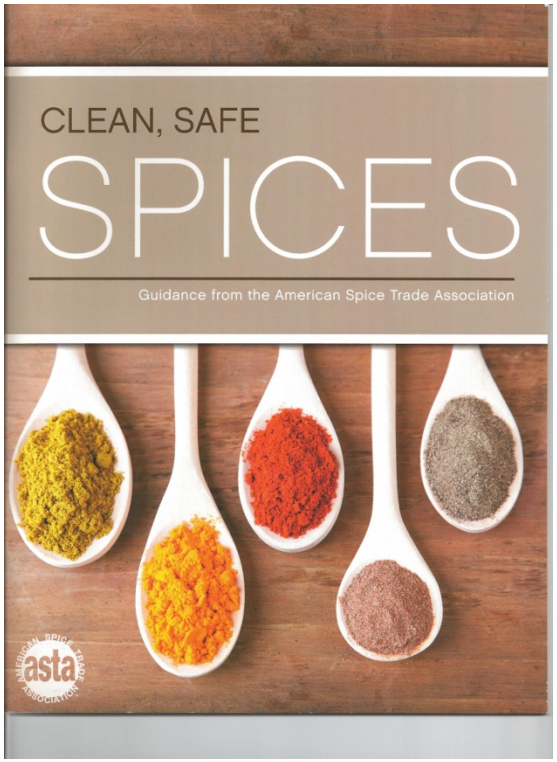
ASTA Clean, Safe Spices Guidance Document: FDA Perspective



ASTA Regulatory/Legislative Workshop

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Introduction:

FDA remains interested in the purity of spices from both a filth and pathogen perspective.

We support industry efforts to address these issues and their potential impact on public health.

ASTA Guidance Document is a significant step toward enhancing understanding about production of safe spices.

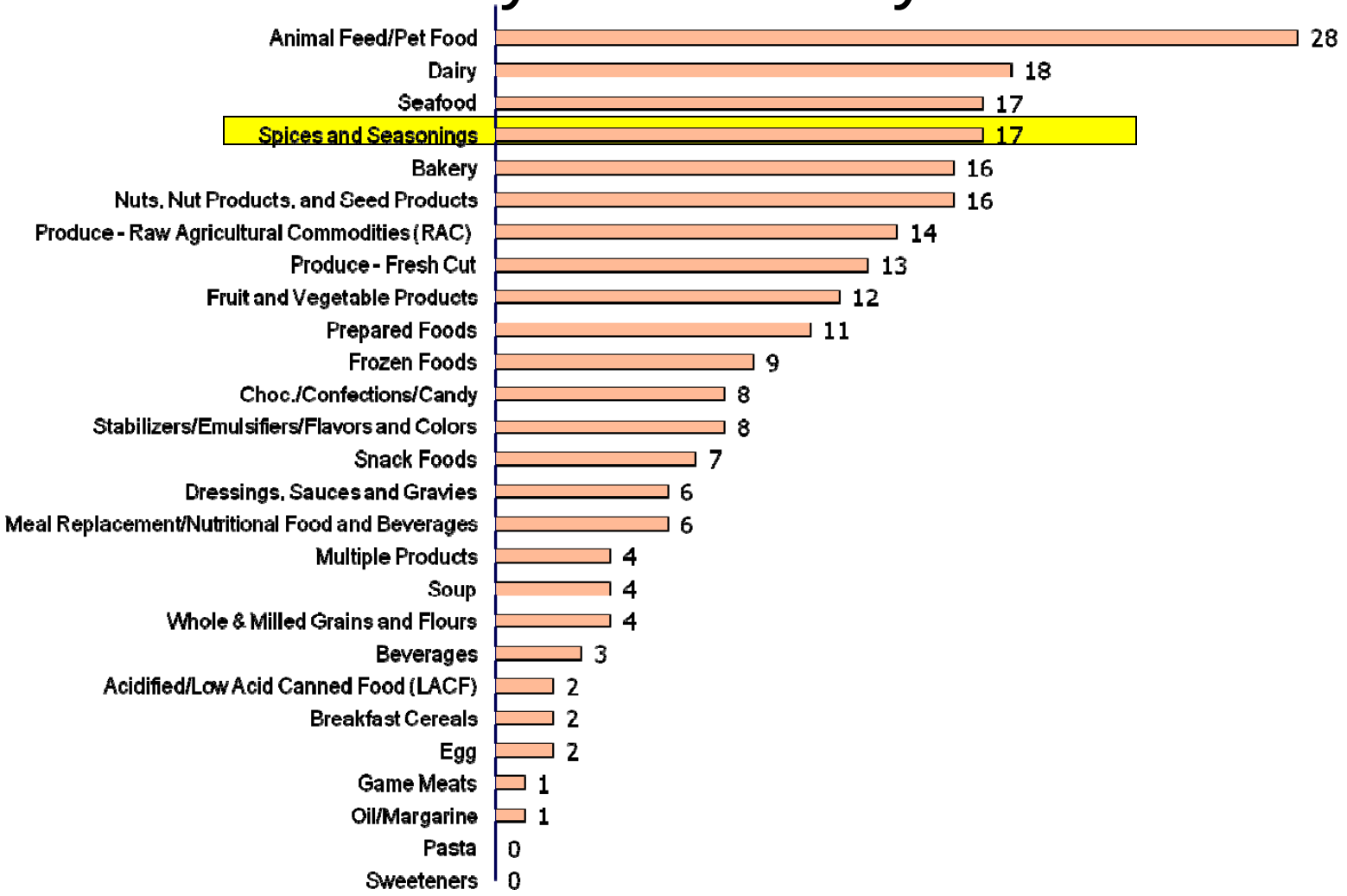
FDAAA of 2007 – Section 1005
Reportable Food Registry

- Amends FD&C Act by creating new section 417, Reportable Food Registry

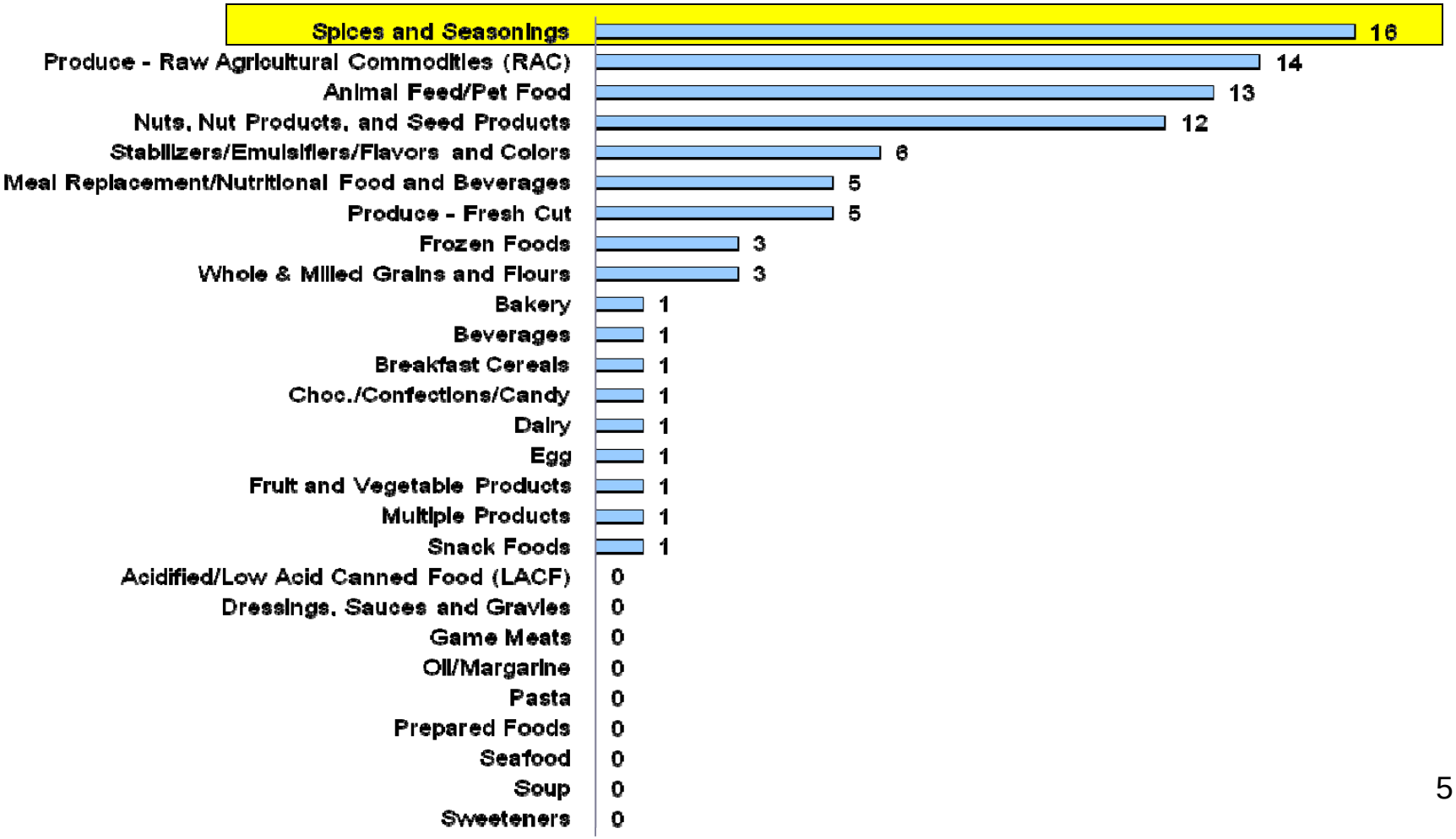
- Requires the Secretary of HHS to establish a Reportable Food Registry within FDA

- Requires FDA to establish an electronic portal by which instances of reportable food may be submitted

Distribution of 229 Primary RFR Entries by Commodity

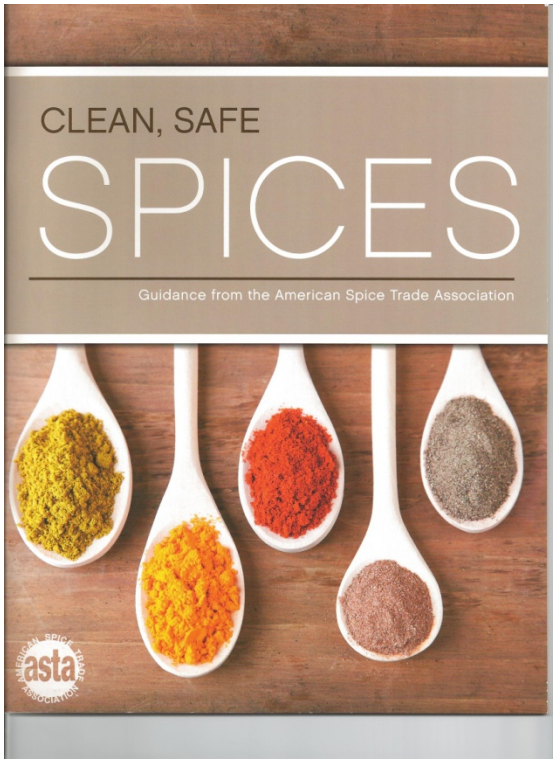


Distribution of 86 Primary *Salmonella* RFR Entries by Commodity (86/229)



Review:

ASTA Clean, Safe Spices Guidance Document



Outline

I. Executive Summary

II. Introduction

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

IV. Filth and Filth Reduction Strategies

V. Pathogens in Spices

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

VII. Microbial Reduction Techniques

VIII. Product and Environmental Testing

IX. Summary and Conclusions

I. Executive Summary

Suggestions for consideration:

Part 1: Title: “Minimize risk for introduction of filth throughout the supply chain”

Title may not fully reflect the impact of pathogens as discussed in this part.

Part 1, GAPs bullets:

Use of the term “manure” could be clarified whether “raw manure” or not.

Timing of manure application has been an issue for other industry groups involved in producing guidance.

I. Executive Summary

Suggestions for consideration:

Part 3 on use of validated microbial reduction techniques:

To be consistent with HACCP, change “control points” to “critical control points” under last entry of 4th bullet.

We strongly agree with the statement that validations should be conducted “using representative product**s** to which it is applied.”

I. Executive Summary

Suggestions for consideration:

Part 4, “Perform post-treatment testing to verify a safe product”:

Common misunderstanding of difference between “verification” and “validation”

We agree with the hold and release concept in 3rd bullet

We support statement under 4th bullet, “no number of negative results can override a single positive result on the lot.”

I. Executive Summary

Suggestions for consideration:

Part 5, “Test to verify a clean and wholesome manufacturing environment”:

Bullet 1 topic of environmental monitoring program: FDA is considering appropriate environmental monitoring procedures as required in FSMA.

Bullet 3 states: “Product contact surfaces in the post-lethality area should be routinely tested for indicator organisms (e.g., aerobic plate counts, coliforms, or enterobacter).” APCs would not be considered good indicator organisms for *Salmonella*

II. Introduction

Suggestions for consideration:

Figure 1: Very comprehensive. Provides good overall view of supply chain.

a. A legend might be helpful to distinguish product flow among solid, dotted and dashed lines.

b. Note that imports that test positive for *Salmonella* can arrive with a COA indicating the pathogen's absence.

II. Introduction

Suggestions for consideration:

Figure 1: Very comprehensive. Provides good overall view of supply chain.

c. If an ASTA member sells untreated raw spice to a consignee, they may wish to determine if that spice will receive a pathogen reduction treatment prior to consumer purchase. Liability issues.

d. Consider labeling of bulk treated product to prevent mix ups with untreated product.

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

Suggestions for consideration:

B. Safe Spices:

"…that ~~active~~ viable pathogens will not be present in spices…"

C. FDA's Regulatory Activities:

*"Therefore, **much** of the responsibility for maintaining a safe food supply rests with the food industry."*

Keep in mind that a food manufacturer is fully responsible for the safety of products sold in commerce.

IV. Filth and Filth Reduction Strategies

Suggestions for consideration:

"FDA considers contamination from "filth" to be a potential hazard to humans consuming spices."

Both filth and pathogens are important but do not go hand-in-hand.

While "filth" may be a hazard *per se*, *Salmonella* is a more significant hazard of concern in spices.

A significant amount of filth in a spice is not necessarily correlated with the presence of *Salmonella*.

Conversely, the absence of filth in spice is not necessarily correlated with the absence of *Salmonella*.

IV. Filth and Filth Reduction Strategies

Suggestions for consideration:

Repeat issue from Executive Summary:

There are concerns about use of raw manure. Properly composted or heated manure is considered more appropriate than raw manure for soil application.

Timing related to the application of (raw) manure may need to be better described. A 120 day harvest standard may not be appropriate in all cases.

V. Pathogens in Spices

Suggestions for consideration:

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

We agree. Important to keep in mind that drying is not a kill step that will eliminate pathogens.

Notable incidents: 1) Additional recalls have occurred since the period covered by Vij et al. in 2006; 2) There are other spice-related outbreaks than those mentioned in the document.

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

Suggestions for consideration:

A. Supply Chain Approval and Re-evaluation Programs:

"A ~~risk assessment~~ hazard analysis should be applied to each raw material."

B. Good Manufacturing Practices:

"Some of the recent Salmonella *outbreaks in the pistachio and peanut industries…"*

This needs correction. An outbreak of illness was not linked to the pistachio recall. http://www.cdc.gov/salmonella/pistachios/update.html

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

Suggestions for consideration:

A. Supply Chain Approval and Re-evaluation Programs:

FDA is glad to see that ASTA recommends a robust supplier approval program. It should be noted that FSMA requires supplier verification activities as a preventive control.

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

Suggestions for consideration:

D. HACCP Plans

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 is essential…" for prevention, elimination or reduction of a hazard.

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

Suggestions for consideration:

HACCP Principle 7: Establish Verification Procedures

"Validation, the initial phase in which the plan is tested and reviewed."

Validation: The element of Verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

Verification: Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/HACCPPrinciplesApplicationGuidelines/default.htm

VII. Microbial Reduction Techniques

Suggestions for consideration:

Section covers effectiveness of treatments: ETO, PPO, steam and irradiation.

There is little scientific literature on validation of treatment conditions needed to produce a specific reduction of *Salmonella* in spices; however, data on APCs are abundant.

Support emphasis on validation of technologies using representative products

NACMCF document: Parameters for Determining Inoculated Pack/Challenge Study Protocols. *Journal of Food Protection*, V.73(1), pp. 140-202; 2010.

VII. Microbial Reduction Techniques

Suggestions for consideration:

"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." Excellent point.

Surrogate organisms used in validation studies should be justified for the spice and process conditions.

Surrogate *Enterococcus faecium* NRRL B-2354 (*Pediococcus* sp.) must be justified for use on commodities other than almonds. Lab comparisons with *Salmonella* serotypes of interest.

VII. Microbial Reduction Techniques

Suggestions for consideration:

"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*."* ASTA may wish to reword.

"Microbial reduction can also be achieved by heat without steam with certain technologies." Dry heat generally will not produce a 5-log reduction of heat-resistant salmonellae without significantly impacting product quality.

VIII. Product and Environmental Testing

Suggestions for consideration:

"Product testing alone is not a reliable means for assuring the absence of microbial pathogens." **Thank you!**

It is not unusual to receive reconditioning proposals that rely almost exclusively on post-treatment end-product testing as the "validation" that the treatment was effective. Greater justification of treatment effectiveness is needed than end-product testing.

VIII. Product and Environmental Testing

Suggestions for consideration:

There may be some confusion on environmental sampling with sponges and swabs (pages 30 and 31).

Use of sponge or swab is independent of zone. Use sponges in any zone for large flat surfaces, and swabs for cracks and crevices in zones 1, 2, 3 or 4.

IX. Summary and Conclusions

Suggestions for consideration:

We strongly support ASTA's summary and conclusions, especially as related to supplier approval programs, treatment validation, post-process product sampling, and establishing a robust environmental monitoring program.

Thank you!