August 26, 2019

Submitted Electronically Via Regulations.gov

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

Re: Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting: Guidance for Industry; Draft Guidance (Docket No. FDA-2018-D-4534)

Dear Sir or Madam:

The American Seed Trade Association (ASTA) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) regarding its Draft Guidance entitled *Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting* (the "Draft Guidance"). Founded in 1883, ASTA is one of the oldest trade organizations in the United States. Our membership consists of more than 700 companies involved in seed production and distribution, plant breeding, and related industries in North America. ASTA advocates science and policy issues of industry-wide importance, promoting the development of better seed to produce better crops for a better quality of life.

ASTA supports FDA's efforts to provide guidance on food safety practices for the seeds for sprouting industry. While ASTA's members primarily condition seeds for planting, there are companies in our membership that condition seeds for sprouting. ASTA and our members appreciate the important role that seeds play for sprout safety, and we agree that everyone in the sprout supply chain can do their part to help ensure sprouts are safe to eat. When FDA finalizes this Guidance, we encourage the agency to reinforce to sprouters that this does not mitigate their own obligations under the Produce Safety Rule.

The Draft Guidance generally aligns with the practices our members currently follow to ensure that seed for sprouting is safely grown and handled. However, there are a few aspects of the Draft Guidance that we recommend modifying to ensure that the agency's recommendations are practical, helpful, and economically feasible. In particular, FDA should bear in mind that seed for sprouting is a raw agricultural commodity (RAC) that is grown in a manner more analogous to growing wheat than fresh produce. The parties in the seeds for sprouting supply chain can control whether they introduce additional hazards, but cannot mitigate the hazards inherent in this raw product.

In the comments that follow, we offer the following recommendations:

- The recommendations in the Draft Guidance regarding cleaning and sanitizing food contact surfaces are not practical for seed and should be modified to provide more flexibility;
- It is not practical to assess crops for potential contamination during the growing season or to prevent affected crops from being harvested;

- The Guidance should recommend that sprout seed wholesalers selling directly to sprouters label seeds to indicate that they are intended for sprouting; and
- FDA should conduct or commission updated research to assess sources of contamination in sprout-related outbreaks.

More details on these points follow below.

1. **More Flexibility Should Be Provided for Cleaning and Sanitizing Food Contact Surfaces**

The Draft Guidance recommends that if you grow, condition, pack, hold, or distribute seeds for sprouting, you should (1) ensure that food contact surfaces (FCS) are cleanable, and (2) clean FCS regularly and sanitize them as appropriate. These recommendations are not practical for many seed operations, as seed is a RAC that is grown in the soil and harvested using commercial farming equipment.

The seed growing and harvesting environment is inherently dusty and exposed to the elements. Additionally, the equipment used to harvest, transport, clean, and/or hold seed (e.g., combines, gravity tables, clippers, trailers, buckets) is not made out of "food grade" stainless steel that is able to be cleaned and sanitized like a FCS inside a food production facility. Rather, the equipment more typically is made from soft metals, or sometimes of wood. This equipment typically cannot tolerate sanitizing chemicals. Moreover, wet cleaning methods and sanitizing chemicals can introduce moisture that can both destroy the integrity of the seed and introduce potential food safety risks. For these reasons, the "cleaning" for such equipment tends to consist of dry-cleaning activities like sweeping, brushing, and blowing. While machinery is generally kept in clean condition, a certain amount of dirt and chaff is unavoidably present on some equipment.

Accordingly, FDA should modify its recommendations in the Draft Guidance to provide more flexibility regarding cleaning and sanitizing, as this recommendation does not reflect the realities of sprout seed growing and conditioning. It is not operationally or economically practical for all segments of the supply chain to have food-grade equipment that is capable of being cleaned and sanitized in the traditional sense of those terms. FDA should replace this recommendation with a less prescriptive, more flexible recommendation such as: "Ensure that food contact surfaces are cleaned, as appropriate and practical." FDA also should caution against introducing moisture through cleaning methods, as we are concerned that the Draft Guidance could be interpreted to suggest that wet cleaning should be used.

Recommendation: ASTA recommends the draft guidance provide more flexibility regarding cleaning and sanitizing, include language warning about the risks associated with wet cleaning practices, and include various suggested dry sanitation practices that are practicable for each segment of the supply chain.

2. **It is Not Practical to Assess Crops for Potential Contamination During the Growing Season and to Prevent Affected Crops From Being Harvested**

The Draft Guidance recommends that growers of seeds for sprouting monitor crops for contamination during the growing season and "mark [any] affected area in a manner that will ensure it is not harvested." While growers do monitor crops throughout the growing season in keeping with

Good Agricultural Practices (GAPs), without substantial financial investments and modifications to existing practices, growers cannot meet this recommendation. Unlike produce RACs, sprouting seeds are often grown in fields that may be hundreds of acres in size and are harvested by large commercial combines. Based on the commodity nature of seeds and their low market price, very few, if any, growers can financially afford the extra resources and personnel that would be required to engage in monitoring activities for issues such as animal intrusion across hundreds of acres of land. As mentioned above, growing sprouting seeds is more like growing wheat than like growing produce, so functionally FDA's recommendation would be very challenging. Moreover, this proposed practice is parallel to requirements in the Produce Safety Rule (21 CFR § 112.112), but we note that operations that grow seeds for sprouting are not covered by that rule. FDA should not use Guidance to apply a regulatory requirement to operations that are exempt from the Produce Safety Rule.

Recommendation: FDA should delete this recommendation from the Guidance or modify it to be more practical and tailored to the growing of seeds.

3. FDA Should Recommend that Sprout Seed Wholesalers Selling Directly to Sprouters Label Seeds for Sprouting to Identify their Intended Use

FDA accurately recognizes in the Draft Guidance that "the end use of seed may sometimes be unknown by the farmers who grow the seed and by the conditioners and distributors who handle the seed." Because of this, the agency explains that its recommendations to prevent seeds for sprouting from becoming adulterated should be followed when a "grower, holder, conditioner, or distributor reasonably believes that its seeds are expected to be used for sprouting." Because seeds for sprouting are a fungible RAC, it is not always visually apparent to sprouters whether the seeds they purchase are intended for sprouting. ASTA believes that it would be helpful if seeds for sprouting are clearly labeled by seed wholesalers that sell seed directly to sprouters to identify their intended use—for example, by adding "for sprouting" or "sprouting" to the product label and/or marketing materials. This would help sprouters know whether they are using appropriate seeds for sprouting, and would help protect seed wholesalers whose products may be diverted by third parties to sprouters without their knowledge.

Recommendation: The Guidance should recommend that seeds for sprouting that are sold by seed wholesalers directly to sprouters be labeled to indicate that they are intended for sprouting.

4. FDA Should Conduct Research to Assess the Sources of Contamination in Sprout-Related Outbreaks

As mentioned throughout these comments, ASTA supports FDA's Draft Guidance and agrees that seed for sprouting should be grown, conditioned, packed, held, and distributed in a manner to prevent adulteration. We note, however, that FDA's comment in the Draft Guidance that "[s]tudies indicate that contaminated seed is the likely source of most sprout-related outbreaks" relies on an outdated reference from 1999 that does not reflect the significant changes in the industry during the past 20 years.[1] We encourage FDA to conduct or commission research to assess the sources of contamination for sprout-related outbreaks now that the industry has broadly adopted GAPs and

[1] National Advisory Committee on Microbiological Criteria for Foods (NACMCF), "Microbial Safety Evaluations and Recommendations on Sprouted Seeds," *International Journal of Food Microbiology* 52(1999): 123-153.

sprouters are operating under the Produce Safety Rule. This research would help support future food safety initiatives by providing insights on weak links in the sprout supply chain that could be further bolstered with modifications to existing practices.

Recommendation: FDA should conduct or commission updated research to assess the role of seeds in sprout-related outbreaks.

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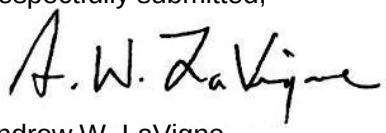
ASTA appreciates the opportunity to provide this input to FDA. Please do not hesitate to contact us if we can provide additional information that may be helpful.

Respectfully submitted,



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