CLEAN, SAFE SPICES

Guidance from the American Spice Trade Association

AMERICAN SPICE TRADE ASSOCIATION asta

The American Spice Trade Association (ASTA) was established in New York City in 1907 to provide representation for the American spice trade. Today, ASTA is based in Washington, D.C. and its members include companies involved in all aspects of the spice trade — importing, growing, processing, and marketing at the wholesale and retail levels. On behalf of its members, ASTA works with federal and state regulators and legislators, and assists its members in addressing a variety of technical issues to help its members provide an adequate supply of safe and wholesome spices for their industrial, food service, and consumer customers.

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I. Executive Summary

Many spices are grown in developing countries where sanitation and food handling practices may not be adequate. Agricultural products such as spices are commonly exposed to dust, dirt, insects, and animal waste before they are even harvested. There are many additional opportunities for the introduction of pathogenic microorganisms and filth to spices during primary processing and storage, in transport, and after they have arrived in the U.S. ASTA produced this guidance document to assist the spice industry in developing programs that minimize 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 consumer customers.

Historically, *Salmonella* is the most common bacterial pathogen associated with product recalls and outbreaks in spices and is the primary focus of this guidance. Many of the preventive measures that mitigate risk for introduction of filth in spice products also reduce risk for contamination with *Salmonella* or other pathogens. The guidance includes five key recommendations.

1. Minimize risk for introduction of filth throughout the supply chain

Spice manufacturers should adhere to ASTA's Cleanliness Specifications and Food and Drug Administration (FDA) Defect Action Levels (DALs) for extraneous matter and filth in spices. As with other agricultural products, actions should be taken at each stage of the supply chain to minimize the potential for contamination of spices by mammalian excreta, rodent hair, insect fragments and other foreign materials. Filth can be minimized in spice processing and storage facilities through a number of measures.

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- Develop supply chain approval and re-evaluation programs
- Adhere to Good Manufacturing Practices (GMPs) during processing and storage of spices, particularly those concerning pest control, worker personal hygiene, sanitation, grounds maintenance, and inspection of incoming raw materials
- Implement product- and process-specific Hazard Analysis Critical Control Point (HACCP) plans as outlined in the ASTA HACCP Guide for Spices and Seasonings
- Encourage suppliers to adhere to prerequisite programs
  - Good Agricultural Practices (GAPs)
    - Use clean and uncontaminated sources for water, especially water to be used for cleaning and rinsing spices
    - Do not use untreated waste as fertilizer

        - Incorporate manure into soil at least two weeks before planting, and do not harvest within 120 days of application; short-season crops require properly composted manure
        - Do not allow animals, including livestock, poultry or pets, to roam in crop areas, especially near harvest time
        - Exclude rodents, insects, and other pests from growing areas where possible
        - Provide appropriate hand-washing instructions and clean toilet facilities for field workers
        - Clean and sanitize harvest containers before use
        - Drying of raw materials should be accomplished on clean, elevated racks, concrete floors, or mats and not on the bare ground
        - Utilize mechanical versus open air drying when possible to limit exposure of raw spices to pathogens and filth. If open air drying is utilized, covers should be installed to prevent contamination from birds flying overhead.
        - Exclude field debris from packing and storage facilities by cleaning the outsides of harvest bins and requiring workers to wear clean clothes in these areas
        - Use new, unused bags to pack product for further transport and sale
    - Good Manufacturing Practices (GMPs)
    - Hazard Analysis Critical Control Point (HACCP) plans for each supplier in the supply chain

2. Prevent environmental contamination, cross-contamination, and post-processing contamination during processing and storage

- Reduce the risk for entrance of pathogens into the facility by developing supplier approval and re-evaluation programs that emphasize adherence to GAPs, GMPs, and their own supplier HACCP plans
- Practice strict moisture control
- Do not allow livestock, pets, rodents, insects, and birds to enter processing or storage facilities
- Establish and enforce personal hygiene codes for workers
- Food contact surfaces should be constructed of appropriate, easy to sanitize materials. For example, wood is inappropriate for many food contact applications because it is difficult to sanitize.
- Adhere to GMPs, including clear designation of pre-lethality areas (i.e., low-risk) and post-lethality (i.e., high-risk) areas
    - Construct physical barriers between pre-lethality and post-lethality areas
    - Use dedicated equipment for the pre-lethality and post-lethality areas
    - Restrict movement of personnel and vehicles (e.g., forklifts, pallet jacks) between pre-lethality and post-lethality areas
    - Maintain the post-lethality area under positive air pressure relative to adjacent areas and ensure that ventilation systems do not allow air or dust to travel from the pre- to post-lethality area
    - Establish stringent worker hygiene controls, particularly in areas adjacent to the post-lethality area

- Adopt sanitation standard operating procedures (SSOPs) that include written instructions describing each sanitation procedure, how to properly complete the task, the frequency with which each procedure is performed, and the identity of the person(s) responsible for the implementation and maintenance of the SSOP
- Protect food-contact packaging materials during shipment, storage, and use
- Implement product- and process-specific HACCP plans as outlined in the ASTA HACCP Guide for Spices and Seasonings
- Implement traceability programs to allow for the determination of product sourcing

3. Use validated microbial reduction techniques

- ASTA recommends the use of validated microbial reduction techniques
- Options, dependent on spice and final use, are
  - Ethylene oxide (EtO; In the U.S.: 7 ppm residue tolerance on spices and dried vegetables; ethylene chlorohydrin residues permitted up to 940 ppm on spices and dried vegetables); exception is basil, for which EtO treatment is prohibited
  - Propylene oxide (PPO; In the U.S.: 300 ppm residue tolerance for spices)
  - Irradiation
  - Steam treatment, or other appropriate, effective heat treatment
- All microbial reduction techniques should be used in accordance with U.S. EPA and label directions and be validated to destroy *Salmonella*
- Validation should focus on the critical control point used to deliver a reduction in the microbial load (i.e., the lethality step)
  - Determine the critical limits (e.g., thermal and time parameters) required to achieve the target log reduction
  - Confirm that the process equipment consistently delivers the critical limit parameters and/or target log reduction
  - Monitor the control points and have documented action steps should the parameters not be met
- Each process should be validated using representative products to which it is applied
- Effects of treatment on packaging material and effects of packaging on effectiveness of treatment should be considered

4. Perform post-treatment testing to verify a safe product

- ASTA recommends post-treatment product testing
- Sampling plans should be statistically valid
  - The FDA Bacteriological Analytical Manual (BAM) method is the standard for product and environmental sampling in the U.S. (FDA 2003; FDA 2007).
  - Alternative methods should be of equivalent specificity and sensitivity to this method.
- Whenever product testing is performed:
  - Lots tested for *Salmonella* should be isolated, held, and only released into commerce if the product tests negative
  - Sampling should be performed at various points throughout the lot

  - Collection instruments, such as scoops and bags, must be sterile and sealed to prevent cross-contamination
  - Samples should be stored in a clean, cool, dry location to avoid contamination
  - Proper hand washing techniques and the use of gloves is recommended
- If a product sample tests positive for a microbial pathogen:
  - The tested lot should be considered adulterated and should not be released into commerce unless it is reconditioned by a validated process sufficient to destroy or reduce the pathogen present to appropriate levels
  - Retesting should not be conducted for the purpose of negating the initial test results; no number of negative results can override a single positive result on the lot
  - Corrective actions including retreatment and testing should be taken if a microbial pathogen is detected in finished product samples (GMA, 2009)

5. Test to verify a clean and wholesome manufacturing environment

- An environmental monitoring program for *Salmonella* should be established based on the zone system (GMA, 1999; Chen et al., 2009; Scott et al., 2009; ABC, 2010)
- Sampling for *Salmonella* should be most frequent in post-lethality areas, particularly in areas adjacent to product contact surfaces
- Product contact surfaces in the post-lethality area should be routinely tested for indicator organisms (e.g., aerobic plate counts, coliforms, or enterobacter)
- Product contact surface testing may be done as part of corrective actions for an environmental positive, depending on the location of the positive and other contributing factors (e.g. potential for cross-contamination)
- Compositing or pooling of environmental samples is not recommended
- A rotation schedule should be developed to allow all areas of the facility to be sampled on a periodic basis

II. Introduction

Spices have been used for centuries for both the flavor they impart to food as well as the ability of some spices to preserve foods. As with any food product, the safety and wholesomeness of spices are of utmost concern to the spice industry, their customers, consumers, and regulators. The American Spice Trade Association (ASTA) has sponsored many programs to assist its members in assuring that spices sold to food processors and consumers are safe and wholesome. Because most spices are grown in developing countries near the tropics, the spice industry, like other agricultural products industries, must be vigilant to protect against the possible presence of pathogens and extraneous matter in the spices that are imported into the U.S. ASTA's programs actively seek to assist its members and others in the industry in addressing these important issues.

The U.S. Centers for Disease Control and Prevention (CDC) estimated that about 48 million people in the U.S. get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases (Scallan et al., 2010(a); Scallan et al., 2010(b); Morris, 2010). Recent events involving the recall of foods contaminated with bacterial pathogens, primarily *Salmonella*, have focused the attention of ASTA, regulators, the public, and the media on the need to ensure that spices to be consumed in the U.S. are pathogen-free. ASTA produced this guidance document to assist its members and others in the industry in providing an ample supply of clean, safe spices to their industrial, food service and consumer customers. This document combines information and recommendations from the spice and food industries, the U.S. Centers for Disease Control (CDC), the U.S. Food and Drug Administration (FDA), the International Commission on Microbiological Specifications for Foods (ICMSF), and the U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF). It is intended to serve as a resource for anyone with an interest in the spice trade and represents a "toolbox" that may assist spice companies in providing clean, safe spices to their customers, including food manufacturers and the public. Members of the spice trade are encouraged to use this document together with other sources of information to develop and implement programs to assure that the spices they sell are clean and safe. As always, it is an individual company decision how this document may be best used in meeting company goals and objectives.

Although some spices possess antimicrobial properties, many spices can harbor microorganisms, including pathogens.

A. Growing regions and issues associated with global spice commerce

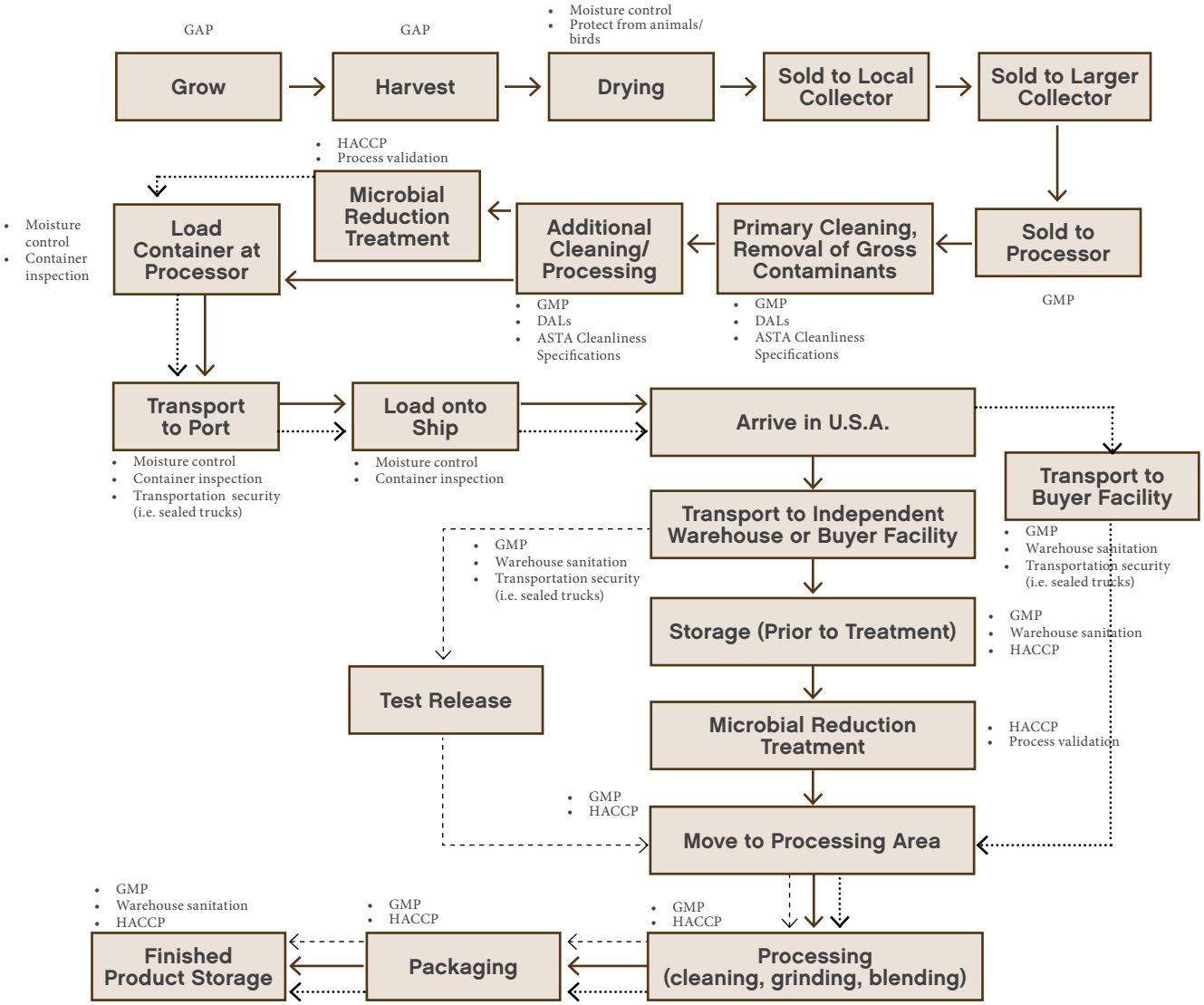
Although some spices possess antimicrobial properties (Ceylan and Fung, 2007), many spices can harbor microorganisms, including pathogens. Most spices originate in tropical and semi-tropical developing countries where sanitation and food handling practices may not be adequate. The producers are often small-scale farmers who may not be fully aware of the need to protect their spice crops from conditions that lead to the presence and growth of pathogenic microorganisms. Some pathogenic microorganisms are indigenous to the soil, and others come

from dust, dirt, insects, and animal material that may come into contact with spices during growing, harvesting, and processing. Additional opportunities for introduction of pathogens between harvesting of spices and purchase by a consumer include the processes of washing, drying, transport, blending, packaging, storage, or distribution.

B. The American spice trade

The American spice trade relies heavily on worldwide sourcing. Spices are produced in a number of nations including India, China, Mexico, and Indonesia, where farmers sell raw materials to collectors, who, in turn, sell them to processors. Overseas processors may or may not clean and treat spices before selling them to U.S. buyers. Once imported to the U.S., buyers store, treat, process, and package spice products for sale to their customers. Extraction of spices to isolate oleoresins or essential oils may be performed prior to import or by U.S.-based manufacturers. U.S. spice companies may sell finished product to individual consumers, retail stores, restaurants, institutions, or food manufacturers. **Figure 1** illustrates transport and processing options, and potential control points for most spices imported into the U.S. Other options exist, including treatment after packaging if product has not been treated.

Figure 1. Transport and Processing Options and Control Points



III. Regulation of the Safety and Cleanliness of Spices in the U.S.

All spices imported into the U.S. are required to meet federal regulatory requirements for safety and cleanliness. The U.S. Food and Drug Administration (FDA) is the primary regulatory agency with authority to regulate the safety and cleanliness of spices. Three other agencies have jurisdiction over other aspects of the spice trade: Customs and Border Protection (CBP), the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA). CBP is tasked with clearing merchandise through Customs and determining appropriate duties. USDA regulates meat and poultry including the use of spices in these foods, and manages the Federal Noxious Weed Seed and National Organic Programs. The EPA regulates agricultural chemicals that may be applied to spices including fumigants that may be used in microbial reduction strategies. FDA enforces EPA's pesticide tolerances in food. More information regarding regulation of spice importation and safety is provided in ASTA's Clean Spices handbook **(Appendix 1).**

FDA has confirmed that spices are "generally recognized as safe" (GRAS) consistent with Section 201(s) of the Federal Food, Drug, and Cosmetic Act (FFDCA). The marketing of spices is largely addressed by FDA through its authority to regulate what should not be included in spices, making contaminated spices subject to the adulteration and misbranding provisions in FFDCA Sections 402 and 403.

A. The FDA Definition of "Spice"

FDA defines "spice" as:

"…any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, such as onion, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of any volatile oil or other flavoring principle has been removed" (21 CFR 101.22[a][2]) **(Appendix 2)**.

The FDA definition at 21 CFR 101.22(a)(2) also contains a list of materials considered spices that is largely consistent with the ASTA spice list **(Appendix 3)**, and the FDA list of GRAS spices at 21 CFR 182.10. The definition also points out that paprika, turmeric, saffron, and other spices may be multi-functional and may be used for their coloring properties in addition to their contribution to a food's flavor. Many essential oils derived from spices are also considered GRAS as described at 21 CFR 182.20.

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B. Safe Spices

The concept of "safety" within the context of U.S. food law and regulations is generally considered to be a "reasonable certainty" standard — absolute safety is not required. While FDA has not promulgated a specific definition for "safe" or "safety" solely for spices, FDA's safety standard for food additives and GRAS substances applies to spices. Specifically, FDA states:

"Safe or safety means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance" (21 CFR 170.3[i]).

Therefore, with specific reference to the potential presence of pathogens in spices, FDA's standard can be interpreted to require a reasonable certainty that active pathogens will not be present in spices as spices are entered into interstate commerce with focus on consumption of spices either as constituents of processed foods or applied to foods by consumers in the home without cooking — the definition of ready-to-eat.

C. FDA's Regulatory Activities

FDA relies on education and the prospect of regulatory enforcement action and monetary penalties to encourage industry to maintain its own programs to prevent food-borne illness. FDA has significant inspection authority but the vast scale of the U.S. food industry means that food manufacturing facility inspections have limited preventive potential. Therefore, much of the responsibility for maintaining a safe food supply rests with the food industry. ASTA and members of the spice industry have an opportunity, through this guidance document and other resources, to assist FDA in addressing concerns about the role of spices in food-borne illness.

IV. Filth and Filth Reduction Strategies

FDA considers contamination from "filth" to be a potential hazard to humans consuming spices. FDA considers "filth" to mean "extraneous materials" as defined in FDA's Defect Levels Handbook: "Any foreign matter in a product associated with objectionable conditions or practices in production, storage, or distribution." This 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 2009 Defect Levels Handbook).

A. The ASTA Cleanliness Specifications

The ASTA Cleanliness Specifications establish limits for macroscopic extraneous matter for domestic and imported spices, seeds, and herbs coming into the U.S. The Cleanliness Specifications also include microscopic filth limits (e.g., insect fragments, rodent hairs) for specific products that are also addressed by the U.S. FDA Defect Action Levels (DALs) **(Appendix 4)**. However, the ASTA Cleanliness Specifications are generally more stringent than the FDA DALs and include some spice products that have not been assigned DALs (e.g., cardamom, coriander, turmeric, and tarragon). The Cleanliness Specifications do not address microbiological contamination of spices or the adulteration of spices through the inclusion of dyes or other materials not permitted in spices. In the U.S. such instances are governed by the Federal Food, Drug, and Cosmetic Act and the relevant regulations and policies of FDA.

The ASTA Cleanliness Specifications **(Appendix 5)** are widely recognized within the spice industry and should be applied in transactions between buyers and sellers of spices, including instances when an ASTA contract is utilized. For the purposes of this guidance, extraneous matter is defined as everything foreign to the product itself and includes, but is not limited to: stones, dirt, wire, string, stems, sticks, nontoxic foreign seeds, excreta, manure and animal contamination. The level of contaminants permitted by the Cleanliness Specifications fall *below* those shown in **Table 1**, except for the column Δ "Whole Insects, Dead" which cannot *exceed* the limits shown. Analytical methods for detection of filth are provided in **Appendix 6**.

The ASTA Cleanliness Specifications establish limits for macroscopic extraneous matter for domestic and imported spices, seeds, and herbs coming into the U.S.

Table 1. ASTA Cleanliness Specifications for Spices, Seeds, and Herbs

Name of spice, seed, or herb	Δ Whole insects, dead	Excreta, mammalian	Excreta, other	Mold	Insect defiled/ infested	Extraneous/ foreign matter
	By count	By mg/lb	By mg/lb	% By Weight	% By Weight	% By Weight
Allspice	2	5	5.0	2.00	1.00	0.50
Anise	4	3	5.0	1.00	1.00	1.00
Sweet basil	2	1	2.0	1.00	1.00	0.50▪
Caraway	4	3	10.0	1.00	1.00	0.50
Cardamom	4	3	1.0	1.00	1.00	0.50
Cassia	2	1	1.0	5.00	2.50	0.50
Cinnamon	2	1	2.0	1.00	1.00	0.50
Celery seed	4	3	3.0	1.00	1.00	0.50
Chillies	4	1	8.0	3.00	2.50	0.50
Cloves*	4	5	8.0	1.00	1.00	1.00
Coriander	4	3	10.0	1.00	1.00	0.50
Cumin seed	4	3	5.0	1.00	1.00	0.50
Dill seed	4	3	2.0	1.00	1.00	0.50
Fennel seed	SF[2]	SF[2]	SF[2]	1.00	1.00	0.50
Ginger	4	3	3.0	SF[3]	SF[3]	1.00
Laurel leaves**	2	1	10.0	2.00	2.50	0.50
Mace	4	3	1.0	2.00	1.00	0.50
Marjoram	3	1	10.0	1.00	1.00	1.00▪
Nutmeg (broken)	4	5	1.0	SF[4]	SF[4]	0.50
Nutmeg (whole)	4	0	0.0	SF[5]	SF[5]	0.00
Oregano***	3	1	10.0	1.00	1.00	1.00▪
Black pepper	2	1	5.0	SF[6]	SF[6]	1.00
White pepper****	2	1	1.0	SF[7]	SF[7]	0.50
Poppy seed	2	3	3.0	1.00	1.00	0.50
Rosemary leaves	2	1	4.0	1.00	1.00	0.50▪
Sage**	2	1	4.0	1.00	1.00	0.50
Savory	2	1	10.0	1.00	1.00	0.50▪
Sesame seed	4	5	10.0	1.00	1.00	0.50
Sesame seed, hulled	4	5	1.0	1.00	1.00	0.50
Tarragon	2	1	1.0	1.00	1.00	0.50▪
Thyme	4	1	5.0	1.00	1.00	0.50▪
Turmeric	3	5	5.0	3.00	2.50	0.50

* Clove stems: Less than (<) 5% allowance by weight for unattached clove stems over and above the tolerance for Other extraneous matter is permitted.
** Laurel leaves and sage: "Stems" will be reported separately for economic purposes and will not represent a pass/fail criteria.
*** Oregano: Sumac negative-Analysis for presence of Sumac shall not be mandatory if samples are marked "Product of Mexico."
**** White pepper: "Percent black pepper" will be reported separately for economic purposes and will not represent pass/fail criteria.
[2] Fennel seed: In the case of fennel seed, if 20% or more of the subsamples contain any rodent, other excreta or whole insects, or an average of 3 mg/lb or more of mammalian excreta, the lot must be reconditioned.
[3] Ginger: More than 3% moldy pieces and/or insect infested pieces by weight
[4] Broken nutmeg: More than 5% mold/insect defiled combined by weight.
[5] Whole nutmeg: More than 10% insect infested and/or moldy pieces, with a maximum of 5% insect defiled pieces by count.
[6] Black pepper: 1% moldy and/or infested pieces by weight.
[7] White pepper: 1% moldy and/or infested pieces by weight.
Δ Whole insects, dead: Cannot exceed the limits shown.
▪ Extraneous matter: Includes other plant material, e.g., foreign leaves

Table 1 continued: Ground Processed Spice*
(Cannot exceed limit shown)

Spices	Whole equivalent insects	Insect fragments	Mites	Other insects	Rats/mouse hairs	Animal hairs
Ground paprika		Average of more than 75 fragments/ 25 g			Average of more than 11 rodent hairs/25 g	

* Microanalytical methods for paprika and ground capsicums can be found in the "Analytical Procedures" section of the ASTA Cleanliness Specifications for Spices, Seeds, and Herbs (Appendix 5).

B. Filth mitigation strategies

Actions should be taken at each step of the supply chain to minimize the potential for contamination of spices by mammalian excreta, rodent hair, insect fragments and other foreign materials. For U.S. spice companies, these actions include development of supplier approval and re-evaluation programs that focus on suppliers' adherence to Good Agricultural Practices (GAPs). GAPs are detailed in FDA's Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (FDA, 1998), the International Organisation of Spice Trade Associations' General Guidelines for Good Agricultural Practices—Spices **(Appendix 7)** and in Food Safety Begins on the Farm: A Grower's Guide (Rangarajan et al. 2008) **(Appendix 8)**.

Adherence to Good Manufacturing Practices (GMPs) and Hazard Analysis Critical Control Point (HACCP) programs are also key elements to ensuring cleanliness of spices. GMPs are "the minimum sanitary and processing requirements for producing safe and wholesome food" and serve as one basis for FDA inspections. GMPs have been outlined elsewhere, including the FDA cGMP regulations 21 CFR 110 (CFR, 2008) (**Appendix 9**) and the Codex general principles of food hygiene (CAC, 2003) (**Appendix 10**). HACCP programs reduce the risk of food safety hazards in finished products by identifying the potential risks in the process. Although the primary objective of HACCP programs in spice facilities is to eliminate contamination of spices by organisms that pose a threat to human health, adherence to HACCP plans also reduces filth. Each spice manufacturer should develop HACCP programs as outlined in the ASTA HACCP Guide for Spices and Seasonings (**Appendix 11**) and in section V.

Filth mitigation strategies for the U.S. spice industry

- Adhere to ASTA's Cleanliness Specifications and FDA DALs for extraneous matter and filth in spices
- Develop supply chain approval and re-evaluation programs, with particular emphasis on adherence to GAPs, GMPs, and HACCP plans
- Adhere to GMPs, particularly those concerning pest control, worker hygiene, sanitation, grounds maintenance, and inspection of incoming raw materials
- Implement product- and process-specific HACCP plans as outlined in the HACCP Guide for Spices and Seasonings

Good agricultural practices (GAPs) for growing and harvesting spices

- Use clean and uncontaminated sources for water, especially water to be used for cleaning and rinsing spices
- Do not use untreated waste as fertilizer
- Incorporate manure into soil at least two weeks before planting, and do not harvest within 120 days of application; short-season crops require properly composted manure
- Do not allow animals, including livestock, poultry or pets, to roam in crop areas, especially near harvest time
- Exclude rodents, insects, and other pests from growing areas where possible
- Provide appropriate hand-washing instructions and clean toilet facilities for field workers
- Clean and sanitize harvest containers before use
- Drying of raw materials should be accomplished on clean, elevated racks, concrete floors, or mats and not on the bare ground. If open air drying is utilized, covers should be installed to prevent contamination from birds flying overhead.
- Utilize mechanical versus open air drying when possible to limit exposure of raw spices to pathogens and filth
- Exclude field debris from packing and storage facilities by cleaning the outsides of harvest bins and requiring workers to wear clean clothes in these areas
- Use new, unused bags to pack product for further transport and sale

V. Pathogens in Spices

A. Pathogens of concern

Due to the environments in which they are grown, spices and herbs often harbor bacteria and fungi. These include potential spoilage organisms and organisms of public health significance. Although a number of microorganisms are killed during the drying of spices and herbs, many bacteria and fungi can survive. If the products are not stored and shipped properly, mold may grow or pathogens may be introduced. If water activity is kept below 0.75, most fungi and bacteria will not grow in the spice **(Table 2)**. However, if bacteria are present in low levels and the product is incorporated in intermediate or high moisture foods, such as processed meats or dairy products, the foods may be capable of supporting growth of the microorganisms.

A number of variables affect the extent of microbial contamination in spices. These factors affect survival and multiplication of pathogens and generally fall into one of four categories:

- Intrinsic physical characteristics and composition at each step of preparation
  - Water activity **(Table 2)**
  - Typical microbial content when stored in clean, sealed containers
  - Antimicrobial constituents
- Characteristics of the microbial population
  - Ability to form spores
  - Adaptability to dry conditions
  - Oxygen dependence (aerobic versus anaerobic)
- Handling and storage at every stage from farm to consumer possession
  - Agricultural and harvesting practices (e.g., handling practices, pest control)
  - Sanitation (e.g., water, equipment) and worker hygiene
  - Temperature and humidity
  - Isolation methods (e.g., packaging, storage containers)
- Use of microbial reduction processes (e.g., irradiation, ethylene oxide, propylene oxide, steam)
  - Reduces microbial load, but post-processing controls are required to prevent recontamination

> Although a number of microorganisms are killed during the drying of spices and herbs, many bacteria and fungi can survive.

The bacterial and fungal species in spices include aerobic spoilage organisms, spore-forming bacteria, high heat stable toxin producing bacteria, proteolytic

and gas-producing bacteria, and mycotoxin-producing microorganisms. Of all the spices, black pepper typically has the highest aerobic plate counts, usually in excess of 10^6 cfu/g. Paprika, celery seed, coriander, turmeric, thyme, basil and other spices can also have plate counts in the millions per gram. Microorganisms that may be found in spices are listed in **Table 2**.

Table 2. Microorganisms that may be found in spices

Bacteria	Minimum water activity for growth (A_w)
Salmonella	0.93–0.94
C. perfringens	0.97
C. botulinum	0.94
Bacillus cereus	0.93
E. coli	0.95
Listeria monocytogenes	0.92
Halobacterium halobius	0.75
Staphylococcus aureus	0.82
Fungi, Yeast and Molds	**Minimum water activity for growth (A_w)**
Aspergillus flavus/parasiticus	0.80
Botrytis cinerea	0.97
Penicillium ssp.	0.79–0.82
Saccharomyces cerevisiae	0.90
Rhizopus stolonifer	0.89
Zygosaccharomyces rouxii	0.62
Xeromyces bisporus	0.61

Salmonella is the most common bacterial pathogen associated with product recalls and outbreaks in spices and is the primary focus of this guidance. There are over 2,500 serotypes of *Salmonella* (CDC 2010). *Salmonella* present in low numbers can present a human health hazard when no lethality step is applied prior to consumption. *Salmonella* is very stable in dry environments and can survive through production, distribution, and eventually consumption. Finally, the composition of a food ingredient (e.g. fat) may protect *Salmonella* from destruction by gastrointestinal acids, which may lead to illness. In such cases, a person does not need to consume a large amount of contaminated product to become ill. In some instances, illnesses have occurred upon consumption of low-moisture products contaminated at levels <1 cfu/g (Lehmacher et al. 1995).

Most persons infected with *Salmonella* develop diarrhea, fever, and abdominal cramps twelve to 72 hours after infection. Infection is usually diagnosed by culture of a stool sample. The illness usually lasts from four to seven days. Although most people recover without treatment, severe infections may occur. Infants, elderly persons, and those with weakened immune systems are more likely than others to develop severe illness. When severe infection occurs, *Salmonella* may spread from the intestines to the bloodstream and then to other body sites and can cause death unless the person is treated promptly with antibiotics (CDC 2010).

Although the following bacterial outbreaks provide valuable lessons for the U.S. spice industry, it is important to note that most foodborne illness is not recognized or reported. Bacterial contamination is only likely to be recognized if many people are severely sickened by a single food product (AAM, 2010).

A. Notable incidents involving spices

FDA Review of Spice Recalls (1970-2003)

FDA published a review of spice recalls that occurred in the U.S. from 1970 to 2003 (Vij et al. 2006). Twenty-one recalls due to bacterial contamination were reported during this time period. The recalls involved twelve spice types **(Table 3)**, with paprika implicated in the highest number of recalls (4). Origins of recalled spices included India, Spain, Turkey, Egypt, Jamaica, Mexico, Taiwan, and the U.S. In all but one instance, the recalled spices contained *Salmonella*.

Table 3. Spice recalls due to bacterial contamination monitored by the U.S. FDA, October 1, 1969 to December 31, 2003 (Vij et al. 2006)

Spice	No. of recalls
Basil leaves	1
Bay leaves	1[a]
Black pepper (ground)	1
Cerase spice	1
Cumin (ground)	2
Oregano (ground)	3
Paprika	4
Red pepper (powder)	1
Sage (ground)	2
Sesame seeds	3[b]
Thyme (ground)	2[c]
Total	21

[a]Contaminated with *Listeria monocytogenes*, all other products listed in table contaminated with *Salmonella*.
[b]Two of the three recalls involved the same bulk lot of sesame seeds (one recall involved plain sesame seeds, and the other recall involved green seasonings that contained sesame seeds); the third recall entailed "Sesame seed Anjoli," a product that consisted of almondlike seeds often used in oriental cuisine as a garnish, as an hors d'oeuvre, or as a salad ingredient.
[c]One product was a combination of ground thyme and poultry seasonings.

Salami (2010)

Beginning in August 2009, the CDC identified a geographically dispersed cluster of cases with the most common DNA fingerprint being that of *Salmonella* Montevideo. In early 2010, the CDC and public health officials in multiple states completed an epidemiology study that linked 19 illnesses to the purchase of ready-to-eat salami products. The salami was made with black pepper. An extensive recall of the salami was conducted. The outbreak strain of *Salmonella* Montevideo was identified in samples of black and red pepper sold

to the salami manufacturer. This resulted in recalls of certain lots of black and red pepper intended for use in salami production (CDC 2010). The pepper recalls led to recalls of a number of other food products that may have contained contaminated pepper (FSIS 2010). As of April 28, 2010, a total of 272 individuals with the outbreak strain of *Salmonella* Montevideo were identified from 44 states and the District of Columbia. Infected individuals ranged in age from <1 to 93 years of age, with a median age of 37 years. Among the 203 patients with available information, 52 (26%) were hospitalized. No deaths were reported (CDC 2010).

Selected international incidents

- Norway, 1981-1982: Black pepper imported from Brazil via Germany was associated with 126 culture-confirmed cases of *Salmonella* Oranienburg infection (CDC 1982)
- Germany, 2003: Contaminated potato chips seasoned with paprika imported from South America were associated with 1,000 cases of salmonellosis. A number of *Salmonella* serotypes were documented in patients and paprika-containing foods (Lehmacher et al. 1995)

B. Reports to FDA — Reportable Food Registry

The Reportable Food Registry (RFR) was called for by Congress in 2007 and required FDA to create a mechanism by which the food industry must report incidents in which there is a reasonable probability that a food (including spices) will cause serious adverse human (or animal) health consequences. Congress' intent was to help FDA track patterns of food and feed adulteration and target inspection resources. Registered Food Facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. are required to report within 24 hours any "reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals." Federal, state, and local government officials may also use the RFR portal to report information they receive about reportable foods. RFR submissions include primary reports, the initial submissions about reportable foods, and subsequent reports, those submitted by either a supplier or a recipient of a food for which a primary report has been submitted. The RFR applies to all FDA-regulated categories of food and feed with the exceptions of dietary supplements and infant formula, which are assigned to other mandatory reporting systems (FDA 2010).

The RFR electronic portal opened on September 8, 2009 and, at this writing, data were available through September 7, 2010. A total of 2240 reportable submissions were entered in the RFR during this time period. The February 2010 recall of hydrolyzed vegetable protein (HVP) was responsible for 1001 entries, 113 of which involved spices and seasonings. Only 229 (226 industry, 3 regulatory) reportable submissions entered were primary reports, and 17 pertained to spices and seasonings. Sixteen of these reports were for *Salmonella* contamination and one was for undeclared allergens/intolerances (FDA 2010 [RFR]). On May 24, 2010, the RFR became part of FDA and National Institutes of Health (NIH) Safety Reporting Portal (FDA 2010). More information about reporting requirements is available at http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/UCM2019388.htm and in **Appendix 12**.

VI. Prevention of Microbial Contamination of Spices During Processing and Storage

Actions can be taken at every step throughout the growing, harvesting, drying, transportation, and processing of spices to ensure that a clean, safe spice is ultimately delivered to the consumer. Development of supply chain approval and re-evaluation programs and adherence to GAPs (discussed in section IV), GMPs, and HACCP plans reduce the likelihood of microbial contamination throughout the supply chain. As discussed in section IV, these programs also help reduce the introduction of filth, which, in turn, reduces risk for microbial contamination.

A. Supply Chain Approval and Re-evaluation Programs

Spice manufacturers should establish robust supplier prerequisite programs to evaluate and approve suppliers. These programs may include audits of supplier facilities; periodic requalification that takes into consideration whether the supplier conducts microbiological monitoring of their process environment or uses validated microbial reduction techniques; and periodic raw material/ingredient testing upon receipt. A risk assessment should be applied to each raw material. Suppliers should provide necessary documentation on traceability of product (minimum requirement one back) and on their implementation and use of GAP, GMP and their own HACCP programs. A Certificate of Analysis (COAs) should be obtained from the supplier that includes results of microbial testing, sample size analyzed, and method and lab certification. These controls may be difficult to implement when materials are purchased from markets of collectors, and the burden of ensuring a pathogen-free spice falls on the domestic spice importer and/or processor.

Spice manufacturers should establish robust supplier prerequisite programs to evaluate and approve suppliers

B. Good Manufacturing Practices (GMPs)

GMPs have been outlined elsewhere, including the FDA cGMP regulations 21 CFR 110 (CFR, 2008) and the Codex general principles of food hygiene (CAC, 2003). Manufacturing facilities involved in the processing of spices should manage their operations following GMP guidelines. Sections focusing on worker hygiene, cleaning/sanitizing of physical facilities, utensils, and equipment; pest control; rubbish disposal; and the design and construction of plants and equipment to facilitate cleaning are particularly pertinent to reducing the risk of microbial contamination of spices.

FDA cGMP regulations 21 CFR 110 (CFR, 2008) also address segregation of treated and untreated materials. FDA considers ready-to-cook foods those that have to be cooked according to the instructions on the package (e.g., boxes or pouches of rice dishes or frozen dinners). These foods are low risk when consumers follow the

Prevention of environmental contamination, cross-contamination, and post-processing contamination during processing and storage

- Avoid entrance of *Salmonella* into processing and storage facilities
- Prevent *Salmonella* growth and the establishment of *Salmonella* niches through strict moisture control
- Do not allow livestock, pets, rodents, insects, or birds to enter processing or storage facilities
- Adopt SSOPs, i.e., written instructions describing each sanitation procedure, how to properly complete the task, the frequency with which each procedure is performed, and the identity of the employee(s) responsible for the implementation and maintenance of the SSOP
- Apply sanitary design principles (i.e., minimize number of equipment parts and ensure accessibility for cleaning)
- Enforce worker hygiene codes that encourage hand washing; use of protective clothing; removal of jewelry; eating, drinking, and smoking in appropriate areas; and reporting of illness
- Develop supply chain approval and re-evaluation programs that emphasize microbiological monitoring of the process environment, pathogen testing of spice materials with appropriate documentation, and use of GAPs, GMPs and HACCP programs
- Adhere to GMPs, including clear designation of pre-lethality areas (i.e., low-risk) and post-lethality (i.e., high-risk) areas and controls necessary for prevention of cross-contamination and post-processing contamination
  - Construct physical barriers between pre-lethality and post-lethality areas
  - Use dedicated equipment for the pre-lethality and post-lethality areas
  - Restrict movement of personnel and vehicles (e.g., forklifts, pallet jacks) between pre-lethality and post-lethality areas
  - Maintain the post-lethality area under positive air pressure relative to adjacent areas and ensure that ventilation systems do not allow air or dust to travel from the pre- to post-lethality area
  - Establish stringent personal hygiene controls, particularly in areas adjacent to the post-lethality area
- Protect food-contact packaging materials during shipment, storage, and use
- Implement product- and process-specific HACCP plans as outlined in the ASTA HACCP Guide for Spices and Seasonings (Appendix 11)

cooking instructions as written. The directions are meant to raise the temperature of the food to a certain level for long enough to kill bacteria, including *Salmonella*. **Ready-to-eat** foods are processed foods that consumers are not expected to cook or bake (e.g., snack chips and powdered products used to make dips or salad dressings or spices sold directly to consumers). These foods pose a higher risk if they were made without a validated lethality step, a food processing step that kills *Salmonella* (FDA 2010).

Some of the recent *Salmonella* outbreaks in the pistachio (http://www.fda.gov/Safety/Recalls/MajorProductRecalls/Pistachio/default.htm) and peanut industries (http://www.fda.gov/Safety/Recalls/MajorProductRecalls/Peanut/default.htm) may have been due to contaminated raw material in the facility coming in contact with finished product which had

already been subjected to a lethality step. Such a route could be common packing lines, transport belts, and/or processing equipment, or simply dust particles travelling from a low-risk to a high-risk area of the facility.

C. Sanitation standard operating procedures (SSOPs)

Each plant should adopt the eight sanitation standard operating procedures (SSOPs) specified in 21 CFR 120.6. These are written instructions describing each sanitation procedure, how to properly complete the task, the frequency with which each procedure is performed, and the need to record the identity of the person(s) responsible for the implementation and maintenance of the SSOP. SSOPs should address:

1. Safety of the water that comes into contact with food or food contact surfaces
2. Condition and cleanliness of food contact surfaces, including utensils, gloves, and clothing
3. Prevention of cross contamination from insanitary objects to food, and from raw product to processed product
4. Maintenance of hand washing, hand sanitizing, and toilet facilities
5. Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants
6. Proper labeling, storage, and use of toxic compounds
7. Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces
8. Exclusion of pests from the food plant

D. Hazard Analysis Critical Control Point (HACCP) Plans

HACCP is a key tool to ensure food safety at all stages of the food chain. An effective HACCP study allows for the identification of specific hazard(s) (i.e., any biological, chemical, or physical property that adversely affects the safety of the food) and specifies measures for their control. A HACCP plan consists of the following seven basic principles (NACMCF, 1998):

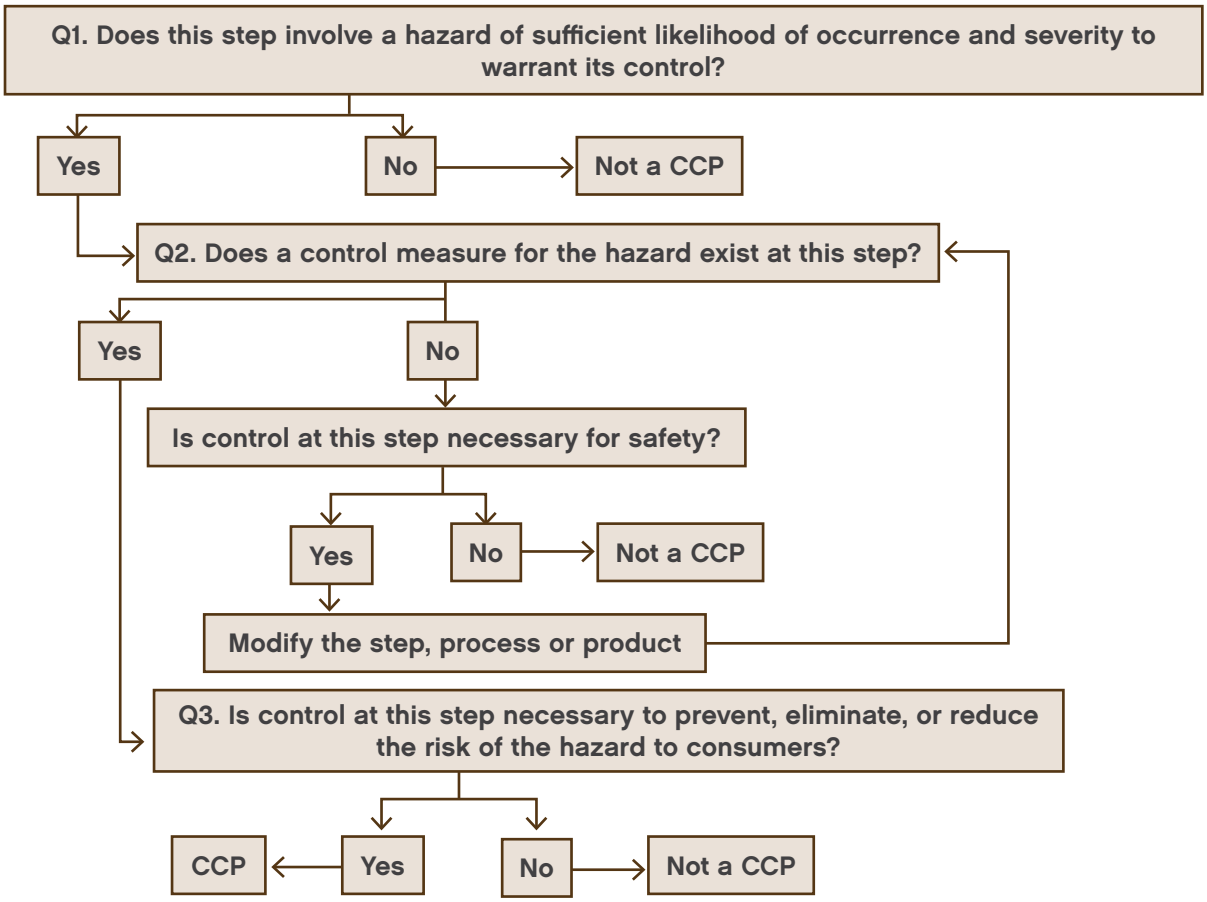
Principle 1: Conduct a hazard analysis

Step 1: Identify the microbiological, chemical, and physical hazards to human health that may be introduced into the food product.

Step 2: Identify preventive measures that could be used to control the food safety hazard.

Principle 2: Identify Critical Control Points

A Critical Control Point (CCP) is a step in a food production process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. A decision tree, like that on page 22, is used at the steps where a hazard has been identified. It should be noted that a subsequent step in the process may be a more effective point at which to control a hazard and thus, may be the preferred CCP. Furthermore, more than one step in a process may be involved in controlling a hazard, and more than one hazard may be controlled by a specific control measure.



Principle 3: Establish Critical Limits for Each CCP

Critical limits are the boundaries of safety for preventive measures put in place at CCPs. A critical limit will usually be a reading or observation such as temperature, time, or pH. A critical limit can be an upper limit where a set amount or level cannot be exceeded or a lower limit where a minimum amount is required to produce the safe effect.

Principle 4: Establish Monitoring Procedures

Monitoring procedures are routine tasks (performed either by employee or mechanical means) that measure the process at a given CCP and create a record for future use. Continuous monitoring is preferred when it is possible. It is important that the person responsible for the CCP monitoring is given specific, documented, CCP training.

Principle 5: Establish Corrective Actions

Establish corrective actions to be taken when monitoring shows that there is a deviation from a critical limit. Listed below are some questions that may help when developing corrective actions:

- How will people be informed when the deviation occurs?
- Who will be responsible for controlling the product that may have been affected by the deviation?
- How will we decide what caused the deviation?
- Who will be involved in deciding how to get the process back in control?

- Who in the company needs to sign off on any modifications to plan?
- Who will be responsible for keeping the records of things done in response to a deviation from a critical limit?

Principle 6: Establish Recordkeeping Procedures

Record keeping is an essential feature of a HACCP plan.

- Use simple understandable forms.
- Make sure employees know exactly what is expected if they are responsible for making a record entry.
- Make sure the records are signed and dated at the time a specific event occurs.

Principle 7: Establish Verification Procedures

Verification procedures are needed to make sure the plan is working correctly. There are three types of verification:

- Validation, the initial phase in which the plan is tested and reviewed.
- Ongoing verification, which ensures that the HACCP plan is working effectively on a day-to-day basis. Typically verification includes management review and sign off.
- Reassessment, an overall review of the plan that must be performed at least annually, or whenever any changes occur that could affect the hazard analysis or alter the HACCP plan.

HACCP reduces the risk of food safety hazards in finished products by identifying the potential risks in the process. Each spice manufacturer should develop product- and process-specific HACCP plans as outlined in the ASTA HACCP Guide for Spices and Seasonings **(Appendix 11)**. The Guide is available from the ASTA office in Washington, DC, and includes:

- Benefits of use of HACCP
  - Can be applied to receipt, decontamination (cleaning and microbial reduction), blending, packaging, storage, and distribution processes
  - Cost effective, preventative approach that reduces product losses
  - Approved by U.S. regulatory and international authorities as a means of controlling food borne illnesses
  - Compliments other quality control systems and prerequisite programs (e.g., GMPs)
- Steps for assembling a HACCP team, with an emphasis on inclusion of members with different roles in the plant
- Instructions for development of a process flow diagram examining
  - All the steps in the process where a hazard may exist
  - The potential for specific types of hazards at each step
- Relevant product considerations
  - Use
  - Packaging
  - Shelf-life
  - Intended consumer
  - Regulatory requirements
  - Labeling
- Appropriate HACCP documentation
  - Product description
  - Process flow diagram
  - Hazard analysis
  - CCP documentation

- Discussion of potential chemical, physical, and biological hazards, including
  - Specific hazards (e.g., *Salmonella*, sharp objects)
  - Suggested controls for prevention of hazards
  - Methods for eradication of hazards
- A checklist of considerations to ensure a thorough hazard analysis process. These include
  - Presence of "sensitive" ingredients
  - Physical characteristics of the food product and their ability to support pathogen growth
  - Existence and timing of a lethality step
  - Opportunities for post-processing contamination
  - Storage conditions and their likelihood of supporting microbial hazards
  - Facility design that allows separation of pre-processing and ready-to-eat foods
  - Ability of equipment to provide time/temperature control to meet critical limits
  - Sanitation and employee hygiene
- Examples of HACCP plans for
  - Processed spices
  - Processed seasonings

VII. Microbial Reduction Techniques

FDA considers spices to be ready-to-eat products. In order to provide a greater assurance of spice safety in the absence of cooking, a variety of microbial reduction techniques are employed within the spice industry. These include fumigants (ethylene oxide and propylene oxide), irradiation, and steam. Each technique has advantages and limitations in effectiveness, quality impact, and consumer acceptance. ASTA has worked with FDA to provide information on proper validation of microbial reduction techniques and members can obtain this information by contacting the ASTA office. These treatments are often followed by product testing, which serves as a measure of food safety and may be required to meet customer specifications. A combination of treatment and testing is very effective in reducing the risk for *Salmonella* in the spice. Though *Salmonella* is a moisture-dependent pathogen, it should be noted that dehydration is not a validated lethality step. *Salmonella* needs moisture to grow but can survive long periods of time in low-moisture foods.

A. Ethylene oxide and propylene oxide

Ethylene oxide (EtO) or propylene oxide (PPO), when applied either under vacuum or under pressure, with or without an inert gas diluent, can kill bacteria, yeast, mold, and pathogens without the need for high temperatures. Ethylene oxide, in particular, has been widely applied in the treatment of spices, gums, starch, flour, yeast, and milk.

The U.S. spice industry uses EtO to eliminate pathogenic microbial contaminants such as *Salmonella* and *E.coli* in spices. EtO is a flammable, colorless gas at temperatures above 51.3 F (10.7 C). When used directly in the gaseous form or in nonexplosive gaseous mixtures with nitrogen or carbon dioxide, EtO serves as a disinfectant, fumigant, sterilizing agent, and insecticide. On an annual basis, the spice industry uses approximately 800,000 pounds of EtO, or less than 10% of all of the EtO used for sterilization purposes in the U.S. The majority of EtO is used for the sterilization of medical equipment.

When applied in a validated process, EtO can be extremely effective in eliminating *Salmonella* and *E. coli* as well as reducing overall bacterial load, yeast and mold, coliforms, and other pathogens. Although exact numbers are difficult to determine, ASTA estimates that between 40% and 85% of spices in the U.S. are treated with EtO each year. EtO is also used to treat spice packaging material. The main advantage of EtO is that its use on spice generally has no significant impact on the appearance or flavor of the spice. Appearance and taste are essential for spices, thus EtO treatment can resolve the potential public health issues without negatively effecting the marketability of the spice. However, the effect of EtO on spores (i.e., thick-coated, metabolically inert cells that are dormant forms of the

> A combination of treatment and testing is very effective in reducing the risk for *Salmonella* in the spice.

vegetative cells and that are resistant to stress) is not as great as for vegetative cells (i.e., cells that are capable of active growth) (www.textbookofbacteriology.net; Pafumi 1986; Inglis and Lark, 1996).

ASTA supports the Food Quality Protection Act Tolerance Reassessment Decision Document as developed by the EPA, including the tolerances for EtO residue of 7 ppm on spices and dried vegetables, as well as the ethylene chlorohydrin (ECH) residue tolerances of 940 ppm on spices and dried vegetables. ASTA has established specific use directions for the EtO label that assure consistency of treatment. Since 2008, any spice treated with EtO in the U.S. must be treated using the process detailed on the label. New microbial reduction techniques will be considered for approval by the EPA as long as the residues are below the tolerances. If product is treated outside the U.S., the product being imported must meet the tolerances for EtO and ECH. These tolerances must be met for all spices, even if they are to be added to a spice blend prior to shipping to the U.S. An exception to the established residue tolerances is basil, which cannot be treated with EtO.

As with EtO, tolerances for PPO for food fumigation are established by EPA and PPO has a residue tolerance of 300 ppm for nutmeats, cocoa powder, and spices, including basil (40 CFR 185.15). Fumigation exposure times are also regulated. In 2007, FDA issued a letter of determination for PPO treatment of raw almonds after the Almond Board of California demonstrated its effectiveness to achieve a 5-log reduction of *Salmonella*. Unlike EtO, the residual product of PPO, propylene glycol does not have a separate tolerance (Blanchard & Hanlin, 1973). However, PPO is less commonly used than EtO to treat spices.

B. Irradiation

Irradiation is a process by which certain foods may be exposed to radiant energy. Multiple irradiation methods are approved in the U.S. Ionizing radiation (e.g. gamma rays, x-rays) is approved for the microbial disinfection of foods, including spices (21 CFR 179.26). In 1963, FDA found the irradiation of food to be safe, and U.S. food regulations allow the irradiation of meat and poultry, wheat and wheat powder, white potatoes, many spices, dry vegetable seasonings, fresh shell eggs, and fresh produce. The International Atomic Energy Agency (IAEA), the World Health Organization (WHO), and the Food and Agricultural Organization (FAO) of the United Nations have uniformly concluded that the food irradiation process does not present any toxicological, microbiological, or nutritional hazard beyond those brought about by conventional food processing techniques (Diehl 1995). Still, there is great confusion among consumers as to what food irradiation is. Some consumers fear that irradiated food is radioactive, and others are concerned that irradiated food contains free radicals and radiolytic products. Consumer education regarding the advantages (process safety, reduction of chemical use, and improved quality and safety of foods) and limitations/drawbacks (a slight reduction in nutrients) of food irradiation has improved consumer acceptance of irradiated food products (Morehouse and Komolprasert, 2004).

Since 1966, FDA has required that labeling on all irradiated food for both retail and non-retail use bear a statement that such food has been treated with ionizing radiation (Pauli and Takeguchi, 1986). The wholesale label must include either the statement "Treated with radiation, do not irradiate again," or the statement "Treated by irradiation, do not irradiate again." The retail label must include the radura logo shown at the left, along with either the statement "treated with radiation," or the statement "treated by irradiation."

As with thermal pasteurization or sterilization, irradiation may alter organoleptic properties (taste, color, smell, texture) of food. FDA believes that these changes, although of no safety concern, are sufficiently important that the consumer should know that this process has been used. However, the retail labeling requirement applies only to food that has been directly irradiated (first-generation food), not to food that merely contains an irradiated ingredient (second-generation food). Therefore, a food containing an irradiated spice does not have to bear labeling identifying the product as having been irradiated (Pauli and Takeguchi, 1986). However, spices sold directly to consumers do require irradiation labeling.

FDA has established a maximum dose of 30 kilogray for irradiation of spices (21 CFR 179.26). Irradiation is particularly useful for treating high-risk ingredients that would not otherwise receive a lethality step for *Salmonella*.

When spices are packaged prior to irradiation, a number of factors must be considered. These include the size and shape of the package, the penetrability of the packaging material to the type of radiation being used, and the effects of radiation on the packaging material. Irradiation can cause changes to the packaging that may compromise packaging and create an opportunity for recontamination. Irradiation might also produce radiolysis products that could migrate into food, affecting odor, taste, and possibly safety. In the U.S., components of food packaging used during irradiation must undergo premarket approval by FDA and may be used only if they comply with the regulations in 21 CFR 179.45 or are the subject of an effective food contact notification or Threshold of Regulation exemption. Regardless of the review channel, chemistry data supporting the identity of and human dietary exposure to a new food-contact substance intended to be used during the irradiation of prepackaged food, as well as its radiolysis products, must be submitted to FDA. If the packaging material is already approved for unirradiated uses, comparisons can be made to an unirradiated control to determine exposures that would result from use with irradiation (Morehouse and Komolprasert, 2004).

C. Steam Treatment

Steam treatment for dried food products is usually defined as a process (time and temperature), that is sufficient to achieve a 5-log or greater reduction of the most heat-resistant form of *Salmonella*. Steam treatment of dried food products can achieve significant reductions and can substantially reduce aerobic plate counts, coliforms, yeast, and mold load of the spice, usually from 1 to 5 logs. Microbial reduction can also be achieved by heat without steam with certain technologies (Vancauwenberge, 1981).

Various forms of steam treatment are currently in use and the choice between saturated, dry, and superheated steam depends on the technology and product to be treated. As a result, the microbiological reduction, as well as the output moisture, organoleptic properties, and water activity of the product will vary according to the steam and technology used (AHPA, 2009). As with most microbial reduction techniques, spore-forming pathogens are more difficult to kill with steam than are non-spore-forming pathogens.

Use and validation of microbial reduction techniques in spices

- ASTA recommends the use of validated microbial reduction techniques
- Options, dependent on spice and final use are EtO, PPO, irradiation, or steam
- Members should comply with EPA tolerances for EtO, ECH, and PPO residues
- All microbial reduction techniques should be used in accordance with EPA and label directions and be validated to destroy *Salmonella* or other target organisms
- Validation should focus on the critical control point used to deliver a significant reduction (e.g., the lethality step)
  - Determine the critical limits (e.g., thermal and time parameters) required to achieve the target log reduction
  - Confirm the process equipment consistently delivers the critical limit parameters and/or target log reduction
  - Monitor the control points and have documented action steps should the parameters not be met
- Each process should be validated using representative products to which it will be applied

If saturated steam is used, a drying step may be necessary to remove added moisture and prevent growth after treatment. Some technologies can control the condensation of the steam, so that the moisture remains the same. In some instances, no drying is necessary but it is essential that water activity is controlled on products after steam treatment.

Steam treatment can be applied to whole or ground spices. Treating the whole product is technically easy, and can be done in the growing/exporting country. In this case, the post-treatment handling needs to follow strict hygiene rules in order to limit the risks of recontamination during grinding, handling, storage and packing. Treatment of ground spices has the advantage of limiting the risk of recontamination, as the product can be packed right after it is treated. In the case of batch systems, product may form lumps that need to be ground after treatment. Continuous technologies that allow direct screening and packing are available.

In the U.S., steam is most commonly used to treat whole seed spices such as white and black pepper. Steam is more effective than dry heat for microbial reduction because of the heat transfer capabilities of moist heat. However, use of steam requires understanding of factors that affect microbial heat resistance. For example, *Salmonella* demonstrates greater resistance to heat in products with lower water activity (FSIS, 1999; Goepfert and Biggie, 1968). As with any heat-based treatment, steam may reduce the aromatic character, flavor components, and natural color of spices (Tainter and Grenis, 2001).

A variety of steam technologies are validated for the almond industry under a USDA marketing order (72 Fed. Reg. 15021. 30 March 2007) and they deliver a 4-log to 5-log reduction in *Salmonella* without affecting the quality of the nuts. In Europe, where the use of EtO and PPO is not approved, steam treatment is widely used for microbial reduction in spices.

D. Validation of microbial reduction protocols

In general, NACMCF recommends applying any process, treatment, or combination thereof, to reduce the most resistant *Salmonella* serotype "to a level that is not likely to present a public health risk under normal conditions of distribution and storage" (NACMCF, 2006). Ideally, the target log reduction is determined for each food product on the basis of frequency and level of occurrence of the bacteria. However, these parameters are likely to vary widely for spices and have not been published. A 5-log reduction is considered appropriate for risk management by FDA for some foods such as almonds (Danyluk et al. 2006).

It is important for companies relying on microbial reduction techniques to validate each process using representative products to which it will be applied. Validation should focus on the critical control point(s) used to deliver the target log reduction. When a lethality step is needed to inactivate potential contaminants such as *Salmonella*, the processing parameters used should be adequate to inactivate the level of the organism likely to be present. Validation of lethality steps for spices involves determining the critical limits (e.g., thermal and time parameters) required to achieve a significant reduction in the target organism and confirming the process equipment consistently delivers the critical limit parameters (NACMCF, 1998; Scott et al., 2006). Critical limits should be developed based on thermal and non-thermal parameters (e.g., D- and z-values, thermal death times) of the most resistant and pertinent *Salmonella* serotype that could occur in the spice or processing environment.

Several approaches can be used for validating the adequacy of process parameters. If the process can be mimicked reasonably well in a laboratory, then *Salmonella* or other target pathogens can be used in process validation to confirm that the critical limits, when achieved, consistently result in the target log reduction. If the process cannot be mimicked in a lab setting, lethality can be confirmed based on the processing conditions (e.g., integrated lethality based on time and temperature profiles) or through use of a validated surrogate. For example, *Enterococcus faecium* NRRL B-2354 has been determined to be an appropriate surrogate for *Salmonella* in the validation of processing methods for almonds (ABC, 2007). The suitability of a microorganism to be used as a surrogate for a pathogen should be validated in each product and for each process (e.g., fumigant, steam, irradiation, or other) in which it is to be used.

VIII. Product and Environmental Testing

A. Product testing

A sound sampling and testing plan is an integral part of a comprehensive safety system that minimizes safety risks due to microbial contamination of spices. Routine microbiological testing of products is used to determine the acceptance of purchased ingredients, raw materials, and finished products, and may be performed by a spice vendor, customer company, and/or FDA anywhere in the supply chain. However, product testing alone is not a reliable means for assuring the absence of microbial pathogens (ICMSF, 2002a). In instances where the contamination rate is low, the reliance on microbiological testing as the lone measure of food safety may be misleading as negative results do not always ensure safety. For more information on the usefulness of pathogen testing, the International Commission for the Microbiological Safety of Foods has provided a decision tree (ICMSF, 2002).

> Product testing alone is not a reliable means for assuring the absence of microbial pathogens

Treatment of spices using validated methods such as irradiation, ethylene oxide, propylene oxide, or steam, plus statistically valid post-treatment sampling is an effective way to reduce the risk of contamination. Less intensive sampling plans are required for products that have undergone microbial reduction procedures versus their untreated counterparts. This is due to the reduced likelihood of the organism being present in a product that has undergone a validated lethality step. In samples collected prior to final processing and packaging, microbiological results may not be representative of the product shipped due to potential cross-contamination in the processing or packaging equipment. However, testing prior to final processing and packaging, in combination with a robust environmental testing program, will confirm that the control steps employed were effective.

Factors that influence the effectiveness of a sampling plan include whether random samples are collected from a lot, how samples are prepared, and the sensitivity and specificity of the analytical method. Lot acceptance sampling plans assume the microbial population to be randomly distributed throughout the lot. This is often not true, especially for non-liquid foods. For this reason, more complete information about the true microbiological population within a lot can be obtained by analyzing more than one sample. The number of samples that are collected from a lot is a balance between risk, accuracy, available resources, time, and cost.

Recommended sampling plans include those described in the Chapter 1 of the FDA Bacterial Analytical Manual (BAM; FDA April 2003; **Appendix 13**) and by ICMSF (ICMSF, 2002a). Chapter 5 of the FDA BAM details methods for the detection of *Salmonella* (FDA, December 2007) An alternative method may be used after it is validated as equivalent in sensitivity and specificity to the standard reference method for the product being tested. The Grocery Manufacturers Association (GMA) guidance on control of *Salmonella* in low-moisture foods provides

Spice product sampling and testing

- ASTA recommends product testing in combination with a good environmental testing program
- Testing protocols for microbiological contamination must incorporate statistically-guided sampling plans and sound handling methods
- Recommended sampling plans include those described in the FDA Bacterial Analytical Manual (FDA 2003 and 2007; Appendix 13) and by ICMSF (ICMSF, 2002a)
- Whenever product testing is performed:
  - Lots tested for *Salmonella* should be isolated, held, and only released into commerce if the product tests negative
  - Collection instruments, such as scoops and bags, must be sterile and sealed to prevent cross-contamination
  - Samples should be stored in a clean, cool, dry location to avoid contamination
  - Proper hand washing techniques and the use of gloves is recommended
- If a product sample tests positive for microbial contamination:
  - The tested lot should be considered adulterated and should not be released into commerce unless it is reconditioned by a validated process sufficient to destroy or reduce the pathogen present to appropriate levels
  - Retesting should not be conducted for the purpose of negating the initial test results; no number of negative results can override a single positive result on the lot
  - Corrective actions must be taken when microbial contamination is detected in finished product samples (GMA, 2009)

additional recommendations for product sampling and testing (GMA, 2009).

If FDA samples a spice on import and finds *Salmonella* or other pathogenic microorganisms in the product, the product is held and must be treated with a microbial reduction technique, destroyed, or returned to source. The list of spices held by FDA is published in the FDA's OASIS database monthly and is available on-line (http://www.fda.gov/ForIndustry/ImportProgram/ImportRefusals/default.htm). The products are listed by shipper, country, and spice.

B. Environmental testing

Environmental monitoring is an essential component for microbial control, as it provides insight into a plant's microbiological profile as well as an assessment of the effectiveness of the overall microbial control program (Zink, 2007; McNamara, 2007; Hall, 2007). Thus, environmental monitoring is not a control measure, but rather an assessment tool. Results of environmental monitoring provide critical information that should be used to improve microbial control.

Salmonella is the target organism for environmental monitoring of product-contact and non-product contact surfaces in a low-moisture food manufacturing facility, such as a spice plant. Scientific literature suggests *Salmonella* adapts well to warm, dry environments. The focus of an environmental monitoring program should be on the Primary *Salmonella* Control Area. This area is defined as the area subsequent to the lethality step up to the packaging step. For processes that do not have a *Salmonella* lethality step, the entire processing area is considered the Primary *Salmonella* Control Area (GMA, 2009).

The zone concept is recognized throughout the food industry as an appropriate approach to environmental monitoring (Zink, 2007). Zones within a ready-to-eat food manufacturing facility are defined based on the proximity and likelihood of the food being contaminated by the environment. Zone 1 is the most sensitive to contamination and represents food contact surfaces. Product contact swabs are used to verify cleaning effectiveness. Thus, these areas are swabbed after wet cleaning or after cleaning and sanitation for indicator microorganisms such as aerobic plate count bacteria, coliforms, and/or *Enterobacteriaceae*.

Testing for *Salmonella* or other specific pathogens on product contact surfaces requires a product hold until results are received. Product contact surface testing may be done as part of corrective actions for an environmental positive, depending on the location of the positive and other contributing factors (e.g. potential for cross-contamination).

Zones 2, 3, and 4 are non-product contact areas. They are more conceptual than the former and are sampled for *Salmonella*, typically with sponges instead of swabs. It is important to obtain non-product contact samples at points in production when the environment is likely to be at its worst. Non-product contact surfaces in the immediate area surrounding product contact surfaces are considered Zone 2. If these areas are contaminated with *Salmonella*, it is likely that Zone 1 could be contaminated. Zone 3 is outside of Zone 2 and represents areas that if contaminated, could possibly lead to contamination of product contact surfaces via humans or equipment. Zone 4 is defined as non-product contact surfaces outside of the processing area such as locker rooms, dining/cafeteria facilities etc. *Salmonella* contamination in these areas may spread to the processing area via humans or equipment. The emphasis for swabbing non-product contact surfaces should be Zone 2, followed by Zone 3, and then Zone 4.

A rotation schedule should be developed to ensure all areas of the facility are sampled on a periodic basis, and testing frequency should be increased during and after construction or equipment installation or repair. Compositing or pooling of environmental samples is not recommended. The FDA BAM method (Chapter 5) is the standard for testing environmental and product samples in the U.S. (FDA 2003; FDA 2007). Alternative methods should be of equivalent specificity and sensitivity to this method. The Grocery Manufacturers Association (GMA) guidance on control of *Salmonella* in low-moisture foods provides additional recommendations for environmental monitoring (Chen et al., 2009a & b; Scott et al., 2009; GMA, 2009).

Environmental testing in spice processing and storage facilities

- Sampling priorities should be established based on the zone system
- Environmental monitoring for *Salmonella* should focus on non-product contact surfaces in the Primary *Salmonella* Control Area (i.e., post-lethality area)
- Product contact surfaces should be routinely tested for indicator microorganisms
- A rotation schedule should be developed to ensure all areas of the facility are sampled on a periodic basis
- Compositing or pooling of environmental samples is not recommended

IX. Summary and Conclusions

ASTA is committed to assisting its members and others in the industry in assuring that spices consumed in the U.S. are clean and safe. A complete food safety program minimizes the risk for contamination by filth or pathogenic microorganisms at each stage of the supply chain. Implementation of the following elements will help U.S. spice companies to consistently deliver clean, safe spices to their customers.

- Supplier approval and re-evaluation programs that emphasize supplier adherence to GAPs, GMPs, and their own HACCP plans to minimize introduction of filth and microbial contaminants
- Adherence to GMPs in processing and storage facilities, including strict controls to prevent cross-contamination between treated and untreated product
- Development of HACCP programs
- Use of validated microbial reduction techniques (i.e., EtO, PPO, irradiation, or steam)
- Statistically valid post-treatment product sampling and testing
- Robust environmental sampling and testing programs

A complete food safety program minimizes the risk for contamination by filth or pathogenic microorganisms at each stage of the supply chain

X. Appendices

Appendix 1. ASTA Clean Spices handbook (http://www.astaspice.org/files/members/Clean.Spices.Handbook.2008.pdf)

Appendix 2. FDA definition of spices and relevant regulations (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.22)

Appendix 3. ASTA Spice List (http://www.astaspice.org/i4a/pages/index.cfm?pageid=3723)

Appendix 4. FDA Defect Action Levels Handbook (http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/sanitation/ucm056174.htm)

Appendix 5. ASTA Cleanliness Specifications (http://www.astaspice.org/files/members/CleanlinessRevised2007Version.pdf)

Appendix 6. ASTA Official Analytical Methods (http://www.astaspice.org/i4a/pages/index.cfm?pageid=3745)

Appendix 7. General Guidelines for Good Agricultural Practices — Spices. http://astaspice.org/files/public/IOSTA__GAP__Final.pdf

Appendix 8. Food Safety Begins on the Farm: A Grower's Guide (http://sfp.ucdavis.edu/pubs/articles/foodsafetybeginsonthefarm.pdf)

Appendix 9. FDA cGMP regulations 21 CFR 110 (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/CurrentGoodManufacturingPracticesCGMPs/ucm110877.htm)

Appendix 10. Codex General Principles of Food Hygiene (http://www.fao.org/docrep/005/Y1579E/y1579e02.htm)

Appendix 11. ASTA HACCP Guide for Spices and Seasonings (http://www.astaspice.org/files/members/HACCP.Guide.for.Spices.Seasonings-2006.Update.pdf)

Appendix 12. FDA RFR requirements (http://www.fda.gov/food/foodsafety/foodsafetyprograms/rfr/default.htm)

Appendix 13. FDA Bacterial Analytical Manual (http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm)

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The American Spice Trade Association (ASTA) is committed to assisting companies in the spice trade, regulators, and the public in assuring an adequate supply of clean, safe spices. This report is intended to serve as a resource for anyone with an interest in the spice trade. For companies in the spice trade, this report may assist you in providing clean, safe spices to your customers, including food manufacturers and the public. For members of the spice trade, we encourage you to use this report together with other sources of information to develop and implement your programs to assure that the spices you sell are clean and safe. ASTA is not responsible for either the use or nonuse of this report and the information in it, or any actions or failure to act by anyone using this report. It is each individual's responsibility to verify the information in this report before acting on it, and to comply with all relevant federal, state, and local laws, regulations, and ordinances. We urge you to consult with appropriate experts regarding circumstances relevant to clean, safe spices.

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