FDA's Risk Profile:
Pathogens & Filth in Spices

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Concerns

The effectiveness of current control measures to reduce or prevent illness from spices have been renewed by recent events

- 2009 Outbreak of *Salmonella* Rissen illness *linked to imported ground white pepper*
- 2010 Outbreak of *Salmonella* Montevideo illness linked to black and red pepper products
- 19% of *Salmonella* Primary Reportable Foods Registry Entries are Spices and Seasonings

What is a Risk Profile?

A science-based document that…

1) Describes the current state of knowledge about a specific food safety problem or issue

2) Provides an evaluation of the data and information to support current interventions or new approaches to reduce or prevent illnesses

Ref: Codex Alimentarius Commission, 19th Procedural Manual, *http://www.codexalimentarius.net/web/ procedural_manual.jsp*, accessed April 13, 2010

What is a Risk Profile (cont.)?

A science-based document that….

Provides qualitative answers to questions about the hazard and options for controlling it, based on available data

Current Risk Profile Efforts

- Hepatitis A Virus in Produce
- Transmission of Norovirus
- Listeria in Fresh Produce
- Pathogens in Raw-Milk Cheese
- Pathogens and Filth in Spices

Spice Risk Profile Objectives

1. Describe the nature and extent of the public health risk by identifying the most commonly occurring microbial & filth hazards in spices

2. Describe and evaluate current mitigation & control options

3. Identify potential additional mitigation or control options

4. Identify research needs and data gaps

Questions to be Answered

- What is known about the frequency and levels of pathogen and/or filth contamination of spices throughout the food supply chain (e.g., on the farm, at primary processing/manufacturing, intermediary processing (where spices are used as ingredients in multi-component products), distribution (including importation), retail sale/use, and the consumer's home)?

- What is known about differences in production and contamination of imported and domestic spices?

Questions cont.

- What is known about the effectiveness, cost, and practicality of currently available and potential future interventions to prevent human illnesses associated with pathogen and/ or filth contamination of spices (e.g., practices and/or technologies to reduce or prevent contamination, surveillance, inspection, import strategies, or guidance)?

- What are the highest priority research needs related to prevention or reduction of pathogens and/or filth in spices?

Scope: Spices

Any aromatic vegetable substances in the whole, broken, or ground form whose significant function in food is seasoning rather than nutritional, and from which no portion of any volatile oil or other flavoring principle has been removed.

Scope: Pathogens & Filth

- Microbiological pathogens and filth in spices that are identified in the published literature, outbreaks, recalls, and submissions to the Reportable Food Registry (RFR).

- Filth = “Extraneous Materials” for the purposes of this risk profile:
  - ‘‘any foreign matter in a product associated with objectionable conditions or practices in production, storage, or distribution

    * * * [including] objectionable matter contributed by insects, rodents, and birds; decomposed material; and miscellaneous matter such as sand, soil, glass, rust, or other foreign substances.’’

    [Food and Drug Administration Defect Action Levels Handbook]

Risk Profile Process

1. Commission the profile.
2. Data and information gathering, analysis and evaluation.
3. Report development and review.
4. Issue report.

Education & Outreach

Some examples:

- Meetings with trade organizations such as ASTA
- Federal Register Notice
- Site visits to growers, treatment facilities and processors (foreign & domestic)

Federal Register Notice:
Requesting Data & Information

1) Data, including unpublished data, on the incidence of contamination in spices
2) Factors that influence the survival, growth, and levels of pathogens
3) Consumption patterns (including serving size and frequency) in the United States.
4) Intended use (e.g., ready-to-eat, ingredient in a prepared food).
5) Manufacturing practices, including the use of spices as ingredients in prepared foods.

Federal Register Notice:
Requesting Data & Information

6) Data, including unpublished data, on the identity & effectiveness of control measures or interventions to reduce levels and frequency of pathogens and/or filth in spices during growing, harvesting, processing, manufacturing, packaging, storage, and transportation prior to retail sale.

7) Data relating to supplier specifications including required treatments, performance standards, microbial testing, and audit programs.

8) Any other data related to the occurrence and control of pathogens and/or filth in spices that are applicable to the risk profile.

Responses to FRN

- 4 Trade Associations
  - ASTA, NSMA, CFA, USPC
- 2 Individual Companies
  - Spice, Treatment
- 1 Citizen

What we have learned

- Spice Farms can very small (<1 acre); “lots” may contain products from tens of thousands of farms
- Drying out-of-doors is common; storage can be for years
- *Salmonella* can survive in the low moisture environment of spices
- Wide diversity of *Salmonella* serotypes are found in spices
- Single spice vehicle can be contaminated with multiple *Salmonella* strains

What we have learned, cont.

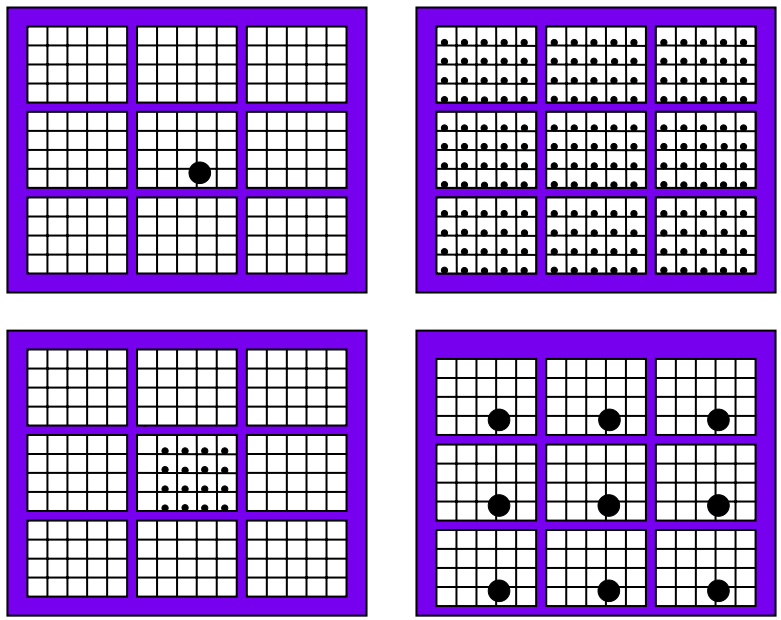
- Despite small “serving size”, pathogen loads can be sufficient to cause illness
- Spices are widely dispersed in the US food supply
- Identifying “outbreaks” arising from spice-contamination & identifying spice as the food vehicle is extremely difficult
- Application of Current Control & Prevention Strategies are insufficient to prevent consumer exposure to & illness from contaminated spices

How will FDA Use the Risk Profile?

- FDA has adapted this tool as a new approach to assist the agency in its regulatory decision making.
- The information in a risk profile may affect a range of decisions, such as whether or not to commission a quantitative risk assessment or a request for research, or whether or not to implement an immediate and/or provisional regulatory decision.
- In some cases, it may reveal that no further action is needed.

Challenges

- What log reduction is required to assure safety of initially contaminated spices?
  - How is contamination distributed – typical & outbreak?
  - What is the typical range of *Salmonella* (MPN/g) in contaminated spices?



Challenges

- How effective are pathogen reduction treatments and which factors influence the efficiency?
  - How do the levels of *Salmonella* differ before and after treatment?
  - Does grinding and other processes influence the level/distribution of contamination?

- Which spices pose the greatest risk for illness and which sub-populations are at greatest risk?
  - Which spices have the largest frequency of *Salmonella* or filth contamination
  - Which spices are commonly eaten raw (or “flash cooked”)?
  - Which cuisines & types of foods typically feature uncooked spices?

How can we engage industry to help answer these questions?

QUESTIONS