FDA'S DRAFT RISK PROFILE ON PATHOGENS AND FILTH IN SPICES

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AGENDA

- Overview
  - Why FDA Conducted the DRP
  - Risk Profiles v. Risk Assessments
- FDA's Key Conclusions
- Scientific Assessment
- ASTA's Comments
- FDA Meeting Takeaways
- What's Next
- Recommendations for ASTA Members

BACKGROUND

- FDA was concerned about new evidence that questioned the effectiveness of current control measures for spices
  - Recent outbreaks also put spices on FDA's radar
- The DRP provides information for FDA to use in the future development of plans for reducing the risk of illness from spices contaminated by microbial pathogens and/or filth

BACKGROUND

- The objectives of the DRP were to:
  - (1) identify the most commonly occurring microbial hazards and filth in spices to understand the public health risk
  - (2) describe and evaluate current mitigation and control options
  - (3) identify potential additional mitigation and control options and
  - (4) identify critical data gaps and research needs

RISK PROFILE V. RISK ASSESSMENT

- FDA is conducting similar assessments on:
  - *Listeria monocytogenes* in retail delicatessens,
  - *Salmonella* in tree nuts, and
  - Arsenic in apple juice
- These assessments will function as preliminary guidance for each industry regarding the preventive controls that should be implemented under FSMA
- The DRP on spices is the first to use the qualitative approach rather than the quantitative approach but the end goal is the same

FDA'S KEY CONCLUSIONS

- Potential adulteration of spices arises from poor or inconsistent application of appropriate preventive controls, such as:
  - failing to limit animal access to the spice source plant during the harvest or drying phases,
  - failing to limit insect and rodent access to spices during storage, or
  - failing to subject all spices to an effective pathogen reduction treatment.
- Identified mitigation and control options include capacity building, guidance, enforcement, communication, education, and training.

SCIENTIFIC ASSESSMENT OF THE DRP

1. The majority of the data represents spices before any mitigation treatments have been applied
   a. FDA sampled at the port of entry, or shortly thereafter
   b. Most spices are subjected to microbial reduction treatments, or used in multi-component foods which undergo treatment
   c. FDA sampled 2844 individual lots of spices, 187 of which were positive (6.58% +)
   d. Of the 2844 lots, 137 (4%) had been subjected to a pathogen reduction treatment, 4 were positive

SCIENTIFIC ASSESSMENT OF THE DRP

2. Spices have been associated with very few foodborne disease outbreaks and recalls
   a. 3 outbreaks associated with spices between 1973 and 2010
   b. CDC reported 13,405 outbreaks between 1998 and 2008
   c. Spices would account for only 0.02% of the outbreaks
   d. Note: FDA gives undue emphasis on two recent outbreaks that occurred close in time to each other (black pepper / white pepper – 2009 – 2010)

SCIENTIFIC ASSESSMENT OF THE DRP

3. The laboratory methodology to analyze spices for microbial contamination should be reviewed to assure that the accuracy and precision are the best available
   a. Analysis only gives presence or absence
   b. From a risk standpoint, the number of Salmonellae present are important (1 per 375 grams vs 100 per gram)
   c. Some spices have anti-microbial properties which may interfere with the analysis

SCIENTIFIC ASSESSMENT OF THE DRP

4. A quantitative risk assessment of the potential burden of foodborne illness from spices is needed to provide additional information and perspective
   a. A quantitative risk assessment would address the “true” risk of spices
   b. Would incorporate the impact of microbial reduction treatments at various stages

SCIENTIFIC ASSESSMENT OF THE DRP

5. There is essentially no difference in the risk of illness between a 3 $\log_{10}$ and a 5 $\log_{10}$ microbial mitigation process as applied to spices, based on the "worst case" data from the DRP
   a. Using FDA's data and basic assumptions on consumption
   b. A 3 $\log_{10}$ intervention would mean that 211 Americans, out of 317 million, would be exposed to a single salmonellae cell in the course of a year
   c. A 5 $\log_{10}$ intervention would mean that 2 Americans, out of 317 million, would be exposed to a single salmonellae cell in the course of a year

SUMMARY OF ASTA'S COMMENTS

- Risk characterization
- FDA's focus on import data
- Microbial reduction treatment
- Data gaps
- Quantitative risk assessment

1. THE DATA SUPPORT A LOWER RISK LEVEL

- The outbreak data and recall data cited in the DRP simply do not support the conclusion that spices present as high of a risk as FDA suggests.
  - FDA's own data show that spices accounted for less than 1% of all outbreaks and recalls associated with *Salmonella* in food.
    - 3 outbreaks in the US between 1973 to 2010
    - 11 outbreaks in other countries
    - 14 outbreaks attributable to spices in 37 years
  - This very low rate of outbreaks and recalls reinforces that the spices consumers eat have a much lower risk level than suggested by FDA

2. THE IMPORT DATA DO NOT REPRESENT THE SPICES CONSUMERS ACTUALLY EAT

- FDA considers data for all imported spices rather than the relevant subset of only imported spices that have already been processed and treated and are ready for consumers to eat.
- Many imports will be further treated domestically
- FDA should sample spices at other steps in the production chain—after treatment and prior to consumption—to properly assess risk
- Major data gap regarding the prevalence of *Salmonella* in spices as sold at retail

3. FDA SHOULD ESTABLISH IMPORT PRODUCT CODES FOR TREATED SPICES

- FDA lacks a way to focus its import inspection and testing resources in a risk-based manner.
- Simple change on FDA's part
- FDA could target inspection efforts to RTE products
- Consistent with the foreign supplier verification program (FSVP) proposed rule

4. MICROBIAL REDUCTION TREATMENT (KILL STEP)

- Spices need to be safe and free of *Salmonella*
- FDA should therefore encourage spices to be subject to effective microbial reduction treatment
- Effectiveness should be established by proper validation
- FDA should issue validation guidance based on the ASTA whitepaper
- Manufacturers should be given the discretion to determine whether they have products for which a kill step will not add value for food safety

5. ADDITIONAL RESEARCH NEEDS

- FDA should determine *Salmonella* prevalence
  - at retail
  - at the food processor level
  - at spice processing facilities after treatment
- FDA testing needs to be directed to spices when they are RTE, not before they undergo treatment

6. QUANTITATIVE RISK ASSESSMENT

- FDA should conduct a full quantitative risk assessment for spices, as it has done for other commodities
- The current qualitative approach does not provide adequate quantitation to support FDA's conclusions or provide necessary information, such as the appropriate level of mitigation for spices
- FDA should fill important data gaps and then reevaluate the risk posed by RTE spices, using a quantitative risk assessment.

FDA MEETING TAKEAWAYS

- FDA is not going to change its view that spices are a higher risk food
- Some members of the agency support a quantitative assessment, others do not
- The agency is open to exploring ways to facilitate the import process
- Strong emphasis on validated treatment for all spices – FDA does not agree that some spices have adequate antimicrobial properties to avoid the need for treatment

WHAT'S NEXT?

- FDA will consider comments and work toward a final risk assessment
- Retail study underway
- ASTA will continue to engage with FDA
- Overlap with FSMA implementation
  - Validation

RECOMMENDATIONS FOR ASTA MEMBERS

- Validate
  - Microbial reduction methods
- Sampling and Testing
  - Consistent with FDA methods
- Distribution data on spices
  - Interventions, directly or indirectly applied
  - Further processing vs. retail
- Prevalence of Salmonella
  - As RTE or at retail

PRACTICAL ASPECTS

- Validated Microbial Reduction Treatment
  - Current research projects to develop validation methodologies sponsored by International Life Science Institute and ASTA are underway
    - Will result in the identification of surrogate organisms to use for process validation
  - Dr. Anderson, Tuesday 11:00-Noon
- Sampling and Testing Consistent with FDA

FDA SAMPLING AND TESTING

- **Food Category II.** - Foods that would not normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption

- 30 analytical units for Category II foods, and 15 analytical units for Category III foods. Individual 25 g analytical units may be combined into 375 g composites

- Two, 375g composite samples

FDA SAMPLING AND TESTING

- **Bacteriological Analytical Manual (BAM)**
- http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm

- **Chapter 1**
  Food Sampling and Preparation of Sample Homogenate

FDA SAMPLING AND TESTING

- Chapter 5
  Salmonella

- Appendix 1 Rapid Methods for Detecting Foodborne Pathogens

CONCLUSIONS

- Risk does not appear to be as great as FDA states
- Additional data required closer to the point of consumption
- A quantitative risk assessment would clarify issues
- Strong emphasis on treatment and validation
- Industry sampling plans need to be consistent
- Laboratory methods need to be improved

QUESTIONS?