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November 14, 2013

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
78 *Federal Register* 3646 (January 16, 2013)

To Whom It May Concern:

We appreciate the opportunity to submit comments under the "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food", 78 *Fed. Reg*. 3646 (January 16, 2013) in which FDA proposes to amend current good manufacturing practices (CGMPs), and establish and implement hazard analysis and risk-based preventive controls for human food. The agency also proposes to amend the definition of "farm" therefore changing the scope of exemption from registration requirements provided by the Federal Food, Drug, and Cosmetic (FD&C) Act.

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 the food system.

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 and consumers. ASTA recently published *Clean Safe Spices, Guidance from the American Spice Trade Association* to

provide industry with information and tools to mitigate the risk of filth and microbial contamination. 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. The paper provides direction on the steps that need 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.

ASTA General Comments on the Preventive Controls Rule

In the sections that follow below, ASTA offers feedback on specific provisions of the preventive controls rule. ASTA also offers the following general input on the proposal:

- 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 urges 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.

- The promulgated rules must be flexible enough to allow individual facilities to tailor their programs based on their own unique circumstances. One size does not fit all. What works for one company and one product may not be sufficient for another product, manufacturing process, or company.

- Furthering the foundation of the HACCP model, the proposed rule should build on effective and reliable food safety systems that are already in use by industry in many cases. (Guidance documents such as ASTA HACCP guidance and Clean, Safe Spices are instrumental in assisting industry in important food safety plan implementation.)

- Very small business should be defined as offered in Option 3 with average annual sales of less than $1 million. We believe this definition is most in line with the types of very small businesses operating today and the other co-proposed definitions are too narrow.

- Because FDA did not propose codified language on environmental/product testing and supplier verification, we respectfully request that the agency establish a mechanism for public comment on the specific codified language that the agency intends to adopt before this language is finalized. We suggest using tentative or interim final rules that will not become effective until after the agency receives and considers comments as a mechanism to achieve this goal. Regardless of whether the proposed rule appropriately foreshadowed these issues, an opportunity for comment should be allowed as a matter of procedural fairness and to align with the spirit of the Administrative Procedures Act.

ASTA Comments on Specific Provisions of the Preventive Controls Rule

1. Food Safety Plans and Preventive Controls

ASTA supports a requirement for registered facilities to prepare food safety plans in order to protect public health and ensure food safety. FDA's preventive controls regulation should be focused on food safety outcomes and needs to incorporate flexibility. FDA should modify the proposed rule to achieve this goal and to be consistent with the legal framework under the statute. The proposed rule tries to retrofit the regulation into the seafood and juice HACCP model, which is not what the statute dictates. The seafood and juice HACCP programs focus

only on critical control points (CCPs), but preventive controls are broader than just CCPs. Under FSMA, "preventive controls" include well-established prerequisite programs like employee training, sanitation, GMPs, and supplier verification.

FDA should revise the regulation to provide for consideration of "known or reasonably foreseeable hazards," as opposed to "reasonably likely to occur" hazards as in the proposed rule. 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 does not make sense here.

We also feel strongly that FDA needs to amend the regulation to allow implementation of a range of preventive controls (not just at critical control points) applied with the rigor and oversight needed to control the hazards. The level of rigor used to manage this range of preventive controls should be commensurate with the nature of the risk and the type of controls being used. We urge FDA to allow preventive controls oversight to provide flexibility based on the associated risk, with CCPs receiving the most rigorous management oversight.

For example, FDA's proposal is too prescriptive with respect to verification activities. Verification should only be required where appropriate, not for all preventive controls. Different companies have different needs and base their verification on risk assessment that is necessary for specific product. Companies should be thoughtful about how they apply preventive controls and manage their programs and this critical thinking cannot be achieved under a prescriptive regulation.

Similarly, not every preventive control can be reasonably validated. Validation should only be required where it is necessary and appropriate. This is consistent with the statute, which does not require validation. FDA can help facilities understand what preventive controls are capable of validation through commodity-specific guidance. We also suggest that validation should not be required for each individual preventive control, but rather it should be permissible to validate combinations or systems of controls. Furthermore, the six-week time limit given for validation in the proposed rule is too restrictive. Instead, 90 days should be provided to conduct validation, which is consistent with FSIS's draft guidance on this issue.

We also want to make the following points regarding subpart C:

- We support consideration of radiological hazards as a subset of chemical hazards rather than as a stand-alone category of hazards that must be identified. Facilities should not have to revise their food safety plans to separate out these hazards under a different heading.
- In conducting a hazard analysis, consideration should be given to the benefits derived from existing prerequisite programs, like GMPs.
- ASTA supports FDA's on-site records access to the full range of preventive controls, including prerequisite programs that provide the foundational support for preventive controls (but not to records exempt from FDA access under FD&C Act section 414(d)(4), such as product formulas and financial data).
- Hazards that may be intentionally introduced for economic reasons should not be required to be addressed in the food safety plan. Instead, these hazards should be addressed under FDA's future regulations concerning intentional contamination.
- Developing a full food safety plan is cumbersome and restrictive for pilot plants and test kitchens. FDA should exempt such facilities from registration, establish modified requirements, or exercise enforcement discretion.

- ASTA supports the role of the Food Safety Preventive Controls Alliance and the importance of education as FDA moves into the compliance stage of FSMA implementation.

2. Supplier Approval and Verification

Supplier verification is a critical issue to the spice industry. ASTA concurs with FDA that supplier approval and verification is always a necessary part of an effective food safety plan, regardless of whether the inputs are produced in the US or are imported products. 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.

As part of considering supplier risk for spices, one particularly important determination 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. Accordingly, we support FDA's approach in the Foreign Supplier Verification Program (FSVP) proposed rule to differentiate between the supplier verification activities that would be required for imported ingredients depending on the intended use and processing that will occur by the importer or the importer's customer. Following this approach would ensure that spices intended for RTE consumption are the focus of attention for supplier verification efforts, so that more resources are focused on ensuring these products are safe than assessing supplier of spices that will undergo further processing and a validated microbial reduction treatment later in the supply chain. We encourage the agency to take the same approach in the preventive controls proposed rule, differentiating between the verification activities required depending on the intended use of an ingredient. This is 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 when import determinations are made and also as part of development of a food safety plan. We urge you to approve moving forward with the project so resources can best be targeted to the areas of greatest need.

FDA asks whether the Agency should specify that a receiving facility take appropriate action if the facility determines that the supplier is not controlling hazards that the receiving facility has identified as reasonably likely to occur. ASTA agrees that taking appropriate action is necessary to ensure the safety of the ingredient procured if information comes to the receiving facility's attention that raises concerns. There would be great benefit from enhanced food safety requirements in this regard. Information that may trigger the need to conduct a follow-up action may include changes in-country government that causes a reduction in security or changes in supplier ownership. An appropriate action by the receiving facility could include ceasing to procure product from this supplier, requiring an immediate re-audit by a third-party auditors, or use of a second-party audit to gain an updated perspective. The receiving facility also may determine that it is necessary to further process the product upon receipt in order to further reduce or control the hazard. There are many scenarios and options, as indicated above. ASTA urges FDA to provide flexibility to allow a company to determine the appropriate course of action based on the unique circumstances and to not be overly prescriptive. Such an

approach would follow the Congressional spirit of FSMA, which was to hold industry accountable for food safety while allowing flexibility as necessary for proper implementation.

ASTA believes that when it comes to determining appropriate verification activities, the owner, operator, or agent in charge of a facility should consider information from a wide range of sources, which may include but should not be limited to consideration of relevant regulatory information regarding the supplier. Whether the raw material or ingredient is the subject of a FDA Warning Letter or import alert relating to the safety of the food may be helpful information but also may not be relevant to the specific import. We believe what is more important than receipt of a Warning Letter, for example, is what corrections the supplier took in response to the Warning Letter and whether those corrective actions remain in place. ASTA does not believe that FDA should be overly prescriptive and mandate requirements in this regard and instead should establish a flexible requirement for importers and manufacturers to conduct due diligence about their suppliers' compliance history, which may include compliance with industry standards as well as regulatory compliance.

FDA's regulation should allow importers and manufacturers flexibility to determine the appropriate verification activities depending on the seriousness of the hazard. FDA's regulation should not affix a level of seriousness to certain hazards, but rather this determination should be left to importers and manufacturers. FDA should not establish mandatory requirements that attempt to fit all circumstances into one requirement. Therefore, we encourage the agency to adopt Option 2 under the FSVP proposal in both that regulation and in the parallel provisions under preventive controls. Option 2 would allow companies the flexibility to incorporate option 1 principles when appropriate or when warranted.

ASTA recommends 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).

ASTA recommends that the regulation not specify a set frequency for verification activities, as sometimes activities like an audit will be appropriate to occur annually at a minimum but other times certain circumstances or issues require an audit more or less frequently. More than one verification activity may be necessary to provide adequate assurances that the hazard is significantly minimized or prevented in some instances. The possibility exists that due to issues with a supplier, changes in ownership, changes in country status, health risks or proven product liability, a need would exist to adjust the type and frequency of verification activities to minimize risk. For example, a supplier with a long track record of excellent performance would not need to be audited at the same frequency as a new supplier or a supplier that has had problems in the past.

ASTA recommends providing for alternative requirements if a supplier is a qualified facility. ASTA also encourages FDA to establish guidance on supplier verification that incorporates current industry best practices to assist in upgrading supplier compliance.

3. Facility Profiles

Congress is very clear in FD&C Act section 415 regarding the scope of information that can be collected. Collection of this information is not authorized. ASTA strongly opposes any requirement to submit hazard and control information as part of biennial facility registrations ("facility profiles"). A food safety plan or subset of information thereof should not be read in a vacuum prior to inspection. In order to be thoroughly understood, it is important that the

inspector read the information on-site at the particular facility with the ability to receive visual and verbal clarification and context. Pre-determined judgment on a situation prior to observation could unfairly cloud and skew the inspector's assessment. Although FDA points to FSMA's direction to allocate resources to inspect high-risk food facilities with greater frequency according to the known food safety risks, ASTA does not agree with FDA's logic that keeping electronic profiles within a database will be of benefit to achieve this goal.

ASTA members have recently faced significant delays with the facility registration process and, at various times, applications were rejected due to FDA's computer system. Additional information that the FDA is requesting, therefore, may be subject to similar problems and, more importantly, some members may classify certain information as proprietary. It is unclear how information about hazards and controls can be meaningfully understood outside of the facility context. There also is a considerable volume of such information, so submission alone presents a considerable burden. Insofar that FSMA implementation is behind schedule and the agency is struggling with appropriate resource allocation to carry out the mandate set by Congress through passage of FSMA, it is important for FDA to remain focused on the greatest needs of the agency. Allocating precious human resources to maintaining a database that may not provide helpful information does not appear to be best use of FDA's limited resources.

ASTA proposes that information FDA seeks on a company's risk profile could just as easily be maintained by FDA inspectors who capture the information as part of their inspection, through a revamping of the Establishment Inspection Report process. Another option for targeting inspectional resources would be to utilize information already available through the Reportable Food Registry (RFR). Currently, when a serious food safety violation or recall is mandated, the FDA invariably will visit the plant and investigate the source.

Finally, it is important to emphasize that FDA lacks the legal authority to require submission of facility profiles. Congress is very clear in FD&C Act section 415 regarding the scope of information that can be collected. Collection of this information is not authorized.

4. Records

ASTA supports a two year timeline for records retention, consistent with the statute. However, FDA should allow flexibility for the location where records are stored. Records should be able to be kept in the location where they are created, which may be a corporate headquarters for documents like testing records and supplier verification materials. The six-month restriction on storage of documents on-site at the production facility is arbitrary and imposes burdens due to space constraints at some facilities.

ASTA proposes that instead of requiring records to be provided within 24 hours of an official request, the agency should establish a more flexible standard to provide records within a reasonable time which could be considered as five working days. This should exclude holidays, weekends and weather related circumstances. In instances where public health is at risk, FDA can access records more quickly under its emergency records access authority under FD&C Act section 414.

In response to FDA's proposal to require application of electronic recording requirements under 21 CFR Part 11, ASTA advocates strongly for an exemption from this onerous regulation. Part 11 is sufficiently unworkable that the agency is currently exercising enforcement discretion for many of its requirements. Rather than requiring compliance with a regulation that the agency has acknowledged needs significant revision, FDA should simply require modified steps to assure authenticity for electronic records. Especially given that FDA has publically stated that it is

currently revising the Part 11 regulations, it does not make sense to require the food industry to spend considerable resources to come into compliance with a regulation that likely will be replaced in a few years.

We also strongly disagree with any provision in the final rule that would allow FDA to remotely access facility records. Such an activity is outside of the scope of FDA's statutory authority. The lack of legal authority to remotely access records is particularly clear in light of the fact that the version of FSMA that passed the House of Representatives would have given FDA this authority but the version of the legislation in the Senate (that was ultimately enacted) did not grant such authority. Congress's selection of one provision over the other is clearly indicative of legislative intent. Furthermore, remote submission of records raises many concerns about security from potential hackers, as well as protection of proprietary information that should only be kept on-site and not be submitted outside of the industry. ASTA believes that it would be burdensome for FDA to maintain appropriate protection for these records and that FDA does not have the resources to adequately manage and maintain such propriety information.

Summary

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