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

Re: Food and Drug Administration, HHS
Docket No. FDA–2011–N–0920
79 *Federal Register* 58524 (September 29, 2014)

To Whom It May Concern:

We appreciate the opportunity to submit comments under the supplemental proposed rule for "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food", 79 *Fed. Reg*. 58524 (September 29, 2014) in which FDA proposes to amend key provisions of FDA's original proposal relating to the current good manufacturing practices (CGMP) requirements for hazard analysis and risk-based preventive controls for human food under the FDA Food Safety Modernization Act (FSMA) of 2011. These comments are submitted in addition to comments on the previously published rule relating to the same subject.

American Spice Trade Association

The American Spice Trade Association (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.

FDA Role to Protect Public Health and the Food Supply

Passage of the FDA Food Safety Modernization Act (FSMA), signed into law on January 4, 2011, underscored the role of the Food and Drug Administration (FDA) to protect human health and the critical mission it plays in ensuring that our nation's food supply is safe. The proposed preventive controls rule for human food is intended to build a food safety system that makes science-, and risk-based preventive controls the norm across all sectors of a food safety system to

provide adequate assurances that food in the United States is produced safely in a manner as required under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Food Safety – Our Highest Priority

ASTA shares FDA's commitment to safety. The highest priority of ASTA and its members is providing clean, safe spices to their customers: food manufacturers, food service and consumers. ASTA's *Clean Safe Spices, Guidance from the American Spice Trade Association* provides industry with information and tools to mitigate the risk of filth and microbial contamination that can occur in spices. This critical resource was cited as a reference in the proposed FSMA rule for preventive controls for human food. ASTA has also recently published a white paper on process validation that provides direction on the steps needing to be considered in validating any process used to obtain the desired log reduction and inactivate any viable for *Salmonella*. The use of validated microbial reduction techniques is one of the five key recommendations in the *ASTA Clean, Safe Spices Guidance*. Since the proposed rule on preventive controls for human feed was originally published, ASTA has also submitted comments to FDA on the Draft Risk Profile on Pathogens and Filth in Spices which we strongly urge FDA to consider as the FSMA rules are finalized. Food safety and education are core parts of our mission and we continue to work hard to collaborate with FDA in these efforts. We strongly support the core principles that all spices consumers eat must be safe.

ASTA General Comments on the Supplemental Preventive Controls Proposed Rule

In general, ASTA offers the following input on the supplemental proposal on preventive controls:

- ASTA reaffirms our previously submitted position that preventive controls requirements and policy for human food must be based on the best available science from a recognized institution that is evidence based and peer reviewed. ASTA continues to urge FDA to utilize the latest scientific data and literature available from recognized scientific institutions and authoritative bodies in the development of policy relating to preventive controls.

- We support FDA's supplemental proposal that provides much needed flexibility to industry to carry out analysis and necessary corresponding controls to mitigate risks associated with food safety. Allowing individual facilities to tailor programs to their own unique circumstances reflects a framework that is risk-based, taking into account the nature and appropriateness of preventive controls in determining when and how to establish and implement the management of such controls. One size does not fit all and what works for one company and one product may not be sufficient for another product, manufacturing process, or company. The supplemental proposal provides this flexibility that is required while focusing on the outcome of insuring a safe food supply.

ASTA Detailed Comments on Supplemental Proposal

<u>Preventive Controls Terminology Regarding Degree of Hazard</u>

ASTA agrees with FDA's supplemental proposal to eliminate the terminology "reasonably likely to occur" referred to in the rules as a step to reduce the potential for misinterpretation that all preventive controls must be critical control points (CCPs) and therefore diluting the purpose of establishment of such controls. The phrase "reasonably likely to occur" is used in the HACCP regulations as a way to identify CCPs. Given that FSMA is intended to be broader than HACCP and not all preventive controls are CCPs, use of the term is not appropriate, and we appreciate FDA recognizing that point. We are concerned that FDA's proposed replacement term ("significant hazard") raises many of the same concerns as that term has also been used traditionally in conjunction with CCPs. We therefore recommend FDA adopt a more neutral term, such as "food safety hazard" in order to avoid any confusion. ASTA supports the broader framework to clarify the scope of hazard analysis that should be risk-based, taking into account both the severity and probability of the hazard.

Supplier Verification

ASTA supports FDA's proposed requirement within the preventive controls rule that supplier verification of raw materials and ingredients is always necessary when the receiving facility (or its customer) does not control the hazard identified and instead relies on the supplier to control hazards. The level of scrutiny for a given supplier should be increased or decreased by a manufacturer or an importer based on the risk and history of the items sourced, the country of origin, supplier reputation/history, changes in government in the country of origin or changes in US regulatory requirements that impact the country or its products based on particular risks or scenarios that arise. Manufacturers and importers should be provided flexibility to scrutinize their product supply chain based on these factors. Accordingly, we agree with FDA's modification in the supplemental proposal to base supplier verification on a combination of food risk and supplier risk.

We agree with FDA that risk analysis for foreign suppliers should identify, for example, whether the imported product is raw and will be processed in the U.S. or is ready-to-eat such that the foreign supplier is responsible for controlling the hazards. As we have noted in previous comments on the FSMA rules, and in our submission on the Draft Risk Profile, many imported spices are raw agricultural commodities that will be further processed in the U.S., such that the importer controls the hazards. Differentiating between spices that are raw agricultural commodities or Ready to Eat (RTE) will allow for appropriate focus. And, an understanding of who controls the hazard should be sufficient without requiring further evaluation or application of verification activities. Thus, we support FDA's proposed focus on who controls the hazards (whether biological, chemical, or physical) because there is no need to verify suppliers when the hazards are being controlled domestically, here in the U.S. This is similar to FDA's regulation of raw milk where government properly focuses on the facility where the milk is pasteurized and not on the raw milk supplier.

One particularly important determination when considering supplier risk for spices is whether a spice that will be imported into the United States is a ready-to-eat (RTE) spice or if the ingredient will undergo further processing upon entry. Spices intended for RTE consumption should be the focus of attention for supplier verification efforts, so that more resources are focused on ensuring these products are safe than assessing suppliers of spices that will undergo further processing and a validated microbial reduction treatment later in the supply chain. We

encourage the agency to differentiate between the verification activities required depending on the intended use of an ingredient, a concept especially important to the spice industry as a large number of spices are treated to control microbial contamination by the receiving party, not the supplier.

ASTA has developed a pilot project on this proposed differentiation and has discussed it with FDA's Center for Food Safety and Applied Nutrition (CFSAN). As part of our discussions, we have emphasized that not all spices have the same intended use. Intended use (e.g., RTE or for further processing) should be considered as part of development of a food safety plan. We urge FDA to approve moving forward with the project so resources can best be targeted to the areas of greatest need.

Potential for Economically Motivated Adulteration (EMA) of Imports

In a report commissioned by the Dept. of Homeland Security and funded by the Natl. Center for Food Protection and Defense (Univ. of Minnesota), Food Fraud (i.e. EMA) was defined as a collective term that encompasses the deliberate substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging, or false or misleading statements made about a product for economic gain. There are numerous examples of EMA throughout history involving many food products including spices and herbs.

The three main categories of EMA in Foods are: (1) Complete or partial replacement of a food ingredient or valuable authentic constituent with a less expensive substitute without the purchasers' knowledge, (2) The addition of non-authentic substance to mask inferior quality ingredient without the purchasers' knowledge, and (3.) Removal of an authentic and valuable constituent without the purchasers' knowledge.

While there are documented examples of each of these types of EMA throughout history, types 1 and 2 above can clearly result in serious public health consequences if the substitute or added non-authentic ingredient is an undeclared allergen, a non-food grade chemical, a toxic ingredient, etc. In some circumstances, EMA can be food safety risks that, if known, have to be part of a company's raw material risk assessment process for this type of ingredient. As such, the risks inherent in these types of raw materials should be identified in a company's food safety plan and mitigated through the implementation of preventive controls for both raw material sourcing and supplier approval.

As such, ASTA works to provide guidance to members when an occurrence of EMA of spices happens. We work with our Food Safety and Government Relations and Advocacy Committees to formulate courses of action for our membership, including the development of ASTA analytical procedures to detect and identify the adulterant in the spice product. This course of action is followed for all three types of EMA identified above, whether it is a Food Safety issue or a Quality/Value issue.

However, many types of EMA are not food safety issues at all, but are product quality or product value issues. Since many of these types of EMA can be unique to a specific product, from a specific country purchased through a specific vendor that has done business with a specific collector, it is a very complex issue that needs much more than a brief mention within the

Preventive Controls and Supplier Verification regulations of the Food Safety Modernization Act (FSMA), and it requires careful thought and deliberation on how to adequately address the issue.

There is an opportunity for ASTA as well as other industry associations to work with the FDA in defining and setting forth reasonable and logical risk assessment guidelines regarding spices as they relate to Food Safety Issues, Economic Adulteration and Quality Issues. We agree with the FDA that any regulations developed to address EMA should only focus on food safety issues and not quality issues.

In summary, EMA of food incidents present a particular challenge to the food industry and regulators alike because they are deliberate acts that are intended to evade detection. It is clear that changes in regulatory systems (i.e. FSMA implementation) and the implementation of novel, non-traditional testing methodologies and other deterrent strategies need to be developed and deployed. As such, ASTA believes the food industry-wide issue of EMA is best served and addressed under a future FDA regulation specific to the unique characteristics surrounding the intentional adulteration of food products, the need for innovative methods for detecting it and for targeting crucial resources toward the riskiest of food products.

Testing

In the proposed supplemental rule on preventive controls FDA proposes to require product testing as a verification activity, as appropriate, requiring that product testing procedures would be in place, specifying the procedures for identifying samples, conducting samples, the tests that would be conducted and corrective actions that would be taken as appropriate with a focus on Ready To Eat (RTE) product. This more flexible approach requires necessary and thoughtful deliberation of testing protocol procedures to be developed proactively while providing flexibility needed to adequately conduct testing procedures. We agree with FDA's proposed direction taken in the supplemental proposal, particularly as described in the preamble, to provide facilities with the flexibility to design product testing programs that are appropriate to their circumstances. We urge FDA to modify the codified language in the final rule to reflect this same degree of flexibility. ASTA recommends that any further details on product testing should be addressed within guidance as opposed to the preventive controls rule.

Environmental Monitoring

FDA proposes to require procedures be in place to identify locations and sites for routine environmental monitoring. Under FDA's proposal, these should include the timing and frequency and also address the presence of an environmental pathogen or appropriate surrogate as part of the hazard evaluation of environmental pathogens whenever a RTE is exposed to the environment prior to packaging and the food does not receive treatment or the environmental pathogen is determined to be a significant hazard. ASTA agrees with FDA that environmental monitoring is an important verification activity if contamination with an environmental pathogen is a significant hazard and requests that flexibility be granted to make the determination based on the risk associated with said product. As with product testing, we ask FDA to ensure that the language in the codified section for the final rule reflect FDA's intent to provide flexibility as described in the preamble to the supplemental proposed rule.

Auditing

As ASTA discussed in our previous comment submission, we recommend that audits should be able to be conducted by any party that is appropriately qualified, including third parties (that may or may not be accredited by FDA) as well as the company/organization that is initiating the purchase from this supplier (i.e., second parties). We ask that FDA provide greater clarity on the qualifications that would be acceptable to be termed "a qualified individual" for auditing purposes. We also agree that any third parties should be independent and free of any conflict of interest.

Conclusion

ASTA and its members are committed to ensuring the safety of spices. We thank you for the opportunity to comment on this notification and respectfully request your consideration as you draft the final rule on preventive controls for human food.

Sincerely,

Cheryl Deem
Executive Director

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