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Via electronic submission

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

Re: Food and Drug Administration, Designation of High-Risk Foods for Tracing; Request for Comments and for Scientific Data and Information; Docket No. FDA–2014–N–0053; 79 *Federal Register 6596* (February 4, 2014)

Dear Sir or Madam:

The American Spice Trade Association (ASTA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) draft model for designating high-risk foods for tracing as part of its implementation of Section 204 of the FDA Food Safety Modernization Act (FSMA). ASTA appreciates the work that FDA has done to develop the draft model, but believes the agency's current approach needs considerable revision.

As a general matter, the approach is not consistent with Section 204 of FSMA. It is inconsistent with both the goal of the provision – identifying which foods need additional recordkeeping requirements in order to protect the public and to prevent or mitigate a foodborne illness outbreak – as well as the statutory factors Congress directed FDA to consider when making this determination. Most importantly, any model FDA uses to designate high-risk foods for tracing must sufficiently consider steps taken during manufacturing to reduce the possibility of contamination so that foods that undergo a microbial reduction treatment are not subject to additional recordkeeping requirements. We detail these and other concerns in the comments that follow.

Introduction

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.

Joint Role to Protect Public Health and the Food Supply

Passage of FSMA, signed into law on January 4, 2011, underscores FDA's role to protect human health and the critical mission it plays in ensuring that our nation's food supply is safe.

ASTA shares FDA's commitment to safety. The highest priority of ASTA and its members is providing clean, safe spices to customers: food manufacturers and consumers. ASTA continues to engage actively in the regulatory process by providing comments to FDA as it implements FSMA. ASTA also continues to provide needed resources to members to share with the entire supply chain as appropriate, including tools to assist in the manufacturing, handling and processing of clean safe spices. The recently published *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. This critical resource was cited as a reference in the proposed FSMA rule for preventive controls for human food. ASTA has submitted this document as part of its preventive controls comment submission.

Background

Section 204(d)(1) of FSMA requires FDA to issue proposed recordkeeping requirements in order to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak . . . ." These recordkeeping requirements can apply only to those "high-risk foods for which additional recordkeeping requirements are appropriate and necessary to protect the public health."[1]

Section 204(d)(2)(A) of FSMA states that the designation of high-risk foods must be based on the following factors:

1. Known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention;
2. Likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the process used to produce such food;
3. Point in the manufacturing process of the food where contamination is most likely to occur;
4. Likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;
5. Likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and,
6. Likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.

FDA's draft approach would use a semi-quantitative risk ranking model that evaluates foods against the following seven criteria:

1. Frequency of outbreaks and occurrence of illnesses;
2. Severity of illness, taking into account illness duration, hospitalization and mortality;
3. Likelihood of contamination;
4. Growth potential/shelf life;
5. Manufacturing process contamination probability/intervention;

[1] FDA Food Safety Modernization Act § 204(d)(2)(A).

6. Consumption; and
7. Economic impact.

Classification of foods (or categories of food) for the risk ranking would be based on the 28 Reportable Food Registry (RFR) commodity definitions, and FDA would select representative foods within each category for use in the model. FDA would evaluate foods against the seven criteria through "food-hazard pairs" (i.e., the characteristics of the foods and their known or reasonably foreseeable hazards). For each of the seven criteria itemized above, data and information would be grouped into defined scoring bins and assigned a numerical value of 0, 1, 3, or 9. The risk score for each food-hazard pair would be calculated by adding the scores for each criterion. If multiple hazards occur in the food, and therefore the food has multiple risk scores, the food's total risk score would be the sum of the individual food-hazard pair risk scores. Inclusion on the high-risk food list would be based on the total risk score for foods or food categories after application of the risk model.

The Proposed Model is Not Consistent with FSMA Section 204

<u>The Model is Not Aligned with the Purpose of Identifying High-Risk Foods</u>

Section 204(d)(2)(A) of FSMA directs FDA to designate high-risk foods for which additional recordkeeping requirements "are appropriate and necessary to protect the public health." These recordkeeping requirements, as described in Section 204(d)(1), are intended to "rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak . . . ." Accordingly, there are two companion questions any model must answer – whether the food presents a high risk of foodborne illness to consumers and whether additional recordkeeping requirements for that food are necessary and appropriate to protect the public health.

FSMA prescribes a number of factors to help FDA make this determination. ASTA asserts that the most critical of these is "the steps taken during the manufacturing process to reduce the possibility of contamination" (FSMA Factor 4). We believe that, when a company applies a microbial reduction treatment to its product that food should not be considered high-risk under Section 204 and in need of additional tracing related recordkeeping requirements. Such foods would not present a high-risk of contamination and would not likely result in a foodborne illness outbreak. Indeed, the importance of strong manufacturing controls is one of the central principles of food safety and is why FSMA places the responsibility on food manufacturers to conduct a hazard analysis and identify and implement preventive controls. As result, strong manufacturing controls (and the use of a microbial reduction treatment in particular), should preclude a food from being considered high-risk. For example, spices that have been cleaned and subjected to a pathogen reduction treatment should not be considered high-risk. [2]/

In addition, FDA must consider whether additional recordkeeping requirements "are appropriate and necessary to protect the public health." These are recordkeeping requirements needed to track and trace food beyond those currently required by other FDA labeling and recordkeeping requirements. Consistent with the language of the statute, FDA should consider existing tracing related recordkeeping requirements when designating any food as high-risk for tracing purposes. Certainly, for those foods which are subject to existing "one-up, one-back" requirements and which do not present a high risk of foodborne illness to consumers (because they have been processed in a way to reduce that likelihood or because the nature of the hazard does not pose a risk of foodborne illness) additional recordkeeping requirements are not "necessary

[2]/ This conclusion is reinforced by the low number of positive test samples found in the first third of FDA 's ongoing retail spice testing assignment, which we understand to be approximately 0.5% (based on about 1,100 retail samples). It is the same point made by ASTA in our comments filed earlier this year to FDA's Draft Risk Profile (DRP) for spices—namely, that spices treated with a microbial reduction treatment do not present a high risk to consumers.

and appropriate" in order "to protect the public health" and "prevent or mitigate a foodborne illness outbreak."

The Model is Not Aligned with the Statutory Factors for Determining High-Risk Foods

ASTA also is concerned that FDA has drafted a complex model that does not align with the statutory factors for determining high-risk foods for tracing related recordkeeping requirements: Some of the factors in FSMA are considered multiple times, FDA adds criteria not included in the statute, and other statutory factors are merged into a single criterion. For example:

- FSMA directs FDA to consider "the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food." This is one factor, not two, as in FDA's draft approach (criteria 2 and 7).

- FSMA does not direct FDA to consider the percent of the population that consumes a particular food (FDA criterion 6). If FDA considers this criterion, popular foods are more likely to be considered high-risk even if those foods are subject to preventive controls and processing steps that make the foods safe and they have not been associated with foodborne illness outbreaks. FSMA's direction for FDA to consider the "likelihood that consuming a particular food will result in foodborne illness due to contamination" does not mean that FDA should consider consumption rates. If anything, this factor refers consumer use/handling (e.g., do consumers routinely cook the food, do they consume small amounts at a time, etc.).

- FSMA identifies "the point in the manufacturing process of the food where contamination is most likely to occur" and "the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination" as two separate factors (factors 3 and 4). FDA's draft approach, however, merges these into one criterion (criterion 5), which has the effect of minimizing the impact of these elements. This is especially problematic as the application of a microbial reduction treatment in the manufacturing process should effectively prevent a food product from being designated as needing additional tracing recordkeeping requirements. Further, the point where contamination is "most likely to occur" should be construed more broadly to reflect the point in the overall supply chain where contamination may occur, not the point within the manufacturing process. The latter is typically facility specific and would not reflect industry-wide or intrinsic risk. Whereas, considering where in the supply chain contamination might occur or have occurred will help FDA distinguish between raw, imported spices not ready for human consumption, and spices that have been cleaned and processed for safety so that they are ready for human consumption—foods that have very different risk-profiles.

Additional Concerns

Subjective Risk-Ranking. ASTA is concerned that the draft approach is a "semi-quantitative" risk based approach. As such, the risk for many criteria is weighted by categories, such as low, moderate and high. The determination of what qualifies in each of these categories in many cases is subjective. For example, one of the criteria, severity of illness, proposes to use a weighted system of "0" for a hospitalization rate of 0%, while "1" would be a hospitalization rate of ≤ 10%. The reality is that there are very few, if any, foodborne illness outbreaks which result in 0% hospitalization rate, when you consider the entire spectrum of the population, including high-risk individuals. However, 10% is somewhat arbitrary, and implies that a hospitalization rate of 9.9% is a "1", while a hospitalization rate of 10.1% is a "3". We recognize that some type of limit must be set, however, we do not believe the existing data is sufficient to draw a distinction as such. There are other examples in the weighting criteria where the distinction between low, moderate, and

high are even more subjective and we urge FDA to address these issues. ASTA is concerned that in the context of human health, the default will be to rank the risk higher than what it may actually be. To address this, the risk ranking process should be transparent, and the designations should be based, to the greatest extent possible, on numerical standards, not on subjective rankings.

Lack of a "Cut-Off" Score. Although the draft model provides a method for identifying risk scores associated with a given food, it does not explain what total score value will be used to identify or classify foods as "high-risk." ASTA cannot evaluate the actual effects of FDA's draft model without this information. FDA should ensure that the ultimate model used produces results which clearly differentiate between high-risk and non-high risk foods for tracing related recordkeeping requirements.

Contribution of Multiple Hazards. ASTA is concerned that by summing food-hazard pair risk scores to determine a total risk score for a food, foods with multiple hazards will be more likely to be designated high-risk. FDA's approach should ensure that its model takes sufficient consideration of other factors – such as processing controls – to safeguard against foods with multiple hazards automatically being considered "high-risk" for tracing.

Skewed Score Values. FDA's proposal to group information and data into scoring bins with assigned numerical values (0, 1, 3, and 9) would result in skewed scoring. The scoring bins should have evenly distributed values and medium/high or high/medium determinations should not be assigned the same numerical value as a high/high determination. It is important that risk designations are not over inflated thereby diluting the purpose of the risk ranking model --to capture those foods which are high-risk and need additional tracing related recordkeeping requirements.

Use of Data. ASTA urges FDA to carefully consider relevant data when designating high-risk foods. For example, data should reveal intrinsic risks associated with a particular food, rather than a single, isolated event or problems attributed to a particular facility. It also should be timely and should ensure that food safety practices adopted by the food industry are accurately reflected in the results. ASTA also cautions FDA against using data from the Reportable Food Registry (RFR) to determine likelihood of contamination. The RFR contains information not relevant to determining which foods are at high-risk of contamination as it reflects incidents relevant to specific facilities and contains reports that may meet the statutory criteria for reporting, but do not reflect a health risk (thereby negating the need for tracing records). Furthermore, the RFR does not differentiate between treated and non-treated spices, or between raw agricultural commodities intended for treatment and spices which are ready-to-eat.

Chemical Hazards. FDA should not consider chemical hazards under any approach, as those are rarely the cause of foodborne illness outbreaks and the purpose of additional recordkeeping requirements under Section 204 of FSMA is to prevent or mitigate food borne illness outbreaks.

FDA's List of Foods Subject to Additional Tracing Requirements. ASTA recommends FDA implement Section 204 by publishing a list of foods *subject to additional tracing requirements*, but should not label that list as being comprised of *high-risk* foods. ASTA is concerned that any list of foods designated as high-risk could be misunderstood by consumers or misused by product liability attorneys. In addition, FDA must ensure that such a list of foods subject to additional tracing requirements is not used for other purposes, such as inspection frequency/intensity or performance standards. FSMA uses "high-risk" in a number of different ways and in very different contexts. FDA should determine and use high-risk as specified by Congress in each separate statutory provision and should not use its list of foods subject to additional tracing requirements for other purposes.

ASTA also urges FDA to share its thinking regarding the manner and the frequency with which it will

update or modify the list of foods subject to added tracing requirements. It is likely that with the implementation of FSMA there will be significant changes in the way foods are processed throughout the system. If a food is ranked "high-risk" in 2014, and then the industry undertakes major changes in production practices to lower the risk, it should no longer be designated high-risk. We also recommend FDA consider reviewing the risk rankings at regular intervals, for example, every two years. Regardless, FDA should explain how frequently it intends to review information to determine which foods are high-risk and FDA should update the published list of high-risk foods accordingly.

Conclusion

ASTA and its members are committed to ensuring the safety of spices. Due to the complexities of this issue, ASTA strongly encourages that the revised risk ranking model be re-published for further review before finalizing.

We thank you for the opportunity to comment on this important subject and respectfully request your consideration as you draft the final methodology on the designation of high-risk foods.

Sincerely,

Cheryl Deem
Executive Director