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Is FDA's Spice Risk Profile Good News or Bad News for the Spice Industry?

American Spice Trade Association

2018 Annual Meeting

April 16, 2018

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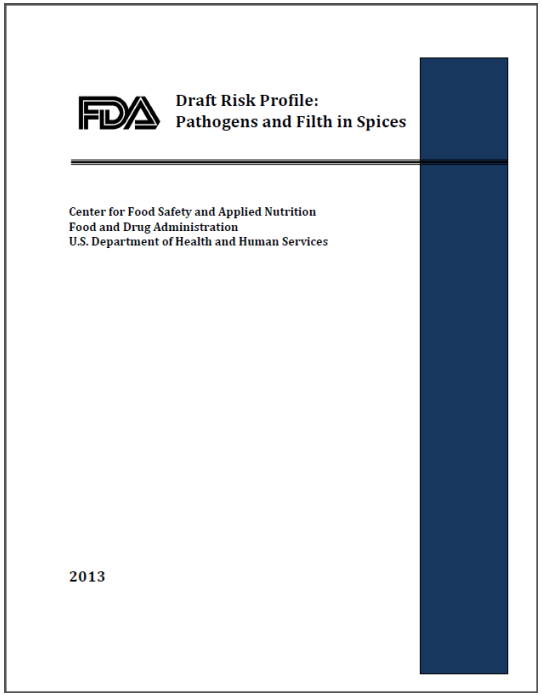
Agenda

- FDA's 2013 Draft Risk Profile for Spices
- ASTA's Comments
- FDA's 2017 Update to the Draft Risk Profile
- Results of FDA's Retail Study
- Recommendations for ASTA Members



FDA's Draft Risk Profile for Spices

- Issued by FDA in October 2013
- FDA was concerned about the effectiveness of control measures for spices
- FDA's objectives:
  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
- Followed a qualitative approach

Key DRP Conclusions

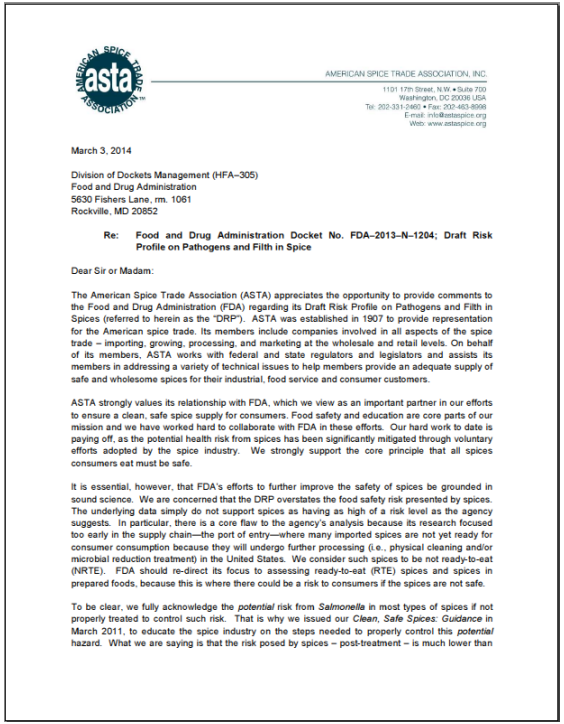
- The overall prevalence of *Salmonella*-contaminated shipments of imported spices was 6.6% for FY2007-FY2009
- This value is 1.9 times the prevalence found for other shipments of FDA-regulated foods examined during the same period
- *Salmonella* was found in shipments of many different types of spices, in a variety of forms (whole, cracked, ground or blended) and from many different countries
- FDA concluded that the presence of *Salmonella* is a general problem in the spice supply chain rather than a problem of a specific type/form of spice or source country

Key DRP Conclusions

- Food safety issues occur due to poor or inconsistent application of appropriate preventive controls, such as:
  - Failing to limit animal access to the spice source plant during harvest and drying
  - Failing to limit insect and rodent access to spice during storage
  - Failing to subject all spice to an effective pathogen reduction treatment (or other lethality step)
- Knowledge and technology are available to significantly reduce the risk of illness from consumption of contaminated spices in the United States
- Enhanced communication between FDA and the spice industry and within the spice and food manufacturing industry itself, combined with training across the spice supply chain, are needed to ensure understanding of appropriate preventive controls and how to implement and maintain them

ASTA's Comments on the DRP

- The DRP overstates the food safety risk presented by spices
- FDA's research focused too early in the supply chain – on the point of entry – where many imported spices are not yet ready for consumer consumption because they will undergo further processing in the U.S.
  - i.e., FDA's data were on NRTE spices
- FDA should instead assess RTE spices by assessing *Salmonella* rates in spices at retail, the food processor level, and spice processing facilities post-treatment



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March 3, 2014

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Food and Drug Administration Docket No. FDA–2013–N–1204; Draft Risk Profile on Pathogens and Filth in Spice

Dear Sir or Madam:

The American Spice Trade Association (ASTA) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) regarding its Draft Risk Profile on Pathogens and Filth in Spices (referred to herein as the "DRP"). ASTA was established in 1907 to provide representation for the American spice trade. 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 members provide an adequate supply of safe and wholesome spices for their industrial, food service and consumer customers.

ASTA strongly values its relationship with FDA, which we view as an important partner in our efforts to ensure a clean, safe spice supply for consumers. Food safety and education are core parts of our mission and we have worked hard to collaborate with FDA in these efforts. Our hard work to date is paying off, as the potential health risk from spices has been significantly mitigated through voluntary efforts adopted by the spice industry. We strongly support the core principle that all spices consumers eat must be safe.

It is essential, however, that FDA's efforts to further improve the safety of spices be grounded in sound science. We are concerned that the DRP overstates the food safety risk presented by spices. The underlying data simply do not support spices as having as high of a risk level as the agency suggests. In particular, there is a core flaw to the agency's analysis because its research focused too early in the supply chain—the port of entry—where many imported spices are not yet ready for consumer consumption because they will undergo further processing (i.e., physical cleaning and/or microbial reduction treatment) in the United States. We consider such spices to be not ready-to-eat (NRTE). FDA should re-direct its focus to assessing ready-to-eat (RTE) spices and spices in prepared foods, because this is where there could be a risk to consumers if the spices are not safe.

To be clear, we fully acknowledge the *potential* risk from *Salmonella* in most types of spices if not properly treated to control such risk. That is why we issued our *Clean, Safe Spices: Guidance* in March 2011, to educate the spice industry on the steps needed to properly control this *potential* hazard. What we are saying is that the risk posed by spices – post-treatment – is much lower than

FDA's Spice Retail Study

- Following ASTA's recommendation, FDA conducted a survey to evaluate *Salmonella* prevalence and aerobic plate counts in packaged (dried) spices offered for sale at retail establishments in the U.S.
- Preliminary results shared with ASTA in May 2014
  - 0.5% positive rate
  - FDA acknowledged that results were skewed by focusing on spices with problems in the past
- ASTA sent follow-up letter to FDA and responded to FDA questions about lack of correlation between APC counts and positive *Salmonella* findings
  - Dr. Jim Dickson prepared an analysis explaining that no such relationship is to be expected

FDA Q&A – Signs of Progress

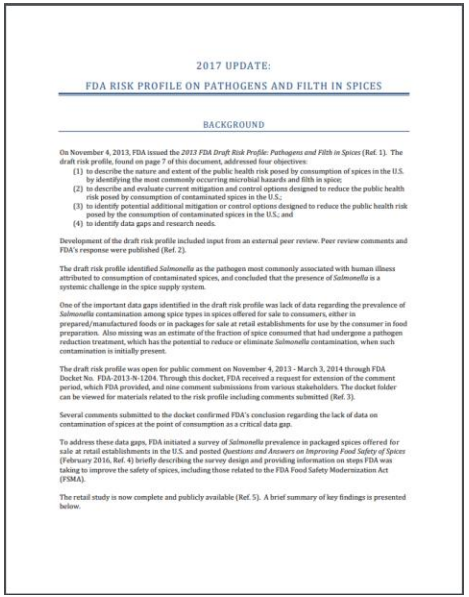
- In February 2016, FDA posted "Questions & Answers on Improving the Safety of Spices"
- "Because many imported spices are treated after entry to the U.S. to reduce contamination before they are sold to consumers, we knew that the 6.6 percent contamination rate found at the import level did not reflect what was actually reaching consumers. We needed retail data to better evaluate the true risk to consumers."
- "The FDA is not recommending that consumers change their consumption or use of spices."

FDA's Update to the DRP

- In February 2018, FDA released an update to the 2013 DRP on spices, which was based on the results of its retail study
- The FDA collected data on the presence of *Salmonella* in 11 types of packaged, dried spices offered for retail sale
- Except for dehydrated garlic and basil, *Salmonella* prevalence was significantly LOWER in retail samples than estimated prevalence for shipments of imported spice offered for entry to the U.S.
- FDA acknowledged that the findings are consistent with public comments from the domestic food industry that responsible manufacturers apply a pathogen reduction treatment to many spices after entering the U.S., prior to retail sale.

Updated DRP

- "The results of this study are consistent with the assumption that most (bulk) shipments of spice undergo a pathogen reduction treatment following entry to the United States and prior to releasing for retail sale, as recommended in industry guidance such as the "Clean, Safe, Spices Guidance Document" by American Spice Trade Association (Ref. 12)."
- "Considering the regulatory changes instituted through the FDA- FSMA, and the new information provided in the study described above, the Agency concludes that with this update, the Risk Profile on Pathogens and Filth in Spices is final at this time."



2017 UPDATE:

FDA RISK PROFILE ON PATHOGENS AND FILTH IN SPICES

BACKGROUND

On November 4, 2013, FDA issued the *2013 FDA Draft Risk Profile: Pathogens and Filth in Spices* (Ref. 1). The draft risk profile, found on page 7 of this document, addressed four objectives:

(1) to describe the nature and extent of the public health risk posed by consumption of spices in the U.S. by identifying the most commonly occurring microbial hazards and filth in spice;
(2) to describe and evaluate current mitigation and control options designed to reduce the public health risk posed by consumption of contaminated spices in the U.S.;
(3) to identify potential additional mitigation or control options designed to reduce the public health risk posed by the consumption of contaminated spices in the U.S.; and
(4) to identify data gaps and research needs.

Development of the draft risk profile included input from an external peer review. Peer review comments and FDA's response were published (Ref. 2).

The draft risk profile identified *Salmonella* as the pathogen most commonly associated with human illness attributed to consumption of contaminated spices, and concluded that the presence of *Salmonella* is a systemic challenge in the spice supply system.

One of the important data gaps identified in the draft risk profile was lack of data regarding the prevalence of *Salmonella* contamination among spice types in spices offered for sale to consumers, either in prepared/manufactured foods or in packages for sale at retail establishments for use by the consumer in food preparation. Also missing was an estimate of the fraction of spice consumed that had undergone a pathogen reduction treatment, which has the potential to reduce or eliminate *Salmonella* contamination, when such contamination is initially present.

The draft risk profile was open for public comment on November 4, 2013 - March 3, 2014 through FDA Docket No. FDA-2013-N-1204. Through this docket, FDA received a request for extension of the comment period, which FDA provided, and nine comment submissions from various stakeholders. The docket folder can be viewed for materials related to the risk profile including comments submitted (Ref. 3).

Several comments submitted to the docket confirmed FDA's conclusion regarding the lack of data on contamination of spices at the point of consumption as a critical data gap.

To address these data gaps, FDA initiated a survey of *Salmonella* prevalence in packaged spices offered for sale at retail establishments in the U.S. and posted *Questions and Answers on Improving Food Safety of Spices* (February 2016, Ref. 4) briefly describing the survey design and providing information on steps FDA was taking to improve the safety of spices, including those related to the FDA Food Safety Modernization Act (FSMA).

The retail study is now complete and publicly available (Ref. 5). A brief summary of key findings is presented below.

Retail Study Findings

- 7,250 retail samples of 11 spice types were collected between 2013 and 2015
- FDA's key findings from the retail study were published as a peer-reviewed scientific journal article:
  - "Prevalence of Salmonella in eleven spices offered for sale from retail establishments and in imported shipments offered for entry to the United States disclaimer icon."
  - *Journal of Food Protection*, Vol. 80, No. 11, 2017, Pages 1791–1805

Journal of Food Protection, Vol. 80, No. 11, 2017, Pages 1791–1805
doi:10.4315/0362-028X.JFP-17-072
Published 2017 by the International Association for Food Protection
This is an open access article

Research Paper

Prevalence of *Salmonella* in 11 Spices Offered for Sale from Retail Establishments and in Imported Shipments Offered for Entry to the United States

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MS 17-072: Received 17 February 2017/Accepted 13 June 2017/Published Online 4 October 2017

ABSTRACT

The U.S. Food and Drug Administration conducted a survey to evaluate *Salmonella* prevalence and aerobic plate counts in packaged (dried) spices offered for sale at retail establishments in the United States. The study included 7,250 retail samples of 11 spice types that were collected during November 2013 to September 2014 and October 2014 to March 2015. No *Salmonella*-positive samples (based on analysis of 125 g) were found among retail samples of cumin seed (whole or ground), sesame seed (whole, not roasted or toasted, and not black), and white pepper (ground or cracked), for prevalence estimates of 0.00% with 95% Clopper and Pearson's confidence intervals of 0.00 to 0.67%, 0.00 to 0.70%, and 0.00 to 0.63%, respectively. *Salmonella* prevalence estimates (confidence intervals) for the other eight spice types were 0.19% (0.0048 to 1.1%) for basil leaf (whole, ground, crushed, or flakes), 0.24% (0.049 to 0.69%) for black pepper (whole, ground, or cracked), 0.56% (0.11 to 1.6%) for coriander seed (ground), 0.19% (0.0049 to 1.1%) for curry powder (ground mixture of spices), 0.49% (0.10 to 1.4%) for dehydrated garlic (powder, granules, or flakes), 0.15% (0.0038 to 0.83%) for oregano leaf (whole, ground, crushed, or flakes), 0.25% (0.03 to 0.88%) for paprika (ground or cracked), and 0.64% (0.17 to 1.6%) for red pepper (hot red pepper, e.g., chili, cayenne; ground, cracked, crushed, or flakes). *Salmonella* isolates were serotyped, and genomes were sequenced. Samples of these same 11 spice types were also examined from shipments of imported spices offered for entry to the United States from 1 October 2011 to 30 September 2015. *Salmonella* prevalence estimates (based on analysis of two 375-g composite samples) for shipments of imported spices were 1.7 to 18%. The *Salmonella* prevalence estimates for spices offered for sale at retail establishments for all of the spice types except dehydrated garlic and basil were significantly lower than estimates for shipments of imported spice offered for entry.

Key words: Import; Prevalence; Retail; *Salmonella*; Serotype; Spice

In 1989, the U.S. Food and Drug Administration (FDA) documented the presence of *Salmonella* in samples of whole black pepper offered for import to the United States, finding four different serotypes in the pathogen-positive samples *(21)*. In 2006, Vij et al. *(37)* reported that *Salmonella* contamination of spices was the cause of 95% of the U.S. food recalls associated with spices in 1969 to 2003. From 2007 to 2010, several foodborne outbreaks in the United States were attributed to consumption of *Salmonella*-contaminated spices and seasonings and led to 457 laboratory-confirmed cases of salmonellosis *(9, 12, 15, 22, 36)*. These outbreaks were associated with consumption of black pepper and red pepper (*Salmonella* serotypes Montevideo and Senftenberg), white pepper (*Salmonella* Rissen), and a seasoning mix consisting of broccoli powder, parsley powder, and other spices (*Salmonella* serotypes Wandsworth and Typhimurium). Since 2010, *Salmonella*-contaminated spices have been continued to be reported to the FDA Reportable Food Registry *(31)*. In 2013, the FDA issued a risk profile on pathogens and filth in spices *(29)* that addressed four objectives: (i) to describe the nature and extent of the public health risk posed by consumption of spices in the United States by identifying the most commonly occurring microbial hazards and filth in spices; (ii) to describe and evaluate current mitigation and control options designed to reduce the public health risk posed by consumption of contaminated spices in the United States; (iii) to identify potential additional mitigation or control options designed to reduce the public health risk posed by the consumption of contaminated spices in the United States; and (iv) to identify data gaps and research needs. This risk profile revealed that *Salmonella* is the pathogen most commonly associated with human illness attributed to consumption of contaminated spices and that the presence of *Salmonella* is a systemic challenge in the spice supply

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Study Findings

TABLE 1. *Estimated* Salmonella *prevalence in 125 g of spices offered for sale at retail establishments*

Spice type[a]	Total no. of samples tested	No. of samples positive for *Salmonella*	*Salmonella* prevalence (%)	Clopper and Pearson's 95% confidence interval (%)
Basil	529	1	0.19	0.0048–1.1
Black pepper	1,264	3	0.24	0.049–0.69
Coriander, grd	543	3	0.56	0.11–1.6
Cumin	549	0	0.00	0.00–0.67
Curry powder, grd	518	1	0.19	0.0049–1.1
Dehydrated garlic, grd	615	3	0.49	0.10–1.4
Oregano	669	1	0.15	0.0038–0.83
Paprika, grd	816	2	0.25	0.030–0.88
Red pepper, grd	633	4	0.64	0.17–1.6
Sesame seed, whole	526	0	0.00	0.00–0.70
White pepper, grd	588	0	0.00	0.00–0.63

Study Findings

TABLE 3. *Presence of* Salmonella *in spices labeled conventional and organic and offered for sale at retail establishments*

Spice type[a]	Conventional		Organic		
	No. sampled	No. positive	No. sampled	No. positive	*P* value[b]
Basil	503	1	26	0	NS
Black pepper	1205	3	59	0	NS
Coriander, grd	442	2	101	1	NS
Cumin	489	0	60	0	NA
Curry powder, grd	443	1	75	0	NS
Dehydrated garlic, grd	548	2	67	1	NS
Oregano	636	1	33	0	NS
Paprika, grd	789	1	27	1	NS
Red pepper, grd	605	4	28	0	NS
Sesame seed, whole	421	0	105	0	NA
White pepper, grd	531	0	57	0	NA

Study Findings

TABLE 5. *Estimated* Salmonella *prevalence in samples from shipments of imported spices offered for entry to the United States*

Spice type[a]	Total no. of samples tested	No. of positive samples	Prevalence (%)	Clopper and Pearson's 95% confidence interval (%)	Prevalence comparison[b]
Basil	20	1	5.0	0.13–25	NS
Black pepper	223	15	6.7	3.8–11	0.0001
Coriander, grd	92	17	18	11–28	0.0001
Cumin	130	11	8.5	4.3–15	0.0001
Curry powder, grd	177	7	4.0	1.6–8.0	0.0004
Dehydrated garlic, grd	59	1	1.7	0.043–9.1	NS
Oregano	78	8	10	4.5–19	0.0001
Paprika, grd	85	3	3.5	0.73–10	0.007
Red pepper, grd	337	36	11	7.6–14	0.0001
Sesame seed, whole	155	12	7.7	4.1–13	0.0001
White pepper, grd	50	3	6.0	1.3–17	0.0005

[a] grd, spice sample was crushed, cracked, granules, flakes, or powder (i.e., not whole). When no form designation is listed, both whole and ground samples were examined.

[b] Comparison at U.S. entry versus retail, Fisher's exact test. NS, not significant.

Study Findings

- "Of particular interest in this study was whether the *Salmonella* prevalence estimates for each spice type at the point of entry to the United States were different from those for the same spice type at the point of retail purchase by U.S. consumers, particularly for the spices where the U.S. supply is overwhelmingly imported . . . . *Salmonella* prevalence in all spice types offered for sale in retail establishments and examined in this study, except dehydrated garlic and basil, was significantly lower than the estimate for imported shipments."
  - FDA also acknowledged that the basil data was impacted by the low number of samples that were collected at entry.

Recommendations for ASTA Members

- Understand the RTE/NRTE status of every ingredient you receive
- Identify imports intended for further processing in a way that signals they are NRTE
- Be prepared for sudden aggravation at the border for imports requiring further treatment domestically
- Implement robust sanitation controls and environmental monitoring program to address potential post-processing contamination
- Validate your lethality process
- Work with legal counsel to develop a strategy for managing import and FSMA issues – attorneys aren't just for when you get into trouble!

Conclusion

- ASTA's engagement with FDA had a significant positive impact on the outcome of the DRP
- The retail study results generally support the proposition that spices sold at retail are safe to eat
  - The study did not assess whether or what type of treatment was applied for retail products
- FDA HQ now understands that imports can be NRTE, but it will take time for this message to get communicated to and applied at the border
- FDA's emphasis will now shift to FSMA implementation – effective treatment and preventing post-processing contamination are critical
  - FSMA inspections have started and rigor will increase with time

Questions?

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