Draft Risk Profile: Pathogens and Filth in Spices

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Food and Drug Administration
U.S. Department of Health and Human Services

2013

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ACKNOWLEDGEMENTS

The *FDA Draft Risk Profile: Pathogens and Filth in Spices* benefited from contributions, conversations and information provided by many individuals, organizations, and government officials listed below. We thank and acknowledge each one for their contributions.

American Spice Trade Association, American Dehydrated Onion and Garlic Association, and the Indian Government (Indian Spices Board) for organizing and hosting site visits to spice production and processing facilities and to the employees of the companies visited, for providing information about spices, the spice supply chain, and common practices used in the spice industry.

The spice and food industry for sharing and discussing industry guidance, best practices and common challenges through submission to the Federal Register in response to FDA's call for data and information to support this risk assessment, presentation at scientific meetings, and discussions in meetings with FDA and the American Spice Trade Association for submitting microbiological sampling data to the Federal Register.

Food and Drug Administration scientists for sharing their data, expertise and information, especially Régis Pouillot and Robert Blodgett (modeling and statistics); Susanne Keller, Elizabeth Grasso, Lindsay Halik, Brenda Aloi, Yinqing Ma, Marilyn Balmer, Linda Fabbri, Kristin Kamas, Norman Fogg, Mercedes Loftis, and Office of Regulatory Affairs scientists & field personnel (special laboratory experiments and field assignments); Tracy DuVernoy, Erica R. Pomeroy, and Capt. Suzan Gordon (U.S. outbreaks); Michael DiNovi, Alison Edwards, Ewa Carlton and Karin Hoelzer (consumption); Nicole Nolan (RFR); Rosemary Gary and Martin J. Stutsman (U.S. regulations); Christine Keys, David Melka, Errol Strain, and Mark Allard (PFGE and NGS); John W. Larkin and Nathan Anderson (pathogen reduction treatment); Patrick McDermott , Maureen Davidson and Claudine Kabera (antimicrobial susceptibility); Marjorie Davidson (retail establishment and consumer guidance); Stephanie Briguglio and Mary Same (intern) (literature searches and document preparation), and Amy Miller and Lawrence D'Hoosteleare (filth adulteration).

Centers for Disease Control and Prevention (CDC) and state public health departments for their data, expertise and information regarding U.S. outbreaks, especially Shauna L. Mettee, Hannah Gould, and Ian Williams (CDC); Jeffrey Higa (California Department of Public Health); and Robert Ireland and Daniela Quilliam (Rhode Island Department of Public Health).

International scientists Christine L. Little (while at Health Protection Agency, United Kingdom), Gilles Delmas (Institut de Veille Sanitaire, France), Andrea Altieri (European Food Safety Authority), Jordi Serratosa (European Food Safety Authority), and Tobin Robinson (European Food Safety Authority) for providing additional information about published reports of international outbreaks and spice contamination.

Versar, Inc. (David Bottimore, Kathy Coon, and Stephanie Sarraino) for organizing the External Peer Review of the draft report.

Larry R. Beuchat (University of Georgia), Linda J. Harris (University of California, Davis), Margaret Hardin (IEH Laboratories and Consulting Group), Jeffrey Lee Kornacki (Kornacki Microbiology Solutions), and Christine L. Little (independent contractor) for their peer review of the draft report.

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ABBREVIATIONS AND ACRONYMS

Acronym	Definition
APC	aerobic plate count
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
ASTA	American Spice Trade Association
a_w	water activity
CC	controlled condensation
CDC	Centers for Disease Control
CDPH	California Department of Public Health
CF	coliforms
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CFU	colony forming units
CGMPs	Current Good Manufacturing Practices
CI	confidence interval
CO_2	carbon dioxide
COA	certificate of analysis
Codex	Codex Alimentarius
CORE	Coordinated Outbreak Response and Evaluation Network
DALs	Food Defect Action Levels
DWPE	Detention Without Physical Examination
EB	*Enterobacteriaceae*
EC	*Escherichia coli*
EFSA	European Food Safety Authority
EIC	Export Inspection Council of India
EO	ethylene oxide
EPA	U.S. Environmental Protection Agency
ERS	Economic Research Service
ERU	Emergency Response Unit
FACTS	“Field Accomplishments and Compliance Tracking System,” an FDA database that includes sampling data
FAO	Food and Agriculture Organization
FAS	Foreign Agricultural Service
FC	fecal coliform
FCID	Food Commodity Intake Database
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDA	U.S. Food and Drug Administration
FDB	Food and Drug Branch
FDOSS	Foodborne Disease Outbreak Surveillance System
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act

Acronym	Definition
FSIS	Food Safety Inspection Service
FSMA	FDA Food Safety Modernization Act
GACP	Good Agricultural and Collection Practices
GAPs	Good Agricultural Practices
GC/FID	gas chromatography with flame ionization detection
GC/MS	gas chromatography with mass spectrometry detection
GC/O	gas chromatography with olfactometry
GFN	Global Foodborne Infection Network
GMA	Grocery Manufacturers Association
GMPs	Good Manufacturing Practices
GRAS	Generally Recognized as Safe
H_2O	water
HACCP	Hazard Analysis and Critical Control Points
IBD	Inflammatory Bowel Disease
ICMSF	International Commission on Microbiological Specification for Foods
ISO	International Organization for Standardization
JIFSAN	Joint Institute for Food Safety and Applied Nutrition
kGy	kilo gray
MPN	most probable number
N_2	Nitrogen
NACMCF	National Advisory Committee on Microbiological Criteria for Foods
NAI	no action indicated
NCBI	National Center for Biotechnology Information
NCDEX	National Commodity and Derivatives Exchange
NEC	Not Elsewhere Classified
NGS	Next Generation Sequencing
NHANES	National Health and Nutrition Examination Surveys
NIH	National Institute of Health
OAI	official action indicated
PHF	Potentially Hazardous Food
PSCA	Primary *Salmonella* Control Area
FSPCA	Food Safety Preventive Controls Alliance
RASFF	Rapid Alert System for Food and Feed
RFR	Reportable Food Registry
RH	Relative Humidity
RR	Relative Risk
SRA	Sequence Read Archive
SSA	Seasoning and Spice Association
UNCTAD	United Nations Conference on Trade and Development
U.S.C.	United States Code
USDA	United States Department of Agriculture
USP	U.S. Pharmacopeia

Acronym	Definition
VAI	voluntary action indicated
WHO	World Health Organization
WTO	World Trade Organization
WWEIA	What We Eat in America
YM	yeast and mold

EXECUTIVE SUMMARY

Overview

In light of new evidence calling into question the effectiveness of current control measures to reduce or prevent illness from consumption of spices in the United States, the United States Food and Drug Administration (FDA) developed a risk profile on pathogens and filth in spices. The objectives of the risk profile were to (1) describe the nature and extent of the public health risk posed by consumption of spices in the United States by identifying the most commonly occurring microbial hazards and filth in spice (2) describe and evaluate current mitigation and control options designed to reduce the public health risk posed by consumption of contaminated spices in the United States (3) identify potential additional mitigation and control options and (4) identify critical data gaps and research needs. The draft risk profile for pathogens and filth in spices provides information for FDA to use in the development of plans to reduce or prevent illness from spices contaminated by microbial pathogens and/or filth.

Scope

For the purpose of this risk profile, the term "spice" means "any [dried] aromatic vegetable substances in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, whose significant function in food is seasoning rather than nutritional, and from which no portion of any volatile oil or other flavoring principle has been removed" and includes additional dried plants listed as spices by the Environmental Protection Agency, the American Spice Trade Association, and the Seasoning and Spice Association, such as dehydrated onion and garlic, as well as other dehydrated vegetables used as seasoning.

The specific microbial hazards and filth elements in spices considered in this risk profile include pathogens and filth adulterants detected in spices, implicated in outbreaks, reported as the reason for recalls, and reported in submissions to the Reportable Food Registry. This report primarily focuses on *Salmonella*, among the pathogens detected in spices, because it is the only spice-associated pathogen linked with human illness, food recalls, or Reportable Food Registry reports in the United States.

Research Methods

Research for the report included a comprehensive review of the refereed scientific literature and available government/agency reports, and analyses of relevant FDA and CDC data. Data and information from stakeholders were formally requested in a Federal Register Notice developed by FDA. Submissions to the docket provided critical information on industry guidance and spice sampling and testing by the spice industry. Site visits to spice farms and spice processing and packing facilities, facilitated by spice industry trade organizations and the government of India, provided the Risk Profile Team with first-hand knowledge of current practices. In order to fill some critical data gaps, FDA field assignments and laboratory research were also undertaken.

Types of Pathogens and Filth Adulteration Found in Spices

Microbial pathogens that have been found in spices include *Salmonella*, *Bacillus* spp. (including *Bacillus cereus*), *Clostridium perfringens*, *Cronobacter* spp., *Shigella*, and *Staphylococcus aureus*. Filth adulterants found in spices include insects (live and dead whole insects and insect parts), excrement (animal, bird, and insect), hair (human, rodent, bat, cow, sheep, dog, cat and others), and other materials (decomposed parts, bird barbs, bird barbules, bird feathers, stones, twigs, staples, wood slivers, plastic, synthetic fibers, and rubber bands).

Foodborne Illness Outbreaks from Microbial Contaminants in Spices

During the period 1973-2010, fourteen reported illness outbreaks were attributed to consumption of pathogen-contaminated spice. Countries reporting outbreaks included Canada, Denmark, France, Germany, New Zealand, Norway, Serbia, United Kingdom, and the United States. Together, these outbreaks resulted in 1946 reported human illnesses, 128 hospitalizations and two deaths. Infants and children were the primary population segments impacted by five of the spice-associated outbreaks. *Salmonella enterica* subspecies *enterica* was identified as the causative agent in ten outbreaks accounting for 87% of reported illnesses. *Bacillus* spp. was identified as the causative agent in four outbreaks, accounting for 13% of reported illnesses. Consumption of ready-to-eat foods prepared with spices applied after the final food manufacturing pathogen reduction step accounted for 70% of the illnesses. Pathogen growth in spiced food is suspected to have played a role in some outbreaks, but it was not likely a contributing factor in three of the larger *Salmonella* outbreaks, which involved low-moisture foods. Root causes of spice contamination included contributions from both early and late stages of the farm-to-table continuum.

Prevalence and Concentration of Salmonella *and Filth in Spices*

Limited data were available from the refereed scientific literature on the prevalence of pathogens in spices at most points in the farm-to-table continuum. The majority of data available were from shipments of imported spice offered for entry to the United States (FDA sampling data), lots of spice in spice industry facilities (spice industry sampling data), and retail settings outside the United States (data collected primarily by public health government agencies or academic researchers). Most spices consumed in the United States are imported. Analysis of FDA sampling and testing data for shipments of imported spice offered for entry to the United States during the three year period FY2007-FY2009 revealed an average shipment prevalence for *Salmonella* of 6.6% (750 g sample size; 95% CI 5.7-7.6%). The average prevalence of *Salmonella* in sampled spice shipments during this period was 1.9 times (95% CI 1.6-2.3%) the average prevalence determined for shipments of all other FDA-regulated foods sampled during that time (where screening tests examined 375-1500 g). When only considering shipments of other imported FDA-regulated foods that were sampled with the same FDA Category II food sampling protocol as that used for spices, it was found that the *Salmonella* shipment prevalence for spices was 4.4 times (95% CI 3.4-5.8%) that of other FDA-regulated imported foods during FY2007-FY2009.

A wide diversity of spice types and forms was found to contain *Salmonella* among shipments of imported spice offered for entry to the United States during FY2007-FY2009; differences in prevalence rates were observed for some spice types/forms. More than 80 different *Salmonella* serotypes were isolated from spices in contaminated shipments during the three-year period; 6.8% of isolates exhibited antimicrobial-resistant properties. Some shipments reported to have been subjected to a pathogen reduction treatment before being offered for United States (U.S.) entry were found contaminated. Contaminated shipments identified during FY2007-FY2009 were exported by many different countries; some differences in *Salmonella* shipment prevalence were identified.

FDA undertook a short-term targeted study during Aug-Dec 2010 to collect enumeration data for contaminated shipments of imported capsicum and sesame seed. The mean *Salmonella* concentration estimates varied widely among contaminated shipments, with ranges of 6 x 10^{-4} to 0.09 MPN/g-spice (6 MPN per 10,000 g to 9 MPN per 100 g) for shipments of imported capsicum and 6 x10^{-4} to 0.04 MPN/g-spice (6 MPN per 10,000 g to 4 MPN per 100 g) for shipments of imported sesame seeds offered for entry to the United States. A gamma-Poisson model of within- and between-shipment contamination provided the best fit to observations among six parametric models considered. Contaminated spice shipments of capsicum or sesame seed were typically large in size, constituting millions or tens of millions servings. Approximately one-fifth of the contaminated shipments of capsicum or sesame seed was packaged for retail sale (20% for capsicum and 22% for sesame seed). No comparable prevalence or enumeration data are available for other imported spices or for domestically produced spices.

The American Spice Trade Association (ASTA) provided sampling and testing data collected in spice secondary processing/packing facilities of member companies over a two-year period during 2007-2009. Analysis and interpretation of these data were complicated by an absence of information characterizing sample size examined. The spice industry data provided evidence that the prevalence of *Salmonella* in spice lots that had undergone a pathogen reduction treatment was smaller than that for untreated spice lots. These data also provided evidence that the prevalence of *Salmonella* in these industry sampled treated spice lots was smaller than the average prevalence found for sampled shipments of imported spices offered for import to the United States during FY2007-FY2009 (FDA surveillance sampling).

We were unable to identify any reports characterizing the prevalence or concentration of *Salmonella* in spices at retail (in food/grocery stores, food service, restaurants, or in homes) in the United States. Studies outside the United States reported prevalence values ranging from 0% (with non-zero upper limits) to 10% with varying confidence intervals. Concentrations of *Salmonella* reported in retail spice samples outside the United States ranged from <0.1 to 0.2 MPN/g-spice (0.086 MPN/g for black pepper and capsicum spice in Japan and from <0.1-0.2 MPN/g for sesame seeds and mixtures of seeds in the United Kingdom) for surveillance samples. Concentrations of *Salmonella* determined in traceback investigations of spice-associated foodborne outbreaks ranged from <0.03-11 MPN/g-spice.

Recent prevalence estimates for filth adulteration of spices were only available for shipments of imported spice offered for entry to the United States. No data were available for domestically produced spices. Analysis of FDA surveillance sampling data for FY2007-FY2009 showed that the average prevalence of filth adulteration of shipments of imported spice was 12% (95% CI 10-15%), which was 1.8 times (95% CI 1.4-2.2%) the value found for the average of all other imported FDA-regulated food shipments examined during that period. Prevalence of filth adulteration of imported shipments of ground/cracked and whole spice were similar. The prevalence of filth adulteration of imported shipments of imported black pepper was smaller than that for several other types/categories of spice shipments. The most common types of filth adulterants were insect fragments, whole/equivalent insects, and animal hair. Nearly all of the insects found in spice samples were stored product pests, indicating inadequate packing or storage conditions. The presence of rodent hair (without a root) in spices generally is generally indicative of contamination by rodent feces. Direct evidence of animal fecal and/or insect fecal contamination was found in a small number of the samples. The presence of these filth adulterants is indicative of insanitary conditions and failures in the application of Current Good Manufacturing Practices (CGMPs). Data on the prevalence of filth adulteration of spice at retail in the United States were last gathered in the 1980's by FDA and were used to set the maximum concentrations of natural or unavoidable defects in foods to concentrations achievable by CGMPs.

Characterization of Contaminants

A variety of animal hosts may introduce *Salmonella* into a spice production site. *Salmonella* can survive in the natural environment (outside of an animal host) for extended periods and can persist in some food production areas for years. *Salmonella* can also survive for extended periods (exceeding 1 year) in low moisture foods including spices. The magnitude of the *Salmonella* population reduction rate in spice depends on the water activity of the spice (or equivalently, the humidity of the spice environment) and temperature, when the water activity/humidity is elevated. When *Salmonella*-contaminated spices are stored in an environment that meets spice industry standards for low water activity/humidity, the reduction in population of *Salmonella* in spice with time may be minimal (shown for ground black pepper). FDA research has also demonstrated that *Salmonella* can grow efficiently in wet ground black pepper (no additional nutrients needed), such as might occur if spice is improperly processed, packaged or stored.

Overview of Spice Farm-to-Table Continuum and Potential Sources of Pathogen and Filth Contamination

A wide diversity of farm sizes and agricultural practices is used in the production of spices around the globe. Many spices are produced on very small farms where farm animals are used to plow, crops are harvested by hand, and spices are dried in open air. Multi-cropping is also common. Spice from small farms is typically aggregated with that of other farms. These collections of spice are later sold to exchanges or to spice processing/packing companies. Producers may store whole spice for years before selling to a buyer. Larger farms, such as those used to produce dehydrated onion and garlic in the United States, may be owned by or contracted with a single major/large spice company that dictates/controls growing, harvest, drying, and storage practices. Spice companies may also contract with groups of farmers in a single region to educate and better control growing, harvest, drying, and storage practices. World Health Organization (WHO), Codex Alimentarius (Codex), and industry standards and guidance designed to minimize/prevent introduction of pathogens or filth to the source plant or dried spice, such as those related to irrigation water, restriction of animals in the growing area, and farm worker hygiene, can be challenging to implement at many primary production sites.

The distribution of spice from primary producer to consumer can be very complex, involving multiple locations, multiple processing and/or packing steps and long periods. Inappropriate packing and storage of spice during any one of these steps may lead to the introduction of *Salmonella* or filth into spice.

Application of additional mechanical and electromagnetic cleaning processes as well as grinding/cracking, blending, and packing typically take place in secondary spice processing facilities. To prevent creation of niches, spice processors may use dry sanitation and cleaning processes in process areas handling spice that has been subjected to a pathogen reduction treatment. Some level of spice dust is unavoidable so equipment and facility design play critical roles in limiting the need for wet cleaning in the spice processing areas and preventing cross-contamination of treated spices with untreated spice dust. Replacement of equipment or re-design of facilities can be particularly challenging for small spice firms and use of common equipment for multiple types of spice is common.

Pathogen reduction treatments are not uniformly applied to all types of spices or all lots of spice of a given type at the secondary processing stage. The efficacy of the most commonly applied pathogen reduction treatment methods (steam, irradiation, and ethylene oxide) is dependent on a variety of conditions, which can alter reductions by orders of magnitude. No studies have systematically examined efficacy of these processes for reductions of *Salmonella* in spices but data available suggest that each of these methods has the potential to achieve substantial decimal reductions in spices under appropriately controlled conditions.

Similar food safety concerns, described above for secondary spice processing facilities, exist in seasoning and food manufacturing facilities as well as in wholesalers that pack and re-pack spices. In addition, spice is sometimes added to foods after the final food manufacturing pathogen reduction step has been applied, if such as step is part of the food preparation process.

In institutional food services, restaurants, and households, application of untreated spice to foods after the final lethality (cooking) step and the potential for pathogen growth in foods to which *Salmonella*-contaminated spice has been added are of primary concern. In addition, the potential for contamination of spice by pests in the food preparation and storage environments or cross-contamination of spice from surfaces or utensils used to prepare other contaminated foods are also of concern. Preventive controls to minimize most of these outcomes include application of the principles described in the state regulations, the *FDA Food Code*, and consumer guidance. At this time, spice sold in retail settings (to households) do not generally carry an indication of whether the spice had been treated for reduction of pathogens.

Spice Production and Consumption

Most of the U.S. spice supply is imported with the exception of dehydrated onion. U.S. farms also produce large fractions of the U.S. supply of dehydrated garlic, capsicum, and mustard seed. Consumer survey data in the Mintel survey reveal that a large majority of U.S. households, estimated to be 86%, use fresh or dried herbs, spices and seasonings. Spice use in the United States, as measured by food availability, has been increasing by approximately 0.5 lbs./decade since 1966. In 2010, the estimated per capita annual spice consumption was 3.64 lbs. (1653 g), excluding dehydrated garlic. Estimates from the FDA/CDC National Health and Nutrition Examination Surveys (NHANES) indicate a typical consumption range of 0.3-1.7 g-spice per eating occasion for three eating occasions per day. Estimates of the variability and frequency of spice consumption are not available.

Current Mitigation and Control Options

Current U.S. regulatory mechanisms available to mitigate and control adulteration of spice with *Salmonella* or filth include CGMPs, inspections of and environmental sampling in spice manufacturing/packing facilities, product sampling, refusals and reconditioning, import alerts (with or without green lists and country agreements), and some provisions of the FDA Food Safety Modernization Act.

Rates of compliance with CGMPS among spice firms in the United States for the period FY2007-FY2012 was approximately the same as that found for firms handling other FDA-regulated low moisture foods. Insufficient data were available to evaluate compliance with CGMPS in spice facilities outside the United States. FDA inspections of 59 domestic firms that manufacture/pack/re-pack spices in 2010 revealed that a significant fraction (10%) had *Salmonella* in the (primarily post-processing) facility environment. Lack of effective pest management was the most frequently cited observation in these inspections. No environmental sampling data from FDA were available to determine the prevalence of *Salmonella* in international spice facility environments.

During the period FY2007-FY2010, 906 imported spice shipments (including sesame seeds) were refused entry to the United States based on the presence or potential for presence of *Salmonella* and/or filth. Among these shipments, 749 shipments of spice were refused entry because of the presence or potential presence of *Salmonella* and 238 shipments were refused because of the presence or potential presence of filth. During the period 2007-2012, CFSAN accepted 50 out of 155 reconditioning proposals for spices, 37of which addressed contamination with *Salmonella*.

Five U.S. import alerts address adulteration of spice by *Salmonella* or filth and four of these are specific to spice. Import Alert 99-19 lists firms and specific foods for which evidence has indicated the likelihood of *Salmonella* contamination; a majority of firms and foods listed are spices (71% in 2010 and 67% in 2010, excluding sesame seeds cited as a seed rather than a spice).

Import Alert 28-02 for Indian Black Pepper includes an agreement that leverages in-country regulatory authority to improve the food safety of shipments of the imported spice offered for entry to the United States. This combination of incentives appears to be effective in reducing the prevalence of *Salmonella* or filth contamination in shipments of Indian black pepper offered for entry to the United States. Expansion of this type of mechanism to other spices and/or to other countries should lead to further improvements in contamination rates.

The FDA Food Safety Modernization Act provides important new tools to mitigate and control contamination and post treatment cross contamination of spices with *Salmonella*, including authority to mandate recalls and increase in the frequency of foreign and domestic inspections (implemented), and prevention standards and import safety mandates (proposed rules issued in January 2013 (78 Federal Register 3646) and July 2013 (78 Federal Register 45730), respectively).

The spice and food trade organizations have developed detailed guidance to prevent and control adulteration of spice with pathogens or filth in finished spice or food products. These guidance documents reflect current scientific knowledge including the ability of *Salmonella* to survive in low-moisture foods such as spices, the enhanced heat resistance of some *Salmonella* strains, and lessons learned from past contamination and outbreak events. *Clean, Safe Spices: Guidance from the American Spice Trade Association*, published in 2011, highlights the application of Good Agricultural Practices (GAPs) for growing and harvesting spices, supply chain approval and re-evaluation programs, Good Manufacturing Practices (GMPs), validated microbial reduction processes, ASTA Cleanliness Specifications, post-treatment sampling and testing program, environmental sampling and testing program, and the development of Hazard Analysis and Critical Control Point (HACCP) plans. The Grocery Manufacturers Association *Control of* Salmonella *in Low-Moisture Foods* guidance and associated journal articles highlight additional preventive controls including stringent control of hygienic practices in the Primary *Salmonella* Control Area (PSCA) and moisture control. The extent to which the recommendations in these guidance documents are applied by the spice and food industry is unknown. Guidance from Codex and Food and Agriculture Organization (FAO)/WHO provide science-based general principles for hygienic production and harvesting, establishment design and hygiene requirements, personnel hygiene, establishment hygienic processing, and end-product specifications that can be applied to spice. The spice-specific *Code of Hygienic Practice for Spices and Dried Aromatic Plants* does not reflect current knowledge in hygienic practices and is being revised by the Codex Committee on Food Hygiene (at the time this report was written).

General Conclusions and Potential Future Mitigation and Control Options

Failures identified in the farm-to-table food safety system potentially leading to adulteration of consumed spice generally arose from poor/inconsistent application of appropriate preventive controls, such as failing to limit animal access to the spice source plant during harvest or drying phases, failing to limit insect and rodent access to spice during storage, or failing to subject all spice to an effective pathogen reduction treatment (or other lethality step). Based on our research, we concluded that knowledge and technology are available to significantly reduce the risk of illness from consumption of contaminated spices in the United States.

We developed a list of potential future mitigations and control options for consideration based on the scientific data, information, and analysis in this report. The list includes mitigation and control options that FDA, the spice industry, government agencies, food manufacturers/preparers, and the consumer may consider to reduce the prevalence and concentration of *Salmonella*, other pathogens, and filth in spices and to reduce the public health burden resulting from consumption of contaminated spices or foods containing contaminated spices. Mitigation and control options identified include capacity building, guidance, enforcement and regulatory strategies, communication, education, and training. We emphasize capacity building through the creation of partnerships with stakeholders to facilitate improvements in spice safety and reduce the risk of illness from consumption of pathogen-contaminated spices. These include enhanced communication between FDA and the spice industry and within the spice and food manufacturing industry itself, combined with training across the spice supply chain to ensure understanding of appropriate preventive controls and how to implement them.

Data Gaps and Research Needs

The development of the risk profile revealed many gaps in information and data regarding the adulteration of spices by pathogens and filth and the potential for this contamination to impact public health. We identified these gaps and the research needed to fill them, particularly focusing on research that could improve our ability to assess the public health risk posed by consumption of spices in the United States, to better characterize system failures that lead to spice contamination, and to explore additional potential future mitigations.

1. INTRODUCTION

The FDA Draft Risk Profile on Pathogens and Filth in Spices was initiated by the Center for Food Safety and Applied Nutrition in response to a large 2008-2009 outbreak of *Salmonella* illness associated with the consumption of microbiologically contaminated ground white pepper in the United States. Subsequently, the United States had a larger outbreak of *Salmonella* illness, this time associated with consumption of products containing black and red pepper. This second outbreak, as well as other reports in the literature and within FDA served to underscore the importance of researching food safety issues associated with spices.

The Draft Risk Profile on Pathogens and Filth in Spices was primarily developed to provide information for the Food and Drug Administration (FDA) risk managers and others to use in regulatory decision-making. The information may also be useful to stakeholders and interested parties such as spice producers and importers, spice and food manufacturers, retail foods establishments, and consumers.

1.1 RISK PROFILE OBJECTIVES AND SCOPE

The Spice Risk Profile has four main objectives:

1. Describe the nature and extent of the public health risk posed by consumption of spices in the United States by identifying the most commonly occurring microbial hazards and filth in spice.
2. Describe and evaluate current mitigation and control options designed to reduce the public health risk posed by consumption of contaminated spices in the United States.
3. Identify potential additional mitigation or control options designed to reduce the public health risk posed by the consumption of contaminated spices in the United States.
4. Identify data gaps and research needs.

For the purpose of this risk profile, the term “spice” means “any [dried] aromatic vegetable substances in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, whose significant function in food is seasoning rather than nutritional, and from which no portion of any volatile oil or other flavoring principle has been removed” (Title 21 Code of Federal Regulations (CFR), section 101.22) (FDA, 2012p) and includes spices listed at 21 CFR 182.10 and 21 CFR 184 (FDA, 2012f; FDA, 2012g) and additional dried plants listed as spices by the Environmental Protection Agency (EPA), the American Spice Trade Association (ASTA) (ASTA, 2012) and the Seasoning and Spice Association (SSA) (SSA, 2012), such as dehydrated onion and garlic, as well as other dehydrated vegetables used as seasoning.

The specific microbial hazards and filth elements in spices considered in this risk profile include pathogens and filth adulterants detected in spices, implicated in outbreaks, reported as the reason for recalls, and reported in submissions to the Reportable Food Registry (RFR). Emphasis is placed on the pathogen(s) with the strongest evidence for illness related to consumption of contaminated spices (e.g., outbreaks) and for which the potential for exposure in the United States has been established (i.e., outbreaks, recalls, submissions to the RFR, and surveillance sampling).

The risk profile also addresses specific questions posed by risk managers, which include the following:

1. What is known about the frequency and concentrations of pathogen and/or filth contamination of spices throughout the food supply chain (e.g., on the farm, at primary processing/manufacturing, at intermediary processing (where spices are used as ingredients in multi-component products), at distribution (including importation), at retail sale/use, and at the consumer’s home)?
2. What is known about differences in production and contamination of imported and domestic spices?
3. What is known about the effectiveness and practicality of currently available and potential future mitigations and control options to prevent human illnesses associated with contaminated spices (e.g.,

practices and/or technologies to reduce or prevent contamination, surveillance, inspection, import strategies, or guidance)?

4. What are the highest priority research needs related to prevention or reduction of contamination of spices with pathogens or filth?

Completion of the risk profile involved decisions about cutoff dates for data inclusion. Within the constraints of data access, collection, analysis, and review, we provide a review of current data that address the risk management objectives and questions posed. For the review of outbreaks and analysis of FDA and industry sampling data, the availability of data and the complexity of the analyses involved determined upper year cutoffs for these studies.

2. FOODBORNE ILLNESS OUTBREAKS FROM MICROBIAL CONTAMINANTS IN SPICES, 1973-2010

We undertook a comprehensive literature search and reviewed the Centers for Disease Control and Prevention's Foodborne Disease Outbreak Surveillance System (CDC's FDOSS) to identify and describe all the foodborne illness outbreaks that have been reported and attributed to consumption of pathogen-contaminated spices throughout the world during the years 1973 through 2010. The original report of this study was published in *Food Microbiology* (Van Doren *et al.*, 2013b). The risk profile includes additional search criteria, added in response to suggestions by external peer reviewers, but no additional outbreaks beyond those reported in the original report have been identified.

The specific objectives of this study were to (1) characterize the public health burden arising from consumption of spices contaminated with microbial pathogens, (2) identify the types of microorganisms implicated in foodborne illness outbreaks caused by consumption of contaminated spice, (3) identify and characterize the types of spices and countries of origin implicated in spice-associated illness outbreaks, and (4) identify the leading causes of microbial contamination of spices associated with foodborne outbreaks.

We define a spice-associated outbreak as the occurrence of two or more similar illnesses resulting from ingestion of a food containing a common spice(s) as an ingredient. Only outbreaks with laboratory detection of the suspected causative agent in the spice/spice blend and either culture-confirmed detection of the causative agent in clinical samples or analytical epidemiological evidence providing a statistically significant associated between consumption of the food vehicle and being a case in the outbreak were included. These inclusion criteria were selected to ensure that the outbreaks identified had compelling evidence that a contaminated spice ingredient was the cause of the reported illnesses. The review included outbreaks taking place during the years 1973-2010. The period of review began in 1973 because it was the year CDC's Foodborne Disease Outbreak Surveillance System (FDOSS) was initiated and the period ended with 2010 because it was the most recent year for which data from FDOSS was available when this report was written.

To identify and learn about foodborne illness outbreaks associated with consumption of spices, we reviewed the refereed scientific literature and available government/agency reports using MEDLINE and Google Scholar to search the English-language literature using different combinations of the following keywords: outbreak, foodborne, spice, seasoning, herb, pathogen, *Bacillus*, *Campylobacter*, *Clostridium*, *Cronobacter*, *Escherichia coli*, *E. coli*, O157, O104, *Mycobacterium bovis*, *Mycobacterium tuberculosis*, norovirus, *Salmonella*, *sakazakii*, *Shigella*, and *Staphylococcus aureus*. We also queried the CDC's FDOSS to identify outbreaks reported to CDC during 1973-2010 where a spice was reported as the implicated food (CDC, 2012a). We reviewed paper citations and references contained in the articles identified in our search and contacted public health agencies in France, New Zealand and the United Kingdom to follow up on reports in the literature. Through these contacts, we learned of one additional outbreak**,** which has not been previously reported in the literature. For the two most recent illness outbreaks in the United States, additional information was gathered from investigations by FDA and CDC.

2.1 SUMMARY OF OUTBREAKS, 1973-2010

The review identified fourteen spice-associated illness outbreaks occurring between 1973 and 2010 (Table 2.1). Four of these outbreaks were identified in a previous review of salmonellosis outbreaks associated with consumption of spices and fresh herbs (Zweifel and Stephan, 2012). Together, these outbreaks resulted in 1946 reported human illnesses, 128 hospitalizations (7% of cases) and two deaths (0.1%). Countries reporting outbreaks were Canada (1 outbreak), Denmark (1), France (1), Germany (2), New Zealand (1), Norway (1), Serbia (1), United Kingdom (3), and the United States (3).

Table 2.1. Summary of enteric illness outbreaks taking place during 1973-2010 associated with consumption of microbial contaminants in dried spices and seasonings or foods containing these contaminated ingredients

Spice Linked to Outbreak	Date	Country: Outbreak (Spice)[a]	Pathogen[b]	Total Cases[c]	Hospital-izations (Deaths)	Other pathogens isolated during investigation	Comments	Reference(s)
Black pepper (*Piper nigrum*)	Dec 1973 – May 1974	Canada (India)	*Salmonella* Weltevreden	17	1 (Not reported)	None reported	Microbiological link between spice and illness established. Outbreak identified in Mar 1974 after laboratory surveillance detected increased human cases of *S.* Weltevreden illness; 2 samples of black pepper positive for *S.* Weltevreden had been previously identified in Aug 1973. One case attributed to consumption of white pepper; *S.* Weltevreden isolated from opened container of white pepper with same trademark as *S.* Weltevreden positive black pepper samples.	Laidley *et al.*, 1974; WHO, 1974
Black pepper (*Piper nigrum*)	Nov 1981 - Aug 1982	Norway (Brazil)	*Salmonella* Oranienburg	126	>25% (at least 1)	*S.* Senftenberg, *S.* Lexington, *S.* Abaetuba from samples of implicated black pepper. *S.* Sendai, *S.* Glostrup from other samples of black pepper from Brazil.	Microbiological link between spice and illness established. The Brazilian black pepper was first shipped to the Federal Republic of Germany; only a fraction of the original shipment was later shipped to Norway. It is not known whether the pepper was processed or repackaged in Germany before shipment to Norway. Enumeration of *Salmonella* in 12 samples of black pepper found concentrations in the range 0.1 to >2.4 MPN/g.	Gustavsen and Breen, 1984

Spice Linked to Outbreak	**Date**	**Country: Outbreak (Spice)[a]**	**Pathogen[b]**	**Total Cases[c]**	**Hospital-izations (Deaths)**	**Other pathogens isolated during investigation**	**Comments**	**Reference(s)**
Paprika (*Capsicum annum*) (on paprika-powdered potato chips)	Apr - Sep 1993	Germany (South America)	*Salmonella* Prevailing serotypes: Saintpaul, Rubislaw, and Javiana	~1000 [d]	Not reported (Not reported)	Multiple *Salmonella* serotypes	Microbiological link between spice and illness established. Spice mix applied after chip temperature dropped to 60°C. Enumeration of *Salmonella* in paprika and paprika-containing spice mixes found concentrations in the range 0.04-11 MPN/g.	Lehmacher *et al.*, 1995
Turmeric *(Curcuma longa)* (on lamb seekh kebab)	1995[e]	United Kingdom (not known)	*Bacillus subtilis* & *Bacillus pumilus*	2	0 (0)	None reported	Microbiological link between spice and illness established. Outbreak attributed to consumption of lamb seekh kebab in a restaurant; *B. subtilis* and *B. pumilus* were detected in the turmeric powder used to make the lamb seekh kebab.	Little *et al.*, 2003; Little, 2012; Health Protection Agency, 2011
Black pepper (*Piper nigrum*)	Aug 1996	United Kingdom (not known)	*Salmonella* Enteritidis PT4	8	1 (0)	None reported	Microbiological link between spice and illness established. *S.* Enteritidis detected in ground black pepper used in meal preparation in a restaurant.	Little *et al.*, 2003; Little, 2012; Health Protection Agency, 2011
Pepper (type not specified)	1997	New Zealand (Malaysia)	*Bacillus subtilis*	2	None reported (None reported)	None reported	Microbiological link between spice and illness established. Outbreak attributed to consumption of peppered steak; *B. subtilis* detected in cooked and uncooked steak, pepper mix, and peppercorns (>10^4 CFU/g).	Cameron, 1998

Spice Linked to Outbreak	**Date**	**Country: Outbreak (Spice)**[a]	**Pathogen**[b]	**Total Cases**[c]	**Hospital-izations (Deaths)**	**Other pathogens isolated during investigation**	**Comments**	**Reference(s)**
Curry Powder (*blend of spices*)	Aug 2002	United Kingdom (India)	*Salmonella* Braenderup	20	1 (0)	None reported	Microbiological link between spice and illness established. *S.* Braenderup detected in curry powder added as garnish to an egg dish in a restaurant; dish was kept at room temperature before serving; *S.* Braenderup found in samples from both opened and unopened packages of curry powder.	Little, 2012; Health Protection Agency, 2011
Anise seed (*Pimpinella anisum*) (in tea containing anise seed, fennel seed, and caraway)	Oct 2002 -Jul 2003	Germany (Turkey)	*Salmonella* Agona	42	21 of 39 (0)	Other unspecified *Salmonella* serotypes	Microbiological link between spice and illness established. Identification of implicated vehicle aided by knowledge during hypothesis generation that *S.* Agona had been isolated from anise seed during routine food safety monitoring in 2002. All cases of illness in infants <13 months. Enumeration of *Salmonella* in samples of anise seed-containing tea found a concentration of 0.036 MPN/g.	Koch *et al.*, 2005; Rabsch *et al.*, 2005

Spice Linked to Outbreak	Date	Country: Outbreak (Spice)[a]	Pathogen[b]	Total Cases[c]	Hospital-izations (Deaths)	Other pathogens isolated during investigation	Comments	Reference(s)
Seasoning mix & broccoli powder (coating a snack puff)	Jan 2007 – Dec 2007	United States (China for dried broccoli powder; sources of other ingredients in seasoning mix not reported)	*Salmonella* Wandsworth	69	6 of 56 (0)	*S.* Typhimurium, *S.* Kentucky, *Cronobacter sakazakii* from unopened snack puff bags; *S.* Typhimurium, *S.* Haifa from finished product in the manufacturing facility; *S.* Mbandaka from parsley powder used in the puff snack seasoning mix.	Microbiological link between spice and illness established. Seasoning mix applied after final pathogen reduction step. Isolating *S.* Typhimurium from seasoning mix led to identification of a linked *S.* Typhimurium outbreak.	Sotir *et al.*, 2009
Seasoning mix & broccoli powder (coating a snack puff) continued	Jun 2007 – Sep 2007	United States (China for dried broccoli powder; sources of other ingredients in seasoning mix not reported)	*Salmonella* Typhimurium	18	2 of 18 (0)	*S.* Wandsworth plus "Other pathogens" listed above for related *S.* Wandsworth outbreak.	Microbiological link between spice and illness established. Outbreak identified after sample of snack food seasoning mix taken during *S.* Wandsworth outbreak investigation was positive for *S.* Typhimurium.	Sotir *et al.*, 2009
Spice Blend (in couscous dish)	2007	France (Not reported)	*Bacillus cereus*	146	0 (0)	Unknown	Analytical epidemiological evidence and laboratory detection of *B. cereus* in the spice blend used in the couscous dish. Outbreak in school/kindergarten.	EFSA, 2013; EFSA, 2009a; Delmas, 2013

Spice Linked to Outbreak	Date	Country: Outbreak (Spice)[a]	Pathogen[b]	Total Cases[c]	Hospital-izations (Deaths)	Other pathogens isolated during investigation	Comments	Reference(s)
Fennel seed (*Foeniculum vulgare*) (in "baby" tea containing fennel seed, anise seed, and caraway)	Mar 2007- Sep 2008	Serbia (Not reported)	*Salmonella* Senftenberg	14	4 of 14 (Not reported)	None reported	Microbiological link between spice and illness established. Parents of case-patients reported pouring boiling water over (dry) baby tea mixture during preparation but did not heat tea infusion to boiling. 71% of cases of illness in infants <12 months.	Ilic *et al.*, 2010
White pepper (*Piper nigrum*)	Dec 2008 - Apr 2009	United States (Vietnam)	*Salmonella* Rissen	87	8 of 60 ; 14 additional patients were hospitalized before illness (1)	None reported	Microbiological link between spice and illness established. Environmental samples from spice processing facility tested positive for the outbreak strain. Multiple violations of CGMP noted during inspection of spice processing facility. Identification of implicated vehicle aided by knowledge that the outbreak strain had been isolated in 2006 from an FDA import sample of black pepper.	CDPH/FDB/ ERU, 2010; FDA, 2009a; Higa, 2011; Hajmeer and Myers, 2011; Higa, 2012
Black pepper (*Piper nigrum*) and red pepper (*Capsicum* spp.) (on Italian-style salami)	Jul 2009 – Apr 2010	United States (black pepper- Vietnam; red pepper - India & China)	*Salmonella* Montevideo	272[f]	52 of 203 (0)	*S.* Senftenberg	Microbiological link between spice and illness established. Black pepper and red pepper applied to salami products after the final pathogen reduction step. Isolating *S.* Senftenberg from implicated product led to identification of a linked *S.* Senftenberg outbreak.	CDC, 2010; Gieraltowski *et al.*, 2012; DuVernoy, 2012

Spice Linked to Outbreak	Date	Country: Outbreak (Spice)[a]	Pathogen[b]	Total Cases[c]	Hospital-izations (Deaths)	Other pathogens isolated during investigation	Comments	Reference(s)
Black pepper (*Piper nigrum*) and red pepper (*Capsicum* spp.) (on Italian-style salami) continued	Jul 2009 – Apr 2010	United States (black pepper-Vietnam; red pepper - India & China)	*Salmonella* Senftenberg	11	Not reported (Not reported)	*S.* Montevideo	Microbiological link between spice and illness established. Outbreak identified during *S.* Montevideo outbreak investigation after sample of unopened retail package of salami was positive for *S.* Senftenberg.	CDC, 2010; DuVernoy, 2012
White pepper (*Piper nigrum*) (in stew)	2010	Denmark (Unknown)	*Bacillus cereus*	112	0 (0)	Unknown	Microbiological link between spice and illness established. Contaminated white pepper in stew. Canteen/workplace catering setting. Storage time/temperature abuse suspected as contributing.	EFSA, 2013; EFSA, 2011a

[a] Country where outbreak occurred following by country of origin of the spice in parentheses.

[b] *Salmonella* serotypes listed are serotypes of *Salmonella enterica* subspecies *enterica*.

[c] Number of cases of illness listed are the number of documented cases of illness. Several sources indicate that this number significantly underestimates the actual number of illnesses associated with the outbreak (Scallan *et al*, 2011; Mead *et al.*, 1999; Voetsch *et al.*, 2004; Chalker and Blaser, 1988). See text for further details.

[d] Number of human cases of illness associated with rare serotypes of *Salmonella* found in paprika or paprika-powdered potato chips during the outbreak. Approximately 42% of illnesses were associated with the three prevailing *S.* serotypes

[e] Duration of outbreak not known (Little, 2012; Health Protection Agency, 2011)

[f] Number of cases of illness listed are number of epidemiologically linked cases of illness (CDC, 2010). A SNP-based evolutionary analysis of Montevideo isolates suggests that a portion of the epidemiologically linked cases of illness may not be associated with this outbreak (see text, den Bakker *et al.*, 2011).

Ten of the fourteen (71%) spice-associated outbreaks and 87% of the illnesses were caused by serotypes of *Salmonella enterica* subspecies *enterica*. Four outbreaks were caused by *Bacillus* spp., accounting for 13% of the illnesses. Four outbreaks were associated with two or more different organisms (multiple serotypes of *Salmonella* or multiple species of *Bacillus)*. *Salmonella* serotypes associated with human illnesses in these outbreaks included Agona (1 outbreak), Braenderup (1), Enteritidis (1), Javiana (1), Montevideo (1), Oranienburg (1), Rissen (1), Rubislaw (1), Saintpaul (1), Senftenberg (2), Typhimurium (1), Wandsworth (1), and Weltevreden (1) (Table 2.1). *Bacillus* species identified as causative agents in spice-associated outbreaks included *B. cereus* (2 outbreaks), *B. subtilis* (2) and *B. pumilus* (1). The evidence for the spice-associated *B. subtilis* and *B. pumilus* illness outbreaks reported in Table 2.1 included both epidemiological and microbiological data (Little, 2012). *B. subtilis* and *B. pumilus* are seldom reported as foodborne pathogens but these organisms may produce a mild toxin after growing to high numbers in a food (Logan, 2011).

Spices implicated in the outbreaks were black pepper (*Piper nigrum*; 4 outbreaks), red pepper (*Capsicum* spp.; 2 outbreaks), white pepper (*Piper nigrum*; 2 outbreaks), unspecified pepper (1 outbreak), curry powder (a blend of spices; 1 outbreak), anise seed (*Pimpinella anisum*; 1 outbreak), fennel seed (*Foeniculum vulgare*; 1 outbreak), turmeric (*Curcuma longa*; 1 outbreak), a spice blend (1 outbreak) and a seasoning blend containing contaminated broccoli powder (1 outbreak); some outbreaks were associated with multiple spices or food vehicles (Table 2.1). Seventy-one percent (10/14) of the outbreaks were associated with spices classified as fruits or seeds of the source plant. The countries/regions of origin of the implicated spices were identified in nine outbreaks and included Brazil (1 outbreak), China (2), India (3), Malaysia (1), South America (1), Turkey (1), and Vietnam (2) (Table 2.1). In every case where it could be determined (9/14 outbreaks), the spices implicated in the outbreaks were imported. This observation is not unexpected because many of the countries in which outbreaks were identified are not major spice producing countries (FAO, 2013b). In at least two of the outbreaks, post-import cross-contamination is suspected to have contributed to the outbreak (*Salmonella* Rissen in white pepper [*Piper nigrum*] and *Salmonella* Montevideo in black pepper [*Piper nigrum*] and red pepper (*Capsicum* spp.); see discussion in Section 2.2).

2.2 OUTBREAKS IN THE UNITED STATES

Three foodborne illness outbreaks attributed to consumption of pathogen-contaminated spices were reported in the United States during the study period. All three outbreaks took place within a 40 month period (Jan 2007-April 2010) and accounted for 457 laboratory-confirmed illnesses, 68 hospitalizations, and one death (Table 2.1). Age data were available for 404 of the 457 confirmed cases. The age breakdown for these three outbreaks was: <1 year, 5%; 1 to 4 years, 17%; 5 to 9 years, 14%; 20 to 49 years, 32%; and >50 years, 32%. The distribution of ages affected in these three U.S. outbreaks demonstrates that nearly all ages in the population have been affected by these outbreaks.

In the earliest spice-associated outbreak identified in the United States, 69 cases of *Salmonella* Wandsworth illness were confirmed from 23 states between January 2007 and December 2007; 96% of ill persons were children < 6 years old (Sotir *et al*., 2009). Public health investigations performed by state and federal regulatory authorities implicated a seasoning mix consisting of broccoli powder, parsley powder, and other spices used to coat a snack puff after the final food manufacturing pathogen reduction step (Sotir *et al*., 2009). The only ingredient in the seasoning mix to test positive for *Salmonella* Wandsworth was the broccoli powder, collected at two U.S. snack food manufacturing facilities and imported from China. It is not known whether the broccoli powder had undergone a pathogen reduction treatment before its application to the snack food (Sotir *et al*., 2009). None of the environmental samples collected in the two snack food manufacturing facilities tested positive for *Salmonella* (Sotir *et al*., 2009). Product testing also identified *Salmonella* Typhimurium from the seasoning mix and *Salmonella* Mbandaka from parsley powder (Sotir *et al*., 2009). A cluster of 11 human cases of *Salmonella* Typhimurium illness epidemiologically linked to the snack puffs was subsequently identified; no confirmed human cases of *Salmonella* Mbandaka illness were reported (Sotir *et al*., 2009).

In the second spice- associated outbreak in the United States, 87 cases of *Salmonella* Rissen illness that occurred between December 2008 and April 2009 were reported from 5 states (CDPH/FDB/ERU, 2010; Higa, 2011). Human cases of illness resulted from food consumption at restaurants and hospitals and included individuals from age 5 months to 94 years (Higa, 2011). Epidemiologic investigations, traceback investigations, and product testing implicated white pepper (*Piper nigrum*) ground and packed by a single company in California (CDPH/FDB/ERU, 2010; Higa, 2011; Hajmeer and Myers, 2011).

Samples of whole and ground white pepper were collected from the California spice processing and packing facility and analyzed during the investigation. One unopened bag of imported whole white peppercorns was found to contain the *Salmonella* Rissen outbreak strain, suggesting contamination of the spice took place before import (CDPH/FDB/ERU, 2010). The whole white peppercorns implicated in this outbreak originated from Vietnam and had been sold as “steam washed” (CDPH/FDB/ERU, 2010; Myers and Higa, 2011; Hajmeer and Myers, 2011). While steam treatments are often applied to spices to reduce/eliminate microbial pathogens (ASTA, 2011), “steam washing” is primarily used to clean dirt from spices and may not provide an effective pathogen reduction step (Myers and Higa, 2011; Hajmeer and Myers, 2011). No other pathogen reduction treatment had been applied to the spice (Myers and Higa, 2011) but the suspected imported whole white pepper lot was accompanied by a Certificate of Analysis (COA) that indicted that the lot had tested negative for *Salmonella* before import (CDPH/FDB/ERU, 2010). The sensitivity of the screening test used for the COA is not known so it is possible that the lot could have contained a low concentration of *Salmonella* or a highly clustered distribution of *Salmonella* undetected by the screening test (ICMSF, 2002; Bassett *et al.*, 2010).

Environmental sampling data collected in the implicated spice processing and packing facility in California found widespread contamination of the spice processing facility, with ~40% (46/116) of swab samples taken throughout the facility testing positive for *Salmonella* (CDPH/FDB/ERU, 2010). All of the *Salmonella* isolates for which a strain was determined (19/46) matched the *Salmonella* Rissen outbreak strain (CDPH/FDB/ERU, 2010). Contamination of the grinding room was particularly extensive, with 94% (34/36) of swabs collected in the grinding room testing positive for *Salmonella* Rissen and 100% (14/14) of the isolates examined for strain, matching the outbreak strain (Hajmeer and Myers, 2011; FDA, 2009). Inspections (CDPH/FDB/ERU, 2010; FDA, 2009; Hajmeer and Myers, 2011) of the facility revealed multiple violations of the Current Good Manufacturing Practices (CGMP) regulation for foods at 21 CFR 110 (FDA, 2012i; U.S.C., 2007). FDA issued a Warning Letter to the firm that stated in part, “The finding of *Salmonella* in multiple processing locations within your facility indicates that this pathogenic organism may have become established in a niche environment in your facility” (FDA, 2009). With such gross contamination of the spice processing/packing facility, it is possible that cross-contamination from the facility environment to the spice also played a role in this outbreak.

During the third spice- associated outbreak in the United States, epidemiological investigations identified 272 laboratory-confirmed cases of *Salmonella* Montevideo illness from 44 states and the District of Columbia during the period July 2009 to April 2010 (CDC, 2010; Gieraltowski *et al.*, 2012); ill persons ranged in age from <1 to 93 years (CDC, 2010; Gieraltowski *et al.*, 2012). A next generation sequencing (NGS) analysis of human isolates collected during the time of the outbreak suggested that the total number of cases of illness associated with this outbreak may have been significantly smaller (den Bakker *et al.*, 2011). However, the NGS analysis only included 20 putative outbreak isolates and relied on comparison with NGS data from known outbreak isolates analyzed on a different experimental platform (Lienau *et al.*, 2011) which may have impacted the study conclusions.

Epidemiologic and traceback investigations of the *Salmonella* Montevideo outbreak implicated consumption of ready-to-eat salami products (including pepper-coated salami) manufactured by a single company in Rhode Island (Gieraltowski *et al.*, 2012). Traceback and product testing determined that black pepper (*Piper nigrum*) from Vietnam and red pepper (*Capsicum* spp.) from India and China used in the salami products were contaminated with *Salmonella* Montevideo (CDC, 2010; Gieraltowski *et al.*, 2012; DuVernoy, 2012). A private laboratory also isolated *Salmonella* Senftenberg from an unopened retail sample of the implicated product (Gieraltowski *et al*., 2012). PulseNet subsequently identified 11 human cases of *Salmonella* Senftenberg with the same pulsed-field gel electrophoresis pattern (PFGE), and two of the patients reported purchasing the implicated product (Gieraltowski *et al*., 2012).

Evidence collected during the outbreak investigation revealed that some of the black pepper used in the manufacture of the salami products was reported to have been treated with steam (Gieraltowski *et al*., 2012). Descriptions of the treatments included "steam washed" and "steam sterilized" (DuVernoy, 2012). Some of the red pepper lots implicated in the investigation were reported to have been treated with ethylene oxide, some before and some after import into the United States (DuVernoy, 2012). It is not known if the steam or ethylene oxide treatments had been validated as an effective reduction step for *Salmonella*. Some of the treated imported black pepper shipments were accompanied by Certificates of Analysis (COAs) reporting negative tests for *Salmonella* (DuVernoy, 2012). However, review of the COAs revealed that at least some of the tests were conducted on a smaller sample size than FDA typically uses to examine spices at import (i.e., examining one 25 g sample as compared with 30 x 25 g [two-375 g composite samples]) (Andrews and Hammack, 2003). Therefore, it is possible that some of the treated imported black pepper contained low concentrations of *Salmonella* or highly localized contamination (ICMSF, 2002; Bassett *et al*., 2010) unreached by steam. As in the *Salmonella* Wandsworth outbreak associated with snack puffs, investigation of the food manufacturing process revealed that spices were applied to the salami products after the final (meat production/fermentation and drying) pathogen reduction step (CDC, 2010; Gieraltowski *et al*., 2012). Growth of *Salmonella* in the salami products is not suspected as contributing to this outbreak because salami is a low-moisture, shelf-stable food.

While it was not possible to definitively determine where in the supply chain the spices were contaminated, the weight of evidence suggests that contamination of the black and red pepper with *Salmonella* Montevideo took place after the spice shipments were imported into the United States, that is, from cross-contamination. Experimental evidence supporting this hypothesis includes the NGS study that demonstrated that clinical, product, and environmental isolates associated with the outbreak were most closely related with one *Salmonella* Montevideo isolate collected from the east coast of the United States and were distinct from Montevideo strains from other parts of the world (Lienau *et al*., 2011; Allard *et al*., 2012). Other evidence supporting post-import contamination includes the facts that the spice associated with the outbreak was imported from three different countries that are geographically distinct (CDC, 2010; Gieraltowski *et al*., 2012) and that "a common source in the distribution path from production to the Company A facility [salami manufacturing facilities] was not identified between the black and red pepper" (Gieraltowski *et al*., 2012). While "unopened" boxes of spice in the salami manufacturer were found to contain the outbreak strain (Gieraltowski *et al*., 2012), the spice in these boxes came from U.S. suppliers who had stored, repacked, and in some cases, processed (e.g., ground/cracked) the spice before shipment to the salami manufacturing facility (DuVernoy, 2012).

2.3 SELECTED NON-U.S. OUTBREAKS

The largest spice-associated outbreak was identified in Germany in 1993 (Lehmacher *et al*., 1995; Table 2.1) in which an estimated 1000 cases of *Salmonella* illness occurred between April and September 1993. The majority of illnesses were in children ≤14 years old, including 14 infants <1 year old. A large number of *Salmonella* serotypes were associated with this outbreak; *Salmonella* Saintpaul, Javiana, and Rubislaw accounted for 42% of the human illnesses and many other *Salmonella* serotypes were isolated from patients or implicated foods (Lehmacher *et al*. 1995).

Traceback investigations and product testing identified paprika (*Capsicum annum*), used in seasoning for potato chips, as the contaminated food vehicle (Lehmacher *et al*., 1995). Some, if not all, of the paprika was imported from South America. It was not known where or when the paprika was contaminated or whether a pathogen reduction treatment had been applied to the paprika. Enumeration experiments revealed that the concentrations of *Salmonella* in samples of spice and food implicated in the outbreak were small – 2.5 MPN/g (25 MPN per 10 g; paprika), 0.04-11 MPN/g (4 MPN per 100 g to 11 MPN per g; paprika-containing spice mixes) and 0.05-0.45 MPN/g (5 MPN per 100 g to 45 MPN per 100 g paprika-powdered potato chips) – and that *Salmonella* can survive in the dry environments of paprika and paprika-powdered potato chips for at least 8 and 12 months, respectively (Lehmacher *et al.*, 1995). As noted for other outbreaks, the spice mix was applied after the final food manufacturing (potato chip) pathogen reduction step (Lehmacher *et al.*, 1995).

Four outbreaks of *Bacillus* spp. illness attributed to consumption of foods containing contaminated spice took place in Denmark (EFSA, 2011a; EFSA, 2013), France (EFSA, 2009a; EFSA, 2013), New Zealand (Cameron, 1998), and the United Kingdom (Little *et al.*, 2003; Little, 2012; Health Protection Agency, 2011), accounting for 262 illnesses. Three of these outbreaks took place in settings where food services provide meals for large numbers of people (a canteen/workplace, a restaurant, and a school/kindergarten). Growth of the pathogen in the food was suspected as contributing to at least one of the outbreaks (EFSA, 2011a).

Two outbreaks were attributed to consumption of tea infusions prepared from *Salmonella*-contaminated spices and served primarily to infants who were ≤13 months of age (Koch *et al.*, 2005; Rabsch *et al.*, 2005; Ilic *et al.*, 2010). Taken together, 52 (93%) of 56 of the individuals who became ill in these two outbreaks were infants (Koch *et al.*, 2005; Ilic *et al.*, 2010). In both investigations, contamination of the multicomponent tea was traced to a single contaminated spice ingredient: aniseed (*Pimpinella anisum*) in the *Salmonella* Agona outbreak in Germany (Koch *et al.*, 2005; Rabsch *et al.*, 2005) and fennel seed (*Foeniculum vulgare*) in the *Salmonella* Senftenberg outbreak in Serbia (Ilic *et al.*, 2010). Epidemiological investigations revealed that in some cases, boiling water was not used (Koch *et al.*, 2005) or was probably not used (Ilic *et al.*, 2010) to prepare the tea infusions. Subsequent growth of surviving *Salmonella* cells in the cooled tea infusion may have also contributed to the number of cases of illness observed (Koch *et al.*, 2005). The outbreak investigations did not reveal where in the supply chain tea contamination took place but both identified weaknesses in supplier control, i.e., the use of unregistered producers (fennel seed; Ilic *et al.*, 2010) and the reported use of manure as fertilizer in seed production (anise seed, reported by the spice importer; Koch *et al.*, 2005).

2.4 PUBLIC HEALTH BURDEN

Although an estimated 1946 human illnesses were identified in the fourteen outbreaks reported above, the actual health burden is likely much larger due to underreporting and challenges in foodborne disease surveillance and outbreak response. In the United States, the CDC estimates that 1.0 million people in the United States become ill from *Salmonella*-contaminated food consumed each year (Scallan *et al.*, 2011; CDC, 2011). This estimated value includes a correction for underreporting derived from data obtained from several surveillance/reporting systems (Scallan *et al.*, 2011). Applying the CDC underreporting multiplier for *Salmonella* (29.3; Scallan *et al.*, 2011), the public health burden of the three spice-associated outbreaks in the United States is roughly estimated at ~13,400 human illnesses.

Many countries do not have the ability to track foodborne illness and for those countries that do track foodborne illness, the reporting structure/information may be insufficient to attribute outbreaks to spices. For example, until recently, European Union member country reports of outbreaks attributed to spices were reported together with outbreaks attributed to fresh herbs (see for example EFSA, 2009a) and the additional information reported did not always allow distinction between fresh and dry. In the United States, reporting to PulseNet is limited to selected pathogens, which makes detection of geographically dispersed outbreaks of other pathogens, such as *Bacillus* spp., more difficult. Even when a spice is suspected as being the contamination source, it cannot or is not always confirmed. For example, our research identified seven additional outbreaks attributed to consumption of contaminated spice (4 *Salmonella* illness outbreaks, 2 *Bacillus cereus* illness outbreaks, 1 *Clostridium perfringens* outbreak) (Millet and Staff, 1999; Little *et al.*, 2003; Little, 2012; Health Protection Agency, 2011; EFSA, 2013), but which did not meet our inclusion criteria (lacking microbiological or epidemiological evidence specified in Section 2: Materials and Methods). As a result, the number of world-wide outbreaks associated with consumption of pathogen-contaminated spice is likely underreported.

Ingredient-related outbreaks are especially challenging to investigate because of the many possible foods that could be involved and the potentially complex supply chains associated with each ingredient. In addition, consumers of contaminated food may not be aware of all ingredients in the food, especially minor ingredients such spices. As a result, it is possible that more spice-associated outbreaks occurred within the United States or in other countries that reported one or more spice- associated outbreaks. According to the CDC, only 43% of reported foodborne disease outbreaks in the United States in 2009-10 had a food reported (CDC, 2013a). The long shelf-life of spices and the ability of pathogens to persist in spice for long periods (demonstrated for *Salmonella*) also create challenges for outbreak identification because illnesses from consumption of contaminated spice may be separated by time and space.

2.5 RELATED OUTBREAKS – SPICE INGREDIENTS USED IN NON-SPICE CAPACITIES

At least five outbreaks associated with spice ingredients that are used in non-spice capacities took place during the study period. Three *Salmonella* outbreaks associated with tahini (Unicomb *et al*., 2005) and one *Salmonella* outbreak linked to helva (Andersson *et al*., 2001; Fisher *et al*., 2001; Little, 2001; Brockmann, 2001; Guérin *et al*., 2001) were identified during the literature review. Both of these products are made predominantly of sesame seeds (*Sesamum* spp.). Together these outbreaks were responsible for at least 128 illnesses in six countries (Unicomb *et al*., 2005; Andersson *et al*., 2001; Fisher *et al*., 2001; Little, 2001; Brockmann 2001; Guérin *et al*., 2001). Some spice seeds, such as fennel (*Foeniculum vulgare*) and mustard (*Brassica* spp.), are also used to produce sprouts for human consumption. Numerous sprout-associated outbreaks have occurred, and many of these outbreaks have been traced to bacterial contamination of the seed (EFSA, 2011b) amplified during the sprout production process. One *B. cereus* illness outbreak associated with sprout consumption took place in the United States in 1973 and was traced to contamination of the seed mixture, which included soy, cress and mustard (Portnoy *et al*., 1976). The large-scale 2011 outbreak of Shiga-toxin producing *Escherichia coli* serotype O104:H4 in Germany and France, while not in the temporal scope of this review, was also attributed to sprout consumption and traced to contaminated fenugreek seeds (*Trigonella foenum-graecum*), although the bacterium was never isolated from the seeds (EFSA, 2011c). These outbreaks highlight the fact that some spices have multiple applications in food production and can carry a risk of foodborne illness in these other applications. Application of mitigation and control strategies to the production, storage and handling of spices could also reduce the risk of illness from these foods.

2.6 GENERAL OBSERVATIONS REGARDING FOODBORNE ILLNESS OUTBREAKS ATTRIBUTED TO MICROBIAL CONTAMINANTS IN SPICES

Our review identified fourteen foodborne illness outbreaks attributed to consumption of pathogen-contaminated spices between 1973 and 2010. These outbreaks demonstrate that consumption of pathogen-contaminated spices can result in human illnesses and that the illnesses that arise can be severe enough to necessitate hospitalization and, occasionally, result in death. The review also demonstrates that outbreaks attributed to consumption of contaminated spice can involve large numbers of illnesses. Individuals of all ages can be affected, including infants and young children, who comprised the majority of cases of illness in five outbreaks and were the apparent target consumer of some of the contaminated foods consumed (Lehmacher *et al*., 1995; Koch *et al*., 2005; Ilic *et al*., 2010; Sotir *et al*., 2009; EFSA, 2009a). Within our review, *Salmonella enterica* subspecies *enterica* and *Bacillus* spp. were the most common bacterial pathogens linked to spice-associated outbreaks. A single spice vehicle can be contaminated with multiple *Salmonella* serotypes or *Bacillus* species, resulting in multi-serotype/species outbreaks. As evidenced by the 1993 paprika

(*Capsicum annum*)-associated outbreak (Lehmacher *et al*., 1995) and documented by other studies (Keller *et al*., 2013; Podolak *et al*., 2010 and references therein) *Salmonella* can survive in dried spices and other low moisture foods for prolonged periods. Enumeration data collected during three outbreak investigations found low concentrations of contamination, indicating that low concentrations of contamination in spices can cause human illness (Gustavsen and Breen, 1984; Lehmacher *et al*., 1995; Koch *et al*., 2005). The *Salmonella* Wandsworth outbreak (Sotir *et al*., 2009) illustrated that dried vegetable powders used in seasoning blends may carry the risk of illness if contaminated.

Consumption of ready-to-eat foods prepared with spices applied after the final food manufacturing pathogen reduction step accounted for at least 70% of the illnesses (CDC, 2010; Sotir *et al*., 2009; Lehmacher *et al*., 1995). In three out of four outbreaks for which spice process treatment information was recorded, it was found that no pathogen reduction treatment had been applied to the spice (Rabsch *et al*., 2005; Sotir *et al*., 2009; Myers and Higa, 2011). Pathogen growth in spiced food was suspected to have played a role in some outbreaks but it was probably not a contributing factor in three of the larger *Salmonella* illness outbreaks, which involved low-moisture foods (CDC, 2010; Sotir *et al*., 2009; Lehmacher *et al*., 1995) that do not support microbial growth when maintained at a low water activity.

The root cause of spice contamination was not determined in most of the outbreaks. In four outbreaks, the outbreak strain was isolated from unopened packages of the spice ingredient in the food manufacturing facility, which supports the hypothesis that contamination of the spice took place at an early stage in the farm-to-table continuum (e.g., during production, early processing, or packing/storage before import) (Laidley *et al*., 1974; Gustavsen and Breen, 1984; CDC, 2010). In two outbreaks, evidence supported possible contributions from cross-contamination in later stages of the farm-to-table continuum (e.g., post-import spice processing or food manufacturing environments) (Hajmeer and Myers, 2011; Lienau *et al*., 2011; Allard *et al*., 2012). Most investigations did not report whether the spice had been subjected to a pathogen reduction treatment before receipt by the spice/food manufacturer/retail user and did not enumerate the pathogen in the spice ingredient and food. Gathering this information in future outbreak investigations, could help investigators determine which of the possible routes of contamination were involved.

3. TYPES OF PATHOGEN AND FILTH CONTAMINATION FOUND IN SPICES

3.1 MICROBIAL PATHOGENS FOUND IN SPICES

3.1.1 TYPES OF MICROBIAL PATHOGENS FOUND IN SPICES

In order to determine the types of microbial pathogens found in spices, we reviewed the refereed scientific literature and available government/agency reports using Web of Science, Google Scholar, and PubMed to search the English-language literature using different combinations of the following keywords: microbiological, microbial, quality, survey, outbreak, foodborne, spice, seasoning, herb, pathogen, *Bacillus*, *bovis*, *Campylobacter*, *Clostridium*, *Cronobacter*, *Escherichia coli*, *E. coli*, O157, O104, *Mycobacterium bovis*, *Mycobacterium tuberculosis*, norovirus, *Salmonella*, *sakazakii*, *Shigella*, and *Staphylococcus aureus*. We reviewed paper citations and references contained in the articles identified in our search. The literature review examined publications and reports published between January 1, 1985 and July 1, 2012.

We also reviewed the CDC PulseNet database for information about the types of spices in which *Salmonella* has been detected and evidence that other pathogens had been detected in spices.[1] The review for pepper and pepper-type spices (entries including the words "pepper", "chili", or "cayenne" and, for the capsicums, clearly indicated as a dry product) included information on isolates uploaded to PulseNet during the period Sept 2001-February 2010 while the review for non-pepper spices included information on isolates uploaded between January 2001 and June 2010. Bacteria isolated from food products tested as part of routine food safety surveillance and compliance programs as well as foodborne outbreak investigations in the United States are normally submitted to PulseNet. Finally, we also reviewed the FDA "Field Accomlishments and Compliance Tracking System" (FACTS)[2] database for the years 2006-2010, to identify spices not captured in the PulseNet review.

A diversity of microorganisms has been detected in spices. Table 3.1 lists the microbial pathogens detected in spices as reported in the scientific literature, the CDC PulseNet database or the FDA FACTS database during the review periods described above. A few studies examined selected spices for *Escherichia coli* O157:H7 (Singh *et al*., 2007; Beki 2008; Kahraman and Ozmen, 2009); none was found. Investigations of the 2011 Shiga-toxin producing *Escherichia coli* O104 illness outbreak in Europe that was attributed to contaminated fenugreek seeds (used in sprout production) were unsuccessful in detecting the outbreak strain in seeds from the same source (EFSA, 2011c). Investigations of the *Clostridium botulinum* outbreak in Japan in 1984 involving consumption of fried lotus rhizome solid mustard did not isolate the organism from any of the 11 kinds of mustard samples examined (Otofuji *et al*., 1987). The report of *Listeria monocytogenes* identified in bay leaves (Vij *et al*., 2006) was later clarified as a contaminant in fresh bay leaves rather than dried bay leaves (Hogan, 2011).

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[1] PulseNet is a national network of public health and food regulatory agency laboratories in the United States coordinated by the CDC. The network consists of state health departments, local health departments, and federal agencies (CDC, USDA/FSIS, FDA). PulseNet participants perform standardized molecular subtyping (or "fingerprinting") of foodborne disease-causing bacteria by pulsed-field gel electrophoresis (PFGE). PFGE can be used to distinguish strains of organisms such as *Salmonella*. DNA "fingerprints," or patterns, are submitted electronically to a dynamic database at the CDC. The PFGE data are stored in the CDC PulseNet database.

[2] FACTS is an FDA database that includes results of experimental food or environmental sampling tests performed by FDA.

Table 3.1. Microbial pathogens detected in spices, 1985-2012: Review of the scientific literature and the CDC PulseNet and FDA FACTS databases[a]

Microbial Pathogens	Spice[b]	Reference
***Salmonella* spp.**	ajowan, alfalfa seeds, allspice, anise seed, asafetida, basil, bay, black pepper, capsicum (hot and sweet), cardamom, cayenne, celery seed, cinnamon, coriander, cumin, curry leaf, fennel, fenugreek leaves and seeds, fingerroot, garlic, ginger, nigella, London rocket, mace, mint, mustard seed, nutmeg, oregano, parsley, sage, thyme, sumac, sesame seeds, turmeric, white pepper, spice mixes/seasonings (e.g., curry, five spice, garam masala)	Arias *et al.*, 1997; Banerjee and Sarkar, 2003; CDC-PulseNet[c]; DOH/Victoria/AU, 2010; FSAI, 2004; Gustavsen and Breen, 1984; FDA-FACTS[d]; Hampikyan *et al.*, 2009; Hara-Kudo *et al*,. 2006; Higa, 2011; Kaul and Taneja, 1989; Kneifel and Berger 1994; Koch *et al.* 2005; Moreira *et al.* 2009; Sagoo *et al.* 2009; Satchell *et al.* 1989; Singh *et al.* 2007; Shamsuddeen, 2009; Stewart *et al.* 2001; Vij *et al.* 2006
***Bacillus* spp. (including *B. cereus*)**	ajowan, alligator pepper, allspice, asafetida, basil, bay leaf, black pepper, capsicum (hot and sweet), caraway, cardamom, celery seed, chervil, chives, cinnamon, cumin, cloves, coriander, cumin, dill, fennel seeds, fenugreek, fennel, garlic, ginger, nutmeg, mace, marjoram, mustard seed, nutmeg, onion, oregano, unspecified pepper, poppy seed, rosemary, saffron, thyme, turmeric, white pepper, spice mixes/seasonings	Antai, 1988; DOH/Victoria/AU, 2010; Banerjee and Sarkar, 2003; Brown and Jiang, 2008; Cosano *et al.*, 2009; FSAI, 2004; Garcia *et al.*, 2001; Hampikyan *et al.*, 2009; Kahraman and Ozmen, 2009; Kneifel and Berger, 1994; Kovács-Domján 1988; Little *et al.*, 2003; Moreira *et al.*, 2009; Pafumi, 1986; Sagoo *et al.*, 2009; Witkowska *et al.*, 2011
Clostridium perfringens	ajowan, anise seed, bay leaf, black cumin, black pepper, capsicum (hot and sweet), caraway, chives, cinnamon, clove, coriander, cumin, ginger, fenugreek, garlic, ginger, mace, mustard seed, nutmeg, onion, oregano, parsley, saffron, white pepper	Aguilera *et al.*, 2005; Banerjee and Sarkar, 2003; Cosano *et al.*, 2009; Pafumi, 1986; Rodriguez-Romo, 1998; Sagoo *et al.*, 2009; Shamsuddeen, 2009
***Cronobacter* spp.**	anise seed, rosemary	Ahene *et al.*, 2011; Baumgartner *et al.*, 2009; Iverson and Forsythe (2004); Jaradat *et al.*, 2009; Turcovský *et al.*, 2011
Shigella	ajowan, bay leaf	Banerjee and Sarkar, 2003
Staphylococcus aureus	asafoetida, black pepper, capsicum, cardamom, cinnamon, garlic, ginger, white pepper.	Banerjee and Sarkar, 2003; Hampikyan *et al.*, 2009; Moreira *et al.*, 2009; Kahraman and Ozmen, 2009; Shamsuddeen, 2009

[a] Literature reviewed period: January 1, 1985 through July 1, 2012. The CDC PulseNet database was reviewed between Sept. 2001 and February 2010 for pepper and pepper-type spices and reviewed between January 2001 and June 2010 for non-pepper spices uploaded to the CDC PulseNet database, supplemented by the FDA *Salmonella* isolate database reviewed during the period 2006-2010 for spices not captured in the CDC PulseNet database review for the period 2006-2010.

[b] Different forms of the same spice or spice mixture are generally not distinguished, e.g., dried coriander leaves and seeds, or masala spice mix for chicken and masala mix for beef. Capsicum may include both hot and sweet varieties such as cayenne, paprika, chili powder, and other dried whole or ground spices made from capsicum peppers. A single common name was selected for a spice in this table, which may differ from the name in the original reference, e.g., ajowan instead of bishop's weed or omum.

[c] *Salmonella* isolates from (a) pepper and pepper-type spices (entries including the words "pepper", "chili", or "cayenne" and, for the capsicums, clearly indicated as a dry product) uploaded to the CDC PulseNet database between Sept. 2001 and February 2010 and (b) all other spices uploaded to the CDC PulseNet database between January 2001 and June 2010.

[d] *Salmonella* isolates from spices sampled by FDA during 2006-2010, reported in the FDA FACTS database.

As discussed in Chapter 2, only *Salmonella* and *Bacillus* spp. have been definitively linked to human illness outbreaks resulting from consumption of contaminated spices. Furthermore, *Salmonella* contamination of spices has been the leading cause for spice-associated recalls in the United States (1970-2003: Vij *et al.*, 2006; 2008-2009: Ma, 2013) and the leading hazard reported for spices and seasonings in the Reportable Food Registry in first three annual reports (Sept. 8, 2009 - Sept 7, 2012) (FDA, 2013a; FDA, 2012a; FDA, 2012b). Therefore, as dictated by the scope of the risk profile, the remainder of the risk profile focuses on *Salmonella* contamination of spices and also addresses contamination by commonly occurring types of filth.

3.1.2 *SALMONELLA* SEROTYPES IDENTIFIED IN SPICES

In order to probe the diversity of serotypes found in spices, we focused on *Salmonella* isolates from spices collected in the United States. Data was gathered from the CDC PulseNet database and the FDA FACTS database. Two separate analyses of the CDC PulseNet database were performed to identify bacterial pathogens isolated from pepper and non-pepper spices. The first analysis, completed in March 2010, evaluated *Salmonella* isolated from black pepper, white pepper, and/or capsicum, limiting the latter to dried chili or cayenne pepper. The second analysis was completed in July 2010, and reviewed bacterial pathogens isolated from all other spices. For this analysis, products that were labeled as a "spice" in the CDC PulseNet database were included in the spice analysis with the following exceptions: herbs also labeled "fresh", black pepper, white pepper, chili/cayenne pepper capsicum, and products outside of the scope of the risk profile (e.g., tahini). Items not labeled as "spice" but which met the risk profile definition of "spice" were included in the analysis (e.g., paprika and sesame seeds) with the following exceptions: herbs labeled "fresh" or not labeled as dry, ground, powdered or otherwise indicated as low moisture. Additional serotypes were identified from the FDA FACTS database, examining years 2006-2010, including both surveillance and compliance product sampling. Data in the CDC PulseNet and FDA FACTS databases are collected from reports from a number of labs so they may contain errors unknown to the authors. All FDA data submitted to these databases, regardless of the lab in which the data was collected, were first reviewed by a supervisor for accuracy of analysis.

Table 3.2 lists the serotypes and the spices in which they were found. A wide diversity of *Salmonella* serotypes were isolated from domestic or imported spices in the United States or in spice shipments offered for entry to the United States between 2001 and 2010. The serotype of some *Salmonella* isolates from spices was not determined, was pending or was not reported from these databases; these isolates were not included in Table 3.2.

Table 3.2. *Salmonella* species and serotypes found in spices in the United States, 2001-2010.[a]

Serotype[b]	**Spice**[c]
Abaetetuba	basil, black pepper, capsicum, curry leaf
Aberdeen	black pepper, coriander, curry powder, ginger
Adabraka	coriander
Agona	anise, black pepper, capsicum, cumin, curry powder, garam masala, mint, nutmeg, oregano, sesame seed
Alachua	cumin
Altona	capsicum
Amersfoort	sesame seed
Amsterdam	sesame seed
Anatum	capsicum, coriander, cumin, fenugreek, sesame seed, spice mix
Augustenborg	turmeric
Bahrenfeld	cumin, London rocket
Ball	black pepper, sage
Bangkok	curry, turmeric
Bardo	black pepper
Bareilly	capsicum, coriander, cumin, curry powder, fennel, ginger, garam masala, sesame seed, turmeric, spice/seasoning mix
Barranquilla	capsicum, pepper
Bergen	curry powder, sesame seed, spice mix
Bere	coriander, masala
Bispebjerg	oregano, sage
Blockley	basil
Bonn	sesame seed
Bovismorbificans	capsicum

Serotype[b]	**Spice**[c]
Braenderup	black pepper, turmeric
Brandenburg	black pepper, thyme
Brazzaville	capsicum
Bredeney	capsicum
Brindisi	sage
Brooklyn	sage
Canada	black pepper
Caracas	basil, cumin
Carmel	coriander
Carrau	oregano, sesame seed, paprika
Cerro	capsicum, sesame seed, turmeric
Champaign	capsicum, chili powder, fenugreek
Chandans	masala mix, oregano
Chingola	spice and seasonings
Claibornei	coriander
Colindale	cumin
Corvallis	cumin
Cubana	celery, coriander, cumin, sesame seed, garam masala
Derby	black pepper, capsicum, five spice, sage
Djibouti	coriander
Dublin	curry
Eastbourne	turmeric
Elokate	black pepper
Enteritidis	black pepper, capsicum, fenugreek, oregano, spice/seasoning mix
Everleigh	sesame seed
Freetown	capsicum, cumin, spice/seasoning mix
Fresno	sesame seed
Gamaba	cumin
Gaminara	anise seed, capsicum, coriander, sesame seed
Give	capsicum, oregano, sesame seed, turmeric
Glostrup	Sage, sesame seed
Gozo	capsicum
Grumpensis	capsicum
Haifa	basil
Havana	anise seed, capsicum, coriander, masala, sesame seed
Heidelberg	black pepper, sesame seed
Hermannswerder	sage
Hindmarsh	capsicum
Hvittingfoss	basil, black pepper, capsicum, coriander, fenugreek leaf, turmeric, sesame seed, white pepper
Idikan	sesame seed, white pepper
Infantis	capsicum, spice/seasoning mix
Inpraw	turmeric powder
Istanbul	capsicum
Javiana	allspice, black pepper, cumin, sage, white pepper
Johannesburg	ginger
Kentucky	capsicum, cumin, mint, fennel, sesame seed, thyme
Kingabwa	capsicum
Kottbus	black pepper, white pepper
Kumasi	black pepper
Lexington	ginger
Liverpool	oregano

Serotype[b]	**Spice**[c]
Livingstone	cumin
Llandoff	sesame seed
London	coriander, fenugreek
Luke	garam masala
Madelia	oregano, white pepper
Magwa	cumin
Martonos	capsicum
Mbandaka	black pepper, capsicum, cumin, curry powder, garlic, fennel seed, parsley, sesame seed, turmeric, spice/seasoning mix
Mgulani	black pepper, capsicum, coriander, turmeric, spice/seasoning mix
Miami	sage
Mikawasima	laurel leaf
Milwaukee	capsicum
Minnesota	basil, sesame seed
Molade	capsicum
Montevideo	arnica, black pepper, capsicum, coriander, cumin, mint, oregano, nutmeg, sesame seed, thyme, spice/seasoning mix
Muenchen	capsicum, cumin, thyme
Muenster	spice/seasoning mix
Nchanga	cumin
Newport	allspice, black pepper, capsicum, cardamom, coriander, cumin, curry powder, nutmeg, oregano, sesame seed, turmeric, spice/seasoning mix
Nordrhein	capsicum
Nottingham	capsicum, oregano
Onarimon	cumin
Onderstepoort	cumin, rosemary
Oranienburg	capsicum, coriander, oregano, sage
Orion	anise seed, curry powder
Oslo	black pepper
Othmarschen	sage
Panama	capsicum
Paratyphi B	turmeric, sage, spice mix
Paratyphi B var. L(+) tartrate +	black pepper, capsicum, coriander, mint, turmeric, spice mix
Pomona	turmeric
Poona	black pepper, capsicum, celery, coriander, turmeric, sesame seed, spice/seasoning mix
Potsdam	cumin, sesame seed
Reading	cumin
Richmond	capsicum, coriander, fenugreek, masala, rosemary[d], sesame seed, spice/seasoning mix
Rissen	black pepper, capsicum, white pepper
Rubislaw	black pepper, caraway seed, sesame seed, white pepper, spice/seasoning mix
Saintpaul	coriander, cumin, ginger, mustard, sesame seed, spice/seasoning mix
Salford	cumin, sage
Sandiego	black pepper, capsicum, cardamom, coriander, cumin
Saugus	capsicum
Schleissheim	sesame seeds, thyme, turmeric
Schwarzengrund	capsicum, sesame seed, turmeric, spice/seasoning mix
Senftenberg	black pepper, capsicum, celery seed, coriander, cumin, curry powder, garam masala nutmeg, sesame seed, thyme
Simi	sage
Singapore	capsicum
Stanley	black pepper, capsicum, cumin, white pepper

Serotype[b]	Spice[c]
Stormont	curry powder
Sundsvall	capsicum, chili powder
Tallahassee	masala
Teddington	annatto seed
Telaviv	cumin, laurel leaf, mint, sage
Telelkebir	cumin
Telhashomer	fenugreek leaf, spice/seasoning mix
Tennessee	capsicum, celery, sesame seed, spice/seasoning mix
Thompson	capsicum, curry powder, spice/seasoning mix
Treforest	capsicum
Tucson	capsicum
Typhimurium	basil, black pepper, capsicum, coriander, curry powder, dill weed, fenugreek, five spice, ginger, masala, mint, oregano, rosemary, saffron, sage, sesame seed
Umbilo	five spice, garam masala
Urbana	black pepper
Vejle	black pepper
Virchow	basil, black pepper, turmeric, coriander, spice/seasoning mix
Wandsworth[d]	broccoli powder[d]
Warragul	sage
Weltevreden	anise, basil, bay, black pepper, capsicum, coriander, cumin, curry powder, mace, masala, nigella, onion, sesame seed, turmeric, white pepper, spice/seasoning mix
Westhampton	capsicum
Westminster	cumin, sesame seed
Wichita	spice/seasoning mix
I 3,15,34:d:-	sesame seed
II 40:z4,z24:-	oregano
II 40:z4,z24:z39	anise seed, oregano
II 48:d:z6	cinnamon
IIIa 48:z4,z24:-	sesame seed
IIIb 60:r:e,n,x,z15	capsicum, cumin
IV 43:z4,z23:-	fingerroot
VI 6,14:a:1,5	spice mix

[a] *Salmonella* isolates from (a) black pepper, white pepper, and chili/cayenne pepper capsicums uploaded to the CDC PulseNet database between Sept. 2001 and February 2010 (b) all other spices uploaded to the CDC PulseNet database between January 2001 and June 2010 and (c) additional isolates from spices sampled by FDA during 2006-2010 in the FDA FACTS database. Data in the CDC PulseNet and FDA FACTS databases are collected from reports from a number of labs so they may contain errors unknown to the authors.

[b] *Salmonella enterica* subspecies *enterica* (I) unless noted otherwise

[c] Different forms of the same spice or spice mixture are generally not distinguished, e.g., dried coriander leaves and seeds, or masala spice mix for chicken and masala mix for beef. Capsicum may include both hot and sweet varieties such as cayenne, paprika, chili powder, and other dried whole or ground spices made from capsicum peppers. A single common name was selected for a spice, which may differ from the name in the original reference, e.g., ajowan instead of bishop's weed or omum.

[d] Broccoli powder was the contaminated ingredient in the seasoning mix implicated in the S. Wandsworth outbreak (Sotir *et al*., 2009; see also Chapter 2 and Table 2.1).

Investigations of the microbiological quality of spices produced and examined outside of the United States have reported some of the same serotypes reported in Table 3.2 but also have identified additional serotypes isolated from spices. For example, Sagoo *et al.* (2009) identified four additional serotypes associated with spices (Aequatoria, Edinburg, Friedenau, and Hato) and isolated 13 of the serotypes listed in Table 3.2. These studies demonstrate that a wide variety of spices can become contaminated with a wide variety of *Salmonella* serotypes. We were unable to identify any data to support the hypothesis that spice contamination is limited to a subset of *Salmonella* serotypes. Frequency data for individual serotypes (e.g., numbers of isolates reported) derived from the CDC PulseNet or FDA FACTS databases are not reported because these data cannot be easily interpreted, e.g., serotypes associated with a large outbreak are likely to have multiple entries arising from sampling during the outbreak investigation and therefore provide no information on relative prevalence in the spice supply (percentage of the contaminated spice supply containing a particular serotype). *Salmonella* prevalence in spices (percentage of the spice supply contaminated with *Salmonella*), including relative prevalence by serotype and antimicrobial resistance, was estimated for shipments of imported spice offered for entry to the United States during FY2007-FY2009 and is discussed in Chapter 4.

3.2 FILTH ADULTERANTS FOUND IN SPICES

A finding of filth adulteration of spice can arise from the presence of avoidable defects in spice or excessive concentrations of natural or unavoidable defects in spice. Avoidable defects in spice are extraneous materials, defined by FDA as "any foreign matter in a product associated with objectionable conditions or practices in production, storage, or distribution" and includes "objectionable matter contributed by insects, rodents, and birds; decomposed material; and miscellaneous matter such as sand, soil, glass, rust, or other foreign substances" (FDA, 2012g). Spice adulterated with avoidable filth can result in a food being deemed "adulterated" under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) , which prohibits "any poisonous or deleterious substance that may render it injurious to health," or section 402(a)(4) of the FD&C Act, which prohibits foods "prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." The concentration of avoidable filth elements that constitute filth adulteration depends on the nature of the adulterant and is determined on a case-by-case basis.

FDA regulations at 21 CFR 110.110 (FDA, 2012h) address how FDA establishes maximum concentrations of natural or unavoidable defects in foods for human use that present no health hazard. FDA established Food Defect Action Levels (DALs) which define the maximum "levels" (concentrations) of specific elements of filth in specific foods (FDA, 2013g). FDA based DALs on an extensive survey of retail foods including spices in the 1980s and set values to reflect significant deviation from the best practices of industry and agriculture at that time. The spices for which a DAL has been established are given in Table 3.3. Not all spices have DALs nor have DALs been established for all possible adulterants in a spice. If no DAL has been established for a filth

Table 3.3. Spices for which filth Food Defect Action Level(s) has/have been established in the United States

Spice	Ground	Whole
Allspice	x	x
Bay (Laurel) Leaves		x
Capsicum	x	x
Paprika	x	
Cinnamon or Cassia	x	x
Cloves		x
Condimental seeds		x
Cumin seed		x
Curry Powder	x	
Fennel seed		x
Ginger		x
Hops		x
Mace		x
Marjoram	x	x
Nutmeg	x	x
Oregano	x	x
Pepper (black or white)	x	x
Sage	x	x
Sesame seeds		x
Spices, leafy		x
Thyme	x	x

element in a spice then FDA will review the analytical results of filth in that shipment on a case-by-case basis taking into account the types of filth elements found, concentration of the filth element in the sample, and the risk to public health to determine whether it violates the FD&C Act. Spice with excessive concentrations of natural or unavoidable defects violate section 402(a)(3) of the FD&C Act, "consisting in whole or in part of any filthy, putrid, or decomposed substance or is otherwise unfit for food" (FDA, 2012h).

In order to determine the types of filth adulterants found in spices, we reviewed FDA sampling data (reported in the FDA FACTS database) for shipments of imported spice offered for entry to the United States during the three year period FY2007-FY2009. Table 3.4 lists the various filth adulterants that were isolated from spices as part of FDA surveillance sampling of spice shipments offered for U.S. entry, FY2007- FY2009. Almost all of the insects that were found in these shipments were stored product pests, which indicate that the spice was prepared, packed, or held under insanitary conditions whereby it became contaminated. Among the insects isolated from the spices is *Monomorium pharaonsis* (L.), Pharaoh ant, a known carrier of *L. monocytogenes* (Olsen *et al.*, 2001). The presence of rodent hair or hair fragments without a hair root is generally indicative of fecal contamination of spice (Vazquez, 1977) because when grooming, rodents ingest hair and hair fragments, which are excreted in their feces. Other adulterants may result from improper cleaning of the spices (e.g. staples, sticks, stones) or improper storage (e.g. bird feathers or barbs, animal or insect excreta).

Table 3.4. Types of filth adulterants found in spices: Surveillance sampling of spice shipments offered for U.S. entry, FY2007-FY2009.

Insect *Scientific Name*	**Insect Common Name**	**Hair**	**Other**
Acarus siro L.	grain mite	Human hair	Animal
Ahasverus advena (Waltl)	foreign grain beetle	Bat	Animal Fecal Material
Ahasverus rectus (LeConte)		Cat	Animal Hair
Araecerus fasciculatus (De Geer)	coffee bean weevil	Cow	Insect Excreta
Cadra cautella	almond moth	Dog	Bird Barbs
Cheyletus eruditus (Schrank)		Mammalian	Bird Barbules
Cryptolestes ferrugineus (Stephens)	rusty grain beetle	mouse/rat	Bird Excreta
Cryptolestes pusillus (Schonherr)	flat grain beetle	other	Bird Feathers
Dienerella costulata (Reitter)		Rabbit	Rancid
Enicmus consimilis Mannerheim		Rat	Moldy
Eurytoma tylodermatis Ashmead		Rodent	Dirt
Hippodamia convergens (Guerin)	convergent lady beetle	non-striated	Fiber, Synthetic
Laccifer lacca (Kern)		Sheep	Paper
Lasioderma serricorne (F.)	cigarette beetle	Striated	Plastic
Lophocateres pusillus (Klug)	Siamese grain beetle		Rubber Band
Monomorium pharaonis (L.)	Pharaoh ant		Seed
Oryzaephilus mercator (Fauvel)	merchant grain beetle		Staple
Oryzaephilus surinamensis (L.)	Saw-toothed grain beetle		Stick
Plodia interpunctella (Hubner)	Indian meal moth		Stone
Rhyzopertha dominica (F.)	lesser grain borer		Twig
Sitophilus granarius (L.)	granary weevil		Wood Sliver
Stegobium paniceum (L.)	drugstore beetle		
Tribolium castaneum (Herbst)	red flour beetle		
Typhaea stercorea (L.)	hairy fungus beetle		

4. PREVALENCE AND CONCENTRATION OF *SALMONELLA* AND FILTH IN SPICES

We reviewed the scientific literature and available government/agency reports for surveillance studies that reported measurements of prevalence and/or concentration of *Salmonella* and filth in spices at any point along the farm-to-table continuum. We also researched *Salmonella* concentrations found in spice samples associated with foodborne outbreaks as well as antimicrobial resistance found in *Salmonella* strains that have been isolated from spices. Our literature review primarily used PubMed, Google, and Google Scholar to search the English-language literature using different combinations of the following keywords: *Salmonella*, filth, prevalence, level, enumeration, spice, herb, microbiological, quality, bacteriological, quality, evaluation, safety, profile, antimicrobial, activity, resistance, property, properties, drug, resistant, resistance. We also reviewed citations and references contained in the articles identified in our internet searches on this topic and other references collected during our work on this report (e.g., foodborne outbreaks, Chapter 2).

In addition to the literature search, we analyzed FDA surveillance sampling data for *Salmonella* and filth in imported spice shipments offered for import over a three year period, FY2007-FY2009. Full details of the sampling protocols and inclusion criteria are provided in Van Doren *et al*. (2013a). FDA undertook a targeted sampling assignment to gather information on typical concentrations of *Salmonella*. Under this assignment, FDA analyzed samples of capsicum and sesame seeds from shipments offered for import to the United States during a five month period in 2010 for *Salmonella*. Full details of the study design, *Salmonella* prevalence and concentration results, and data analysis are provided in Van Doren *et al*. (2013c). The 2010 study also examined shipments for the presence of filth and these results are compared with the FY2007-FY2009 study results in Section 4.2.3. Finally, we analyzed FDA surveillance data over a ten year period (FY2000-FY2009) to explore the potential correlation between presence of *Salmonella* and filth in imported spice shipments. Details of the U.S. study are provided in Section 4.3.

FDA requested scientific data and information from the spice industry and other stakeholders through a Federal Register Notice announcing the risk profile project, identifying data gaps, and requesting comments and scientific data and information to help fill the data gaps (FDA, 2010e). In response to this request, the American Spice Trade Association submitted spice sampling data collected in ASTA member spice processing facilities over a two year period by some of its members (ASTA, 2010; Ruckert, 2010). These data are discussed in Section 4.1.4.

The discussion that follows summarizes data available from studies around the world on the prevalence and concentration of *Salmonella* and/or filth in spices. Comparison of prevalence values in different studies is complicated by the fact that each study may have examined a different amount of spice, which generally leads to a different limit of detection. For this reason, we report the mass examined whenever reporting prevalence values, e.g., 6.6 % (750 g; 95% CI 5.7-7.6%). Where possible, we report the 95% confidence intervals (95% CI) for the prevalence values as shown in the previous example. Different studies may have employed different methods of analysis, which can lead to differences in test sensitivities or selectivities. We assume that methods employed in the reported peer-reviewed and government studies have been validated and that results among studies are comparable. Interpretation of differences in prevalence or concentration values across studies should consider context (because the spice examined in each study is different), which we provide in our discussion.

4.1 *SALMONELLA*

4.1.1 *SALMONELLA* PREVALENCE AND CONCENTRATION IN SPICE: FROM FARM TO TABLE OVERVIEW

Limited data are available from the scientific literature on the prevalence of pathogens in spices at different points in the farm-to-table continuum. Information provided by studies published during the period 2000-2012 is summarized in Table 4.1. All of the values listed in Table 4.1 are from surveillance studies and most samples were collected from retail establishments. It is likely that a majority of spices examined in Australia, Belgium, Czech Republic, Federal Republic of Yugoslavia, Germany, Hungary, Ireland, Japan, the Netherlands, Slovakia, Slovenia, and the United Kingdom in these studies were imported because these countries are not major producers of the spices examined. All spices examined in the U.S. study described in Table 4.1 were imported. Nineteen studies examined samples exclusively from retail; the observed *Salmonella*-prevalence in spices in these studies ranged from 0 to 10% (3-135 g; 95% CI 0-40%). Two studies examined samples of spices exclusively from spice processing/packing facilities; these reported *Salmonella* prevalence values ranging from 0 to 1% (25-135 g; 95% CI 0 – 10%). Two studies examined spices exclusively from the point of import, finding prevalence values of 0.5-6.6% (25-750 g; 95% CI cannot be calculated for one study). Two studies examined “non-irradiated spices”, which we presume to mean spice that had not been subjected to a pathogen reduction treatment, and reported prevalence values ranging from 3 to 10% (25 g; 95% CI 0.3-30%).

A majority of the studies summarized in Table 4.1 reported observed *Salmonella* prevalence values in the range of zero to one percent, regardless of setting, and many of the reported prevalence values reported are statistically smaller than the value determined in the U.S. study (Fisher exact test, $p < 0.05$). Because the screening test protocols used in all of the non-U.S. studies examined a smaller mass of spice than that used in the U.S. study, it is likely that at least some of the observed differences between the smaller *Salmonella* prevalence values reported in tests conducted outside the United States versus tests conducted in the United States arise from different limits of detection. The smaller prevalence values reported in the different countries and settings may also reflect real differences in prevalence either arising from a difference in the microbiological quality of the spices examined or differences resulting from the application of one or more processes intended to reduce the microbial load. Pathogen reduction treatments such as ethylene oxide, steam treatment or irradiation are commonly applied to spices to reduce the risk of microbial contamination (ASTA, 2011; see Section 8.2.1 a discussion of pathogen reduction treatments). Some insight into this latter hypothesis is provided in Section 4.1.3, where the prevalence of *Salmonella* contamination in spice shipments offered for import to the United States are compared on the basis of applied processes, and in Section 4.1.4, where the prevalence of *Salmonella* in spice lots examined post-pathogen reduction treatment is compared with the value for spice lots pre-treatment. *Salmonella* prevalence in retail spice samples in the United States is unknown.

Neither FDA nor the spice industry collects enumeration data on a regular basis because the regulatory standard is absence of *Salmonella*. Table 4.2 summarizes *Salmonella* concentrations measured in spices and products associated with salmonellosis outbreaks attributed to contaminated spices or determined in surveillance studies. While the outbreaks associated with alfalfa seeds were attributed to consumption of alfalfa sprouts, the enumeration data are included in this table because the concentrations were determined in the dry seeds and alfalfa seeds can be consumed as spices.

Salmonella concentrations ranging from 0.0007 to 11 MPN/g-spice (7 MPN per 10,000 g to 11 MPN per g) have been reported as shown in Table 4.2. Most of the *Salmonella* concentrations determined for spices in surveillance and outbreak investigations in other countries reported in Table 4.2 are in the same range as the values for capsicums and sesame seeds determined in the 2010 U.S. surveillance study (Van Doren, *et al.*, 2013c) but the largest values, reported for samples of spice gathered during the paprika- and black pepper-attributed outbreaks listed in Table 4.2 (Lehmacher *et al*., 1995; Gustavsen and Breen, 1984), are at least one order of magnitude larger than the largest values observed in surveillance studies. It should be noted that the concentrations of *Salmonella* in spice samples analyzed in surveillance and outbreak investigations may not necessarily reflect actual concentrations in food at the time of consumption.

Surveillance data on the prevalence and concentrations of *Salmonella* in shipments of imported capsicum or sesame seed shipments were gathered by FDA in 2010. These data were used to develop a descriptive model of contamination prevalence and concentrations between-and within- imported shipments of capsicum or sesame seed offered for entry to the United States and are discussed in Section 4.1.3. The study found shipment mean concentrations of *Salmonella* in contaminated capsicum or sesame seed shipments vary widely between shipments and that many contaminated shipments contain low concentrations of contaminating organisms (Van Doren *et al*., 2013c).

The *Salmonella* concentrations reported in spices, Table 4.2, are small but not atypical of concentrations reported in other foods associated with foodborne salmonellosis (WHO/FAO, 2002). However, in contrast with many other types of foods, spices are consumed in very small amounts during a single eating occasion (Section 7.2.2) so the *Salmonella* dose expected from consumption of spice during a single eating occasion is expected to be smaller than that for other foods with similar concentrations of contamination but consumed in larger quantities.

Table 4.1. Summary of scientific surveillance studies measuring the prevalence of *Salmonella* in spices, 2000-2012

Country[a]	Sample Collection Point	Sample Size (g)[b]	N	Prevalence (%)	95% CI[c]	Spices sampled[d]	Spices containing *Salmonella*[e]	Reference
Australia	Retail	125[f]	217	0	0-1	caraway, chili, cloves, coriander, cumin, fennel, fenugreek, ginger, mustard, nutmeg, sumac, turmeric, Chinese five spice mix, garam masala, other spice mixes	none	DOH/Victoria/AU, 2010
Australia	Import	25	not reported	0.5; 4.9[g]		peppercorn; paprika	peppercorn; paprika	DOH/Victoria/AU, 2010; FSANZ, 2001
Belgium	Processing plant	25	22	0	0-10	not reported	none	EFSA, 2006a
Brazil	Retail	25	233	5.6	3.0-9.4	bay, basil, black pepper, cinnamon, clove, cumin, dehydrated green onion, oregano, parsley	black pepper, cumin	Moreira, *et al*. 2009
Czech Republic	Retail/ Production Plants	25	74	3	0.3-9	non-irradiated spice	not reported	EFSA, 2006a
Egypt	Retail	25	297[h]	0	0-1	geranium, basil, marjoram, peppermint, spearmint, jews mallow, dill, celery, parsley, cumin, caraway, anise, fennel, coriander, dill, black pepper, chamomile, karkade, saffron	none	Abou Donia, 2008
Estonia	Retail	25	20	0	0-10	not reported	none	EFSA, 2006a
Federal Republic of Yugoslavia[i]	Retail	25	101	0	0-3	bay, basil, black pepper, capsicum, caraway, cinnamon, clove, coriander, curry, dill, ginger, mustard, nutmeg, oregano, rosemary, sesame, thyme, white pepper	none	Stankovic *et al*., 2006
Germany	Retail	25	16	10	2-40	sesame seed	sesame seed	Brockmann *et al*., 2004
Hungary	not reported	25	198	1	0.1-4	not reported	not reported	EFSA, 2010a
Hungary	not reported	25	267	0.4	0.009-2	not reported	not reported	EFSA, 2009b

Country[a]	Sample Collection Point	Sample Size (g)[b]	N	Prevalence (%)	95% CI[c]	Spices sampled[d]	Spices containing *Salmonella*[e]	Reference
India	Retail	25	154	1	0.2-5	allspice, aniseed, asafetida, bay (tejpat), bishop's weed, black cumin, black pepper, caraway, cardamom, celery seed (ajmud), chili, cinnamon, clove, coriander, cumin, fenugreek, garlic, ginger, mustard, poppy, turmeric	ginger, poppy seed	Banerjee and Sakar, 2003
Ireland	Primarily Pre-Retail[j]	125[f]	25	0	0-10	capsicum, curcuma (including turmeric), ginger, nutmeg, other spices and herbs	none	FSAI, 2005
Ireland	Primarily Retail	25	647	0.93	0.3-2	capsicum, curcuma (including turmeric), ginger, nutmeg, piper spp. (e.g., black and white pepper), other spices and herbs	chili pepper and chili powder, curry, sesame seeds, turmeric[j]	
Japan	Retail	25	259	0.8	0.09-3	allspice, ajowan, anise, artemisia, capsicum, basil, bay leaves, black pepper, capsicum, caraway, celery, Chinese five spice, cinnamon, clove, coriander, cumin, curry powder, curry leaf, dill weed, fennel, fenugreek, garlic, garam masala, mandarin, mustard, nutmeg, oregano, paprika, parsley, sage, star anise, turmeric, white pepper, other dried peppers, other spice mixtures	black pepper, red pepper	Hara-Kudo *et al.*, 2006
Mexico	Retail	3	304	0[l]	0-1	bay, cumin, garlic, pepper, oregano	none	Garcia *et al.*, 2001
Netherlands	Retail	25	1857	3.4	2.6-4.3	not reported	not reported	EFSA, 2010b; EFSA, 2011d
Slovakia	not reported	25	27	10	4-30	non-irradiated spice	not reported	EFSA, 2007a
Slovenia	Retail	25	40	0	0-7		none	EFSA, 2006a; EFSA, 2006b
Slovenia	Retail	25	30	0	0-9		none	EFSA, 2007a; EFSA, 2007b
Slovenia	Retail	25	44	0	0-7	Noted as convenience sample	none	EFSA, 2011e; EFSA, 2012
Turkey	Retail	25	75	0	0-4	allspice, black pepper, cinnamon, cumin, red pepper	none	Beki and Ulukanli, 2008

Country[a]	Sample Collection Point	Sample Size (g)[b]	N	Prevalence (%)	95% CI[c]	Spices sampled[d]	Spices containing *Salmonella*[e]	Reference
Turkey	Spice Producers and Retail	25	170	0	0-2	black pepper, capsicum, cumin, peppermint, thyme	none	Kahraman and Ozmen, 2009
Turkey	Retail	25	420	2.9	1.5-4.9	allspice, black pepper, capsicum, coriander, cumin, ginger, white pepper	allspice, black pepper, coriander, cumin, ginger, red pepper	Hampikyan *et al.*, 2009
Turkey	Retail	25	65	0	0-5	basil, mint, thyme	none	Ulukanli and Karadag, 2010
United Kingdom	Retail	25	1031[m]	1	0.74-2.3	alfalfa, poppy, sesame	alfalfa, sesame seed	Willis *et al.*, 2009; Willis *et al.*, 2013
United Kingdom	Retail	135[f]	2833	1.1	0.74-1.5	aniseed, allspice, basil, bay, black pepper, capsicum, cinnamon, coltsfoot, coriander, cumin, dill, fennel, fenugreek, garam masala, ginger, lemongrass, mace, mustard, nutmeg, oregano, parsley, saffron, sage, tarragon, thyme, turmeric, white pepper, other piper spp. (e.g., green, red, mixed), other spices and spice mixes[n]	allspice, black pepper, cayenne, chili, cinnamon, coriander, cumin, curry, fennel, fenugreek, garam masala, mint, okra, sage, turmeric[m]	Sagoo, *et al.*, 2009, Little, 2012
United Kingdom	Manufacturing and Packing	135[f]	132	1	0.2-5			
United Kingdom	Retail	25	386	0.3	0.1-1	spice mixes (not specified)	spice mix (not specified)	Little *et al.*, 2003
United States	U.S. Import	750[p]	2844	6.6	5.7-7.6	Wide variety of spices and spice mixes (see Table 4.3)	Wide variety of spices and spice mixes including basil, black pepper, capsicum, cinnamon, coriander, cumin, curry powder, fennel, fenugreek, mustard, oregano, sesame seed, turmeric, white pepper	Table 4.3
Multiple Countries	Spice Producer	25	79	0	0-4	saffron	none	Cosano *et al.*, 2009

[a] Country were sample was collected.

[b] Total mass examined by *Salmonella* screening test.

[c] 95% exact confidence limit (Clopper and Pearson, 1934).

[d] Spices sampled list combines different forms of the same kind of spice under one name (e.g., ground and whole caraway seeds are listed as caraway) and combines related species under one name (e.g., cayenne, chili, paprika, and "red pepper" are listed as capsicum). See reference for more detailed list.

[e] Spices containing *Salmonella* list reports spice name as noted in the reference.

[f] Studies tested five sub-samples per spice sample; total mass examined is listed (i.e., five times sub-sample mass).

[g] Spice-specific prevalence values for peppercorns (0.5%) and paprika (4.9%).

[h] Does not include tea samples.

[i] Currently the State Union of Serbia and Montenegro.

[j] Majority of samples from importers/distributors, producers/blenders, packers/wholesalers or food manufactures/preparers (establishments using large amount of spice).

[k] Four of six samples testing positive for *Salmonella* were from retail; one turmeric sample was collected from import/production/wholesaler and the curry powder sample was collected from an establishment that uses large amounts of spices for food production.

[l] Samples examined for the presence of *Salmonella* Typhi.

[m] Only includes seed samples (sesame, poppy, and alfalfa).

[n] Sagoo *et al*. (2009) reported spice types from all sample collection points together.

[p] Protocol involved two screening tests, each 375-g composite sample derived from 15 25-g sub-samples (total of 30 sub-samples).

Table 4.2. Concentration of *Salmonella* in spices and spice-containing foods implicated in salmonellosis illness outbreaks

Spice/Food	Type of Sample[a]	Concentration (MPN/g)	N[b]	Reference
Black Pepper	Outbreak	0.1 - >2.4	12	Gustavsen and Breen, 1984
Paprika	Outbreak	2.5	1	Lehmacher *et al*., 1995
Paprika-containing spice mixtures	Outbreak[c]	0.04-11	9	Lehmacher *et al*., 1995
Aniseed-containing tea	Outbreak	0.036	4	Koch *et al*., 2005
Paprika Flavored Potato Chips	Outbreak	0.04-0.45	5	Lehmacher *et al*., 1995
Tahini, hummus, and sesame seed -helva	Outbreak	<0.03-0.46	10	Unicomb *et al*., 2005
Alfalfa seeds	Outbreak-Sprout	0.0007-0.016[d]	30	Inami *et al*., 2001
Alfalfa seeds	Outbreak-Sprout	< 1[e]	NA	Stewart *et al*., 2001
Black Pepper and Red Pepper	Surveillance (retail)	0.086[f]	2	Hara-Kudo *et al*., 2006
Sesame seeds and mixtures of seeds[g]	Surveillance (retail)	<0.1-0.2	6	Willis *et al*., 2009; Willis, 2013
Alfalfa seeds	Surveillance[h]	0.0036	30	Inami *et al*., 2001
Capsicum	Surveillance (Import into U.S)	0.002-0.23	18	Table 4.8; Van Doren *et al*., 2013c
Sesame seed	Surveillance (Import into U.S)	0.002-0.23	23	Table 4.8; Van Doren *et al*., 2013c

[a] Samples collected as part of salmonellosis illness outbreak investigations or surveillance. Unless otherwise noted, the outbreak was associated with consumption of the spice or low-moisture food containing the spice.

[b] Number of total samples tested. NA indicates the number of samples examined was not reported.

[c] Enumeration measurements took place approximately 1 year after the salmonellosis outbreak; samples were produced during the outbreak time period.

[d] Values reported are for the dry seed. Values in table were derived from data reported by Inami *et al*. (2001) using the excel spreadsheet provided in the FDA Bacteriological Analytical Manual (Blodgett, 2010).

[e] Values reported are for the seed but seeds were soaked in water for three hours before beginning the enumeration procedure (Stewart *et al*., 2001), which may have led to some bacterial growth.

[f] Value was derived from the observations reported by Hara-Kudo *et al*. (2006) (positive screening test and negative MPN tubes) as described in Van Doren *et al*. (2013c).

[g] Mixtures of seeds contained sesame, pumpkin, sunflower, linseed, and hemp (Willis, 2013). Identity of seeds sampled from Willis (2013); enumeration values from Willis *et al*. (2009).

[h] Location of surveillance sampling in the seed supply chain was not reported.

4.1.2 PRIMARY PRODUCTION

We were unable to identify any studies examining *Salmonella* contamination in/on spice producing plants pre-harvest. As a result we can provide no information on the prevalence of *Salmonella* in/on spice producing plants at this point of production.

Cosano *et al*. (2009) examined 79 25-g samples of saffron spice collected directly from producers from a variety of countries and found no *Salmonella*, placing a 95% CI on the observed prevalence in these samples of 0-4% (25 g, Table 4.1). Kahraman and Ozmen (2009) examined 25-g spice samples from producers and retailers in Turkey (distribution of samples from the different points in the spice food chain was not specified) and found no *Salmonella*. It is not possible to evaluate the limit on prevalence specific for primary production from the reported data from Kahraman and Ozmen (2009) but the combined sample set yielded a 95% CI of 0-2%, Table 4.1. The Food Safety Authority of Ireland (FSAI, 2005) reported finding one 25-g sample of turmeric collected from “import or production or packing premises or wholesaler” positive for *Salmonella* (reported in the “primarily retail” sample set listed in Table 4.1). None of the batch samples examined from “primarily pre-retail” settings, which included a majority of samples from “import or production or packing premises or wholesaler” tested positive for *Salmonella* (FSAI, 2005). As noted above, the sample size examined in these studies was only 25 g, which limited detection to larger concentrations of *Salmonella* in the spice samples.

4.1.3 DISTRIBUTION AND STORAGE

As described in Chapter 6, the supply chain for spices can be complex and span long times. Distribution and storage steps can take place at multiple points in the supply chain. Surveillance data on the prevalence and concentration of *Salmonella* in spices during distribution and storage is limited to evaluations of these quantities at the point of import. We were not able to identify any surveillance studies of *Salmonella* prevalence or concentrations in spices located in storage facilities or at other points of the distribution chain. Prevalence data reported between 2000 and 2012 is available from Australia and the United States, Table 4.1. In Australia, the prevalence of *Salmonella* in peppercorns (type not specified) collected at the point of import, was determined to be 0.5% (25 g) while that for paprika was 4.9% (25 g) (DOH/Victoria/AU, 2010). Without knowledge of the total number of samples examined, it is not possible to determine whether the observed differences in prevalence for these two types of spice are significant or whether the observed prevalence values determined in Australia are statistically different from those in the United States. As noted in Table 4.1 the study by the Food Safety Authority of Ireland (FSAI, 2005) included batch and single samples from “import or production or packing premises or wholesaler” as well as from other points in the spice supply chain. One 25-g sample of turmeric collected from “import or production or packing premises or wholesaler” in Ireland tested positive for *Salmonella* (FSAI, 2005). Reports of *Salmonella*-positive spice samples in the FDA RFR also provide information on the frequency of *Salmonella*-positive spice samples found in FDA-registered facilities, which include facilities that distribute, manufacture, process, pack/re-pack, and store spices. Data from the first three years of the RFR are described in Section 4.1.2. Food recalls associated with *Salmonella*-positive spice may result from samples collected during distribution or storage and these are described in Section 4.1.6.

4.1.3.1 *SALMONELLA* IN SHIPMENTS OF IMPORTED SPICE OFFERED FOR ENTRY TO THE UNITED STATES

Data reported in this section were derived from two studies of FDA surveillance sampling data unless otherwise noted: (1) review of results of the annual sampling program for the three years FY2007-FY2009 and (2) review of sampling results from a targeted sampling assignment in 2010 (August-December) that focused on enumeration of *Salmonella* in shipments of imported capsicum and sesame seed offered for entry to the United States. Full reports of both studies were originally published in *Food Microbiology* (Van Doren *et al*., 2013a; Van Doren *et al*., 2013c). The data from these studies are compared with an earlier study of *Salmonella* prevalence in spice shipments offered for import to the United States (Satchell *et al*., 1989) and other relevant data.

Observed prevalence of **Salmonella** *in shipments of imported spice offered for entry to the United States, FY2007-FY2009*

Salmonella prevalence in imported spice shipments offered for entry to the United States during FY2007-FY2009 was 6.6% (750 g; 95% CI 5.7-7.6%), Table 4.3. This value does not differ statistically from the value determined by FDA for examination of a set of 31 imported spice shipments offered for entry to the United States during the period March 1987-January 1988, 6% (750 g; 95% CI 0.8-20%) (Satchell *et al*., 1989). These two studies are the only published studies to examine the prevalence of *Salmonella* contamination of spices in the United States.

During FY2007-FY2009, sampled imported spice shipments offered for entry to the United States were 1.9 times more likely to be found contaminated than sampled shipments of all other FDA-regulated foods offered for U.S. entry combined (relative risk[3] (RR), 95% CI 1.6-2.3; Fisher exact test for difference, $p<0.001$). Interpretation of this value is complicated by the fact that a number of different sampling protocols were used for imported shipments of FDA-regulated foods other than spices and these differences could lead to test sensitivity differences. Comparing only data for shipments that were sampled with the same FDA Category II food sampling protocol used for spices (Andrews and Hammack, 2003), we found an even larger RR for contamination of imported spice shipments as compared with shipments of other imported FDA-regulated foods: RR = 4.4 (95% CI 3.4-5.8; Fisher exact test for difference, $p<0.001$). The larger prevalence of *Salmonella* in imported shipments of spices as compared with other imported FDA-regulated foods can be surprising to some because the low water activity of spices does not support *Salmonella* growth, whereas the high water activity of some other imported FDA-regulated foods will support growth when other conditions for growth are met (e.g., nutrients and pH) (FDA, 2012d). Further, many spices have inhibitory compounds that provide antibacterial activity against *Salmonella* (Arora and Kaur, 1999; Hammer *et al*., 1999; Ceylan and Fung, 2004; Indu *et al*., 2006; Du *et al*., 2009a and 2009b; Tajkarimi *et al*., 2010; Hussien *et al*., 2011; discussed in Section 5.1.2). These compounds can limit growth and survival of *Salmonella* in (wet/inoculated) spices and foods containing spices or their essential oils under some conditions (Arora and Kaur, 1999; Hammer *et al*., 1999; Ceylan and Fung, 2004; Indu *et al*., 2006; Du *et al*., 2009a and 2009b; Tajkarimi *et al*., 2010; Hussien *et al*., 2011). Clearly, other factors, including the ability of *Salmonella* to survive in a variety of low moisture foods including some, if not all, spices (Podolak *et al*., 2010; Lehmacher *et al*., 1995; Keller *et al*., 2013), are more important in determining the prevalence of *Salmonella* in imported spice shipments offered for entry to the United States.

Impact of spice properties on observed prevalence of **Salmonella** *in shipments of imported spice offered for entry to the United States, FY2007-FY2009*

Spices are derived from a variety of plant parts, which may result in differences in exposure to pathogen-containing wildlife, insects, and soil during growth, harvest or primary processing. In order to determine whether these differences influence the proportion of imported spice shipments contaminated with *Salmonella*, we grouped spice screening test results by plant part, Table 4.3. Spices derived from plant fruits, such as black pepper, white pepper, and capsicums, or plant seeds, such as cumin, mustard and sesame, were grouped together in the fruit/seed category. Spices derived from plant roots included dried roots, such as turmeric and ginger, as well as dehydrated onion and garlic. Examples of spices included in the leaf category are oregano, basil, and varieties of mint. Examples of spices included in the bark/flower category include cinnamon/cassia, cloves, and saffron. Data for shipments in which the plant part was ambiguous were excluded from this part of the analysis, e.g., shipments described as “coriander” but lacking information as to whether it was the seed or leaf.

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[3] Relative risk is the ratio of prevalence values.

Table 4.3. Observed prevalence of *Salmonella*–contaminated shipments of imported spice and other imported FDA-regulated food shipments offered for entry to the United States, FY2007-FY2009.

Spice/Food	# Positive	N	*Salmonella* Shipment Prevalence (%)	95% Confidence Interval[a]
All Imported Spices[b]	187	2844	6.6	5.7-7.6
All other Imported FDA-regulated Foods[b]	600	17508	3.4	3.2-3.7
Categories of Spices[c]				
Fruit/Seed[d]	92	1465	6.3	5.1-8.0
Root[d]	15	202	7.4	4.2-12
Leaf[d]	18	160	11	6.8-17
Bark/Flower[d]	1	66	2	0-10
Spices subjected to different processes				
Spices subjected to a Pathogen Reduction Treatment[e]	4	137	3	0.8-7
Spices Not Treated/Not Known if treated[e]	183	2707	6.8	5.8-7.8
Spice Blend[f]	43	790	5.4	4.0-7.3
Spice Not-Blend[f]	141	1999	7.1	6.0-8.3
Ground/cracked Spice	131	1658	7.9	6.6-9.3
Whole Spice	51	884	5.8	4.3-7.5
Specific Spices[g]				
Capsicum[h]	35	492	7.1	5.0-9.8
Cinnamon/Clove/Nutmeg	1	73	1	0-7
Coriander	16	110	15	8.5-23
Cumin	11	138	8.0	4.0-14
Curry Powder	17	195	8.7	5.2-14
Fennel/Fenugreek/Mustard	3	112	2.7	1-8
Oregano/Basil	10	82	12	6.0-21
Pepper, Black	13	291	4.5	2.4-7.5
Pepper, White	1	87	1	0-6
Sesame Seed	20	177	11	7.0-17
Turmeric	8	118	7	3-10
Spices/Spices and Seasonings, NEC[i]	32	685	4.7	3.2-6.5
All Other spices	20	284	7.0	4.4-11

[a] 95% exact confidence limit (Clopper and Pearson, 1934).

[b] All shipments of imported FDA-regulated spices or other imported foods that were sampled during the study period. *Salmonella* screening tests for spices examined 750 g of spices; screening tests for all other FDA-regulated foods examined 375, 750, or 1500 g of food, depending on the FDA food category (Andrews and Hammack, 2003).

[c] Categorizations derived from product code (FDA, 2012j) and description. When description was insufficient to categorize, the sample was not included.

[d] Categorization of spice shipment based on the part of the plant from which it is derived.

[e] Spice shipment classified as “commercially sterile”, “heat treated” or “irradiated” and those in which the product description identified treatment (e.g., “treated with steam” or “treated with ethylene oxide”) are categorized as “Treated Spices.” All other spices are categorized as “Not Treated/Not Known if treated.”

[f] The category “Spice Blend” includes shipments of spice mixtures while “Spice Not Blend” includes shipments of a single type of spice.

[g] Different forms of spices with the same name, such as dried coriander leaves and seeds, are grouped together.

[h] Capsicum includes paprika as well as hot and other sweet dried capsicum peppers.

[i] Shipments of spices “not elsewhere classified” (NEC) in the product code (FDA, 2012j) are assigned to “Spices, NEC”, “Spices and Seasonings, NEC”, or “Mixed Spices and Seasonings, NEC.”

Prevalence values among the plant part categories ranged from a mean of 2% (750 g; 95% CI 0-10%) for spices derived from the bark/flower of the plant to 11% (750 g; 95% CI 6.8-17%) for spices derived from plant leaves and differences among some of the categories are significant (chi-square test statistic for multiple proportions (8.8) > chi-square critical value (7.8) at the 95% confidence level). Application of the Marascuilo procedure establishes that a (statistically) larger proportion of imported shipments of spices in both leaf and fruit/seed spice categories offered for entry to the United States are contaminated with

Salmonella than imported shipments of bark/flower spices. Because 95% of the bark/flower samples examined were either cinnamon/cassia or clove, the difference could arise from reduced test sensitivity for these spices (Section 2.2), the antibacterial activity of these spices against *Salmonella* (Arora and Kaur, 1999; Ceylan and Fung, 2004; Du *et al*., 2009a; Tajkarimi *et al*., 2010; Hussien *et al*., 2011), or differences in growing/processing conditions, including *Salmonella* exposure. Reduced test sensitivity and antibacterial activity against *Salmonella* (Hammer *et al*., 1999; Burt, 2004; Du *et al*., 2009b; Tajkarimi *et al*., 2010) were not sufficient to significantly limit the prevalence of *Salmonella* in imported shipments of oregano and allspice in the U.S. study; the shipment prevalence of *Salmonella* for these two spices was 12% (750 g; 95% CI 5.8-22%).

Salmonella frequency and prevalence in shipments of specific types of imported spices was also evaluated, Table 4.3. Values are presented for spices for which there were at least 65 shipments examined during the three-year period. In this section of Table 4.3, different spices with the same common name, such as coriander seed and leaf, were grouped together. “Capsicum” includes paprika as well as hot and other sweet dried capsicum peppers. In a few cases, we grouped results for different spices together in order to be able to include these data in Table 4.3 and meet the minimum number of shipments. We included the “spices/spices and seasonings, NEC (not elsewhere classified)” category because “NEC” products codes are commonly assigned to imported spice shipments and this category includes less common spices and spice mixtures. Observed prevalence values ranged from 1%, for shipments of white pepper (750 g; 95% CI 0-6%) or the sum of shipments of cinnamon/cassia, clove and nutmeg (750 g; 95% CI 0-7%), to 14% (750 g; 95% CI 8.3- 22%) for coriander. Application of the chi square test for multiple proportions indicates that the prevalence values for the different types of spices are not all the same (test statistic (50.8) > chi-square critical value (21.03) at the 95% confidence level). However, there are not enough data for each type/category of spice to identify which differences are significant; the Marascuilo procedure did not identify any pairs of spice types that were statistically different. Additional research is needed to distinguish prevalence values among the spice types but these data demonstrate that *Salmonella* shipment contamination is common among a wide range of spice types.

The spice-specific prevalence values in Table 4.3 can be compared with values determined for these spices in other countries. Moreira *et al*. (2009) found major brands of retail black pepper collected in Botucatu, San Paolo, Brazil between January 2004 and April 2006 to have a statistically larger prevalence (18%, 25 g; 95% CI 1-30%, p <0.001) than that found in imported black pepper shipments in this report, even though the Brazilian screening test protocol was less sensitive (examined 25 g as compared with 750 g). While Brazil is a major global producer of black pepper, only 3 (1%) of the black pepper shipments examined in the U.S. study were imported from Brazil. Willis *et al.* (2009) found a smaller *Salmonella* prevalence for sesame seeds at retail in the United Kingdom (1.7%; 25 g; 95% CI 0.9-2.9%) than that found in the U.S. study (p<0.001). In this U.K. study, the mass of spice examined in the screening test was smaller than that used in the U.S. study (25 g as compared with 750 g; Willis *et al*., 2009; Van Doren *et al*., 2013a; Table 4.1), which could have led to the smaller observed prevalence value.

Impact of processing on observed prevalence of **Salmonella** *in shipments of imported spice offered for entry to the United States, FY2007-FY2009*

The frequency and prevalence of *Salmonella* in shipments of spices that had undergone different processes, including pathogen reduction treatments, blending, or grinding, are compared to those for spices that had not undergone the process in Table 4.3. Spice shipments which were classified as “commercially sterile”, “heat treated”, or “irradiated” or for which the industry supplied product description specified that a pathogen reduction process treatment had been applied to the spice (for example, “steam treated” or “treated with ethylene oxide”) were grouped together in Table 4.3 as “Spices subjected to a Pathogen Reduction Treatment.” A more detailed analysis of these data was precluded because some of these classifications do not differentiate among treatment types and the total number of shipments in this group was small. All other shipments were grouped in “Spices Not Treated/Not known if treated.” We do not know whether the small number of spice shipments in this category is a true reflection of the proportion of imported spice shipments that have been subjected to such treatments because importers are not required to provide process treatment information unless the spice shipment has been irradiated and even in this case, the FDA product code builder (FDA, 2012j) allows importers to choose other ways of defining their product. Therefore, it is possible that the "Spices Not Treated/Not known if treated" group includes spice shipments that had undergone a pathogen reduction treatment before U.S. entry.

The observed *Salmonella* prevalence for spice shipments subjected to a pathogen reduction treatment before U.S. entry was approximately one-half that for shipments of spices that were not treated or for which no treatment information was provided but the difference is not statistically significant (Fisher Exact Test). The confounding of treated and untreated spice shipments in the "Not treated/Not known" category could be responsible for the similarity of these prevalence values. What is more important is the fact that shipments of "treated" spices were found to contain *Salmonella*. Effective pathogen reduction treatments should not leave any viable *Salmonella* bacteria in the spice. Sagoo *et al*. (2009) also reported finding "treated" spice samples at retail in the United Kingdom with unsatisfactory microbiological quality but did not note whether *Salmonella* was found. *Salmonella* contamination of "treated" shipments could reflect insufficient pathogen reduction treatment and/or post-treatment contamination. No information was available on whether the treatment processes applied to the spices had been validated and as is discussed in detail in Section 8.2.1, different treatment processes and treatment conditions can result in very different net reductions in microbial populations.

The *Salmonella* prevalence for shipments of blended spices (mixtures) was statistically similar to that for non-blended spice shipments. Similarly, shipments of ground/cracked spice were not found to have statistically different prevalence values than shipments containing whole spice. While no differences were apparent when comparing the average prevalence for these different categories of spice shipments across all types of spices, significant differences did exist for some types of spices. For example, larger prevalence values were found for shipments of imported ground/cracked capsicum and coriander shipments as compared with their whole counterparts, Table 4.4, with relative risks of contamination of 11 (750 g; 95% CI, 2-220) and >10 (750 g; 95% CI , 2-∞) respectively. In contrast, differences in shipment prevalence were not observed for ground/cracked cumin or black pepper as compared with their whole counterparts, Table 4.4. In the United Kingdom, Sagoo *et al*. (2009) found that a larger proportion of spice flakes had unsatisfactory microbiological quality than those in their whole form, but did not specify whether this difference was primarily related to *Salmonella* presence/absence. There are a number of hypotheses that can explain the differences in observed prevalence for ground/cracked versus whole forms of capsicum or coriander observed (e.g., introduction of *Salmonella* during the grinding/cracking process or more efficient detection of *Salmonella* in these ground spices due to dispersion of originally highly localized contamination); additional research is needed to distinguish among them.

Table 4.4. Comparison of observed prevalence of *Salmonella*-contaminated shipments of some whole and ground/cracked imported spice offered for entry to the United States, FY2007-FY2009.

	Whole Spice[a]			Ground/Cracked Spice[a]			
Spice	**# Positive**	**N**	***Salmonella* Shipment Prevalence (%)**	**# Positive**	**N**	***Salmonella* Shipment Prevalence (%)**	**Relative Risk (RR) [95% CI][b]**
Capsicums	1	122	0.8	33	366	9.0	11 [2-220]
Coriander	0	43	0.0	16	68	24	>10 [2- ∞]
Cumin	5	59	8	6	79	8	0.9 [0.2-3]
Pepper, Black	7	156	4	6	135	4	1.0 [0.3-3]

[a] Categorizations derived from product code (FDA, 2012j) and description. When description was insufficient to categorize, the sample was not included.

[b] Relative risk of shipment contamination for ground/cracked spice as compared with whole spice ; 95% exact confidence limit (Clopper and Pearson, 1934).

Impact of source country on observed prevalence of Salmonella *in shipments of imported spice offered for entry to the United States, FY2007-FY2009*

In order to examine whether the "country of origin" impacts the observed prevalence of *Salmonella* contamination of imported spice shipments offered for entry to the United States, values were determined for spice shipments imported from different countries without regard to spice type. In most cases, the exporting country is the country where the spice was grown, dried and, if applicable, processed but in some cases, the export country of record is not the country where the spice was grown.

Shipments from 79 different countries were examined during the study period; contaminated shipments came from 37 different countries. Contamination of spice shipments is not limited to only a few source countries. *Salmonella* shipment frequency and prevalence values by country are provided in Table 4.5; only countries for which at least 65 imported shipments were examined are included. Country-specific prevalence values range from 0.9% (750 g; 95% CI 0-5%) for spice shipments imported from Canada to 14% (750 g; 95% CI 8.6-21%) for shipments imported from Mexico. Application of the chi-square test for multiple proportions determined that the *Salmonella* prevalence values among this set of countries are not all statistically similar (Van Doren *et al.*, 2013a). More research is needed to understand the differences in prevalence of *Salmonella* in spice imported from some countries.

Table 4.5. Observed prevalence of *Salmonella*-contaminated imported spice shipments offered for entry to the United States as a function of export country, FY2007-FY2009

Exporting Country	# Positive	N	*Salmonella* Shipment Prevalence (%)	95% Confidence Interval[a]
Canada	1	110	0.9	0-5
China	9	245	4	2-7
India	92	1057	8.7	7.1-11
Indonesia	2	82	2	0-9
Mexico	19	136	14	8.6-21
Pakistan	6	205	3	1-6
Thailand	6	111	5	2-10
Vietnam	7	149	5	2-9
All other countries[b]	45	749	6.0	4.4-8.0

[a] 95% exact confidence limit (Clopper and Pearson, 1934).

[a] Totals 71 other countries for which fewer than 65 imported shipments were examined per country during FY2007-FY2009.

Willis *et al*. (2009) found the *Salmonella* prevalence for retail samples of seeds sold in the United Kingdom was smaller for seeds imported from the European Union member countries than for seeds imported from non-European Union member countries. Making the same comparison, we find that spice shipments from European Union member countries did not have a statistically smaller *Salmonella* prevalence value than shipments from non-European Union member countries ($p>0.05$), but we note that the total number of shipments from these European Union member countries was small (79).

Salmonella *serotype diversity isolated from spices in shipments of imported spice offered for entry to the United States, FY2007-FY2009*

Salmonella serotypes were identified (or partially identified) for isolates from most of the contaminated spice shipments (180/187). Multiple serotypes were identified in 12% (22) of the contaminated shipments yielding a total of 204 unique isolates. Nearly all of the isolates characterized were determined to be *Salmonella enterica* subspecies *enterica*. Six isolates were characterized as *Salmonella enterica* subspecies II, IIIa or IIIb, Table 4.6. The serotype *Salmonella* Rissen was not among the serotypes identified from *Salmonella* isolates examined in this surveillance study despite its association with a large scale outbreak attributed to contaminated imported white pepper that took place during the study period (CDPH/FDB/ERU, 2010). It was isolated from investigative samples associated with the outbreak.

The data in Table 4.6 establish that shipments of imported spices can be contaminated by a wide diversity of *Salmonella* serotypes. The most frequently observed serotype during the three year study was *Salmonella* Weltevreden, which constituted only 6.3% of all isolates characterized. Other studies have also reported a wide diversity of serotypes found in spices (Lehmacher *et al*., 1995; Sagoo *et al*., 2009; Willis *et al*., 2009). The observation that a single sample of spice can be contaminated with multiple *Salmonella* serotypes is also not unusual. In one paprika sample, Lehmacher *et al*. (1995) isolated eleven different serotypes.

Table 4.6. *Salmonella* serotype frequency and percentage among isolates[a] in surveillance samples of spice from shipments of imported spice offered for entry to the United States, FY2007-FY2009.

Serotype	# unique Isolates[b]	% of unique Isolates[b]	Spice
Weltevreden	13	6.3	anise, bay, capsicum, coriander, curry powder, onion, sesame seed, spices and seasonings NEC, white pepper
Newport	12	5.9	capsicum, cumin, curry powder, oregano, sesame seed, spices NEC
Mbandaka	11	5.4	capsicum, cumin, curry powder, garlic, sesame seed, spices and seasonings NEC
Agona	10	4.9	anise, black pepper, capsicum, cumin, curry powder, oregano
Bareilly	8	4	capsicum, coriander, cumin, curry powder, fennel, ginger
Montevideo	6	3	allspice, capsicum, coriander, mint, spices NEC
Senftenberg	6	3	curry powder, sesame seed, spices and seasonings NEC
Typhimurium	6	3	basil, black pepper, coriander, curry powder, five spice mix,
Anatum	5	2	capsicum, cumin, sesame, spices NEC
Aberdeen	4	2	ginger, coriander, curry powder
Cubana	4	2	celery, spices and seasonings NEC
Give	4	2	capsicum, oregano, sesame seed
Hvittingfoss	4	2	basil, coriander, spices NEC, turmeric
Mgulani	4	2	capsicum, spices and seasonings NEC
Paratyphi B var. L(+) tartrate +	4	4	capsicum, coriander, mint, spices and seasonings NEC
Rubislaw	4	2	black pepper, spices NEC
Tennessee	4	2	capsicum, sesame seed, spices and seasonings NEC
Virchow	4	2	basil, spices and seasonings NEC, turmeric
Derby	3	1	black pepper, five spice mix, sage
Enteritidis	3	1	black pepper, spices and seasonings NEC
Poona	3	1	celery, coriander, turmeric
Sandiego	3	1	cardamom, coriander, cumin
3,10:b:-	2	1	capsicum, sesame seed
Bere	2	1	coriander, spices and seasonings NEC
Bergen	2	1	curry powder, spices and seasonings NEC
Cerro	2	1	sesame seed, turmeric
Havana	2	1	sesame seed, spices and seasonings NEC
Javiana	2	1	allspice, black pepper
Kentucky	2	1	cumin, sesame seed
London	2	1	coriander, fenugreek
Saintpaul	2	1	cumin, mustard
Schwarzengrund	2	1	capsicum, turmeric
II 40:z4,z24:z39	2	1	anise, oregano
IIIb	2	1	mint, spices NEC
Barranquilla	1	0.5	capsicum
Brindisi	1	0.5	sage
39:z10:z6	1	0.5	cumin

Serotype	# unique Isolates[b]	% of unique Isolates[b]	Spice
43:z4,z23:-	1	0.5	spices NEC
47: z4, z23: -	1	0.5	curry powder
48:d:z6	1	0.5	cinnamon/cassia
6, 14 : a : 1, 5	1	0.5	spices NEC
6,7,14:e,n,z15	1	0.5	capsicum
Abaetetuba	1	0.5	basil
Adabraka	1	0.5	coriander
Altona	1	0.5	capsicum
Ball	1	0.5	black pepper
Bangkok	1	0.5	spices and seasonings NEC
Bonn	1	0.5	sesame seed
Braenderup	1	0.5	black pepper
Brazzaville	1	0.5	capsicum
Bredeney	1	0.5	capsicum
Canada	1	0.5	black pepper
Carmel	1	0.5	coriander
Carrau	1	0.5	oregano
Dublin	1	0.5	curry powder
Eastbourne	1	0.5	turmeric
Elokate	1	0.5	black pepper
Freetown	1	0.5	spices NEC
Gamaba	1	0.5	cumin
Gaminara	1	0.5	coriander
Glostrup	1	0.5	sesame seed
Hermannswerder	1	0.5	sage
Idikan	1	0.5	sesame seed
Lexington	1	0.5	ginger
Llandoff	1	0.5	sesame seed
Martonos	1	0.5	capsicum
Minnesota	1	0.5	basil
Molade	1	0.5	capsicum
Muenchen	1	0.5	capsicum
Muenster	1	0.5	spices and seasonings NEC
Nordrhein	1	0.5	capsicum
Nottingham	1	0.5	oregano
Oranienburg	1	0.5	oregano
Orion	1	0.5	curry powder
Othmarschen	1	0.5	spices NEC
Paratyphi B	1	0.5	turmeric
Potsdam	1	0.5	sesame seed
Richmond	1	0.5	spices and seasonings NEC
Simi	1	0.5	sage
Stanley	1	0.5	capsicum
Sundsvall	1	0.5	capsicum
Telelkebir	1	0.5	cumin
Telhashomer	1	0.5	fenugreek
Umbilo	1	0.5	five spice mix
Vejle	1	0.5	black pepper
Westminster	1	0.5	sesame seed
Wichita	1	0.5	spices and seasonings NEC
IIIa 48:z4,z24:-	1	0.5	sesame seed
IIIa	1	0.5	capsicum

[a] *Salmonella enterica* subspecies enterica unless otherwise note; partial serotypes included. Where appropriate, serotype names reported have been combined in this frequency table e.g., “Sieburg” is listed with Cerro, as compared with the table presented in Van Doren *et al.*, 2013a.

[b] For each spice shipment sampled, the number of unique isolates identified is the number of different serotypes identified. Therefore, the number (percent) of isolates is the number (percent) of contaminated spice shipments found with that serotype.

Similar serotype diversity has been observed among *Salmonella* isolates from all FDA-regulated imported foods (Zhao *et al*., 2003; Zhao *et al*., 2006). Further, the most common serotypes found in spice shipments offered for entry to the United States do not appear to differ substantially from those reported for all types of FDA-regulated imported food shipments offered for entry and sampled by FDA (Zhao *et al*. 2003, Zhao *et al*. 2006). For example, Weltevreden and Newport were the two most common serotypes isolated from imported spice shipments offered for entry to the United States during FY2007-FY2009 (U.S. study) and were among the top four serotypes isolated in 2000 and 2001 from examined imported shipments of FDA-regulated foods offered for U.S. entry (Zhao *et al*., 2003; Zhao, *et al*. 2006). These data support the hypothesis that the serotypes most frequently isolated from imported spices are not specific to or preferentially found in spices. A more detailed comparison of serotype prevalence values for spices and other imported FDA-regulated foods is not possible because of the significant differences in sample design between the FDA FY2007-FY2009 study (Van Doren *et al*., 2013a) and the studies of Zhao and coworkers (Zhao *et al*., 2003; Zhao *et al*., 2006; Zhao, 2008), where data for spices and targeted samples, such as samples collected as part of an outbreak investigation, were included in the summary statistics. Inclusion of targeted samples in the analysis of serotype prevalence will generally bias values to serotypes associated with the triggering event because multiple samples of the same food source are sampled.

We can also compare the *Salmonella* serotypes isolated from spices offered for import to the United States with those isolated from food samples in other countries. Among the 42 serotypes isolated from food samples collected during 2007-2009 in Asia (a major source of spices for the United States) and reported to the World Health Organization (WHO) Global Foodborne Infections Network (WHO/GFN, 2012), half were also isolated from spices in the U.S. study (Table 4.6).

The serotype diversity observed for isolates from spices offered for import to the United States and imported FDA-regulated foods in general, differs in character with that generally observed for isolates from animal meats for which a small number of predominant serotypes is common (USDA/FSIS, 2012; FDA, 2012a; FDA, 2012c; Sasaki *et al*., 2012; Guo *et al*., 2011; Yang *et al*., 2010; Kudaka *et al*., 2006; Cui *et al*., 2005). The much wider diversity of *Salmonella* serotypes found in spices may be a reflection of a much wider diversity of contamination sources, such as soil, water, rodents, birds, and insects, as compared with that for animal-derived meat products.

Antimicrobial resistance of* Salmonella *isolated from spices in shipments of imported spice offered for entry to the United States, FY2007-FY2009

Fourteen (6.8%) of the *Salmonella* isolates from imported spice shipments offered for entry to the United States during the three-year study period FY2007-FY2009 were found to exhibit antimicrobial resistance, Table 4.7. Approximately half (8/14) of the isolates with antimicrobial resistance were found to be resistant to three or more antimicrobials. Two isolates (*Salmonella* serotypes Agona and Newport) were resistant to seven antimicrobials. Perhaps most importantly, approximately one-quarter of the resistant strains (4/14) were resistant to first-line antimicrobial agents used to treat salmonellosis in some populations (Guerrant *et al*., 2001; Thielman and Guerrant, 2004): trimethoprim/sulfamethoxazole (2) and ceftriaxone (2). None of the isolates was resistant to ciprofloxacin, another first-line antimicrobial for salmonellosis (Guerrant *et al*., 2001), although many were resistant to nalidixic acid (8/14), which has been found to be an indicator of low level resistance to fluoroquinolones (Rodriguez-Avial *et al*., 2005; Threlfall *et al*., 2006) and may be a first step towards the development of resistance to ciprofloxacin (Van Looveren *et al*., 2001). Other common antimicrobial resistances exhibited among the resistant isolates were to sulfisoxazole (10/14), tetracycline (9/14), chloramphenicol (6/14), streptomycin (5/14), kanamycin (4/14) and ampicillin (3/14). No resistance was observed among the isolates to amikacin, amoxicillin/clavulanic acid, or cefoxitin. The isolation of highly resistant *Salmonella* strains from spices has been reported by others (Zhao *et al*., 2006, Zhao, 2008; Brockmann *et al*., 2004) including *Salmonella* Typhimurium DT 104, which was involved in the 2001 salmonellosis outbreak associated with sesame seed-helva consumption (Fisher *et al*., 2001; Brockmann, 2001; Little, 2001; Guérin, 2001) and is characteristically resistant to ampicillin, chloramphenicol, streptomycin, sulfonamide and tetracycline (ACSSuT). This phenotype was observed in one isolate each of serotype Typhimurium and Agona in the U.S. study, Table 4.7.

The prevalence of antimicrobial resistant *Salmonella* strains in imported spices contaminated with *Salmonella* does not appear to be larger than that found for strains isolated from imported FDA-regulated foods in general (Zhao *et al*., 2003; Zhao *et al*., 2006; Zhao, 2008) and is smaller than that reported for retail meats in the United States (USDA/FSIS, 2012), Japan (chickens; Sasaki *et al*., 2012) or in China (Yang *et al*. 2010). As with the serotype diversity, the smaller antimicrobial resistance profile for spices as compared with retail meats is consistent with a much wider diversity of contamination sources.

Table 4.7. Antimicrobial Resistance of *Salmonella enterica* subspecies *enterica* isolates from FDA surveillance sampling of spices from shipments of imported spice offered for entry to the United States, FY2007-FY2009.

Serotype	Amikacin	Amoxicillin/ Clavulanic Acid	Ampicillin	Cefoxitin	Ceftriaxone	Chloramphenicol	Ciprofloxacin	Gentamicin	Kanamycin	Nalidixic Acid	Sulfisoxazole	Tetracycline	Trimethoprim/ Sulfamethoxazole	Streptomycin	Export Country	Spice
43:z4,z23:-	s	s	s	s	s	s	s	s	s	s	R	s	s	s	Thailand	spices NEC
Agona	s	s	R	s	R	R	s	s	R	s	R	R	s	R	Mexico	oregano
Bareilly	s	s	s	s	s	s	s	s	s	s	R	s	s	s	Trinidad and Tobago	curry powder
Bredeney	s	s	s	s	s	s	s	s	R	R	R	R	s	R	Syrian Arab Republic	capsicum
Derby	s	s	s	s	s	R	s	s	s	R	s	R	s	s	China (Mainland)	five spice mix
Give	s	s	s	s	I	s	s	s	s	R	s	s	s	s	India	capsicum
Havana	s	s	s	s	s	R	s	s	s	s	s	s	s	s	India	spices and seasonings NEC
Muenster	s	s	s	s	s	R	s	s	s	R	R	R	s	R	Pakistan	curry mix
Newport	s	s	R	s	s	s	s	R	R	s	R	R	R	R	Mexico	oregano
Siegburg	s	s	s	s	s	s	s	s	s	R	s	s	s	s	India	turmeric
Typhimurium	s	I	R	s	s	R	s	s	s	R	R	R	s	R	Egypt	basil
Typhimurium	s	s	s	s	s	s	s	s	s	s	R	R	s	s	Pakistan	curry mix
Virchow	s	s	s	s	s	s	s	s	s	R	R	R	R	s	India	turmeric
Virchow	s	s	s	s	s	R	s	s	R	R	R	R	s	s	Egypt	basil

[a] Resistant (R), Intermediate (I), Susceptible (s), Not Tested (-).

Salmonella *concentration in shipments of imported capsicum and sesame seed offered for entry to the United States, Aug-Dec 2010*.

In order to determine the typical concentrations of *Salmonella* in spice shipments offered for entry to the United States, FDA undertook a special sampling assignment targeting two spices: capsicum and sesame seed. The short term assignment was designed to sample shipments randomly and thereby provide a snapshot of the shipment distribution with respect to *Salmonella* presence and concentration. A full report on this study has been published (Van Doren *et al.*, 2013c). A total of 299 capsicum and 233 sesame seed shipments were sampled. Results and discussion relevant to this section of the risk profile are presented below. Full details of the sampling plan and methods used in the study as well as characteristics of the shipments sampled are provided in Appendix C.

Screening and MPN test results are presented in Table 4.8. Between-shipment distributions of *Salmonella* mean concentrations in contaminated shipments examined varied widely among sampled shipments with estimated mean shipment concentrations among contaminated shipments ranging from 6×10^{-4} to 0.09 MPN/g (6 MPN per 10,000 g to 9 MPN per 100 g) for capsicum shipments and 6×10^{-4} to 0.04 MPN/g (6 MPN per 10,000 g to 4 MPN per 100 g) for sesame seed shipments. Within-shipment contamination observed was not inconsistent with a Poisson distribution. Our experiments were not capable of discerning the within-shipment contamination distribution among spice-serving sized samples.

Observations from this 2010 FDA study were used to develop a model of between- and within-shipment *Salmonella* contamination of imported capsicum or sesame seed shipments offered for entry to the United States. Six parametric models were examined; four of these are illustrated in Figures 4.1 and 4.2. The best-fit models of contamination for both shipments of imported capsicum and imported sesame seed were gamma-Poisson distributions (nominal shipment contamination prevalence of 100%), as determined by AIC, i.e., between-shipment mean concentrations of contamination were described by a gamma distribution while within-shipment distribution was described by a Poisson distribution. The assumption of Poisson-distributed within-shipment contamination was explicitly examined in the study for both types of spices and it was found that the data were not inconsistent with the assumption (Van Doren *et al.*, 2013c).

The observations and models developed in the 2010 FDA study predict that most contaminated shipments of capsicum or sesame seeds contain relatively small mean concentrations of *Salmonella*. As a consequence, sampling plan design, particularly selections of an appropriate sample size and validated method of analysis, are critical to ensure efficient surveillance. For the best-fit parametric model descriptions of *Salmonella* contamination found in this study, we estimate that approximately 25-50% of contaminated capsicum or sesame seed shipments examined would be detected by FDA's standard 750 g or 1500 g testing protocols. In contrast, sampling protocols examining only 25 g of sample would be much less efficient, detecting approximately 5-10% of contaminated shipments examined. These results and others are shown in Appendix C, Table C3.

Table 4.8. Screening and enumeration test results for *Salmonella* in sampled shipments of imported capsicum or sesame seed offered for entry to the United States August-December 2010

Spice	# Shipments	Mean Composite Concentration (MPN/g) [95% CI] (MPN Pattern)[a]				Mean Shipment Concentration (MPN/g)[a] [95% CI]
		Composite 1	Composite 2	Composite 3	Composite 4	
Capsicum	3	0.002 [0.00027-0.015] (1/0,0,0,0)	(0/NA)	(0/NA)	(0/NA)	0.0006 [0.00008-0.0043]
	1	0.0097 [0.0026-0.036] (1/2,0,0,0)	(0/NA)	(0/NA)	(0/NA)	0.0020 [0.0006-0.0062]
	1	0.002 [0.00027-0.015] (1/0,0,0,0)	0.002 [0.00027-0.015] (1/0,0,0,0)	(0/NA)	(0/NA)	0.0011 [0.0003-0.0046]
	1	(1/POS)	(1/POS)	(1/POS)	(0/NA)	0.0054 [0.0021-0.0135]
	1	0.002 [0.00027-0.015] (1/0,0,0,0)	0.0048 [0.0011-0.021] (1/1,0,0,0)	0.0080 [0.0023-0.028] (1/1,1,0,0)	(0/NA)	0.0035 [0.0015-0.0081]
	1	0.0048 [0.0011-0.021] (1/1,0,0,0)	0.0048 [0.0011-0.021] (1/1,0,0,0)	0.0097 [0.0026-0.036] (1/2,0,0,0)	(0/NA)	0.0045 [0.0020-0.0097]
	1	0.002 [0.00027-0.015] (1/0,0,0,0)	0.002 [0.00027-0.015] (1/0,0,0,0)	0.002 [0.00027-0.015] (1/0,0,0,0)	0.0097 [0.0026-0.036] (1/2,0,0,0)	0.0033 [0.0014-0.0076]
	1	0.023 [0.0057-0.093] (1/3,0,0,0)	0.092 [0.022-0.38] (1/3,2,0,0)	0.23 [0.057-0.94] (1/3,3,0,0)	0.23 [0.057-0.94] (1/3,3,0,0)	0.092 [0.045-0.19]
Sesame Seed	2	(1/POS)	(0/NA)	(0/NA)	(0/NA)	0.0014 [0.0003-0.0056]
	7	0.002 [0.00027-0.015] (1/0,0,0,0)	(0/NA)	(0/NA)	(0/NA)	0.0006 [0.00008-0.0043]
	1	0.0048 [0.0011-0.021] (1/1,0,0,0)	(0/NA)	(0/NA)	(0/NA)	0.0013 [0.0003-0.0051]
	1	(1/NA)	(1/NA)	(0/NA)	(0/NA)	0.0018 [0.0004-0.0076]
	1	(1/NEG)	(1/POS)	(0/NA)	(0/NA)	0.0019 [0.0006-0.0061]

Spice	# Shipments	Mean Composite Concentration (MPN/g) [95% CI] (MPN Pattern)[a]				Mean Shipment Concentration (MPN/g)[a] [95% CI]
		Composite 1	Composite 2	Composite 3	Composite 4	
	2	0.002 [0.00027-0.015] (1/0,0,0,0)	0.002 [0.00027-0.015] (1/0,0,0,0)	(0/NA)	(0/NA)	0.0011 [0.0003-0.0046]
	1	(1/NA)	(1/NA)	(1/NA)	(0/NA)	0.0037 [0.0011-0.0126]
	2	(1/POS)	(1/POS)	(1/POS)	(0/NA)	0.0054 [0.0021-0.0135]
	1	0.0043 [0.001-0.018] (1/0,1,0,0)[b] Revised[c]: (1/POS)	0.032 [0.013-0.078] (1/2,0,2,2)[b] Revised[c]: (1/POS)	0.038 [0.0096-0.15] (1/3,0,1,0)[b] Revised[c]: (1/POS)	(0/NA)	0.0104 [0.0059-0.019]
	1	(1/POS)	(1/POS)	(1/POS)	(1/POS)	> 0.006
	1	0.0048 [0.0011-0.021] (1/1,0,0,0)	0.0097 [0.0026-0.036] (1/2,0,0,0)	0.0097 [0.0026-0.036] (1/2,0,0,0)	0.015 [0.0046-0.048] (1/2,1,0,0)	0.0091 [0.0048-0.017]
	1	0.0097 [0.0026-0.036] (1/2,0,0,0)	0.0097 [0.0026-0.036] (1/2,0,0,0)	0.015 [0.0046-0.048] (1/2,1,0,0)	0.023 [0.0057-0.093] (1/3,0,0,0)	0.013 [0.0069-0.024]
	1	0.023 [0.0057-0.093] (1/3,0,0,0)	0.042 [0.0098-0.18] (1/3,1,0,0)	0.042 [0.0098-0.18] (1/3,1,0,0)	0.093 [0.022-0.39] (1/3,2,0,0)	0.042 [0.020-0.088]
	1	0.023 [0.0057-0.093] (1/3,0,0,0)	0.023 [0.0057-0.093] (1/3,0,0,0)	0.023 [0.0057-0.093] (1/3,0,0,0)	0.23 [0.057-0.94] (1/3,3,0,0)	0.036 [0.017-0.074]

[a] Screening and enumeration test results as reported and described in Van Doren *et al.*, (2013c). 95% confidence limits on mean concentration are provided in brackets (Blodgett, 2010). MPN pattern for composite samples, given in parentheses, includes 1/ for the positive screening test followed by the number of tubes at each dilution that tested positive, ordered from highest to lowest sample mass used (375g/100g,10g,1g,0.1g); 1/POS for composites in which one or more tubes in the dilution assay tested positive for *Salmonella*; 1/NEG for composites in which none of the dilution assay tubes tested positive; 1/NA or 0/NA for composites in which no follow-up dilution assay was performed. Estimates for the mean *Salmonella* concentration in the shipment was determined from the full set of test results for that shipment. See Van Doren *et al*. (2013c) for details.

[b] Rarity index for dilution assay results is small (<0.05), indicating the pattern is unusual/unexpected.

[c] We use the binary dilution assay result (POS/NEG) (noted as "Revised") when developing models of shipment contamination. See Van Doren *et al*. (2013c) for additional detail

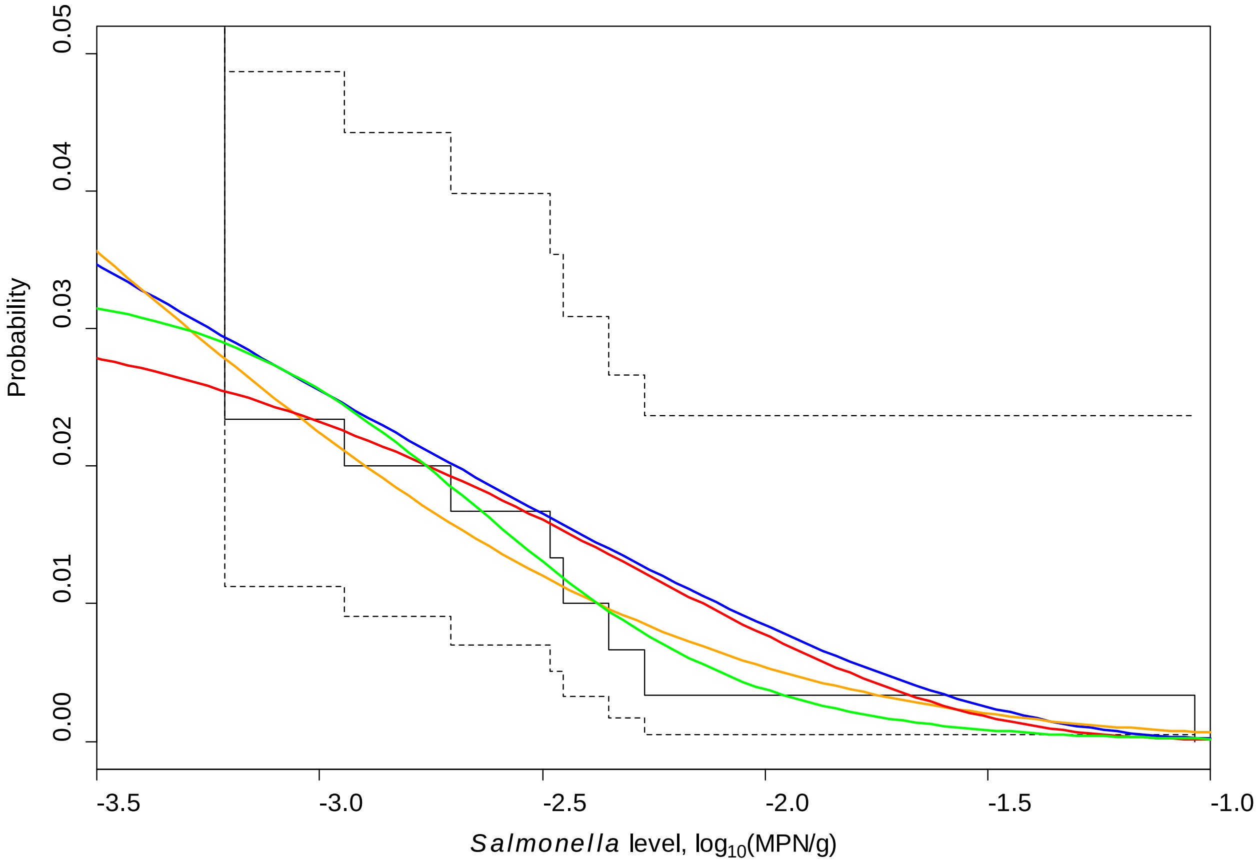

Figure 4.1. Complementary cumulative distribution functions (p × (1-CDF(λ)) for models of *Salmonella* contamination among shipments of imported capsicum offered for entry to the United States compared with observations. The series of solid black steps illustrates the observed between-shipment distribution; dashed series of steps describe the 95% confidence limits for observed values (Kaplan-Meier estimates; Kaplan and Meier, 1958). Smooth curves illustrate model estimates: gamma-Poisson (blue), lognormal-Poisson (orange), log-logistic-Poisson (green), and Weibull-Poisson (red).

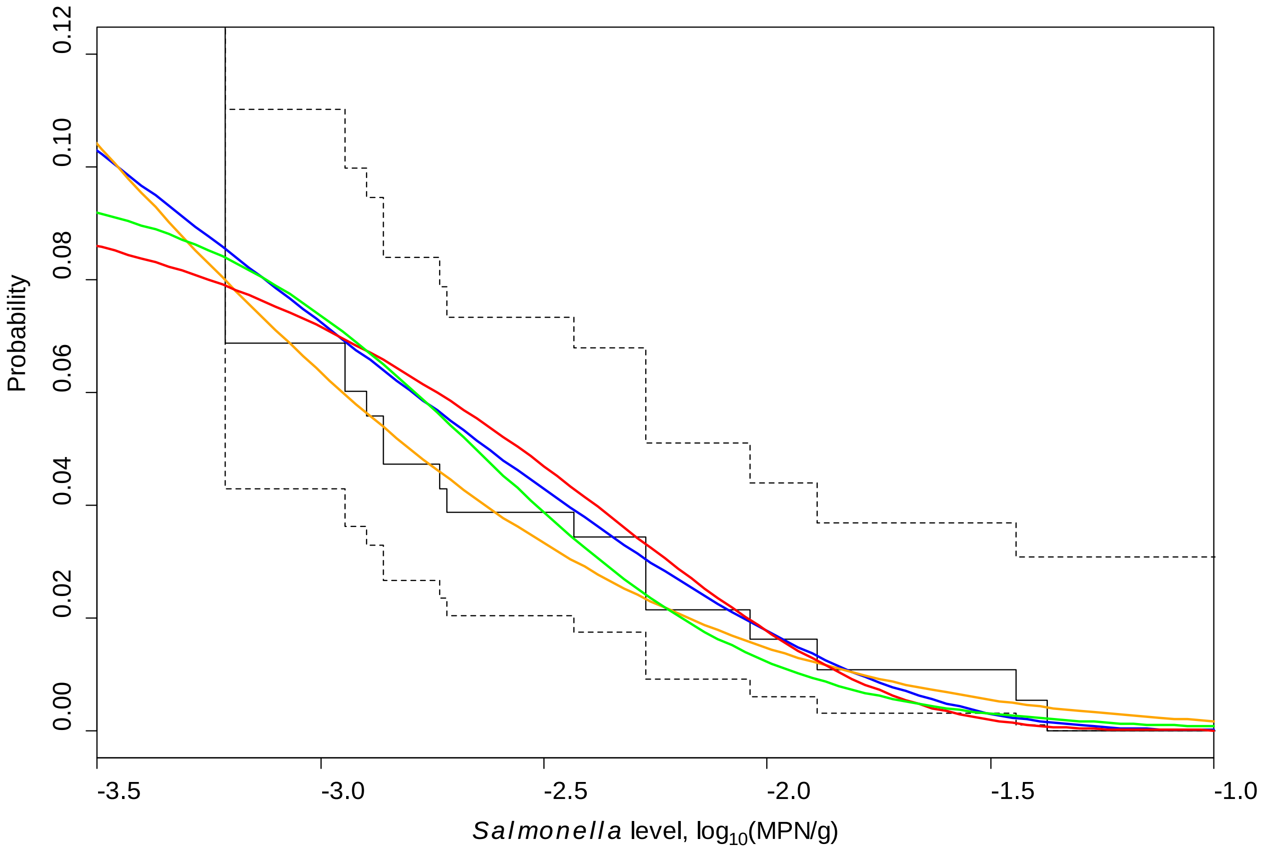

Figure 4.2. Complementary cumulative distribution functions (p× (1-CDF(λ)) for models of *Salmonella* contamination among shipments of imported sesame seeds offered for entry to the United States compared with observations. The series of solid black steps illustrates the observed between-shipment distribution; dashed series of steps describe the 95% confidence limits for observed values (Kaplan-Meier estimates; Kaplan and Meier, 1958). Smooth curves illustrate model estimates: gamma-Poisson (blue), lognormal-Poisson (orange), log-logistic-Poisson (green), and Weibull-Poisson (red).

4.1.4 SECONDARY PROCESSING AND FOOD MANUFACTURING

As described in Chapter 6, spices may undergo a number of processes such as removal of debris, cracking/grinding, blending, pathogen reduction treatment, and/or re-packing at secondary spice processing facilities and may be added to foods in food manufacturing facilities. Once added to foods, the spice may be subjected to a pathogen reduction treatment, such as cooking. Because spices are shelf-stable, they are commonly warehoused.

Information about the prevalence of *Salmonella* in spice lots in ASTA member spice processing facilities was provided by data submitted by ASTA in response to the Federal Register Notice and is discussed below in Section 4.1.4.1. Sagoo *et al*. (2009) found a *Salmonella* prevalence of 1% (135 g; 95% CI 0.2-5%) for a wide variety of spices collected from spice “production” facilities (secondary spice processing facilities) in the United Kingdom, Table 4.1. Two of the *Salmonella*-positive spice samples in the study reported by the Food Safety Authority of Ireland (FSAI, 2005) were from (1) an “import or production or packing premises or wholesaler” and (2) an “establishment[s] using large amounts of herbs/spices for food preparation.” A study examining spices in processing plant facilities in Belgium found no samples contaminated with *Salmonella* (25 g; 95% CI 0-10%; EFSA, 2006a), Table 4.1. The FDA RFR also provides data on the frequency of *Salmonella*-positive spice samples found in FDA-registered facilities, which include facilities that distribute, process, pack/re-pack, and store spices. Data from the first three years of the RFR are described below. Spice/food recalls associated with *Salmonella*-positive samples may arise from samples collected from pre-retail sites or retail/end user sites. Information about spice-associated U.S. recalls is provided in Section 4.1.6.

4.1.4.1 *SALMONELLA* PREVALENCE IN SPICE SAMPLES COLLECTED IN SPICE INDUSTRY MANUFACTURING FACILITIES (ASTA MEMBERS)

ASTA submitted a large set of microbiological testing data on spice lots (ASTA, 2010; Ruckert, 2010) in response to the Federal Register Notice requesting scientific data and information to support development of the risk profile on pathogens and filth in spices (FDA, 2010e). According to the submission, "The ASTA members that provided the information handled more than 50% of the spices distributed during the reporting period (August 1, 2007-July 31, 2009)" (Ruckert, 2010), i.e., domestic and imported spices sold in the United States (Van Doren, 2011). Unfortunately, it is not possible to determine from the information provided, the fraction of spice distributed that are represented by this data set. However, this data set does provide some information on the relative prevalence of *Salmonella* and generic *Escherichia coli* in spice lots that had not undergone a pathogen reduction treatment as compared with those that had undergone such a treatment, information that is not easily determined from FDA surveillance data.

Methods of analysis and sample mass tested in the *Salmonella* screening tests varied somewhat among the different contributing ASTA members, according to the ASTA submission (Ruckert, 2010). Specifically, the submission indicates that at least one composite sample was tested for *Salmonella* for each result, that "a number of participants followed the Bacteriological Analytical Manual FDA Category II or Category III testing procedures for *Salmonella*," and that the mass of that composite sample "ranged between 25 to 375 grams." (Ruckert, 2010). No other method/sample-mass information was provided. Because the sensitivity of the test depends strongly on the mass of spice analyzed and can also depend on the sample compositing scheme (Bassett *et al.*, 2010), the absence of this information complicates interpretation of the *Salmonella* lot prevalence values derived from these data and quantitative comparisons within this data set and with other data sets.

Table 4.9 summarizes the data ASTA provided on the prevalence of *Salmonella* in spice lots that had not been subjected to a pathogen reduction treatment and includes an average prevalence value for all spice lots tested and individual prevalence values for types of spice for which at least 55 lots were tested. We decided to use this slightly smaller cutoff for inclusion to allow more comparisons between pre/no treatment and post-treatment spice from this data set. Confidence limits are provided for all values.

Table 4.9. Observed prevalence of *Salmonella* contamination in spice lots from some ASTA member companies to which no pathogen reduction treatment had been applied, August 1, 2007-July 31, 2009

Spice	# Positive[a]	N	*Salmonella* Lot Prevalence (%)[a]	95% Confidence Interval[b]
All Spices	228	12178	1.87	1.64-2.13
Specific Spices				
Cassia	0	877	0	0.0-0.3
Cloves	0	60	0	0-5
Cumin Seed	50	191	26	20-33
Parsley	0	1032	0	0.0-0.3
Paprika	155	9731	1.59	1.35-1.86
Pepper, Black	19	55	35	22-49
All other spices	4	232	2	0.5-4

[a] Screening tests examined a total of 25-375 g spice.

[b] 95% exact confidence limit (Clopper and Pearson, 1934).

The average *Salmonella* prevalence value for all spice lots examined (1.87%; 25-375 g; 95% CI 1.64-2.13%) is strongly influenced by the prevalence among paprika lots because 80% of the lots tested were paprika. Assuming that the distribution of testing procedures were approximately the same for the different types of spice, these data suggest that lots of untreated black pepper and cumin seed are more likely to be contaminated with *Salmonella* than lots of other types of spice and that lots of untreated cassia, parsley, and possibly also cloves, are unlikely to be contaminated, at least from the sources and suppliers used by the members of ASTA who contributed to this data set.

Table 4.10 provides information on the prevalence of *Salmonella* in spice lots that had been subjected to a pathogen reduction treatment, including values for specific types of spice for which at least 65 lots were tested.

Table 4.10. Observed prevalence of *Salmonella* contamination of spice lots from some ASTA member companies to which a pathogen reduction treatment had been applied, August 1, 2007-July 31, 2009

Spice[a]	N	# Positive[b]	*Salmonella* Lot Prevalence (%)[b]	95% Confidence Interval[c]
All Spices	3	18421	0.02	0.0-0.5
Specific Spices				
Anise	0	155	0.00	0-2
Basil	0	1383	0.00	0.0-0.2
Bay	0	123	0.00	0-2
Cassia/Cinnamon	0	460	0.00	0.0-0.6
Celery	0	310	0.00	0.0-1.0
Cloves	0	488	0.00	0.0-0.6
Coriander	0	488	0.00	0.0-0.6
Cumin	0	795	0.00	0.0-0.4
Dill	0	170	0.00	0-2
Fennel	0	533	0.00	0.0-0.6
Ginger	0	91	0.00	0.00-0.03
Marjoram	0	354	0.00	0.0-0.8
Nutmeg	0	256	0.00	0-1
Oregano	0	1192	0.00	0.0-0.3
Paprika	0	903	0.00	0.0-0.3
Parsley	0	95	0.00	0-3
Pepper, Black	1	5456	0.02	0.0-0.1
Pepper, White	0	971	0.00	0.0-0.3
Pepper, Red	1	2363	0.04	0.0-0.2
Rosemary	0	312	0.00	0-1
Sage	0	597	0.00	0.0-0.5
Savory	0	141	0.00	0-2
Thyme	0	436	0.00	0.0-0.6
Turmeric	0	136	0.00	0-2
All other spices	1	213	0.5	0.01-3

[a] Spice categories include all lots described by this name, e.g., "Pepper, Red" includes lots described as "Pepper, Red" and "Pepper, Red – High Heat" and "Dill" includes lots described as "Dill", "Dill Seed", or "Dill Weed."

[b] Screening tests examined a total of 25-375 g spice.

[c] 95% exact confidence limit (Clopper and Pearson, 1934).

Only three lots of treated spices tested positive post treatment during the two-year period: one lot each of black pepper, red pepper, and tarragon leaves. Of these lots, two had been treated with steam (one lot treated in the United States and the other lot treated in the source country) and one had been treated with ethylene oxide outside the spice source country (non-source/"other" country). There are not enough *Salmonella*-positive results to compare prevalence values by either treatment type or location.

The overall prevalence of *Salmonella* in the ASTA-member pathogen reduction treated spice lots sampled is statistically smaller than the value for imported spice shipments sampled at the point of entry to the United States during FY2007-FY2009. The difference is so large that it cannot be fully explained by a difference in sample size examined in the screening tests (25-375 g versus 750 g). Assuming that the methods of analysis used by ASTA members were validated and are comparable with the data from FDA and that the distribution of contamination within lots was not dramatically different than that found in the shipments examined by FDA, a plausible explanation for the difference observed is a difference in the sampled lots/shipments that had undergone a pathogen reduction treatment.

ASTA members also tested spice lots for generic *Escherichia coli* post treatment during this time period, Table 4.11. As with *Salmonella* sampling and testing data, contributing members used a number of different methods of analysis for *Escherichia coli*. "Typically," two methods with similar detection limits were employed (AOAC method 991.14 (< 10 CFU/g; as reported by Ruckert, 2010)[4] and AOAC method 966.24 (< 3 MPN/g; as reported by Ruckert, 2010). We presume both methods examined 50 g of sample (AOAC method 966.23, referenced in methods 991.13 and 966.24). Method descriptions are available from AOAC International (2005a, 2005b, 2005c). The three lots that tested positive for *Salmonella* post-treatment were not tested for the presence of *Escherichia coli*.

The data on the prevalence of generic *Escherichia coli* post-treatment in Table 4.11 provide insights into the effectiveness of bacterial reduction treatments and post-treatment preventive controls. The predominance of black pepper lots in the data set (representing 30% of all lots sampled and 78% of lots testing positive) strongly influences the summary statistics and confounds other factors such as spice form (ground/whole) or the type of pathogen reduction treatment applied. The observations of positive *Escherichia coli* tests on spice lots after pathogen reduction treatment indicate that either the treatments were not totally effective or post-treatment preventive controls were ineffective in preventing contamination or growth of remaining *Escherichia coli* in the spice. Further research is needed to determine the cause(s) for these observations and whether the cause could have implications for contamination of spice lots with other pathogens.

The sampling results in Table 4.11 also indicate that lots of ground black pepper sampled had a statistically larger prevalence of *Escherichia coli* when compared with raw/whole black pepper. This differs from the result found for *Salmonella* prevalence among sampled shipments of black pepper offered for entry to the United States (Table 4.4). These same data are reflected in the summary data for all raw/whole spices and ground spices in Table 4.11. Additional data are needed to determine the reason for the difference.

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[4] Ruckert (2010) reported AOAC method 991.1 but it is likely the method was 999.14, which is the Petrifilm™ *Escherichia coli* /Coliform Count Plate™ method.

Table 4.11. Frequency and prevalence of generic *Escherichia coli* contamination in spice lots in some ASTA member companies to which a pathogen reduction treatment had been applied, August 1, 2007-July 31, 2009

Spice	N	# Positive[a]	*Escherichia coli* Lot Prevalence (%)[a]	95% Confidence Interval[b]
All Spices[b]	25604	213	0.83	0.72-0.95
Spices subjected to different processes				
Raw/Whole spices[c]	11119	30	0.27	0.18-0.39
Ground Spices[c]	9291	170	1.83	1.57-2.12
Whole Black Pepper[c]	3742	18	0.48	0.28-0.76
Ground Black Pepper[c]	3966	138	3.48	2.93-4.10
Spice treated with Ethylene Oxide	11601	4	0.03	0.01-0.09
Spice treated with Steam	12086	208	1.72	1.50-1.97
Spice treated with Irradiation	345	0	0.0	0.0-0.9
Spice treated with PPO	303	1	0.3	0.01-2
Spice treated with unspecified pathogen reduction process[d]	1270	0	0.0	0.0-0.0.2

[a] We presume both methods examined 50 g of sample (AOAC method 966.23, referenced in methods 991.13 and 966.24).

[b] 95% exact confidence limit (Clopper and Pearson, 1934).

[b] Test data for one lot was excluded because of ambiguity as to whether the lot had undergone a pathogen reduction treatment before testing.

[c] Test data on lots for which raw/whole/ground status could not be determined were excluded in this analysis.

[d] Test data on lots for which a unique pathogen reduction process was not specified were grouped into this category.

4.1.4.2 FREQUENCY OF REPORTABLE FOOD REGISTRY ENTRIES ASSOCIATED WITH *SALMONELLA* –CONTAMINATED SPICES AND SEASONINGS.

The Reportable Food Registry was established by Section 1005 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), which amended the FD&C Act by creating a new section 417 of the FD&C Act, Reportable Food Registry [21 U.S.C. 350f.] (U.S.C. 2007)

The FDA Reportable Food Registry tracks patterns of adulteration of food in the United States by requiring industry (responsible parties) (FDA, 2010b) to submit reportable food (FDA, 2010c) reports when "there is reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals" (FDA, 2010c) and accepting voluntary reports from federal, state and local public health officials. More details about the program are provided in Section 8.1.3.4.

Within the "Spices and Seasonings" category, described in the RFR Commodity Definitions document (FDA, 2012e), *Salmonella* contamination led all other hazards reported in the first three years of the program. This category includes spices identified at 21 CFR 182.10 (FDA 2013f), and also lists examples of products such as whole and ground spices, rooibos, sesame seeds, poppy seeds, caraway, anise, fenugreek seeds, meat coatings and rubs, seafood seasonings, dried herbs, and dried ginger (FDA, 2012e.)

The number of primary entries, or the initial reports submitted by industry (responsible party) (FDA, 2010b) about a reportable food (FDA, 2010c) to FDA, reported for *Salmonella* in "Spices and Seasonings" was 16, 23, and 5 for years 1 (September 8-2009-September 7, 2010), 2 (September 8, 2010 – September 7, 2011), and 3 (September 8, 2011 – September 7, 2012), respectively. The frequency of primary entries for *Salmonella* in "Spices and Seasonings" was the largest among all 28 food categories in Year 1, second largest in Year 2 and tied for fourth largest (with two other RFR food commodities) in Year 3. However, it is difficult to interpret frequency values and relative rankings without knowledge of the total number of products/lots tested of each food commodity type.

4.1.5 RETAIL/END USER

We were unable to identify any reports characterizing *Salmonella* prevalence or concentration in spices at retail (food service, grocery store, restaurants, or in the home) in the United States. Information from the FDA targeted sampling assignment in 2010 established that shipments of imported spice offered for entry to the United States and packaged for retail may be contaminated and may comprise a significant percentage of the contaminated shipments (~ 20% for imported capsicum and sesame seed shipments sampled during the Aug-Dec 2010 study period; Van Doren *et al*., 2013c). Surveillance studies at retail have been conducted in a number of different countries, Tables 4.1 and 4.2. Observed prevalence values ranged from 0% (with non-zero upper limits) to 10% with varying confidence limits listed in Table 4.1. *Salmonella* has been found in a wide variety of spices and spice blends at retail (listed in Table 4.1). As mentioned previously, most of the studies examined small samples of spice, which limit the ability of the screening test to detect *Salmonella* at low concentrations.

Determinations of *Salmonella* concentrations in spices found at retail are listed in Table 4.2, with most arising from outbreak investigations. The largest concentration of *Salmonella* reported in a spice/spice blend was 11 MPN/g (Lehmacher *et al*., 1995), sampled from the food manufacturer's spice supply for the food implicated in the salmonellosis outbreak. A surveillance study from retail samples of black pepper and red pepper (capsicum) in Japan found mean concentrations of *Salmonella* of 0.086 MPN/g (86 MPN per 1000 g; Hara-Kudo *et al*., 2006; see Table 4.2 for details of calculation). Another surveillance study in the United Kingdom reported a range of *Salmonella* concentrations in sesame seeds and mixtures of seeds of <0.1-0.2 MPN/g (<10-20 MPN per 100 g; Willis *et al*., 2009).

4.1.6 FREQUENCY OF FOOD RECALLS IN THE UNITED STATES ASSOCIATED WITH *SALMONELLA*–CONTAMINATED SPICES

Recalls of food products can provide insights into the prevalence of contamination in foods at retail but can also involve spice/spiced-foods collected at other stages of the farm-to-table continuum, e.g., during spice processing or food manufacturing. In the United States, recalls are typically initiated when analysis has identified that a food does not meet regulatory requirements, e.g., the product is contaminated or is mislabeled, or when a spice/food has been linked to human illness, such as an outbreak. Class I recalls involve "a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death" whereas Class 2 recalls involve "a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote" (FDA, 2013c). FDA further distinguishes recall events as either primary or secondary. Primary recall events are recalls initiated by the firm in which the triggering violation was found or that caused the violation whereas secondary recalls arise from firms that are recipients of the violative products for use as an ingredient in a final product.

From 1969-2003, FDA identified 20 primary recalls of spices, all of which were because of *Salmonella* contamination (Vij *et al*., 2006). The one other recall noted in the report, associated with *Listeria monocytogenes* in bay leaves, was later determined to be a recall for fresh bay leaves, rather than dried bay leaves (Hogan, 2011). Most of the recalls (15/20) took place in the final four years of the study, 2001-2003. The large increase in recalls associated with *Salmonella*-contaminated spices in the latter four years of the study was attributed primarily to an increase in surveillance of Florida spice companies following a contamination finding in 2001 (Vij *et al*., 2006). None of the recalls were linked to outbreaks, despite the fact that some of the spice recalled had been marketed for some period of time (1-18 months; Vij *et al*., 2006).

More recently, FDA has reviewed primary recall events associated with contaminated spices during the two year period January 1, 2008-December 31, 2009 (that were classified by FDA by March 23, 2010). Eight primary recall events involving one hundred and sixteen different products were initiated because of the presence/potential presence of *Salmonella* (Ma, 2013). The eight spice-associated recalls represented 2% of all Class I and II primary recall events and 26% of the Class I and II primary recall events associated with *Salmonella* contamination during that time period (Ma, 2013). Products recalled in one spice-associated event were also implicated in or related to the *Salmonella* Rissen outbreak (described in Chapter 2) attributed to consumption of contaminated white pepper (Ma, 2013).

Root causes for the spice recalls were determined by a panel of seven FDA scientists from an analysis of the data and information provided by industry and FDA. Lack of supplier control was identified as a contributing factor in each of the eight primary recall events associated with *Salmonella* contamination of spices. In addition, insufficient/inadequate sanitation controls, environmental monitoring and training were also identified as root causes for the recalls associated with the white pepper outbreak (Ma, 2013).

The scope of spice recalls is not easily captured by the number of events or products recalled. For example, the single recall event in the United States involving ready-to-eat salami products related to the *Salmonella* Montevideo/Senftenberg outbreak associated with contaminated black and red pepper resulted in 234,686 pounds of salami products being recovered from the marketplace (USDA/FSIS, 2010). In the *Salmonella* Wandsworth and Typhimurium outbreak associated with a contaminated broccoli powder ingredient in a snack puff food, recalls focused on trying to capture some of the ~1.3 million bags of the snack food that had been distributed in the United States and Canada (Hogan, 2010).

4.1.7 INTERNATIONAL REPORTS OF FOOD SAFETY HAZARDS ASSOCIATED WITH *SALMONELLA*–CONTAMINATED SPICES - RASFF

The European Commission Rapid Alert System for Food and Feed (RASFF) notifies member states of the "existence of a serious direct or indirect risk to human health deriving from food or feed, this information is immediately notified to the Commission under the RASFF" (EC/DG SANCO, 2012a). During the years 2001-2011, 44.8% of RASFF notifications on selected biological hazards (including *Salmonella*, *Escherichia coli*, *Bacillus* spp., *Campylobacter* spp., *Listeria monocytogenes*, *Shigella* spp., *Staphylococcus aureus*, *Clostridium botulinum*, Hepatitis A, norovirus, and Caliciviruses) in food of non-animal origin were from the category "Herbs and Spices." Eighty percent of the "Herbs and Spices" RASFF notifications during this time period were associated with *Salmonella* (Altieri and Robinson, 2013; EC/DG SANCO, 2012b). Products in the "Herbs and Spices" category may include dry or fresh products.

4.2 FILTH

Methods of analysis used to determine filth adulteration of spice vary with filth element and spice type and form (e.g., ground or whole). All methods of analysis used by FDA are described in the Macroanalytical Procedures Handbook (FDA, 1998a). To determine whether the concentration of filth is less than the DAL (for natural or unavoidable defects in foods), FDA typically examines six spice subsamples taken from different portions of the spice shipment/lot. For example, the DALs for ground black pepper include specifications for insect fragment parts (≥475 insect fragments per 50-g spice) and rodent hairs (≥2 rodent hairs per 50-g spice). To determine whether a shipment of ground black pepper is adulterated with filth, FDA collects six 50-g samples and examines each subsample for insect fragment and rodent hairs. The shipment would be adulterated if the average concentration of either of the filth elements was not smaller than the DAL.

4.2.1. FILTH ADULTERATION PREVALENCE OF SPICE: FROM FARM TO TABLE OVERVIEW

Little experimental data have been reported on the prevalence or concentration of filth in spices throughout the farm-to-table continuum. FDA regularly samples imported foods including spices, for filth and these data were analyzed to provide a measure of the extent of filth contamination of imported spices at the point of import.

4.2.2. PRIMARY PRODUCTION

We were unable to identify any reports characterizing filth contamination in/on spice source plants pre-harvest, filth adulteration of spices, or concentrations of filth elements in spices at primary production sites. Because spices are derived from parts of plants and are often dried in open air environments, the presence of twigs, dirt and field insect parts are not unexpected (ASTA, 2011). These types of filth are termed “natural or unavoidable defects” by FDA and are acceptable when found in spices at concentrations below the DALs.

4.2.3. DISTRIBUTION AND STORAGE

Surveillance data on the prevalence of filth adulteration of spices during distribution and storage is limited to evaluations of these quantities at the point of import; we were not able to identify any surveillance studies of the prevalence of filth adulteration of spice located in storage facilities or at other points of the distribution chain. However, inspections of spice processing/packing facilities and food manufacturing facilities provide some information about the potential for adulteration of spice/food in the storage areas of the facilities. Inspections are discussed in Section 8.1.3.1.

4.2.3.1 FILTH ADULTERATION OF SHIPMENTS OF IMPORTED SPICE OFFERED FOR ENTRY TO THE UNITED STATES

Data reported in this section are derived from two studies of FDA sampling data (1) review of results from the annual sampling program for the years FY2007-FY2009 and (2) review of sampling results from a targeted sampling assignment in 2010 (August-December) that focused on examining imported shipments of capsicum and sesame seed offered for entry to the United States for potential filth adulteration.

Selection of shipments of imported spice/other food for examination under FDA’s annual field work plan is based on a number of factors including the inherent risk of the product, general surveillance activities described in the FDA work plan, FDA work performance goals and/or congressional work performance goals. All data examined in the FY2007-FY2009 study presented below were drawn from “surveillance sampling activities”, as described above, as opposed to compliance activities.

All shipments of imported capsicum or sesame seed were eligible for sampling for the 2010 targeted study. A total of 299 shipments of capsicums and 233 shipments of sesame seeds were sampled at the point of import into the United States between August and December 2010. The shipments sampled constituted approximately 10 or 20 percent of all shipments of imported capsicum or imported sesame seed shipments, respectively, offered for entry to the United States.

Observed filth adulteration in shipments of imported spice offered for entry to the United States

Summary results for prevalence of filth adulteration (defined in Section 3.2) in imported shipments of spices offered for entry to the United States during FY2007-FY2009 are presented in Table 4.12. The overall prevalence for filth adulteration of imported spice shipments during that time period was 12% (95% CI 10-15%). This value is 1.8 times (RR 95% CI 1.4-2.2) the value found for all other shipments of imported FDA-regulated foods sampled during this time period.

Table 4.12. Prevalence of filth adulteration in shipments of imported spice or other FDA-regulated foods offered for entry to the United States, FY2007-FY2009

Spice/Food	# Positive	N	Filth Shipment Prevalence (%)	95% Confidence Interval[a]
All Imported Spices[b]	82	665	12	9.9-15
All other Imported FDA-regulated Foods[b]	585	8350	7.00	6.47-7.57
Spices Subject to different processes[c]				
Ground/cracked Spice	28	257	11	7.4-15
Whole Spice	24	165	15	9.5-21
Specific Spices				
Capsicum[d]	21	115	18	12-27
Pepper, Black	1	54	2	0-10
Sesame Seed	7	71	10	4-19
Spices/Spices and Seasonings, NEC[e]	28	181	15	10-22
All other spices	25	244	10	6.7-15

[a] 95% exact confidence limit (Clopper and Pearson, 1934).

[b] All shipments of imported FDA-regulated spices or other imported foods that were sampled during the study period.

[c] Categorizations derived from product code and description. When description was insufficient to categorize, the sample was not included. Note that analytical methods used to determine filth in ground/cracked spices differs from those used to determine filth in whole spices. See text for details.

[d] Capsicum includes paprika as well as hot and other sweet dried capsicum peppers.

[e] Shipments of spices "not elsewhere classified" (NEC) in the product code are assigned to "Spices, NEC", "Spices and Seasonings, NEC", or "Mixed Spices and Seasonings, NEC."

Our data indicate that the prevalence rates for imported shipments of ground/cracked spice do not differ statistically from that of whole spice ($p>0.05$). When comparing filth adulteration prevalence values for shipments of different types of spice, we find that the prevalence for shipments of imported black pepper was smaller than that for shipments of imported capsicum, "spices/spices and seasonings, NEC", or the category "all other spices" (Marascuilo procedure) among those sampled during FY2007-FY2009. Results from the 2010 sampling assignment targeting imported shipments of sesame seeds and capsicums found essentially the same filth adulteration prevalence for capsicum (18% 95% CI 14-24%) but a much smaller filth adulteration prevalence for shipments of sesame seed (0.5%, 95% CI 0.0-2.5%) than was observed for the period FY2007-FY2009. More data are needed to determine whether the smaller prevalence value reflects a sustained reduction in the prevalence of filth in imported sesame seed shipments.

The types of filth adulteration found in sampled shipments of imported spices offered for import during the three year study period are presented in Table 3.4. The most prevalent types of filth elements were insect fragments, whole/equivalent insects, and animal hair. As mentioned in Chapter 3, almost all of the insects found in these spice samples are stored product pests with some test portions analyzed containing four or more species of pests in a single test portion. The presence of the specific insects found indicates poor handling, storage, or cleaning of the spices. One of the species found, *Monomorium pharaonis* (Pharaoh ant), has been identified as a vector of food borne pathogens (Olsen *et al.*, 2001). Another, *Acarus siro* (grain mite), has been associated with allergic reactions in people handling products containing this mite (Olsen, 1998b).

A review of the FDA sampling database for imported spice shipments offered for U.S. entry FY2007-FY2009 showed that hair was detected in 253 (38% of sampled) shipments of imported spice (Table 4.13), although not all of these shipments were determined to be adulterated by filth. Of the hair found, 38% was identified to be from rodents. As discussed in Chapter 3, the presence of rodent hair without a hair root in spices generally is an indication that the spice had been contaminated with rodent feces. All hairs found in food are indicative of insanitary conditions and therefore failures in the application of Good Agricultural Practices (GAPs) and Current Good Manufacturing Practices (CGMPs). For example, human hair in spice could arise when workers handling the spice fail to use hair nets while cat/dog hair could arise if the spice processing/packing/storing facility employs these animals for rodent control. In addition, direct evidence of animal fecal and/or insect fecal contamination was found in a small number of the samples.

Table 4.13. Hairs found in shipments of imported spice offered for entry to the United States, FY2007-FY2009

FY 07-09 Hair Summary	# Test Portions	# Shipments
Human hair	47	35
Bat	1	1
Cat	32	19
Cow	1	1
Dog	1	1
Mammalian	23	11
Mouse/Rat	244	85
Other	19	10
Rabbit	3	3
Rat	1	1
Rodent	15	11
Non-striated	13	7
Sheep	1	1
Striated	37	18
Unknown	129	49
All Hairs	**567**	**253**

Foreign substances found in spices ranged from twigs and sticks to staples, stones, and various fibers (Table 3.4). Most of these materials can be classified as hard and/or sharp objects; e.g. sticks, stones, staples; which are physical hazards in foods (Olsen, 1998a) and are classified as action Category 1 analytes (indicators of a potential food safety hazard) according to the 1999 revised filth strategy, and violate section 402(a)(1) of the FD&C Act. Others, such as fibers or rubber bands, are action category 2 (detectable and objectionable to the consumer), potentially violating section 402(a)(4) of the FD&C Act.

4.2.4. SECONDARY PROCESSING AND MULTI-COMPONENT FOOD MANUFACTURING

We were unable to identify any reports characterizing the prevalence or concentrations of filth adulteration in spice found in processing, packing or food manufacturing facilities. Spice manufacturers regularly apply physical cleaning techniques to remove filth elements from raw spice during secondary processing. However, inspections of spice processing/packing facilities and food manufacturing facilities provide information about the facility environment and the potential for adulteration of the spice/food within that environment. Inspections are discussed in Section 8.1.3.1. Review of FDA inspection data for a group of 59 domestic spice firms inspected as part of a special assignment to support this risk profile revealed that the presence of pests was among the most common findings reported.

4.2.5. RETAIL/END USER

We were unable to identify any reports characterizing the prevalence or concentrations of filth in spice at retail other than the surveys FDA conducted in the 1980s (Gecan *et al*., 1983; Gecan *et al*., 1986) which were used to set the DALs for the spices listed in Table 3.3. FDA generally set DALs to values that would reflect significant deviation from the best practices of industry and agriculture at that time.

4.3 PREVALENCE OF BOTH *SALMONELLA* AND FILTH ADULTERATION OF SPICES

In 1960, Kenton Harris wrote in Food and Drug Technical Bulletin No. 1:

> "Often the line of demarcation between a harmful and a filthy food is exceedingly narrow. Many of the sources of filth in food products are potential sources of disease organisms. It is well known that rodents are vectors of several diseases transmissible to man, including typhus, plague, infectious jaundice, and *Salmonella* infection. Flies and roaches may harbor pathogenic bacteria and transmit infection to foods. Rodents, flies, and other insects closely associated with filth and insanitary conditions are capable of mechanically transferring pathogenic and spoilage organisms from such filth directly to food products. Therefore, certain forms of filth contamination of food carry implications of danger to health although the demonstration of specific agents of disease may be difficult or impossible"

By 2001, the body of scientific evidence demonstrating a relationship between some types of filth and specific agents of disease had grown significantly, as described in detail in FDA's 2001 review of the scientific literature (Olsen *et al*., 2001). Insects, rodents and other animals possessing the following five attributes: "synanthropy, endophily, communicative behavior, attraction to filth and to human food, and harborage of pathogens in the natural (wild) populations" are recognized as having the potential to spread pathogens to human food (Olsen *et al*., 2001 and references therein). As a consequence, it is possible that the presence of filth and pathogens in spices could be correlated, at least at some points along the farm-to-table continuum.

In 1989 FDA performed a limited study comparing the microflora recovered from samples of spice and fecal pellets found in spice from shipments of spice offered for entry to the United States and reported no correlation (Satchell *et al*., 1989). Interpretation of these data with regard to the correlation between filth and spice contamination with pathogens is limited because the results were based on a very small data set. In the 1989 study, 1-4 fecal pellets from each of nine shipments were examined for microflora and compared with microbiological test results on two 375 g samples from each shipment. *Escherichia coli* (generic) was found in two pellets but neither *Salmonella* nor *Escherichia coli* was found in spice samples from the nine shipments (Satchell *et al*., 1989).

In order to address whether adulteration of spice by filth and *Salmonella* are correlated at the point of entry to the United States, we analyzed FDA sampling data for shipments of imported spices and food offered for entry during the years FY2000-FY2009 (except FY2002 for which there were incomplete data). A total of 883 shipments of imported spice were examined for both *Salmonella* and filth during this time period. Results of FDA tests are presented in Table 4.14. Evaluation of the Fisher exact p-value indicates that the correlation between *Salmonella* and filth contamination of imported spices at the point of import is not significant ($p>0.05$) for the sampled shipments examined. In contrast, correlation between *Salmonella* and filth contamination in other imported FDA-regulated food shipments examined for both contaminants during this same time period (4557 shipments) was found to be highly significant (p<0.001), as shown in Table 4.15.

Table 4.14. Examination of relationship between presence of filth and *Salmonella* adulteration of shipments of imported spice offered for entry, FY2000-FY2009 (except) FY2002

Filth	**# Positive for *Salmonella***	**# Negative for *Salmonella***	**Fisher Exact p-Value**[a]
# Positive for Filth	13	100	na
# Negative for Filth	59	711	na
Fisher Exact p-Value[a]	na	na	0.195

[a] Fisher exact p-value (SAS, 2012). "na" indicates measure is not applicable for the cell.

Table 4.15. Examination of relationship between presence of filth and *Salmonella* adulteration of shipments of imported foods offered for entry, FY2000-FY2009 (except) FY2002

Filth	**# Positive for *Salmonella***	**# Negative for *Salmonella***	**Fisher Exact p-Value**[a]
# Positive for Filth	25	234	na
# Negative for Filth	151	4147	na
Fisher Exact p-Value[a]	na	na	<0.001

[a] Fisher exact p-value (SAS, 2012). "na" indicates measure is not applicable for the cell.

The absence of a correlation for shipments of imported spices offered for entry to the United States may result from a lack of statistical power (data for a small number of shipments are compared) or may signify that spices or the spice supply chain practices before import are characteristically different (on average) with regard to contamination with *Salmonella* and filth from those of other imported FDA-regulated products (among those sampled). It is common for spice producers and/or processors to physically clean raw spices to remove visible filth; this often takes place at primary production, while additional cleaning can take place during secondary processing (see Chapter 6). Pathogen reduction treatments are also commonly applied to some spices. Such treatments are performed in the secondary processing phase of the spice farm-to-table continuum, which may take place before or after import. The combination of these practices may remove any correlation between the presence of *Salmonella* and filth in shipments of imported spice at the point of entry to the United States, if any existed initially. More research is needed to understand how the prevalence of filth and *Salmonella* adulteration of spices changes along the supply chain from farm to the consumer table.

5. CHARACTERIZATION OF CONTAMINANTS

The goal of this section is to highlight the characteristics of *Salmonella* and filth adulteration that impact their potential risk to public health when found in spices. The sections below are not meant to reproduce or comprehensively review the vast literature on *Salmonella* or filth but rather provide general/representative references for key statements.

Data on the survival of *Salmonella* in spices and the potential for growth of *Salmonella* in wet spices were very limited. In order to begin to address this data gap, FDA scientists undertook a series of experiments to evaluate these properties in ground black pepper. A full description of the experiments and results can be found in Keller *et al*. (2013). In sections 5.1.2 and 5.1.3, we present key results and conclusions and compare our results with related reports in the literature.

5.1 *SALMONELLA*

5.1.1 GENERAL CHARACTERISTICS OF *SALMONELLA*

There are two species of *Salmonella*: *S. enterica* and *S. bongori* (WHO, 2007). *Salmonella enterica* is further divided into six subspecies, each with many serovars: *enterica* (I), *salamae* (II), *arizonae* (IIIa), *diarizonae* (IIIb), *houtenae* (IV), and *indica* (VI) (WHO, 2007). As shown in Table 3.2, all of the *Salmonella* strains isolated from spices in the United States have been *Salmonella enterica* and have included strains from five of the six *S. enterica* subspecies.

While the primary habitat for *Salmonella* is considered to be the intestinal tract of vertebrates such as birds, animals, rodents, reptiles, and humans (FDA, 2012d) most variants can survive for extended periods in non-host environments. For example, it has been shown that *Salmonella* can survive in soil (Garcia *et al*., 2010; Bech *et al*., 2010), water (Ceballos *et al*., 2003; Skariyachan *et al*., 2012; Micallef *et al*., 2012), plants (Franz and van Bruggen, 2008; Barak *et al*., 2011; Gu *et al*., 2013), manure and soil amended with manure (Ongeng *et al*., 2011; Bech *et al*., 2010; Semenov *et al*., 2009; Islam *et al*., 2004; Garcia *et al*., 2010), on equipment/surfaces (Mattick *et al*., 2003; Castelijn *et al*., 2013), and in low moisture foods (Podolak *et al*., 2010; Ristori *et al*., 2007; Beuchat and Scouten, 2002; Komitopoulou and Penaloza, 2009; Lehmacher *et al*., 1995; Uesugi *et al*., 2006; Keller *et al*., 2013; FDA, 2012d). Indeed, a key characteristic of *Salmonella* related to spice contamination is its ability to resist dry, desiccation conditions for extended periods (Beuchat and Scouten, 2002; Hiramatsu *et al*., 2005; Du *et al*. 2010; Beuchat and Mann, 2010; Podolak *et al*., 2010; Kimber et al., 2012; Blessington et al., 2012).

Salmonella has been found in and on insects, which can transport the bacteria from one location to another (Crumrine *et al*., 1971; Holt *et al*., 2007; Wang *et al*., 2011; Hoelzer *et al*., 2011; Pava-Ripoll *et al*., 2012). Beyond survival, most variants of *Salmonella* can grow in a variety of non-host environments, given sufficient water, nutrients, and other appropriate environmental conditions (Combase Consortium, 2012; Harris *et al*., 2003; Brandl, 2006; Danyluk *et al*., 2008; Franz and van Bruggen, 2008; Du *et al*., 2009a; Beuchat and Mann, 2010; Keller *et al*., 2013). This adaptability enables *Salmonella* to cycle between animal host and environment, thereby extending the lifetime of the bacteria/bacterial colony and “ensuring its passage to the next host” (Winfield and Groisman, 2003; Foster and Spector, 1995; Podolak *et al*., 2010).

A direct consequence of *Salmonella*’s ability to survive in non-host environments is that it is widely dispersed in nature and that when *Salmonella*-contaminated material (animate or inanimate) comes in contact with the spice source plant or spice before human consumption it may be a potential source of viable bacterial contamination.

5.1.2 ANTIMICROBIAL PROPERTIES OF SOME SPICES

Essential oils of some spices possess antimicrobial properties which can inhibit the growth of bacteria including *Salmonella*, *Bacillus cereus*, *Staphylococcus aureus*, and *Escherichia coli* under some conditions (Al-Delaimy and Ali, 1970; Farbood *et al.*, 1976; Shelef *et al.*, 1980; Shelef, 1983; Shelef, *et al.*, 1984; Aktug and Karapinar, 1986; Karapinar and Aktug, 1987; Zaika, 1988; Billing and Sherman, 1998; Smith-Palmer *et al.*, 1998; Arora and Kaur, 1999; Hammer *et al.*, 1999; Dorman and Deans, 2000; Ceylan and Fung, 2004; Burt, 2004; Du *et al.*, 2009a; Du *et al.*, 2009b; Tajkarimi *et al.*, 2010; Weerakkody *et al.*, 2011). For example, Al-Delaimy and Ali (1970) reported that 1% v/v garlic extract inhibited growth of *Escherichia coli* and *Salmonella* Typhi while Smith-Palmer et al. (1998) reported that essential oils of bay, cinnamon, clove and thyme inhibited growth of *Salmonella* Enteritidis at a concentration of 0.075%.

Many studies have demonstrated that the strength of the inhibitory effect depends on the essential oil, its concentration, and the pathogen (including strain), among other factors (Al-Delaimy and Ali, 1970; Farbood *et al.*, 1976; Shelef *et al.*, 1980; Shelef, 1983; Shelef *et al.*, 1984; Aktug and Karapinar, 1986; Karapinar and Aktug, 1987; Zaika, 1988; Billing and Sherman, 1998; Smith-Palmer *et al.*, 1998; Arora and Kaur, 1999; Hammer *et al.*, 1999; Dorman and Deans, 2000; Ceylan and Fung, 2004; Burt, 2004; Tajkarimi *et al.*, 2010; Weerakkody *et al.*, 2011). For example, Shelef *et al.* (1980) reported that *Salmonella* Typhimurium needed 10 times more sage for inhibition in broth than *B. cereus*. Karapinar and Aktug (1987) reported that eugenol, which is the key antimicrobial compound in cloves, had a smaller minimum inhibitory concentration for *Salmonella* Typhimurium than thymol or anethole, essential oils in thyme and anise seed, respectively.

Spices containing essential oils with strong inhibitory effects towards *Salmonella* may limit the growth of the pathogen in some foods if the concentration of the spice/essential oil is sufficient and other conditions are appropriate. What is not known is the extent to which the presence of antimicrobial essential oils in some spices impact survivability of *Salmonella* in low moisture foods in general or the spice itself. The relatively large *Salmonella* prevalence found by FDA for shipments of oregano and allspice offered for import to the United States during FY2007-FY2009 demonstrates that the antimicrobial activity against *Salmonella* is not sufficient to eliminate *Salmonella* contamination from shipments of these types of spices (as discussed in Section 4.1.3.1).

5.1.3 SURVIVABILITY IN SPICES

It is well established that salmonellae survive long periods in low moisture foods and dry environments (Beuchat and Scouten, 2002; Hiramatsu *et al.*, 2005; Du *et al.* 2010; Beuchat and Mann, 2010; Podolak *et al.*, 2010; Kimber et al., 2012; Blessington et al., 2012). Lehmacher *et al.* (1995), analyzing samples of paprika, demonstrated that *Salmonella* can survive for at least 8 months in samples of that spice but the specific conditions under which the spice was stored and how these impacted survival were not recorded. FDA undertook a series of experiments to characterize how survival of *Salmonella* in a spice depends on storage conditions (Keller *et al.*, 2013). Samples of ground black pepper were inoculated with a cocktail of *Salmonella* strains, held at 35 or 25°C, and stored under either high relative humidity (RH, 97%) or under low RH (typically ≤ 40%). Results for these experiments are presented in Figures 5.1-5.4.

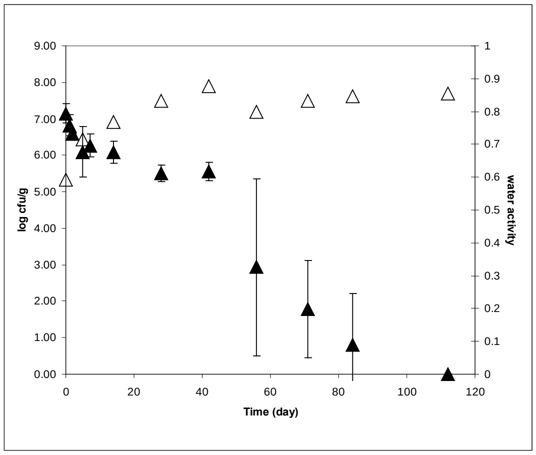

Figure 5.1. Survival of *Salmonella* at 25°C and high (97%) RH. Mean and standard deviation of *Salmonella* population (▲); black pepper water aw, (Δ). Error bars represent the standard deviation calculated from three replicate samples; absence of detection was assigned a value of zero. Limit of detection (LOD) for the analysis was 1.69 log CFU.

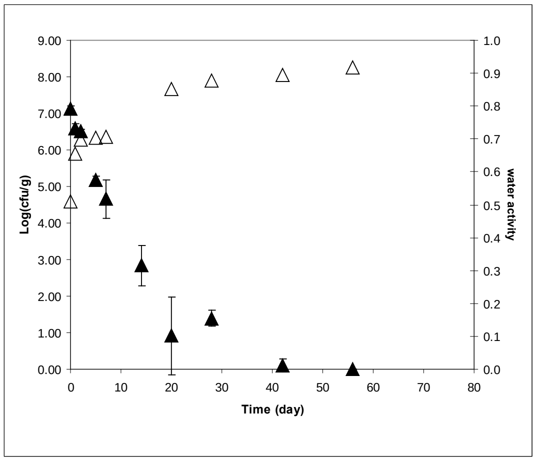

Figure 5.2. Survival of *Salmonella* at 35°C and high (97%) RH. Mean and standard deviation of *Salmonella* population (▲); black pepper water aw, (Δ). Error bars represent the standard deviation calculated from three replicate samples; absence of detection was assigned a value of zero. LOD for the analysis was 1.69 log CFU.

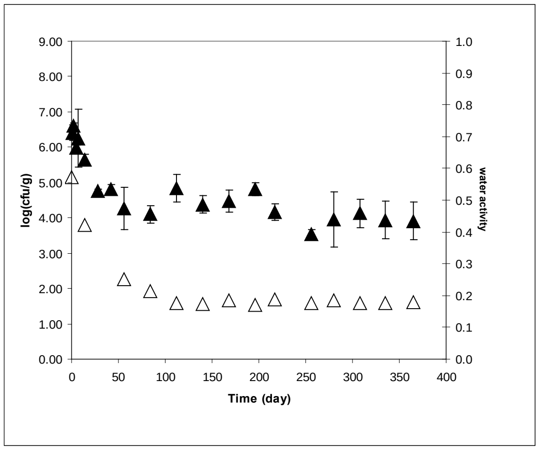

Figure 5.3. Survival of *Salmonella* at 25°C and ambient (≤40) RH. Mean and standard deviation of *Salmonella* population (▲); black pepper water aw, (Δ). Error bars represent the standard deviation calculated from three replicate samples; absence of detection was assigned a value of zero. LOD for the analysis was 1.69 log CFU.

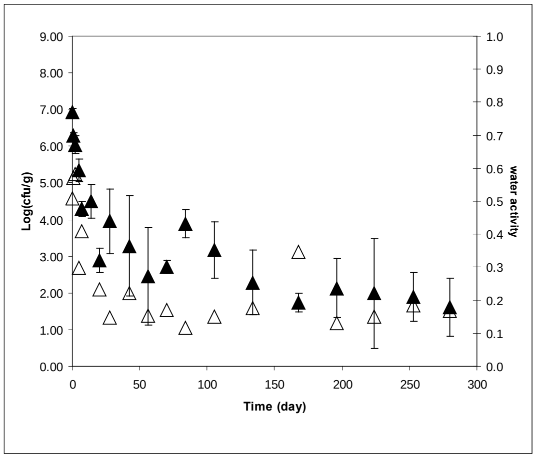

Figure 5.4. Survival of *Salmonella* at 35°C and ambient (≤40) RH. Mean and standard deviation of *Salmonella* population (▲); black pepper water aw, (Δ). Error bars represent the standard deviation calculated from three replicate samples; absence of detection was assigned a value of zero. LOD for the analysis was 1.69 log CFU.

Under high humidity conditions, a rapid decline in the population of *Salmonella* was observed (Figures 5.1 and 5.2) and was faster at 35^{o}C than at 25^{o}C. At 35^{o}C, the surviving *Salmonella* population fell below detection limits (1.69 log CFU/g) after 60 days, while at 25^{o}C, *Salmonella* decreased below this point after 100 days of storage. In contrast, at low RH, population reduction rates were much smaller, with *Salmonella* survival exceeding 280 days at 35°C and 365 days at 25°C (the length of the experiments), as illustrated in Figures 5.3 and 5.4. Figures 5.1-5.4 also illustrate how the humidity of the environment affects the water activity (a_w) of the exposed black pepper and suggests that the *Salmonella* population reduction rate is related to the water activity of the black pepper. Beuchat and Scouten (2002), investigating *Salmonella* population reduction rates in alfalfa seeds, also found that *Salmonella* population reduction rates decreased with decreasing water activity or temperature. Ristori *et al*. (2007), examining *Salmonella* Rubislaw in black pepper, also found *Salmonella* population reduction rates increased with storage temperature but did not find statistically different population reduction rates for a_w in the range 0.663-0.937. The absence of a significant a_w dependence for the population reduction rate in their experiments may be related to the short time scale of the experiment (15 days) and the limited a_w range examined (Ristori *et al*., 2007). Similarly slow population reduction rates have been found for *Salmonella* on almonds, pistachios, or walnut kernels held at 23-24°C, after initial drying following addition of a wet inoculum (Kimber *et al*., 2012; Blessington *et al*., 2012).

Although the humidity of the storage environment may vary from location to location and in some locations, may not be well controlled, it may not often reach the high levels examined in the FDA study that resulted in reduced survival of *Salmonella*. Storage conditions meeting spice industry standards (ASTA, 2011; ESA, 2011) will result in spice with relatively low water activity, a condition that can result in long-term survival of *Salmonella*, if present.

The mechanism by which Salmonella is able to survive desiccation so efficiently is an active area of research. Some studies have pointed to that Salmonella morphological changes such as the formation of filamentous cells and multicellular morphology (rdar) during desiccation are critical for its survival (White *et al*., 2008; Mattick *et al*., 2000), while other studies have identified that the o-antigen capsule determined by extracellular polysaccharides is critical for Salmonella persistence in dry environments (Garmi *et al*., 2008; Gibson *et al*., 2006; Finn *et al*., 2012). Transcription analysis at genomic level suggests the involvement of fatty acids metabolism and osmotic compatible solutes in Salmonella desiccation stress response (Li *et al*., 2012). The relative importance of these and other factors in facilitating the survival of Salmonella in low moisture foods has yet to be determined.

Resistance to heat, irradiation, and disinfectants.
Salmonellae are desiccated/dehydrated when in low moisture foods such as spices and desiccation/ dehydration of some strains of *Salmonella* has been shown to increase the organism's tolerance to heat, UV irradiation, and disinfectants (Doyle and Mazzotta, 2000; Hiramatsu et al., 2005; Podolak et al., 2010; Gruzdev et al., 2011; Keller et al., 2012; Harris et al., 2012) as compared with the non-desiccated organism. For example, Gruzdev *et al*. (2011) found that application of 100°C for 1 hour to desiccated *Salmonella enterica* serovar Typhimurium was insufficient to eliminate all viable bacteria in the sample. Other studies have shown that heat and irradiation tolerance are related to water activity of the food/sample (Barrile and Cone, 1970; Goepfert *et al*., 1970; Jeong *et al*., 2012). The extent of tolerance can also be dependent on serotype and food matrix (Gruzdev *et al*., 2011; Nascimento *et al*., 2012) and decimal reductions during thermal pathogen reduction treatments can exhibit non-linear behavior where the rate of decline decreases with increasing time (Beuchat and Mann, 2012; Abd *et al*., 2012; Blessington *et al*., 2012). Gruzdev et al. (2011) found that rehydration of previously desiccated *Salmonella* may not fully restore susceptibility to heat. These observations indicate that application of pathogen reduction and disinfection methods developed for foods other than spices may not be as effective as anticipated when applied to spices.

5.1.4 POTENTIAL FOR GROWTH IN MOISTENED SPICES AND SPICE-CONTAINING FOODS

The threshold water activity for growth of *Salmonella* is reported to be 0.94 (ICMSF, 1996) which is much higher than the water activity recommended for storage of spices by the spice industry (≤0.75, ASTA, 2011; 0.65, ESA, 2011). Therefore, *Salmonella* will not grow in spice when maintained at recommended water activities. However, we wanted to determine whether *Salmonella* could grow in spice when water is added, i.e., are there sufficient nutrients in spice to support growth when wet that could potentially lead to increased concentrations of *Salmonella* in spice or create *Salmonella* niches in the spice supply chain environment that could facilitate cross-contamination? Whole black pepper could be exposed to moisture during the drying process, if not protected from rain, or during storage, if the packing material is not waterproof. Ground black pepper, either in the production line or in the spice /food manufacturing environment, could become wet during processing/packing as a result of wet cleaning or poor facility design/maintenance. Ground black pepper could also become wet during storage if the material in which it is packaged or stored is not waterproof and the environment in which it is stored is not designed and maintained properly (e.g., holes in the roof, condensation, or high humidity). In addition, ground black pepper could become wet during food preparation in a home or restaurant, e.g., when exposed to steam or humid air. To minimize the occurrence of these possibilities, Codex Alimentarius (Codex) has developed guidance for spice production, processing and use (Codex Alimentarius, 1995), the U.S. has developed the Current Good Manufacturing Practices (FDA, 2012a) and the spice and food industries have developed guidance for processing and food manufacturing facilities handling low moisture foods (ASTA, 2011; ESA, 2011; GMA, 2009).

FDA scientists designed experiments to determine whether *Salmonella* can grow in moist/wet black pepper at temperatures typical of spice processing, storage and use (excluding cooking) and if so, whether growth rates are comparable to those in optimized media (Keller *et al*., 2013). The water activity threshold for growth in ground black pepper at 35^{o}C was determined to be 0.979 ± 0.003 (Keller *et al*., 2013) which is higher than the threshold (0.94) reported for *Salmonella* in other food products (ICMSF, 1996). The difference between the threshold for *Salmonella* growth in ground black pepper and the threshold reported in other foods may be related to the presence of antimicrobial compounds in ground black pepper but also could be related to other differences in the black pepper growth environment as compared with an optimized growth environment.

Salmonella generation times in ground black pepper under permissive water activity conditions were short, similar to maximum growth rates recorded in optimal growth media (ICMSF, 1996). Therefore, growth of *Salmonella* could represent a substantial risk to the food industry should the pepper become wet, that is, when industry standards for spice water activity are exceeded. These experiments demonstrated that ground black pepper at water activities near the threshold for growth of *Salmonella* may not be noticeably wet, as shown in Figure 5.5. Small, local areas of high water activity may be able to develop if condensate or other small drops of water are allowed to contaminate stored black pepper or black pepper dust that may accumulate in the spice processing/packaging or food manufacturing environments. These local areas may also develop from the condensation of moisture from insect respiration (Williams *et al*., 2004). Such small localized areas may not be obvious during storage and manufacture but could result in a significant risk of *Salmonella* growth in contaminated black pepper products or in the creation of environmental niches. However, generation and lag times increased when the water activity of the ground black pepper was lowered below the optimal value (Keller *et al*., 2013). This means that in the case of an accidental addition of water to ground black pepper, growth may be limited if the time for evaporation is shorter than the lag time for growth initiation.

Spice-containing foods can exceed the threshold water activity value for growth and provide nutrients and an environment that support growth (Combase Consortium, 2012). However, not all moist foods will support growth due to intrinsic characteristics of the food such as pH and salt content. For example, Fedoruk (2011) estimated the risk of salmonellosis from consumption of dairy-based snack food dips made from contaminated spice and found that the acidity of the food limited growth.

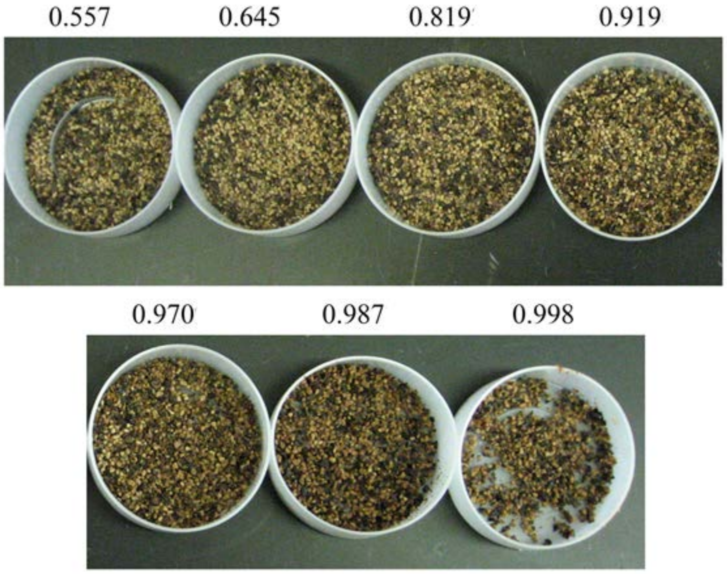

Figure 5.5. Appearance of ground black pepper at different water activities (a_w).

5.1.5 CHARACTERISTICS OF THE NON-TYPHOIDAL SALMONELLOSIS

Salmonella *Dose-Response*

While there is no dose-response model specifically derived from outbreak investigations or challenge studies of *Salmonella* in spices or low moisture foods, the WHO/FAO developed a dose-response model for *Salmonella* in 2002 based on 20 outbreaks associated with food (WHO/FAO, 2002). Figure 5.6 illustrates the WHO/FAO beta-Poisson model and the insert shows predictions for low dose, illustrating a nearly linear dose-response relationship predicted for doses up to ~20 CFU. Low dose exposures are expected from consumption of contaminated spices based on the concentrations of *Salmonella* reported in spices (Section 4.1.1 and Table 4.2) and the typical serving size for spice per eating occasion (Section 7.2.2).

This beta-Poisson model predicts that a dose of approximately 4 CFU (95% CI 3-5 CFU) would infect 1% of the exposed population (ID1) while a dose of approximately 63 CFU (95% CI 44-90 CFU) would infect 10% of the exposed population (ID10). Although data used to develop the dose-response model did not include spices, the ID1 predicted by the WHO model is consistent with the rough estimate made by Lehmacher *et al*. (1995) of 4-45 MPN, based on data from the 1995 salmonellosis outbreak attributed to consumption of contaminated paprika in paprika-powdered potato chips. Low doses of *Salmonella* from consumption of contaminated spices would be anticipated from the concentration of *Salmonella* found in contaminated spices (Table 4.2) and the typical amounts of spice consumed in a single eating occasion (Section 7.2.2).

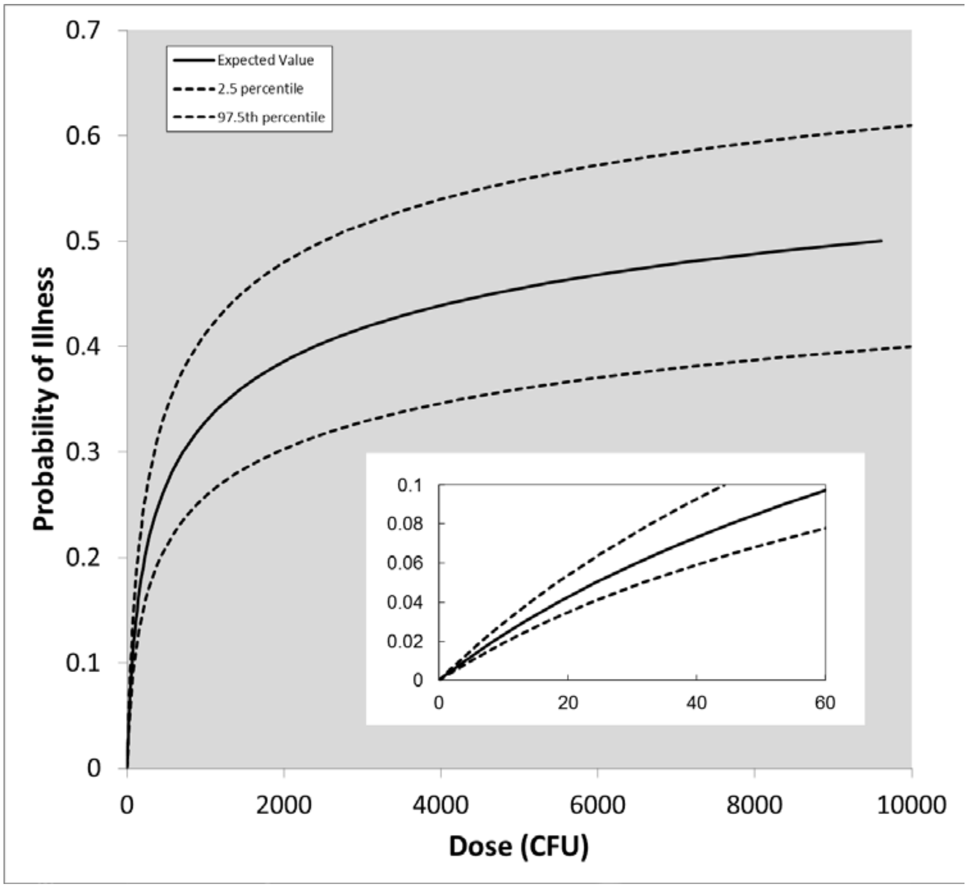

Figure 5.6. WHO/FAO dose-response model for *Salmonella*. Solid line is expected value; dashed lines bracket 95% confidence limits, derived from WHO/FAO, 2002. Inserted graph is an expansion of the main graph in the dose range 0-60 CFU.

Teunis *et al*. (2010), analyzing an expanded data set from that used by WHO/FAO and using more complex modeling strategies that included a two-level dose-response model, predicts the ID1 for illness to be 0.395 CFU (95% CI: 0.01-89.7 CFU). The study examined whether the dose-response relationship differed by serotype or susceptibility (defined as less than 12 years of age or older than 65 years of age) and reported no statistically significant differences in models for different serotypes or susceptibility categories among those considered.[5]

Bollaerts *et al*. (2008), also using a two-level dose-response model, re-examined the dataset used by WHO and found differences in dose-response models for different *Salmonella* serotype-food matrix combinations. Spices were not among the foods in the data set but an outbreak involving one low moisture food (cheddar cheese) was included. The models developed by Bollaerts *et al*. (2008) were not able to separate the effects of serotype and food matrix. The dose-response models of Bollaerts *et al*. (2008) predict larger probabilities of illness for susceptible populations (>60 years of age) for certain ranges of dose. For the serotype-food matrices with the steepest dose-response relationships, susceptible individuals are predicted to have a greater probability of illness at low dose than non-susceptible individuals. For the serotype-food matrices with less steep dose-response relationships, differences in susceptible and non-susceptible populations are

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[5] Teunis *et al.* (2010) used his model to estimate the number of people exposed in the outbreak attributed to consumption of contaminated paprika-powdered potato chips. However, the estimated attack rate taken from Lehmacher *et al.* (1995) quoted in Teunis *et al.* (2010) was incorrect.

predicted for high doses (Bollaerts *et al.*, 2008). For all other doses, susceptible and non-susceptible populations have similar responses.

None of the three dose-response models address the severity of illness or health outcome and whether these differ with age.

Primary Disease and Sequelae

The onset of symptoms of salmonellosis, a gastrointestinal disease, typically occurs 12-72 hours after infection and typically lasts 4-7 days, although times outside the general ranges have been reported (see for example, that, 2003 (reporting on Guthrie, 1992)). Symptoms often include diarrhea, fever and abdominal pain (CDC, 2013b). Antibiotic resistant strains of *Salmonella* can cause complications in patients (Lynch and Tauxe, 2009). Death may occur when the infection spreads beyond the intestines to other parts of the body. Infants, elderly, and immuno-compromised individuals are most likely to have severe symptoms (CDC, 2013b). In addition to these factors, some data suggest that the severity of illness may also depend on serotype (Jones *et al.*, 2008). Overall estimates of hospitalization and mortality rates among infected individuals are 2% and 0.03% , respectively, based primarily on 2000-2008 public health data (value includes correction for underreporting; Scallan *et al.*, 2011) and are shown in Table 5.1.

Table 5.1. Estimated percentage of salmonellosis cases associated with different health endpoints and typical duration of illness.

Health Endpoint	Fraction of Cases[a]	Typical Duration
Gastroenteritis: unconfirmed	0.966	4-7 days
Gastroenteritis: culture-confirmed	0.034	11 days[c]
Gastroenteritis: Hospitalization	0.019	16 days[c]
Mortality in general population	0.0003	n/a
Reactive Arthritis	[b]	0.5-≥7 years[d]

[a] Data from Scallan *et al.* (2011b) unless otherwise noted. Hospitalization and mortality fractions include the correction for underreporting. Sum of unconfirmed and culture-confirmed cases of gastroenteritis percentages is 1. Percentages for individuals who were hospitalized, died, or later acquired reactive arthritis are relative to the full set of salmonellosis cases.

[b] Value not well established. See text for details.

[c] Data from Kemmeren *et al.* (2006) based on data collected in the Netherlands; duration of culture-confirmed illness equated with illness associated with a visit to a medical doctor.

[d] Data from Curry *et al.* (2010) for reactive arthritis regardless of etiology. See text for details.

A breakdown of hospitalization and mortality rates by age from CDC's FoodNet Surveillance Report for 2011 (CDC, 2012b) is illustrated in Figure 5.7. These data suggest that hospitalization rates generally increase with age, with largest rates for individuals who are ≥80 years of age. However, infants (<1 year of age) have an increased risk of hospitalization relative to older children. Fatality rates also increased with age for older adults beginning at ages >40 years old (CDC, 2012b).

Reactive arthritis can develop several weeks after initial illness (Locht *et al.*, 1993; Dworkin *et al.*, 2001; Hannu *et al.*, 2002; Townes *et al.*, 2008) in some cases, however the incidence rate is not well established (Townes, 2010; Townes *et al.*, 2008; Kemmeren *et al.*, 2006). Curry *et al.* (2010), examining reactive arthritis cases among U.S. military personnel, found that reactive arthritis symptoms can last for years; 35.5% of cases (Reiter's disease or post-dysenteric arthropathy) still had symptoms after two years and ~30% had symptoms after seven years.

Inflammatory bowel disease (IBD) has been associated with salmonellosis (see for example, Helms *et al.*, 2006; Gradel *et al.*, 2009; Kemmeren *et al.*, 2006) but there is disagreement in the literature as to whether a person's relative risk for IBD is increased following infection with *Salmonella* (Jess *et al.*, 2011; Mann and Saeed, 2012).

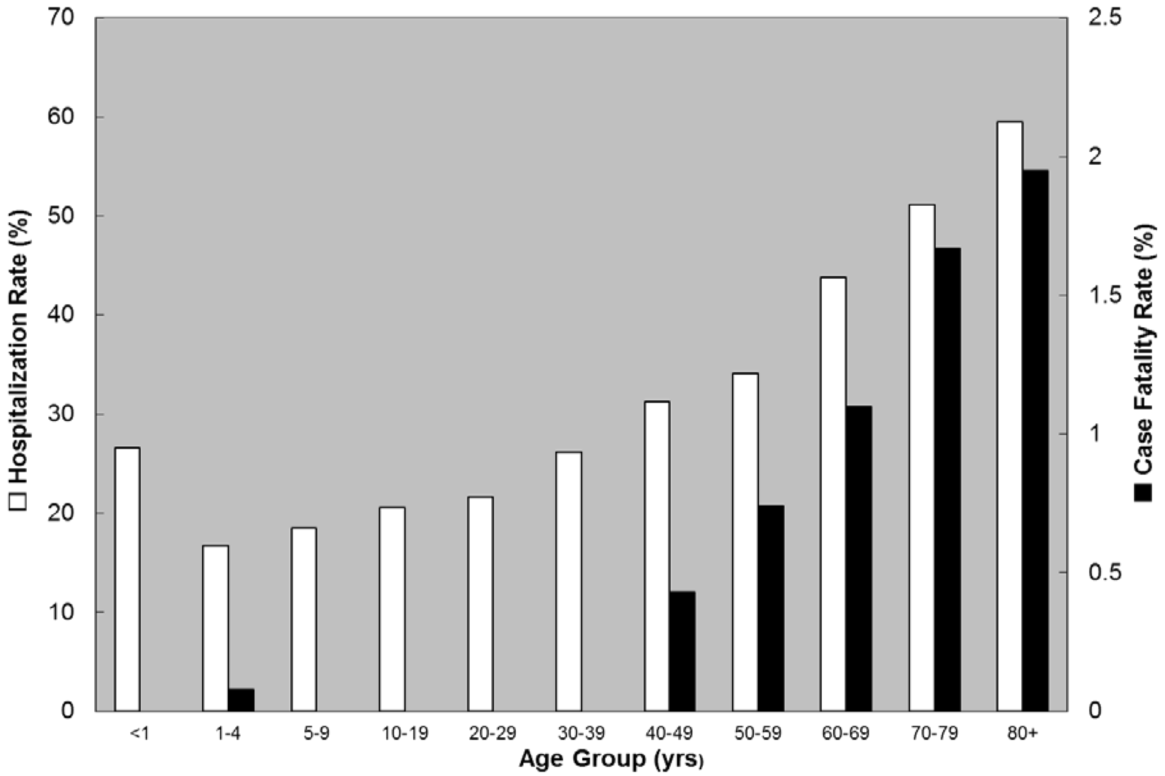

Figure 5.7. Age dependence of hospitalization and fatality rates for foodborne salmonellosis in the United States, 2010. Hospitalization rate (%) (☐ white bars) and Fatality Rate (%) (■ black bars) as a function of age of the individual with *Salmonella*-caused illness. Data from FoodNet 2011 Surveillance Report (CDC, 2012b), based on 8273 total laboratory-confirmed salmonellosis infections.

5.2 FILTH

Filth can be broadly broken down into three categories, each of which has different health and regulatory impacts (Olsen *et al*., 2001). In the first category are adulterants that can be direct food safety hazards. This group would include hard and sharp objects that can cause physical injury to the consumer. This group also contains those insects that exhibit attributes for a contributing factor (synanthropy, endophily, communicative behavior, attraction to excrement and to human food, and ability to harbor pathogens in wild populations; Olsen *et al*., 2001), for the spread of food-borne pathogens when there is no effective control in place to eliminate or neutralize the hazard. For example house flies, *Musca domestica*, are attracted to filth and human food and readily move between them. They also travel between the outside and inside of homes and processing facilities and have a close association with people. Most importantly, they are vectors for human diseases and the disease organism can be found in the wild populations of the insect. Pava-Ripoll *et al*. (2012) found *Salmonella* spp. (6% of the flies tested), *Cronobacter* spp. (14%) and *Listeria monocytogenes* (3%) in wild populations of *M. domestica*.

Rats and mice are attracted to excrement, to other pathogen reservoirs, and to human food. Wild populations harbor food-borne pathogens, especially disease causing strains of *Escherichia coli*, *Salmonella*, and *Listeria*. These diseases can be transmitted from rodent to rodent. Rodents have been implicated in at least nine documented outbreaks of salmonellosis in humans (Olsen *et al*., 2001). Rodents can also be vectors for plague, murine typhus, and Weil's disease (Vazquez, 1977). Evidence of their presence in foods, e.g., rodent hairs and feces, is indicative of insanitary conditions, suggesting failures in the application of GAPs or CGMPs.

The second category includes those filth elements that are alive and/or are clearly detectable and objectionable to the consumer. This category would include live infestation of insects/mites in the food or adulteration with foreign matter associated with objectionable conditions or practices in production, storage, or distribution that are clearly visible to the consumer.

The third category includes those filth elements that are natural or unavoidable filth and would include hair fragments, whole insects or insect fragments, mold filaments, etc. The same filth element could be classified in all three categories based on its size, life stage, life status (alive/dead), and whether the product has been subject to a microbial kill step (Olsen *et al*., 2001). FDA has analyzed spices that were adulterated by all three categories of filth elements at the same time.

6. OVERVIEW OF SPICE FARM-TO-TABLE CONTINUUM AND POTENTIAL SOURCES OF PATHOGEN AND FILTH CONTAMINATION

An overview of the farm-to-finished product storage continuum for spices created by ASTA is shown in Figure 6.1. This comprehensive figure illustrates the basic processes involved in primary production and secondary processing of spices. Not all spice products pass through each of the processes, e.g., some spices are not subjected to a pathogen reduction treatment, some spices are not ground, and some spices are not transported by ship because they are grown domestically. ASTA has included in the figure some of the key preventive practices that may be used during these phases to support the food safety of spices such as Good Agricultural Practices (GAPs), Good Manufacturing Practices (GMPs), moisture control (of dried product), process validation, warehouse sanitation, container inspection, and a Hazard Analysis Critical Control Point system. The diagram also notes product cleanliness specifications such as the DALs and the ASTA Cleanliness Specifications.

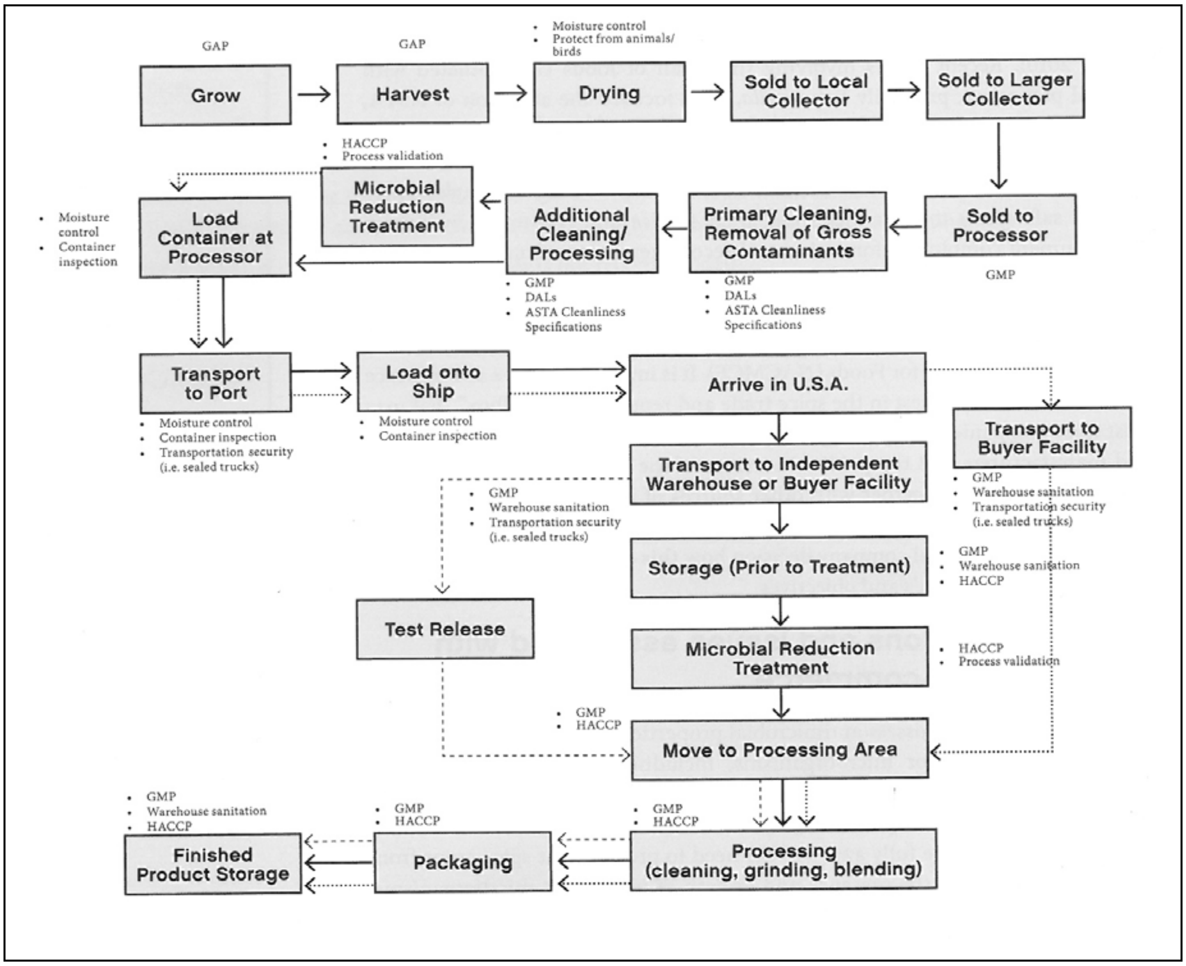

Figure 6.1. Typical stages in spice farm-to-finished product continuum for spices including transport and processing options and control points. Figure developed by ASTA for "Clean, Safe Spices: Guidance from the American Spice Trade Association" (Figure 1) published in 2011 by ASTA. Reprinted with permission.

The supply chain from finished spice product-to-consumer can be relatively simple or very complicated, as illustrated by Figure 6.2. Spice manufacturers may sell/transfer their spice products wholesale to a seasoning manufacturer, food manufacturer, food wholesaler, institutional food service, or restaurant, each of which will further handle and possibly also process the spice. Spice manufacturers may also package their own spice for retail sale, selling directly to grocers, or retail food establishments where consumers may purchase them.

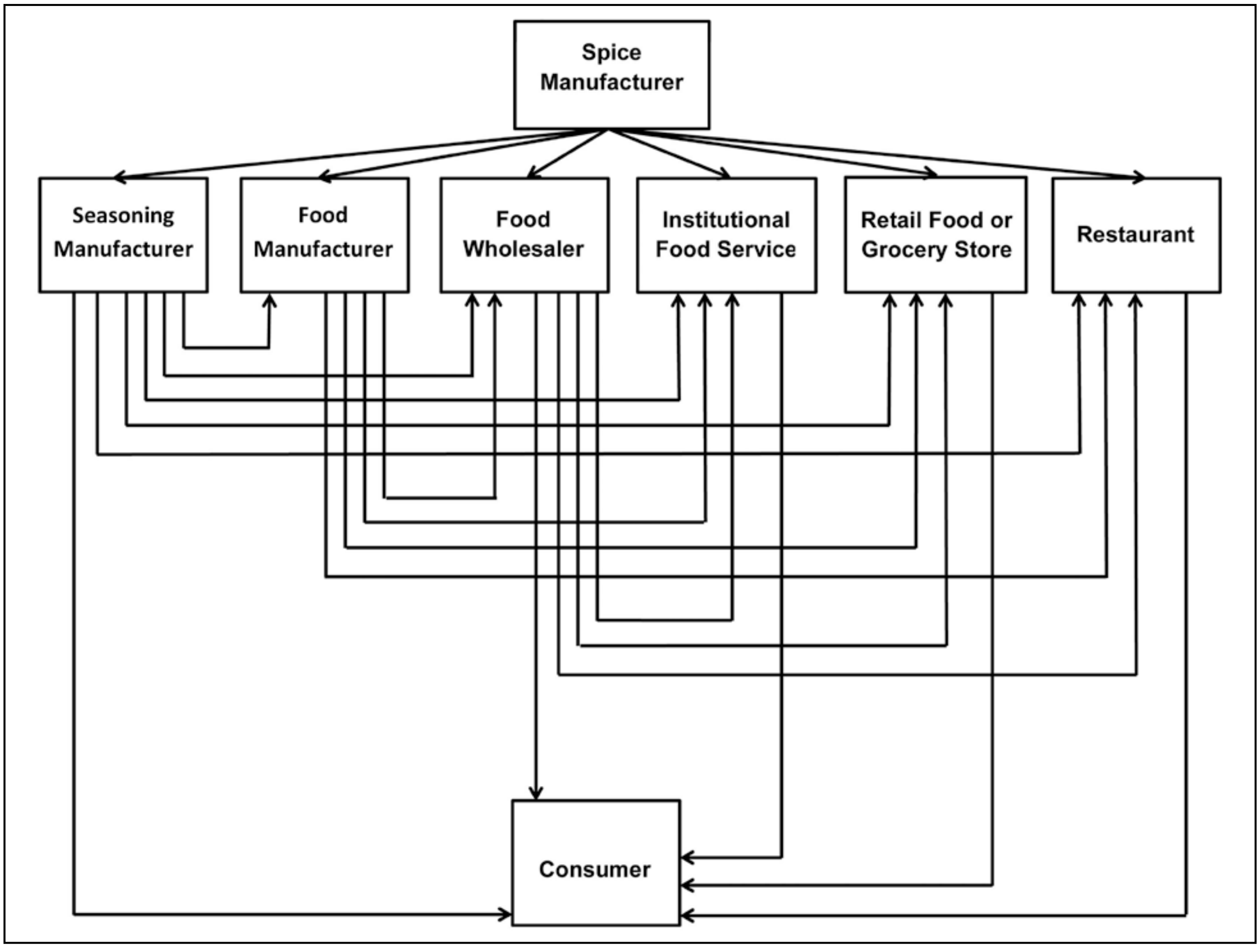

Figure 6.2. Possible pathways for spice from spice manufacturer to consumer.

6.1 PRIMARY PRODUCTION

Spices are a large, diverse group of plants, some of which have been domesticated, cultivated, and used since the times of the pharaohs to enhance the flavor of foods or as drugs. It is impossible to describe in this report the wide variety of agricultural practices involved for each of the spices. Instead, we provide a brief overview of spices, typical growing practices, and potential sources of pathogen or filth contamination during primary production.

Spice and lifecycle diversity

Any part of a particular plant can be used as a spice. Table A3 in Appendix A provides a list of over 80 different plants that are used as spices and the part of the plant used or sold in commerce. For this report, they have been grouped into broad categories of bark, flowers, fruit/seeds, leaf, or roots. These terms are not used in their narrow botanical definitions but in the colloquial use of the term. For example, the flower group contains whole dried flowers such as calendula (*Calendula officinalis*) or just part of the flower such as the stamen of saffron *Crocus sativus* (saffron); or the dried flower bud such as cloves, *Syzygium aromaticum*. Similarly, the root group includes rhizomes such as ginger (*Zingiber officinale*); bulbs such as onion (*Allium cepa*) or garlic (*Allium sativum*); or true roots such as horseradish (*Armoracia lapathifolia*). The part of the plant used has a great impact on how it is harvested, dried, processed, and the kinds of pests that may affect it.

Likewise, the life cycle of the plant has a great influence on its processing as well. Some plants are annuals, coriander (*Coriandrum sativum*); others are perennials, nutmeg/mace (*Myristica fragrans*), while others are long lived annuals or perennials that are grown as annuals, chili peppers (*Capsicum annuum*, *C. frutescens*).

The growth pattern of the plant influences the ease of harvest and exposure to potential pathogens. Some spices grow on vines, e.g., black pepper (*Piper nigrum*), others are leafy shrubs, e.g., oregano (*Lippia spp.*), while others are the fruits of a tall tree, e.g., nutmeg or mace (*Myristica fragrans*).

In some cases, the species of the plant that sold in commerce may not be known. For example, spices sold as "oregano" may be any of over 200 species of herbs, shrubs, or small trees of the family Verbenaceae, genus, *Lippia*. "Oregano" may also be of the family Labiatae, *Origanum vulgare* but the same species may also be named "marjoram." FDA regulations at 21 CFR 182.10 (FDA, 2012f) provide a list of "Spices and other natural seasonings and flavorings" by common and botanical name that are considered to be "Generally Recognized as Safe" (GRAS) substances. To add to the confusion regarding precise identification of source plant materials, there have been significant taxonomic changes since the last revision of 21 CFR 182.10 (FDA, 2012f).

Growing practices

As discussed in more detail in Chapter 7, many types of spices grow in tropical or semi-tropical environments. A few are temperate crops (garlic, onion, mustard, horseradish). The size of the farm and the agricultural techniques used to grow spices varies with the particular spice and growing region. For example, many spice farms in India are comprised of an acre or less and large farms typically contain less than 100 acres. In contrast, in the United States spice-producing farms are typically larger, where small farms are typically comprised of tens of acres and large farms are typically comprised of hundreds of acres. Of course, only a few types of spices can be easily grown on farms in the United States (see Chapter 7 for a discussion of spice production).

Spices can be grown in monoculture (chili peppers, garlic), intercropped with other species (black pepper grown with nutmeg/mace, rubber, cocoa, etc.), wild-crafted (collected in the wild) or semi-wild-crafted (oregano/marjoram). Many spices are produced on very small farms where farm animals are used to plow, irrigation water is taken from nearby surface water sources, fertilization is achieved with manure/soil-amended manure, and crops are harvested by hand. Spice source plants on these farms are on mats, cement slabs, or on raised platforms in the sun, but may in some cases be left to dry directly on the ground.

For some spices (e.g., capsicum in India or dehydrated garlic in the United States) a larger spice company may contract with growers and supply them with seed, fertilizers, pesticides, and technical expertise on agricultural and food safety growing and harvesting practices. Spice farms in the United States producing dehydrated onion and garlic are generally owned by or contracted with a single spice company that dictates/controls growing and harvest practices and may even provide their own proprietary seed. Use of automated equipment to plant, grow and harvest the spice source plant crops, and temperature/moisture controlled ovens to dehydrate source plants is more common on large farms.

Spices are typically cleaned to remove foreign matter and extraneous materials at the primary production site but may also undergo additional cleaning at one or more points along the supply chain. The cleaning process can range from hand sorting to remove sticks, stones, or other extraneous materials to the use of simple winnowing, brushing, or sieving machines to remove the extraneous materials. The technology for cleaning spices typically involves simple milling and sieving. Metal detectors are commonly employed during primary processing to remove extraneous metallic material that may have inadvertently been added to the spice during harvest or processing (e.g., a staple).

Potential sources of pathogens or filth in spices during production

A variety of animals including birds, animals, rodents, reptiles, insects, and humans may introduce *Salmonella* or filth into the spice production environment. Once present in the environment, *Salmonella* may remain viable for long periods and may possibly even grow in the soil, irrigation water, manure or soil-amended manure (Chapter 5 and references therein). Spice source plants may become contaminated with *Salmonella* or other pathogens when contaminated animals or environmental materials come in contact with them.

During the traceback investigation for one spice-related outbreak, the importing company declared that manure fertilizer used during production was the likely contamination source (Koch *et al.*, 2005; Chapter 2). In addition to fertilizer source, irrigation water quality, application method (overhead, flooding, or drip), and timing, as well as animal access to the crop are likely to be critical parameters in determining whether the spice source plant or (dry) spice could become contaminated. In a review of risk factors for microbial contamination of fruits and vegetables, Park *et al.* (2012) identified contaminated irrigation water and soil as among the most critical and the prevention and control of contamination in irrigation water and soil as the most effective targets for pre-harvest risk management.

The drying phase for spices is another critical point where filth and pathogen contamination may occur, particularly for spices that are dried in the open environment on mats or directly on the ground for extended periods (1-7 days). During drying, the spice may be exposed to possible rodent, bird, flies, and field pests. If the spices are not dried quickly enough or adequately, mold growth may take place. Some strategies for drying spice source plant material can reduce the risk of contamination during this phase, for example, use of raised platforms with simple tarp roofs will reduce the risk of contamination of spices by bird feces as compared with drying on mats on the ground without a roof.

Cross-contamination from equipment to spice source plants or spices may take place if equipment used to plant, harvest. dry or store the spice source plants becomes contaminated and is not adequately cleaned. Human transfer of pathogens or filth is possible when harvest or other aspects of the production process are primarily manual and personal hygiene is insufficient.

Filth is not a major issue during the pre-cultivation step because the spice has not developed. As the plants get older and the economically important parts start to develop, the risk of contamination by filth such as insects and animals increases (Table 6.1). Cross-contamination from equipment or field workers can also be an issue during primary production. Contamination of the spice of interest with other parts of the dried source plant may occur if appropriate cleaning/harvesting methods are not applied. The ranking in Table 6.1 was derived by FDA from site visits, knowledge of source plants and pests, and data on filth adulteration of spice.

The extent to which the identified potential sources of contamination contribute to contamination of spice depends on the specific production practices employed.

Table 6.1. Evaluation of risks for filth contamination at different stages during the production of spices

Production steps	Filth[1]
Pre-cultivation	-
Field Cultivation	+
Harvest	++
Intermediate storage	+++
Transportation	(+)
Processing (cleaning/cutting/drying/packaging)	+
Final product (package/stored)[3]	- to ++

[1] Explanation of symbols: - usually no risk, (+) no to low risk, + low to medium risk, ++high risk, +++ very high risk.

[3]. The risk depends on the packaging of the spice and how it is stored.

6.2 DISTRIBUTION AND STORAGE

The distribution system can be very complex and as a result, storage may occur at many different points. Some crops are harvested, processed, and sold relatively quickly because their quality starts to decrease immediately upon picking (for example, capsicum). Other crops, if left whole, have a long shelf life. For example, whole black pepper can be held in storage for 5-7 years before it is sold. FDA personnel learned during their visits to India that because black pepper is a readily sold cash crop, small farmers may keep the whole (dried) spice on site for years, to serve as an emergency fund for unexpected events.

Producers may sell to a local buyer or directly to a spice processor/packer. In India, black pepper is often sold to a local buyer, sometimes in lots as small as one kilogram. The buyer consolidates small lots from tens to hundreds of farms to create a 50-100 kilogram lot, which is then sold to a regional buyer. The regional buyer collects spice into a much larger lot to sell on the NCDEX (National Commodity and Derivatives Exchange Ltd., Mumbai; 1 metric tonne needed) or directly to a spice processor/packer. Larger farms may produce sufficient volumes of spice to avoid some of the aggregation steps (that may increase the risk for contamination of the spice) and the ensuing delay to market associated with it. Some spice manufacturers who contract groups of farmers for production of spices may coordinate and control aggregation of spices from contractors.

Spice processing may take place before and/or after export. For example, the Spices Board of India has created “spice parks” where producers can bring their spices to undergo filth and pathogen reduction treatments as well as microbiological testing to ensure compliance with U.S. standards (Spices Board India, 2013; see discussion of the Indian EIC certificate program in Chapter 8 for more details on processing of black pepper).

Individual shipments of imported spice offered for import to the United States often contain large amounts of spice, e.g., thousands or tens of thousands of kilograms (Table C1; Van Doren *et al.*, 2013c). After arrival, the lot may be processed, and/or re-packaged and distributed multiple times before being used in food preparation.

Potential sources of pathogens or filth in spices during distribution and storage

At each stage of the often complex and lengthy spice distribution process, spice is stored for some period. This characteristic of the spice farm-to-table continuum makes proper packaging and storage a critical issue for preventing contamination. When improperly packaged or stored, the spice may become contaminated through contact with animals or contaminated soil, water, or equipment, or may become wet, which can facilitate the growth of pathogens such as *Salmonella* and/or mold. Re-use of storage bags/boxes may enhance the potential for contamination of spice, particularly if the bag is in direct contact with the spice.

FDA observed problems with storage conditions during some of its site visits and inspections. Some facilities had gaps in walls or around doors, open unscreened windows, holes in walls, ceilings, or roofs. These facility features provide opportunities for insects, rodents, birds, and water to enter the facility. FDA analysis of filth adulteration of spices in shipments of imported spice offered for entry to the United States during the three-year period FY2007-FY2009 found that most of the insect adulterants were stored product pests, indicative of poor handling, storage, and cleaning of the spices.

Transportation can also be a source of contamination if trucks and cargo holds of ships are not maintained, cleaned or sanitized, and spice packaging allows the spice itself to come in contact with contaminated surfaces. Adulteration has been documented for other commodities in transit.

The extent to which the identified potential sources of contamination contribute to contamination of spice depends on the specific distribution and storage practices employed.

6.3 SECONDARY PROCESSING AND MULTI-COMPONENT FOOD MANUFACTURING

As with the other stages of the spice supply, the practices involved in processing, packing and food manufacture can vary tremendously. Spice secondary processing typically includes additional cleaning steps to remove element of filth, application of a pathogen reduction treatment, and for some spices, grinding, cracking and/or blending procedures. Processing practices can vary tremendously among facilities and firms. For example, some spice processors/packers may pack finished spice product manually while other use a completely automated system. Smaller firms tend to use less automation and may use common pieces of equipment or lines for different spices or processing activities. Combinations of practices in a single firm has also been observed.

Based on conversations with ASTA, we know that a majority of spices in U.S. commerce are used by food manufacturers as ingredients in the production of multi-component foods. These secondary manufacturers range in size from very small firms to multi-national corporations. Some spice is also sold to foodservices and restaurants (or restaurant chains) as well as to retail outlets for consumers, as shown in Figure 6.2.

Manufacturing processes for multi-component foods can be as complicated as the myriad of foods currently available on the U.S. market. However, three basic scenarios illustrate the spectrum of possibilities with regard to the application of a pathogen reduction step: (1) a manufacturing process that does not include any pathogen reduction step (e.g., some dry spice blends); (2) a manufacturing process that includes a pathogen reduction step after the spice ingredient has been added to the food (e.g., canning of low acid foods); (3) a manufacturing process that includes a pathogen reduction step before addition of the spice ingredient(s) to the food (e.g., spice coatings on deli meats/cheeses, snack food coatings, garnish). In the case of (1) and (2), manufacturers typically use spice that has been already subjected to a pathogen reduction step (e.g., by the spice processor).

Potential sources of pathogens or filth in spices during secondary processing and multi-component food manufacturing

In a recent review published in the Journal of Food Protection, Podolak *et al*. (2010) identified five factors contributing to contamination by *Salmonella* in low-moisture food manufacturing: (1) contamination associated with poor sanitation practices; (2) contamination associated with poor facility and equipment design and maintenance; (3) contamination associated with lack of GMPs; (4) contamination associated with poor ingredient control and handling; and (5) contamination associated with poor pest control. The review provided many examples from foodborne outbreaks attributed to these types of system failures.

Cleaning and sanitation is particularly challenging in facilities processing low moisture foods because the presence of water, used to clean equipment, floors and walls, may facilitate growth of *Salmonella* or other pathogens, once present in the facility environment, which could lead to sustained opportunities for cross-contamination through the creation of *Salmonella* niches. For this reason, spice processors and food manufactures of low moisture foods generally apply dry cleaning and sanitation methods, particular in the "Primary *Salmonella* Control Area (PSCA)," the post-pathogen reduction treatment area in the facility (Chen *et al*., 2009b; GMA, 2009). In some instances, wet cleaning is used, e.g., after grinding dehydrated garlic and preparing to grind cinnamon with the same grinder. If the equipment cannot be disassembled, it is cleaned in place. FDA personnel observed excess water on floors and near spice grinding/mixing equipment during site visits to both domestic and foreign spice processors. The potential for *Salmonella* to actively grow under these specific conditions and create niches in the processing environment from which cross-contamination may occur cannot be ruled out without further study.

Dry cleaning and sanitation methods for food contact surfaces may not remove all spice particles or eliminate all *Salmonella*. As a result, use of common equipment for processing different spices or foods, such as a common grinder or common transfer line, can lead to cross-contamination of previously uncontaminated spice with contaminated spice. During a visit to one facility, FDA personnel observed that the same piping was used to transfer raw and pathogen reduction treated spice to the finished product area and the processing worker was unaware that the system allowed for cross-contamination of treated spice with untreated spice.

For spices, grinding/crushing/cracking of whole spices creates a lot of spice dust that, if not contained, may lead to cross-contamination in a processing facility. For example, widespread spice and *Salmonella* contamination of the grinding room was found and cross-contamination was suspected as a contributing cause of the 2009 *Salmonella* Rissen outbreak associated with ground white pepper. *Salmonella* was also found in the environment of 10% of domestic spice manufacturing/packing/re-packing facilities inspected in 2010 (Aug-Dec). When air, personnel and material flow is not adequately controlled, "raw" spice that may be contaminated with *Salmonella* may contaminate spice in the PSCA (after it has undergone a pathogen reduction treatment) (see examples in Podolak *et al.*, 2010 and GMA, 2009).

As noted above, FDA has learned that some spice does not undergo a pathogen reduction treatment during the secondary processing phase. If contaminated spice does not undergo such a treatment or kill step before consumption, consumers may become ill. In many cases, spice processors sell untreated spice to a food manufacturer who will apply a lethality step to the spice before allowing it to reach the consumer. Ineffective or inefficient pathogen reduction treatments may allow some *Salmonella* to survive. Pathogen reduction treatments that have not been validated or for which the process parameters are not monitored and verified, have the potential for insufficient treatment.

Spice processors as well as seasoning and food manufacturers that purchase spice that has not been produced, transported, distributed, or stored using appropriate preventive controls may have a higher risk of purchasing contaminated spice.

FDA inspections of domestic spice facilities found that pests were the most often cited CGMP violation. Surprisingly, most of the facilities inspected for which information was available, did have established pest control programs. Pests can transfer *Salmonella* or other pathogens from one location to the spice.

Poor facility design and lack of control of movement of people and material in areas where finished product is located can enhance opportunities for contamination of the environment or cross-contamination to the product (see for example, Podolak *et al.*, 2010 and Beuchat *et al.*, 2013).

The extent to which the identified potential sources of contamination contribute to contamination of spice depends on the specific spice processing and/or multi-component food manufacturing practices employed.

6.4 RETAIL/END USER

Retailers (institutional foodservices, restaurants, and retail food stores) may source their spices from a diversity of company types including importers, warehouses, re-packers, secondary processers (grinders/blenders) and wholesalers. Depending on the retail facility type, spice may be stored in a large warehouse, small storage room or directly in the kitchen area and/or customer access areas. Consumers purchasing spice for home use may obtain their spice products in small pre-packaged retail containers or from bulk bins via direct purchase from retail stores, markets, internet venders, etc., or from home gardening (limited by climate). Storage in consumers' homes can be in the kitchen, pantry or elsewhere, in the original retail packaging or transferred into other containers (e.g., spice rack specific containers). When adding spice to foods, it is not uncommon for food preparers to shake the spice out of its container directly into the food or cooking pot rather than using a utensil to do so.

Potential sources of pathogens or filth in spices in the retail or home environment

The greatest concern for spice at the retail/home setting is the potential for growth of *Salmonella* in foods to which contaminated spice has been added when food is not maintained at an appropriate temperature. It is suspected that growth contributed to the illness rates observed in several of the spice-related outbreaks, such as the outbreaks associated with spice-containing tea (Chapter 2). It is not known whether the practice of shaking a spice container over a pot during cooking can add sufficient moisture to the container to allow growth of *Salmonella*. Keller *et al*. (2013) found that initiation of *Salmonella* growth in contaminated ground black pepper at permissive water activities and room temperature generally includes a long lag-time. In such a case, evaporation of added moisture may reduce the water activity of the spice below the threshold for growth before growth begins. (Keller *et al*., 2013).

Cross-contamination may also take place, if the spice is allowed to come in contact with contaminated surfaces in the food preparation area such as the surfaces of common utensils used for spices and other foods. Contamination of spice by insects or rodent feces/hairs may take place if the spice is kept in open containers for extended periods and insects and rodents can enter the facility. These pests, if allowed access to the spice, can introduce pathogens into the spice.

The extent to which the identified potential sources of contamination contribute to contamination of spice depends on the specific distribution and storage practices employed.

7. SPICE PRODUCTION AND CONSUMPTION

7.1 U.S. SPICE SUPPLY

7.1.1 U.S. PRODUCTION

Only five spices are produced in the United States in large quantities: dehydrated onion, dehydrated garlic, capsicum, mustard seed, and sesame seed (USDA/ERS, 2012a-c; ASGA, 2012). Dry weight production values are available from the USDA Economic Research Service and are shown for 2010 in Table 7.1. The value for garlic in Table 7.1 includes production for both the dehydrated and fresh markets (converted to dry weight); separate values are not available (USDA/ERS, 2012b). As of 2010, imports of four out of five of these spices exceeded U.S. production (USDA/ERS, 2012a-c).

Table 7.1. U.S. production of spices in 2010: Dehydrated onion, dehydrated (and fresh) garlic, capsicum, mustard seed, and sesame seed.

Spice	U.S. Production (million lbs., dry weight)
Dehydrated Onion[a]	104.3
Dehydrated and Fresh Garlic[b]	138.4
Capsicum[c]	93.0
Mustard Seed[c]	41.9
Sesame Seed[d]	>22

[a] Dehydrated weight, estimated by dividing fresh weight by factor of 9. Data and conversion factor from USDA/ERS (2012a)

[b] Dehydrated weight for combined dehydrated and fresh garlic supply, estimated by dividing fresh weight by factor of 2.7 Data and conversion factor from USDA/ERS (2012b).

[c] Data from USDA/ERS (2012c).

[d] Data from ASGA (2012) which reported “over 11,000 tons.”

Domestic production of dehydrated onions is much larger than import, and has been for at least the past 30 years, Figure 7.1. As of 2010, 90% of the total U.S. supply was produced domestically (USDA/ERS, 2012a). Production far exceeds U.S. needs for the food supply; approximately half of U.S. production is exported (USDA/ERS, 2012a). Although small in a relative sense, dehydrated onion imports have grown over the last decade in both absolute and relative terms (USDA/ERS, 2012a).

Domestic production of garlic (dehydrated and fresh) accounted for all of the U.S. supply until 1969 and then ~85% of the U.S. supply until 1997, Figure 7.2. After 1997, the relative contribution of domestically produced garlic began to decrease annually, until 2006. Comparing absolute production and import values for the period after 1997, one finds that the observed change arose from an acceleration of garlic imports and a relatively stagnant, then decreasing, domestic production (USDA/ERS, 2012b). Since 2006, imports have surpassed domestic production, but only slightly. A change in U.S. import restrictions issued in 2011 may expand garlic imports even further by allowing importation from the European Union and several other countries (39 countries in all) (USDA/APHIS, 2011).

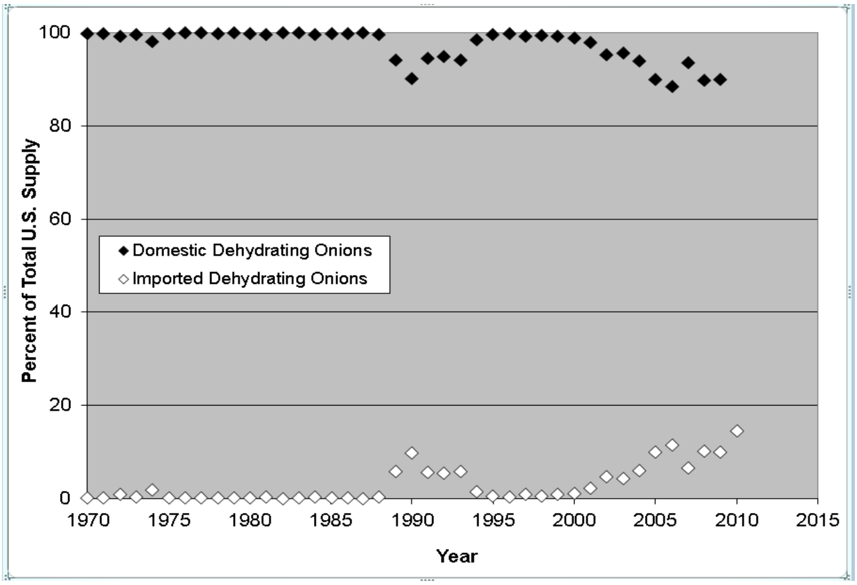

Figure 7.1. Relative contributions of domestic and imported dehydrated onion to the total annual U.S. supply, 1970 to 2010. Total annual supply values used to calculate relative contributions only include new crop and imports; beginning stocks and loss of domestic product during processing were excluded. Data derived from USDA/ERS 2012a.

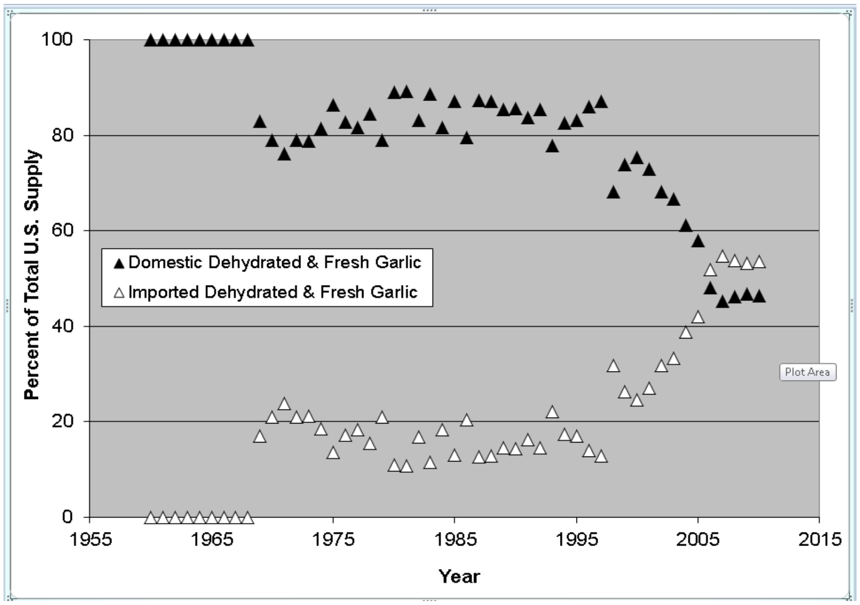

Figure 7.2. Relative contributions of domestic and imported garlic to the total annual U.S. supply, 1960 to 2010. Data includes California production only (the major producing state) and combines dehydrated and fresh garlic. Data derived from USDA/ERS (2012b).

The relative contributions of domestic production and importation of capsicum to the total U.S. spice supply have varied over the years, Figure 7.3, while the total supply has increased more than 750%, from 41.5 million pounds in 1966 to 320.8 million pounds in 2010 (peak supply was 382.9 million pounds in 2006; USDA/ERS, 2012c). The increase in the relative contribution of domestic capsicum production to the supply from 1966 to 1980, Figure 7.3, is a reflection of increased domestic production; imports were approximately constant during that period (USDA/ERS, 2012c). After 1980, both domestic and importation supplies increased through 1992 but after 1992, domestic production generally decreased while imports continued to increase in volume (USDA/ERS, 2012c). The contribution of imported capsicum to the total supply has exceeded domestic production since 1998. In 2010, domestic production of capsicums constituted 20% of the total capsicum supply (USDA/ERS, 2012c).

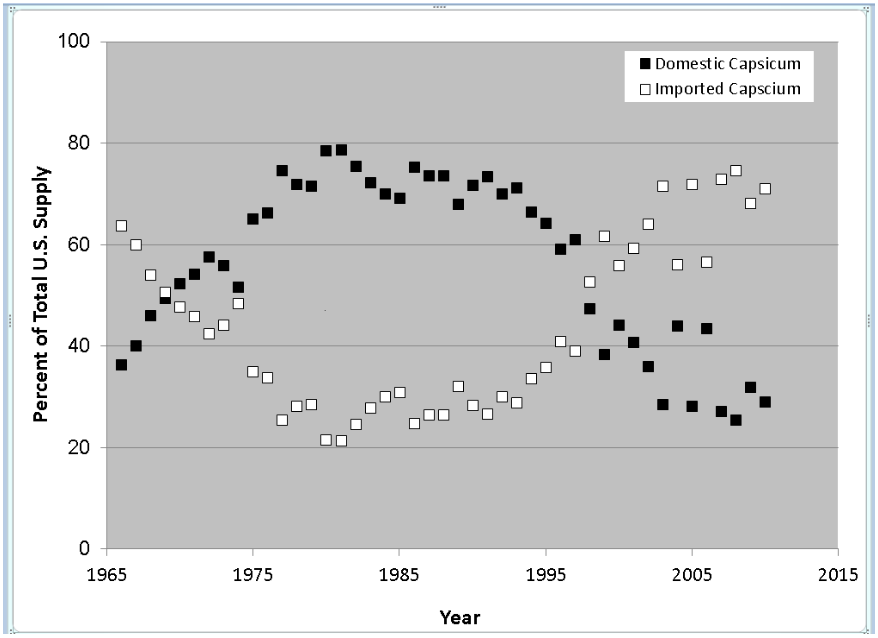

Figure 7.3. Relative contributions of domestic and imported capsicum (including paprika) to the total annual U.S. supply, 1966 to 2010. Data includes California production and New Mexico production (beginning 1976). Data derived from USDA/ERS (2012c).

The U.S. supply of mustard seed is also primarily derived from imports, Figure 7.4. From 1966 to 2010, imports have contributed more than 60% of the total U.S. supply (except for 2002, when U.S. production was exceptionally large; USDA/ERS 2012c). In 2010, 20% of the mustard seed supply was produced domestically (USDA/ERS, 2012c).

Production of domestic sesame seeds has recently increased from approximately 5 million pounds per year to over 22 million pounds in 2009 and 2010 (ASGA, 2012). As a proportion of the supply, the domestic production in 2010 represents at least 21% of the total supply (USDA/ERS 2012c; ASGA, 2012). Part of this growth in production can be attributed to the development of non-dehiscent varieties, which allow drying in the field and mechanical harvest techniques to be used (ASGA, 2012).

Several other types of spice source plants can grow effectively in the United States, e.g., basil, oregano and thyme, and are even wild harvested (see for example, Oregon's Wild Harvest, 2012) but production of the (dried) spices is small.

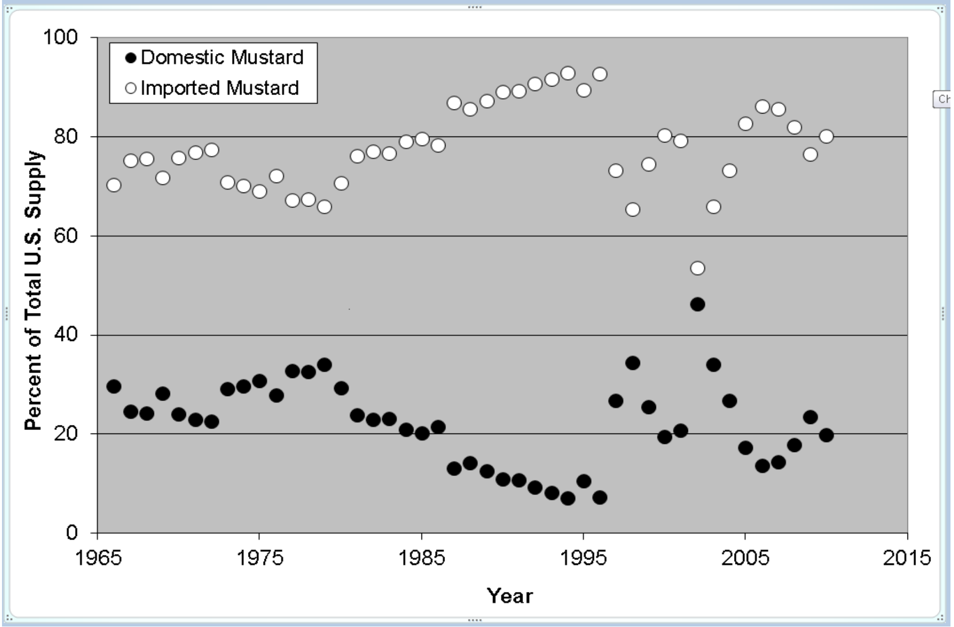

Figure 7.4. Relative contributions of domestic and imported mustard seed to the total annual U.S. supply, 1966 to 2010. Domestic mustard seed production weights used to calculate relative contribution is determined from the previous year's production minus product used as seed. Data derived from USDA/ERS (2012c).

7.1.2 U.S. IMPORTS

The United States is the single largest export market for spices (International Trade Center UNCTAD/WTO, 2006), importing more than 1.1 billion pounds of spices in 2009 (USDA/ERS 2010, 2011a). Import data for individual spices are provided by the USDA Economic Research Service (USDA/ERS, 2010) and data for 2009 is provided in Table 7.2. The relative contributions to total imports are calculated for each spice with the caveat that garlic has been excluded (because the relative proportions of imports intended for the dehydrated market is not available). While five spices (capsicum, mustard seed, black and white pepper (tabulated together), and ginger root) accounted for one half of the 2009 imports by weight, a much larger number of spices and spice blends account for the other half. Indeed, the USDA Economic Research Service found in its 2007 report that "the share of traditional spices, such as peppers, cinnamon, and vanilla declined [between 1998 and 2007] as the U.S. palate increasingly sought diverse tastes and increased its demand for such products as nutmeg, saffron, fennel and turmeric" (Brooks *et al.*, 2009).

Spices are primarily produced in developing countries (International Trade Centre UNCTAD/WTO, 2006). However, data from the USDA Foreign Agricultural Service (FAS) on U.S. imports of spices show that spice imports to the United States came from over 140 countries (USDA/FAS, 2011). Table 7.3, derived from FAS tables, identifies the top 20 countries for 2010 U.S. spice import, based on value; dehydrated onion and garlic are not included in these figures. The table also provides a comparison of imports from the same countries one decade earlier. Comparing 2010 with 2000, we see that total spice imports increased by nearly 60% by value over this time period, with imports valued at more than 1 billion dollars in 2010. The relative contribution to spice imports from different countries has also changed with time.

Table 7.2. Spice imports in 2010 by weight.

Spice	2010 Import Weight[a] (million pounds)	2010 Percent of Total Spice Imports[b] (%)
Capsicum[c]	227.8	18.7
Mustard Seed	169.3	13.9
Pepper, Black and White	155.4	12.8
Ginger Root	97.4	8.0
Sesame Seed	81.6	6.7
Cassia and Cinnamon	54.3	4.5
Cumin Seed	22.7	1.9
Dehydrated Onion[d]	17.8	1.5
Coriander Seed	10.6	0.9
Poppy Seed	10.2	0.8
Fennel Seed	8.6	0.7
Turmeric	7.8	0.6
Caraway Seed	6.2	0.5
Sage	5.0	0.4
Anise Seed	4.7	0.4
Celery Seed	4.7	0.4
Vanilla Beans	3.9	0.3
Nutmeg	3.9	0.3
Pimento (Allspice)	2.8	0.2
Cloves	2.8	0.2
Mace	0.7	0.1
Dehydrated and Fresh Garlic	159.6[e]	–[e]
Other Spices	317.7	26.1
Total Spice Imports (excluding dehydrated garlic)	1215.9	100.0

[a] Data from USDA/ERS (2012c), unless noted otherwise

[b] Total spice weight used to calculate percent values excludes garlic.

[c] Capsicum includes dried capsicum and paprika.

[d] Dry weight equivalent. Data from USDA/ERS (2012a).

[e] Dry weight equivalent. Data from USDA/ERS (2011b).

Table 7.3. Spice imports by value, 2000-2010.

Country	2000 Import Value[1] (million $)	2010 Import Value[1] (million $)	2010 Percent of All Imports	Change in Percentage of All Imports, 2000-2010
India	101.9	161.8	16.1	-0.1
Indonesia	132.4	146.2	14.6	-6.5
China	26.9	109	10.9	6.6
Canada	30.2	70.9	7.1	2.3
Mexico	42	64.3	6.4	-0.3
Vietnam	18.6	64.3	6.4	3.4
Peru	1.5	49.5	4.9	4.7
Spain	17.7	42	4.2	1.4
Brazil	40.7	39.9	4	-2.5
Madagascar	30.6	28.3	2.8	-2.0
Guatemala	20	23.7	2.4	-0.8
Turkey	18.4	20.4	2	-0.9
Egypt	7.3	19.2	1.9	0.7
Germany	3.9	15.6	1.6	0.9
Sri Lanka	7.4	15.4	1.5	0.3
Israel	10.4	12.6	1.3	-0.4
France	5.9	10.4	1	0.1
Colombia	0.5	10.3	1	1.0
Syria	7.5	8.1	0.8	-0.4
Pakistan	1.8	7.2	0.7	0.4
Other Countries	102.4	83.3	8.3	-8.0
World Total	627.9	1002.4	100	-

[1] Data from USDA/FAS (2011).

China's share increased by 6.6 percentage points from 2000 to 2010 while that of Indonesia decreased by nearly that amount. Smaller gains in import share during this period were observed for Peru, Vietnam, and Canada, in decreasing order of gain. In 2010, India, Indonesia and China together provided nearly 42% of imported spices (excluding dehydrated onion and garlic). Ten countries supplied 77% of spice imports by value in 2010 (excluding dehydrated onion and garlic). It is also noteworthy that some countries, for example, Germany, that are not major spice producers, are major exporters of spice to the United States. These countries import spice from developing countries and may process, blend, or re-package it before exporting it to the United States. In 2007, crushed black pepper imports from Germany were valued at $8 million (Brooks *et al.*, 2009).

The relative contributions from each country to U.S. supplies of individual spices have been reviewed by the USDA Economic Research Service for 1980-1994 (Buzzanell *et al.*, 1995) and 1998-2007 (Brooks *et al.*, 2009). In 2007, capsicums were primarily imported from China, Mexico, Peru and India whereas black pepper was imported from Brazil, Vietnam and India (Brooks, *et al.*, 2009). Mustard seed is primarily imported from Canada (Buzzanell *et al.*, 1995) while ginger is primarily imported from China (Brooks *et al.*, 2009). More than 70% of vanilla imports in 2007 were from Madagascar with smaller contributions from Uganda, Indonesia, India and Papua New Guinea. Cumin seeds are imported from a number of countries including India, Syria, Turkey, China and Pakistan while cinnamon is imported from Indonesia, Sri Lanka, Vietnam, Brazil and China. The country-spice import matrix for the United States continues to evolve. Appendix B lists the main spice-producing countries and their absolute and relative contributions to world-wide production for 2010. Review of the tables included in Appendix B (from FAO 2013a-b) demonstrate the wide diversity of production countries and illustrates the potential for future growth and evolution of the U.S. import market.

7.2 SPICE CONSUMPTION IN THE UNITED STATES

7.2.1 CONSUMER POPULATION

A large fraction of the U.S. population consumes spices. Based on a retail study of household use in July 2009, an estimated 86% of households in the United States use fresh or dried herbs, spices, or seasoning blends (Mintel International Group, 2009). A similarly large fraction, 78%, of households report using herbs, spices and seasoning blends beyond salt and pepper (Mintel International Group, 2009). Small differences in household use by gender, age, ethnicity/race, and household income are reported. Among the survey participants (aged 18-65+ years), a slightly larger percentage of women (84%), people in the age range 25-34 (82%), Hispanic households, and households with annual incomes in the range $100K-149K (84%) report using herbs, spices and seasoning blends other than salt and pepper (Mintel International Group, 2009). These estimates do not include the additional percentage of the population that may only consume spices in foods prepared or seasoned outside the home, e.g., by food manufacturers, food services, restaurants or other prepared food suppliers. Indeed, a majority of the spice supply is sold wholesale and most is ultimately incorporated into prepared foods (Buzzanell *et al*., 1995).

7.2.2 CONSUMPTION MASS AND FREQUENCY

An estimate of annual per capita spice consumption in the United States is provided by the USDA Economic Research Service. This estimate is based on annual food availability data and the U.S. population. From 1966 to 2010, per capita consumption of spices other than dehydrated onion and garlic, increased nearly 300%, with an average rate of increase of 0.5 lbs./decade (USDA/ERS, 2012c), Figure 7.5. Per capita consumption of garlic, dry and fresh, has also increased dramatically with a rate of increase of ~0.3 lbs./decade (dry weight equivalent rate), between 1970 and 2010 (USDA/ERS, 2012b). In contrast, per capita consumption of dehydrated onion, as estimated from the total net supply, has been approximately constant since 1970 (USDA/ERS, 2012a). In 2010, annual per capita consumption of spices excluding dehydrated onion and garlic was approximately 3.47 lbs. (1575 g) and including dehydrated onion was approximately 3.64 lbs. (1653 g; USDA/ERS, 2012c). Assuming spices are consumed in three meals per day, the per capita spice consumption is estimated to be 1.4 g per eating occasion.

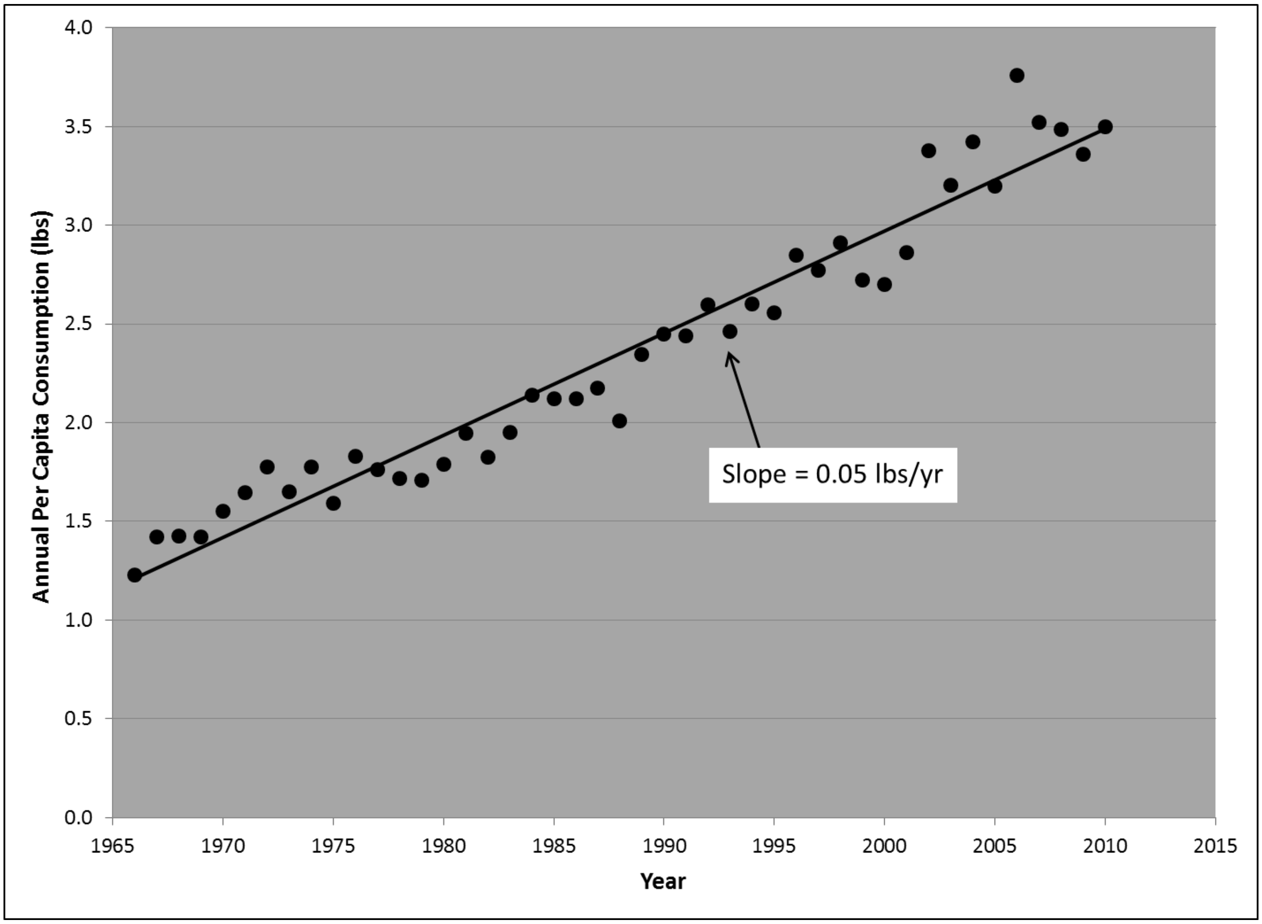

Figure 7.5. Annual per capita spice consumption in the U.S excluding dehydrated onion and garlic, 1966-2010. Data from USDA/ERS (2012c).

The FDA/CDC National Health and Nutrition Examination Surveys (NHANES), employing the U.S. EPA Food Commodity Intake Database (FCID), which includes commodity-specific intake data derived from the *What We Eat in America* (WWEIA) survey, provide estimates of daily spice intake for spice consumers in the United States. For 2003-2006, average daily consumption was approximately 1 g for spices other than capsicum and 5 g for spices including capsicum (DiNovi and Edwards, 2013; EPA, 2012a). These estimates include consumption of fresh herbs and chili peppers and are derived from standard recipes for foods consumed and reported to WWEIA. Based on these estimates, the mean spice consumption per eating occasion is 0.3-1.7 g for 3 eating occasions per day (DiNovi and Edwards, 2013; EPA, 2012a). The inclusion of fresh herbs and chili peppers (in capsicums) positively biases this estimate while the use of standard recipes, which do not necessarily include minor spice ingredients, increases its uncertainty.

Daily or eating occasion consumption estimates for certain individual spices are available from the NHANES database while others can be derived from food availability data. The NHANES database indicates that the highest mean eating occasion consumption estimates for individual spices are for sesame seeds and dried basil, at approximately 150 mg/eating occasion (DiNovi and Edwards, 2013; EPA, 2012a). Capsicum consumption is larger, ~1.4 g/eating occasion, but this value includes dry and fresh. Table 7.4 provides estimates for daily consumption of a wide range of spices based on food availability data. Except for dehydrated onion and the combined estimate for dehydrate and fresh garlic, where net supply estimates are available, the consumption estimates in Table 7.4 provide upper limits to the per capita daily consumption of each spice because the values are derived from gross supply data. Further, the per capita estimates assume all spices in the supply are consumed each year and that everyone in the population is a consumer. These assumptions increase the uncertainty in these values as measures of true consumption. Finally, the food availability-based daily consumption estimates for spices that are infrequently consumed or consumed by only a small segment of the population, will provide particularly poor estimates of actual consumption.

Table 7.4. Estimated per capita spice consumption based on food availability, 2010[a].

Spice	lbs./yr.	g/day
Capsicum[b]	1.0	1.3
Other spices	1.0	1.3
Dehydrated and Fresh Garlic[c]	0.9	1.1
Mustard	0.7	0.8
Black and white pepper	0.5	0.6
Sesame seed	0.3	0.4
Ginger	0.3	0.4
Dehydrated Onion	0.2	0.2
Cassia	0.2	0.2
Cumin	0.07	0.09
Coriander	0.03	0.04
Poppy	0.03	0.04
Fennel	0.03	0.03
Turmeric	0.03	0.03
Caraway	0.02	0.02
Sage	0.02	0.02
Anise Seed	0.02	0.02
Vanilla Beans	0.01	0.02
Celery	0.02	0.02
Cloves	0.01	0.01
Allspice	0.01	0.01
Mace	0.002	0.003

[a] Based on gross supply (USDA/ERS, 2012c) except for dehydrated onion and garlic, where net supply data was available (USDA/ERS, 2012a-b). See text for discussion.

[b] Includes paprika

[c] Dehydrated weight for combined dehydrated and fresh garlic supply, estimated by dividing fresh weight by factor of 2.7 Data and conversion factor from USDA/ERS (2012b).

Estimates of the variability and frequency of spice consumption for all spices, for individual spices, and for different segments of the population are not available. We know that some dishes or foods contain amounts of spice larger than the per eating occasion means listed above, e.g., black pepper encrusted foods such as salami, and when consuming these foods, exposure may be larger if the food is contaminated with *Salmonella*. Despite the absence of data variability, based on experience we do not expect consumption of any particular spice during a single eating occasion to exceed more than a few grams. The most important data gap with regard to consumption of spices is a measure of the fraction of spices that are cooked sufficiently to provide an effective kill step for microbial pathogens such as *Salmonella*.

8. CURRENT MITIGATION AND CONTROL OPTIONS

8.1 U.S. REGULATORY STANDARDS AND PROGRAMS

In this section we briefly review major regulatory standards and discuss regulatory programs that address the food safety of spices with respect to adulteration by pathogens or filth.

8.1.1 FEDERAL FOOD, DRUG, AND COSMETIC ACT

FDA can take action against a food if it is adulterated, misbranded, or otherwise not in compliance with all applicable federal laws. Four main sections in the *Federal Food, Drug, and Cosmetic Act* (FD&C Act) address spice adulteration:

For spices adulterated with any poisonous or deleterious substance: section 402(a)(1) of the FD&C Act – "A food shall be deemed adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health." This means that a spice containing *Salmonella* or another human pathogen violates the FD&C Act.

For spices adulterated with filth: section 402(a)(3) of the FD&C Act – "A food shall be deemed adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance or is otherwise unfit for food." The Defect Action Levels describe the maximum concentrations of natural or unavoidable defects in foods that present no health hazards for humans. If the Defect Action Levels (DALs) 21 CFR 110.110 (FDA, 2012h) are exceeded, FDA would consider that spice to be adulterated.

For spices manufactured under insanitary conditions: section 402(a)(4) of the FD&C Act – "A food shall be deemed adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

For spices offered for import into the United States: section 801(a)(3) of the FD&C Act authorizes FDA to detain a regulated product that appears to be adulterated or misbranded.

8.1.2 PUBLIC HEALTH SERVICE ACT

The Public Health Service Act (42 U.S.C., Chapter 6A, Subchapter II, Part G, Section 264; FDA, 2013p) allows the Surgeon General, with approval of the Secretary of Health and Human Services, "to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession."

8.1.3 U.S. REGULATORY MECHANISMS

8.1.3.1 CURRENT GOOD MANUFACTURING PRACTICES (CGMPS), INSPECTIONS AND ENVIRONMENTAL SAMPLING

FDA provides regulatory oversight of food through its field staff. Current Good Manufacturing Practices (CGMP) regulations for manufacturing, packing or holding human food describe general food safety principles and specific aspects of production that impact the safety of a product. These regulations currently can be found at 21 CFR 110 (FDA, 2012i); proposed changes to these regulations can be found in proposed 21 CFR 117 (78 Federal Register 3646, January 16, 2013) (FDA, 2013s).

FDA performs both foreign and domestic inspections of food (including spice) manufacturing, packing, and storage facilities each year. Some inspections include environmental sampling. While most of the spice supply is imported, domestic firms handling imported spice may process (e.g., treat, grind, crack, and/or blend), pack and/or re-pack the spice before the product is made available to the consumer/customer.

Domestic inspections differ from foreign inspections in a number of ways, including the fact that domestic inspections can be unannounced, whereas foreign inspections need to be planned and coordinated well in advance. Additionally, domestic inspections may include environmental and/or product sampling, whereas, except in very limited circumstances (i.e., outbreak investigations), FDA inspectors do not currently take environmental or product samples during foreign inspections.

Effectiveness of CGMPs, Inspections and Environmental Sampling in preventing contamination of spice with pathogens or filth. FDA evaluates compliance of food facilities with CGMPS through inspections, which may include environmental sampling. Data from FDA inspection reports on firms that manufacture, pack or re-pack spices for the years FY2007-FY2012 are shown in Table 8.1. Each inspection is assigned one of three classifications: Official Action Indicated (OAI), Voluntary Action Indicated (VAI), or No Action Indicated (NAI). In addition, FDA evaluates all the evidence collected during inspections and determines whether additional actions are warranted, e.g., issuing a warning letter, recall, or regulatory meeting.

Table 8.1 provides the average annual percentage of FDA domestic or foreign inspections of firms that manufacture, pack, or re-pack spices that were classified as OAI or VAI. In addition, FDA evaluates all the evidence collected during inspections and determines whether additional actions are warranted, e.g., issuing a warning letter, recall, or regulatory meeting.

During FY2007-FY2012, FDA inspected 2649 domestic firms that manufacture, pack, or re-pack spices, with the annual total inspections for this group of firms in the range of 321-555. Between FY2007-FY2010, there were too few foreign inspections of firms that manufacture, pack, or re-pack spices to provide a meaningful rate for these classifications. However, during FY2011-FY2012, 70-73 foreign inspections of firms that manufacture, pack, or re-pack spices were performed annually and rates for OAI and VAI classifications are provided.

Table 8.1. Classification of inspections of firms that manufacture, pack or re-pack spices, FY2007-FY2012

	Domestic Firms		Foreign Firms[a]	
Fiscal Year	OAI Classification Percentage (%)	VAI Classification Percentage (%)	OAI Classification Percentage (%)	VAI Classifications Percentage (%)
2007	0.3	33	NA	NA
2008	0	31	NA	NA
2009	1	38	NA	NA
2010	1	35	NA	NA
2011	3	34	0	49
2012	0.7	26	6	60

[a] No statistics are calculated for years in which fewer than 30 inspections were performed.

As illustrated in Table 8.1, only a small percentage of domestic or foreign inspections of firms that manufacture, pack, or re-pack spices during the years FY2007-FY2012 identified significant objectionable conditions or practices. A substantial percentage of inspections were classified as VAI, with a significantly larger proportion of foreign inspections in FY2012 resulting in this decision as compared with domestic inspections during that year. Because the observations that lead to a VAI classification do not necessarily pertain to an immediate food safety issue, interpretation of the VAI classification rates is difficult.

Comparison of the inspection statistics for firms that manufacture, pack, or re-pack spices with those for other food sectors provides a relative measure of compliance with CGMPs. Table 8.2 provides statistics for domestic inspections of firms that manufacture, pack, or re-pack spices as well as firms that manufacture, pack, or re-pack other low moisture foods. Annual numbers of domestic inspections for the firms in the food sectors listed in Table 8.2 ranged from 78-758 during this time period. Also provided in Table 8.2 are the average statistics for inspections of all other FDA regulated foods sectors, which numbered annually in the range ~17,000 – 24,000 for FY2007-FY2012. The rate of OAI and VAI classifications for inspections of domestic firms manufacturing, packing or re-packing spices is not statistically different (p>0.05) from rates for firms manufacturing, packing or re-packing other low moisture foods, such as cereals, chocolate, coffee/tea, nuts/edible seeds, milled whole grain, or the average rate for firms handling other categories of foods.

Table 8.2. Classification of domestic inspections of firms that manufacture, pack or re-pack low moisture foods, average annual rates FY2007-FY2012

	Average Annual Percentage of FY2007-FY2012 Domestic Inspections			
Product Group	**OAI Classifications Percentage of firms mean %**	**(SD)**	**VAI Classifications Percentage of firms mean %**	**(SD)**
Spices	1.0	(1.0)	33	(4)
Cereal prepared/Breakfast food	0.1	(0.3)	32	(5)
Chocolate/Cocoa Powder	0.5	(0.4)	34	(2)
Coffee, Tea	0.7	(0.4)	33	(5)
Nuts/Edible Seeds	1.3	(1.0)	38	(6)
Whole grain, milled	1.4	(1.5)	29	(5)
All Other FDA-regulated Food Categories	1.9	(1.1)	38	(3)

In order to learn more about spice manufacturing, packing and re-packing environments, a special assignment was issued by FDA in 2010 for inspections of 59 domestic firms of varying sizes that manufacture, pack and/or re-pack spices. Each inspection included environmental sampling and the collection of additional information. Inspectors were instructed to restrict environmental sampling to non-food contact surfaces in order to gauge the potential for cross-contamination in the facility. Sampling was focused in processing and packing areas positioned after the pathogen reduction step in the product flow, if such a step took place in the firm, which has been referred to by the food industry as the "Primary *Salmonella* Control Area (PSCA)" (Chen *et al.*, 2009b; GMA, 2009). Inspectors were instructed to sample areas where cross contamination between the floor or other surfaces and food contact surfaces and equipment may take place as well as locations/pathway where pre-treatment products (e.g. spice dust) may be transported to the post-treatment areas inadvertently. Inspectors were also asked to sample and identify areas where moisture was observed or was likely to occur in the processing area.

Ten percent of spice firms inspected (6/59) were found to have *Salmonella*-positive environmental samples. Among the six firms with *Salmonella*-positive environmental samples, two were very small (<$100,000 annual sales), three were medium size ($1,000,000 –$9,999,999 annual sales), and one was very large (>$50,000,000 annual sales). Most of the firms (5/6) processed spices and many also packed/re-packed spices; one firm was engaged in only packing/re-packing spices.

Multiple *Salmonella*-positive environmental samples were found in two of the firms, with 7% (14/193) and 23 % (24/103) of environmental samples collected in these firms testing positive, respectively. *Salmonella*-positive swab samples obtained in the six spice firms were recovered from three different zones: zone 2 (non-product contact surfaces in close proximity to product such as the exterior of spice grinding equipment, floors or walls), zone 3 (non-product contact surfaces in the spice processing/handling areas of the facility that are not in close proximity to food contact surfaces such as forklifts, drains, or walls) and zone 4 (non-product contact surfaces far from the spice processing/handling areas of the facility such as locker rooms, bathrooms, hallways, and stairways). Most samples, including most positive samples, were collected from areas classified by inspectors as Zone 2. Common locations for *Salmonella*-positive samples were in the grinding and packing/re-packing areas, where cross-contamination from the environment to the product could occur.

Two of the firms in which *Salmonella* was found in the environment had undergone FDA environmental sampling in past inspections and one of them had had *Salmonella*-positive environmental samples during the past inspection. Some of the samples that tested positive in the firm with a past history of *Salmonella*-positive environmental samples contained the same *Salmonella* strain (identical PFGE) as that found two years earlier. This observation raises the possibility that the *Salmonella* strain was never eradicated from the environment after the first inspection or that a common/frequent source of contamination is responsible for re-contamination of the facility. These data demonstrate that serotyping *Salmonella* isolates found in the environment (or product) provides additional information about the contamination that may be useful in investigating possible contamination sources. Product samples were not taken as a part of this study so a relationship between the observation of positive environmental samples and the likelihood of contamination of finished product could not be determined.

Data on CGMP practices, applications of pathogen- and pest-reduction processes, and product testing were collected for many of the firms. The most commonly reported CGMP citations listed on the FDA Form 483's issued to the firms in these inspections are listed in Table 8.3. Citation frequencies ranged from 2 to 12 firms among the 59 inspected.

Grouping citations into major CGMP categories, these inspections identified a number of areas of concern: (1) cleaning (e.g., accumulation of food particles on equipment or within the facility, equipment not easily cleanable, insufficient cleaning; 21 firms, 23% of all FDA Form 483 citations), (2) pests (17 firms, 19% of citations), (3) employee hygiene issues (e.g., using bare hands on spices, lack of hand washing, failure to provide hand washing facilities at each necessary location; 16 firms, 17% of citations) and (4) issues with the facility design or state of repair (e.g., holes in the ceiling, cracks in floors, no bathroom doors, product debris in unreachable areas; 19 firms, 15% of citations). Even though pests were often identified in CGMP citations, a majority of firms reported having a regular pest-prevention/reduction program (28/29 inspected firms for which this information was available).

FDA Form 483 citations for moisture (e.g., leaking water from ceiling, dripping water from air conditioning vent, standing water) were issued to 6 firms. One inspector observed whole dried capsicums being sprayed with water and was told the practice was used to reduce the likelihood of cracking/breaking during packaging.

Information on the frequency that spices handled by each firms underwent a pathogen reduction treatment was also gathered. Of the 26 firms for which this information was gathered, 23 firms reported some (10/23) or all (13/23) of the spice handled by the firm treated. In most cases (15/23 firms), spice was treated before reaching the facility.

Information on environmental sampling and *Salmonella* product sampling and testing programs within firms was recorded in 25 of the inspections. Among these, a larger percentage of large spice firms (>$10 million annual sales) reported having environmental sampling programs (73% (11/15)) and/or product sampling programs (87% (13/15)) than smaller spice firms (<$10 million annual sales) where 10% (1/10) of firms reported having environmental sampling program and 30% (3/10) of firms reporting having product sampling programs.

Table 8.3. Sixteen most frequent citations reported on FDA Form 483 issued during domestic spice firm inspections, August-December 2011

Rank	Citation[a]	21 CFR Reference	Short Description	Long Description
1	1560	110.35c	Lack of effective pest exclusion	Effective measures are not being taken to [exclude pests from the processing areas] [protect against the contamination of food on the premises by pests].
2	1306	110.20(b)(7)	Screening	Failure to provide adequate screening or other protection against pests.
3	1422	110.20B4	Floors, walls and ceilings	The plant is not constructed in such a manner as to allow [floors] [walls] [ceilings] to be [adequately cleaned and kept clean] [kept in good repair].
4	1553	110.35a	Buildings/good repair	Failure to maintain [buildings] [fixtures] [physical facilities] in repair sufficient to prevent food from becoming adulterated.
5	3652	110.37e1	Suitable locations	Failure to provide [hand washing] [hand sanitizing] facilities at each location in the plant where needed.
6	1554	110.35a	Cleaning and sanitizing operations	Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of [food] [food-contact surfaces] [food-packaging materials].
7	1695	110.80b2	Manufacturing conditions	Failure to [manufacture] [package] [store] foods under conditions and controls necessary to minimize [the potential for growth of microorganisms] [contamination].
8	2392	110.80b1	Maintenance of equip., utensils, and finished food packaging	Failure to maintain [equipment] [utensils] [finished food containers] in an acceptable condition through appropriate cleaning and sanitizing.
9	1125	110.40a	Materials and workmanship	The [design] [materials] [workmanship] of [equipment] [utensils] does not allow proper [cleaning] [maintenance].
10	1293	110.20b2	Contamination with microorganisms, chemicals, filth, etc.	Proper precautions to protect [food] [food-contact surfaces] [food-packaging materials] from contamination with [microorganisms] [chemicals] [filth] [extraneous material] cannot be taken because of deficiencies in plant [size] [construction] [design].
11	1406	110.10b6	Effective use of hair restraint	Failure to wear [hair nets] [head bands] [caps] [beard covers] [appropriate hair restraints] in an effective manner.
12	1427	110.20b5	Safety lighting and glass	Failure to provide safety-type [light bulbs] [lighting fixtures] [skylights] [glass] suspended over exposed food.
13	1552	110.35a	Buildings/sanitary	Failure to maintain buildings, fixtures, or other physical facilities in a sanitary condition.
14	1701	110.80b7	Equipment, containers, utensils	Failure to [construct] [handle] [maintain] equipment, containers and utensils used to [convey] [hold] [store] food in a manner that protects against contamination.
15	2386	110.80a1	Storage	Failure to store raw materials in a manner that [protects against contamination] [minimizes deterioration].
16	2394	110.80b6	Contamination by raw materials, refuse, other ingredients	Failure to take effective measures to protect finished food from contamination by [raw materials] [refuse] [other ingredients].

[a] The citation number is an FDA number for the specific observation described in the corresponding long description. Several different observations may be associated with the same section of the CFR, so the CFR reference is not sufficient to identify the observation.

In summary, when measured by FDA inspection classifications, ≤ 3% of domestic firms that manufacture, pack, or re-pack spices were found to be out of compliance with FDA regulations regarding food safety and sanitation during the years FY2007-FY2012. The annual percentage of domestic firms that manufacture, pack, or re-pack spices that were inspected and found to be out of compliance during the years FY2007-FY2012 was not statistically different from the annual percentages for inspections of firms that manufacture, pack, or re-pack other low moisture foods. More data are needed to evaluate the rate of compliance among foreign firms.

Information gathered in 2010 from 59 inspections of domestic firms that manufacture, pack, or re-pack spices provide additional information about the potential for contamination within firms and preventive control programs and practices used by firms. *Salmonella* was found in the environment of ten percent of firms inspected including in the PSCA and most contamination sites were in locations where cross-contamination to spice product is most likely to occur (Zone 2). Among the 26 firms for which this information was available, 88% reported that some (38%) or all (50%) of the spice handled by the firm had been or would be subjected to a pathogen reduction treatment before leaving the firm. Regular environmental and product sampling programs were common in large firms (≥73%) but not as common in small firms (≤30%).

8.1.3.2 PRODUCT SAMPLING, REFUSALS, AND RECONDITIONING

Product sampling is a mechanism used within the FDA Import Foods - General Compliance Program, which covers imported food entries, and within the FDA Domestic Food Safety - Compliance Program, covering food products in domestic commerce. Spices may be sampled as part of either of these programs. Because spices are primarily produced outside the United States, the majority of sampling activities related to spices target imported shipments of spice offered for entry to the United States. In addition to general surveillance activities, FDA can issue field assignments to request targeted activities for a particular food. Field assignments are often used to gather data regarding a specific problem or product that are not addressed directly in a routine compliance program. Additionally, spices may be sampled at different points along the food chain, e.g., as part of a foodborne illness outbreak investigation.

The FDA regulatory programs help prevent contaminated spices from reaching the U.S. consumer by (1) directly identifying contaminated spice shipments/lots and either having them removed from the food supply or reconditioned to meet food safety requirements, (2) placing importers with shipments found contaminated on import alert and (3) indirectly encouraging the spice industry to prevent/remove contamination and eliminate/mitigate practices that would lead to contamination to avoid FDA enforcement actions for shipments found violative.

When a food is found to be adulterated with pathogens or filth, it is refused admission. When a product is initially refused admission, the importer can (1) export the product; (2) destroy the product; or (3) request permission from FDA to recondition the product to bring the product into compliance. If the importer requests reconditioning, the reconditioning proposal is approved by FDA and the reconditioning is successful in remedying the violation, FDA will release the product into U.S. commerce.

Effectiveness of product sampling, refusals and reconditioning in preventing contaminated spice from entering the U.S. food supply. Refusal of or reconditioning contaminated shipments identified by the FDA product sampling program prevents the contaminated spice from entering the U.S. supply or eliminates the contamination from the spice. During the period FY2007-FY2010, 906 imported spice shipments (including sesame seeds) were refused entry on the basis of the presence or potential for presence of *Salmonella* and/or filth. Among these shipments, 749 shipments of spice were refused entry because of the presence or potential presence of *Salmonella* and 238 shipments were refused because of the presence or potential presence of filth. Data on reconditioned imported shipments is provided in section 8.2.1.1.

While only a small fraction of shipments of imported spice offered for entry to United States are examined by FDA for the presence of *Salmonella* (~1%) or filth (~0.05%), when a shipment is found violative, the importer can be placed on import alert. Once on import alert, all subsequent shipments of the same spice from that importer would be subject to “detention without physical examination.” FDA’s decision to remove a product from detention without physical examination is based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved. FDA’s decision to remove the product from the

Import Alert is based on evidence that provides confidence that future entries will be in compliance with the FD&C Act. In this way, the product sampling program can identify and prevent importers of contaminated spice from impacting the food safety of spice in the United States. Import Alerts related to shipments of spice contaminated with *Salmonella* or filth are discussed in the next section (8.2.1.3).

The indirect deterrent effect of regulatory sampling is difficult to measure but comparisons of compliance rates among surveillance samples provide insights into the extent of contamination of spices with *Salmonella* and/or filth; these were discussed in Sections 4.1.3 and 4.2.3.

Finally, FDA has examined the efficacy of its sampling protocol for spices (Andrews and Hammack, 2003) in detecting shipments of imported spice contaminated with *Salmonella*. Based on models developed from *Salmonella* prevalence and enumeration data collected for shipments of imported capsicum and sesame seed, the sampling protocols employed by FDA to test samples of spice for the presence of *Salmonella* are predicted to be efficient in detecting the more highly contaminated spice shipments, which contain the majority of the *Salmonella* in the imported supply (Appendix C, Table C3; Van Doren *et al.*, 2013c). Additional research is needed to determine the applicability of these predictions to other types of imported spice.

8.1.3.3 IMPORT ALERTS, GREEN LISTS AND COUNTRY AGREEMENTS

Import Alerts. An Import Alert is a communication tool developed by FDA to disseminate import information (problems, violations, trends, etc.) for inspectional and compliance operating instructions to FDA field personnel, Centers (such as the Center for Food Safety and Applied Nutrition) and the Office of Regulatory Affairs headquarter units. FDA's use of Import Alerts results in effective and uniform import coverage nationwide, as well as significantly improving the uniformity of enforcement in import problem areas. The subject of an Import Alert may be a specific hazard, commodity, geographical area, firm, or any combination thereof.

Historically, FDA has decided that issuance of an Import Alert is appropriate when (1) there is evidence of the importation of violative products; (2) there is evidence of the importation of products that may appear violative; or (3) when other information indicates that future entries of an imported product may appear violative. For example, when an imported product is found to be adulterated or misbranded, FDA can use that information as evidence that future shipments from that manufacturer appear to violate the FD&C Act. FDA can subject future entries to "Detention Without Physical Examination" (DWPE), and list the manufacturer and product on an import alert. If there is no existing import alert to address the violation, FDA can create a new import alert.

Products subject to DWPE will be detained without examination when they are offered for entry to the United States. Firms have the opportunity to submit evidence to overcome the appearance of the violation. If they are successful, the product will be allowed entry. If they are unable to overcome the appearance of the violation, the product will be refused admission.

For spices, the most common causes for DWPE are filth and pathogens. Table 8.4 lists the import alerts involving DWPE that are primarily/exclusively associated with spices and address issues of pathogen and/or filth adulteration (FDA, 2013h).

Import Alert 99-19 (Detention Without Physical Examination of Food Products Due to the Presence of *Salmonella*; FDA, 2013i) lists firms and the specific foods for which evidence has indicated the likelihood of *Salmonella* contamination. Firms importing shipments of imported spices other than black pepper from India and white and black pepper from Brazil (which are covered by Import Alerts 28-02 and 28-04, respectively) may be listed on this import alert. As can be seen from Table 8.5, a majority of the firms on Import Alert 99-19 are cited for the likelihood *Salmonella* contamination of spices and/or sesame seeds, even though the import alert is not limited to spices and sesame seeds. The names and numbers of firms on the import alert have changed through time but the proportion of firms cited for the likelihood of *Salmonella* contamination of spices remains large.

Table 8.4. Import Alerts involving DWPE that are primarily/exclusively associated with spices and address issues of pathogen and/or filth adulteration.

Number	Years Active[a]	Problem	Type	Action[b]
99-19	1994-present	*Salmonella*	Firm	DWPE particular foods from each firm
28-02	1987-present	*Salmonella*, filth, mold, foreign matter	Country/World Wide	DWPE of Indian Pepper
28-04	1989-present	*Salmonella*	Country/World Wide	DWPE of Black and White Pepper from Brazil
24-11	1988-present	excessive mold	Country/World Wide	DWPE Dried Peppers from Mexico
28-03	1977-present	Filth (mammalian and other excreta, insect filth)	Firm	DWPE Sesame seeds from Mexico and surveillance of sesame seeds from other countries

[a] First year in range is date when the Import Alert was initiated. For the "Firm" type Import Alerts, this data corresponds to the date when the import alert was initiated. The date when each food/firm was put on the Import Alert is listed in the Import Alert.
[b] DWPE means "detention without physical examination."

Table 8.5. Number of firms listed on Import Alert 99-19 for DWPE in October 2010 and June 2013

Number of Firms on Import Alert 99-19	# Firms (2010)[a,b]	# Firms (2013)[b,c]
Total firms with one or more products identified for DWPE	733	882
Firms with spices cited as industry code 28	520 (71%)	595 (67%)
Firms with spices cited as industry code 23K-02	110 (15%)	83 (9%)

[a] Data taken from Import Alert 99-19 as of October 2010 (FDA, 2013i).
[b] Included in the count may be multiple listings of the same parent company because the company used several FEI numbers, listed different addresses or spelled its name differently.
[c] Data taken from Import Alert 99-19 as of June 2013 (FDA, 2013i).

The firms listed on Import Alert 99-19 are from many different countries. Table 8.6 lists the countries with the largest number of firms identified for DWPE of one or more types of spices (sum of firms with industry 28 and/or product code 23K02) as of July 1, 2011 and June 26, 2013. The largest number of firms on Import Alert 99-19 cited for the likelihood of *Salmonella* contamination of spices are from India and the "top ten" list of countries in Table 8.6 is nearly the same in 2013 as it was in 2011 (nine out of the ten countries listed are the same). The numbers of firms listed for each country is in part a reflection of the numbers of shipments offered for import and sampled. Based on the FDA FY2007-FY2009 study comparing *Salmonella* prevalence in shipments of imported spice offered for import to the United States by export country, the prevalence of *Salmonella* in shipments is not strongly dependent on export country (Van Doren *et al.*, 2013a; discussed in Section 4.2.3 and Table 4.5).

Green Lists and Country Agreements. If certain conditions are met, FDA may allow exemptions to DWPE for some firms. For example, for Import Alert 28-02, imports of Indian black pepper that are accompanied by an official Indian Export Inspection Council certificate will not be subject to DWPE when the Indian EIC certificate indicates that the spice shipment has been sampled and tested for compliance with U.S. requirements for *Salmonella*, filth, mold and foreign matter (see Import Alert 28-02 for a detailed list of information the certificates must include; FDA, 2013j) Another example is Import Alert 24-11 where firms that provided information to overcome the appearance of a continued violation for foods, particularly mold, can apply for exemption from DWPE (FDA, 2013k). Regardless of importer status, FDA may monitor or sample any shipment of regulated product offered for import to the United States.

Table 8.6. Countries with the largest number of firms listed on Import Alert 99-19 for DWPE of spices[a] due to "presence of *Salmonella*"

2011		2013	
Country	**# Firms[b,c]**	**Country**	**# Firms[c,d]**
India	172	India	187
Mexico	36	Mexico	37
Turkey	34	Turkey	37
Syrian Arab Republic	33	Syrian Arab Republic	34
Vietnam	30	Vietnam	29
Egypt	26	Egypt	29
China	25	China	26
Indonesia	15	Indonesia	18
Thailand	15	Thailand	18
Pakistan	14	Lebanon	16

[a] Spices identified as industry code 28 or product code 23K02 (sesame seeds)
[b] Data taken from Import Alert 99-19 as of 7/1/2011 (FDA (2013i).
[c] Included in the count may be multiple listings of the same parent company because the company used several FEI numbers, listed different addresses or spelled its name differently.
[d] Data taken from Import Alert 99-19 as of 6/26/2013 (FDA, 2013i).

Effectiveness of Import Alerts and Country Agreements in preventing contaminated spice from entering the U.S. food supply. Shipments subject to DWPE at entry to the United States must be accompanied by evidence that the shipment meets U.S. requirements before the product is allowed to enter U.S. commerce. Typical evidence for compliance with the *Salmonella* and filth requirements includes results from third party microbiological or filth tests and/or certification that the shipment has been subjected to an effective microbial reduction treatment. In this regard, import alerts are expected to be highly effective in reducing the risk of contamination in the particular products from the particular firms/countries identified.

FDA periodically examines the effectiveness of exemption programs for imports by sampling spice in shipments from exempted firms. An audit of the exemption program for Import Alert 28-02, took place in 2010. For a period of one month, FDA examined all 55 Indian black pepper shipments offered for entry to the United States during that time period. Most of the shipments were accompanied by an Indian EIC certificate (51/55), although some of the certificates were out of date or had other discrepancies.

Using FDA sampling and testing protocols (750 g for *Salmonella*; Andrews and Hammack, 2003; Andrews *et al.*, 2011; 6 x 50 g spice for ground black pepper and ~ 4kg (8 x 500 g) for whole black pepper; FDA, 1998a), the 55 shipments were tested for the presence of *Salmonella* and filth adulteration. None of the samples from the 51 shipments accompanied by an EIC certificate were found to contain *Salmonella* or to be adulterated by filth. Of the four shipments that were not accompanied with a certificate, two were adulterated by *Salmonella*, none were adulterated by filth, and two were not actually Indian black pepper, but rather were imported to India from Vietnam.

This audit provides evidence that the exemption program for Import Alert 28-02, which requires assurance of food safety be provided by a certificate from the government of the country of origin, does provide some assurance that the black pepper shipment will comply with U.S. regulations for *Salmonella* and filth in spices. Specifically, the absence of *Salmonella* or filth in all of the shipments with EIC certificates indicates that the prevalence of *Salmonella* or filth in these shipments is in the range of 0.0-5.7% (750 g; 95% C.L.). More data are needed to determine whether the exemption program provides added food safety value, i.e., shipments accompanied by an EIC certificate have a smaller likelihood of being contaminated with *Salmonella* or filth than other shipments of black pepper from India. Collecting these data would be difficult because it appears that most of the shipments of black pepper from India offered for entry to the United States are accompanied by an Indian EIC certificate (51/55 in this study).

8.1.3.4 REPORTABLE FOOD REGISTRY

The Food and Drug Administration Amendments Act of 2007 required FDA to establish an electronic portal by which instances of reportable food may be submitted; this is the Reportable Food Registry (FDA, 2013d). Under section 417(a)(2) of the FD&C Act, a reportable food is "an article of food… for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals." FDA interprets the definition of a reportable food to include those foods that would meet the definition of a Class I recall situation, for example, spice contaminated with *Salmonella*.

Reportable foods must be reported by industry (responsible party) (FDA, 2010b) while federal, state, and local public health officials have the option to submit voluntary reports. Public health officials with knowledge of a reportable food can inform a food facility that it may be required to submit a food report.

The congressionally-identified purpose of the Reportable Food Registry is to provide a reliable mechanism to track patterns of adulteration in food in order to support efforts by FDA to target limited inspection resources to protect public health.

Effectiveness of the Reportable Food Registry in preventing contaminated spice from entering the U.S. food supply. Data on primary entries (initial reports) submitted during the first three years of the Reportable Food Registry program are listed in Table 8.7. Reports for all FDA-regulated foods except dietary supplements and infant formula (for which FDA has other mandatory reporting systems) are included in the RFR. The FDA-regulated food commodities covered by the RFR have been separated into 28 types. "Spices and Seasonings" is the food commodity type that includes spices.

Most of the primary entries associated with "Spices and Seasonings" reported contamination with *Salmonella*. No other pathogens were associated with "Spices and Seasonings" primary entries. Other hazards reported for "Spices and Seasonings" during this time period included undeclared allergens (4), presence of a foreign object (1) and presence of lead (1).

As seen in Table 8.7, the number of primary entries reported for "Spices and Seasonings" during the first two years of the program were larger than that for most of the other food commodity types for all hazards and for *Salmonella* in particular. However, the absolute and relative (e.g., rank) number of primary entries for "Spices and Seasonings" were much smaller in Year 3 of the program. As mentioned previously, the absence of information about the total number of tests performed or lots examined, makes it difficult to interpret the meaning of these data, including changes from year to year. However the publication of the reports and summary statistics has been effective in alerting the industry to reported problems.

Each primary entry may be followed by many related "subsequent reports" (defined as a report by either a supplier (upstream) or a recipient (downstream) of a food/feed (including ingredients) for which a primary report has been submitted; FDA, 2013d). The number of subsequent reports depends on whether the primary report is on a widely used ingredient or a finished food distributed to many different locations. For example, a food manufacturer may test a spice for *Salmonella* and find that it is contaminated. Subsequent reports will then be expected from the supplier of the spice and downstream recipients of spice from the implicated lot, if applicable. In this way, the Reportable Food Registry, with the help of industry, is able to identify and remove contaminated spice from the food supply.

Data from the RFR on spices and other commodities has increased the speed with which FDA and its state and local partners investigate reports and take appropriate follow-up action, including removing reportable foods from commerce when necessary (FDA, 2013d). The data has also improved FDA's understanding of how products including spices are distributed through commodity supply chains, increasing FDA's ability to trace reportable foods upstream and downstream (FDA, 2013d). Data from the RFR has also supplied information to help FDA target inspections, plan work, and identify and prioritize risks (FDA, 2013d).

Table 8.7. Primary entries reported to the FDA Reportable Food Registry September 8, 2009-September 7, 2012

Reportable Food Registry Food Commodity	Hazard	Year 1[a]	Year 2[a]	Year 3[a]
All FDA-regulated Food Categories	all	229	225	224
“Spices and Seasonings”	all	17	25	8
Rank out of total number of primary entries for “Spices and Seasonings” among all 28 RFR food commodity types[b]	all	*3rd-4th*	*2nd*	*10th*
All FDA-regulated RFR Food Categories	*Salmonella*	86	86	63
“Spices and Seasonings”	*Salmonella*	16	23	5
Rank of number of primary entries for “Spices and Seasonings” among all 28 RFR food commodity types	*Salmonella*	*1st*	*2nd*	*4th* (tied)

[a] Year 1 included September 8, 2009-September 7, 2010; Year 2 included September 8, 2010-September 7, 2011; Year 3 included September 8, 2011-September 7, 2012.

[b] Dietary supplements and infant formula are excluded.

[c] Tied with two other RFR food commodities.

8.1.3.5 GOOD AGRICULTURAL PRACTICES

Good agricultural practices (GAPs) are a collection of science-based principles of on-farm production and post-production processes that, when used, result in safer food. GAPs criteria are developed and applied based, in part, on the type of agricultural production system in use. Although many GAPs principles (such as worker health and hygiene) are applicable to any agricultural system, GAPs guidance in the United States has been developed mainly for the fresh produce industry (FDA, 1998b; USDA/ARS, 2013). The FDA *Guide to Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* (FDA, 1998b) has relevance for spice crops grown in systems similar to fresh produce crops (e.g., capsicums) as does the *Produce GAPs Harmonized Food Safety Standards* (USDA/ARS, 2013).

While FDA and USDA/ARS currently have no GAPs guidance for small-scale, multi/inter-cropping and/or ‘managed wild-craft’ agricultural systems, which are internationally used to grow spice crops, FDA has worked with WHO to create guidance for rural workers who grow fresh fruits and vegetables (WHO, 2012). The *Five keys to growing safer fruits and vegetables: promoting health by decreasing microbial contamination* manual was designed “to be easy to use, adopt and adapt so that community and health educators can tailor the training materials to meet local needs” (WHO, 2012). The target audience for this guidance is “rural workers, including small farmers who grow fresh fruits and vegetables for themselves, their families and for sale in local markets” but could also be used by small-scale spice producers (WHO, 2012).

Effectiveness of Good Agricultural Practices in preventing contamination of spices with *Salmonella* and/or filth during primary production. WHO, FDA, and USDA guidance documents were developed based on the best available science, and as a result, it is expected that application of the principles and recommendations outlined in these guidance documents should reduce the risk of contamination of fresh produce (including capsicums) with microbial pathogens and filth. We are unaware of any systematic studies that have measured changes in the prevalence of microbial or filth contamination in capsicums or other spice source plants as a result of applications of these principles or any surveys that measure the extent to which these practices have been adapted by the food industry in general or the spice industry in particular. However, FDA commissioned a study to examine the cost-effectiveness of practices intended to prevent tomato-related foodborne illness, which quantified the predicted relative impact specific growing and harvest practices have on the risk of *Salmonella* contamination (Robert *et al*., 2009). In support of the proposed produce rule (FDA, 2013e), FDA also completed a quantitative assessment of the impact of Enterohemorrhagic *Escherichia coli* (EHEC) contamination of irrigation water on the risk of illness from consumption of leafy greens (FDA, 2013e).

8.1.3.6 RETAIL ESTABLISHMENT AND CONSUMER GUIDANCE

The *FDA Food Code* is a model code developed and regularly updated by FDA that "assists food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail and food service segment of the industry. Local, state, tribal, and federal regulators use the *FDA Food Code* as a model to develop or update their own food safety rules and to be consistent with national food regulatory policy" (FDA, 2013m)

Nearly all of the U.S. states have adopted the *FDA Food Code* as the basis for their food safety regulatory oversight of retail food and institutional facilities (FDA, 2013b). The *FDA Food Code* uses the term "Potentially Hazardous Food" (PHF) to define foods that should have time/temperature controls for safety to limit pathogen growth or toxin formation. The definition of PHF takes into consideration pH, water activity (a_w), pH and a_w interaction, heat treatment, and packaging. Several decision trees and tables are included in the annex to the *FDA Food Code* to aid in determining if a food is considered a PHF. According to the *FDA Food Code* algorithms (FDA, 2013n), spices would not be classified as a PHF because the typical a_w is too small.

The U.S. Government provides consumers general safe food handling information such as the current multi-media Advertising Council campaign Safe Food Families that provides messages on cleaning utensils and surfaces, preventing cross-contamination, safe cooking and proper chilling of food. Education campaigns also provide product/pathogen-specific advice for high profile, recurring hazards (e.g., egg safety, or food safety for pregnant women). The information and learning materials are disseminated through the media, E-newsletters to health educators, school-based programs, and FDA Consumer Updates, food safety agency websites, agency displays at regional food shows and health fairs, and health care provider offices. FoodSafety.gov is a "Gateway to Federal Food Safety Information" website that provides information on outbreaks and recalls, as well as feature articles delivering messages to consumers. Guidance for consumers regarding the safe handling of low-moisture foods, such as spices has not been addressed.

Effectiveness of retail establishment and consumer guidance in preventing contamination of spices with *Salmonella* and/or filth in retail establishments, including consumer homes, and in preventing consumption of contaminated spice. While neither the *FDA Food Code* nor consumer guidance developed by FDA currently provide specific guidance on preventive practices for spices, these documents provide general information on practices that are designed to reduce the likelihood of contamination of food with pathogens (such as *Salmonella*) and filth and practices that limit growth and survival of pathogens in foods. FDA evaluated trends in food safety practices in retail food establishments (institutional foodservice, restaurants, and retail food stores) during the period 1998-2008, evaluating compliance with 42 different foodborne illness risk factors (FDA, 2010d). All but one (nursing homes) of the facility types investigated, showed a statistical improvement in applying food safety practices that reduce the prevalence of risk factors for foodborne illness (e.g., maintaining food at 5^{o}C or below except during preparation, cooking, cooling or when time is used as a public health control).

All major education campaigns for consumers are developed through the use of formative evaluation with the target audiences, and each program is evaluated with the end users. Because consumers receive food safety information through a variety of outlets, it is difficult to evaluate the impact of a particular educational campaign on the population as a whole.

8.1.3.7 FDA FOOD SAFETY MODERNIZATION ACT

The FDA Food Safety Modernization Act (FSMA) was signed into law January 4, 2011 (FDA, 2011a). FSMA addresses five areas of food safety (1) preventive controls (2) inspection and compliance (3) imported food safety (4) response and (5) enhanced partnerships. Some of the provisions of FSMA have been implemented while other regulations and guidance documents required by FSMA were either under development by FDA or under review by appropriate authorities when this report was written. Below we briefly describe the FSMA provisions that have been implemented and which are expected to significantly impact the food safety of the U.S. spice supply. The information provided below was gathered from the FDA FSMA information website available to the public (2013o), unless otherwise noted.

FDA is increasing the frequency of domestic and foreign inspections pursuant to section 201 of FSMA. FDA also has the authority to detain food if, during an inspection, examination, or investigation, FDA "has reason to believe" that the product is "adulterated or misbranded" (section 207 of FSMA). FDA also has the authority to deny entry of products to the United States from foreign food facilities that refuse access to FDA inspectors or third party inspectors authorized by the agency (section 306 of FSMA).

In general, before an imported food can enter the United States, a prior notice must be submitted to FDA (21 CFR 1.279; FDA, 2013r). Implementation of section 304 of FSMA adds the requirement that the notice provide the name of "any country to which the article has been refused entry." This requirement should help FDA stop refused shipments from being allowed entry to the United States by a different U.S. port.

FDA now has the authority to mandate food recalls for all FDA-regulated foods (section 206 of FSMA). Prior to FSMA, FDA only had the authority to mandate recalls of infant formula. This authority allows FDA to require recalls of foods to protect the public health in cases when industry does not voluntarily do so.

FDA has developed an International Food Safety Capacity-Building Plan (FDA, 2013q) to "expand technical, scientific and regulatory food safety capacity of foreign governments and their respective food industries" (section 305 of FSMA) (FDA, 2013q). Building capacity is an important part of FSMA (Section 305). As one part of its capacity building efforts, FDA has begun to set up new and expand established international posts in a range of countries and regions including China, India and Latin American.

Important new rules to implement Sections 103 and 301 of FSMA related to spice safety (proposed rule "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" (78 Federal Register 3646; January 16, 2013) (FDA, 2013s) and "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" (78 Federal Register 45730; July 29, 2013) (FDA, 2013t) are discussed under future efforts since they were not finalized at the time this report issued.

Effectiveness of the FDA Food Safety Modernization Act in improving spice food safety. Data addressing the effectiveness of each of the provisions of FSMA described above was not available at the time this report was written because of the brief period since implementation.

8.2 INDUSTRY PROGRAMS

8.2.1 PATHOGEN REDUCTION

8.2.1.1 INTRODUCTION

While post-harvest treatments such as physical cleaning and garbling (inspecting and removing refuse) of raw spices may reduce filth and possibly sources of pathogenic bacteria, they are not sufficient to eliminate or reduce microbial populations associated with the spices. The most common spice processing treatments that impact the viability of microorganisms, including human pathogens such as *Salmonella*, can generally be grouped into three categories: 1) steam treatment, 2) gamma radiation, and 3) fumigation with ethylene oxide (EO). These treatments are also commonly used for other materials such as pharmaceuticals and biologics as described by the U.S. Pharmacopeia (USP, 2011).

Other treatment options have been studied and are described in the scientific literature; however, they are not currently used or are only minimally used on a commercial basis for spice treatment. These include dry heat, microwave radiation, high pressure processing, supercritical carbon dioxide (CO_2), ozone, pulsed light, and an alternative steam treatment “controlled condensation.” These technologies are explained in more detail in Section 8.2.1.8 which describes alternative pathogen reduction treatments.

As mentioned in Section 8.1.3.2, imported spice shipments initially refused for import on the basis of microbial hazards may be accepted for entry after reconditioning. Between January 2007 and December 2012, CFSAN accepted 50 out of 155 reconditioning proposals for spices (Table 8.8). Thirty-seven proposals (74%) addressed contamination with *Salmonella* (amaranth [1], anise seed [1], basil [1], black pepper [4], celery seed [1], chili pepper powder/flakes [5], coriander powder [1], cumin powder [1], dill seeds [1], ginger [1], onion granulated [1], parsley powder [1], sage leaves [1], sesame seeds [16], turmeric [1]). Ten proposals (22%) were for contamination with filth (chili/paprika powder/flakes/whole [7], cumin [1], ginger [1], and sesame seeds [1]). One sesame seed proposal (2%) addressed contamination with both filth and *Salmonella.*

Table 8.8. Accepted reconditioning proposals for spices, 2007 – 2012 (December)

Product	CFSAN Review Year	Country of Origin	Adulteration	Type of Reconditioning
Amaranth	2012	India	*Salmonella*	Controlled condensation steam treatment
Anise Seeds	2012	Turkey	*Salmonella*	Irradiation
Basil	2011	Egypt	*Salmonella*	Irradiation
Black Pepper	2008	Mexico	*Salmonella*	Irradiation
Black Pepper	2010	Vietnam	*Salmonella*	Irradiation
Black Pepper	2011	Indonesia	*Salmonella*	Ethylene Oxide
Black Pepper	2011	Indonesia	*Salmonella*	Propylene Oxide
Celery Seeds	2011	India	*Salmonella*	Ethylene Oxide and Steam
Chili pepper flakes	2008	Mexico	Filth	Cold treatment
Chili pepper flakes	2012	Mexico	*Salmonella*	Irradiation
Chili pepper, whole dried (Ancho)	2012	Mexico	Filth/Mold	Separate/sort/treat and visible inspection
Chili pepper, whole dried (Ghost)	2011	India	Filth	Separate/sort/treat and visible inspection
Chili pepper, whole dried (Habanero)	2012	Mexico	Filth	Separate/sort/treat and visible inspection
Chili pepper, whole dried (Puya)	2012	Mexico	Filth	Separate/sort/treat and visible inspection
Chili pepper, whole dried	2011	China	Filth/Mold	Steam/sort, visual inspection
Chili powder	2011	India	*Salmonella*	Irradiation
Chili powder	2011	India	*Salmonella*	Irradiation
Chili powder	2011	Mexico	*Salmonella*	Irradiation
Chili powder	2009	Mexico	Filth	Blend and sort
Chili powder	2012	Mexico	*Salmonella*	Irradiation
Coriander powder	2012	India	*Salmonella*	Irradiation
Cumin powder	2011	India	*Salmonella*	Irradiation
Cumin Seeds	2008	Turkey	Filth	Aspirate and sort
Dill Seeds	2012	India	*Salmonella*	Ethylene Oxide
Fennel	2012	India	Filth	Steam; clean (separate/sift) and mill
Ginger, dried split	2011	Nigeria	*Salmonella*	Controlled condensation steam treatment
Ginger, whole dried	2008	China	Filth/Mold	Propylene oxide (mold); tumble; aspirate

Product	CFSAN Review Year	Country of Origin	Adulteration	Type of Reconditioning
Onion, granulated	2011	Egypt	*Salmonella*	Irradiation
Paprika peppers, dried whole mild	2012	China	Filth/Mold	Separate/Sort and visible inspection
Parsley powder	2010	Hungary	*Salmonella*	Irradiation
Paprika peppers, dried whole mild	2012	Peru	*Filth/Mold/Mites*	Separate/Sort and visible inspection and fumigation
Sage Leaves	2011	Germany	*Salmonella*	Propylene Oxide
Sesame Seeds	2009	Mexico	*Salmonella*, Filth	Irradiation (*Salmonella*); Scalp and sift, hull, dry (filth)
Sesame Seeds	2010	India	*Salmonella*	Irradiation
Sesame Seeds	2010	India	*Salmonella*	Ethylene Oxide
Sesame Seeds	2010	India	*Salmonella*	Ethylene Oxide
Sesame Seeds	2010	India	*Salmonella*	Ethylene Oxide
Sesame Seeds	2007	Venezuela	*Salmonella*	Ethylene Oxide
Sesame Seeds	2010	India	*Salmonella*	Irradiation
Sesame Seeds	2011	Guatemala	*Salmonella*	Irradiation
Sesame Seeds	2011	India	*Salmonella*	Irradiation
Sesame Seeds	2011	India	*Salmonella*	Irradiation
Sesame Seeds	2012	India	*Salmonella*	Irradiation
Sesame Seeds, hulled	2011	India	*Salmonella*	Irradiation
Sesame Seeds, hulled	2011	India	*Salmonella*	Controlled condensation steam treatment
Sesame Seeds, hulled	2011	India	*Salmonella*	Irradiation
Sesame Seeds, hulled	2011	Guatemala	*Salmonella*	Irradiation
Sesame Seeds, hulled	2011	India	Filth	Cold treatment
Sesame Seeds, hulled	2012	India	*Salmonella*	Controlled condensation steam treatment
Turmeric	2011	India	*Salmonella*	Ethylene Oxide

Indigenous Spice Microflora. The microflora of different spices is highly variable in size and scope. Not only will the population of microorganisms differ among various spices, it will also differ within a spice category based on cultivation, handling, storage and processing conditions. Spices are derived from botanic sources typically cultivated outside and exposed to environmental contamination such as dust, water, insects, animals, and human contact. Additionally, spices are subject to various handling, storage and processing techniques that expose them to other possible contamination sources. Because they are agricultural commodities, it should not be surprising that spices have a large and varied microflora including occasional contamination with pertinent human pathogens.

The presence and survival of *Salmonella* in various spices is well established (Chapters 4 and 5). While numerous researchers have reported the presence of *Salmonella* in spices, few have provided enumeration data. Based on available data (Table 4.2) and analysis (Section 4.1.3; Figures 4.1 and 4.2; Van Doren *et al.*, 2013c), the bioburden of *Salmonella* in adulterated spices is thought to be low, typically averaging less than 1 MPN/g but documented as being as large as 11 MPN/g (Lehmacher *et al.*, 1995) in samples associated with a spice-attributed salmonellosis outbreak.

8.2.1.2 COMMONLY USED TREATMENTS

To evaluate the efficacy of processes designed to inactivate pathogens, a review of scientific refereed literature related specifically to treatment of spices was conducted. Information below in text and related tables reflect this analysis. Data on changes in microbial populations before and after treatment were obtained from graphs, tables and text in the refereed papers. Because of the widespread utilization of steam, gamma radiation and EO treatments, direct comparisons of results from these processes were made for the microbial populations reported. Seventy-four publications related to spice treatments were obtained as refereed journal articles or book chapters after a review of literature, including 11 related to steam treatment, 42 to gamma radiation, 14 to EO, and 35 related to other treatments such as microwave heating, dry heat, hydrostatic high pressure, pulsed light, pulsed electric field, high pressure CO_2, x-rays and electron beam. (The sum of individual treatments is greater than the total reviewed because many papers conducted direct comparisons of more than one treatment.) A number of these refereed papers did not contain original treatment data because they were review articles or addressed other spice issues such as toxicology or quality effects. The number of publications with original microbiological data that were used to construct the tables were five for steam, five for EO, and 19 for gamma radiation. The reviewed refereed papers and book chapters were published between 1942 and 2010.

Data from an individual refereed paper was selected for analysis when the numerical size of a microbial population was clearly presented in tabular or graphical form for spice samples taken before and after treatment. The decimal reduction for a specific spice and treatment combination was calculated from these data pairs. Because some "after" treatment results were reported as "zero", it was assumed the microbial population was below the limit of detection for the enumeration method used. In those cases, the decimal reduction was assumed to be "greater than" (>) the beginning population. This assumption was modified only if the paper indicated that the lower limit of detection was greater than 1 CFU/g. Most data pairs reported were for total aerobic plate counts (APC) while those for yeasts and molds, coliforms, *Escherichia coli* and *Enterobacteriaceae* were also included. The more valuable decimal reduction data were obtained from APCs because they are generally several logs higher than other measurable populations before treatment. Having a larger initial population increased chances of obtaining a measurable population after treatment therefore yielding a discrete decimal reduction.

It was noteworthy that none of the reviewed studies involved experiments on spices inoculated with a pathogen or pathogen surrogate. While reductions in the overall microbial populations (APCs) observed in these studies may provide a relative comparison of the efficacy of different treatment types, results do not predict expected *Salmonella* reductions. Specific treatment validation studies using *Salmonella* or appropriate surrogates are needed and highly recommended.

8.2.1.3 STEAM TREATMENT

Steam treatment of foods is a well-known traditional technology used to address both quality and safety issues. It is well characterized and has been the subject of considerable scientific study for many decades. According to Pflug and Holcomb (2001), there are three general factors affecting the thermal resistance of microorganisms to heat: 1) microbial inherent resistance, 2) environmental influences during cell growth and/or sporulation, and 3) environmental influences during the heating cycle. Microbial thermal resistance is traditionally measured in terms of D- and z-values where D, standing for Decimal Reduction Time, is the time at a specific temperature needed to reduce the target population by one log (90%) and z-value, representing the reciprocal of the slope of the line in a Thermal Death Time curve is the change interval in temperature needed for the line to pass through to increase/decrease the D-value by one log. Environmental influences during cell growth and spore formation of vegetative cells and spores impact the cell physiological state, which has an impact on the thermal resistance. These influences include issues such as incubation temperature, nutrient medium composition, and cell age. Environmental influences during the heat cycle may include, among others, medium pH, ionic strength, substrate composition, and the presence of antimicrobial compounds that might impact cell survival.

Perhaps the best known and studied steam process for foods is retorting whereby canned foods are rendered commercially sterile using pressurized, saturated steam. As an example, cans of low acid foods are packed into a steam chamber and subjected to steam at 121°C and pressure of 15 psig for a set time period. Microbial death (lethality) occurs based on numerous factors including, among others, the time and temperature of treatment and thermal resistance characteristics (D and z values) of the target organism.

In steam treatment of spices, lethality arises from the time and temperature of exposure of the spice microflora to steam. Treatments that provide thorough exposure of spice particles to steam for an appropriate time should successfully eliminate vegetative bacterial pathogens (e.g., *Salmonella*). Steam system designs vary greatly in their abilities to fully expose spice particles to steam, and may or may not include pressure and saturated steam. Traditional steam treatments expose spice to steam that consists of vaporized water and usually a very small portion of liquid water (saturated steam) at a pressure (or vacuum) to control its temperature. Steam treatments employing a vacuum-steam-vacuum process create an environment that removes the gases from within the chamber and allows for the steam to penetrate throughout the product. The steam temperature, because it is saturated steam, will be dependent on the vacuum held within the processing chamber. A final vacuum step is used for these processes to remove any water that may have condensed onto the spice. Steam treatments that include supplemental electrical or indirect heat employ saturated steam condensation and heat conduction to both heat the spice to remove any microbial contamination and control the moisture level of the spice so that it does not change during the process. These dual heating systems may not include a drying step, but could include a cooling step to cool the spice back to pre-processing conditions. Both vacuum-steam-vacuum and dual heating processes aim to reduce the undesirable effects of excessive wetting of spice that may take place during traditional steam treatment.

Two basic methods used for steam treatments include batch and continuous processing. In batch processing, packages of spices are palletized, loaded into a treatment chamber followed by steam injection into the chamber with or without pressure. Due to variations in bulk density among spices (as well as other factors such as packing permeability and stacking configuration), there is no set of conditions for steam treatments that would be effective for all spices; therefore, processors should determine treatment time that will ensure steam penetration throughout the package for an adequate time period to reduce the number of vegetative pathogens.

Continuous steam processing involves equipment designed to continually move spice through a system where steam is injected. System designs differ in the way in which the unpackaged product is exposed to steam and conveyed through the system. Some may use rotational devices to provide tumbling action for enhanced exposure of spice particles to the steam and to convey the spice through the steam chamber. Others may layer spices on a conveyor belt without enhanced mixing action of the spice particles as they traverse the steam chamber. Other systems may use different conveyance systems. In a properly designed and operated system, all particles will be directly exposed to steam for an appropriate time period. Continuous systems that agitate spice particles within the steam chamber theoretically need less exposure time than the batch method, which relies on passive steam penetration. A continuous system that has less mixing action (e.g., conveyor belt) would need longer exposure time to ensure complete coverage as compared to continuous systems that use mixing action.

***Applicability and Practicality* of steam treatments.** Steam treatments can effectively reduce microbial populations in dried spices but may impact spice quality. Advantages are that the technology is well established and effective when properly applied, and equipment is readily available. Disadvantages are that some systems are not designed to provide the most effective reduction in microbial populations, and physicochemical quality parameters related to color and flavor may be negatively impacted by steam.

Effectiveness of steam treatment in reducing *Salmonella* in spices. Refereed publications that address spices inoculated with *Salmonella* populations are limited to presence/absence data after steam treatment and do not discuss enumeration. However, data on thermal inactivation of *Salmonella* in low moisture foods are available. In a review by Doyle and Mazzotta (2000), the thermal resistance of salmonellae in chocolate, a low moisture food, was shown to be much higher than for higher moisture foods. For example, D-values at 71°C ranged between 210 and 1,200 min for *S*. Anatum in chocolates with various moisture contents between 0 and 4% whereas *S*. Typhimurium in roast beef had a D-value of 0.095 min at 70°C. As discussed in Section 5.1.3, many refereed publications have established that salmonellae in low moisture foods have significantly higher D- and z-values compared to other foods with higher moisture levels (Podolak *et al*., 2010; Hiramatsu *et al*., 2005; Gruzdev *et al*., 2011; Keller *et al*., 2012; Harris *et al*., 2012), It has also been shown that reductions are not always linear and that significant tailing may occur (Beuchat and Mann, 2010; Abd *et al*., 2012; Blessington *et al*., 2012).

Reductions of different microbial populations in spices (aerobic plate counts, yeast/mold counts, total coliforms, fecal coliforms, *Escherichia coli*, and *Enterobacteriaceae*) by steam treatments were reviewed in four refereed publications (Table 8.9).

Table 8.9. Decimal reductions of microbial populations in spices from heat treatments

STEAM								
Spice	**Trmt Time[a] (min)**	**Trmt Temp[a] (°C)**	**Pressure (psig)**	**Type of Count[b]**	**Process Type[c]**	**Decimal Reduction**		**Adapted from:**
Paprika	0.1	160	15	APC	C		2	Almela *et al*.,2002
Paprika	0.1	160	30	APC	C	>	4.8	Almela *et al*., 2002
Paprika	0.1	160	15	CF	C	>	3.5	Almela *et al*., 2002
Paprika	0.1	160	30	CF	C	>	3.5	Almela *et al*., 2002
Paprika	0.1	160	15	*EB*	C	>	3.9	Almela *et al*., 2002
Paprika	0.1	160	30	*EB*	C	>	3.9	Almela *et al*., 2002
Pepper, black ground	20	115	10	APC	B		4.8	Yesair and Williams (1942)
Pepper, black ground	15	121	15	APC	B		7.9	Yesair and Williams (1942)
Pepper, black ground	5	108	5	APC	B		4.3	Yesair and Williams (1942)
Pepper, black ground	16	~100	0	APC	B		2.6	Waje *et al*., 2008
Pepper, black ground	16	~100	0	CF	B		4.2	Waje *et al*., 2008
Pepper, black ground	16	~100	0	YM	B		2.3	Waje *et al*., 2008
Pepper, black whole	3	130	0 assumed	APC	U		0.8	Sádecká, 2010
Pepper, red ground	16	~100	0	APC	B		1.3	Rico *et al*., 2010
Pepper, red ground	16	~100	0	YM	B		2.7	Rico *et al*., 2010

DRY HEAT								
Spice	**Trmt Time[a] (min)**	**Trmt Temp[a] (°C)**	**Pressure (psig)**	**Type of Count[1]**	**Process Type[2]**	**Decimal Reduction**		**Adapted from:**
Anise seed	15	70	0	APC	B		1.9	Farag Zaied *et al.*, 1996
Anise seed	15	70	0	YM	B		2.5	Farag Zaied *et al.*, 1996
Coriander	15	70	0	APC	B		2	Farag Zaied *et al.*, 1996
Coriander	15	70	0	YM	B		2.3	Farag Zaied *et al.*, 1996
Fennel seed	15	70	0	APC	B		3	Farag Zaied *et al.*, 1996
Fennel seed	15	70	0	YM	B		3	Farag Zaied *et al.*, 1996
Paprika	0.1	152	0	APC	C		1.6	Almela *et al.*, 2002
Paprika	0.1	152	30	APC	C		1.8	Almela *et al.*, 2002
Paprika	0.1	152	0	CF	C		1.3	Almela *et al.*, 2002
Paprika	0.1	152	30	CF	C		2.4	Almela *et al.*, 2002
Paprika	0.1	152	0	*EB*	C		3.8	Almela *et al.*, 2002
Paprika	0.1	152	30	*EB*	C	>	3.9	Almela *et al.*, 2002
Pepper, black whole	15	70	0	APC	B		3	Farag Zaied *et al.*, 1996
Pepper, black whole	15	70	0	YM	B		3.1	Farag Zaied *et al.*, 1996
Turmeric	15	70	0	APC	B		2.9	Farag Zaied *et al.*, 1996
Turmeric	15	70	0	YM	B		2.7	Farag Zaied *et al.*, 1996

MICROWAVE							
Spice	**Trmt Time[a] (min)**	**Trmt Temp[a] (°C)**	**Pressure (psig)**	**Type of Count[1]**	**Process Type[2]**	**Decimal Reduction**	**Adapted from:**
Oregano	15	100	0	APC	C	1.2	Legnani *et al.*, 2001
Oregano	15	100	0	*EC*	C	0.2	Legnani *et al.*, 2001
Oregano	15	100	0	FC	C	3.8	Legnani *et al.*, 2001
Pepper, black ground	0.67	160	0	APC	B	1.3	Emam *el al.*, 1995
Pepper, black ground	1.25	240	0	APC	B	3.5	Emam *el al.*, 1995
Pepper, black whole	15	100	0	APC	C	0.1	Legnani *et al.*, 2001
Pepper, black whole	15	100	0	*EC*	C	0.2	Legnani *et al.*, 2001
Pepper, black whole	15	100	0	FC	C	2.5	Legnani *et al.*, 2001
Pepper, red chili	15	100	0	APC	C	1.3	Legnani *et al*, 2001
Pepper, red chili	15	100	0	*EC*	C	0.7	Legnani *et al.*, 2001
Pepper, red chili	15	100	0	FC	C	3.6	Legnani *et al.*, 2001
Rosemary	15	100	0	APC	C	1.6	Legnani *et al.*, 2001
Rosemary	15	100	0	*EC*	C	0.2	Legnani *et al.*, 2001
Rosemary	15	100	0	FC	C	3	Legnani *et al.*, 2001
Sage	15	100	0	APC	C	1.5	Legnani *et al.*, 2001
Sage	15	100	0	*EC*	C	0.8	Legnani *et al.*, 2001
Sage	15	100	0	FC	C	3.7	Legnani *et al.*, 2001

[a] Trtmt = treatment.

[b] APC = total aerobic plate count, CF = coliforms, *EB* = *Enterobacteriaceae*, *EC* = *Escherichia coli*, FC = fecal coliforms, YM = yeasts and molds.

[c] B = batch, C = continuous, U = unknown

APC population reductions ranged from 1.3 log for a 16 min continuous process at 100°C at atmospheric pressure to 7.9 log for an autoclave process in saturated steam at 121°C for 15 min. Data in Table 8.9 indicate that steam treatment produces a relatively higher reduction of spice microflora than dry heat or microwave treatment; however, this comparison is limited by the small number of steam-treated spices in the studies (black pepper, red pepper and paprika), the small number of studies published in scientific literature with usable data, especially for dry heat and microwave treatments, and the different study conditions and thermal processes used in the studies. For example, some studies used steam chambers with pressure while others used only flowing steam without pressure. Another noteworthy issue is that all studies reviewed for this document used the native microflora of test spices rather than inoculating with specific microorganisms of concern or a surrogate.

Therefore, none of the published studies specifically address *Salmonella*. Despite this difficulty in making direct comparisons among the studies, conclusions can be drawn:

- Some steam treatments effectively reduce microbial populations on dried spices, and based on APC decimal reductions achieved appears to be more effective than dry heat or microwave treatment;
- Steam systems that use saturated steam and pressure under specific time/temperature constraints reduce microbial populations more than those that do not. Those not utilizing pressure reduced APCs between <1 and 4 logs depending upon time/temperature and exposure conditions while APC reductions in steam systems that used pressures ranged from 2 logs in a continuous system to almost 8 logs in a batch system with 15 psig pressure. Microbial reductions from dry heat and microwave treatments ranged from 1.3 to 3.9 logs and 0.1 to 3.7 logs, respectively.

Early tests conducted by Yesair and Williams (1942) established that ground black pepper could be autoclaved at various temperature/pressure combinations to yield low total counts of microorganisms. They reported minimal change to pepper sensory quality. Treatment conditions ranged from 5 min at 108°C (5 psig pressure) to 15 min at 121°C (15 psig pressure) yielding 4.3 and 7.9 decimal reductions in APC, respectively. Pepper quality was determined using subjective sensory methods and did not incorporate chemical analyses. Sádecká (2010) reported that heat treatment of black pepper for 3 min with dry steam at 130°C produced “a remarkable decrease in the overall aroma of heat sterilized black pepper” which is counter to the report from Yesair and Williams (1942). The Sádecká study used gas chromatographic instrumentation (GC/FID, GC/MS) including a combined instrumentation/sensory technique (GC olfactometry, or GC/O) to establish changes in volatile compounds in the pepper, whereas Yesair and Williams conducted qualitative human sensory evaluation without instrumentation.

A unique continuous process designed and tested by Almela *et al.* (2002) used dry nitrogen with and without various amounts of steam at a constant temperature of 160°C and pressure of 1 or 2 kg/cm^2 (15 or 30 psig) for 6 seconds. Treatment combinations that used steam combined with dry nitrogen was more effective at reducing microbial populations than the use of dry nitrogen alone (Almela *et al.*, 2002).

Rico *et al.* (2010) determined that atmospheric steam treatment (16 min, 100°C) of dried whole red peppers in a commercial tumbling chamber before re-drying and grinding into powder produced a reduction in APC of less than 2 logs with greater negative impact on physicochemical properties compared to gamma radiation or control pepper. This laboratory also studied these same treatments on black pepper with similar results (Waje *et al.*, 2008). APC, coliform and yeast/mold counts were reduced 2.6 log, 4.2 log, and 2.3 log, respectively, with significant loss of color and flavor of the black pepper due to steam treatment.

An alternative steam treatment that relies on “controlled condensation” is discussed below in 8.2.1.8. This type of treatment was designed to reduce the impact on sensory quality of spices while also reducing/eliminating salmonellae that might be present in the spice. It appears that this type of steam treatment may produce an acceptable reduction in *Salmonella* while having a reduced impact on the spice sensory qualities as compared to more rigorous steam treatments.

8.2.1.4 GAMMA RADIATION TREATMENT

Radiation is an efficient method to eliminate pathogens from foods. Cobalt-60 and cesium-137 are commonly used sources of gamma rays to which pre-packaged foods are exposed for specific time periods to provide a dose that effectively reduces microbial populations. Dosage of gamma rays decreases with wave penetration into a food such that food particles closer to the source receive a higher dose. For this reason, gamma irradiators usually increase penetration efficiency with use of a system whereby food packages are not static but are moved past the gamma ray source during the exposure time to ensure thorough coverage of the package. Suggested minimum doses for a variety of spices are found in the ASTM Standard Guide for Irradiation of Dried Spices, Herbs, and Vegetable Seasonings to Control Pathogens and Other Microorganisms (ASTM International, 2010) and range from a low of 3 to 8 kilogray (kGy) for caraway, cinnamon, paprika, red pepper and turmeric to a high of 7 to 15 kGy for onion powder. Ranges for minimum doses are necessary to address lot-to-lot variability in initial microbial populations.

Under section 201(s) of the FD&C Act, sources of irradiation used on food are included in the definition of food additives. Food additives are subject to premarket review and approval by FDA. FDA reviews the evidence to determine whether a food additive is safe for its intended use in food. FDA regulations permit the irradiation of spices up to a 30 kGy maximum absorbed dose (21 CFR 179.26(b)(5) (FDA, 2012k). As with all permitted food additives, the dose used on spices should be no greater than that needed to achieve the desired technical effect. Three sources of radiation may legally be used; gamma sources (which include the isotopes cobalt-60 and cesium-137), electron beam sources with a maximum energy of 10 MeV, and X-ray sources with a maximum energy of 7.5 MeV. Although electron beam and x-ray sources are allowed for food treatment under 21 CFR 179 (FDA, 2012l), these technologies have to date not been described in proposals submitted for FDA review on reconditioning of violative spices. Published information on the effectiveness for these technologies is covered at the end of this section under Alternative Pathogen Reduction Treatments.

FDA regulations also specify the types of packaging materials allowed for irradiation treatment of foods (21 CFR 179.45) (FDA, 2012m). Package labeling to indicate the spice has been irradiated is required under 21 CFR 179.26(c) (FDA, 2012n); however, the labeling requirement does not apply to a food that contains ingredients irradiated before being incorporated into the food.

Applicability and Practicality of gamma radiation treatments. Gamma radiation is described in literature as a cost effective method of microbial inactivation that provides minimal impact on physicochemical characteristics of spices compared to either steam or EO. In a review by Kiss and Farkas (1988), numerous citations were given for research that demonstrates “no substantial changes” in the volatile oil content of most spices treated up to 15 kGy. Steam treatment adds moisture to spices that may have detrimental quality effects while EO may cause chemical changes that impact quality (Kiss and Farkas, 1988) and toxicity (e.g., EO residues). The major disadvantage with gamma radiation is consumer resistance to the use of this technology on foods.

Effectiveness of gamma radiation treatment in reducing *Salmonella* in spices. Effects of gamma radiation on various strains of *Salmonella* in foods have been reported in literature. Although little published information exists for the irradiation kinetics of *Salmonella* inoculated into spices, D-values (kGy dose that reduces a population by 1 log) exist for a variety of products. *Salmonella* D-value results for a few low moisture products that might be considered representative for spices are 1.0 kGy (alfalfa seeds; Thayer *et al.*, 2003), 0.7 to 1.1 kGy (broccoli seeds; Rajkowski *et al*,. 2003), 0.9 kGy (bone meal; calculated from Ley *et al.*, 1963) and 1.5 kGy (desiccated coconut; calculated from Ley *et al.*, 1963). Notably, reported D-values are lower for *Salmonella* inoculated onto produce and meats before irradiation, ranging from about 0.2 to 0.7 kGy.

Among the refereed publications reviewed, 19 contained original treatment data related to gamma radiation of at least 25 spices at various dosage levels ranging between 2 and 20 kGy (Table 8.10). When viewed as a function of dosage level across all spices, observed APC decimal reductions fall within the following ranges:

- 1.6 to 5.8 decimal reduction for doses between 2 and 5 kGy (n=52)
- 2.2 to >6.9 decimal reduction for doses between 6 and 10 kGy (n=49)
- 3.5 to >6.9 decimal reduction for doses between 11 and 20 kGy (n=8)

The differences in spice results at any particular dosage level likely reflect treatment and biological variability within the experimental conditions for a particular study. Differences within a spice category and specific dosage level suggest that other elements of the studies impact results. Issues such as accurate dosimetry and dose mapping, the type of enumeration method and medium, the type of spice, and diversity of microbial species in the spice could impact final population counts after treatment.

Table 8.10. Decimal reductions from gamma radiation for microbial populations of various spices

Spice[a]	kGy dose	Decimal Reduction		D-value (kGy/decimal reduction)		Type of Count[b]	Adapted from:
Allspice	5		3.0		1.7	APC	Kiss and Farkas, 1988
Allspice	8		4.9		1.6	APC	Vajdi and Pereira, 1973
Anise seed	4		2.1		1.9	APC	Grecz *et al.*, 1986
Anise seed	5		2.8		1.8	APC	Farag Zaied *et al.*, 1996
Anise seed	5		3.5		1.4	APC	Kiss and Farkas, 1988
Anise seed	7		3.9		1.8	APC	Grecz *et al.*, 1986
Anise seed	10		5.2		1.9	APC	Farag Zaied *et al.*, 1996
Anise seed	5		2.8		1.8	YM	Farag Zaied *et al.*, 1996
Anise seed	10	>[c]	2.9	>	3.4	YM	Farag Zaied *et al.*, 1996
Cardamom	2		1.6		1.3	APC	Grecz *et al.*, 1986
Cardamom	5		1.6		3.1	APC	Sharma *et al.*, 1984
Cardamom	10	>	2.6	>	3.8	APC	Sharma *et al.*, 1984
Celery seed	8		3.7		2.2	APC	Vajdi and Pereira, 1973
Chili	5		2.4		2.1	APC	Munasiri *et al.*, 1987
Chili	5		4.5		1.1	APC	Singh *et al.*, 1988
Chili	5		4.0		1.3	APC	Alam *et al.*, 1992
Chili	10		5.1		2.0	APC	Munasiri *et al.*, 1987
Chili	10		6.3		1.6	APC	Alam *et al.*, 1992
Cinnamon	5		1.2		4.2	APC	Sharma *et al.*, 1984
Clove	5		1.4		3.6	APC	Sharma *et al.*, 1984
Coriander	5		1.6		3.1	APC	Farag Zaied *et al.*, 1996
Coriander	5		1.8		2.8	APC	Munasiri *et al.*, 1987
Coriander	5		1.6		3.1	APC	Alam *et al.*, 1992
Coriander	5		4.0		1.3	APC	Kiss and Farkas, 1988
Coriander	10	>	4.1	>	2.4	APC	Farag Zaied *et al.*, 1996
Coriander	10	>	4.2	>	2.4	APC	Munasiri *et al.*, 1987
Coriander	10		4.1		2.4	APC	Alam *et al.*, 1992
Coriander	5	>	2.8	>	1.8	YM	Farag Zaied *et al.*, 1996
Coriander	10	>	2.8	>	3.6	YM	Farag Zaied *et al.*, 1996
Cumin	2		3.0		0.7	APC	Grecz *et al.*, 1986
Cumin	5		2.6		1.9	APC	Alam *et al.*, 1992
Cumin	5		4.1		1.2	APC	Kiss and Farkas, 1988
Cumin	10	>	4.0	>	2.5	APC	Alam *et al.*, 1992
Curry	4		2.3		1.7	APC	Grecz *et al.*, 1986
Curry	10	>	5.0	>	2.0	APC	Munasiri *et al.*, 1987
Fennel seed	5		2.7		1.9	APC	Farag Zaied *et al.*, 1996
Fennel seed	10		4		2.5	APC	Farag Zaied *et al.*, 1996
Fennel seed	5		3.3		1.5	YM	Farag Zaied *et al.*, 1996
Fennel seed	10	>	3.3	>	3.0	YM	Farag Zaied *et al.*, 1996
Garlic	4		3.0		1.3	APC	Vajdi and Pereira, 1973
Ginger	5		2.5		2.0	APC	Farag *et al.*, 1995
Ginger	10		3.0		3.3	APC	Farag *et al.*, 1995

Spice[a]	kGy dose	Decimal Reduction		D-value (kGy/decimal reduction)		Type of Count[b]	Adapted from:
Marjoram	5		1.7		2.9	APC	Farag *et al.*, 1995
Marjoram	5		4.6		1.1	APC	Kiss and Farkas, 1988
Marjoram	10		2.1		4.8	APC	Farag *et al.*, 1995
Nutmeg	5		1.8		2.8	APC	Sharma *et al.*, 1984
Nutmeg	10	>	3.1	>	3.2	APC	Sharma *et al.*, 1984
Onion powder	4		2.5		1.6	APC	Kiss and Farkas, 1988
Onion powder	4		1.8		2.2	APC	Silberstein *et al.*, 1979
Onion powder	4		2.1		1.9	APC	Silberstein *et al.*, 1979
Onion powder	5		2.9		1.7	APC	Kiss and Farkas, 1988
Onion powder	8		2.3		3.5	APC	Silberstein *et al.*, 1979
Onion powder	8		3.5		2.3	APC	Silberstein *et al.*, 1979
Onion powder	9		1.1		8.2	APC	Silberstein *et al.*, 1979
Onion powder	9		2.2		4.1	APC	Silberstein *et al.*, 1979
Onion powder	9		2.0		4.5	APC	Silberstein *et al.*, 1979
Onion powder	10		3.3		3.0	APC	Kiss and Farkas, 1988
Onion powder	10		3.1		3.2	APC	Silberstein *et al.*, 1979
Onion powder	10		4.5		2.2	APC	Silberstein *et al.*, 1979
Onion powder	13		4.8		2.7	APC	Silberstein *et al.*, 1979
Onion powder	13		4.6		2.8	APC	Silberstein *et al.*, 1979
Onion powder	15		5.5		2.7	APC	Silberstein *et al.*, 1979
Onion powder	15		4.8		3.1	APC	Silberstein *et al.*, 1979
Onion powder	15		5.5		2.7	APC	Silberstein *et al.*, 1979
Onion powder	15		4.8		3.1	APC	Silberstein *et al.*, 1979
Oregano	5		5.0		1.0	APC	Legnani *et al.*, 2001
Oregano	6		3.2		1.9	APC	Vajdi and Pereira, 1973
Oregano	10		5.4		1.9	APC	Legnani *et al.*, 2001
Paprika	5		2.0		2.5	APC	Kiss and Farkas, 1988
Paprika, added oil	6.5		2.2		3.0	APC	Franco *et al.*, 1986
Paprika, fine grind	6.5		2.8		2.3	APC	Franco *et al.*, 1986
Paprika, granulated	6.5		2.7		2.4	APC	Franco *et al.*, 1986
Paprika	8		4.3		1.9	APC	Vajdi and Pereira, 1973
Paprika	9		2.6		3.5	APC	Kiss and Farkas, 1987
Paprika	11		3.5		3.1	APC	Kiss and Farkas, 1988
Pepper, black ground	4		2.8		1.4	APC	Soedarman *et al.*, 1984
Pepper, black ground	4		3.0		1.3	APC	Singh *et al.*, 1988
Pepper, black	5		5.8		0.9	APC	Legnani *et al.*, 2001
Pepper, black	5		3.2		1.6	APC	Kiss and Farkas, 1988
Pepper, black ground	5		2.3		2.2	APC	Farkas and Andrássy, 1984
Pepper, black ground	5		2.3		2.2	APC	Farkas and Andrássy, 1984
Pepper, black ground	5		3.8		1.3	APC	Farkas and Andrássy, 1984
Pepper, black ground	5		3.8		1.3	APC	Farkas and Andrássy, 1984
Pepper, black ground	5		4.1		1.2	APC	Sharma *et al.*, 1984
Pepper, black ground	5		2.7		1.9	APC	Grecz *et al.*, 1986
Pepper, black ground	5		3.3		1.5	APC	Munasiri *et al.*, 1987
Pepper, black ground	5		1.1		4.5	APC	Emam *et al.*, 1995
Pepper, black whole	5		2.1		2.4	APC	Farag Zaied *et al.*, 1996
Pepper, black whole	5	>	6.0	>	0.8	APC	Sádecká, 2010
Pepper, black ground	6		4.1		1.5	APC	Soedarman *et al.*, 1984
Pepper, black ground	7.5		5.0		1.5	APC	Singh *et al.*, 1988
Pepper, black ground	8		5.9		1.4	APC	Soedarman *et al.*, 1984
Pepper, black ground	9		5.0		1.8	APC	Grecz *et al.*, 1986
Pepper, black ground	10	>	6.2	>	1.6	APC	Soedarman *et al.*, 1984
Pepper, black ground	10	>	5.7	>	1.8	APC	Sharma *et al.*, 1984
Pepper, black ground	10	>	5.5	>	1.8	APC	Munasiri *et al.*, 1987
Pepper, black ground	10		3.3		3.0	APC	Emam *et al.*, 1995

Spice[a]	kGy dose	Decimal Reduction		D-value (kGy/decimal reduction)		Type of Count[b]	Adapted from:
Pepper, black	10		6.8		1.5	APC	Legnani *et al.*, 2001
Pepper, black	10	>	6.9	>	1.4	APC	Shigemura *et al.*, 1991
Pepper, black powder	10		3.9		2.6	APC	Waje *et al.*, 2008
Pepper, black whole	10		4.7		2.1	APC	Farag Zaied *et al.*, 1996
Pepper, black ground	12		5.0		2.4	APC	Vajdi and Pereira, 1973
Pepper, black	17	>	6.9	>	2.5	APC	Shigemura *et al.*, 1991
Pepper, black	20	>	6.9	>	2.9	APC	Shigemura *et al.*, 1991
Pepper, black whole	5		2.4		2.1	YM	Farag Zaied *et al.*, 1996
Pepper, black	10	>	3.7	>	2.7	YM	Shigemura *et al.*, 1991
Pepper, black powder	10		2.8		3.6	YM	Waje *et al.*, 2008
Pepper, black whole	10	>	3.4	>	2.9	YM	Farag Zaied *et al.*, 1996
Pepper, black	17	>	3.7	>	4.6	YM	Shigemura *et al.*, 1991
Pepper, black	20	>	3.7	>	5.4	YM	Shigemura *et al.*, 1991
Pepper, black ground	4		2.3		1.7	*EB*	Soedarman *et al.*, 1984
Pepper, black ground	8	>	4.2	>	1.9	*EB*	Soedarman *et al.*, 1984
Pepper, black whole	5	>	0.9	>	5.6	COL	Farag Zaied *et al.*, 1996
Pepper, black powder	10		4.6		2.2	COL	Waje *et al.*, 2008
Pepper, black whole	10	>	0.9	>	11.1	COL	Farag Zaied *et al.*, 1996
Pepper, red chili	5		5.7		0.9	APC	Legnani *et al.*, 2001
Pepper, hot (red)	5		4.5		1.1	APC	Farag *et al.*, 1995
Pepper, hot (red)	10		4.8		2.1	APC	Farag *et al.*, 1995
Pepper, red chili	10		6.0		1.7	APC	Legnani *et al.*, 2001
Pepper, red powder	10		5.1		2.0	APC	Rico *et al.*, 2010
Pepper, red powder	10		2.3		4.3	YM	Rico *et al.*, 2010
Pepper, white	5		3.0		1.7	APC	Kiss and Farkas, 1988
Pepper, white	10	>	6.8	>	1.5	APC	Shigemura *et al.*, 1991
Pepper, white	17	>	6.8	>	2.5	APC	Shigemura *et al.*, 1991
Pepper, white	20	>	6.8	>	2.9	APC	Shigemura *et al.*, 1991
Rosemary	5		3.9		1.3	APC	Legnani *et al.*, 2001
Rosemary	10		4.1		2.4	APC	Legnani *et al.*, 2001
Sage	5		5.4		0.9	APC	Legnani *et al.*, 2001
Sage	10		4.9		2.0	APC	Legnani *et al.*, 2001
Thyme	4		1.8		2.2	APC	Grecz *et al.*, 1986
Thyme	7		3.5		2.0	APC	Grecz *et al.*, 1986
Turmeric	5		3.1		1.6	APC	Farag Zaied *et al.*, 1996
Turmeric	5		3.7		1.4	APC	Munasiri *et al.*, 1987
Turmeric	5		4.0		1.3	APC	Singh *et al.*, 1988
Turmeric	5		3.5		1.4	APC	Alam *et al.*, 1992
Turmeric	7.5		5.5		1.4	APC	Singh *et al.*, 1988
Turmeric	10	>	3.2	>	3.1	APC	Farag Zaied *et al.*, 1996
Turmeric	10	>	5.0	>	2.0	APC	Munasiri *et al.*, 1987
Turmeric	10	>	6.5	>	1.5	APC	Alam *et al.*, 1992
Turmeric	5	>	2.8	>	1.8	YM	Farag Zaied *et al.*, 1996
Turmeric	10	>	2.8	>	3.6	YM	Farag Zaied *et al.*, 1996

[a] Spice descriptors taken from references.

[b] APC = total aerobic plate count, COL = coliforms, EB = *Enterobacteriaceae*, YM = yeasts and molds

[c] ">" symbol used when microbial count after treatment is below the detectable limit. Number represents the population before treatment based on the enumeration method.

Decimal reductions in Table 8.10 were calculated by subtracting the log of the microbial population after treatment from that of the population before treatment. When the final microbial population after treatment was below detectable limits, the decimal reduction was calculated based upon the type of enumeration method used and the initial population, and was expressed with a "greater than" symbol. When initial populations were small, such as typically seen for yeast/mold, coliforms or *Enterobacteriaceae*, and the population after treatment was not detectable; it is difficult to draw inferences about the actual decimal reduction. In theory, the actual decimal reduction for "greater than" results could have been significantly higher than what was reported. In some instances, large initial APC counts were reduced to concentrations below detection after treatments. For example, black and white pepper with initial counts of log 6.8 APCs had non-detectable populations after treatment at 17 or 20 kGy (Shigemura *et al*., 1991). With the assumption that the method of detection allowed an enumeration estimate of 1 colony per gram, the decimal reduction was reported in Table 8.10 as ">6.8."

The average D-value for APCs across all spices for which discrete post-process enumerations were available is 2.2 ± 1.0 kGy (n=102). D-values are commonly generated for a specific species or strain of organism rather than a general group count such as APCs or YM counts, as was done here. With that noted, D-values for irradiation data may provide a useful relative comparison with other treatments but should be interpreted with care. Research on irradiation treatment using *Salmonella* or a suitable surrogate is needed.

Numerous individual refereed publications refer to a range of kGy doses roughly between 3 and 10 for reduction of overall microbial populations to concentrations deemed "acceptable." One publication states that a dose of 20 kGy will reduce microbial populations to less than 10 CFU/g and render a spice "sterile." In a review article on gamma radiation, Sjöberg *et al.* (1991) reported kGy doses that resulted in a 3 decimal reduction for 35 spices. These ranged from a low of 3 kGy to a high of 10 kGy with an average of around 6 kGy to achieve a 3 decimal reduction in APCs. As mentioned earlier, ASTM International (2010) provides ranges of minimum doses to achieve "acceptable levels" (acceptable concentrations) of microorganisms in 19 spices with dosage levels ranging between 3 and 15 kGy.

There exists considerable variability in dose responses reported in Table 8.10. For example, decimal reductions for ground black pepper at 5 and 10 kGy range between 1.1 to 4.1 log and 3.3 to >6.9 log, respectively. This large degree of variability within a single dose suggests additional factors influence the efficacy of gamma radiation. Based on the understanding that significant variability exists in published refereed data, additional research would likely be necessary in order to ensure achievement of a desired decimal reduction related to *Salmonella* in specific spices.

8.2.1.5 ETHYLENE OXIDE TREATMENT

Ethylene oxide (EO or EtO) is a colorless gas that chemically reacts with components of vegetative cells and spores thereby resulting in cell death. Alkylation of nucleic acids in cells treated by EO has been demonstrated (Parisi and Young, 1991) and is thought to contribute to cell inactivation. EO is commonly used as an alternative to heat treatments and has provided a method for sterilization of heat sensitive materials such as plastic-based medical devices, drugs, and treatment of spices or other foods. Use of EO as an antimicrobial treatment is more complex than for steam and irradiation due to the large number of variables that should be controlled for the treatment to be effective. According to USP, variables include temperature, exposure time, humidity, vacuum/positive pressure and gas concentration (USP, 2011). Gilbert *et al.* (1964) demonstrated that desiccation of various organisms increased their resistance to EO treatment and resulted in non-linear inactivation curves. Other variables are the permeability of packaging in which spices are packed and the loading designs of individual pallets and the treatment chamber itself. Variations in package material permeability, spice bulk density and chamber/pallet loading patterns will impact the ability of the gas to penetrate the most inaccessible points within the packs thereby affecting the treatment time. In some cases, such as with foil lined film, packaging material will essentially block penetration of EO rendering the technology ineffective. Additionally, inert balance gases, such as CO_2 or N_2, and a series of chamber air washes at the end of a cycle are needed to address concerns about EO flammability and mutagenic properties of toxic EO residues. While toxic residues of EO in treated materials remains a concern, an assessment of cancer risk (Fowles *et al*., 2001) from EO residues in spices concludes that "risks are practically negligible" based on current understanding of exposure from concentrations of EO found in spices. Factors described here demonstrate the complexity of conducting validation studies for EO treatment chambers and conditions. Despite these limitations, EO is a well-established technology that is commonly used for sterilization of medical devices and pharmacological products resulting in reductions of at least 6 log (USP, 2011). On the other hand, due to concerns about toxicity and safety, EO is banned for fumigation of foods in the European Union and Australia.

Leistritz (1997) provides an overview of steps used in EO processing. Packaged spices are placed into a chamber, which is then sealed. This is followed by a vacuum step and heating of the chamber to the process temperature. Humidity is introduced into the chamber followed by the EO / inert gas mixture. After holding for a specified time period, usually several hours to ensure gas penetration into the package interior, gas is removed from the chamber, which is then flushed with air several times. After the chamber returns to atmosphere pressure, product is removed.

Applicability and Practicality of ethylene oxide treatments. The use of EO as a treatment method for spices is well established although the effectiveness at reducing *Salmonella* may be less than for irradiation or steam treatments. Research opportunities exist to demonstrate clearly the expected decimal reductions of *Salmonella* in spices from EO. Due to the larger number of variables to be controlled with this technology, as compared to steam or irradiation, validation studies would be more complex, but it should be possible to design scientific studies that will specify variables such as gas concentration, exposure time/temp, humidity, and product type and density to achieve successful results.

Under the U.S. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (EPA, 2012b) the Environmental Protection Agency (EPA) regulates substances intended for preventing, destroying, repelling, or mitigating any pest. Ethylene oxide is used to reduce pests and microbiological contamination. In 2008, the EPA reregistered ethylene oxide as a legal pesticide that may be used on spices. Spices may be decontaminated using ethylene oxide consistent with EPA's regulation under 40 CFR 180.151 (EPA, 2012c). Application of ethylene oxide treatment to spices in prohibited in some countries.

Effectiveness of ethylene oxide treatment in reducing *Salmonella* in spices. Five refereed studies on EO treatment of spices were reviewed. Decimal reductions of spice APCs found in refereed scientific journals range from 1.3 log to >6 log with an average of about 3.0 log. Several data points were available for paprika and ground black pepper with only one data point each for allspice, celery seed, cinnamon, garlic and oregano. A comparison of results among the studies is difficult due to substantial differences in gas concentrations, exposure time, temperature and moisture. As stated above, EO treatment involves control of several variables. One data point in Table 8.11 was determined from pre- and post-treatment APC counts provided by a company to FDA after a reconditioning treatment accepted by FDA in 2010 was applied.

Farkas and Andrássy (1984) demonstrated that EO fumigation was more effective at water activities of 0.75 and 0.50 than at 0.25, which supports results by Gilbert et al. (1964), mentioned above.

Michael and Stumbo (1970) studied the effect of EO on lyophilized *Salmonella* Senftenberg (alone and in egg solids) and *Escherichia coli*. Treatment conditions included 40°C, 700 mg/L gas concentration, and relative humidity between 11 and 73%. D-values (min) for lyophilized cells alone were 2.2 at 11% RH, 3.4 at 23% RH, 4.0 at 33% RH, 5.0 at 53% RH and 5.9 at 73% RH indicating that fumigation was more effective at lower relative humidity which is counter to results of Farkas and Andrássy (1984) and Gilbert *el al.* (1964). The reasons for differences in results in these studies is unknown. When cells were lyophilized in an egg solids mixture, the D-value at 11% RH increased from 2.2 to 4.5 min thereby indicating that the food matrix can influence cell survival.

Table 8.11. Decimal reductions of APC counts in spices treated with ethylene oxide

Spice	Time (Hr)	Temp (°C)	Gas Conditions	A_w or % Moisture	Decimal Reduction		Adapted from:
Allspice, ground	12	57	10% EO + 90% CO_2 (w/w)/4.5 m^3	150 mL H_2O/160 cu. ft.		4.6	Vajdi and Pereira, 1973[a]
Celery seed, ground	16	57	10% EO + 90% CO_2 (w/w)/ 4.5 m^3	150 mL H_2O/160 cu. ft.		4.7	Vajdi and Pereira, 1973
Cinnamon, ground	5	80	15cc/11.4 L	NR[b]		2.9	Yesair *et al.*, 1942
Garlic, ground	5	57	10% EO + 90% CO_2 (w/w)/ 4.5 m^3	150 mL H_2O/160 cu. ft.		3.5	Vajdi and Pereira, 1973
Oregano, ground	16	57	10% EO + 90% CO_2 (w/w)/ 4.5 m^3	150 mL H_2O/160 cu. ft.	>	3.5	Vajdi and Pereira, 1973
Paprika, ground	16	57	10% EO + 90% CO_2 (w/w)/ 4.5 m^3	150 mL H_2O/160 cu. ft.	>	6	Vajdi and Pereira, 1973
Paprika, ground	3	54	470 mg/L	23% RH		1.7	Reconditioning treatment
Paprika, ground	NR	NR	NR	NR		2.2	Kiss and Farkas, 1988
Paprika, granulated	48	25	750 g/m^3 [c]	11.12% mois.		1.5	Franco *et al.*, 1986
Paprika, added oil	48	25	750 g/m^3	6.64% mois.		1.3	Franco *et al.*, 1986
Paprika, fine grind	48	25	750 g/m^3	7.05% mois.		1.8	Franco *et al.*, 1986
Pepper, black ground	16	57	10% EO + 90% CO_2 (w/w)/ 4.5 m^3	150 mL H_2O/160 cu. ft.		3.4	Vajdi and Pereira, 1973
Pepper, black ground	5	80	15cc/11.4 L	NR		3	Yesair *et al.*, 1942
Pepper, black ground	6	22	600 g/m^3	0.25 Aw; 8.5%		2.1	Farkas and Andrássy, 1984
Pepper, black ground	6	22	600 g/m^3	0.50 Aw; 11.0%		3.8	Farkas and Andrássy, 1984
Pepper, black ground	6	22	600 g/m^3	0.75 Aw; 15.0%		3.8	Farkas and Andrássy, 1984

[a] Study by Vajdi and Pereira 1973 described gas and moisture conditions based on chamber geometry of 160 cubic feet.

[b] NR = Not Reported, likely ambient

[c] g/m^3 is equivalent to mg/L

8.2.1.6 COMPARISON OF TREATMENT EFFECTIVENESS

Several publications compare gamma radiation to steam and/or EO. Recent studies on red and black peppers suggest gamma radiation of 5 or 10 kGy produces a larger reduction in microbial populations than selected steam treatments with a reduced impact on physicochemical quality (Waje *et al.*, 2008; Rico *et al.*, 2010, Sádecká, 2010); however, the type of steam treatment used in these studies is less effective at reducing microbial populations when compared to the more aggressive steam treatments of other studies (Yesair *et al.*, 1942; Almela *et al.*, 2002). In another comparison of gamma radiation with saturated steam, Kispéter *et al.* (2003) concluded that ionizing radiation was more appropriate than steam treatment of paprika due to changes in quality parameters associated with steam.

In a comparison of EO and gamma radiation, Vajdi and Pereira (1973) concluded that irradiation was more effective at reducing spice microflora with insignificant changes in volatile oil composition or color of paprika compared to EO. Franco *et al.* (1986) also found that irradiation was more effective than EO at reducing paprika microflora. Narayanan *et al.* (2000) concluded that gamma radiation is a superior technology to steam, microwave or EO. They indicated that EO was least desirable due to its flammability and toxic nature.

While all three major treatment types will reduce microbial populations to some degree, an evaluation of data and expert opinion published in the scientific literature suggests that gamma radiation is the most efficient method of pathogen elimination while causing the fewest changes in physicochemical quality parameters of spices. The major disadvantage for gamma radiation is lack of public acceptance whereas steam and EO have disadvantages related to changes in spice quality, e.g., color, flavor, and aroma, while EO has additional disadvantages related to toxicity, complexity of treatment operations, and is prohibited from being applied to spices in some countries. The data in tables 8.9, 8.10, and 8.11 demonstrate that large reductions in microbial populations can be achieved by these treatments under certain circumstances. Data are needed to characterize achievable reductions of *Salmonella*, or an appropriate surrogate, in spices and the conditions necessary to achieve such reductions.

8.2.1.7 TREATMENT VALIDATIONS

The lack of data specifically related to the impact of treatment options on *Salmonella* in spices indicates there is a critical need for comprehensive validation research related to the effects of various treatments on *Salmonella*, and on selection of appropriate surrogates for spice matrices. There is also a need to establish an acceptable performance standard for treatments to destroy pathogens to achieve an appropriate level of protection. Information about methods to validate processes have been published (Scott, 2005; Codex, 2008; NACMCF, 2010; USP, 2011) thereby providing guidance on how to plan and conduct a validation to ensure that a process will inactivate *Salmonella* in spices and meet a relevant food safety objective. Companies that treat spices with an antimicrobial process should validate that the process is effective at eliminating the pertinent pathogen(s).

Generally speaking, steps involved in ensuring that a process will provide a desired kill step include establishing that the equipment and process control instruments will operate within identified parameters, and determining the processing conditions necessary to achieve elimination of the identified hazard to an appropriate level or protection. Determination of these conditions may involve reviewing scientific or technical literature, reviewing previous validation studies, reviewing government documents, mathematical modeling, or operational data and surveys. Alternatively, experiments may be designed and conducted to produce relevant reproducible data on process conditions necessary to eliminate the food hazard. Experiments should be repeated to provide a statistically sound view of variability. Finally in the validation process, companies should document successful completion of the steps taken in the protocol.

In those instances when a pathogen cannot safely be used during a validation challenge study, the pathogen should be replaced with a surrogate. Surrogates should be non-pathogenic and have inactivation characteristics and kinetics that can be used to predict behavior of the target pathogen exposed to the inactivation technology. Other desirable characteristics of surrogates include having stable and consistent growth characteristics, easy preparation and enumeration, being genetically stable, and lack of spoilage characteristics if used on equipment in a production area. (FDA, 2000)

Of critical importance in the validation is determination of the amount of kill needed to achieve the desired objective. For example, the juice HACCP regulation (21 CFR 120) (FDA, 2012o) requires that juices receive a process capable of producing a 5-decimal reduction of the pertinent pathogen. USP standard sterilization treatments (USP, 2011) are to achieve at least a 10^{-6}/unit microbial survivor probability (i.e., greater than a 1 in 1 million chance that a viable cell survives treatment per unit of product). Such a numerical standard is not established for spices although Schaffner *et al*. (2013) provides some discussion about which issues to consider when setting standards for low moisture foods.

A typical USP-like validation protocol would be implemented in different stages including 1) an *installation qualification* stage to ensure that equipment is properly designed, installed and calibrated; 2) an *operational qualification* stage to ensure that the equipment functions properly; 3) a *confirmatory* stage that includes test treatments of materials using appropriate measurements to ensure treatment uniformity that is adequate to produce the pathogen reduction desired ; and 4) a *final* stage whereby all supporting information and data used to execute the validation is properly documented.

An additional resource for information on process validations is the report, “Parameters for Determining Inoculated Pack/Challenge Study Protocols” published by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 2010). Although this report largely addresses growth inhibition challenge studies, portions related to inactivation studies are pertinent to development of studies on treatment of spices. The report provides information on factors related to the product, target organisms, inoculum concentrations and preparation, inoculation method, sampling considerations, sampling intervals, and interpretation of test results. Additionally, the report recommends that “challenge studies must be designed and evaluated by an expert food microbiologist” thereby emphasizing the need for companies to engage experts in the validation process. Other validation information is available from additional sources (GHTF, 2004; Hardin, 2012; Taormina, 2012; FDA, 2011b; Codex, 2008).

8.2.1.8 ALTERNATIVE PATHOGEN REDUCTION TREATMENTS

Research on a variety of alternative processing methods applied to the treatment of spices has been published. A steam method in which condensation and evaporation are controlled to prevent harmful effects on spice quality while reducing concentrations of salmonellae has been developed and is currently available commercially. Other processes, such as electron beam and x-ray radiation, high hydrostatic pressure with heat, ozonation, and high pressure CO_2 with heat, appear to produce significant reductions in microbial populations.

Controlled condensation (CC) steam processes are commercially available whereby condensation and evaporation are controlled to allow thermal inactivation of microorganisms while reducing negative physicochemical quality changes usually associated with pressurized or atmospheric pressure steam treatment (Koco Inc., 2008; Perren, 2008). Experiments on almonds inoculated with *Enterococcus faecium* NRRL B 2354 as a surrogate for *Salmonella* Enteritidis PT30 showed decimal reductions of 2.5, 3.6, 5.0 and 6.1 after CC treatment for 1, 2, 5 and 10 min, respectively. This technology may be appropriate for use on spices, but should be properly validated.

Zhao and Cranston (1995) investigated the effect of ozonized air (6.7 mg/L ozone) on various microorganisms in ground black pepper or water containing whole black pepper. Reductions in *Escherichia coli*, *Salmonella*, of 3 to 4 logs were produced in ground pepper while similar reductions in APCs were seen for whole peppercorns. Researchers concluded that this technology would be best used for treatment of whole peppercorns in ozonized water. Treatment of ground black pepper could result in unacceptable changes in volatile oils depending upon the moisture content of the pepper. Emer *et al.* (2008) reported that an ozone concentration of 0.1 ppm for 360 min could reduce *Escherichia coli* in whole and ground black pepper approximately 7 log without a negative impact on product quality.

Butz *et al.* (1994) showed that a three cycle high pressure processing (HPP) treatment at 70˚C for 30 min at 80 MPa followed by 30 min at 350 MPa successfully inactivated the microflora of spice mixtures. It was necessary to raise the water activity to 0.91 to achieve microbial inactivation possibly making the process less desirable for spices. Skapska *et al.* (2003) demonstrated the application of combined dry heat and high hydrostatic pressure to eliminate vegetative cells from black pepper with minimal impact on volatiles. A minimum treatment of 1000 MPa under argon for 30 min at 60˚C reduced the mesophilic population of the native microflora less than one log. The same treatment at 140˚C reduced the mesophilic population 3.4 logs. Finally, Neetoo and Chen (2011) determined that a two phase treatment using dry heat followed by 600 MPa for 2 min produced a 5 decimal reduction of *Salmonella* spp. and *Escherichia coli* O157:H7 inoculated onto alfalfa seeds, a commodity similar in characteristics to some spices.

Dry heat and microwave heat treatments were addressed by a variety of researchers (Emam *et al.*, 1995; Faraq Zaied *et al.*, 1996; Legnani *et al.*, 2001; and Almela *et al.*, 2002). In general, dry heat and microwave techniques were less effective than steam at reducing microbial populations with reductions ranging from 1.3 to >3.9 log and from 0.1 to 3.8 log, respectively as compared to steam which ranged from 0.8 to 7.9 decimal reductions (Table 8.9). Neetoo and Chen (2011) reported that dry heat of 65°C for 10 days or 70°C for 24 hr. reduced *Salmonella* on alfalfa seeds, a low moisture product similar to spices such as celery seeds by approximately 5 log. Such extreme treatments may not be viable for spices due to changes in volatile oil concentration and quality. A review article by Narayanan *et al.* (2000) suggests that microwave treatments will reduce microbial populations by a factor of 10 to 10^3. Results in Table 8.9 generally fall within that range further indicating that microwave treatment may not provide an adequate reduction of pathogens.

Supercritical CO_2 is a method of using pressurized liquid CO_2 as a processing method for foods and has been demonstrated to reduce *Salmonella* populations in a variety of foods achieving decimal reductions of <1 to >8 (Garcia-Gonzalez *et al.*, 2007). This process method is also currently used to extract volatile oil constituents from spices yielding liquid spice extracts. The usefulness of supercritical CO_2 as an antimicrobial process for raw paprika was investigated by Calvo and Torres (2010) who reported that mild process conditions that would not affect extractable volatiles or color (25-30% moisture, 85-90°C, 60-100 bar pressure) "were sufficient to achieve the disinfection and total count reduction required by the most exigent clients." Data appeared to suggest that the heat used during this treatment was a major contributor to the microbial reductions observed. Further studies would be needed to determine the effect of pressurized CO_2 on *Salmonella* in spices.

Pulsed UV light was studied for microbial inactivation in wheat flour and black pepper. Although a 7-log inactivation of *Saccharomyces cerevisiae* occurred on glass beads and quartz plate, pulsed UV light treatment under the conditions of study produced less than 1 decimal reduction for wheat flour or black pepper (Fine and Gervais, 2004). Further refinements will be needed before this technology would be useful for inactivation of microorganisms in food powders. The effect of another pulsed technology, pulsed electric field, on microflora of spices was investigated by Keith *et al.* (1997) and found to produce no more than a 1 decimal reduction in APCs of dried onion, dill and basil powders.

Electron beam and x-ray radiation treatments of foods have been studied since the 1940s. Proctor *et al.* (1950) reported on the impact of supervoltage cathode rays on the native microflora of several spices and dry food ingredients. APCs were reduced between 3 and >6 logs after treatment. Van Calenberg *et al.* (1998) found that reductions in microflora of spices were similar for electron beam and x-ray radiation and appeared to be >4 log for APCs in white pepper, 3 to 4 log in paprika, and 2 to 3 log in nutmeg at doses of 7.5 kGy. Hayashi *et al.* (1998) showed that "soft electrons" (electrons with an energy of 300 keV or lower; defined by study authors) would reduce the total microbial load in black pepper, white pepper, turmeric, coriander and basil to below detectable concentrations (<10 CFU/g). Nieto-Sandoval *et al.* (2000) reported minimum electron beam irradiation D-values of 2.12 kGy for APCs, 2.66 kGy for *Enterobacteriaceae*, 3.15 kGy for coliforms, 3.84 kGy for sulfide-reducing clostridia, and 3.36 kGy for yeasts/molds. The D-value represents the kGy dosage level needed to produce a 1-decimal reduction. They further reported no impact on the red color of paprika after treatment.

8.2.1.9 APPLICATION OF PATHOGEN REDUCTION TREATMENTS

ASTA "recommends the use of validated microbial reduction techniques" (ASTA, 2011) and many spice processing and packing/re-packing facilities apply such treatments to their spices. However, it is not known what fraction of the total U.S. supply is treated other than it is not 100%. Treatment may take place in the source country, another country or in the country of import, e.g., in the United States information shared by spice producers and manufacturers during our site visits and information gathered during FDA inspections (see Section 8.1.3.1.) indicate that practices differ among spice manufacturers/packers/re-packers and among spices treated. Some spice manufacturers/packers/re-packers subject all or nearly all of the spice they handle to a pathogen reduction treatment (either before acquisition or during their processing) while others subject the spice to a pathogen reduction treatment only when the customer requests it. Some types of spices are more commonly treated with pathogen reduction treatments, e.g., black pepper, than others, e.g., dehydrated onion and garlic. Many spices will be subjected to one or more treatments capable of killing pathogenic bacteria such as *Salmonella* during food preparation (canning or cooking). However, some spices receive no antimicrobial treatment before consumption.

More data are needed to determine treatment conditions to ensure elimination of vegetative pathogens in spices. The data on concentrations of *Salmonella* in imported capsicum or sesame seed shipments offered for entry to the United States (Van Doren, 2013c) and those found in samples of spices associated with foodborne outbreaks (Table 4.2) provide some guidance. Table 8.12 provides estimates of the number of *Salmonella* illnesses resulting from a population consuming raw spice from a single 40,000 lb. (18144 kg) *Salmonella*-contaminated shipment/lot as a function of mean shipment/lot concentration and serving size, assuming the contamination is Poisson-distributed within the lot. The FDA study examining within- and between-shipment distribution of *Salmonella* in imported shipments of capsicum or sesame seeds provides some support for this assumption (Van Doren *et al.*, 2013c).

Table 8.12. Estimates of the number of *Salmonella* illnesses resulting from a population consuming raw spice from a single 40,000 lb. (18144 kg) *Salmonella*-contaminated lot as a function of mean lot concentration and serving size, assuming the contamination is Poisson-distributed within the lot

Lot *S.* Mean Concentration (MPN/g)	Serving Size (g)	Estimated Number of Illnesses if all spice eaten raw[a]	Decimal reduction to reduce illnesses to <1
1	1	45,133	5
0.1	1	4,556	4
0.01	1	456	3
0.001	1	46	2
1	0.15	45,541	5
0.1	0.15	4,561	4
0.01	0.15	456	3
0.001	0.15	46	2

[a] Based on the WHO/FAO *Salmonella* dose-response model (WHO/FAO, 2002).

8.2.2 INDUSTRY GUIDANCE FROM TRADE ORGANIZATIONS ON PRACTICES IMPACTING FOOD SAFETY OF SPICES

Spice and food trade associations have developed and published guidelines on the production, handling and packing of spices and low moisture foods that address food safety issues including mitigation and control programs and practices that prevent/reduce the risk of contamination of spice with pathogens and filth. These include:

- American Spice Trade Association (ASTA)
  - *Clean, Safe Spices: Guidance from the American Spice Trade Association*, 2011
  - *HACCP Guide for Spices and Seasonings*, February , 2006
  - *Clean Spices: A Guidebook for Shippers of Products to the U.S. Spice Trade*, May, 2008
- American Dehydrated Onion and Garlic Association, *Official Standard and Methods, 14th edition*, April 2005.
- International Organization of Spice Trade Associations, *General Guidelines for Good Agricultural Practices Spices*, April 2008
- Grocery Manufacturing Association, *Control of* Salmonella *in Low-Moisture Foods*, Feb. 2009

In addition to the guidance documents identified above, the Grocery Manufacturer Association (GMA) published a series of reports of their research and best practices for controlling *Salmonella* in low moisture foods:

- Control of *Salmonella* in Low-Moisture Foods I: Minimizing Entry of *Salmonella* into Processing Facility (Scott *et al*., 2009)
- Control of *Salmonella* in Low-Moisture Foods II: Hygiene Practices to Minimize *Salmonella* Contamination and Growth (Chen *et al*., 2009a)
- Control of *Salmonella* in Low-Moisture Foods III: Process Validation and Environmental Monitoring (Chen *et al*., 2009b)
- Sources and risk factors for contamination, survival, persistence, and heat resistance of *Salmonella* in Low-moisture foods (Podolak *et al*., 2010).

The *Clean, Safe Spices: Guidance from the American Spice Trade Association* (ASTA, 2011) document was developed to "assist the spice industry in developing programs that minimize the risk for contamination during growing, harvesting, drying transport, processing, and post-processing storage, helping industry firms to provide clean, safe spices to their industrial, food service and consumers customers" (ASTA, 2011). This spice industry guidance provides five major recommendations:

1. Minimize the risk for introduction of filth throughout the supply chain.
2. Prevent environmental contamination, cross-contamination, and post-processing contamination during processing and storage.
3. Use validated microbial reduction techniques.
4. Perform post-treatment testing to verify a safe product.
5. Test to verify a clean and wholesome manufacturing environment.

The guidance identifies the specific programs and practices that should be established in order to implement the recommendations including

- Good Agricultural Practices for growing and harvesting spices
- Supply chain approval and re-evaluation programs
- Good Manufacturing Practices (FDA CGMPs and Codex General Principles of Food Hygiene)
- Hazard Analysis Critical Control Point (HACCP) Plans.
- Validated microbial reduction process
- ASTA Cleanliness Specifications
- Post-treatment product sample and testing program
- Environmental sample and test program

The guidance describes key elements of each program (e.g., evaluation of each potential supplier's implementation and use of preventive controls such as GAPs, GMPs, and HACCP plans as part of a supplier approval program). Figure 6.1, copied with permission from this guidance document, illustrates recommended preventive controls to be applied at each stage of the farm to finished product continuum. ASTA Cleanliness Specifications, described in the guidance document, identify limits for macroscopic extraneous matter for spices similar to FDA DALs. The concentrations in these specifications are in some cases smaller than the FDA DALs and provide limits for some spices for which specific FDA DALs were not established.

Clean Spices: A Guidebook for Shippers of Products to the U.S. Spice Trade (ASTA, 2008) provides descriptions of U.S. regulations regarding importation of spice (including relevant food safety regulations), an overview of CGMPs and HACCP, FDA DALs and ASTA Cleanliness Specifications, warehouse/storage sanitation practices, and cleaning practices to remove extraneous material. This guide describes specific equipment that can used to remove extraneous material from spice and a chart to link spice, filth element, and equipment.

HACCP Guide for Spices and Seasonings (ASTA, 2006) identifies pre-requisite programs, HACCP principles, HACCP plan implementation and documentation as it applies to spices and seasonings. It describes hazards including microbial and physical, and provides examples and suggestions of how to conduct a hazard analysis.

GMA 2009 guidance *Control of* Salmonella *in Low-Moisture Foods* and related reports (Scott, *et al.*, 2009; Chen *et al.*, 2009a; Chen *et al.*, 2009b) identify seven control elements to minimize the risk of *Salmonella* contamination of low moisture foods in the manufacturing environment:

1. Prevent ingress of spread of *Salmonella* in the processing facility.
2. Enhance the stringency of hygiene practices and controls in the PSCA.
3. Apply hygienic design principles to building and equipment design.
4. Prevent or minimize growth of *Salmonella* within the facility.
5. Establish a raw materials/ingredients control program.
6. Validate control measures to inactivate *Salmonella*.
7. Establish procedures for verification of *Salmonella* controls and corrective actions.

These documents also describe common industry practices associated with implementation of each element.

The PSCA in a facility handling low moisture foods such as spices is defined as “the area where handling of ingredient and product requires the highest level of hygiene control. In a facility where products receive a pathogen inactivation treatment, the PSCA is the area subsequent to the terminal pathogen reduction (lethality) step. In a facility where no inactivation step is employed, the entire process area may become the PSCA” (GMA, 2009; Chen *et al.*, 2009a).

General Guidelines for Good Agricultural Practices Spices (IOSTA, 2008) addresses preventive controls to limit the introduction mycotoxins, heavy metals, pesticide residues, allergens, undeclared colors, and processing aides from spices.

The International Organization for Standardization (ISO) has issued over 50 standards for sampling and testing of spices. These recommendations are concerned with quality standards rather than food safety standards.

Effectiveness of industry guidance from trade organizations in preventing contamination of spices with *Salmonella* and/or filth and in preventing contaminated spice from entering the spice supply. The guidance documents represent the spice and food manufacturing industries’ best practices. The guidance has evolved as data have demonstrated the ability of *Salmonella* to survive in low moisture foods and research has revealed causes for contamination not previously recognized, particularly for low-moisture foods. As a result, it is expected that application of the principles and recommendations outlined in these documents would reduce the risk of contamination of spices with microbial pathogens and filth. We are not aware of any surveys that have measured compliance with guidance recommendations or changes in contamination prevalence in spice production sites. As discussed in Section 8.1.3.4 and illustrated in Table 8.7, the number of RFR primary entries for “Spices and Seasonings” in Year 3 of the program, was smaller than that found the previous two years. It is noteworthy that the ASTA guidance *Clean, Safe Spices: Guidance from the American Spice Trade Association* was issued during Year 3. Unfortunately, absence of information about the total number of tests performed or lots examined in each year, makes it difficult to interpret the significance of the observed changes.

As seen in Table 8.7, the number of primary entries reported for “Spices and Seasonings” during the first two years of the program were larger than that for most of the other food commodity types for all hazards and for *Salmonella* in particular. However, the absolute and relative (e.g., rank) number of primary entries for “Spices and Seasonings” were much smaller in Year 3 of the program. As mentioned previously, the absence of information about the total number of tests performed or lots examined, makes it difficult to interpret the meaning of these data, including changes from year to year. However the publication of the reports and summary statistics has been effective in alerting the industry to reported problems.

8.2.3 RECALLS

Until FSMA was enacted in 2011, recalls of spices or spice-containing foods were conducted on a firm's own initiative or by FDA request. FDA did not have the authority to mandate a recall. Classification of recalls and discussion of recent recalls were described in Section 4.1.6.

Effectiveness of recalls in preventing contaminated spice from entering or remaining in the U.S. food supply. Recalls remove contaminated product or potentially contaminated product from the commercial market. As such, they directly impact public health by avoiding illnesses that would otherwise have been realized, if the contaminated food had been consumed. Estimates of (potential) illnesses prevented for each spice-associated recall event is hampered by lack of information about the serving size for each of the products recalled. Development and reporting such a metric would allow comparison of “illnesses prevented’ from recalls to other mitigation strategies.

8.3 CODEX ALIMENTARIUS AND FAO/WHO

Codex Alimentarius (Codex), as a joint effort of the WHO and the Food and Agriculture Organization (FAO), serves to assemble experts from its member nations who set global standards for the safety and quality of foods. A number of guidance documents provided by Codex (Codex Alimentarius, 2013) address practices important to ensure spice food safety including

- General Principles of Food Hygiene (CAC/RCP 1-1969) (CAC, 2003)
- Code of Hygienic Practice for Spices and Dried Aromatic Plants (CAC/RCP 42-1995) (CAC, 1995)
- Guide for the Microbiological Quality of Spices and Herbs Used in Processed Meat and Poultry Products (CAC/GL 14-1991) (CAC, 1991)
- Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) (CAC, 2010)

These documents provide broad requirements for hygienic production and harvesting, establishment design and hygiene, personnel hygiene, establishment hygienic processing, and end-product specifications. The spice-specific code is currently being revised by the Codex Committee on Food Hygiene (USDA, 2012). WHO has established *WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants* and created *Five keys to growing safer fruits and vegetables: promoting health by decreasing microbial contamination* which may be applicable to spice production (WHO, 2003; WHO, 2012). The latter document, which was discussed briefly in Section 8.1.3.5, targets rural workers and adapts the strategy of “Five keys to safer food manual” by providing graphics as well as text to communicate better with the intended audience. FAO of the United Nations has also developed general GAP principles for all commodities that address soil, water, crop selection and rotation, and crop protection from pests (FAO, 2013a).

A “Microbiological Sampling Plan Analysis Tool” is now available from the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA, 2013) and the Codex Committee on Food Hygiene is developing detailed examples for the revised *Principles and Guidelines for the Establishment and Application of Microbiological Criteria for Foods* to aid in its implementation.

Effectiveness of Codex and FAO/WHO guidance in preventing contamination of spices with *Salmonella* and/or filth and in preventing contaminated spice from entering the spice supply. These general guidance documents provide guidance for the spice and food industries based on sound scientific evidence and most have been revised to reflect current knowledge in food safety. As a result, it is expected that application of the principles and recommendations outlined in these guidance documents should reduce the risk of contamination of spices with microbial pathogens and filth. The *Code of Hygienic Practices for Spices and Dried*

Aromatic Plants is not based on currently available data and information but is being revised. We are unaware of any systematic studies that have measured changes in the prevalence of microbial or filth contamination in spices as a result of applications of these guidance documents or any surveys that measure the extent to which these practices have been adapted by the food industry in general or the spice industry in particular.

9. GENERAL CONCLUSIONS AND POTENTIAL FUTURE MITIGATION AND CONTROL OPTIONS

9.1 GENERAL CONCLUSIONS

A wide diversity of pathogens have been found in spices including *Salmonella*, *Bacillus* spp. (including *B. cereus*), *Clostridium perfringens*, *Cronobacter* spp., *Shigella*, *and Staphylococcus aureus*. Human illness outbreaks attributed to consumption of pathogen-contaminated spice have most commonly been associated with *Salmonella* or *Bacillus* spp. contamination. Ten of fourteen (71%) spice-associated outbreaks identified worldwide during the period 1973-2010 and 87% of the documented human illnesses in the outbreaks attributed to consumption of contaminated spices were caused by serotypes of *Salmonella*. *Salmonella* was the only pathogen associated with reported spice-associated outbreaks, food recalls, and Reportable Food Registry reports in the United States, for the review periods covered in this report. The absence of spice-associated *Bacillus* spp. outbreaks or food recalls reported in the United States is somewhat surprising, particularly in light of reports of *Bacillus* spp. outbreaks associated with consumption of contaminated spice in the European Union during the 1973-2010 review period covered in this report, and additional *Bacillus* spp. outbreaks (4) reported in the European Union in 2011 (EFSA, 2013). The apparent differences in the types of outbreaks attributed to contaminated spice and most commonly reported in the United States and the European Union or other regions/countries may arise in part from differences in awareness, surveillance (including test methodology), regulations, clinical diagnoses of suspected foodborne illnesses, and reporting requirement for different kinds of illnesses. Differences in diet, food preparation, and food storage practices may also contribute to the observed differences in types of reported outbreaks.

Evidence described in this report demonstrates the potential for introduction of *Salmonella* into/on spice during primary production, distribution and storage, secondary processing and food manufacturing, and at retail. *Salmonella* can survive in the natural environment (outside of an animal host) for extended periods and may persist in production environments for years. During primary production, contact between the spice source plant during growth, harvest, or drying and *Salmonella*-contaminated materials in the environment, including soil, water, insects, animals, or animal feces, has the potential to contaminate the spice. Once in/on the spice, *Salmonella* can continue to survive for long periods.

Most spices consumed in the United States are imported. The overall prevalence of *Salmonella*-contaminated shipments of imported spice offered for entry to the United States was 6.6% (750 g sample size; 95% CI 5.7-7.6%) for FY2007-FY2009. This value is 1.9 times (95% CI 1.6-2.3) the prevalence found for other shipments of FDA-regulated foods examined during the same period. *Salmonella* was found in shipments of many different types of spices, in a variety of forms (whole, cracked, ground or blended) and from many different countries. As a result, we conclude that the presence of *Salmonella* is a general problem in the spice supply chain rather than a problem of a specific type/form of spice or source country. A few differences in prevalence rates with spice type, form, or country were significant and these should be explored further to better understand the increased/decreased contamination rate.

Salmonella concentrations ranging from 0.0007 to 11 MPN/g-spice (7 MPN per 10,000 g to 11 MPN per g) have been reported. Observations and models developed from an FDA 2010 study of shipments of imported capsicum (299 shipments) or sesame seed (233 shipments) offered for entry to the United States predict wide variability in the mean concentration of contamination among contaminated shipments of these types of spices and that many contaminated shipments contain very low concentrations of *Salmonella*. Estimated prevalence values based on sampling results are likely to be underestimates. Sampling plan design, particularly selections of an appropriate sample size and validated method of analysis, are critical to ensure efficient surveillance.

Salmonella has also been found in the environment of spice/food facilities, including spice/food facilities associated with two of the three spice-associated outbreaks identified in the United States. Cross-contamination from the spice/food manufacturing environment to the spice product was suspected to have been a contributing factor in both of these outbreaks. An FDA surveillance study involving environmental sampling in 59 spice manufacturers/packing/re-packing facilities in the United States during 2010 found 10% of the facilities contained *Salmonella* in the environment. In that study, *Salmonella* was found on non-product contact surfaces in close proximity to product such as the exterior of spice grinding equipment, floors or walls. The relatively large prevalence of *Salmonella*-positive facility environments observed in the survey indicates that *Salmonella* presence in spice manufacturers/packing/re-packing facilities is not uncommon.

Experiments have shown that *Salmonella* can grow quickly in some spices when moistened/wet (in the absence of other nutrients) which means that environmental niches may be created in facilities where *Salmonella* is present in the environment and moisture is not controlled (e.g., where wet cleaning is used).

Site visits and conversations with the spice industry revealed that not all spices sold by spice manufacturers have been treated with a pathogen reduction step. Food manufacturers and food preparers who purchase spice may subsequently apply a pathogen reduction step that would limit the potential for the spice, if initially contaminated, to cause illness. However, investigations of spice-associated outbreaks revealed that in at least three of the outbreaks, the consumed spice had not undergone a pathogen reduction treatment before reaching the consumer. Addition of spices to foods after cooking is not uncommon in the United States (e.g., addition of capsicum or Italian seasoning to a pizza and black pepper to salads, steaks, and other foods). Once present in a moist food, pathogens from spice ingredients may grow if appropriate time/temperature conditions are not maintained. Growth of the pathogen in the food was suspected to have contributed to the numbers of illnesses in some of the outbreaks.

Many of the spice-associated outbreaks during 1973-2010 were associated with consumption of low-moisture foods, including outbreaks leading to large numbers of illnesses. Large numbers of *Salmonella* illnesses can occur from consumption of spices when the exposed population is large, even when the concentration of *Salmonella* in the spice is small. This was the case for the1993 outbreak associated with consumption of contaminated paprika-powdered potato chips. A single contaminated shipment/lot of spice can contain millions to tens of millions of servings.

A diversity of filth adulteration has been found in spices offered for import to the United States that includes insects, excrement, hair, and other materials. Filth shipment prevalence during FY2007-FY2009 was 12% (95% CI 10-15%) which was 1.8 times (RR 95% CI 1.4-2.2) the value found for all other imported shipments of FDA-regulated foods sampled during this time period. Filth was found in shipments of many different types of spices, in a variety of forms (whole, cracked, ground or blended) and from many different countries. As a result, we conclude that the presence of filth is a general problem in the spice supply chain rather than a problem of a specific type/form of spice or source country. However, shipments of imported black pepper during FY2007-FY2009 and sesame seeds during FY2010 had significantly smaller violation rates than many other types of spice. The most prevalent types of filth were storage product insects/insect parts and animal hair (especially rodent). These types of filth are indicative of insanitary conditions and failures in the application of CGMPS.

Current mitigation and control options to prevent or control adulteration of spice by pathogens and filth include GAPs, CGMPS, inspections of and environmental sampling in spice manufacturing/packing facilities, product sampling, refusals and reconditioning, import alerts (with or without green lists and country agreements), recalls, application of pathogen reduction treatments, and guidance from FDA, other U.S. federal agencies, international agencies and industry trade organizations. Many of the current enforcement and regulatory strategies are effective but, with modification, could have greater impact on compliance. One example is Import Alert 28-02 for Indian Black Pepper, which includes an agreement that leverages in-country regulatory authority to improve the food safety of shipments of the imported spice offered for entry to the United States. This combination of incentives appears to be effective in reducing the prevalence of *Salmonella* or filth contamination in shipments of Indian black pepper offered for entry to the United States. Expansion of this type of mechanism to other spices and/or to other countries should lead to further improvements. The FDA Food Safety Modernization Act provides important new tools to mitigate and control contamination and post treatment cross contamination of spices with *Salmonella*, including authority to mandate recalls and increase in the frequency of foreign and domestic inspections. Prevention standards and import safety mandates required by FSMA are included in the potential future mitigation and control options, because they were still in development when this report was written.

Failures identified in the farm-to-table food safety system potentially leading to adulteration of consumed spice generally arose from poor/inconsistent application of appropriate preventive controls, such as failing to limit animal access to the source plant during harvest and drying phases, failing to limit insect and rodent access to spice during storage, and failing to subject all spice to an effective pathogen reduction treatment (or other lethality step). On the basis of our research, we concluded that the knowledge and technology is available to significantly reduce the risk of illness from consumption of contaminated spices in the United States. Capacity building through the creation of partnerships with stakeholders can facilitate improvements in spice safety and reduce the risk of illness from consumption of pathogen-contaminated spices. Specifically, enhanced communication between FDA and the spice industry and within the spice and food manufacturing industry itself, combined with training across the spice supply chain are needed to ensure understanding of appropriate preventive controls and how to implement and maintain them.

9.2 POTENTIAL FUTURE MITIGATION AND CONTROL OPTIONS

We developed the following list of potential future mitigations and control options for consideration based on a review and analysis of the scientific data and information available about the prevalence, concentration and public health risk of pathogen (primarily *Salmonella*) and filth adulteration of spices and our assessment of the efficacy of current mitigation and control options. The list includes mitigation and control options that FDA, the spice industry, government agencies, food manufacturers/preparers, and the consumers may consider to reduce the prevalence and concentration of *Salmonella*, other pathogens, and filth in spices and to reduce the public health burden resulting from consumption of contaminated spices or foods containing contaminated spices. Mitigation and control options identified include capacity building, guidance, enforcement and regulatory strategies, communication, education, and training. Research needed to explore additional potential mitigations is described in Chapter 10. For each mitigation and control option, we briefly describe the observation/data that motivated it, provide a brief description of the option, identify expected benefits/effectiveness, and provide additional comments about implementation (practicality), as needed. Mitigation and control options are organized by the stage in the farm-to-table continuum in which it would be implemented or the part of the continuum that would be most highly impacted. More data are needed to rank the relative importance of the different kinds of system failures identified in the report and the potential impact of the proposed mitigation and control options.

9.2.1 PRIMARY PRODUCTION

Update and produce industry and government guidance documents to reflect current knowledge and practices and improve utility of these documents by creating flexible communication platforms. Poor/inconsistent application of industry and government guidance was identified as one of the contributing factors leading to spice contamination with pathogens and filth. Some of the guidance documents for spice production, storage, distribution, processing, and use described in Chapter 8 do not describe the most up-to-date science-based principles for preventing/limiting contamination during on-farm production and post-production processes of spices (e.g., the Codex Code of Hygienic Practices for Spices and Dried Aromatic

Herbs.) The proposed rule "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (78 Federal Register 3504, January 16, 2013) (FDA, 2013e), which would implement section 105 of FSMA, provides information on mitigation in connection with pre-harvest commodities. It may be applicable to certain types of spice source plant production and could be relevant to updated guidance documents. Each guidance document should be reviewed and updated, as necessary. To improve the utility of these documents, tools should be developed to allow individuals/organizations to create customized extracts/compilations of the guidance(s) to review, share, discuss, and educate with particular groups. For example, one could create a single extract that collects all the sections of Codex documents that are relevant to the primary production of spices from the numerous relevant Codex food hygiene guidance documents. Some of this work is underway (e.g., development of a proposed revision of the Codex Code of Hygienic Practices for Spices and Dried Aromatic Herbs; FDA, 2012f). Alternatively, an alliance of stakeholders could work together to harmonize standards for the industry, as has been done in the produce industry (United Fresh, 2013). Creation of flexible and comprehensive resources, such as the examples described above, would require resources to complete, but may improve adoption by clarifying recommendations.

Enhance education and training for spice primary producers. Poor/inconsistent application of industry and government guidance was identified as one of the causes of spice contamination with pathogens and filth. While a number of guidance documents have been developed and have been reviewed in Chapter 8, some may not be accessible to all primary producers for a variety of reasons, e.g., not available, culturally insensitive, too general, wrong language, or uses the written word. New/revised versions of these documents could be developed to address limitations, perhaps building off of the novel GAPs tools developed by WHO (2013b) and the National GAPs Program at Cornell University (2013). Further improvements in application of guidance may be realized if practical examples are provided, either as part of the guidance or in another document/media format. For example, possible strategies for implementing guidance for primary production could address issues specific to different spices, growing practices/environments, and different available resources. Best practices for training and education resulting from these efforts should be shared as they could be used to enhance the efficacy of other training/education initiates. Development of these new educational tools will require resources and would likely benefit from a collaboration that includes primary spice producers, secondary spice processors, experts in GAPs, and experts in communication. Members of the spice industry have invested much time and effort to understand local regulations, practices, and traditions in different spice producing regions and this information should inform education and training development. Collaborative initiatives in place that might consider taking part in this work include the industry-academia-government Preventive Controls Alliance (FDA, 2013f) or the Joint Institute for Food Safety and Nutrition (JIFSAN)-country specific food safety training partnership (JIFSAN, 2013). The development of a *Collaborative Training Centre for Food Safety and Supply Chain Management in Spices and Botanical Ingredients* in India is already in progress. The partners in this initiative are the Confederation of India Industry Food Agriculture Centre of Excellence (CII-FACE), Spices Board India, and JIFSAN (Food Agriculture Centre of Excellence, 2013.) FDA participated in the initial "train the trainer" programs by training individuals from the CII-FACE, Spices Board India, Indian government officials, and industry representatives who will support the new initiative.

9.2.2 DISTRIBUTION AND STORAGE

FDA work with governments of spice producing countries to enhance food safety oversight by developing and formalizing programs such as the Indian EIC certificate program. FDA audits of the Indian EIC certificate program suggest that the program is effective in reducing the incidence of contamination in imported Indian black pepper, although some discrepancies in its application were found, as described in Chapter 8. Therefore, it is anticipated that reductions in the prevalence of pathogens and filth in imported spice shipments offered for import to the United States may be realized by expanding (and improving) the current program to include other spices imported from India and developing similar programs with other countries that are major sources of spice in the United States. The relatively large *Salmonella*-shipment prevalence for shipments of Indian spices other than black pepper found in the FDA study of FY2007-FY2009 import surveillance data, argues for expansion of the program. The current program provides market advantage to black pepper industry participants because shipments to the United States are no longer subject to DWPE at the border. In the future, the preventive controls, foreign supplier verification program, and voluntary qualified imported program provisions of FSMA (sections 103, 301, and 302 of FSMA) would provide additional incentives and may impact the nature and structure of food safety oversight programs developed. The imported food certification provision of FSMA (section 303 of FSMA) provides FDA with the authority to require a certificate of compliance for imported foods.

Strengthen the capacity of regulatory systems in spice source countries. Many major spice source countries are developing nations with developing food safety systems. Improvements in countries' food safety systems can significantly improve the quality of spices consumed in the country as well as exports. One strategy employed by India is the creation of "spice parks" where producers and aggregators may bring spice to be cleaned, treated and tested. Capacity-building was one of the major recommendations made by the Institute of Medicine of the National Academies in its report "Ensuring Safe Foods and Medical Products through stronger regulatory systems abroad," (IOM, 2012) and is an area of emphasis in FSMA. FDA has developed a comprehensive International Food Safety Capacity-Building Plan (FDA, 2013q; discussed in Section 8.1.3.7) to engage both government and industry leaders in food source countries to improve the quality of food produced and exported. As one part of these capacity building efforts, FDA has begun to set up new and expand established international posts in a range of countries and regions including China, India and Latin America.

Improve storage practices for spices. The prevalence of stored product pests in spices observed in shipments of imported spices offered for entry to the United States during FY2007-FY2009 indicates that insanitary storage conditions are not uncommon. Efficient improvement of storage practices would involve a systematic review of the practices employed and prevalence of stored-product pests in spices across the farm-to-table continuum (or other indicators of poor storage practices) to identify the stages and type of practices that contribute the most to the presence of stored-product pests in spices (see research Chapter 10).

***FDA to improve Import Alert communication*.** Nearly three quarters (71%) of the firms listed on the generalized Import Alert 99-19 for *Salmonella* contamination of imported foods were cited for violations in one or more spices. One option is to consider creating a commodity specific import alert for *Salmonella* and/or filth in spices to enable industry to more easily identify firms on detention and to facilitate tracking and trending analyses. This will communicate to all stakeholders that these specific contaminants may be found in spices. It is not known whether this option would significantly reduce the prevalence of *Salmonella* or filth in imported shipments of spice because shipments from importers on either the current or proposed import alert would be subject to DWPE. Improvements might be realized if this modification more clearly communicated to the food industry the magnitude of the problem and thereby triggered new efforts to prevent contamination of spice. In addition, FSMA includes import food safety mandates that may lead to reductions in the prevalence of pathogen contamination or filth adulteration in shipments of imported spice in the future, e.g., the preventive controls rule for human food (section 103 of FSMA), the foreign supplier verification program (section 301 of FSMA), the prior notice provision (section 304 of FSMA, final rule issued), and possibly also the imported food certification provision (section 303 of FSMA). Final rules and their implementation may determine the extent to which these mechanisms reduce the prevalence of pathogen or filth adulteration in shipments of imported spices.

9.2.3 PRIMARY AND SECONDARY PROCESSING

FDA, industry and academic experts work together to develop regulations, and potentially guidance, for the spice industry (manufacturers, processors including treatment facilities, packers and holders of spice) on developing food safety plans that include preventive controls. Poor/inconsistent application of appropriate preventive controls was identified as one of the contributing factors leading to contamination of spice with *Salmonella* or filth. Section 103 of FSMA "*Hazard analysis and risk-based preventive controls*" requires food facilities to evaluate hazards that could affect food safety, identify and implement preventive controls to prevent hazards, monitor controls and maintain monitoring records, and conduct verification activities. FDA issued the proposed rule "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" (78 Federal Register 3646, January 16, 2013) that would, when finalized, implement section 103 of FSMA. The proposed rule proposes to require facilities to conduct a hazard analysis, identify hazards reasonably likely to occur, and establish preventive controls for such hazards. There are also proposed requirements for a food safety plan, monitoring and corrective actions for preventive controls, validation of preventive controls, and records. In addition the proposed rule "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" (78 Federal Register 45730, July 29, 2013) (FDA, 2013t) proposes to require that importers verify that the foods they import are produced using processes and procedures that ensure the same level of safety as food produced in the United States.

Guidance could also be developed to support the FSMA rulemakings. Guidance may be specific for spices or included in preventive controls guidance for low-moisture foods and should address environmental sampling. Such guidance would **i**mprove awareness of hazards and effective preventive controls. Guidance would be science-based and built off of science-based industry guidance and best practices. Implementation of the guidance by the spice industry may be improved if the guidance is accompanied by outreach following its initial publication. For example, ASTA has been actively engaging the spice industry in webinars about their guidance and presented a webinar on environmental sampling to interested parties in April 2013 (ASTA, 2013).

Enhance education and training for primary and secondary spice processors. Poor/inconsistent application of appropriate preventive controls was identified as one of the contributing factors leading to contamination of spice with *Salmonella* or filth. This option is analogous to that described for primary producers in 9.2.1. A number of guidance documents and reports have been developed by the spice and food industries on preventive controls for primary and secondary processing of spices and low moisture foods (see Section 8.2.2). However, observations and conversations between some spice processors and members of the risk profile development team engaged in educational or inspectional visits revealed lack of awareness or understanding of some provisions in industry spice processing guidance documents. Education and training efforts could include development and application of new strategies to make the information in the documents accessible to all primary and secondary spice processors. Development of practical tools or examples for implementing the guidance for spice processors may also expand implementation of preventive controls. For example, providing floor plans for hygienic design for operations of differing sizes and available resources, ideas on how to adapt facilities and equipment to improve food safety (e.g., sanitary equipment design), and identification of the best approaches for appropriate cleaning and sanitation of spice processing facilities and equipment may be helpful. Already in progress is the development of a *Collaborative Training Centre for Food Safety and Supply Chain Management in Spices and Botanical Ingredients* in India, described in 9.2.1 (Food Agriculture Centre of Excellence, 2013).

FDA develops guidance for industry on the criteria recommended for validation of spice pathogen reduction treatment processes. A significant percentage of reconditioning proposals are rejected by FDA each year and it is suspected that some pathogen reduction treatments applied to spices may not be efficient in reducing the microbial population (evidence that spice shipments/lots that had been subjected to a pathogen reduction treatment were contaminated, although this could have arisen from post-process contamination). FDA, possibly in collaboration with appropriate professional societies, could establish best practices and develop guidance for testing and verifying the process and protocols used to treat spices to reduce microbial loads. Such guidance would clarify FDA expectations for validation studies and is also likely to help industry improve their treatment processes to deliver consistent effective pathogen reduction treatments and thereby reduce the incidence of contamination across the entire U.S. spice supply. Implementation of the guidance by the spice/processing industry may be improved if the guidance is accompanied by outreach following its initial publication.

Increase (or mandate) application of validated pathogen reduction treatments for reduction of **Salmonella** ***to all spices intended for human consumption in the United States at an appropriate point before or after packaging.*** Our research revealed that some raw spice reaches the consumer. The spice and food manufacturing industries could develop new strategies to increase the application of validated pathogen reduction treatments to spice. As mentioned previously, the proposed rule "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" (78 Federal Register 3646; January 16, 2013) (FDA, 2013s) proposes to require validation of food safety preventive controls as part of verification. Such a requirement in a final rule would increase the application of validated pathogen reduction treatment of spices for reduction of *Salmonella*. Because research discussed in this document has revealed that pathogen reduction treatments have not been applied to all spices reaching the consumer, success of such initiatives would likely decrease consumer exposure to potential life threatening microbial diseases.

FDA and spice industry increase inspections of foreign and domestic spice warehouses, spice processing, and spice pathogen reduction treatment facilities that include environmental sampling and assess compliance with CGMPS. Our review of spice facility inspections demonstrated that review of hazard analysis and preventive controls during inspections can identify potential problems before contamination occurs. In addition, appropriate and regular environmental sampling within a facility provides an additional assessment of the facility environment, one that is not necessarily captured by an observational inspection alone. In the event of a *Salmonella*-positive environmental sample, additional sampling in the facility can help to characterize the spatial extent and possibly the source of contamination. Serotyping *Salmonella*-positive environmental samples can determine whether the organism has been found previously in the facility. This information can also help with identifying and eliminating the contamination source. Such an initiative could also involve training for inspectors on hazards and preventive controls for spices (or low moisture foods) and how to conduct preventive control inspections. Such training would improve awareness of hazards and preventive controls among inspectors. FDA is currently implementing an increase in frequency of foreign and domestic food facility inspections, as required by FSMA. As mentioned above, ASTA presented a webinar on environmental sampling in April 2013, which may encourage adoption and improved application of this food safety tool. The proposed rule "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" (78 Federal Register 45781, July 29, 2013) (FDA, 2013u), which, when finalized would implement section 307 of FSMA, would increase the capacity for regulatory and consultative audits of spice warehouses, processing and pathogen reduction facilities, once implemented.

9.2.4 RETAIL/END USER

FDA work with CDC and states to develop methods to facilitate collection of spice consumption and purchase information from individual cases and restaurant sub-clusters during outbreak investigations. Attribution of foodborne illnesses to foods, particularly minor ingredients such as spices, is difficult and is often not accomplished during routine outbreak investigations. This information would improve our ability to characterize the public health risk associated with consumption of spices. New tools/methods could be developed for use by state and local partners that will promote rapid collection of key information for traceback investigations. These tools should consider the potential role of ingredients such as spices in food contamination and could include improved patient/food preparer questionnaires/interviews that would include question(s) about use and consumption of spices and seasonings in the outbreak investigation. The team should also explore methods of using adjunct data sources (e.g., shopper loyalty cards or photo menu cards of dishes consumed at restaurants) to aid investigations. These new strategies will enhance the flow of product information to public health and regulatory agencies during traceback investigations, thereby expediting identification of any common food source. Development and implementation of new tools and methods for outbreak investigations could be facilitated through collaboration between the FDA Coordinated Outbreak Response and Evaluation Network (CORE) and the CDC outbreak and response team.

Increase efforts and improve strategies to identify the root cause of ingredient contamination including whether growth in the food or environment contributed to the outbreak. As revealed by the analysis of spice-associated outbreaks presented in this report, root cause of contamination was rarely identified in spice-associated outbreaks. This information is critical for reducing the burden of illness associated with consumption of contaminated spices because it identifies failure(s) in the food safety system. Once failures have been identified, they can be addressed, thereby improving/strengthening the food safety system. As illustrated by the extensive research efforts that went into trying to reveal the location/root cause of contamination in the *Salmonella* Montevideo outbreak attributed to consumption of black or red pepper-coated salami products, finding the root cause can be extremely difficult, particularly for such a complex supply chain as is typical for spices. Increased efforts could include increased sampling of products and environment at different points in the traceback diagram with serotype determined and NGS analyses or other appropriate subtyping analysis performed. FDA's CORE would likely lead the development of new strategies to better obtain root cause information.

Public health agency scientists involved in outbreak investigations enumerate pathogens in samples of food and ingredients in the food-chain that have been identified as having strains identical to the outbreak strain. Enumeration of pathogens such as *Salmonella* is rarely pursued during outbreak investigations but this information can provide data to indicate the relative role of CGMP and supply-chain failures in the outbreak (e.g., a high concentration of *Salmonella* in a spice could be indicative of conditions that supported growth of the microorganism). Enumeration of the implicated food in an outbreak will also provide a measure of the actual "dose" consumed, which can be used to estimate the size of the exposed population or to explore the impact of food/patient properties on the probability for illness. This information is critical for application of quantitative risk assessment efforts and can be used to characterize the public health burden associated with pathogen contaminated spice as well as the impact of different mitigation and control options on that burden. Enumeration data gathered during outbreak events could be added to the data resources available for FDA's risk ranking tool *iRisk*, which is a publicly available rapid risk assessment and risk ranking tool developed by FDA.

Develop new strategies to identify related illnesses attributed to spices or other low-moisture/long shelf-life foods. Retail packages of spices and other low moisture or shelf-stable products have the potential of being used by a large number of consumers over very long periods (years). As a result related illnesses may be spread out in time and space. Serotype/PFGE data are very helpful in identifying related illnesses, particularly when clustered in time. When serotypes are rare, related illnesses may be able to be linked across time and space. However, when common serotypes are involved, sequencing information, such as afforded by Next Generation Sequencing, are likely needed to link these illnesses across time and space. NIH/NCBI's Sequence Read Archive (SRA) is currently being developed to collect these data (NCBI, 2013). The data deposited in the SRA will be available for public download without geographic and/or political restrictions. The SRA is part of the international partnership of archives (INDSC) at NIH/NCBI, the European Bioinformatics Institute, and the DNA Database of Japan. Data submitted to any of these 3 sites will be shared among them. These new tools will enable researchers to identify more outbreaks, which would lead to a better characterization of the public health risk associated with consumption of spices. The data collected may also provide information such as the regional origin of the pathogen causing illness, which can significantly aid in the determining of root cause/system failures.

FDA, spice industry, and foreign governments work together to develop guidance, and potentially regulations, to improve traceability during outbreaks of illness from spices. The complexity of the spice supply chain complicated the development of an accurate traceback diagram in the *Salmonella* Montevideo outbreak in the United States associated with black or red-pepper coated salami products. Improved traceability would help in identifying and eliminating contaminated spice from the supply and has the potential to identify the cause of contamination, which could prevent future contamination events. Improved traceability would also decrease the time needed for the traceback investigation and as a result, could reduce the numbers of illnesses by more quickly identifying and removing/remediating all potential contaminated spice lots in the supply. Once developed, such guidance may be more effectively implemented if a companion training program is developed and implemented. In implementing section 204(a) of FSMA, FDA established product tracing pilots, which were conducted by IFT. One of these product tracing pilots included an exploration of scenarios involving processed foods containing spice ingredients and this pilot project has been completed. IFT's report about the product tracing pilots (McEntire and Bhatt, 2012), which provides recommendations on strategies that FDA can use to improve product tracing, was made available for public comment by FDA (FDA, 2013v). FDA intends to use the findings from this report and other recent tracing-related efforts to help inform the development of the rulemaking on tracing mandated in Section 204 of FSMA. That rulemaking will establish additional recordkeeping requirements for facilities that manufacture, process, pack or hold foods that FDA designates as high-risk. If FDA designates spices as high-risk, then the requirements established by the rulemaking will improve the traceability of spices.

Report recalls arising from contamination based on serving size of the product recalled in addition to the amount recalled. It is currently very complicated, if not impossible, to determine the number of servings of a product that has been recalled when the product is an ingredient in many different foods. Characterization of recalls on the basis of standard serving size would help to better define the public health impact of each recall event and would enable FDA and others to characterize each recall on the basis of potential foodborne illnesses prevented.

9.2.5 GENERAL

Increase surveillance of pathogens other than* Salmonella *in spices and in human cases of foodborne illness. The absence of evidence for spice-associated illnesses, food recalls, or RFR primary entries linked to pathogens other than *Salmonella* in the United States may arise from lack of surveillance. First efforts should focus on *Bacillus* spp., which was the second most common pathogen associated with spice-associated outbreaks reported during the period 1973-2010. Additional pathogen targets could include *Clostridium perfringens*, which was identified in one of the possible spice-associated outbreaks discussed in Section 2.4 and pathogenic *Escherichia coli*, which has been shown to be able to survive for long periods in low moisture foods (Kimber *et al*., 2012; Blessington *et al*., 2012).

Educate and train regulatory partners, and reach out to countries and food trade organizations to communicate common spice hazards and available preventive controls. Initial efforts could involve developing a variety of communication strategies to effectively share the present risk profile with regulatory partners and stakeholders. Scientific publications and public presentations, including webinars, are one forum open to all stakeholders and FDA has used these forums to communicate results ahead of publication of this report. Additional efforts could include the creation of partnerships with regulatory partners and stakeholders to craft communication tools to improve awareness of common spice hazards and application of available preventive controls. Collaborative initiatives in place that might consider taking part in this work include the industry-academia-government Preventive Controls Alliance or the JIFSAN-country specific food safety training partnerships.

Improve understanding and application of appropriate sample designs and analytical protocols for spice (and environmental) sampling for pathogens. In light of the small concentrations of *Salmonella* reported in spices, it is critical that public health agencies and the spice and food industries use effective product sampling plans (including sample size) when screening spice (or the environment) for *Salmonella*. Guidance for sample designs is available in the published scientific literature (e.g., ICMSF, 2002) and also online (JEMRA, 2013). The Codex Committee on Food Hygiene is developing detailed examples for the revised *Principles and Guidelines for the Establishment and Application of Microbiological Criteria for Foods* to aid in its implementation. Guidance on analytical protocols for detection of *Salmonella* in spices is provided in the FDA Bacteriological Analytical Manual (Andrews *et al*., 2011). These new tools build on the extensive scientific literature on product sampling. All resources noted here are free and publicly available. Education and training on sampling plan design and laboratory methods of detection, isolation and confirmation of *Salmonella* would enhance capacity, improve data quality and most importantly, would ultimately improve detection efficiencies when appropriate plans and methods are used.

FDA alert/communicate with the spice industry as a whole when observations suggest that the application of current preventive controls for pathogens and filth in spices may not be adequate. Observations that might warrant communication could include an increasing or significantly larger prevalence of pathogens or filth in all spices or a particular type of spice as compared with other FDA-regulated foods, an increase or unusually large number of inspections with poor CGMP compliance, or a new or unusual system failure identified as part of an investigation. The form of the communication could vary depending on the urgency and scope of the problem. For example, FDA could issue a constituent update, industry letter, publication, or give a webinar or presentation at a public or scientific meeting. Such communications would heighten awareness across the industry to potential problems and would provide the industry with an opportunity to develop systemic reforms to reduce/eliminate contamination in spices to minimize the public health impact. FDA has already used some of these mechanisms to share key results of this report ahead of publication.

FDA alert/communicate with spice producing countries when observations suggest that the application of current preventive controls for pathogens and filth in spices may not be adequate. Observations that might warrant communication might include an unusually large number of spice firms on Import Alert, or a sudden increase in the prevalence of *Salmonella*-positive spice shipments from that country. Such communications would alert countries to potential systemic or new problems in the spice supply chain that threaten public health in the United States and possibly also the source country.

Overhaul FDA product codes to allow for better identification of products and more precise tracking and trending of products by FDA. Current product codes complicate tracking and trending. Revisions could include providing unique identifiers for low moisture foods such as spices, foods that had undergone a pathogen reduction step, and foods packaged for retail. Such revisions would help FDA to more precisely characterize and compare contamination findings across the spice/food spectrum, such as prevalence in imported shipments offered for import, and would improve the ability to identify emerging food safety problems with spices or other FDA-regulated products and improve FDA's ability to target the types of shipments that pose the greatest public health risk for sampling.

10. DATA GAPS AND RESEARCH NEEDS

The development of the risk profile revealed many gaps in information and data regarding adulteration of spices by pathogens and filth and the potential for this contamination to impact public health. Below we identify these gaps and the research needed to fill them, particularly focusing on research that will improve our ability to assess the public health risk posed by consumption of spices in the United States, to better characterize system failures that lead to spice contamination, and to explore additional potential future mitigations.

10.1 DATA GAPS

10.1.1 FOODBORNE OUTBREAKS

- What stage of the farm-to-table continuum did the spice contamination take place? Where specifically did contamination take place?
- What were the root cause(s)/failure(s) that allowed the spice to be contaminated?
- Were there additional failures in the food safety system that allowed the initial contamination to reach the consumer?
- Did cross-contamination contribute to the outbreak or was it the major cause?
- Did growth of the pathogen in the spice/food contribute to the public health burden (increased numbers of illnesses)?
- What was the concentration of contamination in the spice implicated in causing illness? (was it significantly larger than that found in surveillance?)
- What percentage of foodborne outbreaks attributed to complex foods or for which the food could not be determined were caused by contaminated spice?

10.1.2 PREVALENCE AND CONCENTRATION OF PATHOGENS AND FILTH IN SPICES

- What is the prevalence, concentration and distribution of *Salmonella* or other pathogens in spices (domestic and imported) at different stages of the farm-to-table continuum? Where is the most common point of entry? Are there large differences among spices (including whether it is whole or ground?)
- What is the prevalence of filth in spices (domestic and imported), particularly storage pests, at different stages of the farm-to-table continuum? Which is the most common point of entry and what is the most common cause of contamination? Has the prevalence of filth in spices at retail in the United States changed since last measured in the 1980's? If so, why?
- How does the prevalence of *Salmonella* in imported shipments of raw spice offered for import to the United States compare with that for shipments of spice that have undergone a pathogen reduction treatment? Is this dependent of the type of spice? How do these measures compare for spice at retail? How does contamination prevalence in raw domestic spice differ from domestic spice at retail?
- In which stages of the farm-to-table continuum do the presence of filth and *Salmonella* in spice correlate (if any)?

10.1.3 CHARACTERISTICS OF CONTAMINANTS

- Are the survival of *Salmonella* in (dry) spice and the growth of *Salmonella* in wet spice strongly dependent on spice type?
- What are the survival and growth characteristics of other pathogens in spice?
- How does survival of *Salmonella* differ at low concentrations of contamination; are the antimicrobial compounds sufficient in concentration/number to kill the little *Salmonella* present?

10.2.4 MITIGATION AND CONTROL OPTIONS

10.2.4.1 CGMPS AND ENVIRONMENTAL SAMPLING

- What is the risk for spice contamination when *Salmonella* or other pathogens are found in the facility environment? (What is the relationship between prevalence of *Salmonella* in the environment and prevalence of *Salmonella* or other pathogens in the product? What are typical transfer rates from equipment or surfaces in spice processing/packing facilities to spice?)
- What is the prevalence of *Salmonella* or other pathogens in foreign spice processing/packing facility environments?
- What percentages of spice processing/packing firms follow the guidelines for spices and low moisture foods? Which practices are least often adopted and why? Which CGMP recommendations are most predictive of adulteration of the spice product?
- What percentage of spice processing/packing firms perform regular environmental sampling? Does this sampling include testing the environment for *Salmonella*? Other pathogens?
- What are the economic and social/consumer costs/concerns associated with requiring filth reduction treatments for all spices and seasonings?

10.2.4.2 PATHOGEN REDUCTION

- What is the efficacy of commonly applied pathogen reduction treatments on the population of *Salmonella* in spice?
- What are the economic and social/consumer costs/concerns associated with requiring pathogen reduction treatments for all spices and seasonings?
- What percentage of spice in the U.S. supply subjected to a pathogen reduction treatment before reaching the consumer? How does this percentage vary by spice type, size of spice/food firm, and stage in the farm-to-table continuum?

10.2.4.2 SAMPLING

- How would the efficacy of a three-class attribute system for filth in spices differ from the current system?

10.2.4.3 IMPORT ALERTS

- What is the effectiveness of firm-type import alerts? Does this differ from country-wide commodity specific import alerts?

10.2.5 CONSUMPTION

- What is the distribution of consumption patterns for spice in the U.S. population? How does this depend on the type of spice or consuming population?

- What is the relative frequency of consuming uncooked spice among the various U.S. populations? Are there spices that are more frequently consumed raw or added to foods near the end of cooking? Are there cuisines or specific foods in which raw/lightly cooked spice is generally included?

10.2 RESEARCH NEEDS

10.2.1 FOODBORNE OUTBREAKS

Research novel methods/strategies to efficiently identify the contaminated ingredient in foodborne illness outbreaks. Such methods would improve foodborne illness attribution.

Research novel methods/strategies to efficiently identify the root cause in a foodborne outbreak involving spices. Such methods would identify failures in the spice food safety system, which would enable the spice industry to improve these systems.

Research novel methods/strategies to efficiently traceback spice ingredients to their original source. Traceback for spices can be very complicated because of the multiple sources, suppliers, processors, packers, food manufacturers and retail establishments that may be involved. Novel strategies are needed to more quickly understand the complex web of relationships.

10.2.2 PREVALENCE AND CONCENTRATION OF PATHOGENS AND FILTH IN SPICES

Determine the distribution and concentration of* Salmonella *in spices at critical points in the farm-to-table continuum. Much data are needed to determine the relative importance of contamination at different stages of the spice supply chain, including studies of spices at production, before undergoing a pathogen reduction treatment, and at U.S. retail. Interpretation of analyzed data would be enhanced if the data collected would distinguish pathogen reduction treated spices and spices that had not undergone a pathogen reduction treatment as well as spice type.

Determine the prevalence and concentration of pathogens other than* Salmonella *in spices at critical points in the farm-to-table continuum. A wide diversity of pathogens have been identified in spices outside the United States including *Bacillus* spp. which have been reported to have caused human illness from consumption of contaminated spice. Research should include pathogens detected in spices as well as pathogenic *Escherichia coli* strains (e.g., O104) which have been identified in sprouts of seeds commonly used as spices. Surveillance data are especially needed at the point of import, in spice/food processing facilities, and at retail in the United States.

Determine the prevalence of different kinds of filth at critical points in the farm-to-table continuum. The prevalence of stored product pests in spices observed in shipments of imported spices offered for entry to the United States during FY2007-FY2009 indicates that insanitary storage conditions are not uncommon. A systematic review of the practices employed and prevalence of stored-product pests in spices across the farm-to-table continuum (or other indicators or poor storage practices) would be able to identify the stages and type of practices that contribute the most to the presence of stored-product pests in spices. Similarly, prevalence data on other types of filth along the farm-to-table continuum may reveal additional weaknesses in the food safety system.

Determine the prevalence of filth at retail in the United States. These data would reveal whether spice contamination with filth has improved since the establishment of DALs.

Determine the relationship between prevalence and concentration of* Salmonella *in the spice processing environment and* Salmonella *in spices. These data would better characterize the potential role of cross-contamination from the spice-processing environment to the spice in facilities where *Salmonella* is present, and could include quantitative measures of transfer (e.g., coefficients).

***Determine the percentage of firms that receive pathogen reduction treated spice or that treat spice to eliminate pathogens and the percentage of firms that perform regular environmental sampling for* Salmonella**. These data would provide information about extent of application of these preventive controls in the spice industry.

10.2.3 CHARACTERISTICS OF CONTAMINANTS

Determine how survival of* Salmonella *in dry spice and growth of* Salmonella *in wet/moist spice varies with spice type. This research extends the research initiated by FDA on black pepper and would provide a more comprehensive understanding of survival and potential for growth in spices.

***Determine whether* Salmonella *survival in spice is strongly dependent on the initial numbers/concentration introduced*.** Contamination concentrations detected in “naturally” contaminated samples are small compared with the concentrations used in survival and growth studies. Data are needed to determine whether at low concentrations of contamination, other factors, such antimicrobial compounds present in the spice, lead to different survival rates.

***Determine survival and potential for growth of other pathogens in spices*.** Research should include pathogens detected in spices as well as pathogenic *Escherichia coli* strains (e.g., O104) which have been identified in sprouts of seeds commonly used as spices.

10.2.4 MITIGATION AND CONTROL OPTIONS

Identify and characterize appropriate surrogate microorganisms that can produce similar inactivation results as* Salmonella *for specific technologies in specific spices. Optimal surrogates should be nonpathogenic, have inactivation kinetics that can predict reductions in *Salmonella* populations, be stable and exhibit consistent growth characteristics, easy to prepare in high-density populations, easy to enumerate and differentiate from other microflora, and have injury susceptibility similar to *Salmonella*.

***Measure the relative efficacy of* Salmonella *reduction processes commonly used on spices and validate mitigation treatments*.** The study should include evaluation of the impact of spice form (whole/cracked/ground), equipment design, and critical parameters on the efficacy of *Salmonella* reduction using a variety of treatment processes commonly used on spices. This effort should also address surrogate selection, inoculum preparation, and detection/enumeration of desiccation-stressed salmonellae in spices. Data from such a study would provide critical information to FDA and the spice industry.

Develop new and improved methods of dry cleaning and sanitation that are effective in reducing the prevalence and concentration of* Salmonella *(and other microbial pathogens). The research should include efficacy and validation studies.

***Determine the economic and social/consumer costs/concerns associated with requiring pathogen reduction treatments for all spices and seasonings*.** The research should include a survey that assesses consumer acceptance of spices treated with the most commonly applied pathogen reduction treatment technologies and study to determine the economic impact of a mandate.

Determine the economic and social/consumer costs/concerns associated with requiring all spices receive treatment to remove filth. This research would be needed before a new regulation could be developed. The research should include a survey to assess consumer tolerance of natural and unavoidable defects in food.

Develop a rapid accurate method to measure mold in spices. Analysis for mold, especially in ground spices, is time consuming and complex. Development of a rapid method for detection of mold in spices would allow more samples to be analyzed more accurately and would lead to a better characterization of the prevalence of mold in spices across the supply chain.

Develop a rapid method for screening and/or quantifying filth in spices. Current methods are labor intensive and time consuming, thereby limit the annual capacity for filth sampling by FDA, the spice and food industries. Development of a rapid analytical method would increase capacity for filth analysis.

Optimize methods for detection and enumeration of* Salmonella *(and other pathogens) in spices. Detection of pathogens such as *Salmonella* in spices is challenging for a number of reasons including the desiccated state of bacteria and the presence of antimicrobial compounds in some spices. Contamination concentration is needed to determine probability of illness, efficacy of pathogen reduction treatments, magnitude of growth, and other factors that can help determine root cause in outbreak/contamination investigations yet is rarely collected. Current methods are slow and labor intensive. Rapid reliable analytical methods for both detection and enumeration would improve capacity for government agencies and the spice/food industry to collect these data.

Determine the impact of a three-class attribute system for the evaluation of filth in foods on the quality and food safety of foods. Such a system would eliminate marginally compliant foods from the food supply and thereby improve the quality and food safety of foods. A three-class system increases the ability to detect food lots that have widespread but low concentrations of filth.

Determine metrics and develop plans to assess the efficacy of mitigation and control options including guidance. Better measures of the public health impact of different mitigation and control options will lead to a better characterization of the relative reduction in public health risk afforded by different types of options and will ultimately lead to the development of more effective options.

10.2.5 CONSUMPTION

Determine the fraction and type of spices consumed that had never received a pathogen reduction step (including cooking). These data should distinguish among spice type, cuisine, type of use, and food preparation setting (e.g., food manufacturers, institution, restaurant, or home). This information will help to characterize the public health risk posed by contaminated spices and help to identify the most likely populations to consume contaminated spices. Further characterization could be realized if the fraction and type of spices consumed as “partially cooked” spice (spice added to foods near the end of cooking where the heat treatment may be inefficient) could be estimated.

Determine the distribution and variability of spice consumption servings among general and susceptible U.S. populations. This information cannot be accurately determined with NHANES data. Such data are needed to quantitative characterize the public health risk associated with spice consumption and would be most useful if it included additional data about high consumers and susceptible populations.

Conduct research to determine the fraction and type of spices eaten raw. Research should assess the fraction of spices consumed in the United States that never undergo a pathogen reduction treatment (including cooking), preferably by type of spice.

10.2.6 GENERAL

Develop a quantitative risk assessment to estimate the risk of illness from consumption of spices and determine the relative effectiveness of potential control options to minimize the risk of illness from consumption of spices. The risk assessment would have to address differences among spices or groups of spices. Comparison of the impact of different potential mitigation and control options on predicted risk of illness estimates (e.g., risk of illness per spice serving or annual per capita risk of illness) will provide information for all stakeholders to make appropriate risk management decisions. However, much of the data that would be needed for a fully quantitative model is lacking. FAO is currently engaged in evaluating the risk posed by consumption of spices (FDA, 2012f).

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APPENDIX A: SPICE LIST

Over 100 different plants are commonly used as spices. The list of plants in this appendix was compiled from 21 CFR 182.10 (FDA, 2012f), EPA, and on-line lists of spices maintained by the American Spice Trade Association and the Seasoning and Spice Association. Spices are listed by botanical name (Table A1) and by common name (Table A2). Each is also categorized by the plant part used (Table A3). Typical spice use in foods is characterized in Table A4. Not all plants used as spices are listed in these tables.

Table A1. Spice list by botanical name

Botanical Name	Common Name	Plant Part Used	Source[a]
Allium cepa	Onion[b]	root	ASTA, SSA
Allium sativum	Garlic[c]	root	ASTA, SSA
Allium schoenoprasum	Chives	leaf	21CFR182.10
Alpinia galanga	Greater Galangal	root	SSA
Alpinia galanga	Greater Galangal seed	fruit/seed	SSA
Alpinia officinarum	Galanga (Galangal)	root	21CFR182.10
Amomum melegueta	Grains Of Paradise	fruit/seed	21CFR182.10
Anethum graveolens	Dill[c]	leaf	ASTA, SSA
Anethum graveolens	Dill[c] seed	fruit/seed	ASTA, SSA
Anethum sowa	Dill[d]	leaf	ASTA
Anethum sowa	Dill[d] seed	fruit/seed	ASTA
Angelica archangelica	Angelica	leaf	21CFR182.10
Angelica archangelica	Angelica Root	root	21CFR182.10
Angelica archangelica	Angelica Seed	seed	21CFR182.10
Angelica spp.	Angelica	leaf	21CFR182.10
Angelica spp.	Angelica Root	root	21CFR182.10
Angelica spp.	Angelica Seed	seed	21CFR182.10
Anthemis nobilis	Camomile (Chamomile), English Or Roman	flower	21CFR182.10
Anthriscus cerefolium	Chervil	leaf	21CFR182.10
Apium graveolens	Celery Seed	fruit/seed	21CFR182.10
Armoracia lapathifolia	Horseradish	root	21CFR182.10
Artemisia dracunculus	Tarragon	leaf	21CFR182.10
Bixa orellana	Anatto[c]	fruit/seed	ASTA
Brassica hirta	Mustard, White Or Yellow	fruit/seed	21CFR182.10
Brassica juncea	Mustard, Brown	fruit/seed	21CFR182.10
Brassica nigra	Mustard, Black Or Brown	fruit/seed	21CFR182.10
Calendula officinalis	Calendula	flower	21CFR182.10
Calendula officinalis	Marigold, Pot	flower	21CFR182.10
Calendula officinalis	Pot Marigold	flower	21CFR182.10
Capparis spinosa	Capers	flower	21CFR182.10
Capsicum annuum	Capsicum	fruit/seed	21CFR182.10
Capsicum annuum	Cayenne Pepper	fruit/seed	21CFR182.10
Capsicum annuum	Paprika	fruit/seed	21CFR182.10
Capsicum annuum	Pepper, Cayenne	fruit/seed	21CFR182.10
Capsicum annuum	Pepper, Red	fruit/seed	21CFR182.10
Capsicum frutescens	Capsicum	fruit/seed	21CFR182.10
Capsicum frutescens	Cayenne Pepper	fruit/seed	21CFR182.10
Capsicum frutescens	Pepper, Cayenne	fruit/seed	21CFR182.10
Capsicum frutescens	Pepper, Red	fruit/seed	21CFR182.10
Carum carvi	Caraway	fruit/seed	21CFR182.10
Cinnamomum burmanni	Cassia, Padang Or Batavia	bark	21CFR182.10
Cinnamomum cassia	Cassia, Chinese	bark	21CFR182.10

Botanical Name	Common Name	Plant Part Used	Source[a]
Cinnamomum cassia	Cinnamon, Chinese	bark	21CFR182.10
Cinnamomum loureirii	Cassia, Saigon	bark	21CFR182.10
Cinnamomum loureirii	Cinnamon, Saigon	bark	21CFR182.10
Cinnamomum zeylanicum	Cinnamon, Ceylon	bark	21CFR182.10
Citrus hystrix	Kaffir Lime[d]	leaf	SSA
Citrus hystrix	Kaffir Lime[d]	fruit/seed	SSA
Coriandrum sativum	Coriander	fruit/seed	21CFR182.10
Coriandrum sativum	Coriander	leaf	21CFR182.10
Crocus sativus	Saffron	flower	21CFR182.10
Cuminum cyminum	Cumin (Cummin)	fruit/seed	21CFR182.10
Curcuma longa	Turmeric	root	21CFR182.10
Curcuma zedoaria	Zedoary	root	21CFR182.10
Cymbopogon citratus	Lemon Grass[c]	leaf	SSA
Elettaria cardamomum	Cardamom (Cardamon)	fruit/seed	21CFR182.10
Foeniculum vulgare	Fennel, Common	fruit/seed	21CFR182.10
Foeniculum vulgare var. duice	Fennel, Sweet (Finocchio, Florence Fennel)	fruit/seed	21CFR182.10
Galipea officinalis	Angostura (Cusparia Bark)	bark	21CFR182.10
Hibiscus abelmoschus	Ambrette Seed	fruit/seed	21CFR182.10
Hyssopus officinalis	Hyssop	leaf	21CFR182.10
Illicium verum	Anise, Star	fruit/seed	21CFR182.10
Illicium verum	Star Anise	fruit/seed	21CFR182.10
Juniperus communis	Juniper[c]	fruit/seed	ASTA, SSA
Laurus nobilis	Bay	leaf	21CFR182.10
Lavandula officinalis	Lavender	flower	21CFR182.10
Lippia spp.	Oregano Oreganum, Mexican Oregano, Mexican Sage, Origan)	leaf	21CFR182.10
Majorana hortensis	Marjoram, Sweet	leaf	21CFR182.10
Majorana onites	Marjoram, Pot	leaf	21CFR182.10
Majorana onites	Pot Marjoram	leaf	21CFR182.10
Marrubium vulgare	Horehound (Hoarhound)	leaf	21CFR182.10
Matricaria chamomilla	Camomile (Chamomile), German Or Hungarian	flower	21CFR182.10
Medicago sativa	Alfalfa Herb And Seed	leaf	21CFR182.10
Medicago sativa	Alfalfa Herb And Seed	seed	21CFR182.10
Melissa officinalis	Balm (Lemon Balm)	leaf	21CFR182.10
Mentha piperita	Peppermint	leaf	21CFR182.10
Mentha spicata	Spearmint	leaf	21CFR182.10
Myristica fragrans	Mace	fruit/seed	21CFR182.10
Myristica fragrans	Nutmeg	fruit/seed	21CFR182.10
Nigella sativa	Caraway, Black (Black Cumin)	fruit/seed	21CFR182.10
Nigella sativa	Cumin, Black (Black Caraway)	fruit/seed	21CFR182.10
Ocimum basilicum	Basil, Sweet	leaf	21CFR182.10
Ocimum minimum	Basil, Bush	leaf	21CFR182.10
Origanum vulgare	Oregano[c]	leaf	ASTA, SSA
Papayer somniferum	Poppy Seed	fruit/seed	21CFR182.10
Pelargonium spp.	Geranium	leaf	21CFR182.10
Petroselinum crispum	Parsley	leaf	21CFR182.10
Pimenta officinalis	Allspice	fruit/seed	21CFR182.10
Pimpinella anisum	Anise	fruit/seed	21CFR182.10
Piper nigrum	Pepper, Black	fruit/seed	21CFR182.10
Piper nigrum	Pepper, White	fruit/seed	21CFR182.10
Rosmarinus officinalis	Rosemary	leaf	21CFR182.10
Salvia officinalis	Sage	leaf	21CFR182.10
Salvia sclarea	Clary (Clary Sage)	leaf	21CFR182.10

Botanical Name	Common Name	Plant Part Used	Source[a]
Salvia triloba	Sage, Greek	leaf	21CFR182.10
Sambucus canadensis	Elder Flowers	flower	21CFR182.10
Satureia hortensis (Satureja).	Savory, Summer	leaf	21CFR182.10
Satureia montana (Satureja).	Savory, Winter	leaf	21CFR182.10
Schinus terebinthifolia	Pink Pepper[c]	fruit/seed	ASTA, SSA
Sesamum indicum	Sesame	fruit/seed	21CFR182.10
Syzygium aromaticum	Cloves[c]	flower	ASTA, SSA
Thymus serpyllum[e]	Thyme, Wild Or Creeping	leaf	21CFR182.10
Thymus vulgaris[e]	Thyme	leaf	21CFR182.10
Tilia spp.	Linden Flowers	flower	21CFR182.10
Trifolium spp.	Clover	leaf	21CFR182.10
Trigonella foenum-graecum	Fenugreek	fruit/seed	21CFR182.10
Vanilla planifolia	Vanilla	fruit/seed	21CFR182.10
Vanilla tahitensis	Vanilla	fruit/seed	21CFR182.10
Zanthoxylum piperitum	Sichuan Pepper[b]	fruit/seed	SSA
Zingiber officinale	Ginger	root	21CFR182.10

[a] Plants listed as spices in commerce as cited by 21CFR182.10 (FDA, 2012f), ASTA (2012), or SSA (2012).

[b] Common name is from *Herbs of Commerce* (McGuffin *et al.*, 2000).

[c] Common name is from *Herbs of Commerce* (McGuffin *et al.*, 2000) as per 21 CFR101.4(h) (FDA, 2012q)

[d] Common name from source(s) noted.

[e] ASTA (2012) includes the species *Thymus satureioides* (thyme) on their list of spices. There is no history of use as a food in either GRIN, World Spice Plants, or Mansfeld's World Database of Agricultural and Horticultural Crops. It is a valid scientific name in the Missouri Botanical Garden Tropicos database as *Thymus saturejoides* Coss.

Table A2. Spice list by common name

Common name	***Botanical name***	**Plant Part Used**	**Source**[a]
Alfalfa	*Medicago sativa*	leaf	21CFR182.10
Alfalfa	*Medicago sativa*	seed	21CFR182.10
Allspice	*Pimenta officinalis*	fruit/seed	21CFR182.10
Ambrette Seed	*Hibiscus abelmoschus*	fruit/seed	21CFR182.10
Anatto[c]	*Bixa orellana*	fruit/seed	ASTA
Angelica	*Angelica archangelica*	leaf	21CFR182.10
Angelica	*Angelica spp.*	leaf	21CFR182.10
Angelica	*Angelica archangelica*	root	21CFR182.10
Angelica	*Angelica spp.*	root	21CFR182.10
Angelica	*Angelica archangelica*	seed	21CFR182.10
Angelica	*Angelica spp.*	seed	21CFR182.10
Angostura (Cusparia Bark)	*Galipea officinalis*	bark	21CFR182.10
Anise	*Pimpinella anisum*	fruit/seed	21CFR182.10
Anise, Star	*Illicium verum*	fruit/seed	21CFR182.10
Balm (Lemon Balm)	*Melissa officinalis*	leaf	21CFR182.10
Basil, Bush	*Ocimum minimum*	leaf	21CFR182.10
Basil, Sweet	*Ocimum basilicum*	leaf	21CFR182.10
Bay	*Laurus nobilis*	leaf	21CFR182.10
Calendula	*Calendula officinalis*	flower	21CFR182.10
Camomile (Chamomile), English Or Roman	*Anthemis nobilis*	flower	21CFR182.10
Camomile (Chamomile), German Or Hungarian	*Matricaria chamomilla*	flower	21CFR182.10
Capers	*Capparis spinosa*	flower	21CFR182.10
Capsicum	*Capsicum annuum*	fruit/seed	21CFR182.10
Capsicum	*Capsicum frutescens*	fruit/seed	21CFR182.10
Caraway	*Carum carvi*	fruit/seed	21CFR182.10
Caraway, Black (Black Cumin)	*Nigella sativa*	fruit/seed	21CFR182.10
Cardamom (Cardamon)	*Elettaria cardamomum*	fruit/seed	21CFR182.10
Cassia, Chinese	*Cinnamomum cassia*	bark	21CFR182.10
Cassia, Padang Or Batavia	*Cinnamomum burmanni*	bark	21CFR182.10
Cassia, Saigon	*Cinnamomum loureirii*	bark	21CFR182.10
Cayenne Pepper	*Capsicum annuum*	fruit/seed	21CFR182.10
Cayenne Pepper	*Capsicum frutescens*	fruit/seed	21CFR182.10
Celery Seed	*Apium graveolens*	fruit/seed	21CFR182.10
Chervil	*Anthriscus cerefolium*	leaf	21CFR182.10
Chives	*Allium schoenoprasum*	leaf	21CFR182.10
Cinnamon, Ceylon	*Cinnamomum zeylanicum*	bark	21CFR182.10
Cinnamon, Chinese	*Cinnamomum cassia*	bark	21CFR182.10
Cinnamon, Saigon	*Cinnamomum loureirii*	bark	21CFR182.10
Clary (Clary Sage)	*Salvia sclarea*	leaf	21CFR182.10
Clover	*Trifolium spp.*	leaf	21CFR182.10
Cloves[c]	*Syzygium aromaticum*	flower	ASTA, SSA
Coriander	*Coriandrum sativum*	leaf	21CFR182.10
Coriander	*Coriandrum sativum*	fruit/seed	21CFR182.10
Cumin (Cummin)	*Cuminum cyminum*	fruit/seed	21CFR182.10
Cumin, Black (Black Caraway)	*Nigella sativa*	fruit/seed	21CFR182.10
Dill[c]	*Anethum graveolens*	leaf	ASTA, SSA
Dill[c]	*Anethum graveolens*	fruit/seed	ASTA, SSA
Dill[d]	*Anethum sowa*	leaf	ASTA, SSA
Dill[d]	*Anethum sowa*	fruit/seed	ASTA, SSA
Elder Flowers	*Sambucus canadensis*	flower	21CFR182.10
Fennel, Common	*Foeniculum vulgare*	fruit/seed	21CFR182.10
Fennel, Sweet (Finocchio, Florence Fennel)	*Foeniculum vulgare var. duice*	fruit/seed	21CFR182.10

Common name	***Botanical name***	**Plant Part Used**	**Source[a]**
Fenugreek	*Trigonella foenum-graecum*	fruit/seed	21CFR182.10
Greater Galangal[c]	*Alpinia galanga*	root	SSA
Greater Galangal[c] seed	*Alpinia galanga*	fruit/seed	SSA
Galanga (Galangal)	*Alpinia officinarum*	root	21CFR182.10
Garlic[c]	*Allium sativum*	root	ASTA, SSA
Geranium	*Pelargonium spp.*	leaf	21CFR182.10
Ginger	*Zingiber officinale*	root	21CFR182.10
Grains Of Paradise	*Amomum melegueta*	fruit/seed	21CFR182.10
Horehound (Hoarhound)	*Marrubium vulgare*	leaf	21CFR182.10
Horseradish	*Armoracia lapathifolia*	root	21CFR182.10
Hyssop	*Hyssopus officinalis*	leaf	21CFR182.10
Juniper[c]	*Juniperus communis*	fruit/seed	ASTA, SSA
Kaffir Lime[d]	*Citrus hystrix*	leaf	SSA
Kaffir Lime[d]	*Citrus hystrix*	fruit/seed	SSA
Lavender	*Lavandula officinalis*	flower	21CFR182.10
Lemon Grass[c]	*Cymbopogon citratus*	leaf	SSA
Linden Flowers	*Tilia spp.*	flower	21CFR182.10
Mace	*Myristica fragrans*	fruit/seed	21CFR182.10
Marigold, Pot	*Calendula officinalis*	flower	21CFR182.10
Marjoram, Pot	*Majorana onites*	leaf	21CFR182.10
Marjoram, Sweet	*Majorana hortensis*	leaf	21CFR182.10
Mustard, Black Or Brown	*Brassica nigra*	fruit/seed	21CFR182.10
Mustard, Brown	*Brassica juncea*	fruit/seed	21CFR182.10
Mustard, White Or Yellow	*Brassica hirta*	fruit/seed	21CFR182.10
Nutmeg	*Myristica fragrans*	fruit/seed	21CFR182.10
Onion[b]	*Allium cepa*	root	ASTA, SSA
Oregano[c]	*Origanum vulgare*	leaf	ASTA, SSA
Oregano Oreganum, Mexican Oregano, Mexican Sage, Origan)	*Lippia spp.*	leaf	21CFR182.10
Paprika	*Capsicum annuum*	fruit/seed	21CFR182.10
Parsley	*Petroselinum crispum*	leaf	21CFR182.10
Pepper, Black	*Piper nigrum*	fruit/seed	21CFR182.10
Pepper, Cayenne	*Capsicum annuum*	fruit/seed	21CFR182.10
Pepper, Cayenne	*Capsicum frutescens*	fruit/seed	21CFR182.10
Pepper, Red	*Capsicum annuum*	fruit/seed	21CFR182.10
Pepper, Red	*Capsicum frutescens*	fruit/seed	21CFR182.10
Pepper, White	*Piper nigrum*	fruit/seed	21CFR182.10
Peppermint	*Mentha piperita*	leaf	21CFR182.10
Pink Pepper[c]	*Schinus terebinthifolia*	fruit/seed	ASTA, SSA
Poppy Seed	*Papayer somniferum*	fruit/seed	21CFR182.10
Pot Marigold	*Calendula officinalis*	flower	21CFR182.10
Pot Marjoram	*Majorana onites*	leaf	21CFR182.10
Rosemary	*Rosmarinus officinalis*	leaf	21CFR182.10
Saffron	*Crocus sativus*	flower	21CFR182.10
Sage	*Salvia officinalis*	leaf	21CFR182.10
Sage, Greek	*Salvia triloba*	leaf	21CFR182.10
Savory, Summer	*Satureia hortensis (Satureja).*	leaf	21CFR182.10
Savory, Winter	*Satureia montana (Satureja).*	leaf	21CFR182.10
Sesame	*Sesamum indicum*	fruit/seed	21CFR182.10
Sichuan Pepper[b]	*Zanthoxylum piperitum*	fruit/seed	SSA
Spearmint	*Mentha spicata*	leaf	21CFR182.10
Star Anise	*Illicium verum*	fruit/seed	21CFR182.10
Tarragon	*Artemisia dracunculus*	leaf	21CFR182.10
Thyme	*Thymus vulgaris*	leaf	21CFR182.10
Thyme, Wild Or Creeping	*Thymus serpyllum*	leaf	21CFR182.10
Turmeric	*Curcuma longa*	root	21CFR182.10

Common name	***Botanical name***	**Plant Part Used**	**Source**[a]
Vanilla	*Vanilla planifolia*	fruit/seed	21CFR182.10
Vanilla	*Vanilla tahitensis*	fruit/seed	21CFR182.10
Zedoary	*Curcuma zedoaria*	root	21CFR182.10

[a] Plants listed as spices in commerce as cited by 21CFR182.10 (FDA, 2012f), ASTA (2012), or SSA (2012).

[b] Common name is from *Herbs of Commerce* (McGuffin *et al.*, 2000).

[c] Common name is from *Herbs of Commerce* (McGuffin *et al.*, 2000) as per 21 CFR101.4(h) (FDA, 2012q)

[d] Common name from source(s) noted.

[e] ASTA (2012) includes the species *Thymus satureioides* (thyme) on their list of spices. There is no history of use as a food in either GRIN, World Spice Plants, or Mansfeld's World Database of Agricultural and Horticultural Crops. It is a valid scientific name in the Missouri Botanical Garden Tropicos database as *Thymus saturejoides* Coss.

Table A3. Spice list by part of plant used

Plant Part Used	Botanical Name	Common name	Source[a]
bark	*Cinnamomum burmanni*	Cassia, Padang Or Batavia	21CFR182.10
bark	*Cinnamomum cassia*	Cassia, Chinese	21CFR182.10
bark	*Cinnamomum cassia*	Cinnamon, Chinese	21CFR182.10
bark	*Cinnamomum loureirii*	Cassia, Saigon	21CFR182.10
bark	*Cinnamomum loureirii*	Cinnamon, Saigon	21CFR182.10
bark	*Cinnamomum zeylanicum*	Cinnamon, Ceylon	21CFR182.10
bark	*Galipea officinalis*	Angostura (Cusparia Bark)	21CFR182.10
flower	*Anthemis nobilis*	Camomile (Chamomile), English Or Roman	21CFR182.10
flower	*Calendula officinalis*	Calendula	21CFR182.10
flower	*Calendula officinalis*	Marigold, Pot	21CFR182.10
flower	*Calendula officinalis*	Pot Marigold	21CFR182.10
flower	*Capparis spinosa*	Capers	21CFR182.10
flower	*Crocus sativus*	Saffron	21CFR182.10
flower	*Lavandula officinalis*	Lavender	21CFR182.10
flower	*Matricaria chamomilla*	Camomile (Chamomile), German Or Hungarian	21CFR182.10
flower	*Sambucus canadensis*	Elder Flowers	21CFR182.10
flower	*Syzygium aromaticum*	Cloves[c]	ASTA, SSA
flower	*Tilia spp.*	Linden Flowers	21CFR182.10
fruit/seed	*Alpinia galanga*	Greater Galangal[c] seed	SSA
fruit/seed	*Amomum melegueta*	Grains Of Paradise	21CFR182.10
fruit/seed	*Anethum graveolens*	Dill seed[c]	ASTA, SSA
fruit/seed	*Anethum sowa*	Dill seed[d]	ASTA
fruit/seed	*Angelica archangelica*	Angelica Seed	21CFR182.10
fruit/seed	*Angelica spp.*	Angelica Seed	21CFR182.10
fruit/seed	*Apium graveolens*	Celery Seed	21CFR182.10
fruit/seed	*Bixa orellana*	Anatto[c]	ASTA
fruit/seed	*Brassica hirta*	Mustard, White Or Yellow	21CFR182.10
fruit/seed	*Brassica juncea*	Mustard, Brown	21CFR182.10
fruit/seed	*Brassica nigra*	Mustard, Black Or Brown	21CFR182.10
fruit/seed	*Capsicum annuum*	Capsicum	21CFR182.10
fruit/seed	*Capsicum annuum*	Cayenne Pepper	21CFR182.10
fruit/seed	*Capsicum annuum*	Paprika	21CFR182.10
fruit/seed	*Capsicum annuum*	Pepper, Cayenne	21CFR182.10
fruit/seed	*Capsicum annuum*	Pepper, Red	21CFR182.10
fruit/seed	*Capsicum frutescens*	Capsicum	21CFR182.10
fruit/seed	*Capsicum frutescens*	Cayenne Pepper	21CFR182.10
fruit/seed	*Capsicum frutescens*	Pepper, Cayenne	21CFR182.10
fruit/seed	*Capsicum frutescens*	Pepper, Red	21CFR182.10
fruit/seed	*Carum carvi*	Caraway	21CFR182.10
fruit/seed	*Citrus hystrix*	Kaffir Lime[d]	SSA
fruit/seed	*Coriandrum sativum*	Coriander	21CFR182.10
fruit/seed	*Cuminum cyminum*	Cumin (Cummin)	21CFR182.10
fruit/seed	*Elettaria cardamomum*	Cardamom (Cardamon)	21CFR182.10
fruit/seed	*Foeniculum vulgare*	Fennel, Common	21CFR182.10
fruit/seed	*Foeniculum vulgare var. duice*	Fennel, Sweet (Finocchio, Florence Fennel)	21CFR182.10
fruit/seed	*Hibiscus abelmoschus*	Ambrette Seed	21CFR182.10
fruit/seed	*Illicium verum*	Anise, Star	21CFR182.10
fruit/seed	*Illicium verum*	Star Anise	21CFR182.10
fruit/seed	*Juniperus communis*	Juniper[c]	ASTA, SSA
fruit/seed	*Medicago sativa*	Alfalfa Herb And Seed	21CFR182.10
fruit/seed	*Myristica fragrans*	Mace	21CFR182.10
fruit/seed	*Myristica fragrans*	Nutmeg	21CFR182.10

Plant Part Used	Botanical Name	Common name	Source[a]
fruit/seed	*Nigella sativa*	Caraway, Black (Black Cumin)	21CFR182.10
fruit/seed	*Nigella sativa*	Cumin, Black (Black Caraway)	21CFR182.10
fruit/seed	*Papayer somniferum*	Poppy Seed	21CFR182.10
fruit/seed	*Pimpinella anisum*	Anise	21CFR182.10
fruit/seed	*Pimenta officinalis*	Allspice	21CFR182.10
fruit/seed	*Piper nigrum*	Pepper, Black	21CFR182.10
fruit/seed	*Piper nigrum*	Pepper, White	21CFR182.10
fruit/seed	*Schinus terebinthifolia*	Pink Pepper[c]	ASTA, SSA
fruit/seed	*Sesamum indicum*	Sesame	21CFR182.10
fruit/seed	*Trigonella foenum-graecum*	Fenugreek	21CFR182.10
fruit/seed	*Vanilla planifolia*	Vanilla	21CFR182.10
fruit/seed	*Vanilla tahitensis*	Vanilla	21CFR182.10
fruit/seed	*Zanthoxylum piperitum*	Sichuan Pepper[b]	SSA
leaf	*Allium schoenoprasum*	Chives	21CFR182.10
leaf	*Anethum graveolens*	Dill[c]	ASTA, SSA
leaf	*Anethum sowa*	Dill[d] seed	ASTA
leaf	*Angelica archangelica*	Angelica	21CFR182.10
leaf	*Angelica spp.*	Angelica	21CFR182.10
leaf	*Anthriscus cerefolium*	Chervil	21CFR182.10
leaf	*Artemisia dracunculus*	Tarragon	21CFR182.10
leaf	*Citrus hystrix*	Kaffir Lime[d]	SSA
leaf	*Coriandrum sativum*	Coriander	21CFR182.10
leaf	*Cymbopogon citratus*	Lemon Grass[c]	SSA
leaf	*Hyssopus officinalis*	Hyssop	21CFR182.10
leaf	*Laurus nobilis*	Bay	21CFR182.10
leaf	*Lippia spp.*	Oregano Oreganum, Mexican Oregano, Mexican Sage, Origan)	21CFR182.10
leaf	*Majorana hortensis*	Marjoram, Sweet	21CFR182.10
leaf	*Majorana onites*	Marjoram, Pot	21CFR182.10
leaf	*Majorana onites*	Pot Marjoram	21CFR182.10
leaf	*Marrubium vulgare*	Horehound (Hoarhound)	21CFR182.10
leaf	*Medicago sativa*	Alfalfa Herb And Seed	21CFR182.10
leaf	*Melissa officinalis*	Balm (Lemon Balm)	21CFR182.10
leaf	*Mentha piperita*	Peppermint	21CFR182.10
leaf	*Mentha spicata*	Spearmint	21CFR182.10
leaf	*Ocimum basilicum*	Basil, Sweet	21CFR182.10
leaf	*Ocimum minimum*	Basil, Bush	21CFR182.10
leaf	*Origanum vulgare*	Oregano[c]	ASTA, SSA
leaf	*Pelargonium spp.*	Geranium	21CFR182.10
leaf	*Petroselinum crispum*	Parsley	21CFR182.10
leaf	*Rosmarinus officinalis*	Rosemary	21CFR182.10
leaf	*Salvia officinalis*	Sage	21CFR182.10
leaf	*Salvia sclarea*	Clary (Clary Sage)	21CFR182.10
leaf	*Salvia triloba*	Sage, Greek	21CFR182.10
leaf	*Satureia hortensis (Satureja).*	Savory, Summer	21CFR182.10
leaf	*Satureia montana (Satureja).*	Savory, Winter	21CFR182.10
leaf	*Thymus serpyllum*	Thyme, Wild Or Creeping	21CFR182.10
leaf	*Thymus vulgaris*	Thyme	21CFR182.10
leaf	*Trifolium spp.*	Clover	21CFR182.10
root	*Allium cepa*	Onion[b]	ASTA, SSA
root	*Allium sativum*	Garlic[c]	ASTA, SSA
root	*Alpinia galanga*	Greater Galangal[c]	SSA
root	*Alpinia officinarum*	Galanga (Galangal)	21CFR182.10
root	*Angelica archangelica*	Angelica Root	21CFR182.10

Plant Part Used	Botanical Name	Common name	Source[a]
root	*Angelica spp.*	Angelica Root	21CFR182.10
root	*Armoracia lapathifolia*	Horseradish	21CFR182.10
root	*Curcuma longa*	Turmeric	21CFR182.10
root	*Curcuma zedoaria*	Zedoary	21CFR182.10
root	*Zingiber officinale*	Ginger	21CFR182.10

[a] Plants listed as spices in commerce as cited by 21CFR182.10 (FDA, 2012f), ASTA (2012), or SSA (2012).

[b] Common name is from *Herbs of Commerce* (McGuffin *et al.*, 2000).

[c] Common name is from *Herbs of Commerce* (McGuffin *et al.*, 2000) as per 21 CFR101.4(h) (FDA, 2012q)

[d] Common name from source(s) noted.

[e] ASTA (2012) includes the species *Thymus satureioides* (thyme) on their list of spices. There is no history of use as a food in either GRIN, World Spice Plants, or Mansfeld's World Database of Agricultural and Horticultural Crops. It is a valid scientific name in the Missouri Botanical Garden Tropicos database as *Thymus saturejoides* Coss.

Table A4. Common use of spice in foods

Common use of spice in foods is characterized as raw, cooked or both. Spice use was assigned "raw" when dry spice is typically added to food without a microbial kill step. The term "cooked" was assigned when the cooking step is expected to provide an effective microbial kill step. The term "both" was assigned when both raw and cooked uses were identified or when the cooking step is not expected to always be sufficient to provide an effective kill step. Assignment of spice use is based on recipes and information on spice use available on the internet. More research is needed to distinguish use by cuisine or culture.

Common name	Botanical name	Plant Part Used	How used raw/cooked
Alfalfa	*Medicago sativa*	leaf	raw
Alfalfa	*Medicago sativa*	fruit/seed	both
Allspice	*Pimenta officinalis*	fruit	cooked
Ambrette Seed	*Hibiscus abelmoschus*	fruit/seed	both
Anatto[c]	*Bixa orellana*	fruit/seed	both
Angelica	*Angelica archangelica*	leaf	both
Angelica	*Angelica* spp.	leaf	both
Angelica	*Angelica archangelica*	root	cooked
Angelica	*Angelica* spp.	root	cooked
Angelica	*Angelica archangelica*	seed	cooked
Angelica	*Angelica* spp.	seed	cooked
Angostura (Cusparia Bark)	*Galipea officinalis*	bark	cooked
Anise	*Pimpinella anisum*	fruit/seed	both
Anise, Star; Star Anise	*Illicium verum*	fruit/seed	cooked
Balm (Lemon Balm)	*Melissa officinalis*	leaf	both
Basil, Bush	*Ocimum minimum*	leaf	both
Basil, Sweet	*Ocimum basilicum*	leaf	both
Bay	*Laurus nobilis*	leaf	cooked
Calendula	*Calendula officinalis*	flower	cooked
Camomile (Chamomile), English Or Roman	*Anthemis nobilis*	flower	both
Camomile (Chamomile), German Or Hungarian	*Matricaria chamomilla*	flower	both
Capers	*Capparis spinosa*	flower	both
Capsicum	*Capsicum annuum*	fruit/seed	both
Capsicum	*Capsicum frutescens*	fruit/seed	both
Caraway	*Carum carvi*	fruit/seed	both
Caraway, Black (Black Cumin)	*Nigella sativa*	fruit/seed	both
Cardamom (Cardamon)	*Elettaria cardamomum*	fruit/seed	both
Cassia, Chinese	*Cinnamomum cassia*	bark	both
Cassia, Padang Or Batavia	*Cinnamomum burmanni*	bark	both
Cassia, Saigon	*Cinnamomum loureirii*	bark	both
Cayenne Pepper	*Capsicum annuum*	fruit/seed	both
Cayenne Pepper	*Capsicum frutescens*	fruit/seed	both
Celery Seed	*Apium graveolens*	fruit/seed	both
Chervil	*Anthriscus cerefolium*	leaf	both
Chives	*Allium schoenoprasum*	leaf	both
Cinnamon, Ceylon	*Cinnamomum zeylanicum*	bark	both
Cinnamon, Chinese	*Cinnamomum cassia*	bark	both
Cinnamon, Saigon	*Cinnamomum loureirii*	bark	both
Clary (Clary Sage)	*Salvia sclarea*	leaf	cooked
Clover	*Trifolium* spp.	leaf	both
Cloves[c]	*Syzygium aromaticum*	flower	both
Coriander	*Coriandrum sativum*	leaf	both
Coriander	*Coriandrum sativum*	fruit/seed	both
Cumin (Cummin)	*Cuminum cyminum*	fruit/seed	both
Cumin, Black (Black Caraway); Caraway, black (black cumin)	*Nigella sativa*	fruit/seed	both
Dill	*Anethum graveolens*	leaf	both
Elder Flowers	*Sambucus canadensis*	flower	cooked

Common name	**Botanical name**	**Plant Part Used**	**How used raw/cooked**
Fennel, Common	*Foeniculum vulgare*	fruit/seed	cooked
Fennel, Sweet (Finocchio, Florence Fennel)	*Foeniculum vulgare var. duice*	fruit/seed	cooked
Fenugreek	*Trigonella foenum-graecum*	fruit/seed	both
Greater Galangal[c]	*Alpinia galanga*	root	both
Galanga (Galangal)	*Alpinia officinarum*	root	both
Garlic[c]	*Allium sativum*	root	both
Geranium	*Pelargonium* spp.	leaf	raw
Ginger	*Zingiber officinale*	root	both
Grains Of Paradise	*Amomum melegueta*	fruit/seed	both
Horehound (Hoarhound)	*Marrubium vulgare*	leaf	both
Horseradish	*Armoracia lapathifolia*	root	raw
Hyssop	*Hyssopus officinalis*	leaf	both
Juniper[c]	*Juniperus communis*	fruit/seed	cooked
Kaffir Lime[d]	*Citrus hystrix*	leaf	cooked
Kaffir Lime[d]	*Citrus hystrix*	fruit/seed	both
Lavender	*Lavandula officinalis*	flower	both
Lemon Grass[c]	*Cymbopogon citratus*	leaf	both
Linden Flowers	*Tilia* spp.	flower	both
Mace	*Myristica fragrans*	fruit/seed	both
Marigold, Pot; Pot Marigold	*Calendula officinalis*	flower	cooked
Marjoram, Pot; Pot Marjoram	*Majorana onites*	leaf	both
Marjoram, Sweet	*Majorana hortensis*	leaf	both
Mustard, Black Or Brown	*Brassica nigra*	fruit/seed	both
Mustard, Brown	*Brassica juncea*	fruit/seed	both
Mustard, White Or Yellow	*Brassica hirta*	fruit/seed	both
Nutmeg	*Myristica fragrans*	fruit/seed	both
Onion[b]	*Allium cepa*	root	both
Oregano[c]	*Origanum vulgare*	leaf	both
Oregano Oreganum, Mexican Oregano, Mexican Sage, Origan)	*Lippia* spp.	leaf	both
Paprika	*Capsicum annuum*	fruit/seed	both
Parsley	*Petroselinum crispum*	leaf	both
Pepper, Black	*Piper nigrum*	fruit/seed	both
Pepper, Cayenne	*Capsicum annuum*	fruit/seed	both
Pepper, Cayenne	*Capsicum frutescens*	fruit/seed	both
Pepper, Red	*Capsicum annuum*	fruit/seed	both
Pepper, Red	*Capsicum frutescens*	fruit/seed	both
Pepper, White	*Piper nigrum*	fruit/seed	both
Peppermint	*Mentha piperita*	leaf	both
Pink Pepper[c]	*Schinus terebinthifolia*	fruit/seed	both
Poppy Seed	*Papayer somniferum*	fruit/seed	both
Rosemary	*Rosmarinus officinalis*	leaf	both
Saffron	*Crocus sativus*	flower	cooked
Sage	*Salvia officinalis*	leaf	both
Sage, Greek	*Salvia triloba*	leaf	both
Savory, Summer	*Satureia hortensis (Satureja).*	leaf	cooked
Savory, Winter	*Satureia montana (Satureja).*	leaf	cooked
Sesame	*Sesamum indicum*	fruit/seed	both
Sichuan Pepper[b]	*Zanthoxylum piperitum*	fruit/seed	both
Spearmint	*Mentha spicata*	leaf	both
Tarragon	*Artemisia dracunculus*	leaf	both
Thyme	*Thymus vulgaris*	leaf	both

Common name	Botanical name	Plant Part Used	How used raw/cooked
Thyme, Wild Or Creeping	*Thymus serpyllum*	leaf	both
Turmeric	*Curcuma longa*	root	cooked
Vanilla	*Vanilla planifolia*	fruit/seed	cooked
Vanilla	*Vanilla tahitensis*	fruit/seed	cooked
Zedoary	*Curcuma zedoaria*	root	cooked

[a] Plants listed as spices in commerce as cited by 21CFR182.10 (FDA, 2012f), ASTA (2012), or SSA (2012).

[b] Common name is from *Herbs of Commerce* (McGuffin *et al.*, 2000).

[c] Common name is from *Herbs of Commerce* (McGuffin *et al.*, 2000) as per 21 CFR101.4(h) (FDA, 2012q)

[d] Common name from source(s) noted.

[e] ASTA (2012) includes the species *Thymus satureioides* (thyme) on their list of spices. There is no history of use as a food in either GRIN, World Spice Plants, or Mansfeld's World Database of Agricultural and Horticultural Crops. It is a valid scientific name in the Missouri Botanical Garden Tropicos database as *Thymus saturejoides* Coss.

APPENDIX B: WORLDWIDE SPICE PRODUCTION

The worldwide spice production data for 2009 included in this appendix was obtained from the FAO FAOSTAT Production website (FAO, 2013b). The top 20 producers are listed for each spice and the spice descriptions, country production, percent of worldwide production and data source listed were obtained from this FAO source.

Table B1. Worldwide Spice Production 2009

Spice	Worldwide Production (Metric Tonnes)
Anise, badian, fennel, coriander	499,626
Chilies and peppers, dry	3,137,545
Cinnamon (canella)	155,400
Cloves	104,881
Garlic	22,282,060
Ginger	1,615,974
Mustard seed	683,918
Nutmeg, mace and cardamoms	77,641
Onions, dry	73,231,830
Pepper (Piper spp.)	451,220
Poppy seed	98,835
Sesame seed	3,976,968
Spices, nes[a]	1,588,807
Vanilla	9,815

[a] nes: not elsewhere specified

Table B2. Anise, badian, fennel, coriander

Include: anise (*Pimpinella anisum*); badian or star anise (*Illicium verum*); caraway (*Carum carvi*); coriander (*Coriandrum sativum*); cumin (*Cuminum cyminum*); fennel (*Foeniculum vulgare*); juniper berries (*Juniperus communis*). Seeds and berries from the various plants listed. They are normally used as spices, but also have industrial (e.g. in distilleries) and medicinal applications.

Country	Metric Tonnes	% of Worldwide Production	Data Source[a]
India	176,615	35.35	Im
Mexico	50,000	10.01	F
China	42,000	8.41	F
Bulgaria	33,957	6.80	Im
Iran (Islamic Republic of)	31,431	6.29	Im
Syrian Arab Republic	30,829	6.17	
Morocco	23,000	4.60	F
Egypt	22,000	4.40	F
Russian Federation	11,200	2.24	
Tunisia	9,800	1.96	F
Turkey	9,472	1.90	
Afghanistan	8,904	1.78	Im
Peru	7,194	1.44	F
Canada	7,068	1.41	F
Romania	7,063	1.41	
Viet Nam	5,080	1.02	Im
Ukraine	4,509	0.90	Im
Australia	2,940	0.59	
Hungary	2,906	0.58	Im
Occupied Palestinian Territory	2,706	0.54	F

[a] FAO official data unless noted otherwise. Im: FAO data based on imputation methodology; F: FAO estimate.

Table B3. Chillies and peppers, dry

Red and cayenne pepper, paprika, chillies (*Capsicum frutescens*; *C. annuum*); allspice, Jamaica pepper (*Pimenta officinalis*). Uncrushed or unground fresh pimentos are considered to be vegetables.

Country	Metric Tonnes	% of Worldwide Production	Data Source[a]
India	1,300,000	43.155	F
China	260,000	8.29	F
Pakistan	186,700	5.95	
Thailand	170,125	5.42	
Peru	140,216	4.47	Im
Ethiopia	118,514	3.78	Im
Myanmar	116,000	3.70	F
Viet Nam	112,937	3.60	Im
Bangladesh	109,337	3.48	
Ghana	93,641	2.98	F
Mexico	50,988	1.63	Im
Nigeria	50,000	1.59	F
Egypt	45,600	1.45	F
Romania	35,251	1.12	Im
Democratic Republic of the Congo	32,000	1.02	F
Benin	25,867	0.82	
Bosnia and Herzegovina	20,429	0.65	Im
Côte d'Ivoire	20,000	0.64	F
Hungary	19,982	0.64	
Morocco	18,265	0.58	Im

[a] FAO official data unless noted otherwise. Im: FAO data based on imputation methodology; F: FAO estimate/

Table B4. Cinnamon (canella)

Ceylon cinnamon (*Cinnamomum zeylanicum*); Chinese, common cinnamon, cassia (*C. cassia*). The inner bark of young branches of certain trees of the Laurus family. Includes cinnamon- tree flowers, cinnamon fruit and cinnamon waste (chips), whether whole, crushed or ground.

Country	Metric Tonnes	% of worldwide Production	Data Source[a]
Indonesia	67,209	43.25	Im
China	58,000	37.32	F
Sri Lanka	14,600	9.40	
Viet Nam	13,965	8.99	Im
Madagascar	1,253	0.81	Im
Timor-Leste	133	0.09	Im
Sao Tome and Principe	70	0.05	F
Seychelles	63	0.04	
Dominica	52	0.03	Im
Grenada	37	0.02	F
Comoros	18	0.01	Im

[a] FAO official data unless noted otherwise. Im: FAO data based on imputation methodology; F: FAO estimate.

Table B5. Cloves

Eugenia caryophyllata; Caryophyllus aromaticus. The whole fruit of the clove tree, including the flowers picked before maturity and dried in the sun, and the stems of the clove flowers.

Country	Metric Tonnes	% of Worldwide Production	Data Source[a]
Indonesia	81,000	77.23	F
Madagascar	7,594	7.24	Im
United Republic of Tanzania	7,518	7.17	Im
Sri Lanka	3,790	3.61	
Comoros	2,658	2.53	Im
Kenya	1,159	1.11	Im
China	900	0.86	F
Malaysia	249	0.24	Im
Grenada	13	0.01	F

[a] FAO official data unless noted otherwise. Im: FAO data based on imputation methodology; F: FAO estimate.

Table B6. Garlic

Allium sativum. Numbers reflect fresh garlic production.

Country	Metric Tonnes	% of Worldwide Production	Data Source[a]
China	17,967,857	80.64	
India	1,070,000	4.80	F
Republic of Korea	380,000	1.71	F
Russian Federation	227,270	1.02	
Myanmar	200,000	0.90	F
Ethiopia	179,658	0.81	*
United States of America	178,760	0.80	
Egypt	174,659	0.78	
Bangladesh	154,831	0.69	
Spain	154,000	0.69	
Ukraine	150,100	0.67	
Argentina	120,391	0.54	Im
Turkey	105,363	0.47	
Democratic People's Republic of Korea	101,347	0.45	Im
Brazil	86,752	0.39	
Thailand	71,433	0.32	
Pakistan	67,204	0.30	
Iran (Islamic Republic of)	64,002	0.29	
Romania	63,245	0.28	
Algeria	59,932	0.27	

[a] FAO official data unless noted otherwise. Im: FAO data based on imputation methodology; F: FAO estimate

Table B7. Ginger

Zingiber officinale. Rhizome of a perennial herb. It also is used for making beverages. Includes fresh, provisionally preserved or dried, whereas ginger preserved in sugar or syrup is excluded.

Country	Metric Tonnes	% of Worldwide Production	Data Source[a]
India	380,100	23.52	
China	331,393	20.51	F
Indonesia	192,500	11.91	F
Nepal	174,268	10.78	Im
Thailand	170,125	10.53	
Nigeria	152,106	9.41	Im
Bangladesh	72,608	4.49	
Japan	52,000	3.22	F
Philippines	27,415	1.70	
Cameroon	12,000	0.74	F
Malaysia	11,200	0.69	
Sri Lanka	10,780	0.67	
Côte d'Ivoire	7,680	0.48	Im
Ethiopia	6,834	0.42	Im
Bhutan	3,766	0.23	
Fiji	3,041	0.19	
Republic of Korea	3,000	0.19	F
Costa Rica	1,105	0.07	
United States of America	816	0.05	F
Mauritius	616	0.04	

[a] FAO official data unless noted otherwise. Im: FAO data based on imputation methodology; F: FAO estimate.

Table B8. Mustard Seed

White mustard (*Brassica alba; B. hirta; Sinapis alba*); black mustard (*Brassica nigra; Sinapis nigra*). In addition to the oil extracted from them, white mustard seeds, may be processed into flour for food use. Black mustard seeds also yield oil and are processed into flour that is used mainly in pharmaceutical products.

Country	Metric Tonnes	% of Worldwide Production	Data Source[a]
Canada	208,300	30.46	
Nepal	135,494	19.81	
Myanmar	70,000	10.24	F
Czech Republic	38,651	5.65	
United States of America	22,391	3.27	
Ukraine	118,200	17.28	
Russian Federation	23,690	3.46	
China	18,000	2.63	F
Romania	10,633	1.55	
France	9,500	1.39	
Hungary	9,568	1.40	
Germany	7,411	1.08	Im
Slovakia	3,785	0.55	
Ethiopia	2,924	0.43	Im
Bhutan	1,741	0.25	
Bulgaria	1,222	0.18	Im
Sri Lanka	300	0.04	
Kazakhstan	900	0.13	*
Denmark	30	0.00	Im
Mexico	16	0.00	

[a] FAO official data unless noted otherwise. Im: FAO data based on imputation methodology; F: FAO estimate.

Table B9. Nutmeg, mace and cardamoms

Nutmeg, mace (*Myristica fragrans*); cluster cardamon (*Elettaria cardamomum*); other cardamons (*Aframomum angustifolium*; *A. hambury*; *Amomun aromaticum*; *A. cardamomum*); Malaguetta pepper, grains of paradise (*Aframomum melegueta*). Nutmeg is the inner brown kernel of the fruit of the nutmeg tree. Mace is the net-like membrane between the outer shell and the kernel. Cardamon seeds are enclosed in the capsule produced by perennial herbs of the Zingiberaceae family.

Country	Metric Tonnes	% of Worldwide Production	Data Source[a]
Guatemala	23794	30.65%	Im
India	17000	21.90%	F
Nepal	9774	12.59%	Im
Bhutan	9082	11.70%	Im
Indonesia	8600	11.08%	F
Lao People's Democratic Republic	3982	5.13%	Im
Grenada	2395	3.08%	Im
United Republic of Tanzania	795	1.02%	Im
Malaysia	711	0.92%	Im
Sri Lanka	480	0.62%	
Honduras	285	0.37%	Im
Trinidad and Tobago	192	0.25%	Im
Saint Vincent and the Grenadines	172	0.22%	Im
Malawi	133	0.17%	F
Ethiopia	100	0.13%	F
Kenya	60	0.08%	Im
Togo	35	0.05%	F
Saint Lucia	30	0.04%	F
Madagascar	16	0.02%	Im
Dominica	5	0.01%	F

[a] FAO official data unless noted otherwise. Im: FAO data based on imputation methodology; F: FAO estimate.

Table B10. Onions, dried

Allium cepa. Includes onions at a mature stage, but not dehydrated onions.

Country	Metric Tonnes	% of Worldwide Production	Data Source[a]
China	21,046,969	28.74%	F
India	13,900,000	18.98%	F
United States of America	3,400,560	4.64%	
Turkey	1,849,580	2.53%	
Egypt	1,800,000	2.46%	F
Pakistan	1,704,100	2.33%	
Russian Federation	1,601,550	2.19%	
Iran (Islamic Republic of)	1,512,150	2.06%	
Brazil	1,511,850	2.06%	
Netherlands	1,269,000	1.73%	
Spain	1,263,400	1.73%	
Republic of Korea	1,200,000	1.64%	F
Mexico	1,195,820	1.63%	
Japan	1,154,000	1.58%	
Myanmar	1,050,000	1.43%	F
Algeria	980,160	1.34%	
Indonesia	952,638	1.30%	
Ukraine	875,600	1.20%	
Uzbekistan	795,000	1.09%	*
Bangladesh	735,140	1.00%	

[a] FAO official data unless noted otherwise. F: FAO estimate; *: unofficial figure.

Table B11. Pepper (*Piper* spp.)

Black, white pepper (*Piper nigrum*); long pepper (*P. longum*). Perennial climbing vines. Includes whole, crushed or ground berries. Black pepper is produced from partially ripe berries, while white pepper is from fully ripe berries, which have had the outer hull removed.

Country	Metric Tonnes	% of Worldwide Production	Data Source[a]
Vietnam	137,280	30.42%	*
Indonesia	80,000	17.73%	F
Brazil	65,398	14.49%	
India	47,400	10.50%	
China	28,218	6.25%	F
Sri Lanka	25,300	5.61%	
Malaysia	23,210	5.14%	
Thailand	6,730	1.49%	
Mexico	5,805	1.29%	Im
Madagascar	3,949	0.88%	Im
Ghana	3,584	0.79%	F
Philippines	3,208	0.71%	Im
Cambodia	2,704	0.60%	Im
Ecuador	2,626	0.58%	Im
Rwanda	2,408	0.53%	Im
Niger	2,000	0.44%	F
Uganda	1,901	0.42%	Im
Zimbabwe	1,883	0.42%	Im
Bolivia (Plurinational State of)	1,263	0.28%	
Costa Rica	1,040	0.23%	

[a] FAO official data unless noted otherwise. Im: FAO data based on imputation methodology; F: FAO estimate; *: unofficial figure.

Table B12. Poppy Seed

Papaver somniferum. The source of opium, poppy seeds are also used in baking and confectionery.

Country	Metric Tonnes	% Of Worldwide Production	Data Source[a]
Turkey	34,194	34.60%	
Czech Republic	32,692	33.08%	
Spain	7,000	7.08%	F
France	6,500	6.58%	F
Hungary	3,458	3.50%	
Croatia	3,349	3.39%	
Germany	3,294	3.33%	Im
Occupied Palestinian Territory	2,200	2.23%	F
Romania	1,956	1.98%	Im
Austria	1,504	1.52%	
Serbia	859	0.87%	Im
Slovakia	832	0.84%	
Netherlands	493	0.50%	Im
The former Yugoslav Republic of Macedonia	504	0.51%	

[a] FAO official data unless noted otherwise. Im: FAO data based on imputation methodology; F: FAO estimate.

Table B13. Spices, nes

Including inter alia: bay leaves (*Laurus nobilis*); dill seed (*Anethum graveolens*); fenugreek seed (*Trigonella foenum-graecum*); saffron (*Crocus sativus*); thyme (*Thymus vulgaris*); turmeric (*Curcuma longa*). Other spices that are not identified separately because of their minor relevance at the international level. Because of their limited local importance, some countries report spices under this heading that are classified individually by FAO. This heading also includes curry powder and other mixtures of different spices.

Country	Metric Tonnes	% of Worldwide Production	Data Source[a]
India	1,100,000	69.23%	F
Bangladesh	140,113	8.82%	
Turkey	87,028	5.48%	Im
China	85,987	5.41%	F
Pakistan	45,473	2.86%	Im
Colombia	19,760	1.24%	Im
Nepal	17,404	1.10%	Im
Iran (Islamic Republic of)	13,226	0.83%	Im
Burkina Faso	6,705	0.42%	F
Niger	5,100	0.32%	F
Nigeria	4,959	0.31%	F
Sri Lanka	4,817	0.30%	Im
Indonesia	4,481	0.28%	Im
Bhutan	4,158	0.26%	Im
Occupied Palestinian Territory	4,070	0.26%	Im
Thailand	3,283	0.21%	Im
Zambia	3,257	0.20%	Im
Spain	3,195	0.20%	Im
Georgia	3,100	0.20%	*
Morocco	3,000	0.19%	F

[a] FAO official data unless noted otherwise. Im: FAO data based on imputation methodology; F: FAO estimate; *: unofficial figure.

Table B14. Sesame Seed

Sesamum indicum. Valued for its oil, but also as a food, either raw or roasted, as well as in bakery products and other food preparations.

Country	Metric Tonnes	% of Worldwide Production	Data Source[a]
Myanmar	867,520	21.81%	
India	657,000	16.52%	
China	622,905	15.66%	
Sudan	318,000	8.00%	
Ethiopia	260,534	6.55%	*
Uganda	178,000	4.48%	
Nigeria	110,000	2.77%	*
Niger	75,632	1.90%	
Paraguay	65,000	1.63%	
Somalia	64,445	1.62%	Im
Burkina Faso	56,252	1.41%	
Central African Republic	50,008	1.26%	
United Republic of Tanzania	48,000	1.21%	*
Thailand	46,039	1.16%	
Egypt	41,000	1.03%	*
Chad	35,000	0.88%	*
Pakistan	33,400	0.84%	
Bangladesh	32,306	0.81%	
Afghanistan	32,000	0.80%	*
Cambodia	31,000	0.78%	F

[a] FAO official data unless noted otherwise. Im: FAO data based on imputation methodology; F: FAO estimate; *: unofficial figure.

Table B15. Vanilla

Vanilla planifolia; *V. pompona*. The fruit (or bean) of a climbing plant of the orchid family. Includes whole, crushed or ground.

Country	Metric Tonnes	% of Worldwide Production	Data Source[a]
Indonesia	4,362	44.44%	Im
Madagascar	2,830	28.83%	Im
China	1,382	14.08%	Im
Mexico	524	5.34%	
Tonga	263	2.68%	Im
Turkey	215	2.19%	Im
French Polynesia	74	0.75%	
Comoros	65	0.66%	Im
Uganda	48	0.49%	Im
Malawi	15	0.15%	Im
Kenya	12	0.12%	Im
Réunion	12	0.12%	*
Guadeloupe	8	0.08%	F
Zimbabwe	5	0.05%	Im

[a] FAO official data unless noted otherwise. Im: FAO data based on imputation methodology; F: FAO estimate; *: unofficial figure.

APPENDIX C: FDA 2010 STUDY OF CONCENTRATIONS AND DISTRIBUTION OF *SALMONELLA* IN SHIPMENTS OF CAPISCUM AND SESAME SEED OFFERED FOR ENTRY TO THE UNITED STATES.

The 2010 FDA study "Prevalence, level and distribution of *Salmonella* in shipments of imported capsicum and sesame seed spice offered for entry to the United States: Observations and modeling results" was originally published in *Food Microbiology* (Van Doren *et al*., 2013c). Below we provide information from the study most relevant to the results discussed in the present risk profile document.

Material and Methods

Sample Collection

All imports of dried capsicum and sesame seeds were eligible for sampling during the study period. A total of 299 shipments of capsicums and 233 shipments of sesame seeds were sampled at the point of import into the United States between August and December 2010. The shipments sampled constituted approximately 10 or 20 percent of all shipments of imported capsicum or imported sesame seed shipments, respectively, offered for entry to the United States. Sixty subsamples, each comprised of approximately 160 grams, were collected randomly from each shipment. Typically, each sub-sample was collected from a different container or sack of spice in the shipment selected at random. Samples were sent to U.S. Food and Drug Administration (FDA) laboratories for analysis.

Sample Preparation, Salmonella *Screening, Isolation and Confirmation*

Composite samples were prepared by dividing the 60 subsamples into four groups of fifteen. Twenty-five gram analytical units of product from each of the fifteen subsamples were combined to form a 375 g composite sample (Andrews and Hammack, 2003). Each composite sample was screened for the presence of *Salmonella* using one of the following methods: AOAC's Official Methods of Analysis (OMA): 2004.03, 2001.07, 2001.08, or 2001.09, which are available from AOAC International (2007a, 2007b, 2007c, 2007d). All methods are validated and have similar performance criteria.

Salmonella was isolated from each of the composite samples testing positive using the procedures described in Chapter 5 of the FDA *Bacteriological Analytical Manual* (BAM) (Andrews *et al*., 2011; Jacobson, and Hammack, 2003). Presumptive-positive *Salmonella* isolates were confirmed with OMA methods 978.24 or 991.13 (available from AOAC International (2005d, 2005e). *Salmonella* isolates recovered from the spices were serotyped (Ewing, 1986).

Salmonella *Enumeration*

A dilution assay was undertaken for composite samples of spice that were found to contain *Salmonella* by the screening test. The serial dilution protocol involved a three tube analysis on each of four different dilutions of spice. Spice sampled for the dilution assay analysis were drawn from a composite (thoroughly mixed) sample created from equal proportions of the same set of 15 subsamples used in the corresponding *Salmonella*-positive screening test. Separate composite spice product portions of 100, 10, 1, and 0.1 g were each rehydrated at a 1:9 ratio with a tryptic soy broth pre-enrichment medium by swirling or soaking as instructed in the BAM method (Andrews *et al*., 2011; Jacobson, and Hammack, 2003). This procedure was repeated three times (for three tubes) for each of the four different dilutions (100, 10, 1, and 0.1 g). The enrichment tubes were kept at room temperature for 60 ± 5 min, pH adjusted to 6.8 ± 0.2, if necessary, and then incubated for 24 ± 2 h at 35 ± 2^{o}C. Once incubation was complete, the BAM *Salmonella* culture method was followed (Andrews *et al*., 2011; Jacobson, and Hammack, 2003). The relative likelihood of each reported dilution assay pattern for a thoroughly mixed sample was evaluated on the basis of the rarity index (Blodgett, 2010a; Jarvis *et al*. 2010).

Most Probable Number (MPN) values and 95% confidence intervals for each of the four composite samples were determined from the five results, screening test plus the four dilutions using the excel spreadsheet provided in the BAM (Blodgett, 2010b), where the screening test was treated as another “dilution” for the MPN analysis. For a few shipments, the procedure described above was not followed. For samples in one shipment of capsicum and six shipments of sesame seeds, the dilution assay result patterns were not reported by the field labs but rather the presence/absence of *Salmonella* was reported for the enumeration experiment as a whole. In these cases, we interpret the experiments as providing a second screening test with total spice mass of 333.3 g. For samples from two other shipments of sesame seeds with confirmed positive *Salmonella* samples, enumeration experiments were not performed. MPN estimates and confidence intervals for the mean *Salmonella* concentration in a shipment were calculated taking into account the full set of screening test and dilution assay results.

The assumption of Poisson-distributed contamination within shipments, which was used to estimate the shipment mean concentration of contamination and is part of some of the parametric models developed, was examined. We evaluated for each of the 4 composite sample results, a rarity index (Blodgett, 2010a). Specifically we evaluated the probability to obtain the pattern of results observed for one composite sample given the estimated mean shipment concentration divided by the probability to observe the most probable pattern of results in the composite sample given the estimated mean shipment concentration. This statistic has the advantage of being quantifiable for all of the outcomes obtained in this study including missing dilution assay results and binary dilution assay result outcomes. The second advantage is that this rarity index evaluates in one statistic the adequacy of the assumption of within shipment Poisson distribution and within dilution assay Poisson distribution. There is no *a priori* expectation that contamination concentrations in different composites from the same shipment should be the same/similar because the spice contained in different composites are from different locations in the shipment. If the local concentration in a given composite is far higher or lower than the value estimate at the shipment level, the probability to observe the given pattern will be low with regards to the most probable one, leading to a low rarity index. We use the recommendations of Jarvis *et al* (2010) for thresholds of probability: the pattern of results is likely to occur if its rarity index is ≥0.05; is expected to occur only rarely if the rarity index falls within the range 0.01< rarity index < 0.05; and is expected to occur extremely rarely if the rarity index is ≤ 0.01

Probabilistic Models

Probabilistic models of imported spice shipment contamination were examined for their ability to describe the *Salmonella* sampling data. Features included in the models were selected for their ability to describe between- and within-shipment distributions of *Salmonella* in spices. Each model was fit to the capsicum and sesame seed data separately, and evaluated for its quality of fit. Mathematical descriptions of the models, development of the likelihood functions, and derivation of the maximum likelihood solutions, where applicable, are presented in the Supplementary Material. All information gathered in this study, including positive and negative test results of screening and enumeration experiments, was used in determining model parameter estimates. Maximum likelihood estimates of model parameters were determined from the analytical solutions or determined numerically using the R general-purpose optimization function “optim” (R Development Core Team, 2008). Standard errors for model parameters were derived from the Hessian matrix while confidence intervals for model predications were estimated using a parametric bootstrap procedure. Models are compared for quality of fit on the basis of the Akaike information criterion (AIC). Deviations of model predictions from observations are compared in a number of ways. Model between-shipment contamination distributions are compared with observations graphically. Model predicted prevalence for the sampling plan used in the present study is compared with the observed one. Observed data on the distribution of contamination within each shipment are compared with results predicted under a Poisson distribution assumption (see Section 2.2). Finally, model fits, as quantified by the AIC, are compared with that of an empirical model.

Model 1

Model 1 assumes (1) imported spice shipments offered for U.S. entry can be divided into two populations: uncontaminated shipments (zero probability of one or more bacterium in the shipment, designated "Population I") and contaminated shipments (non-zero probability of one or more bacterium in the shipment, designated "Population II") (2) contamination within Population II shipments is characterized by a Poisson distribution and (3) all contaminated spice shipments (Population II) have the same mean concentration of *Salmonella*. The explicit inclusion of a *Salmonella*-free population in this model and the additional models that follow is similar to the zero-inflated distributions used by others to describe microbial distributions in foods (see for example, Gonzales-Barron *et al*., 2010; Bassett *et al*., 2010; Jongenburger *et al*., 2012). Model 1 is characterized by two parameters, p and λ, which are the probability of being in Population II and the mean concentration of *Salmonella* in Population II shipments, respectively.

Model 2

Model 2 assumes (1) imported spice shipments at U.S. entry can be divided into two populations, i.e., uncontaminated shipments (Population I) and contaminated shipments (Population II) as defined in Model 1 (2) contamination within Population II shipments is concentrated in isolated contamination clusters or "hot-spots" (probability of at least one bacterium in each hot spot is non-zero while the probability outside the hot spot is zero) (3) all hot spots have the same mean concentration of *Salmonella* and (4) the contamination within each hot spot is described by a Poisson distribution. This model is characterized by three parameters, p, h and λ, which are the probability of being in Population II, the probability that a sample taken from a shipment in Population II is from a hot spot, and the mean concentration of *Salmonella* in each hot spot, respectively.

Models 3a-3d

Models 3a-3d assume (1) imported spice shipments offered for U.S. entry can be divided into two populations, i.e., uncontaminated shipments (Population I) and contaminated shipments (Population II) as defined in Model 1 (2) contamination within Population II shipments is characterized by a Poisson distribution and (3) different shipments may have different mean concentrations, where the distribution of mean concentrations is defined by a gamma distribution (3a), lognormal distribution (3b), log-logistic distribution (3c), or Weibull distribution (3d).

Models 3a, 3c, and 3d are characterized by three parameters, p, α, and β. p is the probability of being in Population II. In Models 3a, 3c, and 3d, α is the shape parameter and β is the scale parameter. In Model 3b, α is the mean of the natural logarithm of *Salmonella* concentration and β is the standard deviation of the natural logarithm of *Salmonella* concentration.

Empirical Model

Empirical models were developed for *Salmonella* contamination of imported capsicum and sesame seed shipments offered for entry to the United States. These models assume (1) imported spice shipments offered for U.S. entry can be divided into two populations, i.e., uncontaminated shipments (Population I) and contaminated shipments (Population II) as defined in Model 1 (2) contamination within Population II shipments is characterized by a Poisson distribution and (3) different shipments may have different mean concentrations, where the distribution of mean concentrations is defined empirically from the within-shipment contamination concentration estimated from the observations. The fraction of uncontaminated shipments in each model is given by the fraction of shipments for which all four screening tests (4 composites of 375 g) tested negative, i.e., the observed prevalence. The distribution of mean concentrations among contaminated shipments is drawn from the discrete set of 10 (capsicum) or 23 (sesame seed) contaminated shipment estimated mean concentrations. Thus, the empirical models are saturated models. The empirical model for capsicum shipments includes 11 parameters and the empirical model for sesame seed shipments contains 24 parameters.

Efficacy of Salmonella *Sampling Plans in Reducing Risk*

Four sampling plans were evaluated for their ability to (1) identify *Salmonella* contaminated spice shipments offered for U.S. entry and (2) reduce *Salmonella* contamination in the imported spice supply, assuming identified shipments are reconditioned. Each sampling plan was applied to both the Model 1 and the best model identified among Models 3a-3d. In these analyses, we assumed the screening test has perfect sensitivity and specificity.

Description of Sampled Shipments and Model Results

Table C1. Description of sampled and *Salmonella*-contaminated shipments offered for U.S. entry

Descriptor	Capsicum[a]		Sesame Seed[a]	
	Sampled (299 Shipments)	Contaminated (10 Shipments)	Sampled (233 Shipments)	Contaminated (23 Shipments)
Total Mass and Value for All Shipments[b]	- $\$6.1 \times 10^{6}$	7.5×10^{4} kg $\$1.6 \times 10^{5}$	- $\$5.3 \times 10^{6}$	3.5×10^{5} kg $\$7.1 \times 10^{5}$
Mean Shipment Size[b]: Mass	-	7.5×10^{3} kg	-	1.5×10^{4} kg
Median Shipment Size[b]: Mass	-	4.8×10^{3} kg	-	1.8×10^{4} kg
Shipment Size Range[b]: Mass	-	125 -2.5×10^{4} kg	-	24 - 3.8×10^{4} kg
Percentage of Shipments Retail[c]	≥15	20	≥11	22
Percentage of Shipments Ground/Cracked[d]	46	80	NA	NA
Fraction (Percentage) of Shipments Known to have Undergone a Pathogen Reduction Treatment[e]	≥14/299 (≥4.7%)	0/7 (≤30%)	≥6/233 (≥3%)	0/14 (≤40%)
Fraction (Percentage) Fraction of Shipments with COA Neg. for *Salmonella*[f]	-	2/7 (≥20%)	-	4/14 (≥17%)
Percentage of Imported Shipments Sampled	~10	-	~20	-
Observed Prevalence [95% CI] of *Salmonella*-Contaminated Imported Spice Shipments[g]	3.3% [1.6-6.1%]	NA	9.9% [6.3-14%]	NA

[a] Dash indicates the data were not available; NA indicates the descriptor is not applicable.

[b] Mass and value determined from FDA sample collection report.

[c] Retail defined as shipments packaged in bags/boxes containing ≤5 lbs (2.3 kg).

[d] Percentages of ground/cracked and whole capsicum were determined by FDA product code and description. Information was available to assess form for 297 of the imported shipments

[e] As determined by FDA product code and description for all imported shipments plus documents examined at import for contaminated shipments. Pathogen reduction treatment indications included "commercially sterile", "heat treated", "irradiated", and "steam" or "eto" treated. The numbers of shipments identified is likely an underestimate because industry is not required to supply this information except for the case of irradiated spice and FDA officials are not required to record this information in their collection report.

[f] COA means Certificate of Analysis. Documents provided at import for contaminated shipments were reviewed for COAs; information was available for 7 of the contaminated capsicum shipments and 14 of the contaminated sesame seed shipments.

[g] 95% CI, exact confidence limits for the observed/apparent prevalence determined with the sampling protocol employed in this study (Clopper and Pearson, 1934). Observed/apparent prevalence is a lower limit on the true prevalence.

Table C2. Model parameters and descriptors

Spice	Model[a]: Model #: # populations, Between-Within Distribution	Prevalence[b] [*S*]>0 (SE) (%)	Mean *S.* Concentration in Contaminated Shipments (MPN/g)	Hot Spot Prevalence (SE)[c] (%)	Hot Spot Mean Concentration (SE)[c] (MPN/g)	AIC (unitless)
Capsicum	1: 2 Populations, Poisson	3.4 (1.0)	3.64×10^{-3}			241.4
	2: 2 Populations, Hot Spot	3.5 (1.1)		7.2 (1.9)	5.79 (1.54) x 10^{-2}	217.9
Sesame Seed[d]	1: 2 Populations, Poisson	9.9 (2.0)	3.53×10^{-3}			405.7
	2: 2 Populations, Hot Spot	10.3 (2.1)		5.9 (1.1)	7.75 (1.43) x 10^{-2}	351.7
				Between-Shipment Distribution parameters		
				α (SE)[e]	**β (SE)[e]**	
Capsicum	3a: 1 Population/gamma- Poisson[f]	100	3.20×10^{-4}	0.00833 (0.0031)	0.0384 (0.0315)	174.7
	3b: 2 Populations/lognormal- Poisson	7.3 (7.1)	5.74×10^{-3}	-8.150 (3.067)[g]	2.445 (1.399)[h]	175.1
	3c: 2 Populations/log-logistic- Poisson	3.3 (1.0)	6.54×10^{-3}	1.406 (0.465)	0.00231 (0.00062)	180.0
	3d: 2 Populations/Weibull- Poisson	3.3 (1.0)	7.93×10^{-3}	0.603 (0.153)	0.0053 (0.0028)	184.4
Sesame Seed[d]	3a: 1 Population/gamma- Poisson[f]	100	6.17×10^{-4}	0.02977 (0.0076)	0.02073 (0.0105)	286.6
	3b: 2 Populations/lognormal- Poisson	24.5 (19.3)	4.77×10^{-3}	-8.543 (2.487)[g]	2.529 (1.078)[h]	288.0
	3c: 2 Populations/log-logistic- Poisson	9.9 (2.0)	7.83×10^{-3}	1.319 (0.285)	0.00226 (0.00042)	301.9
	3d: 2 Populations/Weibull- Poisson	9.9 (2.0)	5.77×10^{-3}	0.730 (0.136)	0.00474 (0.00136)	305.9
Capsicum	Saturated Empirical	3.3 (1.3-5.4)	1.13×10^{-2}			167.8
Sesame Seed[d]	Saturated Empirical	9.9 (6.0-14)	5.93×10^{-3}			289.2

[a] Following each model number is an abbreviated description of the model assumptions including the between-shipment distribution of *Salmonella* contamination (number of different populations) and the within-shipment distribution of *Salmonella* (Poisson or Hot Spot). See text for detailed description.

[b] Percentage of *Salmonella*-contaminated shipments (as defined in the text) followed by standard error in parentheses.

[c] SE means standard error.

[d] Models for contamination of sesame seed shipments use the revised data. See Table 2 and text for details.

[e] Distribution parameters shape (α) or scale (β) followed by standard error for that parameter in parentheses, unless otherwise noted.

[f] The optimized zero-inflated gamma-Poisson model was degenerate with the two-parameter gamma-Poisson model, where shipment prevalence for *Salmonella* is 100%. See text for details.

[g] Mean of the of the natural logarithm of concentration followed by standard error for that parameter in parentheses.

[h] Standard deviation of the natural logarithm of concentration distribution followed by standard error for that parameter in parentheses.

Table C3. Predicted Impact of Testing Shipments of Imported Capsicum or Sesame Seed Offered for entry to the United States for the presence of *Salmonella* as a function of the mass of spice examined for contamination distributions in the incoming supply described by Model 1 and Model 3a (the best-fit parametric model).

Spice - Model **Effectiveness Measure**	**Shipment Size[a]** ***(kg)***	**Prevalence (95% CI)** ***(%)***	***Salmonella* Screening Method**			
			25 g COA[b]	***375 g FDA III[c]***	***750 g FDA II[d]***	***1500 g FDA I[e]***
Capsicum - Model 1						
Supply characteristics	All sizes	3.4 (1.4-5.4)				
Expected value for percentage (95% CI) of shipments detected (among all shipments)	All sizes		0.3 (0.1-0.5)	2.5 (1.0-4.1)	3.1 (1.3-5.1)	3.3 (1.3-5.4)
Expected value for percentage (95% CI) of contaminated shipments detected	All sizes		8.7 (6.5-11)	75 (63-83)	93 (87-97)	99.6 (98-99.9)
Expected value for percentage (95% CI) of *Salmonella* in supply captured in detected shipments	All sizes		8.7 (6.5-11)	75 (63-83)	93 (87-97)	99.6 (98-99.9)
Expected value for $\log_{10}$ reduction (95% CI) of *Salmonella* in spice supply if detected shipments are reconditioned[f]	All sizes		0.04 (0.03-0.05)	0.6 (0.4-0.8)	1.2 (0.9-1.5)	2.4 (1.7-3.0)
Capsicum - Model 3a- gamma-Poisson (Best Fit Model)						
Supply characteristics	125 7.5 x 10^{3} 1.5 x 10^{4} Infinite	6.8 (3.3-12) 9.9 (4.7-18) 10.8 (5.2-19) 100				
Expected value for percentage (95% CI) of shipments detected (among all shipments)	All sizes		0.6 (0.1-1.1)	2.2 (0.9-3.6)	2.8 (1.2-4.5)	3.0 (1.7-5.4)
Expected value for percentage (95% CI) of contaminated shipments detected	125 7.5 x 10^{3} 1.5 x 10^{4}		8.2 (1.8-15) 5.6 (1.1-11) 5.2 (1.0-10)	33 (16-41) 23 (10-29) 21 (9.2-27)	41 (24-48) 28 (15-34) 26 (14-32)	49 (33-55) 34 (21-39) 31 (19-36)
Expected value for percentage (95% CI) of *Salmonella* in supply captured in detected shipments	All sizes		49 (10-76)	94 (64-98)	97 (78-99)	98 (88-99.5)
Expected value for $\log_{10}$ reduction (95% CI) of *Salmonella* in spice supply if detected shipments are reconditioned[f]	All sizes		0.3 (0.05-0.6)	1.2 (0.4-1.7)	1.5 (0.7-2.0)	1.8 (0.9-2.3)

Spice - Model **Effectiveness Measure**	**Shipment Size[a]**	**Prevalence (95% CI)**	***Salmonella* Screening Method**			
	(kg)	***(%)***	***25 g COA[b]***	***375 g FDA III[c]***	***750 g FDA II[d]***	***1500 g FDA I[e]***
Capsicum- Empirical						
Supply characteristics	All sizes	3.3 (1.3-5.4)				
Expected value for percentage (95% CI) of shipments detected (among all shipments)	All sizes		0.5 (0.06-1.2)	1.9 (0.6-3.1)	2.4 (0.8-3.8)	2.9 (1.0-4.3)
Expected value for percentage (95% CI) of contaminated shipments detected	All sizes		14 (4.1-40)	56 (42-81)	72 (54-89)	85 (78-99)
Expected value for percentage (95% CI) of *Salmonella* in supply captured in detected shipments	All sizes		14 (4.1-40)	56 (42-81)	72 (54-89)	85 (78-99)
Expected value for log$_{10}$ reduction (95% CI) of *Salmonella* in spice supply if detected shipments are reconditioned[f]	All sizes		0.07 (0.02-0.2)	0.4 (0.2-0.7)	0.6 (0.3-1.0)	0.8 (0.7-2.0)
Sesame Seed - Model 1						
Supply characteristics	All sizes	9.9 (6.5-13.8)				
Expected value for percentage (95% CI) of shipments detected (among all shipments)	All sizes		0.8 (0.5-1.2)	7.3 (4.5-10.3)	9.2 (5.8-13.0)	9.9 (6.4-13.7)
Expected value for percentage (95% CI) of contaminated shipments detected	All sizes		8.4 (7.0-9.9)	73 (66-79)	93 (89-96)	99.5 (98.8-99.8)
Expected value for percentage (95% CI) of *Salmonella* in supply captured in detected shipments	All sizes		8.4 (7.0-9.9)	73 (66-79)	93 (89-96)	99.5 (98.8-99.8)
Expected value for log$_{10}$ reduction (95% CI) of *Salmonella* in spice supply if detected shipments are reconditioned[f]	All sizes		0.04 (0.03-0.05)	0.6 (0.5-0.7)	1.2 (1.0-1.4)	2.3 (1.9-2.7)

Spice - Model **Effectiveness Measure**	**Shipment Size**[a]	**Prevalence (95% CI)**	***Salmonella* Screening Method**			
	(kg)	***(%)***	***25 g COA***[b]	***375 g FDA III***[c]	***750 g FDA II***[d]	***1500 g FDA I***[e]
Sesame Seed - Model 3a - gamma-Poisson (Best Fit Model)						
Supply characteristics	24 1.5 x 10^4 3.8 x 10^4 Infinite	17 (11-24) 31 (20-45) 33 (21-47) 100				
Expected value for percentage (95% CI) of shipments detected (among all shipments)	All sizes		1.2 (0.6-2.0)	6.3 (3.8-8.7)	8.0 (5.0-11)	9.8 (6.0-14)
Expected value for percentage (95% CI) of contaminated shipments detected	24 1.5 x 10^4 3.8 x 10^4		7.3 (3.6-12) 3.9 (1.8-6.8) 3.7 (1.7-6.4)	37 (28-44) 20 (14-25) 19 (13-23)	47 (38-53) 26 (19-30) 24 (18-28)	58 (50-29) 31 (25-35) 30 (34-33)
Expected value for percentage (95% CI) of *Salmonella* in supply captured in detected shipments	All sizes		35 (16-55)	89 (75-95)	94 (86-97)	97 (92-99)
Expected value for $\log_{10}$ reduction (95% CI) of *Salmonella* in spice supply if detected shipments are reconditioned[f]	All sizes		0.2 (0.08-0.3)	1.0 (0.6-1.3)	1.2 (0.9-1.5)	1.5 (1.1-2.0)
Sesame Seed - Empirical						
Supply characteristics	All sizes	9.9 (4.7-12)				
Expected value for percentage (95% CI) of shipments detected (among all shipments)	All sizes		1.2 (0.4-2.1)	5.4 (2.8-7.6)	6.9 (3.6-9.1)	8.3 (4.3-11)
Expected value for percentage (95% CI) of contaminated shipments detected	All sizes		12 (6.6-24)	54 (48-75)	70 (64-86)	84 (81-95)
Expected value for percentage (95% CI) of *Salmonella* in supply captured in detected shipments	All sizes		12 (6.6-24)	54 (48-75)	70 (64-86)	84 (81-95)
Expected value for $\log_{10}$ reduction (95% CI) of *Salmonella* in spice supply if detected shipments are reconditioned[f]	All sizes		0.6 (0.03-0.1)	0.3 (0.3-0.6)	0.5 (0.4-0.9)	0.8 (0.7-1.3)

[a] Shipment sizes selected are the smallest, mean and largest contaminated shipment sizes observed in this study for each particular spice type.

[b] Sample mass examined for *Salmonella* screening tests reported on industry Certificates of Analyses accompanying some of the spice shipments examined in this study.

[c] Typical sample mass used for FDA Category III foods which are foods that would normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption (Andrews and Hammack, 2003).

[d] Typical sample mass used for FDA Category II foods which are foods that would not normally be subjected to a process lethal to *Salmonella* between the time of sampling and

consumption (Andrews and Hammack, 2003).

[e] Typical sample mass used for FDA Category I foods which are foods that would not normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption and are intended for consumption by the aged, the infirm, or infants (Andrews and Hammack, 2003).

[f] Assumes reconditioning eliminates all *Salmonella* from the shipment.