AMERICAN SPICE TRADE ASSOCIATION, INC.
1101 17th Street, N.W. • Suite 700
Washington, DC 20036 USA
Tel: 202-331-2460 • Fax: 202-463-8998
E-mail: info@astaspice.org
Web: www.astaspice.org

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 suggests in the DRP, and that a more accurate assessment of the risk posed by spices should be based on extensive testing at the RTE stage rather than at the point of entry at the U.S. border prior to such treatment. Accordingly, we are recommending that the agency redirect its testing to RTE spices at various stages in the chain and, based on the results of such testing, prepare a quantitative risk assessment. We believe the results of that assessment would reinforce the value of effective treatments for most spices, while characterizing the current risk to American consumers as being much lower than stated in the DRP.

The comments that follow reflect careful consideration by ASTA in consultation with our members, who represent a wide cross-spectrum of industry. Following an executive summary, our comments first provide background information regarding ASTA and the resources we provide to support industry food safety efforts, as well as a discussion of the definition of spices, the spice supply chain, and treatment processes. We then discuss our specific concerns about why we believe the DRP overstates the risk presented by spices and why a quantitative risk assessment is needed. Next we address mitigation strategies and other related issues. Finally, we conclude by discussing additional research we feel is needed to fill key data gaps in the DRP.

To assist with our assessment, we retained an expert consultant, Dr. James Dickson, Professor of the Inter-Departmental Program in Microbiology in the Department of Animal Science at Iowa State University. Dr. Dickson has prepared a scientific review of the DRP that we are attaching as Appendix A to these comments. We reference his assessment throughout these comments to assure the agency that our comments have a sound scientific underpinning.

I. Executive Summary

We are concerned that the DRP does not accurately characterize the true risk presented by spices or the nature of the spice supply chain. Our comments highlight the following points:

- **The underlying data do not support as high of a risk level as FDA suggests.** 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. Indeed, FDA's own data show that spices accounted for less than 1% of all outbreaks and recalls associated with *Salmonella* in food. This very low rate of outbreaks and recalls reinforces that the spices consumers eat have a much lower risk level than suggested in the DRP.

- **The import data FDA relies on are not representative of the spices that 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. Instead, given that 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. In particular, there is a major data gap regarding the prevalence of *Salmonella* in spices as sold at retail.

- **FDA should establish tailored product codes for spices to enable differentiation between imports that have been treated overseas and imports that will be subject to further processing or treatment domestically.** Currently, the agency lacks a way to efficiently focus its import inspection and testing resources in a risk-based manner. This simple change (which could be completed now, before the risk profile is finalized) would

enable FDA to be much more targeted in its inspection efforts at the border by directing its testing to RTE products. Differentiating between treated and untreated spices at the border is consistent with the approach in the foreign supplier verification program (FSVP) proposed rule, which acknowledges if the kill step is to be applied in the U.S., then no supplier verification for pathogen control is needed.

- **FDA should encourage spices to be subject to effective microbial reduction treatment (kill step).** Spices need to be free of *Salmonella* and FDA should therefore encourage spices to be subject to effective microbial reduction treatment (often referred to as a "kill step"). Effectiveness should be established by proper validation, and FDA should issue validation guidance based on the ASTA whitepaper on this subject. Manufacturers should be given the discretion to determine whether they have products for which a kill step will not add value for food safety (e.g., spices with antimicrobial qualities), but in all cases the spice as consumed needs to be safe.

- **Additional research is needed by FDA to fill key data gaps in the DRP.** Specifically, FDA should assess *Salmonella* rates in spices at retail, at the food processor level, and at spice processing facilities after treatment has occurred. FDA testing needs to be directed to spices when they are RTE, not before they undergo treatment steps. Without this key information, there are fundamental gaps in the assessment that provide more questions than answers about spice safety.

- **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, as referenced above, and then reevaluate the risk posed by RTE spices, using a quantitative risk assessment. Our comments and Dr. Dickson's scientific review highlight specific benefits from conducting a quantitative assessment.

We expand on these points, as well as additional risk mitigation strategies suggested in the DRP, in the comments that follow.

II. Background

In this section, we first provide information about the resources ASTA provides to support industry food safety efforts. This is followed by a discussion of the definition of spice, the spice supply chain, and treatment processes.

A. ASTA's Food Safety Activities

ASTA is a leader in ensuring spices are safe. We provide resources to support industry efforts with the goal of ensuring clean, safe spices to consumers. We also use global alliances to reach the entire supply chain. Our most significant efforts to date involved publication of our *Clean, Safe Spices: Guidance* in March 2011. FDA reviewed and provided feedback on the executive summary and an agency expert gave an in-depth evaluation of it from FDA's perspective during our October 2011 Regulatory/Legislative Workshop. A copy of this guidance document is attached to these comments as Appendix B.

We have engaged in extensive outreach to deliver the guidance document to a wide audience. For example, the guidance document was the subject of a pre-conference workshop at the April 2011 ASTA Annual Meeting. There were 119 people in attendance at the workshop, representing 64 companies, including members and non-members. The half day workshop featured an in-depth look at the five key recommendations, and then we engaged in a group exercise and discussion on ways to disseminate the guidance throughout the supply chain. Based on attendee discussion, it was agreed that the best strategy for implementation was to follow a one-up/one-down strategy. That involved pushing the document down to suppliers to ensure they were aware of recommended industry practices and could work with their suppliers to implement these practices. The one-up strategy emphasized the need for spice industry customers to understand industry practices to allow them to ask appropriate questions of their other spice industry suppliers and disseminate information further within the spice industry by having customers expect such practices from all of their suppliers.

The guidance document is available in hard copy from the ASTA office and copies have also been distributed at meetings where it has been profiled. The document is available in its entirely to both members and non-members on the ASTA website, with individuals downloading it required to provide contact information to gain access. Between April 2011 (when the guidance initially was posted on the ASTA website) and November 2013, the *Clean, Safe Spices: Guidance* has been downloaded 1,260 times, 261 times by ASTA members and 999 times by non-members. The non-members include food manufacturers, retailers, laboratories, non-members spice companies, and a wide range of other organizations including state, county, and international government health departments, and academia. Those downloading the document have been located in more than 50 countries, including Egypt, Israel, India, Vietnam, Pakistan, Sri Lanka, and Malaysia. Interest has remained steady, with an average of approximately ten downloads each week.

Representatives of ASTA also have given talks about the guidance document at a wide range of conferences, including the International Association for Food Protection, the Microbiology Committee of the Grocery Manufacturers Association, the International Pepper Community, the World Spice Congress, the National Seasoning Manufacturers Association, the European Spice Association and the Canadian Spice Association. Members of the European and Canadian spice associations have the same suppliers as U.S. companies, and it was felt that having customers around the world asking for the same practices would further serve to underscore their importance. Other audiences have included both suppliers and major food manufacturers to allow ASTA to reach out in line with the one-up/one-down philosophy.

Additional resources prepared by ASTA include the following:

- *Process Validation White Paper*
- *HACCP Guide for Spices and Seasonings*
- *Cleanliness Specifications for Spices, Seeds & Herbs*

Copies of these documents are attached to these comments as Appendices D, E, and E respectively. We also are currently partnering with ILSI North America to fund research on surrogate development.

We are confident that our hard work to date is paying off because the theoretical health risk from spices already has been significantly mitigated through voluntary efforts by the spice industry. Our industry has evolved considerably in recent years, and the types of guidance documents ASTA develops and promotes have helped considerably in this respect. A downward trend in Reportable Food Registry (RFR) filings and inspection citations reflect the success of the spice industry's voluntary efforts:

- FDA's third annual report of RFR reports measures this success by demonstrating a significant decrease in the primary reports filed regarding spices. From September 8, 2011 through September 7, 2012, FDA received 8 primary reports regarding spices, down from 25 primary reports in RFR Year 2 (2010 – 2011) and 17 primary reports in RFR Year 1 (2009 – 2010). Additionally, the proportion of spice-related reports involving *Salmonella* also has decreased, as only 5 of the Year 3 reports concerned *Salmonella* compared to 23 in Year 2 and 16 in Year 1.

- As the DRP reports, based on FDA inspection classifications, less than or equal to 3% of domestic firms that manufacture, pack, or re-pack spices were found to be out of compliance with FDA regulations regarding food safety and sanitation during fiscal years (FYs) 2007 through 2012. Notably, the annual percentage of domestic firms that manufacture, pack, or re-pack spices that were inspected and found to be out of compliance during the years FY 2007 through FY 2012 was not statistically different from the annual percentages for inspections of firms that manufacture, pack, or re-pack other low moisture foods.

ASTA believes that a great extent of these successes is attributable to voluntary industry efforts and adoption of ASTA's guidance documents. We encourage FDA to adopt these successful ASTA programs as agency guidance, so that they are disseminated more expansively from FDA's platform to the broader spice industry beyond ASTA members.

B. Spices, the Supply Chain, and Treatment Processes

ASTA maintains a "spice list" on its website, which explains in detail the scope of foods we consider to be spices.[1] We consider certain dehydrated vegetables, such as granulated or powdered onion and garlic, to be in this category as well because of their use as spices. ASTA considers a "spice" to be an individual commodity, not something that is mixed or blended like a chili or curry powder. Additionally, it is important to recognize that all spices are dried, so they do not include fresh herbs like fresh basil or curly parsley. Moreover, items like alfalfa seeds and angelica are herbal substances that ASTA does not consider spices. Additionally, dehydrated vegetables are not considered spices when they are used primarily for their nutritional benefits. We urge FDA to use a consistent definition of "spice" in the DRP. As discussed further in these comments, we are concerned one of the outbreaks attributed to spices actually did not involve a food that meets the spice definition.

As recognized in the DRP, the supply chain for spices can be complex, spanning long periods of time and many different handlers. Spices are primarily grown outside of the United States and imported into this country. Primary foreign growers may sell to a local buyer or directly to a spice processor/packer. The fact that spices often pass through many different links in the supply chain

[1] The ASTA spice list is available at http://www.astaspice.org/i4a/pages/index.cfm?pageid=3723.

and that manufacturing, processing, distribution, and storage steps can take place at multiple points, underscores the need to focus on the final step(s) in the process that apply the ultimate control over whether the finished food is safe to eat.

The spice industry employs a variety of equipment types and processes to physically clean spices (to ensure they comply with FDA's defect action levels for filth) and reduce the presence of microbial pathogens. Physical cleaning processes include air separators, sifters, spiral gravity separators that separate sticks, stones, hair, insects, and other debris from the spice. The currently used microbial reduction treatments are steam, gamma radiation, ethylene oxide, and propylene oxide.[2]

Some or all of this processing may occur outside of the United States. This means that imported spices are in many different forms, from raw through finished products, and cannot be considered homogeneous. Imports may be RTE or NRTE.[3] Imported RTE spices have been subject to all necessary processing outside of the United States and are intended to be safe for human consumption without any further processing. NRTE spices, in contrast, will require additional processing before they are safe to eat – and are therefore not an appropriate place to devote limited government testing resources.

Within the NRTE category, the spice industry considers spices to either be raw agricultural commodities (RACs)[4] or "ready to use" (RTU). Imported RACs will be cleaned, processed, and subject to microbial reduction treatment domestically before consumption. Imported RTU spices will receive a level of treatment domestically that is commensurate with the needs of any given industrial food customer (e.g., a RTU spice may be cleaned but not subject to microbial reduction because pathogen mitigation will be handled by an industrial customer when the spice is incorporated into another food which receives a kill step). The majority of imported spices are NRTE.

We are concerned that the FDA did not adequately factor some of these issues into its analysis in the DRP. In particular, the complexity of the supply chain and the high frequency of NRTE imports are issues that FDA seems to have overlooked when considering action steps, which we will discuss further in the discussion that follows. FDA should consider the impact of these factors when considering which testing data should properly form the basis of the risk characterization for spices – and, to the extent possible, base any regulatory response on codifying successful industry programs.

III. Spices Present a Lower Risk than Characterized in the DRP

The available data do not establish spices as being as significant a cause of foodborne illness outbreaks or as significant a public health burden as portrayed by FDA. As discussed further in the comments that follow:

[2] We understand the need for validation of microbial reduction treatments under FSMA. ASTA is actively engaged in validation research. We have partnered with ILSI North America to fund research on surrogate development. We encourage FDA to publish validation guidance and to consider ASTA's validation whitepaper (attached as Appendix C to these comments) as this guidance is developed.

[3] Within either of these two product streams, the product can be organic. Organic products must be manufactured in a manner consistent with the requirements of the National Organic Program (NOP), administered by the U.S. Department of Agriculture's Agricultural Marketing Service.

[4] RAC is defined in the Federal Food, Drug, and Cosmetic Act (FFDCA) as "any food in its raw or natural state . . . ." FFDCA § 201(r); 21 U.S.C. § 321(r).

- The data cited in the DRP does not support the conclusion that spices present as high of a risk level as FDA suggests;
- By testing imports that often are NRTE, FDA's sampling of spices focused on too early a step in the production chain and instead sampling should be redirected to RTE spices; and
- FDA should conduct a full quantitative risk assessment, rather than continuing the current qualitative approach.

Our comments support our recommendation for FDA to revise its characterization of spices to be based on prevalence data from RTE spices and spice-containing finished products.

A. The DRP Overstates the Risks Presented by Spices

The data cited in the DRP does not support the conclusion that spices present as high of a risk level as FDA suggests. As discussed below, significantly less than 1% of all outbreaks and food product recalls have been attributed to spices, and the public health burden from spices is not well-established.

First, the information FDA cites demonstrate that only 3 outbreaks in the U.S. have been attributed to spices in 37 years. These involved pepper (2 outbreaks) and broccoli powder (1 outbreak). This is less than 0.02% of total outbreaks during this time. Moreover, ASTA believes that the outbreak involving broccoli powder is not relevant for an assessment of spices. Broccoli powder is a dehydrated vegetable, not a spice, and a dehydrated vegetable in a seasoning blend is not considered a spice on FDA's list of GRAS spices at 21 C.F.R. § 182.10. We also note comments received from a peer reviewer for the DRP noted a concern about this issue, stating:

> I am concerned about the consistency of the definition of "spice" and comparing it with outbreaks, recalls and publications from the industry, other countries and agencies, and from the scientific literature. For example, dried broccoli powder, which is used primarily for its nutritional (health) benefits, does not seem to fit into the definition of "spice" (page 15); however, it is defined as a "spice" in this document and is a contributing factor in a major outbreak of foodborne related illnesses.

The agency's response explained that dehydrated vegetables are considered spices for the DRP "when used as a seasoning." However, in the outbreak at issue broccoli powder was used for its nutritional benefits—not as a seasoning—so this outbreak should be outside of the scope of the Profile. Accordingly, the DRP should only attribute 2 outbreaks to spices in the last 37 years—further reducing the already minute percent of total outbreaks that are attributed to spices to 0.015%. Either way, the percentage of outbreaks in the U.S. associated with spices is well below 1%, and even below one-tenth of 1%.[5]

The DRP also cites several additional outbreaks involving spices that occurred worldwide, boosting the total number of spice-related outbreaks worldwide to 14 in 37 years. The agency does not explain why these other outbreaks are relevant, given that they occurred in countries with different food regulatory regimes, often occurred a long time ago, and the details and validity of attribution to spices is often not available. We are concerned that these foreign outbreaks were only cited because there is insufficient data from U.S. outbreaks to complete the analysis. In our view, the

[5] Appendix A (Scientific Review by Dr. J. Dickson) at 4.

relevance of these other outbreaks is questionable. For example, citing the outbreak of paprika in German potato chips in 1993 is like comparing outbreaks of *E. coli* in meat before and after HACCP was implemented.

Furthermore, for many of the outbreaks cited (both domestic and foreign) specific relevant facts are not identified or are unknown.[6] For example, it is essential to understand whether the spices were treated and, if so, how they were treated in order to pinpoint the weaknesses in the system that led to the outbreak. Without knowing the specific cause of the outbreaks, it is difficult to extrapolate from a very few isolated events to make broader conclusions about the risks presented by spices as a whole.

Second, there have been relatively few recalls for spices in 34 years. If the number of recalls in recent periods is extrapolated over this period, spices would account for only 0.23% of total food recalls during this time – again, less than 1% over a very long period of time.[7]

Third, we also think that the DRP has overestimated the public health burden presented by spices. The DRP estimated the public health burden as about 13,400 cases, although only 457 cases actually were reported between 2007 and 2010. The 13,400 number is just an estimate – not an actual number of consumers that have become ill from spices. FDA should be clear in the DRP that this number is just an estimate so that this figure is not taken out of context.[8]

Notably, the CDC estimates there are approximately 1,027,561 cases of foodborne *salmonellosis* every year and were 4.1 million cases between 2007 and 2010. The percentage of these cases attributable to spices during this time period would be only 1/3 of one percent – or 0.33%.[9] Even then, however, this is just an estimate. The actual number of reported cases is much lower. CDC outbreak data show that spices actually were the cause of 0.16% of the total of 1863 *Salmonella* outbreaks between 1998 and 2011 or 0.26% of all known-source foodborne illness outbreaks during that time period.[10] Consider the number of outbreaks for spices compared with other foods[11]:

[6] *Id.* at 4 - 5.
[7] *Id.* at 10.
[8] *Id.* at 3.
[9] *Id.* at 4 - 5.
[10] Similarly, outbreak data maintained by the Center for Science in the Public Interest only lists three potential outbreaks attributed to spices.
[11] Data source: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx. We have provided the percentages based on either 2 or 3 spice outbreaks, depending on whether the broccoli powder outbreak is considered.

Salmonella Outbreaks in CDC Reports from 1998 to 2011				
Regulatory Agency	Food Type	Number of Outbreaks	Percentage of Known Source Outbreaks (1136 total)[12]	Percentage of All Outbreaks (1863 total)[13]
USDA-FSIS	Red Meat	271	23.86	14.55
	Poultry	241	21.21	12.94
US FDA	Eggs	138	12.15	7.41
	Fruits	69	6.07	3.70
	Dairy	60	5.28	3.22
	Fish/Seafood	48	4.23	2.58
	Vegetables	37	3.26	1.99
	Leafy Greens	34	2.99	1.83
	Sprouts	32	2.82	1.72
	Spices	**3**	**0.26**	**0.16**
	Spices	**2**	**0.18**	**0.11**

Additionally, rather than speculating and extrapolating the number of outbreaks using the Scallan underreporting factor, FDA should rely on this actual outbreak data. To the extent that FDA has concerns about underreporting, it should keep in mind that the Scallan analysis applies the same underreporting factor for all foods and therefore the raw data is equally as applicable as the extrapolated data.

B. FDA's Testing Erroneously Focuses on NRTE, Rather than RTE, Spices

The data do not support FDA's conclusion that spices are 1.9 times more likely to be contaminated with *Salmonella* than other imported foods – as this number suggests or implies that its applies to spices as consumed. Although spices may have higher contamination prevalence at the border, this is not the right measure for assessing public health risk. FDA's consideration includes all imported spices, but instead should only consider the contamination rates for spices that are RTE. Most imported spices are NRTE (RACs and RTU) and therefore are not intended to be pathogen free at the time of entry because they will undergo further processing in the United States.[14] Consistent with this fact, FDA's prevalence data shows a significantly lower prevalence for imported spices subject to a pathogen treatment (3%) versus untreated spices (6.8%).

We believe strongly that FDA's sampling of spices is focused on too early a step in the production chain. Many imports that FDA tested had not yet been processed or treated and were not ready for human consumption. This is because many imported spices are treated here in the U.S. Other spices in U.S. commerce are used by food manufacturers as ingredients in the production of multi-

[12] Calculated as (number of outbreaks/1136) * 100.
[13] Calculated as (number of outbreaks/1863) * 100.
[14] We also are concerned that FDA's numbers are skewed because spices have been a target for testing at the ports. Accordingly, even if FDA is making a comparison with other Category 2 foods, these imports are not all tested with the same frequency.

component foods that themselves undergo microbial reduction processing.[15] The data FDA cites is not representative of spices in commerce that consumers actually eat because it is taken at too early a point in the supply chain. This is analogous to testing raw milk or unprocessed wheat to determine the level of pathogens in pasteurized milk or baked bread – the data simply are not relevant because the material processing steps have not yet been applied.[16] Accordingly, FDA should focus testing on the point of readiness for consumer exposure, not the point of entry into the U.S. To the extent that FDA does test spices at the border, such testing should only apply to spices that enter the U.S. as RTE products.

As discussed further in our comments below, we strongly encourage FDA to conduct an assessment of the prevalence of *Salmonella* in spices at retail because these results will be much more indicative of the risk to consumers than information about prevalence at the port of entry where treatment and processing has not yet occurred. Notably, FDA identifies the prevalence of *Salmonella* in spices at retail as a data gap. We think this is an essential piece of missing information that needs to be addressed and should be highlighted as a necessary next step for this project to continue.

It also is important to recognize that FDA's survey of spices at or near the port of entry (as set forth in DRP Table 4.8) had very low populations, generally under 1 cell per gram. Spices have low water activity, so the hazard does not increase once it is in the product unlike with some other foods. The WHO/FAO dose response curve supports the conclusion that very low levels of exposure are unlikely to result in illness.[17] Furthermore, a very small quantity of a given spice actually is consumed. In the worst case scenario, a consumer would be exposed to 0.59 cells per day according to the analysis conducted by Dr. Dickson—a very low level—which does not consider the application of treatments and mitigation strategies applied after import that further reduces the risk.[18] Accordingly, this data supports the relatively low number of reported recalls, outbreaks, and attribution of foodborne illness to spices.

C. FDA Should Conduct a Quantitative Risk Assessment for Spices

We are concerned that FDA conducted a qualitative risk assessment for spices, which is a divergence from its practice of conducting quantitative risk assessments for foods alleged to be high-risk (e.g., *Listeria* in RTE foods; inorganic arsenic in apple juice; *Listeria monocytogenes* in retail delicatessens; *Listeriosis* from soft-ripened cheese; *Salmonellosis* associated with tree nut consumption [ongoing]). We question why FDA followed this less rigorous approach for spices and wonder if, perhaps, it is because insufficient data existed to follow the usual quantitative process. In any case, any needed data gaps should be filled by FDA – especially collecting data on spices as sold at retail – and a full quantitative risk assessment should be conducted.

ASTA urges FDA to conduct a full quantitative risk assessment for spices. In particular, as part of this assessment FDA should collect data at steps in the supply chain other than the point of entry—including at treatment facilities and retail. Consideration of data from border testing should be limited to RTE products as they enter the U.S. Additionally, further analysis is needed regarding the

[15] One high profile recall involved processed meat, where the spice was applied after the lethality treatment for the meat. After the outbreak, FSIS issued a Notice requiring ingredients applied post-lethality to be demonstrated to be pathogen-free. FSIS Notice 31-13, April 30, 2013.
[16] Appendix A (Scientific Review by Dr. J. Dickson) at 15.
[17] DRP Figure 5.6.
[18] Appendix A (Scientific Review by Dr. J. Dickson) at 13 - 14.

impact of the exposure level on the overall risk assessment. FDA should consider the possible relevance of having a high number of consumers exposed to spices and the low incidence rate of resulting illnesses. Spices are used as ingredients in virtually all prepared foods and consumers use spices widely in home cooking; therefore, we surmise that if spices were a significant factor in contributing to foodborne illnesses, more outbreaks would have been detected and reported. In addition, FDA should evaluate the effect of the low number of *Salmonella* cells detected on spices, and to what extent that may have an effect on the relatively low number of outbreaks and illnesses. A quantitative risk assessment also would better enable determination of the appropriate *Salmonella* $\log_{10}$ reduction needed for spices. We also encourage FDA to focus future efforts on imports that have already been treated (RTE) and spices sold at retail that should be *Salmonella*-free. Dr. Dickson's expert report, appended to these comments, provides more detailed recommendations for the content and focus of a quantitative risk assessment for spices.[19]

IV. Proposed Strategies for Risk Mitigation

In the comments that follow, we provide our feedback on several of FDA's proposed risk mitigation strategies for spices. Specifically, we discuss:

- Differentiation between treated and untreated imported spices;
- Application of microbial treatment processes (kill steps); and
- Education and training for primary producers.

A. Differentiation Between Treated and Untreated Imported Spices

The DRP implies it is impermissible to import spices if they are "adulterated" at the time of entry, even if they will be subject to further processing. We disagree with this perspective because NRTE/untreated spices are not intended for consumption without further processing. The agency should take a more practical, risk-based approach for spice admissibility determinations at the border.

When determining whether an import is admissible into U.S. commerce, FDA should consider whether or not the spice is RTE. We agree that any spices imported for sale at retail (i.e., RTE) need to be pathogen-free at the time of entry. Accordingly, imported RTE spices should be the focus of testing that occurs at the border. If an imported spice is NRTE (RAC or RTU), such that it will be subject to further processing or treatment before consumption, it should be permitted to be imported even though it may not be pathogen-free provided the importer can document the further processing that will occur. This approach would be consistent with the intent of the FSVP proposed rule, which acknowledges if the kill step is to be applied in the U.S., then no supplier verification for pathogen control is needed.[20]

Currently, spices are all imported under the same product code, so border inspectors cannot readily differentiate between RTE and NRTE (RAC and RTU) spices. Additional information about the nature of imports, through tailored product codes that differentiate between RTE and NRTE spices, would allow the agency to readily determine whether a spice is RTE or NRTE and make more risk-based admissibility determinations at the border.

[19] *Id.* at 16 - 20.
[20] 78 Fed. Reg. 45730, 45774-75 (July 29, 2013) (proposed § 1.506).

In April 2013, ASTA submitted to FDA a proposed strategy urging the agency to distinguish between imported spices at the port of entry based on their treatment status (copy attached as Appendix F). As our recommendation explained, without appropriate differentiation, companies experience unnecessary delays at ports for products that will undergo processing, including microbial reduction, during their journey further along the supply chain. ASTA fully supports that RTE spices should be the focus of scrutiny upon entry to protect public health. Systematic differentiation between the two categories of spices is necessary to address this. ASTA also supports the need for importers to provide adequate documentation to ensure that NRTE spices will, in fact, undergo necessary treatment in the U.S. We understand that FDA has taken this approach previously with other commodities and urge the agency to expedite development of information technology solutions to assist with these efforts.

Importantly, this is an action FDA can take now, before it finalizes the spice risk assessment. We believe that RTE/NRTE differentiation at the border will have significant benefits for focusing FDA's resources in a risk-based manner, which is consistent with the agency's public health goals. Another benefit of this approach is that it would allow FDA to apply a uniform policy for all imported spices and abandon the current situation where a reconditioning plan is needed for the entry to be released.

B. Application of Microbial Treatment Processes (Kill Steps)

The DRP suggests mandating application of validated pathogen reduction treatments for *Salmonella* for all spices intended for human consumption at an appropriate point before or after packaging. ASTA supports FDA making a recommendation, through guidance, that strongly recommends for spices to be treated. The key consideration is that treatment occurs somewhere in the supply chain before consumer consumption, with adequate controls in place to protect against post-processing contamination. There should be no restrictions or limitations on where treatment occurs (i.e., domestically or internationally), so long as the treatment method is validated.

FDA's focus should be on ensuring that all spices are free of *Salmonella* at the time of consumer consumption. For example, if a spice arrives in the U.S. as RTE, it must have been fully processed and treated (as necessary) with a validated method overseas. If a spice arrives as a RAC, the processing and any necessary validated treatment must be applied domestically. If a spice arrives as RTU, it must receive domestic treatment commensurate with the needs of the importer's industrial food customers, again using a validated treatment method. As recognized in the FSVP proposed rule, the key issue is that the hazard is controlled before the food reaches consumers but it is acceptable for it to be controlled at any stage of the manufacturing chain.

In all three of these scenarios, it should be acceptable for a manufacturer to determine that treatment is not necessary in those limited situations where it will not add value for food safety. For example, a spice manufacturer may conclude that treatment is not needed for spices with antimicrobial properties (i.e., cinnamon, cassia, cloves)[21] or for dehydrated garlic and onion.

We recognize that when treatment is applied, the process will need to be validated under FSMA. The fact that the FSMA framework requires validation for all preventive controls, regardless of the

[21] Ceylan, E. and Fung, D. Y. C. (2004), Antimicrobial activity of spices. Journal of Rapid Methods & Automation in Microbiology, 12: 1–55.

specific food, is a good example of why spice-specific food safety standards are not necessary. The appropriate food safety standards for spices already will be mandatory under FSMA so no additional spice-specific food safety regulations are needed. As previously discussed, we encourage FDA to develop validation guidance for spices based on ASTA's validation whitepaper (copy attached as Appendix C).

Furthermore, when treatment is applied, we believe a 3 $\log_{10}$ reduction is adequate. As the scientific review from Dr. Dickson demonstrates, considering a worst-case scenario situation using FDA's data, application of a 3 $\log_{10}$ reduction would result in exposure of 1 cell of *Salmonella* to 211 Americans (out of the population of over 317 million) per year.[22] (As noted above, FDA's data demonstrated that even with the current prevalence of import testing for NRTE products, consumers would be exposed to less than 1 cell (0.59 cells) per day before application of treatments, which already is a very low level.) In comparison, a 5 $\log_{10}$ reduction would result in approximately 2 Americans being exposed to one cell of *Salmonella* over the course of 1 year, which is not a meaningful difference.[23] Accordingly, application of a 5 $\log_{10}$ reduction does not provide a corresponding increase in public health benefits given that the potential exposure from a 3 $\log_{10}$ reduction already is so low. Furthermore, application of a 5 $\log_{10}$ reduction would be much more costly for industry, without a commensurate food safety benefit, and can negatively impact the quality attributes of flavor and color, which will result in degradation of the product.

Regardless of whether treatment occurs, the foods that people eat need to be free of *Salmonella*. Accordingly, we do not support a requirement to label products as treated or untreated, or to specify the type of treatment, at the point of consumer sale. Rather, the product should not be marketed if it is not safe.

C. Education and Training for Primary Producers

Many spices are grown in less sophisticated countries by farmers that have little education. In the DRP, FDA is concerned that poor or inconsistent application of industry and government guidance causes spices to become contaminated with pathogens and filth. We think the suggestion to improve education and training for primary producers misses the mark because there are so many links in the supply chain where contamination can occur after the spice leaves the primary producer's control. Instead, the focus should be on control of the hazards later in the chain, closer to the point of consumption, where such efforts will be more effective. There will be limited food safety benefits from improvements in on-farm controls by primary producers.

Focusing on control later in the supply chain is consistent with the strategy FDA has employed in its FSMA regulations. For example, under the produce safety proposed rule, if a RAC is subjected to further processing that constitutes a kill step, there is no need to comply with the produce safety regulation.[24] Similarly, the FSVP proposed rule provides that if the hazard is controlled domestically, there is no need to verify the foreign supplier's controls.[25] The DRP's recommendation to increase the focus on the primary producers overseas does not follow this core principle that the focus should be on the control of hazards later in the supply chain.

[22] Appendix A (Scientific Review by Dr. J. Dickson) at 18.
[23] *Id.* at 19.
[24] 78 Fed. Reg. 3504, 3630 (Jan. 16, 2013) (proposed § 112.2(b)(1)).
[25] 78 Fed. Reg. at 45774-75 (proposed § 1.506).

ASTA has invested considerable resources in education efforts throughout the supply chain. However, we have found these efforts to be most successful when they are focused closer to the point of consumption. There are many challenges to primary producer training that do not justify the use of resources necessary to reach them. For example:

- There are an enormous number of spice farmers;[26]
- The farmers typically operate in remote locations;
- Primary producers sometimes face comprehension challenges (e.g., illiteracy); and
- The majority of spices are produced for local consumption (e.g., 90% are consumed in India), so U.S. exports cannot exert adequate market pressure to drive changes.

Additionally, it is difficult to expect foreign governments to commit significant resources to enhancing primary production safety for the benefit of U.S. consumers.

V. Additional Strategies Suggested by FDA

In the comments that follow we discuss the following additional strategies and options FDA suggests in the DRP:

- Traceability;
- Expansion of targeted Import Alerts;
- Mandatory Import Certification under FSMA; and
- Capacity building and education.

A. Traceability

FDA suggests in the DRP that the agency, spice industry, and foreign governments work together to develop guidance, and potentially regulations, to improve traceability during illness outbreaks attributed to spices. Traceability is a difficult issue with cross-cutting challenges across the entire food industry. FDA should exercise caution in getting ahead of its broader industry-wide traceability efforts under FSMA by focusing only on spice traceability. Additionally, when implementing FSMA's traceability provision, FDA should closely adhere to the statutory limitations on the imposition of new traceability requirements for commingled raw agricultural commodities. The law protects/restricts tracing mandates to "one-up, one-back" for RACs (i.e., those that are combined or mixed after harvesting but before processing).

In contrast, FDA's suggestion about overhauling product codes is something we support in the context of identifying raw (NRTE) versus treated (RTE) spices at the border, as discussed above. However, we do not support mandatory product codes for packaged foods (e.g., potential FDA requirements for UPC codes for spices). We also do not view tailored product codes as a tool to help with tracking and trending, as suggested in the DRP, but rather view them as a way to differentiate between imports.

[26] For example, there are over 100,000 Indian black pepper farmers, over 250,000 Indian red pepper farmers, and over 25,000 Indonesian nutmeg farmers.

B. Expansion of Targeted Import Alerts

FDA proposes creation of a commodity-specific Import Alert for *Salmonella* and/or filth in spices. We do not think that an additional Import Alert will address FDA's underlying concerns about spice safety. Spices may be listed on this Import Alert even if they will be subject to further treatment in the U.S., which will unnecessarily slow their importation and burden trade. Rather, the existing Import Alerts should be updated to focus on spices that are not intended for treatment in the U.S., consistent with our comments recommending use of tailored product codes. Additionally, to the extent FDA focuses efforts on using Import Alerts, they need to be in a searchable, modern database.

FDA also suggests that the agency create more import alerts like IA 28-02 for Indian Black Pepper, where the Export Inspection Council of India issues export certificates. Unless FDA has established a foreign government's food safety system as "comparable" through the systems assessment program being developed under FSMA, we do not support expansion of such programs.

C. Mandatory Import Certification under FSMA

FSMA Section 303 provides FDA with the authority to require import certifications for certain high risk foods. Specifically, the law provides that the need for a mandatory import certification must be based on the risk of the food, including:

- Known safety risks associated with the food;
- Known food safety risks associated with the country, territory, or region of origin of the food; and
- A finding by FDA, supported by scientific, risk-based evidence, that—
    - (i) the food safety programs, systems, and standards in the country, territory, or region of origin of the food are inadequate to ensure that the article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States, and
    - (ii) the import certification would assist FDA in determining whether to refuse or admit the article of food.

The statutory limitations clearly indicate that Congress intended for FDA to use this authority sparingly, and we urge the agency to use extreme caution when making assessments about the need for a mandatory import certification. ASTA strongly believes that import certifications are not necessary to ensure the safety of imported spices – especially spices that are imported while still NRTE – and also that spices would not qualify for such certifications under an analysis of the statutory prerequisite factors.

D. Capacity Building and Education

FDA suggests that the agency, industry, and academic experts work together to develop regulations, and potentially guidance, for the spice industry regarding development of food safety plans and preventive controls. We support coordinated efforts to develop guidance tailored to the spice industry with respect to implementation of the FSMA requirements for food safety plans and preventive controls. We also welcome the opportunity to work with FDA to develop guidance and engage in outreach.

However, the spice industry does not need any targeted regulations outside of the general industry-wide FSMA regulations FDA has proposed. The new FSMA regulations will address the specific concerns FDA raises in the DRP, providing a new set of risk-based regulations that ensure all food sold in the U.S. is safe. FSMA does not require FDA to establish additional food-specific food safety regulations because the broad framework establishes the bar for all foods. Spice-specific food safety regulations are not needed.

For example, even though spices are grown in less developed countries, FSMA will require supplier verification when these suppliers are controlling any food safety hazards. This will mitigate the need for any additional spice-specific regulations. We also note that many ASTA members already engage in robust supplier verification activities based on ASTA guidance.

VI. Additional Research Need to Fill Data Gaps

The DRP identifies several data gaps and we strongly believe that these gaps need to be filled before moving forward. We appreciate that FDA has identified some gaps on its own, but believe there also are other gaps that the agency has not identified.[27] They key point here is that it is not enough to simply identify gaps: further work is needed to actually fill these gaps before additional action is taken by FDA on this project because these issues are fundamental to the assessment.

The single biggest data gap in the DRP is the failure to present adequate information about the frequency of *Salmonella* in the spices that people actually eat. In particular, FDA must consider the frequency of *Salmonella* in spices sold at retail. This should be major point of focus because these are the products that need to be safe to eat in order to protect public health. Without information about the prevalence of *Salmonella* at retail, FDA cannot draw any reliable conclusions about the safety of spices. As discussed throughout our comments, information about the risks presented by spices when they are in an NRTE form (e.g., at the time of import in many instances) is not meaningful for purposes of assessing the public health risk.

FDA also should assess the frequency of *Salmonella* in spices at the food processor level for multi-component foods (e.g., foods made from RTU spices). This would consider whether spices destined for treatment through further processing as part of another food (e.g., heat treatment, acidification) actually receive adequate lethality and are not exposed to post-lethality contamination issues.

Additionally, FDA should consider the frequency of *Salmonella* at spice processing facilities after treatment has occurred. This information would provide a supplement to the retail data.

* * * * *

In conclusion, ASTA and its members are committed to ensuring the safety of spices. We urge the agency to shift its efforts to conducting a quantitative assessment of spices and to focus on spices that consumers actually eat rather than spices at the time of import (unless they are imported in RTE status). We encourage FDA to explore the possibility of developing tailored product codes that will

[27] Appendix A (Scientific Review by Dr. J. Dickson) at 20 - 21.

enable import inspections to differentiate between RTE and NRTE spices, and note that that activity can commence right away as important step forward.

ASTA values its relationship with FDA and appreciates the opportunity to provide these comments and to partner with the agency to ensure the safety of spices. We welcome future opportunities for continued interaction with the agency, both on the DRP and other issues involving spices. If we can provide any further information that may be of assistance, please do not hesitate to call on us.

Sincerely,

Cheryl Deem
Executive Director

Attachments:

Appendix A – Scientific Review by Dr. James S. Dickson
Appendix B – *Clean, Safe Spices: Guidance*
Appendix C – *Process Validation White Paper*
Appendix D – *HACCP Guide for Spices and Seasonings*
Appendix E – *Cleanliness Specifications for Spices, Seeds & Herbs*
Appendix F – ASTA Proposal on Import Product Codes