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FDA Perspectives on Spices

The 38th Session of the International Pepper Community, November 8-12, 2010

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Outline

- Why the concern about spices
 - Outbreaks, sampling results, Reportable Food Registry
- Spice risk profile
 - Call for data and information
 - What we have learned so far
- Recent rulemaking initiatives
 - cGMP modernization
 - Produce safety

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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
- High violation rates for samples of spices taken at the border

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Challenges of Globalization

Globalization has fundamentally changed the environment for regulating food; it has created unique regulatory challenges for U.S. FDA

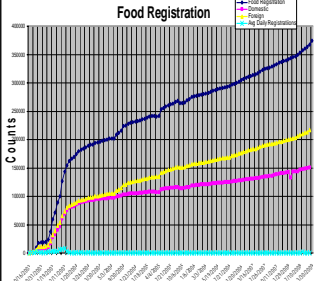
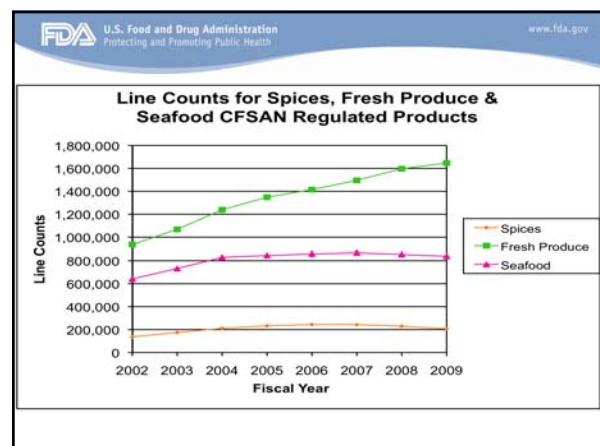
- More foreign food facilities supplying the U.S.
- Increasing volume of imported food products
- More outsourcing of food manufacturing
- Greater complexity in food supply chains
- Imports of food products coming from countries with less well developed regulatory systems, and
- Greater opportunities for economic fraud


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U.S. Import Entry Trends Relative to Foods


Registered food facilities (Foreign facilities in yellow)

- There are over 220,000 registered foreign food facilities
- Over 200 countries/territories export to the U.S. to 300 ports
- 15 -20% of U.S. foods consumed originate from other countries
 - 80% of seafood
 - 35% of produce
 - 60% of spices





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FDA Spice Sampling: Calendar Years 2008, 2009, 2010: “All” Contaminants			
Calendar Year	Total Spice Samples ¹	Total Lab Class “3” ²	AFR ³
2008	1233	92	7.5%
2009	1666	93	5.6%
2010 ⁴	2515	187	7.4%


¹ Industry Code 28 (does not include spices under vegetable or edible seed codes), Class A or B only (whole, cracked or ground, does not include extracts or mixed seasonings, etc.); all contaminant categories included
² Lab Class 3= adverse finding
³ Adverse findings rate
⁴ Thru early November 2010

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FDA Spice Sampling: Calendar Years 2008, 2009, 2010: “Micro” Contamination			
Calendar Year	Total Spice Samples ¹	Total Lab Class “3” ²	AFR ³
2008	894	56	6.3%
2009	995	41	4.1%
2010 ⁴	1438	83	5.8%


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FDA Spice Sampling: Calendar Years 2008, 2009, 2010: “Filt” Contamination			
Calendar Year	Total Spice Samples ¹	Total Lab Class “3” ²	AFR ³
2008	167	15	9.0%
2009	229	19	8.3%
2010 ⁴	510	45	8.8%

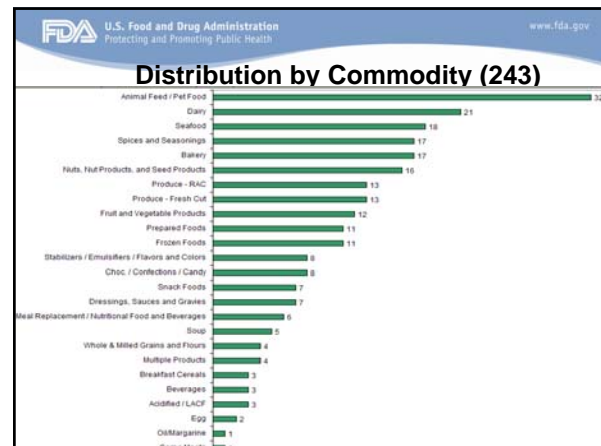
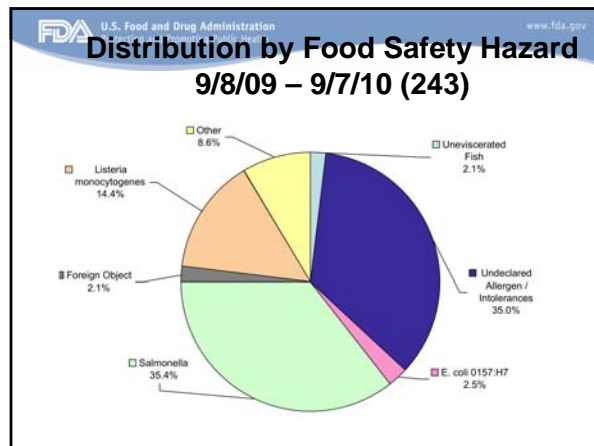
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³ Adverse findings rate
⁴ Thru early November 2010

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FDA Spice Sampling: Calendar Years 2008, 2009, 2010: “Pesticide” Contamination			
Calendar Year	Total Spice Samples ¹	Total Lab Class “3” ²	AFR ³
2008	41	6	14.6%
2009	64	8	12.5%
2010 ⁴	137	32	23.4%

¹ Industry Code 28 (does not include spices under vegetable or edible seed codes), Class A or B only (whole, cracked or ground, does not include extracts or mixed seasonings, etc.)
² Lab Class 3= adverse finding
³ Adverse findings rate
⁴ Thru early November 2010

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FDAAA of 2007 – Section 1005	
<ul style="list-style-type: none"> 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 portable by which instances of reportable food may be submitted 	

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FDAAA §1005 Reportable Food Registry (RFR)	
<ul style="list-style-type: none"> “<u>Reportable food</u>” – an article of food for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals 	



Distribution of 243 Primary RFR Entries by Commodity and Food Safety Hazard (243)

	E. coli O157:H7	Foreign Object	Listeria monocytogenes	Other	Salmonella	Undeclared Allergen / Intolerances	Unvisceralized Fish	Grand Total
Acidified LACF				1		2		3
Animal Feed / Pet Food		5		14	13			32
Bakery	1			1		15		17
Beverages				1	1			2
Breakfast Cereals					1	2		3
Choc / Confections / Candy					1	7		8
Dairy			9	1	2	5		17
Dressings, Sauces and Gravies	1					5		7
Egg				1	1			2
Frozen Foods			4		3	4		11
Fruit and Vegetable Products			2			9		11
Game Meats	1							1
Meal Replacement / Nutritional Food and Beverages			1		5			6
Multiple Products			1	1	2			4
Nuts, Nut Products, and Seed Products			1		12	3		16
OckMargarine						1		1
Prepared Foods			2			9		11
Produce - Fresh Cut	2		5	1	5			13
Produce - RAC					13			13
Seafood			9	2		2	5	16
Snack Foods					1	8		9
Soup						5		5
Spices and Seasonings					16	1		17
Stabilizers / Emulsifiers / Flavors and Colors					5	2		7
Whole & Milled Grains and Flours	1							1
Grand Total	6	6	18	14	35	35	6	243

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
- Routes of Transmission of Norovirus
- Listeria in Fresh Produce
- Pathogens in Raw-Milk Cheese
- Pathogens and Filth in Spices

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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

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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.

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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]

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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?

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Questions, cont'd

- 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?

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Risk Profile Process

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

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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.

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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.

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Responses to FRN

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

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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

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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

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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.

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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?

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Responsibility & Accountability

All entities involved in food production and distribution must take responsibility for assuring safe foods. This includes:

- Foreign Governments
- Growers
- Manufacturers/Processors
- Holders/Distributors and Transporters
- Importers and Consignees

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Produce Safety

- Despite measures such as the GAPs guidance, fresh-cut guidance and other measures, foodborne outbreaks associated with fresh produce continue to occur.
- To reduce the prevalence of produce associated disease, FDA has determined that science-based, enforceable standards, in conjunction with commodity-specific guidance on good agricultural practices are needed.
- *“Our long-term plan is to set enforceable produce safety standards through a regulation.”*

Michael R. Taylor, J.D., Deputy Commissioner for Foods U.S. FDA, before the subcommittee on domestic policy, committee on oversight and government reform, U.S. House of Representatives. JULY 29, 2009

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Produce Regulation Input

- Established public docket – February 2010 (75 FR 8086)
- Participating in regional listening sessions and other engagements

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Food cGMP Regulations

- Current Good Manufacturing Practice (cGMP) regulations (21 CFR Part 110) last revised in 1986
- Many changes have occurred in the food industry since 1986
 - Increased availability of RTE foods, refrigerated prepared foods, heat-and-serve foods
 - Better understanding of foodborne illness, pathogens, allergens

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Food cGMP White Paper

- In 2005, FDA published a White Paper titled “Food cGMP Modernization – A focus on Food Safety”
- White Paper summarizes public comments and details FDA's key findings
- White Paper available at: <http://www.cfsan.fda.gov>

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White Paper: Opportunities for Modernization include...

- Require training for supervisors and workers
- Require a written allergen control plan for processors that produce foods containing a major food allergen
- Require a written environmental pathogen control plan for processors of ready-to-eat foods that support growth of *Listeria monocytogenes*

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White Paper: Opportunities for Modernization (cont.)

- Require that processors develop and maintain written sanitation procedures, at a minimum, for all food contact equipment and food contact surfaces
- Require that food processors maintain certain critical records and that these be made available for review and evaluation by FDA investigators to confirm compliance with GMPs.
- Further comments requested on use of time-temperature relationships for proper refrigerated storage or hot holding

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QUESTIONS