumers on the premises, as "U-pick", at a local farmers' market or roadside stand provided the amount does not exceed two 25-pound boxes per customer.
[9] Specifically the EPA standard is as follows: Culturable *E. coli* at a GM of 126 CFU per 100 ml and an STV of 410 CFU per 100 ml measured using EPA Method 1603, or any other equivalent method that measures culturable *E. coli*.

microbial die-off and/or removal. Wells must be properly constructed and maintained to prevent contamination; and approved water treatments may be used to bring water into compliance with the standards in 40 CFR Part 131.4(c) except that treated water must not be in conflict with local requirements. Furthermore, foliar application at the time of harvest must meet microbial standards for potable water.

- Water used for washing tomatoes after harvest must meet microbial standards for potable water in 40 CFR Part 141.63 (i.e., a zero, non-detectible reading or count of *E. coli*) and surface water that is not treated may not be used.

In terms of soil amendments, only properly composted manure is allowed for use in tomato fields and greenhouses in the Florida program. Untreated or raw manure is prohibited for application to tomato growing areas. Proper treatment requires records of composition, dates of treatment, methods utilized, application dates and letter of guarantee, Certificate of Analysis (COA) or any test results or verification data demonstrating compliance with process or microbial standards to be documented. There is no single standard for “proper treatment”, as an auditor reviews the amendment use documents and records for compliance with prevailing national or local established composting or heat treatment standards or guidelines.

California and Arizona leafy greens marketing agreements (example of marketing agreements that are in place presently and have some standards that are similar to the PS PR) – Due to the popularity of fresh greens and in response to recent food safety concerns, these voluntary programs enacted for their members several standards that improve food safety for consumers of their products. Recalls cost the industry a considerable amount of capital, and subsequent carryover due to delayed consumer response to resume purchasing those products again had economic impacts on the growers of fresh greens.

There are three principal regions of the U.S. where leafy green fresh produce is grown for commercial distribution throughout the country: (1) Winter – November through March – the desert region of southern California and Arizona; (2) Spring and Fall – the San Joaquin Valley of California; and (3) Summer (late Spring and early Fall) – April through late October/early November – the central coast region of California (California Leafy Green Handler Marketing Board, 2012). So, although this is but one distinct commodity, the States involved in the LGMAs account for the vast majority of this class of produce grown in the U.S. for consumer consumption.

The western grower LGMAs are voluntary programs with high participation rates (approximately 99 percent of California commercial leafy greens growers and 85 percent of Arizona’s leafy greens growers). Standards under the LGMAs are mandatory for those who choose to participate. However, leafy greens (edible leaves and shoots from lettuces, cabbages, mesclun, spinach, and similar plants) are only one commodity, albeit one of the most popular produce products currently commonly in use year-round. Therefore, the area of impact does not include the entire covered produce grower community which includes other commodities and States.

These LGMAs include required microbial agricultural water standards for both irrigation (pre-harvest) and holding and packing (post-harvest) processes; these are as follows:

- Pre-harvest water that contacts edible portions of crop, (e.g. overhead irrigation, pesticide/fungicide applications) must be analyzed for generic *E. coli*; and acceptable levels are no more than 126 MPN/100ml (GM of five samples) and no more than 235 MPN/100ml (all single samples), which is more stringent than FDA's PS PR.
- Pre-harvest water where edible portions of crop are not contacted by water, (e.g. furrow or drip irrigation of above-surface crops, and dust abatement water) must be analyzed for generic *E. coli*; and acceptable levels are no more than 126 MPN/100ml (GM of five samples) and no more than 576 MPN/100ml (all single samples), which is more stringent as compared to the PS PR numeric standard when one considers the flexibility FDA provides for post-irrigation microbial die-off and/or removal.
- Postharvest water (with direct produce contact, e.g. re-hydration, core in field, etc.) must be analyzed for generic *E. coli*; and the acceptable level is zero ("negative" or "below detection limits"/100 ml) or must be treated after contact, which is the similar to the PS PR proposed standard for agricultural water that is not used for irrigation.

These LGMAs also include prescribed restrictions on usage of BSAs of animal origin:

- Untreated or "raw" manure cannot be used in edible crop production, which is similar to the PS PR.
- For previously treated fields used for other crops during the prior growing season, a 12-month (1 year) waiting period is required before planting any variety of leafy green crops for human consumption, which is more stringent than the PS PR.
- Treated (composted) BSAs of animal origin (including non-validated heat-processed manure) may be used only if microbe levels are below corresponding action level numbers, then an application interval of at least 45 days before harvest must be observed, which is more stringent than the PS PR.
- Thermally processed treated (heated/treated) soil amendments, for validated process, are allowed with no required application time interval before harvest, which is similar to the PS PR.

Industry-wide food safety standards for fresh mushroom growing, harvesting, and shipping (example of marketing agreements that are in place presently and have some standards that are similar to the PS PR) – Developed by the American Mushroom Institute (AMI) and Penn State University in 2008, the Mushroom Good Agricultural Practices Program provides a set of food-safety standards that mushroom growers can voluntarily follow to ensure the safety of fresh mushrooms. Updated in 2010, the standards are documented in the "Industry-Wide Food Safety Standards for Fresh Mushroom Growing, Harvesting, and Shipping" (commonly referred to as the MGAP standards).

Similar to the PS PR, the MGAP standards are comprehensive in that they cover a wide variety of topics such as water, soil amendments, animal intrusion, personnel training, hygiene, and sanitation of equipment/buildings.

The MGAP's irrigation numeric water standard is more stringent in that it requires mushroom irrigation water to meet the U.S. EPA's microbial standards for drinking water (no detectible generic *E. coli* within 100 ml of water).

Other MGAP standards to note include those regarding soil amendments and pest control. The MGAP standards regarding soil amendments are written to relate to the industry's commodity-specific growing medium for mushrooms, known as substrate. Mushroom substrate typically includes a variety of agricultural materials, such as straw, hay, and manure (Penn State, 2008). Since manure is a common component of the mushroom substrate, the PS PR's standards regarding untreated and treated BSAs of animal origin are relevant. In the mushroom industry, the first step to growing mushrooms is preparing the substrate, a process also frequently referred to as mushroom composting. During this process, substrate is created during a two-phase heating process (Penn State, 2008). Therefore, if the substrate undergoes this physical (thermal) treatment process, it would likely fall under the proposed § 112.54(a) and no application interval is necessary.

In addition, although the high temperatures achieved during mushroom substrate preparation substantially reduce levels of harmful microorganisms, the MGAP standards recognize that there is still the potential for cross-contamination of non-substrate materials and mushrooms with unpasteurized substrate. Therefore, the MGAP standards require that those who choose to comply with the MGAP receive and store raw manure and unpasteurized substrate shall be *as far away as possible* from receiving areas where harvest containers, packaging materials, and other sanitary supplies are received or where mushrooms are shipped.

With regard to wild animals, the MGAP standard is exclusion of pests (includes insects, rodents, and birds) using safe and effective procedures such as minimizing pest entry points, using EPA-approved pesticides according to State and/or Federal regulations, and setting traps.

California cantaloupe program (example of marketing agreements that are in place presently and have some standards that are similar to the PS PR) - Program requirements and controls for the California Cantaloupe program participants include: completing a Food Safety Compliance and Implementation Plan; water testing for irrigation and packing water; worker safety, hygiene, and training; environmental analysis including identification of animal intrusion and contamination from flooding from animal feeding operations; and documentation of soil amendments including compost and fertilizer.

The Cantaloupe program has separate standards for pre-harvest *foliar* application – 126 MPN mean/235 MPN maximum (e.g., overhead spray); and *non-foliar* irrigation water application (e.g., drip or trickle) – 126 MPN mean/576 MPN maximum; and different test frequencies depending on source waters. The numeric standards for cantaloupe are considered more stringent than what is proposed in the PS PR because there is no flexibility added to allow for pathogen die-off, such as what FDA proposes (CCAB, 2013).

The California Cantaloupe program allows the use of treated soil amendments (composted manure) but has several restrictions: 1) a certificate from the producer or seller must be obtained and retained to verify the validated methods to ensure pathogen reduction; 2) the compost must be tested for target organisms (including fecal coliform bacteria, *Salmonella*, and STEC); and, 3) an application interval of greater than 45 days prior to harvest. The program completely disallows the use of raw manure. These restrictions are more stringent than what is proposed in the PS PR.

The Cantaloupe program also has a standard for animal intrusion, and contamination from flooding that interfaces with animal feeding operations (where manure is present or stockpiled). However, there is no preclusion from domesticated animal grazing (which would not occur during the growing season) (CCAB, 2013).

State specific agricultural water quality standards and nutrient management standards - Very few States have set microbial standards for irrigation water (examples of states that have established such standards are Alaska, Colorado, Delaware, and Oregon) outside of commodity-specific marketing agreements with USDA AMS. There are a number of States (e.g., Colorado and Utah) that have state laws with salinity and chemical standards for agricultural water, and some that have some guidelines and possible restrictions on the use of pesticides for agricultural irrigation water. Such standards are State-specific. Conversely, all States have drinking water quality standards and for the most part, these standards are based upon EPA's recreational water quality criteria.[10] Other States may rely on guidance, such as best practices for growing produce relative to where animal operations are managed.

Conversely, a larger number of States regulate the runoff to *receiving* streams from facility activities, but do not have standards on the irrigation water applied to crops themselves. For example, 45 States require farms to prepare nutrient management plans, which are in part designed to better manage nutrient inputs (e.g., treated or untreated manure or chemical fertilizers), in order to help reduce nutrient runoff into receiving surface waters that would otherwise impact State TMDL compliance (see Chapter 3.1). In addition, all States have NPDES requirements that are based on EPA requirements. Under NPDES, most facilities that discharge pollutants from any point source into waters of the United States (regulated waters) are required to obtain a permit. Such permitted activities or businesses related may include CAFOs or AFOs that manage livestock and poultry operations (EPA, 2014o).[11] Approximately 2,829 potentially covered farms manage livestock or poultry operations and also grow covered produce.

Many of these issues and standards are State-specific and include regulatory drivers such as legal issues concerning water rights, clean streams (discharges and non-point contributions to receiving waters), subsurface discharge for aquifer recharge, public health in terms of drinking water, anti-degradation of water for wildlife and public health concerns, and soil quality (factors that could degrade fertility including salinity and target chronic toxins).

FSMA Preventive Controls for Human Food Proposed Rule - This FDA proposed rule, if finalized, would require registered food processing facilities (including farm mixed-type

[10] While the EPA criteria are not specific to irrigation water, it may be that some States rely on the criteria respective of agricultural water for food crops.
[11] The specific Web site that discusses NPDES regulations for CAFOs/AFOs is found at: http://water.epa.gov/polwaste/npdes/afo/CAFO-Regulations.cfm

facilities), with some exceptions, to complete a hazard analysis, and apply preventative controls that include: Process controls, Food allergen controls, Sanitation controls, and a Recall plan.

Very small processing businesses (proposed $1 million in total annual sales of human food) would be excluded. Such businesses may be required to comply with the requirements of the PS PR. The PC HF PR would be phased in over one to three years depending on sales amounts, such that there would be three years for very small facilities; two years for small facilities with fewer than 500 employees; and one year for large facilities.

There are no standards for agricultural water, BSAs of animal origin, or domesticated and wild animals in growing areas specified in the PC HF PRs. However, certain farm mixed-type facilities may rely on compliance with the PS PR provisions for control of microbial hazards in incoming ingredients.

Other parts of the PC HF PR that would be similar to the PS PR include hand washing, cleaning and sanitization of machinery or equipment, and recordkeeping. However, these requirements are duplicative, not additive (if satisfying one rule, both are by definition satisfied; moreover, record-keeping does not need to be duplicative)

There is a potential for certain businesses to be required to comply with both the PC HF PR and the PS PR. Based on revisions to the PC PR for human food and to PS PR in the supplemental proposed rule, farms that pack or hold produce from farms under a different ownership would be subject to the Produce Safety rule, and not to the PC HF rule. However, certain farms that would be subject to the Produce Safety rule (including based on annual sales) that also conduct additional processing or manufacturing may also be subject to the PC HF rule for those activities. Such farms would be considered large businesses under the PS PR: A farm mixed-type facility would need to have sales of $1 million annually of all foods processed before they could become subject to both rules; otherwise such a facility would be excluded from the PC HF rule as a very small business.

5.5 Analysis and Conclusions

A summary of the potential environmental impacts for potentially significant provisions is provided in Chapter 4.7. As discussed in Chapter 4.7, unlike with standards directed at specific potential routes of pathogen introduction (such as for potentially significant provisions), subpart A of the PS PR establishes the level of sales above which a farm growing covered produce would be subject to all the provisions of the rule. Under subpart A, covered farms must comply with the provisions of the rule, including through the use of the management decisions described in Chapters 4.2 to 4.6, or they must switch to crops that are not covered by the proposed rule. In other words, if a farm is covered by the rule as established in proposed subpart A, then all the potential environmental impacts associated with management decisions that the farmer is most likely to make, are also expected to occur.

The potential environmental impacts associated with those likely management decisions is summarized in Chapter 4.7.[12] This summary of potential direct and indirect environmental impacts is subdivided by resource component (e.g., water resources, air quality, etc.).

This cumulative impacts analysis also looks at those resource components and assesses them together with the programs and actions discussed in the previous sections of this Chapter. This assessment represents the "cumulative impact" on the environment that results from the incremental impact of FDA's proposed action when added to other past, present, and reasonably foreseeable future actions presented above. Therefore, the potential environmental impacts discussed below, in some cases, may be more severe than the impacts that were assessed in Chapter 4.7. Likewise, certain agency and/or industry actions may have beneficial effects, and thus may reduce the potential severity of a potential environmental impact. These relationships are discussed below.

Water Resources – The range of potential cumulative impacts nationwide are anticipated to range from not significant to significant adverse and long-term depending on the alternative that FDA may select. The potential cumulative impacts are described in more detail in the following statements.

Water availability
Groundwater withdrawals, as discussed in Chapter 3.1.3.10 and Chapter 4.1 continue to have significant adverse effects on the amount of water in aquifers that is available for agricultural use, human consumption, and industrial and commercial use across the nation. According to USGS data and 2005 estimates, 37 percent of total U.S. groundwater withdrawals were for irrigation water and an additional 2.6 percent covers other agricultural waters. Thermoelectric power accounts for 41.5 percent of withdrawals, domestic uses for 8.5 percent, other publicly supplied users for 5.4 percent, and industrial users accounts for 5 percent. Trends presented in Chapter 3 show that the amount of groundwater withdrawals continues to rise in both number of users and volume of water. Water conservation practices (e.g., drip irrigation) continue to gain in popularity but there are no statistical data that show there is a total measurable effect on the amount groundwater withdrawals nationwide[13]. Nationwide, the availability of groundwater is a condition that continues to worsen, and these conditions may be exacerbated in regions where drought-related climate change effects are experienced the most.

Significant current and ongoing adverse impacts such as reduced water availability, water-table declines, soil subsidence and increased costs for finding and maintaining access to water, resulting from groundwater withdrawals are presently experienced in regions B, C, D, I, J, and U (compare Figure 1.7-4 with Figures 3.1-12 and 3.1-13). These impacts are absent of any final rule. Any

[12] See the heading for **Subpart A: General Provisions (Scope of Coverage of the Proposed Rule); includes impacts related to the cumulative effects of each proposed standard assessed together)**

[13] While it is plausible that water conservation practices have a beneficial impact, the impacts have not been widely studied. It is possible that if water is being spared at one part of the farm for irrigation, it may be used in more volume for other (potentially non-covered crops). In many areas across the US it is impossible for the Government to track exactly how much water is being used by growers because the water is pulled directly from groundwater or surface water sources and is not metered. At present, we cannot know for sure the full extent of benefits or impacts from drip irrigation.

action (personal, Federal, State, local, etc.) in regions B, C, D, I, J, and U that would cause a farmer or any entity to draw from groundwater instead of surface water could exacerbate the current environmental conditions, generally. The analysis in Chapter 4.7 found that under the preferred alternative (subpart E and subpart A) FDA does not anticipate that a final rule would result in the management decisions being that farms switch to groundwater sources. However, some limited number of farms may be expected to switch to groundwater sources, and therefore, would exacerbate the significant impacts currently occurring to this resource. When one considers the potential impact of the rule along with an expectation of growing water demand for residential, commercial, and industrial development; and the continued oil and gas exploration that occurs nationwide (consumes large amounts of water) (see Chapter 3.1), long-term effects to water availability, particularly in regions B, C, D, I, J, and U are anticipated to be incrementally worse. The cause-and-effect relationship is not well defined under such conditions, but the best resource to use when attempting to establish a cause-and-effect relationship under such conditions is to demonstrate how historical impacts may be similar to the current condition described here; thus the most applicable resource is the USGS report on Groundwater Depletion in the United States (1900-2008) (USGS, 2013).[14] Specifically, the report states, "Cumulative total groundwater depletion in the United States accelerated in the late 1940s and continued at an almost steady linear rate through the end of the century. In addition to widely recognized environmental consequences, groundwater depletion also adversely impacts the long-term sustainability of groundwater supplies to help meet the Nation's water needs." (USGS, 2013) Therefore, one may consider the incremental, long-term impacts with respect to water availability to be significant and adverse in regions B, C, D, I, J, and U. These conditions are anticipated to occur even if a final rule were not enacted. Under such conditions, individuals on Native American reservations in regions B and J may be disproportionately adversely impacted as continued groundwater drawdown could have potential environmental impacts including socioeconomic impacts related to access to water on reservations.

State agencies, the Federal Government, and some non-governmental organizations continue to mitigate these expected effects nationwide. Examples of programs that work towards water conservation are State Water Conservation Districts, and the National Association of Conservation Districts. These programs work with users throughout their States and districts to develop techniques and technologies that reduce water use, and implement water savings incentive programs.

Sprouting operations – water availability

The majority of the 285 covered sprouting operations draw from municipal water already, only minimal adverse (not significant), local and not significant impacts may occur from water treatment effluent, and no nationwide or regional impacts are anticipated to water availability from those few operations that may connect to municipal water supplies. These small numbers of operations nationwide are not anticipated to significantly contribute to even cumulative impacts nationwide or regionally.

[14] This study, including data the study used is discussed in Chapter 3.1.

Water quality
As discussed in Chapter 4.7, the added flexibility in meeting FDA's proposed water quality standard is likely to mitigate the need to use chemical treatment of a water source with poor water quality. It is also likely that a farmer might add a post-harvest mechanism to allow for added pathogen die-off or removal. Similar to water availability (discussed immediately above), water quality is a current and ongoing problem throughout the U.S. and is exacerbated by all the same influences as is water availability. As discussed under the No Action Alternative (Chapter 4.1), decreasing water flow and supply tends to make worse the concentrations of water contaminants that may otherwise be diluted under higher water flow conditions.

While FDA does not anticipate the direct and indirect impacts associated with water quality to significantly contribute to water quality concerns (see Chapter 4.7), when one considers the current and ongoing water quality problems (discussed in greater detail in Chapter 3.1) a cause-and-effect relationship is established for addressing potential cumulative impacts and the comparison of current and historical conditions demonstrates that current conditions are expected to be somewhat worsened. Regions that, under these ongoing conditions are important for water quality issues and covered produce, include regions A, B, C, L, R, T, and U (see Chapter 4.1).

It is important to note that many growers of fresh produce already participate in programs that have integrated food safety measures for their agricultural water. Examples of these are found in Table 2.1-1 in Chapter 2.1, and in Table 5.3-1 above. Many of these programs are voluntary; however, the practices of these programs are often mandatory for those who choose to participate in the programs. A few programs, such as T-GAPs, are mandatory for growers of certain commodities. Tables 2.1-1 and 5.3-1 do not represent a comprehensive list of programs. There may be similar programs in other States. For programs such as the CA and AZ LGMA, which contain a high number of the growers that may be subject to a final Produce Safety Rule, many aspects of those programs contain more stringent numeric water quality requirements than what FDA proposes. The same is true for programs such as T-GAPs in Florida, which contributes to a high percentage of the tomatoes consumed nationally. Some other State and industry marketing programs may have high standards, but FDA does not know how such programs are audited and enforced. The USDA GAP&GHP program is an example of an audited program for participants, and the program follows the recommendations FDA provided in its 1998 Guide (FDA, 1998, see also Table 5.3-1, Chapter 1.9, and Chapter 2.1).

While FDA does not know how many growers of covered produce may participate in programs described here, it is evident that for representative agreements such as T-GAPS and CA/AZ LGMA, many growers that may be affected by the requirements in the PS PR already participate in these more stringent programs. FDA does not anticipate that a final rule would lead to changes to the requirements of those programs so that they become less stringent.

Ongoing programs that aid in determining the total challenges associated with water quality, and work to preserve and improve water quality, include Federal and State required NPDES programs and permits and the ongoing efforts to improve municipal separate storm sewer systems (MS4) and to minimize TMDLs of certain common contaminants; and continued improvements to municipal water treatment systems.

Subpart F (untreated) – water quality
A switch to treatment (composting) will require additional storage time, which presents more opportunity for partially processed manure to impact surface and groundwater. Such impacts may be mitigated through best management practices or adherence to the facility's NPDES permit (where applicable) (see Chapters 3.4, 4.3 and 4.7); therefore, potential adverse impacts are not anticipated. Under a decision to switch to chemical fertilizers, any improper use may have an adverse impact on surface and groundwater; however, given the small number of farms that use untreated BSAs of animal origin that could possibly switch to chemical fertilizers (820 covered farms, or 2.3 percent of covered farms nationally) the impact would not be significant and adverse impacts may further be mitigated through proper nutrient management. Therefore, due to the potential for mitigation measures to lessen potential environmental impacts, the anticipated incremental, cumulative, impacts are not expected to be significant.

Biological and Ecological Resources –
As discussed in Chapter 4.7, adverse effects to biological and ecological resources relevant to groundwater drawdown are not expected. Although the potential cumulative effects from groundwater drawdown relative to existing and expected ongoing conditions may potentially be significant, it is important to also consider the context of human influences along with mitigation measures that exist and that are expected to continue.

In addition to water availability, potential cumulative effects on biological and ecological resources would include the pressures of climate change, human development (residential and commercial and its associated environmental effects), and the continued increase in invasive plants and animals that so often disrupt local and regional ecosystems and species populations (see Chapter 3.2.1). Energy development, such as oil and gas exploration activities nationwide have an additive adverse effect to biological diversity, productivity, and fertility, that results from increased levels of toxins contributed to the environment, and loss of habitat that provides food and cover for all types of species.

With respect to water quality, potential adverse effects may occur from the use of disinfectants to treat poor quality water in certain areas (as follows). Disinfectants may be useful for reducing hazards that may cause foodborne illnesses; however, many of these disinfectants may form harmful byproducts. EPA-registered pesticide products are evaluated to determine potential environmental effects and potential impacts to human health specific to their use. As long as the pesticides are handled and applied according to label directions, no significant adverse impacts would result. Such adverse effects may be limited because a high number of growers in key growing regions, such as California, Arizona, and Florida, participate in marketing agreements that have more stringent numeric water quality standards than what FDA has proposed and are already using water that would be in compliance with the proposed standard.

Mitigation measures that are available under water resources (above) or that are currently being implemented by State agencies and other entities involved in water conservation, would contribute to any incremental beneficial effects to biological and ecological resources as well. In addition (non-water-related) conservation programs exist across the U.S. and are implemented by both public and private agencies. Chapter 4.1 (No Action Alternative) cites additional programs that, through public policy afford additional mitigation or conservation protection initiatives, such as through the 2014 Farm Bill, to name an example. The cumulative impacts to biological and ecological resources, unlike water, are more difficult to predict on a wider regional or nationwide basis. The cause-and-effect relationship between human influences and watersheds can be drawn more closely for watersheds that are shared throughout regions; whereas biological and ecological resources impacts may be more localized (e.g., whole watersheds may be impacted by contributing factors, but species within the watershed may adapt to changes and potentially thrive, or may be adversely impacted by specific influences in portions of the watershed). Therefore, such impacts are not well characterized for a cumulative effects analysis on a nationwide scale. Because FDA does not anticipate significant impacts to biological and ecological resources as a result of the rule, and due to the prevalence of mitigation through private and public conservation, the potential cumulative environmental effects may be considered as not significant.

With respect to subpart I (wildlife intrusion), any measures taken to exclude wildlife (including measures to clear land to facilitate monitoring) may involve the use of herbicides, rodenticides, or other materials that may have short-term toxic effects to water resources; biological resources and ecosystems directly adjacent to the farm; and soils. These impacts may be mitigated through proper use and handling in accordance with labeling requirements (discussed above). Through the use of pest management plans, and removal in accordance with State and local regulations (such as through hunting and trapping permits), adverse cumulative effects may be effectively mitigated and considered not significant.

Note that proposed § 112.84 does not require covered farms to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. The preferred alternative, and more likely management decision that a farmer may make is to monitor their fields and evaluate whether produce can be harvested safely.

Soils –

Land subsidence

Under this cumulative effects analysis, it is important to compare the potential anticipated cumulative impacts to soils related to groundwater drawdown that may occur from the PS PR, if finalized (see water resources above). In Chapter 4.7, under the preferred alternative, significant adverse impacts related to groundwater drawdown and the related adverse impacts to soils are anticipated (although the added flexibility in meeting FDA's water quality standard and in light of public comments on the supplemental rule that indicate that because of the added flexibility, a management decision to switch to groundwater sources is not anticipated to be the preferred management decision. When one considers the potential significant adverse effects related to groundwater drawdown (these effects are ongoing, absent of any final rule – and would be anticipated even if a rule were not enacted (see USGS, 2013)), it may be reasonable to predict continued adverse impacts related to land subsidence. Regions that may be most impacted by land subsidence (as discussed in Chapter 4.1) include regions B, C, D, I, J and U. Because land subsidence results in irreversible effects to soils, such impacts in regions B, C, D, I, J, and U may be considered significant adverse.

Mitigation measures (discussed above) that promote water conservation across the nation would potentially reduce the severity of continued land subsidence.

Soil quality

In general, agriculture has lasting (but not irreversible) adverse effects to the natural functions of soils, such that soils require more intense nutrient management in order to sustain crop yields (Chapter 3.2). The effects to agricultural soils nationwide has been improved through the use of more natural fertilizers (e.g., treated and untreated manure and green manuring), and the employment of no-till management practices and cover crops. However, where the use of natural fertilizers is decreasing (Chapter 3.4.3.1), the use of cover crops and no-till techniques are increasing. This has a beneficial impact on soils with respect to agricultural practices.

Relative to all U.S. cropland, the NRCS conducts a National Resources Inventory (NRI) every five years as a means to assess the status, condition, and trends in soil, water, and other natural resources on agricultural lands.[15] The most recent survey results show that 1.725 billion tons of soil is lost per year due to water erosion (960 million tons/year) and wind (765 million tons/year). However, when this information is reviewed over a 25 year period (1982 to 2007), the NRCS found that cropland soil erosion has been reduced by an estimated 43 percent (USDA NRCS, 2007). This is attributed to improved soil conservation efforts nationwide.

With respect to subpart F, a switch away from using untreated BSAs of animal origin to using 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 (discussed above as green manuring, no-till practices, and use of cover crops). Such measures may be protective against (to some extent) the overall loss of soils nationwide (discussed above). A very low number of covered farms that may be impacted by the rule nationwide (estimated at 820 (FDA, 2014b)). When one considers that more farms use treated manure versus untreated, and also considering the growing trends in use of green manuring and other best management practices, FDA expects that the cumulative effects nationwide related to soil health and BSAs of animal origin are not expected to be significant.

In terms of mitigations, the USDA Conservation Practices program helps farmers better manage their soil resources and reduce the effects of soil loss and erosion. In addition, USDA and States established Conservation Districts that help farmers employ measures that reduce adverse impacts to soils and preserve soil quality, and Universities conduct research in conjunction with Federal agencies to help develop new techniques and technologies that farmers may use to further conserve soil resources.

Waste Generation, Disposal, and Resource Use – Much of the analysis under soil quality above also applies here but in terms of use of BSAs of animal origin (not in terms of soil quality). Approximately 12.5 percent of produce farms use BSAs of animal origin, and of those only roughly 18.5 percent use untreated (raw) manure (this is 820 farms nationally, or 2.3 percent of the covered produce farms), and 10.2 percent of covered produce farms use treated BSAs of animal

[15] These surveys are not specific to produce crops or otherwise crops or farms that may be covered by the proposed rule. Therefore, these data were not effective for assessing direct or indirect impacts associated with the PS PR.

origin (this is 3,618 covered farms nationally) (Chapter 2.1 and 3.4.3.1). As discussed in Chapter 4.7, it is likely that growers will choose to switch to a treated (composted) material, use BSAs of non-animal origin, use chemical fertilizers, or change the application method instead of complying with the requisite waiting period. In terms of direct and indirect impacts, composting will require additional storage; however, given the small number of farms that may be affected nationwide (820 or 2.3 percent of covered farms) this is not expected to result in a significant impact. There is no reliable estimate on how many facilities across the nation may compost or otherwise dispose of animal waste. Regions that are important for both producing animal waste (manure) and produce that may be covered by the PS PR include C, L, K, M, A, and B. Many farms that are part of marketing agreements already adhere to application to harvest rates that, in some cases (e.g., CA and AZ LGMA), may be more stringent than in Alternative I, Subpart F (what was previously proposed by FDA) and is currently deferred.

Due to FDA's conclusion to defer finalizing an application interval for raw (untreated) BSAs of animal origin, there is no immediate expected cumulative effect. Once a decision is made, after FDA concludes its robust research agenda, risk assessment, and efforts to support compost infrastructure development in concert with the USDA and other stakeholders, the cumulative impacts evaluation will be reassessed. Nevertheless, given the relatively small number of farms that may be covered by the PS PR as compared with the number of farms that utilize (and or dispose of) the resource annually, any relative cumulative impact is expected to not be significant.

Once a final decision is made on untreated BSAs of animal origin, if application rates were extended by the rule and any excess untreated BSAs build-up, it is assumed this relatively small amount may be sold to farms that grow excluded crops, or otherwise managed in accordance with the farm's NPDES permit, where applicable. Additional information is anticipated once FDA completes its research.

Air Quality and Greenhouse Gases – Air quality (and related greenhouse gas and energy usage) impacts from agriculture that are already occurring include the generation of methane from animal operations (including distribution/transportation of manure, composting, and use on fields), use of fuels to manage farming operations (including equipment, vehicles, and facilities), and use of chemical fertilizers, to name a few. Criteria pollutants and other greenhouse gases are generated daily by commercial and residential development, oil and gas exploration, and other human activities. Nationwide, the net generation of criteria pollutants and other greenhouse gases are not expected to change considerably as a result of finalizing the PS PR.

No new methane production is expected (the general same amount of animal waste that is generated today is not expected to change as a result of the PS PR).

Given the very low number of farming operations that may be affected by the PS PR, the incremental effects expected from the finalizing a rule is not expected to be significant.

Socioeconomics and Environmental Justice –With respect to cumulative impacts, farms all over the U.S. are subjected to pressures from water availability and water quality as a result of competing commercial, residential, and industrial water interests, and the interests of public and private oil and gas exploration efforts. Farms, like the rest of U.S. businesses and residents, are subject to increasing costs for goods (equipment) and services (power and water for example). The result has been an overall increase in operating costs, and an overall decrease in farming (see trends as discussed in Chapter 1.9). Farms have been very adaptable, finding new and innovative methods to plant and harvest crops, regulate the use of water, and apply nutrients to soils (through the use of nutrient management plans – which when accompanied with regular soil testing as most plans accomplish, allow the farmer to better manage nutrient application in a more efficient manner to different parts of even the same field).

FDA considered the economic costs of the PS PR to covered farms when considering the environmental alternatives and associated socioeconomic impacts. The average projected per-farm cost of complying with the provisions of the PS PR, if finalized, is approximately $4,477 for very small farms, $12,384 for small farms, and $29,545 for all other covered farms. While small and very small farms may not be able to afford this added cost burden, FDA anticipates that for these farms, if they are not able to qualify for an exemption to reduce the cost of compliance, they would be the most likely to make management decisions which would either result in them not being subject to the provisions of the PS PR or that would make them exempt from the provisions. Examples might include where a farm is a dual-purpose operation (manages livestock and grows small amounts of produce), although most such farms would likely be excluded given FDA's amendments to Subpart A. As discussed in Chapters 4.7 and 4.2, based on the comments FDA has received to date, FDA does not expect that individual primary farm operators would cease growing covered produce as a preferred management decision except in select instances which are often driven by outside pressures unrelated to this rule (an example cited in Chapter 4.7 includes the state of California that pays farmers to keep land fallow in order to divert water to the cities).

As discussed in Chapter 4.7, if non-covered produce or other agricultural crops that are not produce are grown, requirements to maintain certain water quality conditions would be dependent on any existing state regulations or industry marketing agreements. The type of crop a farmer may select to grow would also be dependent upon the region's climate, soils, water availability, and may involve a decision whether the existing farm's equipment and infrastructure would be sufficient, or would need to be updated, modified, or bought to accommodate a new type of crop.

There are no data to suggest under what conditions specifically such management decisions (discussed above) may occur, and there are no data available to quantify or qualify any related cumulative impacts.

In addition, relevant to subpart E, there may be additional costs to farms that were not projected in FDA's Regulatory Impact Analysis (FDA, 2013b and 2014b), such as if farmers add a post-harvest mechanism (e.g., FDA-approved wash or rinse) to achieve pathogen die-off or removal. These costs could potentially result in additional socioeconomic impacts.

Relevant to subpart F, the production and transport of chemical fertilizers is not expected to have a significant adverse impact on energy use and air quality because the resource use is not expected to change significantly as compared to current conditions.

Also under subpart F, since it is unlikely that growers will observe any requisite waiting period, any costs associated with storing untreated BSAs of animal origin for longer requisite time periods may be unnecessary (under Waste Generation, Disposal, and Resource Use FDA does not anticipate any immediate cumulative effect due to a deferment on decision related to untreated BSAs of animal origin).

Given that, on a nationwide basis an estimated 35,503 farms would be covered by the rule, and some portion of that number would be eligible for qualified exemptions (in the very small and small farm categories), the anticipated incremental, cumulative socioeconomic impact to farmers covered by the rule would be considered to be adverse, but not significant.

Environmental Justice –
As discussed in Chapter 1.9, FDA considers in this draft EIS potential impacts to minority principal farm operators and farmworkers (see also Chapter 3.7.3). USDA NASS survey data provides information on principal operators of farms. Available information related to farmworkers is less extensive, and FDA relied on limited statistics provided by USDA ERS and the U.S. Department of Labor. There are no data specifically reported for farmworkers on produce farms. These data sources also are limited in terms of farmworker ethnicity and income. Based on this limited data, regions where there are populations of minority farmworkers that may be impacted by the rule, if finalized, include regions C, D, I, and J; and the only state for which state-specific income data are reported is California, which is region C. Potential impacts to farm worker employment may be dependent upon multiple factors including (but not limited to) average annual farm income, estimates for crop yield, and commodity prices. Increases in farm operating costs may also impact farm worker employment. Farmworker employment can also be seasonal (USDA ERS, 2014a). Increases in farm operating costs may result in adverse impacts to farmworkers, but such costs may also be transferred to consumers. Although potential cost impacts could be felt by consumers, without more definitive information regarding specific management decisions that might be taken in response to the PS PR, if finalized, it is unreasonable to project direct, indirect, or cumulative impacts on such groups. Therefore, for purposes of this EIS, the discussion of potential socioeconomic impacts is limited to primary farm operators and farm workers (where information is available).

Minority groups: When considering the "meaningfully greater" threshold of 11.6 percent (see Chapters 3.7 and 4.1), regions that are important for identifying potential impacts to minority primary operators are regions A, B, C, D, W, and V.

Principal operators
FDA is not aware of any Federal or State programs that have been implemented or that are presently being considered that may adversely or disproportionately affect minority operators, except that the same economic pressures that are discussed in this chapter and in Chapter 1.9, apply to all farmers. Minority primary operators manage farms of all size classes potentially affected by the provisions of the PS PR and would need to make the same management decisions as primary operators generally regarding whether to comply with the rule or to cease growing covered produce based on cost considerations. As discussed in Chapter 4.7, because of the greater added costs proportional to the amount of sales, primary operators for very small farms are generally more

likely than primary operators of larger farms to make management decisions to stop growing crops altogether if the farm manages livestock operations that also grow small amounts of covered produce, although many such diversified farming-livestock operations would likely be excluded based on the new proposed monetary threshold for excluded farms applied to sales of produce only rather than sales of food. FDA has no data to suggest under what conditions specifically such a management decision may occur, and there are no data available to quantify or qualify any related indirect impacts. Given that on a nationwide basis, an estimated 35,503 farms would be covered by the rule, and some portion of that number would be eligible for qualified exemptions (in the very small and small farm categories), the anticipated incremental, cumulative economic impact to minority primary operators covered by the rule may be considered adverse, but because of the management decisions that are available to these farms, such impacts would not be considered to be significant. As noted above, potentially adverse impacts to minority primary operators are more likely to occur in regions A, B, C, D, W and V.

Minority farmworkers

As discussed in Chapters 3.7 and 4.7, and above, regions where there are populations of minority farmworkers that may be impacted by the rule, if finalized, include regions C, D, I, and J. Costs incurred by farms of all sizes may result in the farm either increasing the costs of their produce for consumers, or may involve the farm primary operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. FDA has no data to determine where in the nation or under what specific circumstances such impacts may occur, as such decisions are highly specific to the individual farm. Regions were such actions may adversely disproportionately affect minority farm workers include regions C, D, I, and J.

Native American operators: As discussed in Chapter 4.7, at most, 5 percent of farms with a Native American principal operator would be covered by the rule. Despite this relatively low number of total Native American owners/operators who may be covered by the rule, there is a potential that added operating costs associated with the rule would impact a disproportionate number of Native American farmers compared to farmers as a whole, given that the average sales for a farm with a Native American principal operator is 30 percent lower than a farm with a non-Native American principal operator farm (per the 2007 Agricultural census). The average reported agricultural product sales for Native American operated farms is $40,331, compared to an average of $134,807 for all farms. The average potential per farm cost of approximately $4,500 could be disproportionally burdensome for Native American operated farms as it would comprise approximately 11 percent of their average annual sales, compared to 8 percent of the average annual sales of all farms.[16] However, the potential impacts for very small and small farms may be entirely mitigated to the extent these farms are eligible for a qualified exemption; therefore, potential incremental cumulative impacts may also be mitigated and would not be considered significant. It is assumed that large farms would be able to absorb any additional costs of complying with the provisions of the PS PR.

[16] $4,500 divided by $40,331 equates to approximately 11 percent.

<u>*Water availability-related impacts*</u>
As discussed in Chapter 4.7 and the discussion above related to water availability, individuals on Native American reservations in regions B and J may be disproportionately adversely impacted as a result of continued groundwater drawdown. These conditions are a result of current and projected ongoing impacts related to water use throughout the U.S. and are anticipated to occur even if a final rule were not enacted.

Low-income: As discussed in Chapter 3.7.3 and 4.7, this class includes any persons whose median household income is at or below the HHS poverty guidelines. The poverty threshold for a family of four in 2012 was set at $23,050. According to the ERS's data sheet, *Principal Farm Operator Household Finances by ERS Farm Typology,* in 2012, median farm operator household income, an average of the farm and off-farm household incomes of residence farms, intermediate farms, and commercial farms, was $68,298.[17] This exceeds both median U.S. household income, and the HHS poverty thresholds for all HHS poverty thresholds. While there may be low-income principal operators that may be adversely impacted by the costs associated with the rule, we cannot identify a low-income population on a national or regional level.

Low-income farmworkers: As discussed in Chapter 4.7, impacts may involve the farm principal operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. FDA has no data to determine where in the nation, or under what specific circumstances may occur as such decisions are highly specific to the individual farm. Based on data provided by the U.S. Department of Labor (information reported for California) (DOL, 2000 and 2005), region C has populations of low-income farmworkers that may be disproportionately impacted by the rule. Note that other regions may experience similar impacts, but there is not enough data available to understand which regions may specifically be impacted.

Human Health and Safety –
<u>*Foodborne illnesses prevented*</u>
Similar to the analysis in Chapter 4.7, FDA estimates that the number of foodborne illnesses prevented when considering the rule as proposed, all provisions, is 1.57 million, annually (FDA, 2014b). This represents a significant beneficial outcome to human health.

<u>*Human health impacts*</u>
Any management decision that may adversely affect primary operator and farm worker health would potentially be related to chemical treatment of agricultural water; however, as long as the pesticides are handled and applied according to manufacturers' instructions no significant adverse impacts to human health are anticipated.[18] Because FDA does not anticipate a potential adverse health effect under the preferred alternative, there are no anticipated cumulative effects.

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[17] There is limited data for principal farm operator income other than on a national level.

[18] As discussed in Chapter 4.2, there is no EPA-approved chemical treatment for contaminated water used to irrigate cropland (EPA, 2014a). While there are no pesticide products registered to treat contaminated water used to irrigate cropland, the EPA maintains a list of approximately 50 Registered Antimicrobial Products as Sterilizers. These products may only be legally applied for the registered use. The compounds on EPA's list of Registered Antimicrobial Products as Sterilizers may not be used to control pathogens in water applied directly to produce. However, farmers who legally use these antimicrobials for their registered use, e.g., pesticides used to prevent fouling of pipes or for treatment of wells, may see some improvement in their water quality.

Under subpart F, the production and transport of chemical fertilizers is not expected to have adverse impacts to air quality, and therefore, significant adverse cumulative impacts are not expected to primary operator or farmworker health.

Comparison of potential cumulative impacts

As discussed at the beginning of this chapter, the comparison is accomplished for alternatives under Subpart A, because if a farm is covered under subpart A, then the other provisions of the rule apply. The potential direct and indirect impacts for the rule are provided in Chapters 4.2 through 4.7, and a summary of these impacts by alternative under subpart A is provided in Chapter 4.7.

Table 5.5-1 provides a summary of the potential cumulative environmental and related socioeconomic and public health impacts from finalizing the PS PR and considering other past, present, and reasonably foreseeable future Federal and non-Federal actions.

Table 5.5-1. Comparison of potential cumulative impacts, by alternative for subpart A

		≤ $25,000 * total produce excluded Alternative I	≤ $50,000** Food, excluded Alternative II	≤ $100,000** Food, excluded Alternative III	≤ $25,000 covered produce excluded Alternative IV
Comply with the rule	Covered Farms	35,503	28,253	20,140	Slightly fewer than Alternative I
	Excluded Farms	130,204	Greater than Alternative I	Greater than Alternative II	Slightly greater than Alternative I
	Environmental impacts (Chapters 4.1 – 4.7)	Greater than baseline	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Economic impacts (domestic costs annually)	$540.49 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Domestic benefits (health-related cost savings)	$930 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Public health benefits (foodborne illnesses prevented annually)	1.57 million	Less than Alternative I (less foodborne illnesses prevented)	Less than Alternative II (less foodborne illnesses prevented)	Slightly fewer than Alternative I (less foodborne illness prevented)
Switch to non-covered	Covered Farms	Less than 35,503	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Excluded Farms	Greater than 130,204	Greater than Alternative I	Greater than Alternative II	Slightly greater than Alternative I
	Environmental impacts (Chapters 4.1 – 4.7)	Less impacts compared with complying	Less impacts compared with Alternative I	Less impacts compared with Alternative II	Slightly fewer than Alternative I
	Economic impacts (domestic costs annually)	Less than $540.49 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I
	Domestic benefits (health-related cost savings)	Less than $930 million	Less than Alternative I	Less than Alternative II	Slightly fewer than Alternative I

		≤ $25,000 * total produce excluded Alternative I	≤ $50,000** Food, excluded Alternative II	≤ $100,000** Food, excluded Alternative III	≤ $25,000 covered produce excluded Alternative IV
	Public health benefits (foodborne illnesses prevented annually)	Less than 1.57 million	Less than Alternative I (less foodborne illnesses prevented)	Less than Alternative II (less foodborne illnesses prevented)	Slightly fewer than Alternative I (less foodborne illness prevented)

*As updated in the Supplemental PRIA, published September 2014.
**The associated estimates are found within the 2013 PRIA (FDA, 2013b).

Water Resources - Overall, the potential impacts nationwide are expected to be somewhat commensurate with the direct and indirect effects, therefore, significant. These impacts may vary by region, State, or locality, and are not quantifiable. The potential exception is related to groundwater withdrawal, where significant adverse long-term impacts to water availability and soils (related to the irreversible impacts from land subsidence) may continue to occur in regions B, C, D, I, J, and U as a result of excessive groundwater use. These effects are the result of the current condition and projected ongoing impacts related to water use throughout the U.S., and are anticipated to occur even if a final rule were not enacted. Individuals on Native American reservations in regions B and J may be disproportionately adversely impacted as a result of continued groundwater drawdown and reduced access to water on reservations.

The problem of downstream degradation of water quality by salts, agrochemicals, and toxic leachates is a serious environmental problem. Regions that grow covered produce and that are already experiencing high exceedances in state surface water quality levels based on CWA Section 303(d) requirements (33 U.S.C § 1313(d)) (compare Figure 3.1-15 in Chapter 3.1.3.9 to Figure 1.7-4 in Chapter 1.7), and groundwater quality impairments (primarily from coliform bacteria) include regions A, B, C, L, R, T, and U (compare Figures 3.1-16 and 3.1-17 in Chapter 3.1.3.9 to Figure 1.7-4).[19]

Biological and Ecological Resources - Because FDA does not anticipate significant impacts to biological and ecological resources as a result of the rule, and due to the prevalence of mitigation through private and public conservation, the potential cumulative environmental effects may be considered as not significant.

Soils - Relative to soil quality and subpart F, when one considers that more farms use treated manure versus untreated, and also considering the growing trends in use of green manuring and other best management practices, FDA expects that the cumulative effects nationwide related to soil health and BSAs of animal origin are not expected to be significant. Potential impacts related to land subsidence is addressed under Water Resources, above.

Waste Generation, Disposal, and Resource Use – Waste generation, disposal and resource use is not expected to be adversely affected to a significant degree.

[19] Regions A, B, C, L, R, T, and U represent the majority of the east and west coast states.

Air Quality and Greenhouse Gases - With respect to air quality, given the very low number of farming operations that may be affected by the PS PR, the incremental effects expected from the finalizing a rule is expected to not be significant.

Socioeconomics and Environmental Justice -
Based on the cost/benefit analysis, the costs of the rule may be easily absorbed by large farms, even considering other additional economic influences. Small and very small farms may be more adversely affected by such costs; however, these farms may be eligible for qualified exemptions, which would effectively mitigate costs of the rule. There are no data to suggest under what conditions specific management decisions (discussed above) may occur, and there are no data available to quantify or qualify any related cumulative socioeconomic impacts resulting from the PS PR, if finalized. In addition, there may be added economic costs not estimated by FDA in the Regulatory Impact Analysis (FDA, 2014b) potentially may include the costs associated with implementing a post-harvest mechanism.

Minority primary operators
Principal operators for very small farms are generally more likely than primary operators of larger farms to make management decisions to stop growing crops altogether if the farm manages livestock operations that also grow small amounts of covered produce, although many such diversified farming-livestock operations would likely be excluded based on the new proposed monetary threshold for excluded farms applied to sales of produce only rather than sales of food. FDA has no data to suggest under what conditions specifically such a management decision may occur, and there are no data available to quantify or qualify any related indirect impacts. Given that on a nationwide basis, an estimated 35,503 farms would be covered by the rule, and some portion of that number would be eligible for qualified exemptions (in the very small and small farm categories), the anticipated incremental, cumulative socioeconomic impact to minority primary operators covered by the rule may be considered adverse, but because of the management decisions that are available to these farms, such impacts would not be considered to be significant. As noted above, potentially adverse impacts to minority primary operators are more likely to occur in regions A, B, C, D, W and V.

Minority farmworkers
As discussed in Chapters 3.7 and 4.7, and above, costs incurred by farms of all sizes may result in the farm either increasing the costs of their produce for consumers, or may involve the farm primary operator terminating the employment of full-time, part-time, or seasonal worker(s) in order to defray their operating costs. FDA has no data to determine where in the nation or under what specific circumstances such impacts may occur, as such decisions are highly specific to the individual farm. Regions were such actions may adversely disproportionately affect minority farm workers include regions C, D, I, and J.

Native American operators
At most, 5 percent of farms with a Native American principal operator would be covered by the rule. Despite this relatively low number of total Native American owners/operators who may be covered by the rule, there is a potential that added operating costs associated with the rule would impact a disproportionate number of Native American farmers compared to farmers as a whole,

given that the average sales for a farm with a Native American principal operator is 30 percent lower than a farm with a non-Native American principal operator farm (per the 2007 Agricultural census). The average reported agricultural product sales for Native American operated farms is $40,331, compared to an average of $134,807 for all farms. The average potential per farm cost of approximately $4,500 could be disproportionally burdensome for Native American operated farms as it would comprise approximately 11 percent of their average annual sales, compared to 8 percent of the average annual sales of all farms.[20] However, the potential impacts for very small and small farms may be entirely mitigated to the extent these farms are eligible for a qualified exemption; therefore, potential incremental cumulative impacts may also be mitigated and would not be considered significant. It is assumed that large farms would be able to absorb any additional costs of complying with the provisions of the PS PR.

As discussed in Chapter 4.7 and the discussion above related to water availability, individuals on Native American reservations in regions B and J may be disproportionately adversely impacted as a result of continued groundwater drawdown. These conditions are a result of current and projected ongoing impacts related to water use throughout the U.S., and are anticipated to occur even if a final rule were not enacted.

Low-income farmworkers
Regions where such actions may adversely disproportionally affect low-income farmworkers include region C.

For any alternative where fewer farms would be covered by the rule (Alternatives II, III, and IV) the potential cumulative environmental, socioeconomic, and public health impacts would be less than what may occur under Alternative I.

- The expected annual economic impacts nationwide would decrease but the expected per farm costs are anticipated to remain the same as Alternative I.
- The expected environmental impacts, both adverse and beneficial, would decrease nationwide, but not to the extent that would reduce any already significant impacts to a less than significant level.
- The expected number of foodborne illnesses would decrease, which means fewer public health benefits would be experienced.

[20] $4,500 divided by $40,331 equates to approximately 11 percent.

6.0 Potential Irreversible and Irretrievable Commitment of Resources

40 CFR 1502.16 requires a review of any irreversible and irretrievable commitments of resources that would be involved should the PS PR be implemented. An irreversible and irretrievable commitment of resources is related to the use of non-renewable resources and the effect that the use (or depletion) of these resources would have on future generations. Irreversible effects primarily result from the use or destruction of a specific resource that cannot be replaced within a reasonable time frame, such as fossil fuels. Irretrievable resource commitments involve the loss in value of an affected resource that cannot be restored as a result of the action (e.g., groundwater depletion).

Relating to the proposed action and potential alternatives, irreversible adverse impacts could result to groundwater and soil structure as a result of groundwater depletion and related land subsidence (gradual settling or sudden sinking of Earth's surface), which is likely to continue to occur and could be exacerbated if farm operators choose to withdraw groundwater in excess of current conditions for the purpose of complying with provisions of the PS PR, if finalized. Land subsidence as a result of groundwater withdrawals has occurred in areas of the country where large volumes of groundwater have been and continue to be removed from the aquifers. Sections 3.1.3.11 and 3.3.3.5 present details on the extent and history of groundwater and land subsidence associated with groundwater withdrawal, respectively. Potential groundwater depletion and subsidence impacts to soils are discussed in Chapter 4 as part of the No Action alternative (Section 4.1) and in discussion of Subpart A (Section 4.7.1) and Subpart E (Section 4.2). Compliance with the proposed Standard directed to agricultural water, if finalized, could cause farm operators to replace surface water sources with groundwater, thereby causing increased groundwater pumping, aquifer depletion, soil subsidence, and soil structure destruction. As a result of these potential impacts, it is FDA's analysis that groundwater depletion and land subsidence may be the only irretrievable resource commitments associated with compliance with the PS PR. However, as discussed in Chapter 4.2, FDA has heard from stakeholders that, given the flexibility added to the proposed requirements for agricultural water sources, it is less likely that operations will need to switch water sources to meet the proposed agricultural water standards, if finalized, thereby alleviating much of the potential for exacerbating existing groundwater depletion and land subsidence issues.

7.0 Potential Unavoidable Adverse Environmental Impacts

Under 40 CFR 1500.2(e), Federal agencies shall, to the fullest extent possible, use the NEPA process to identify and assess reasonable alternatives to proposed actions that will avoid or minimize adverse effects of these actions upon the quality of the human environment. This chapter discusses significant unavoidable impacts for which either no mitigation or only partial mitigation is feasible. An evaluation of impacts associated with the No Action alternative and the potentially significant provisions of the PS PR is included in Chapter 4. The analysis in Chapter 4 includes a discussion of environmental consequences of the alternatives to the potentially significant provisions, and possible management decisions by farm operators, associated with compliance with the provisions of the PS PR, if finalized.

Potential unavoidable adverse impacts associated with the implementation of the PS PR could occur under the following provision and alternative:

Subpart E – Standards Directed to Agricultural Water

Alternative I. Preferred: As Proposed. GM ≤ 126 CFU generic *E. coli*/100 ml and STV ≤ 410 CFU/100 ml

- Under this alternative, switching water source and ceasing to grow covered produce are not expected to be preferred management decisions. As discussed under the No Action Alternative, while there may be current and on-going significant adverse, long-term impacts from lowering the water table, deteriorating water quality, and land subsidence, each resulting from further groundwater withdrawals, such switches to groundwater are already occurring and causing significant adverse impacts that would be independent of the proposed water standard. Any action that may lead to increases in groundwater drawdown would be considered a significant environmental impact. Regions that may be most impacted in terms of potential land subsidence, including any additive effects by switching to groundwater sources, include the regions that already experience the highest groundwater withdrawals; these are regions B, C, D, I, J, and U. Due to the added flexibility to account for pathogen microbial die-off in the field under Alternative I, coupled with the knowledge that a high amount of potentially affected growers participate in marketing agreements with more stringent numeric water quality standards than what FDA proposes, any potential effects related to Alternative I are not expected to significantly contribute significantly to the current significant adverse conditions to the extent that would occur under Alternatives II, III or IV.

Alternative II: GM of no more than 126 CFU (or MPN)/100 mL and a single sample maximum of 235 CFU (or MPN) generic *E. coli* /100 ml single sample or a Geometric Mean of no more than 126 CFU (or MPN)/100 ml

- Under this alternative, switching water source is expected to be the preferred management decision. As compared to Alternative I, this alternative would not have the added flexibility for pathogen die-off and/or removal; therefore, farmers are more likely to decide to switch water sources, particularly away from surface waters to a cleaner source. If the cleanest available source is groundwater, then existing significant adverse conditions (i.e., water drawdown, potential subsidence, and the related continued degradation of water quality) may continue to be exacerbated but to a greater degree than Alternative I, because the water quality requirements would be more stringent under this alternative and more farms are potentially likely to switch to the groundwater source in numbers that may considerably influence groundwater sources. These impacts are expected to be limited to localized regions and are not expected to be widespread. The regions that may be most affected are B, C, D, I, J, and U. These regions may also experience irreversible effects to soils. Therefore, these impacts under Alternative II related to lowering the water table, deteriorating water quality, and land subsidence, are considered significant adverse.

- Native American Tribes may be disproportionately impacted as groundwater drawdown could have potential environmental impacts including socioeconomic impacts related to access to water on reservations, particularly in regions B and J. Such impacts would be considered significant adverse.

Alternative III. As proposed (i.e., Alternative I), with an additional criterion establishing a maximum generic E. coli threshold

- This alternative would be substantially similar to Alternative I; however, the implementation of a threshold may mean that there may be circumstances when a farmer is not able to account for pathogen microbial die-off and/or removal. Such circumstances; however, would be dependent on the numerical criterion of the threshold. Therefore, the likelihood that a farmer may decide to switch to a groundwater source is slightly higher than Alternative I.

Alternative IV. Alternatives for direct water application method

- Alternative IV allows for the standards considered under Alternatives I through III to include or exclude root crops. The analysis of Alternatives I through III assumes that root crops are excluded. Therefore, the impacts on groundwater drawdown and land subsidence for each of those alternatives would be greater under Alternative IV due to the fact that more crops would be covered under the standards directed at agricultural water.

8.0 USDA NRCS Conservation Support

Overview of NRCS

NRCS is a non-regulatory Federal agency that works with private landowners to address conservation needs on private working lands, including produce farms. All work with private land owners (or their managers) who seek NRCS conservation assistance begins with a conservation planning process. NRCS considers the following resource concerns in the conservation planning process: Soil, Water, Air, Plants, Animals, Human (e.g. social and economic factors), and Energy. Conservation Planning is a nine step process described at the following Web site:
http://www.nrcs.usda.gov/wps/portal/nrcs/detail/nh/technical/cp/?cid=nrcs144p2_015695

Once a plan is completed, NRCS Conservation Practice Standards (CPS) and other supporting documents are used to ensure that the best possible knowledge is used to guide the voluntary, site specific implementation of a Conservation Plan. CPS are written by Technical Specialists and implemented by field staff throughout the nation. There are both national CPS and individual state CPS. Even with a standard, how conservation is implemented on an individual farm is site specific. A CPS helps frame the process of implementing the practice, but expected benefits from the practice as well as design, construction and maintenance considerations must be based on a specific setting. Typically Conservation Plans include suites of practices individually tailored to the unique needs of the setting and the landowner interest and ability to implement the plan.

Many NRCS Conservation Practices address pathogen movement in the landscape, for example filter strips and herbaceous riparian vegetation to protect surface water from pathogens that may move to surface waters in run-off from areas of concentrated animal activity or land applied manures. When a farmer expresses concerns about design, installation or management of a conservation practice for any reason, NRCS staff respect farmers' complex market and regulatory requirements, and seek ways to best support conservation while allowing them to make other management decisions necessary in their farm and ranching operations.

USDA NRCS Conservation Practice Standard Review and Development Process

NRCS continually reviews and revises conservation practice standards to reflect advances in both farming and conservation techniques and technologies. According to NRCS Title 450 Part 401.14, each national conservation practice undergoes a formal review process every five years from the date of initial issuance, or date of review.

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10.0 Acronyms

A

ACHP - Advisory Council on Historic Preservation
AEU - Animal Equivalent Unit
AFO - Animal Feeding Operation
AMI - American Mushroom Institute
AOI - Area of Interest
AZ LGMA - Arizona Leafy Greens Marketing Agreement

B

BCAP - Biomass Crop Assistance Program
BEA - Bureau of Economic Analysis
BIA - Bureau of Indian Affairs
BMP - Best Management Practice
BSA - Biological Soil Amendment
BTU - British Thermal Unit

C

Ca - Calcium
CAA - Clean Air Act
CAFF - Community Alliance with Family Farmers
CAFO - Concentrated Animal Feeding Operations
CA LGMA - California Leafy Greens Marketing Agreement
CCAB - California Cantaloupe Advisory Board
CDC - Centers for Disease Control and Prevention
CDHS - California Department of Health Services
CD-ROM - Compact Disk Read Only Memory
CEQ - Council on Environmental Quality
CFR - Code of Federal Regulations
CFU - Colony Forming Unit
CFWC - California Farm Water Coalition
CGMP - Current Good Manufacturing Practices
CH_4 - Methane
Cl_2 - Chlorine
C:N - Carbon to Nitrogen Ratio
COA - Certificate of Analysis
CO - Carbon Monoxide
CO_2 - Carbon Dioxide
CP - Conservation Practice
CPPE - Conservation Practice Physical Effects
CREP - Conservation Reserve Enhancement Program
CWA - Clean Water Act
CWS - Community Water Systems

CWT - a hundredweight, unit of measurement equal to 100 pounds

D

DACS - Florida Department of Agriculture and Consumer Services
DL - Detection Limit
DNA - Deoxyribonucleic acid
DOE - U.S. Department of Energy
DOL - U.S. Department of Labor
DSHS - Texas Department of State Health Services

E

EA - Environmental Assessment
e.g. - (*exempli gratia*) for example
EHEC - Enterohemorrhagic *E. coli*
EIB - Economic Information Bulletin
EIS - Environmental Impact Statement
EJ - Environmental Justice
EO - Executive Order
EPA - U.S. Environmental Protection Agency
EQ - Exceptional Quality
ESA - Endangered Species Act
et al. - (*et alia*) and others
et seq. - (*et sequentes* or *et sequential*) and the following

F

FC - Fecal Coliform
FAO - Food and Agricultural Organization of the United Nations
FDA - U.S. Food and Drug Administration
Fed. Reg. - Federal Register
FETRA - Fair and Equitable Tobacco Reform Act
FFDCA - Federal Food, Drug, and Cosmetic Act
FIFRA - Federal Insecticide, Fungicide, and Rodenticide Act
FoodNet - Foodborne Diseases Active Surveillance Network
FR - Federal Register
FRIS - Farm and Ranch Irrigation Survey
FSMA - FDA Food Safety Modernization Act

G

GAFL - Georgia Florida
GAP - Good Agricultural Practices
GAP&GHP Program - Good Agricultural Practices and Good Handling Practices Program
gdw - Gram Dry Weight

GHG - Greenhouse Gases
GHP - Good Handling Practices
GLP - Good Laboratory Practice
GM - Geometric Mean
GMO - Genetically Modified Organism
GT - Gigaton (or one billion tons)
GWP - Global Warming Potential

H

HACCP - Hazard Analysis and Critical Control Points
HARPC - Hazard Analysis and Risk-based Preventive Controls
HCl - Hydrochloric acid
HClO - Hypochlorous Acid
HHS - U.S. Department of Health and Human Services
HUS - Hemolytic Uremic Syndrome

I

i.e. - (*id est*) in other words; that is to say
IFT - Institute of Food Technologists
IHS - Indian Health Service
IPCC - Intergovernmental Panel on Climate Change
IPM - Integrated Pest Management
ISDEAA - Indian Self-Determination and Education Assistance Act

J

K

K - Potassium
km^2 - Square Kilometer
km^3 - 1,000 Cubic Kilometer
kGy - Kilogray (absorption of one joule of radiation energy by one kilogram of matter)

L

Lbs - Pounds
LGMA - Leafy Greens Marketing Agreement
LP - Liquefied Petroleum
LRR - Land Resource Regions

M

MAF - Million Acre Feet

MAS - Major Aquifer Study
MBTA - Migratory Bird Treaty Act
MCL - Maximum Concentration Limit
MDP - Microbiological Data Program
Mg - Magnesium
MGD - Millions of Gallons Per Day
MGAP - Mushroom Good Agricultural Practices
mg/L - Milligrams Per liter
ml - Milliliter
mV - Millivolt
MMP - Manure Management Planner
MPN - Most Probable Number

N

N - Nitrogen
N_2O - Nitrous Oxide
NA - Not Available
NAAQS - National Ambient Air Quality Standards
NACMCF - National Advisory Committee on Microbiological Criteria for Foods
NaOCl - Sodium Hypochlorite
NASPHV - National Association of State Public Health Veterinarians
NASS - National Agricultural Statistics Service
NATWWG - North American Tomato Trade Work Group
NAWQA - National Water-Quality Assessment
NAWS - National Agricultural Workers Survey
NCAI - National Congress of American Indians
NEPA - National Environmental Policy Act of 1969
NH_3 - Ammonia
NH_4^+ - Ammonium Ion
NHPA - National Historic Preservation Act of 1966 as Amended
NMP - Nutrient Management Plan
NO_2 - Nitrogen Dioxide
NOAA - National Oceanic and Atmospheric Administration
NOI - Notice of Intent
NOP - National Organic Program
NOSB - National Organic Standards Board
NOx - Nitrogen Oxides
NPDES - National Pollutant Discharge Elimination System
NPK - Nitrogen, Phosphorous, and Potassium
NPS - U.S. National Park Service

O

O_3 - Ozone
OCC - Office of Chief Counselor

OEA - Office of External Affairs
OFVM - Office of Foods and Veterinary Medicine
ORA - Office of Regulatory Affairs
ORP - Oxidation Reduction Potential
OSU - Ohio State University

P

P - Phosphorous
PAM - Anionic Polyacrylamide
Pb - Lead
PC PR - FSMA Preventative Controls for Human Food Proposed Rule
PCR - Polymerase Chain Reaction
PEIS - Programmatic Environmental Impact Statement
PFGE - Pulsed-Field Gel Electrophoresis
PM - Particulate Matter
$PM_{2.5}$ - Particulate Matter (Fine Particles) - diameter less than 2.5 micrometer
PM_{10} - Particulate Matter (Inhalable Course Particles) - diameter from 2.5 to 10 micrometers
PMP - Pest Management Plan
PPM - Parts Per Million
PRIA - Preliminary Regulatory Impact Analysis
PSA - Produce Safety Alliance
PSD - Prevention of Significant Deterioration
PS PR - Produce Safety Proposed Rule

Q

Q&A - Question and Answer
QAR - Qualitative Assessment of Risk

R

RFA - Regulatory Flexibility Act
RIA - Regulatory Impact Analysis
ROD - Record of Decision
ROI - Region of Influence

S

§ - Section
§§ - Sections
S - Sulfur
SBA - Small Business Administration
SDWA - Safe Drinking Water Act
SIP - State Implementation Plan
SO_2 - Sulfur Dioxide

SOC - Soil Organic Carbon
SOM - Soil Organic Matter
SSSA - Soil Science Society of America
STEC - Shiga Toxin-Producing *E. coli*
STV - Statistical Threshold Value
SUME - Survival of Microorganisms in Environment
SWQA - Source-Water Quality Assessment

T

T&E - Threatened and Endangered
T-BMP - Tomato Best Practices Manual
T-GAP - Tomato Good Agricultural Practices
Tg CO_2 Eq. - Teragrams of Carbon Dioxide Equivalent
THM - Trihalomethanes
TMDL - Total Maximum Daily Load
TRI - Toxic Release Inventory
TTHM - Total Trihalomethanes
TTPP - Tobacco Transition Payment Program
TVP - Total Value of Production

U

United Fresh - United Fresh Produce Association
UNEP - United Nations Environmental Programme
UNSCEAR - United Nations Scientific Committee on the Effects of Atomic Radiation
U.S. - United States
U.S.C. - U.S. Code
USCB - U.S. Census Bureau
USDA - U.S. Department of Agriculture
USDA AMS - USDA Agricultural Marketing Service
USDA ARS - USDA Agricultural Research Service
USDA CCPO - USDA Climate Change Program Office
USDA ERS - USDA Economic Research Service
USDA NASS - USDA National Agricultural Statistics Service
USDA NRCS - USDA Natural Resources Conservation Service
USFWS - U.S. Fish and Wildlife Service
USGS - U.S. Geological Survey
UV - Ultra-violet
UW - University of Wisconsin

V

VOC - Volatile Organic Compound
VTA - Vegetated Treatment Area

W

WCFS - Western Center for Food Safety
WFA - Wild Farm Alliance
WHO - World Health Organization

X

Y

Z

ZVI - Zero Valent Ion

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11.0 Glossary

A

Adequately Reduce Microorganisms of Public Health Significance - Reduce the presence of such microorganisms to an extent sufficient to prevent illness. The extent of reduction 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. For example, 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* would be a process capable of reducing *Salmonella* by 5 logs per gram of food.

Affiliate - Any facility that controls, is controlled by, or is under common control with another facility.

Agricultural Tea - 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. Agricultural teas are held for longer than one hour before application.

Agricultural Tea Additive - A nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.

Agricultural Water - 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 - Solid or liquid animal waste.

Application Interval - The time interval between application of an agricultural input (such as a biological soil amendment of animal origin) to a growing area, and the harvest of covered produce from the growing area where the agricultural input was applied.

B

Bacteriophage - A virus capable of infecting a bacterial cell.

Bedding - Bedding is the preparation of soil by “plowing, blading, or otherwise elevating the surface of flat land into a series of broad, low ridges separated by shallow, parallel channels with positive drainage.” Bedding is done to improve the drainage of surface water, decrease soil compaction, and to create a warm, dry planting bed for vegetation establishment. The Bedding practice is generally applied to lands with flat to near flat topography and poorly drained soils.

Biological/Ecological Resource - Includes vegetation, wildlife, protected species, and soils within agricultural and allied lands and adjacent 'off-farm' areas within the U.S. and its territories. Vegetation includes native and non-native plant species, including major agricultural crops, invasive, and noxious plant species. Wildlife species include both native and non-native species.

Biological Fixation - The process whereby a substance is removed from the gaseous or solution phase and incorporated into plant tissue, as in carbon dioxide fixation or nitrogen fixation.

Biological Soil Amendment - 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.

Biological Soil Amendment of Animal Origin - 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. The term ''biological soil amendment of animal origin'' does not include any form of human waste.

Biosolids - A primarily organic solid product produced by wastewater treatment processes, also known as "sewage sludge."

C

Calid - Warm or tepid temperature.

Carbon Cycle - The process by which carbon moves between the atmosphere and different reservoirs in the earth.

Carbon Sequestration - The process of capture and long-term storage of atmospheric carbon dioxide (CO_2).

Certifying Agent - An individual or other entity that is accredited by the USDA National Organic Program and who is permitted to certify producers and handlers of agricultural products. According to USDA's Web site there are certifying agents that are USDA-accredited and authorized to certify operations to the USDA organic standards.

Coliphage - A bacteriophage that specifically infects the *Escherichia coli* bacterium.

Colony Forming Unit (CFU) - A measure of viable cells in which a colony represents an aggregate of cells derived from a single progenitor cell.

Co-management - For the purposes of this EIS, co-management means promoting stewardship on the farm, including protecting water and soil quality and conserving wildlife and ecosystem habitat, while balancing food safety and farm productivity goals.

Composting - A process to produce humus in which organic material is decomposed by the actions of microorganisms under conditions for a designated period of time (for example, 3 days) at a designated temperature (thermophilic for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions.

Commingled Raw Agricultural Commodities - Any raw agricultural commodity that is combined or mixed after harvesting but before processing.

Community Supported Agriculture (CSA) Program - A program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season.

Concentrated Animal Feeding Operation (CAFO) - A livestock or poultry feeding and producing facility that (a) confines animals for more than 45 days during a growing season, (b) in an area that does not produce vegetation, and (c) meets certain size thresholds. Three categories of CAFOs are defined by EPA, and determine the conditions and degree to which the facility is regulated by the Clean Water Act, based on Animal Unit Equivalents (AUEs) - Large CAFO (1000 or more AUEs), Medium CAFO (999 to 300 AUEs), and Small CAFO (under 300 AUEs). Federal law requires regulated CAFOs to obtain National Pollutant Discharge Elimination Systems permits before they can discharge wastewater from the facility from a delegated state agency or EPA. CAFOs are also potentially subject to regulation under the Clean Air Act if statutory thresholds are exceeded.

Covered Activity - 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 section 112.3 (79 Fed. Reg. 58434 at 58470).

Covered Produce - Produce that is subject to the requirements of proposed 21 CFR part 112 in accordance with §112.1 and 112.2. The term ''covered produce'' refers to the harvestable or harvested part of the crop.

Cultural Resource - Physical evidence or place of past human activity, such as a site, object, landscape, or structure. A site, structure, landscape, object, or natural feature of significance to a group of people traditionally associated with it. Types of cultural resources include archaeological resources, historic structures, cultural landscapes, and museum objects.

Curing - 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.

D

Direct Water Application Method - 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. (Note: By cross-reference to the definition of "covered produce", this his term only applies to methods in which the water is intended to, or is likely to, contact the harvestable part of the covered produce).

E

Effectively Treated Biological Soil Amendment of Animal Origin - A Biological Soil Amendment of Animal Origin which has undergone a scientifically valid controlled physical process, chemical process, or combination of physical and chemical processes that satisfies one of the microbial standards for *Listeria monocytogenes*, *Salmonella*, and *E. coli O157:H7.*

Endangered Species - The term "endangered species" means any species which is in danger of extinction throughout all or a significant portion of its range other than a species of the Class Insecta determined by the Secretary of the Interior to constitute a pest whose protection under the provisions of this Act would present an overwhelming and overriding risk to man (16 U.S.C. § 1532(6)).

Enteric Fermentation - A digestive process by which carbohydrates are broken down by microorganisms into simple molecules for absorption into the bloodstream of a ruminant animal.

Environmental Justice - The fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. It will be achieved when everyone enjoys the same degree of protection from environmental and health hazards and equal access to the decision-making process to have a healthy environment in which to live, learn, and work.
(http://www.epa.gov/environmentaljustice).

Evident Animal Intrusion - Evidence of animal intrusion includes the observation of significant quantities of animals, animal excreta, or crop destruction via grazing.

F

Facility - Any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Non-bottled water drinking water collection and distribution establishments and their structures are not facilities.

Farm - 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" includes establishments that, in addition to these activities: (i) Pack or hold raw agricultural commodities; (ii) 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 subparagraph (iii)(B)(1) of this definition; and (iii) Manufacture/process food, provided that:

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

This definition is consistent with the definition of ‘farm’ presented in the Supplemental Rule (79 Fed. Reg. 58434 at 58470 – 58471).

Federally Recognized Tribe - An American Indian or Alaska Native tribal entity that is recognized as having a government-to-government relationship with the United States, with the responsibilities, powers, limitations, and obligations attached to that designation, and is eligible for funding and services from the Bureau of Indian Affairs. Furthermore, federally recognized tribes are recognized as possessing certain inherent rights of self-government (i.e., tribal sovereignty) and are entitled to receive certain federal benefits, services, and protections because of their special relationship with the United States. At present, there are 566 federally recognized American Indian and Alaska Native tribes and villages (http://www.bia.gov/FAQs).

Fence - A constructed barrier to livestock, wildlife, or people.

Field Residue - Materials left in an agricultural field or orchard after the crop has been harvested. These residues may include stalks, stems, leaves, and seed pods.

Food - Articles used for food or drink for man or other animals, including chewing gum, and articles used for components of any such article. This definition is consistent with section

201(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321(f). "Food" also includes seeds and beans used to grow sprouts (78 Fed. Reg. 3504 at 3631).

Food-Contact Surfaces - 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, this includes food-contact surfaces of equipment and tools used during harvest, packing, and holding (78 Fed. Reg. 3504 at 3631).

Food Grains - 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.

Food Hazard - A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Food Hub - A regional food hub is a business or organization that actively manages the aggregation, distribution, and marketing of source-identified food products primarily from local and regional producers to strengthen their ability to satisfy wholesale, retail, and institutional demand.

Food Safety Hazard - Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

Foodborne Illness Outbreak - The occurrence of two or more cases of a similar illness resulting from the ingestion of a certain food.

G

Geometric Mean - The positive n^{th} root of the product of a set of n numbers (http://dictionary.reference.com/browse/geometric mean).

Groundwater - Water from an underground aquifer that has not been held or conveyed in a manner open to the environment.

H

Hazard - Any biological agent that is reasonably likely to cause illness or injury in the absence of its control (78 Fed. Reg. 3504 at 3631).

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 on a farm. Harvesting 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. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm are examples of harvesting (79 Fed. Reg. 58434 at 58471).

High - The impact is highly noticeable; the overall effects may be the result of a deliberate requisite shift in management practices, which may cause a major beneficial or adverse consequence.

Holding - The 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 raw agricultural commodity and breaking down pallets)), 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. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks (79 Fed. Reg. 58434 at 58471).

Humus - A stabilized (i.e., finished) biological soil amendment produced through a controlled composting process.

Hyporheic Zone - The region beneath and alongside a stream bed, where the mixing of shallow groundwater and surface water is widespread.

I

Impaired Surface Water - Waters that are too polluted or otherwise degraded to meet the water quality standards set by states, territories, or authorized tribes. (http://water.epa.gov/lawsregs/lawsguidance/cwa/tmdl).

Indian Tribe - Any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined or established pursuant to the Alaska Native Claims Settlement Act (85 Stat.688) (43 U.S.C. 1601 et seq.), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians (25 U.S.C. § 450b).

J

K

L

M

Manufacturing/processing - 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 are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/ processing would not include activities that are part of harvesting, packing, or holding (78 Fed. Reg. 3504 at 3631).

Manure - Animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment.

Microbial Reduction - A decrease in microbial populations as is necessary to protect public health.

Microorganisms - Yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites, including those species that have public health significance.

Minimal - The impact is detectable, and likely reversible; the overall effects may be the result of a slight shift in management practices, which may cause an overall minor beneficial or adverse consequence.

Minority Populations - Pursuant to the Council on Environmental Quality's (CEQ) Guidance for Federal Agencies on Key Terms in EO 12898 (CEQ, 1997a), and for the purposes of this Technical Report and the associated EIS, minority populations are comprised of members of the following population groups:

- Black or African American: a person having origins in any of the black racial groups of Africa;
- Hispanic or Latino: a person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race;
- Asian American: a person having origins in any of the original peoples of the Far East, Southeast Asia or the Indian subcontinent;
- American Indian or Alaskan Native: a person having origins in any of the original people of North America, South America (including Central America), and who maintains cultural identification through tribal affiliation or community recognition; or,
- Native Hawaiian or Other Pacific Islander: a person having origins in any of the original peoples of Hawaii, Guam, Samoa or other Pacific Islands.

Mixed-Type Facility - 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 (78 Fed. Reg. 3504 at 3631).

Moderate - The impact is readily apparent; the overall effects may be the result of a deliberate or essential shift in management practices, which may cause an overall moderate beneficial or adverse consequence.

Monitor - To conduct a planned sequence of observations or measurements in order to assess whether a process, point, or procedure is under control, and, when applicable, to produce an accurate record of the observation or measurement.

N

Non-Fecal Animal Byproduct - 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.

O

Operator - A person who operates a farm, either doing the work or making day-to-day decisions about such things as planting, harvesting, feeding, and marketing. The operator may be the owner, a member of the owner's household, a hired manager, a tenant, a renter, or a sharecropper.

P

Packing - 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 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 (79 Fed. Reg. 58434 at 58471).

Packaging - (verb) Placing food into a container that directly contacts the food and that the consumer receives (78 Fed. Reg. 3504 at 3631).

Packaging - (noun) Containers used for transporting, holding or marketing of food.

Pathogen - A microorganism of public health significance (79 Fed. Reg. 58434 at 58564).

Pathogen Exposure - An event or occurrence that results in contact of humans with a biological hazard that may create the risk of serious adverse health consequences or death.

Pest - Any objectionable animals or insects including birds, rodents, flies, and larvae.

Pre-Consumer Vegetative Waste - 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.

Processed Food - Any food other than a raw agricultural commodity. Includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling (21 U.S.C. 321).

Produce - Any fruit or vegetable (including mixes of intact fruits and vegetables), including mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs. Produce does not include food grains (78 Fed. Reg. 3504 at 3631).

Production Batch of Sprouts - 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).

Protected Species - Plants and animals listed by the federal government as needing protection because of their current status. Includes species listed as either Endangered or Threatened through the Endangered Species Act (16 U.S.C. § 1531 et seq.).

Q

Qualified End-User - (with respect to a food). The consumer of the food, or a restaurant or retail food establishment that is located (i) in the same State as the farm that produced the food, or (ii) not more than 275 miles from such farm (78 Fed. Reg. 3504 at 3632). The term "consumer" does not include a business.

R

Raw Agricultural Commodity - Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing (78 Fed. Reg. 3504 at 3632).

Reasonably Foreseeable Hazard - A potential biological hazard that may be associated with the farm or the food (78 Fed. Reg. 3504 at 3632).

Restaurant - Consistent with 21 CFR 1.227(b)(10), restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. "Restaurant" does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers. Restaurants are (i) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and (ii) Pet shelters, kennels, and veterinary facilities in which food is provided to animals.

Retail Food Establishment - An establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations (21 CFR 1.227 (b)(11)).

Rotational Sequencing - The rotation of crops.

S

Sanitize - 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.

Seasonality - Pertaining to or dependent on a particular season. Relating to the period of each year when native and ornamental plants and crops can be grown.

Sewage Sludge Biosolids - 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), which states: "Solid, semi-solid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes, but is not limited to, domestic septage; scum or solids removed in primary, secondary, or advanced waste water treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generate during preliminary treatment of domestic sewage in a treatment works."

Small Business - A farm, on a rolling basis, where the average annual monetary value of produce (as defined in paragraph (c) of section 112.3) sold during the previous 3-year period is no more than $500,000; and the farm is not a very small business as provided in paragraph (b)(1) of section 112.3 (79 Fed. Reg. 58434 at 58470).

Soil Amendment - Any chemical, biological, or physical material (such as elemental fertilizers, humus, 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. 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 - Water that has been used in the growing of sprouts.

Static Composting - 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. Examples of structural features for introducing air include embedded perforated pipes and a constructed permanent base that includes aeration slots, as well as 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).

Statistical Threshold Value (STV) - STV approximates a specified percentile of a distribution, which depends upon the inherent variability of the observations in a sample as well as their central tendency.

Surface Water - 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.

T

Table Waste - 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.

Tailwater - Excess irrigation water that runs off a farm field that may be carrying sediments, nutrients, and agricultural chemicals.

Thermophilic - Relating to or being an organism living at a high temperature.

Threatened Species - Any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. (16 U.S.C. § 1532(20)).

Turned Composting - A process to produce humus 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.

U

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.

Upland Wildlife Habitat Management - Upland Wildlife Habitat Management is “creating, maintaining, or enhancing areas to provide food, cover, and habitat connectivity for upland wildlife.” This conservation practice is applicable on a land “where the decision maker has identified an objective for conserving a wild animal species, guild, suite or ecosystem and “land within the range of targeted wildlife species and capable of supporting the desired habitat.”

V

Vermicompost - Compost generated through the conversion of organic waste by earthworms.

Very Small Business - A farm, on a rolling basis, where the average annual monetary value of produce (as defined in paragraph (c) of section 112.3) sold during the previous 3-year period is no more than $250,000 (79 Fed. Reg. 58434 at 58470).

W

Water Distribution System - 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.

Water Rights - The right of a user to use water from a water source, such as a river, stream, pond, or a source of groundwater.

X

Y

Yard Trimmings - 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.

Z

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12.0 Preparers and Reviewers

In accordance with 40 CFR § 1502.17, this chapter includes a list of names and qualifications (including position/title, education, experience, and expertise) of individuals who were primarily responsible for preparing the environmental impact statement or significant background papers, including basic components of the statement. Experience is denoted within a range (<5 years; 5-10 years; 10-15 years; 15-20 years; 20-25 years; and 25+ years). The description also identifies the primary role the individual assumed in the preparation of the EIS.

12.1 U.S. Department of Health and Human Services, Food and Drug Administration

Lead Environmental Manager / Key Point of Contact

Annette McCarthy, PhD
Lead Environmental Scientist
Center for Food Safety and Applied Nutrition, Office of Food Additive Safety
Education:
PhD\ Environmental Toxicology
Experience: 10-15 yrs.
Expertise: NEPA Analysis, Environmental Risk Assessment, Pesticide Ecotoxicology
Responsibilities: NEPA Document Manager

Other team members

Samir Assar, PhD
Director Produce Safety Staff
Center for Food Safety and Applied Nutrition, Office of Food Safety
Education:
PhD\ Food Science with emphasis in Microbiology
Experience: 10-15 yrs.
Expertise: Produce Safety, Microbiology,
Responsibilities: Lead on Produce Safety Rule

Kari Barrett
Public Engagement Advisor
FDA Office of Foods and Veterinary Medicine, Strategic Communications and Public Engagement Team
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Expertise: External Stakeholder Engagement
Responsibilities: Public Scoping, Public Meeting

Bradley Brown, PhD
Associate Director, Economics
Office of the Commissioner
Education:
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Expertise: Economics, Cost Benefit Analysis
Responsibilities: Technical Reviewer

Rebecca Buckner, PhD
Supervisory Food Safety Specialist
Office of Foods and Veterinary Medicine
Education:
PhD\Food Chemistry
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Expertise: Food Safety
Responsibilities: Requirements of the FDA Food Safety Modernization Act, Stakeholder Engagement and Feedback, General Review.

Andrew Estrin, PhD
Economist
CFSAN/Office of Regulations Policy and Social Sciences
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Experience: 10- 15 yrs.
Expertise: Regulatory Economics
Responsibilities: Scoping
Expertise: Economics
Responsibilities: Technical Expert-Socioeconomics

Marianne Fatica, PhD
Staff Fellow
Center for Food Safety and Applied Nutrition, Office of Food Safety
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Mary Hitch, MBS, PA
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Expertise: Tribal Consultation, Policy and Outreach, Tribal Law
Responsibilities: Tribal Liaison and Outreach

Zahava Hurwitz, MS
Policy Analyst
Office of Planning and Policy
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Consumer Safety Officer
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Consumer Safety Officer
Center for Food Safety and Applied Nutrition
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Expertise: Good Agricultural Practices
Responsibilities: Technical Expert-Biological Soil Amendments

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Center for Food Safety and Applied Nutrition, Office of Food Safety
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Responsibilities: Technical and Policy Assistance for Produce Safety

12.2 Contractor Team

Lead Environmental Manager / Key Point of Contact

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Program/Project Manager
JMT
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BS\ Biology
BS\ Environmental Science/Marine Science
Experience: 10-15 yrs.
Expertise: EIS preparation; NEPA analysis
Responsibilities: Lead Project Manager, Purpose & Need, Environmental Consequences, Quality Assurance

Other team members

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Senior Environmental Scientist
JMT
Education:
MA\ Geography, Physical Environmental Systems
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Expertise: NEPA Analysis, Technical Editing Control

Mary Alfson Tinsman, MA
Senior Environmental Scientist
JMT
Education:
MA\ Historic Preservation
MDA\ Business Management
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Expertise: Cultural resources
Responsibilities: Cultural Resources, Tribal Resources, Quality control

Lindsey Allen, MA
Architectural Historian
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Expertise: Cultural resources
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David Back, P.G.
Hydrogeologist
SCA
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Responsibilities: Water Resources

Judith Burton, MS
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JMT
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Responsibilities: Soil Resources Issues

Julia Cole, MS
Scientist III
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Crystalann Deardorff, P.E.
Air Quality Specialist
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Education:
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Expertise: Air Quality
Responsibilities: Air Quality Issues

Amber Garr, PhD
Scientist III
EA Engineering, Science, and Technology
Education:
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Responsibilities: Human Health and Safety

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AA\ Specialized Technology
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Expertise: Digital Rendering
Responsibilities: Graphics (renderings)

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Environmental Specialist
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Expertise: NEPA & Environmental Planning
Responsibilities: Impact Presentation

Richard Heimbach, AICP
NEPA Specialist
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Education:
BS\ Environmental Resource Management
Experience: 20-25 yrs.
Expertise: Animal Waste Handling
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Dan Hinckley, PhD
Scientist V
EA Engineering, Science, and Technology-Hunt Valley
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Expertise: Environmental Chemistry, Risk Assessment, Toxicology
Responsibilities: Human Health and Safety, Qualitative Risk

Leyla Lange, MS
Senior Environmental Specialist
JMT
Education:
MS\ Marine-Estuarine Environmental Resources
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Expertise: NEPA Analysis
Responsibilities: Quality Control

Charles Leasure, AICP
Senior Biologist
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Education:
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Expertise: Ecology & Biology
Responsibilities: Biological and Ecological Resources Issues

Matthew Mielke
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WR&A
Education:
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Experience: <5 yrs.
Expertise: Environmental Science, NEPA
Responsibilities: Socioeconomics, Environmental Justice

Craig Nein, MS
Environmental Scientist
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Education:
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Experience: 5-10 yrs.
Expertise: Environmental Science/Herpetology
Responsibilities: Air quality Issues

Katherine Ready
NEPA Specialist
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JD\ Environmental Law
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Expertise: Environmental law
Responsibilities: Public Participation, Research Support, Administrative File

Russ Ruffing
Vice President, Environmental and Natural Resources
JMT
Education:
BS\ Environmental Resource Management
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Expertise: NEPA Oversight
Responsibilities: Quality Assurance

Halie Stannard
Environmental Planner
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Education:
BS\ Environmental Policy and Planning
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Expertise: Environmental Planning, NEPA
Responsibilities: Socioeconomics, Environmental Justice

Kevin Sullivan
GIS Technician
JMT
Education:
BS\ Geography and Environmental Studies
Experience: 5-10 yrs.
Expertise: Mapping
Responsibilities: Graphics (GIS)

Illustration Key

Note: The Healthy, Diverse Ecosystems Help Keep Pathogens in Check illustration is not drawn to scale; it serves as a visual summary of the conservation practices and food safety actions used to address food safety referenced in this document. These practices and actions do not provide complete and conclusive protection against food-borne pathogens on a given farm/ranch, and some vegetative conservation practices may attract wildlife that can vector pathogens. When implementing in-field practices to address food safety, one should take into account the conditions present on the farm/ranch and use this information to assess the effectiveness of a given practice in reducing the risk of food-borne pathogen contamination of crops. [Note that this material is presented in its entirety in *A Farmer's Guide to Food Safety and Conservation*, by the Wild Farm Alliance and the Community Alliance with Family Farmers (WFA and CAFF, 2013).]

1. Sun: UV radiation from the sun may inactivate recently deposited pathogens on the surfaces of soil and leaves, as well as in clear water. The sun also facilitates the desiccation of pathogens, which leads to pathogen reduction.
2. Dust from animal activity is reduced with the application of water by sprinklers and with manure harvesting. Reducing emissions and removing manure proactively are cost-effective means of mitigating pathogen transfer.
3. Diversions redirect water running off of confined animal feeding operations to waste treatment and sedimentation lagoons, preventing the movement of waterborne pathogens to nearby farm traffic areas, fields and waterways. Vegetated diversions also intercept organic matter and soil carrying pathogens running off pasture, and divert potentially contaminated water away from specialty crop fields. The diversions slow pathogen dispersal and provide a matrix for beneficial bacteria and protozoa that compete with and consume pathogens. Plants should be selected for low-flow filtering capacity and the ability for high flows to flow through the vegetation. Selection criteria should also consider how well air and sunlight are able to penetrate into the vegetation, as the cool, moist, shaded interior vegetation may provide favorable habitat for pathogen survival. Otherwise additional maintenance will be required that regularly harvests and removes excess vegetation.
4. Waste storage pond temporarily stores waste, such as manure runoff from confined animal feeding operations, thereby reducing pollution potential in the landscape. The waste storage pond should be properly designed and maintained so that it does not overflow. Food safety Good Agricultural Practices (GAPs) recommend that the effluent from the ponds not be used on crops typically eaten raw. Monitoring of animal movement around the pond and between waste handling areas and crop fields should be a scheduled activity.
5. Restored wetlands can considerably reduce pathogen transport by slowing the water, which increases the interaction time, and pro- viding a matrix for beneficial microbes. The diverse plant and microbial community establishes desirable interactions that serve to limit pathogen persistence. Use of vegetation and designs that facilitate slow moving water over long periods in the wetland allow the best chance for pathogen reduction in water draining from the wetland. The vegetation in the wetland may decrease the ability of UV light to reach the pathogens, which may increase survival. However, pathogens may be retained on vegetation. As water

recedes, the pathogens that are retained on the vegetation may be exposed to sunlight and desiccation.

6. Riparian forest buffers are vegetated areas along bodies of surface water, including streams, wetlands and lakes. They may trap wind- borne pathogens on their vegetation and filter waterborne pathogens attached to suspended organic-soil particulates and other solids. The diverse plant and microbial community in the buffers encourages interactions limiting pathogen persistence.
7. Flooded field: Food safety GAPs recommend that crops typically eaten raw are not planted on lands that often flood. If and when a flood occurs, it may take time for pathogens present in the soil to die off. Depending on the frequency of floods, the field could be fallowed for a period, replanted to a cover crop, or possibly, permanently taken out of production with the restoration of riparian habitat.
8. Windbreaks can trap dust containing pathogens and prevent it from entering specialty crop fields. Plants should be selected with foliar and structural characteristics to optimize dust/pathogen interception. If interior vegetation is too dense, it may provide a cooler, moister and shadier environment, which may create a favorable conditions for temporary pathogen survival.
9. Evidence of animal intrusion in a crop field should be monitored. Food safety GAPs recommend that farmers monitor for animal feces and signs of feeding, and when found, a no-harvest buffer is placed around the contaminated source, or other measures are taken to reduce risk of harvesting the contaminated crop. The following considerations all factor into determining the appropriate risk reduction actions taken: the type and number of animals; whether they are present intermittently or continually; if they are there because of food, a movement corridor, or live next to the crop; and if they are seen initially before planting or right before harvesting.
10. Hedgerows may trap waterborne pathogens in their root systems, and wind-borne pathogens on their vegetation. Shaded interior of the vegetation may provide favorable conditions for temporary survival of pathogen if too dense.
11. Irrigation: Food safety GAPs recommend using sources of irrigation water that are adequately free of contamination. Management techniques that promote infiltration of the water into the soil can reduce runoff and may aid in reducing the movement of pathogens al- ready present in the field. Techniques that aid in infiltration include soil quality management that increases porosity and improves structure, and irrigation management that keeps soil from becoming saturated.
12. Sediment basins capture and detain sediment-laden runoff that may contain pathogens. Correctly designed, basins allow sufficient time for the sediment to settle out of the water. With moist, cool conditions, the basin may support the survival of pathogens. Having a sediment basin that dries down as rapidly as possible helps to alleviate these moist conditions and helps reduce pathogen survival. Moist sediment that is removed from the basin and put on cropland should be treated as contaminated and a time period similar to non-composted soil amendments between its application and the next crop's harvest should be established.

13. Riparian forest root zone: The roots of the riparian forest promote water infiltration and provide biological activity. This helps divert pathogens from surface water, and encourages interactions with other soil microorganisms that can limit pathogen persistence.
14. Stream ecosystem: In a stream ecosystem where diverse microbial communities exist, they are thought to reduce pathogens by com- petition, parasitism, and predation. Clear water allows light to reach pathogens, which can lead to their reduction. Flowing water dilutes pathogen populations. Some algae and protozoa may serve as an alternate host for pathogens, allowing pathogens to survive even when environmental conditions are unfavorable.
15. Diverse microbial populations compete with and consume pathogens in water, soil and on plant surfaces. When diverse microbial populations are present, beneficial microbes compete with pathogens for carbon and nitrogen, while others kill and consume them. Diverse microbial communities in water and on plants also compete for resources and/or consume pathogens. In some instances, biofilms (a matrix of bacteria and carbohydrates) can harbor pathogens.
16. Cover crops: Rotating with cover crops increases soil organic matter and supports soil microbial communities that may aid in suppressing pathogens. Cover crops may also reduce the movement of pathogens in water run-off by trapping pathogens in their roots and leaves. They can be used as part of a ‘waiting-period’ between events that might pose contamination risk (e.g. grazing, flooding) and the planting of a crop typically eaten raw. Cover crops also reduce open soil, which helps reduce dust transmission problems.
17. Integrated pest management (IPM) of vertebrates such as mice and squirrels can be used as a means of control for pest animals that enter crop fields. Having a few predatory animals, such as hawks or owls, on the farm is less of a risk than numerous prey species. A crop should not be planted directly under a raptor nest box or a roost, so that it is not contaminated with raptor feces. Farm traffic should not carry fecal droppings into the cropped area or equipment and storage yard.
18. Harvesting orchard fruit from the tree, not the ground, is recommended by Food Safety GAPs when it will be consumed fresh. Fallen fruit may have come in contact with animal feces.
19. Field borders can intercept and reduce waterborne pathogens moving in overland flow from the field. This planting encourages infiltration and serves as a buffer between the field and the riparian vegetation.
20. Tree bird roost: Food safety GAPs recommend that a no-harvest zone is established under branches that hang over the field to ensure bird feces will not touch the crop.
21. Wildlife corridors allow wildlife to access resources (water, food and cover) without having to walk across crop fields or leave their preferred habitat.
22. Crop placement: Food safety GAPs recommend that leafy green vegetables or other crops typically eaten raw not be planted near manure stockpiles or composting facilities and windrows, or other areas of contamination, as pathogens may transfer to the field via water or wind.
23. Compost: Properly managed compost windrows heat up to a temperature that results in significant pathogen reduction. Compost itself supports beneficial organisms that compete with, inactivate, and consume pathogens. Compost that has been allowed to be re-

contaminated, or compost that is unfinished could be a source of pathogens; thus, measures should be taken to prevent these below par composts from moving onto adjacent fields through wind or water. For information on proper compost management practices refer to ‘Chapter 2: Composting’ in Part 637 of the USDA, NRCS National Engineering Handbook.

24. Conservation cover is used to establish and maintain perennial vegetative cover to protect soil and water resources on land retired from agricultural production or on other lands needing permanent protective cover that will not be used for forage production. Perennial plants may trap wind borne pathogens on the vegetation and waterborne pathogens in the root system.

25. Prescribed grazing uses animals to manage vegetation. It also helps to increase water infiltration, reduce runoff and prevent erosion. This aids in stopping the movement of pathogens in water runoff. Grazing animals are a reasonably foreseeable source of pathogens; thus, measures should be taken to prevent pathogens from the animals’ feces from moving onto adjacent fields through wind or water.

Irrigation Overview (relative to the Produce Safety Proposed Rule)

Introduction

Irrigation is a very old farming practice, dating to early Egyptian, Nubian, Mesopotamian, Sri Lankan, Andean and Peruvian societies (Kumar and Vis, 2010). There are many different modern irrigation practices, some which rely on pressure and some that incorporate gravity. Pressurized irrigation, and other sorts that need water lifted from its natural source were developed after the advent of the pump and siphon. Examples of pumps used today include the windmill pump, Archimedes and Wood's screw pumps, centrifugal impeller pump, peristaltic pump, and hydraulic ram water-pressure pump (Kumar and Vis, 2010). Accordingly, some of these run on electric motors where others can be driven by natural forces including wind and the hydraulic properties of water.

Irrigation allows some arid land to be cultivated, or in other cases is used to increase yields, reduce risk or to grow crops that would otherwise fail to thrive in a certain environment and/or season, for example due to lack of natural precipitation (CDC, 2009). Irrigation allows a wider variety of crops to thrive in a given region than might otherwise occur from natural precipitation. Water application can not only extend the growing season, but can also be used to protect a crop from a frost/freeze situation in the spring and fall growing seasons. For example, Florida citrus crops are spray irrigated during periods of frost to provide warmth to the tree crops). Protection sprays are also applied as sun or heat protection (for example, this approach is used in apples grown in the Pacific Northwest).

There are situations that promote or preclude irrigation, which depend on regional markets, weather patterns, and other factors. In other words, direct application of agricultural water for irrigation varies in prevalence and is not universally practiced; a lot of farms rely on natural precipitation for growing.

The USDA compiles a Farm and Ranch Irrigation Survey (FRIS) the year following each agricultural census, which are conducted every five years; the latest FRIS was completed in 2008 (USDA NASS, 2008). FRIS provides a significant amount of data regarding irrigated acres and crop types but only limited data in terms of water source and the irrigation application methods.

The states with the largest area of irrigated land are Nebraska, California, Texas, Arkansas, and Idaho (USDA NASS, 2008). Three of these "top five" states include states where FDA has conducted FSMA public outreach.

Agricultural water is defined 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). Water applied in any manner that directly contacts covered produce during or after harvest activities, used to make a treated agricultural tea, used to contact food-contact surfaces, or to make ice that will contact food-contact surfaces, or used for washing hands during and after harvest activities is required to meet the standard of no detectable generic *E. coli* in 100 ml of water in the PS PR. The PS PR proposes a water quality standard for agricultural water used during growing activities for covered produce. The potential environmental impact of the proposed standard and alternatives are evaluated in the Environmental Impact Statement.

Irrigation by manual labor, is not included below as an irrigation method, because although this type of irrigation might be practiced on smaller operations, it is assumed those domestic producers using irrigation by manual labor would likely be very small and, therefore, below the threshold of applicability for the PS PR.

It may not be feasible in all cases to change forms of irrigation as a means of complying with the PS PR, due to specific crop requirements, cost or other factors. For example, certain types of produce require daily direct water application for crop protection from sun/heat damage, and accordingly surface, subsurface drip irrigation, and sub-irrigation alone would not be viable solutions for those types of operations.

Below are common forms of irrigation, explained briefly in the context of the applicability of the PS PR (USGS, 2014c and Walker, 1989).

Most Common Forms of Irrigation in the U.S.

1. SURFACE IRRIGATION

Surface irrigation is practiced for crops where ample water can be obtained upgradient or with pumps and diverted into piping or ditches for distribution onto fields or into channels. It sometimes involves dikes, levees, terraces, and furrows to direct the water; and could have an outlet or can be as elaborate as a return-loop system that recycles water. Water is introduced onto the field through gated outlets from a ditch or pipe. It is left to flow down the field for a set amount of time. Inherently, under surface irrigation the upper part of the field is exposed to the irrigation water for a longer time than the lower end. In order to allow ample time for the water at the lower end of the field to infiltrate the soil, the upper end of the field is over-irrigated, while the lower end receives less water than ideal. Thus, efficient surface irrigation is where the water can be rapidly pushed down the field, and the opportunity for infiltration is similar throughout the field.

Many surface irrigation systems are manually controlled, with the irrigator turning the gates of the pumps on or off. There are a wide variety of automation schemes using valves and timers to switch the water from one area to another and decrease the flow as the advancing front of water nears the lower end of the field. Water that exits these systems (excess flow, by design) is referred to as "tailwater" or "runoff". Tailwater can contain excess nutrients and enteric microbes, especially if farming operations are not managed properly. This can be problematic for downstream users.

Flood systems, one type of surface irrigation, works well on certain crops (e.g., rice, celery, potatoes, barley, sugar beets, onions and hydrophytic produce species) that grow in ponded conditions. However, most crops can be grown under some variety of flood irrigation. Flood irrigation is touted as the preferred option on some crops, like onions where the top of the bulb does not get wet from sprinkling and that minimizes ‘neck rot’. This type of rot lowers viable storage time of onions and often lowers the sale price. Many of these systems rely on manual labor for operation and therefore are low in operating costs; however, maintenance costs are still a factor.

Surface irrigation might present some unique challenges for farmers who must comply with the PS PR. If water treatment is necessary, treatment of surface water feeding this type of irrigation system might require a large volume of water to be treated (if the source exceeds the microbial water quality standards established by the PS PR and other options are unable to be applied). Practically, unless the crop demands a high amount of water continuously, a less expensive long-term solution could possibly be to install a different sort of irrigation system that is less water-intensive than to treat large volumes of water. Alternatively, some irrigation systems may warrant a replacement (i.e., ground or another surface) source of water in order to obtain water that may not require treatment prior to application.

		
Level Basin Surface Irrigation	Furrow Irrigation using Siphons	Furrow Irrigation System

2. SPRINKLER IRRIGATION

Sprinkler irrigation is accomplished by placing water under pressure in a piping system and directing the pressurized water through a nozzle. The nozzle could be fixed, spin, or move with an apparatus (e.g., supply pipe). Source water could include surface water, groundwater, or a cistern/tank. Timers, water depth sensors, infrared sensors and soil moisture probes can be used to automate sprinkler irrigation systems or they can be manually controlled at the discretion of the grower.

Systems that rely on machine-driven apparatus have associated operating costs (fixed) and maintenance requirements (variable). Sprinklers that are moved by hand or farm machinery have associated labor and maintenance costs.

If necessary, treatment of water for a sprinkler irrigation system would likely require treatment of a large volume. Practically, it might be a less expensive, long-term solution to install a different type of irrigation system (e.g., drip irrigation) that is less water-intensive than to treat large volumes of water. The need to treat large volumes of water could be mitigated by not using "reclaimed" water (i.e., wastewater treatment plant effluent) and/or recirculated runoff water as sources of irrigation water.

Fixed Overhead and Moving Irrigation Systems

These forms of irrigation rely on overhead fixed piping, or in some cases, wheeled machine-driven mobile applicators that direct their spray downward or outward onto the irrigated crop. There are primarily four types: (1) Center/Central Pivot Irrigation Systems, (2) Lateral Moving Irrigation Systems, (3) Fixed Overhead Systems, and (4) Traveling Gun Systems.

Center Pivot systems, popular in the western U.S. are probably the most commonly recognized type of overhead sprinkler system. Center pivot systems rotate in a circular pattern around a center point and irrigate a circular area. These systems can be overhead on a line that circles the field, or they can be from a central spinning nozzle ejector. Lateral Moving systems can be powered, moved by hand or pulled with farm machinery. Lateral move systems move across the field, either continuously or periodically. A variety of nozzle types can be mounted on the lateral. Overhead irrigation systems effectively mimic the effects of natural precipitation but are fixed in place. Their wetting pattern depends on the overhead track and the types of emitters or sprayheads used, but they are typically designed to wet the full perimeter within the area of coverage. Traveling gun irrigation, self-propelled or continuous, uses a wheeled apparatus with a single rotating sprinkler that expels water as it is moved about on roads between plots. It relies on a delivery line to supply water and is therefore connected to a water source; however, unlike a center pivot system which is fixed to a single water supply, a traveling gun can be moved to different areas.

Traveling Gun System

Two Common Types of Lateral Moving Systems
(Gantry Assembly and Wheel Line)

Overhead irrigation can be more uniform than fixed ground sprinklers. In many cases, this is a custom or singly-designed and built system for an individual farm operation. Water could be piped to these systems from a distance, or a source close to the irrigator (such as a well) could be located near the individual or group of applicators. Overhead systems almost exclusively rely on pumping or pressurized water supplies[1] to achieve the necessary head pressure to actuate the sprinkler, although public water supplies are not commonly used due to the associated costs. These systems require either above-ground or in-ground water supply pipes, and in some cases (except where a static upright main is fixed, like in a pivot system) a flexible hose that travels with the gantry sprayer system atop the ground.

[1] It should be noted that information on New England produce farms shows 26% of covered farms (roughly 5,000) use municipal water supplies as their source water.

			
Fixed Big Gun	Fixed Overhead System in greenhouse	Center Pivot System, specifically End Gun	Aerial View of Center Pivot Irrigation

<u>Sprinkler Sprayhead Irrigation</u>

There are a number of types of sprinkler heads that can be used to comprise a sprinkler system. Spray heads are mounted either on the pipe of a center pivot or wheel line, or on tubes that hang closer to the crop. Although there are differences between spray and impact nozzles, and between fixed pattern spray head or spray head mounted on moving machinery, all of these systems are designed to effectively distribute water to the crop.

- *<u>Pop-up</u>*. These are recessed when not in use (below ground level) and actuated by water pressure. There can be a simple circular stationary sprinkler head, or a rotating sprinkler.
- *<u>Rotary</u>*. These can include gear-driven sprinkler, impact sprayers, common “turf rotors” (e.g., golf course sprinklers).
- *<u>Other</u>*. There are also mist sprayers and circular sprayers used in some applications.

The delivery lines of a fixed sprinkler irrigation system are typically installed in a grid pattern underground (at a depth below the plowzone), with the sprinkler heads at intervals allowing a uniform application rate by overlapping the circular patterns. In that arrangement, the edges of the fields could be slightly deprived of water and could be expected to have a lower yield, unless the planting rows were all located within the uniform spray, with some wasted water or conservation cover crops in peripheral edges.

 Impact Sprinkler	 Pop Up (Pressure Actuated) Head	 Impact Sprinkler with Surface Laterals

3. SUBSURFACE / DRIP IRRIGATION

These systems deliver water directly to the root zone of the crop at or below the soil surface. Various types of outlets can be used to achieve this purpose. Timers can be used with these systems, or they can be manually controlled.

- **Bubblers**: These are designed to apply water in small areas, and can be near the soil surface to achieve that effect. This could be achieved with holes in the piping, or permeable materials to permit water to exit under pressure throughout the entire tube.
- **Drip Emitters**: These can be standard, or pressure compensating. Note that there are drip emitters that can be impregnated with EPA registered biocides, and others that can be fitted for backflushing that (along with micron disc filtration) effectively prevent microbes from being released.
- **Subsurface Textile Irrigation**: Although of limited application in commercial situations, this is an underground system that includes an irrigation line (drip tape or drip tube), a subbase impermeable layer, and permeable textile layer that evenly distributes irrigation water (20-30 cm beneath the surface). Subsurface textile irrigation uses capillary action of the soil to allow the water to wick upwards to the root zone.

In terms of the agricultural water standards of the PS PR, except for systems that allow backflushing, it could be difficult to dose underground drip systems with EPA registered biocides without releasing the full volume of biocides into the soil medium. Therefore, treatment of larger volumes of water might be needed to effectively treat these types of systems. However, in contrast, some underground drip emitters are designed to contain EPA registered integral antimicrobial biocides or mechanical means of trapping microbes in the emitter mechanism (removed by backflushing).

The proposed agricultural water standards only apply to water that comes into direct contact with the harvestable portion of covered produce. Therefore, some subsurface and drip irrigation systems used only for the root zone (with the roots not being harvested or consumed) may not be covered in the PS PR.

4. SUB-IRRIGATION

Sub-irrigation is a process very similar in concept to surface irrigation, although water does not reach the surface. In these systems, water is contained by an underground impervious layer and moves upward through capillary forces, unlike in subsurface drip irrigation where water is added within the root zone directly.

Certain types of crops benefit from certain types of irrigation systems; not all irrigation systems work interchangeably on every type of crop. For example, overhead spray can be used to protect from frost, whereas surface level irrigation practices (e.g., furrow) would not. Also for example, drip irrigation is the most effective sort of application method in arid conditions where water is limited to direct water directly into the root zone to minimize evaporation. And further as an example, certain crops grow best in flood cycle conditions (e.g., water chestnuts, watercress, etc.).

Manure Management Overview

Introduction

The purpose of this memorandum is to provide a broad overview of the use of manure with respect to growing covered produce. The information presented is general in nature; information specific to individual crops, manure types, regional considerations, and best management practices can be obtained through communication with the USDA and local agricultural extension services.

Manure may be defined as animal excreta, alone or in combination with litter (such as straw used for animal bedding and feathers), for use as a soil amendment. Manure is a byproduct of livestock operations and must be appropriately managed and disposed of in order to maintain sanitary conditions. Disposal options include hauling to treatment facilities and/or land application as soil amendments. Green manures are derived from vegetation materials such as yard waste and cover crops and are not considered a potential vehicle for pathogens (when not in contact with for example raw manure); and are therefore excluded from this discussion. For the purposes of this discussion, manure and biological soil amendments (BSAs) of animal origin are synonymous.

Beneficial reuse of manure as a soil amendment has been documented worldwide throughout history (University of Illinois Extension, 2014b). Manure is not only a source of nutrients and minerals necessary for plant growth but also adds organic matter that improves soil structure (Schoenau et al., 2006).

Large volumes of untreated (or raw) manure have a likely probability of containing harmful pathogens that could potentially be transmitted to humans via direct contact (University of Wisconsin-Madison Dept. of Dairy Science & The Babcock Institute, 2010; eXtension, 2014). The use of manure-containing soil amendments as an agricultural input increases the likelihood that produce may become contaminated (Jiang and Shepherd, 2009). Soil amendments, partially composted manure, raw manures or teas made from such materials are potentially significant reservoirs of human pathogens. A biological soil amendment of animal origin can spread contamination it harbors to food it contacts, either directly, or indirectly through contamination of food contact surfaces (Doyle, 2001; and Rangarajan et al., 2000).

Common sources of raw manure include cows (dairy and beef), swine, horses, sheep, goats, and poultry (chickens and turkeys). Nutrient content (concentrations of available nitrogen, phosphorus and potassium) and percent dry matter by weight can vary significantly based on the source (type of animal), whether or not bedding (e.g., straw) is incorporated, how the manure is stored and handled, as well as the method of application (OSU Extension, 2014).

It is important to note that unlike chemical fertilizers, nutrients from raw manure must be transformed from organic to inorganic (soluble/volatile) forms in order to be available for plant uptake (Schoenau et al., 2006). Therefore, treatment technologies such as composting, aerobic and anaerobic digestion are often utilized to accelerate the process. An additional benefit of some of these technologies is that the life cycle of potentially harmful pathogens can be broken, providing that conditions required for survival are not present for a sufficient amount of time.

Proper Manure Application to Land

The proper application of manure is critical for crop productivity and soil health. In determining application rates, timing of application and appropriate methods for application several factors must be considered. These factors include (but are not limited to) the nutrient content of the manure being applied; available nutrients in the existing soils; and type of crop(s) being grown (nitrogen and phosphorus consumption rates). Such factors also include a variety of site specific conditions such as the potential for runoff or leaching through the soil column (OSU Extension, 2014).

Failure to consider these (and other) factors could result in crop failure, degradation of soil structure, deterioration of surface and groundwater supplies, and other potential broad reaching impacts to our Nation's resources (OSU Extension, 2014). Over-application of manure can compromise the quality of soils; in some cases, salts accumulate in the soils, which is known to negatively impact crop production for several growing seasons (OSU Extension, 2014). Appropriate application can vary significantly from year to year and manure application rates should be determined through laboratory analysis.

Common Manure Handling Systems

Most agricultural manures are stored and applied either in solid or liquid form. Solid manures are typically stockpiled and may or may not be subject to treatment such as composting. Surface application followed by incorporation is typically used for solid manures. Incorporation should occur as soon as possible to minimize nitrogen loss as well as control odors (Colorado State University Extension, 2014).

Liquid manure can be collected as surface runoff in storage ponds or through floor drainage systems (often associated with swine and dairy operations) connected to large storage pits (EPA, 2012d). Liquid manures can either be applied to the surface of the soil (preferably quickly followed by incorporation) or directly injected into the soil (EPA, 2012d). Direct injection of liquid manures not only minimizes loss of nutrients to surface runoff and but also provides effective odor control (EPA, 2012d).

Manure Management Guidance

Across the country, states recognize the value of fertilizing with manure as well as the need to prevent pollution and protect resources. More specific guidance with respect to individual crops, regions and prevailing conditions can be obtained from state and local cooperative extension offices. Table C-1 below provides a list of resources for manure management practices/guidelines.

Table C-1. State-specific manure application resources

State	Resources
Arkansas	Nutrient and Fertilizer Value of Dairy Manure (University of Arkansas Cooperative Extension)
Arizona	http://ag.arizona.edu/animalwaste/farmasyst/awfact8.html
Iowa	Using Manure Nutrients for Crop Production (Cooperative Extension Service, Iowa State University)
Maine	Manure Utilization Guidelines: published by Maine Department of Agriculture; reviewed by University of Maine Cooperative Extension
Michigan	Conservation of Fertilizers and Livestock Manure: Pollution Prevention (National Pollution Prevention Center for Higher Education) Managing Manure in Potato and Vegetable Systems (Michigan State University Extension)

Table C-1. State-specific manure application resources (Continued)

State	Resources
Minnesota	Fertilizing Cropland with Beef Manure (University of Minnesota Extension Service, 2002) Fertilizing Cropland with Poultry Manure (University of Minnesota Extension Service, 1992) Fertilizing Cropland with Swine Manure (University of Minnesota Extension Service, 2002) Land Application of Manure: Minimum State Requirements (Minnesota Pollution Control Agency) Manure Management in Minnesota (University of Minnesota Extension Service, 2012) Self Assessment Worksheets for Manure Management Plans (University of Minnesota Extension Service, 1994) Using Manure and Compost as Nutrient Sources for Fruit and Vegetable Crops (University of Minnesota Extension Service)
North Carolina	Dairy Manure as a Fertilizer Source (North Carolina Cooperative Extension Service) Poultry Manure as a Fertilizer Source (North Carolina Cooperative Extension Service) Swine Manure as a Fertilizer Source (North Carolina Cooperative Extension Service)
Ohio	Estimating Manure Production, Storage Size, and Land Application Area (The Ohio State University Extension) Guidelines for Applying Liquid Animal Manure to Cropland with Subsurface and Surface Drains (The Ohio State University Extension)
Oregon	Annual Manure Application Schedule for Western Oregon (Oregon State University Extension Service) Fertilizing with Biosolids (Pacific Northwest Extension) Manure Application Rates for Forage Production (Oregon State University Extension Service)
South Carolina	Land Application of Animal Manure (Clemson University Extension)
Washington	Farming West of the Cascades: Fertilizing with Manure (Pacific Northwest Extension)
Wisconsin	Guidelines for Applying Manure to Cropland and Pasture in Wisconsin (University of Wisconsin Extension)
All	The following site includes link to map of the US that directs to state specific information: http://www.extension.org/pages/14881/state-specific-manure-nutrient-management-information.

Sources: WCFS (2014); eXtension (2011)

Overview of FDA Tribal Consultation regarding the Environmental Impact Statement (EIS)

DATE	ITEM	PARTIES INVOLVED	TOPIC SUMMARY
August 16, 2013	Letter – Initial Invitation to Consultation	FDA; all federally recognized Indian Tribes	Notice to all tribes that the FDA will produce an EIS for the Produce Safety rule
September 10, 2013	Letter – Yocha Dehe Wintun Nation to FDA	Yocha Dehe Wintun Nation; FDA	Tribal response to August 16, 2013 letter, accepting invitation for consultation
September 12, 2013	Letter – Invitation to an upcoming FDA tribal webinar consultation	FDA; all federally recognized Indian Tribes	FDA's proposed rule entitled the Preventative Controls for Human Food proposed rule and the Produce Safety proposed rule, including the FDA's intent to prepare an Environmental Impact Statement
September 23, 2013	Email and Voicemail – Leah Proffitt (FDA) to Yocha Dehe Wintun Tribe	FDA; Yocha Dehe Wintun Nation	Response to September 10, 2013 letter with copy of September 12, 2013 invitation to FDA webinar
October 29, 2013	Letter – Yocha Dehe Wintun Nation to FDA	Yocha Dehe Wintun Nation; FDA	Letter including specific concerns on the proposed rules, and reiterating accepted invitation to consultation
November 5, 2013	Webinar	*FDA Attendees:* • Michael Taylor, Deputy Commissioner for Foods, Office of Foods and Veterinary Medicine (OFVM) • Mary Hitch, FDA • Dan Sepe, FDA • Annette McCarthy, FDA • Ryan Cates, FDA • Jeff Farrar, FDA • Linda Harris, FDA • David Ingram, FDA • Pat Kuntze, FDA • Talia Lindheimer, FDA • Emy Pfeil, FDA • Eric Snellman, FDA • Cynthia Wise, FDA *USDA Attendees:* • Traci Mouw, USDA • Leanne Skelton, USDA	Webinar held in response to request for tribal consultation (from tribal leaders). The purpose of the webinar was to provide more information on the proposed rules and the FDA Food Safety Modernization Act or FSMA.

Overview of FDA Tribal Consultation regarding the Environmental Impact Statement (EIS) (Continued)

DATE	ITEM	PARTIES INVOLVED	TOPIC SUMMARY
November 5, 2013 (Continued)	Webinar	*CDC Attendee:* • Marjorie Santos, CDC *IHS Attendees:* • Debra Grabowski, IHS • Celeste Davis, HIS *Tribal Attendees:* • Adae Romero, (Cochiti Pueblo/Kiowa), LL.M. candidate at University of Arkansas School of Law • Judy Applewhite, Caption Colorado • Les Brown, Columbia River Intertribal • Marsha Whiting, First Nations Development Institute • Ray Foxworth, First Nations Development Institute • Janie Hipp, Indigenous Food and Agriculture Initiative, University of Arkansas School of Law • Peter Matz, Lower Brule Tribe • Colby Druen, National Congress of American Indians • Dineh John, Navajo Agricultural Products Industry • Simon Boyce, Navajo Nation Washington Office • Joanie Buckley, Oneida Tribe • Jeff Mears, Oneida Tribe of Indians of Wisconsin • Mark Kessler, Potawatomi • Danielle Gaines, Reconnecting the Circle • Martha Pearson, Southeast Alaska	Webinar held in response to request for tribal consultation (from tribal leaders). The purpose of the webinar was to provide more information on the proposed rules and the FDA Food Safety Modernization Act or FSMA.
November 14, 2013	Email – Leah Proffitt (FDA) to Samir Assar (FDA)	FDA; Chilkoot Nation	Regarding a message and call with Scott Hansen from the Chilkoot Nation (AK), addressing questions about how the FSMA will affect the Chilkoot Nation

Overview of FDA Tribal Consultation regarding the Environmental Impact Statement (EIS) (Continued)

DATE	ITEM	PARTIES INVOLVED	TOPIC SUMMARY
January 10, 2014	Letter – Invitation to the Annual Tribal Budget Consultation (ATBC) and notice of the 2014 Annual Regional Tribal Consultations	Department of Health and Human Services (HHS); all federally recognized Indian Tribes	Includes a notice to all tribes about the seven upcoming HHS regional tribal consultations occurring between February and April, 2014.
January 17, 2014	Meeting – FDA and Tribal Organizations	*FDA Attendees*: • Michael Taylor, Deputy Commissioner for Foods, Office of Foods and Veterinary Medicine (OFVM) • Rebecca Buckner, Chief Implementation Manager, FSMA, OFVM • Carie Jasperse, Office of the Counselor to the Commissioner (OCC) • Ritu Nalubola, Senior Policy Advisory, Office of Policy • Mary Hitch, FDA Tribal Liaison, OEA • Laura Pillsbury, Special Assistant to the Deputy Commissioner, OFVM • Felecia Hogue, Executive Secretariat, FVM *USDA Attendees:* • Leanne Skelton, USDA Liaison to FDA for the Produce Safety Rule Via Phone: • Jeff Farrar, Director of Intergovernmental Relations, OFVM • Barbara Cassens, Office of Partnerships, ORA • Kelly Weller, OFVM *Tribal Attendees*: • Brian Howard, National Congress of American Indians (NCAI) • Colby Duren, National Congress of American Indians	Meeting between the FDA Office of Foods and Veterinary Medicine and the Tribal organizations, regarding the FSMA Proposed Rules

Overview of FDA Tribal Consultation regarding the Environmental Impact Statement (EIS) (Continued)

DATE	ITEM	PARTIES INVOLVED	TOPIC SUMMARY
January 17, 2014 (Continued)	• Meeting – FDA and Tribal Organizations	• Simon Boyce, Navajo Nation Washington Office Via Phone: • Janie Hipp, Indigenous Food and Agriculture Initiative, University of Arkansas School of Law • Adae Romero (Cochiti Pueblo/Kiowa), LL.M. candidate at University of Arkansas School of Law • Barbara Rasco, Professor, School of Food Science, Washington State University (works on aquaculture and seafood product development) • Representative from Columbia River Inter-Tribal Fish Commission • Representative from First Nations Development Institute	Meeting between the FDA Office of Foods and Veterinary Medicine and the Tribal organizations, regarding the FSMA Proposed Rules
March 27, 2014	Letter – Invitation to Regional consultation at the Indian Pueblo Cultural Center, New Mexico	FDA; Tribal Organizations in HHS Regions 6 and 7	Invitation to consultation to discuss FDA's FSMA Proposed Rules, including the intent to prepare an EIS.
April 23, 2014	Meeting – Regional consultation at the Indian Pueblo Cultural Center, New Mexico	HHS; FDA; Navajo Nation *HHS/FDA Attendees:* • Michael Taylor, Deputy Commissioner for Foods, Office of Foods and Veterinary Medicine (OFVM) • Rebecca Buckner, FSMA Chief Implementation Manager, FDA • Jeff Farrar, Associate Commissioner for Food Protection, FDA • Latonya Mitchell, Denver District Director, FDA • Lillian Sparks Robinson, Commissioner, Administration for Native Americans *Tribal Attendees:* • Governor Mermejo, Picuris Pueblo • John Shije, Lt. Governor, Pueblo of Santa Clara	FDA's proposed rules required by Food Safety Modernization Act, including intent to prepare an Environmental Impact Statement

Overview of FDA Tribal Consultation regarding the Environmental Impact Statement (EIS) (Continued)

DATE	ITEM	PARTIES INVOLVED	TOPIC SUMMARY
April 23, 2014 (Continued)	Meeting – Regional consultation at the Indian Pueblo Cultural Center, New Mexico	• Tod Robertson, Seminole Nation of Oklahoma • Frances Quintana, Pueblo of Pojoaque • Richard Bernard, Pueblo of Pojoaque • Dolly Naranjo, Pueblo of San Ildefonso • Renae Pablo, Navajo Agricultural Products Industry • Dineh John, Navajo Agricultural Products Industry • Pat Beare, Navajo Pride • Rick Vigil, Former Governor of Pueblo of Tesuque	FDA's proposed rules required by Food Safety Modernization Act, including intent to prepare an Environmental Impact Statement

Region I: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

a. Mashantucket Pequot Tribe (Connecticut)
b. Mohegan Tribes of Indians (Connecticut)
c. Mashpee Wampanoag Tribe (Massachusetts)

Region II: New Jersey, New York, Puerto Rico, US Virgin Islands

a. Oneida Nation of New York (New York)

Region III: Delaware, Maryland, Pennsylvania, Virginia, West Virginia

Region IV: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee

a. Seminole Tribe of Florida (Florida)
b. Catawba Indian Tribe (South Carolina)

Region V: Illinois, Indiana, Ohio, Michigan, Minnesota, Wisconsin

a. Saginaw Chippewa (Michigan)
b. Lac du Flambeau Band of Lake Superior Chippewa Tribe (Michigan)
c. Leech Lake Band (Minnesota)
d. Fond du Lac Band (Minnesota)
e. Menominee Indian Tribe (Wisconsin)
f. Oneida Nation of Wisconsin (Wisconsin)
g. Fond du Lac Band (Wisconsin)

Region VI: Arkansas, Louisiana, New Mexico, Oklahoma, Texas

a. Jena Band Choctaw (Louisiana)
b. Pueblo of Cochiti, New Mexico (New Mexico)
c. Pueblo of Laguna (New Mexico)
d. Pueblo of Santa Ana (New Mexico)
e. Pueblo of Taos (New Mexico)
f. Navajo Nation (Arizona, New Mexico, Utah)
g. Choctaw Nation Oklahoma (Oklahoma)
h. Pawnee Nation Oklahoma (Oklahoma)
i. Seminole Nation of Oklahoma (Oklahoma)
j. Muscogee (Creek) Nation (Oklahoma)
k. Absentee-Shawnee Tribe (Oklahoma)

Region VII: Iowa, Kansas, Missouri, Nebraska

Region VIII: Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming

a. Crow Reservation (Montana)
b. Crow Creek Sioux Tribe (South Dakota)
c. Oglala Sioux Tribe of Pine Ridge (South Dakota)
d. Cheyenne River Sioux Tribe (South Dakota)
e. Navajo Nation (Arizona, New Mexico, Utah)

Region IX: Arizona, California, Hawaii, Nevada

a. Gila River Indian Community (Arizona)
b. White Mountain Apache (Arizona)
c. San Carlos Apache Tribe (Arizona)^
d. Navajo Nation (Arizona, New Mexico, Utah)^
e. Lone Band of Miwok Indians (California)
f. Manzanita Band of Diegueno Mission Indians (California)
g. Yocha Dehe Wintun Nation (California)^
h. Chemehuevi Indian Tribe (California)

Region X: Alaska, Idaho, Oregon, Washington

a. Chilkoot Nation of Alaska (Alaska)^
b. Nez Perce Tribe (Idaho)
c. Coeur d' Alene Tribe (Idaho)
d. Crow Cree Band of Umpqua Indians of Oregon (Oregon)
e. Squaxin Tribe of Squaxin Island (Washington)
f. Lummi Nation (Washington)
g. Shoal Bay Tribe (Washington)
h. Confederated Tribes and Band of the Yakama Nation (Washington)

(^) Denotes tribes who have specifically requested consultation with the FDA, beyond their participation in a webinar or conference call.