AMERICAN SEED TRADE ASSOCIATION

November 15, 2013

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-2011-N-0921 (RIN 0910-AG35); Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; 78 Fed. Reg. 3504 (Jan. 16, 2013)

Dear Sir or Madam:

The American Seed Trade Association (ASTA) appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA's) proposed rule addressing Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. ASTA strongly supports the goal of the FDA Food Safety Modernization Act (FSMA) to improve the safety of our food supply and commends the agency for its implementation efforts.

Founded in 1883, ASTA is one of the oldest trade organizations in the United States. Our membership consists of over 700 companies involved in seed production and distribution, plant breeding, and related industries in North America. As an authority on plant germplasm, ASTA advocates science and policy issues of industry-wide importance. ASTA's mission is to be an effective voice of action in all matters concerning the development, marketing and movement of seed, associated products, and services throughout the world. ASTA promotes the development of better seed to produce better crops for a better quality of life.

Our focus in these comments is the agency's proposed regulations that would affect seeds used for sprouting. As discussed further below:

- FDA's produce safety regulation should only cover seeds that are expressly intended for sprouting. If a facility produces seed for planting and a third-party later diverts the seed to a sprouter,[1] the seed facility[2] should not be held accountable for compliance with the produce safety rule. Similarly, seed facilities should only be required to register with FDA (and comply with preventive controls) if they make seeds intended for sprouting.

- We support separate treatment of "raw" sprouts and sprouts that will be subject to commercial processing. This risk-based approach is consistent with FSMA's intent.

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[1] In these comments, we use the term "sprouter" to refer to the person or entity that grows, harvests, packs, and holds sprouts for human consumption.

[2] By "seed facility" or "seed producer," we mean the person or entity that cleans, grades, sizes, disinfects, or engages in other activities to prepare seed for commercial sale.

By "seed grower" we mean the person or entity that grows the crop from which the seed will be harvested.

- To make the regulation risk-based, FDA also should place the primary responsibility for sprout safety on sprouters. Using safe seeds is only one element of making safe sprouts. Sprouters should be required to purchase only seeds that were intended for sprouting.

- We support FDA's proposed codified language that would require seed producers to take appropriate steps to prevent contamination when producing seeds that are intended to be used for sprouting. We appreciate the flexibility in the proposed rule that allows individual seed producers to have the discretion to determine what steps are appropriate to take to prevent contamination.

- We support inclusion of a supplier verification requirement in the final rule, so that sprouters are required to verify that the seed producer took appropriate steps to prevent contamination of the seeds. This will help ensure that sprouters only use seeds that are safe for sprouting.

- The term "treat" should not be used in the produce safety regulation because this is a term of art for seeds referring to seeds applied with a substance "to reduce, control, or repel disease organisms or other pests."[3] If sprouters use "treated" seeds, as the term is defined in the seed laws, this would be very dangerous for food safety because these seeds are not developed for human consumption. A reasonable alternative would be to use the term "disinfect."

- FDA should amend its CPG regarding when sprouting seeds are considered "food" to clarify that seeds are only considered "food" if they are intended for sprouting.

Background

The seed industry primarily produces seed for planting (i.e., agronomic purposes). Only a very small percentage of seed is produced with the intent of being used for sprouting. Seed is highly regulated on both the federal and state levels. In particular, the Federal Seed Act requires accurate labeling and purity standards for seeds in interstate commerce, and prohibits the importation and movement of adulterated or misbranded seeds.[4] There also are robust voluntary industry guidelines in place, which supplement Federal Seed Act requirements, as explained in our Guide to Quality Management Practices for Seed Production.[5]

ASTA strongly supports a requirement for sprouters to only use seeds that are expressly intended for sprouting. Unfortunately, some sprouters currently use seed that was not intended for that purpose. The seed industry cannot control diversion or unintended use of seeds after the seeds leave the producer's facility. We hope that FDA's produce safety regulation can help prevent this diversion problem from occurring in the future by requiring sprouters to verify that the seed they use was intended for sprouting.

It will not improve food safety for FDA's produce safety regulation to impose requirements on facilities that produce seed for agronomic/planting purposes. That is, FDA's regulation should only affect facilities that produce seed expressly intended for sprouting. As noted in previous comments

[3] Federal Seed Act § 101(23); 7 USC § 1561(a)(23).
[4] 7 U.S.C. § 1551, et seq.
[5] A copy of this manual is attached as a reference.

(submitted May 5, 2010), ASTA's Food Safety Pathogen Working Group previously concluded, based on a review of scientific literature and CDC/FDA outbreak reports, that seed used in fields and greenhouses for the production of fresh produce does not contribute to pathogen outbreaks.[6] Therefore, we support FDA's proposed limitation to only regulate seeds under the produce safety rule if they are produced with the express intent to use the seeds for sprouting. We urge FDA to clearly narrow the scope of regulation for seed to only those seeds that are produced with the express intent to use for sprouting.

The Scope of the Final Rule Should Only Cover "Raw" Sprouts Not Intended for Commercial Processing

Not all sprouts present the same level of risk. FDA should only focus its produce regulation on the types of sprouts that have a connection to food safety outbreaks. Accordingly, we support FDA's proposed exemption for produce, including sprouts, which will receive commercial processing to adequately reduce the presence of microorganisms of public health significance (e.g., cooked mung bean sprouts). Such products should not be subject to the sprout-specific requirements because any food safety issues in the raw product will be addressed by the subsequent kill step. FDA should not over-regulate by covering all sprouts regardless of whether they will be cooked.[7]

FDA's regulation should only affect "green" or "raw" sprouts, the subset of the category that has been tied to outbreaks.[8] These products can be safe when produced and handled properly, which is why it is important that FDA establish sprout-specific regulations as part of this rulemaking. We support tailoring the scope of the regulation so that it only covers sprouts that present a significant food safety risk, consistent with the Congressional mandate in FSMA.

Sprouters Should Bear Primary Responsibility for Sprout Safety

We agree that it is important that sprouters only use seeds expressly intended for sprouting. We also agree that seeds that are intended to be used for sprouting should have to meet certain safety standards. Even then, however, the sprouting industry bears primary responsibility for sprout safety. Seed companies cannot control the safety of the sprouts that are produced after their seeds are sold. Outbreaks can occur from safe seeds if sprouters do not follow good sprouting practices. That is, safe seeds can be used to make unsafe sprouts. Safe seeds are only one part of the system needed to produce safe sprouts. That is why we believe that FDA's sprout-safety regulation should primarily focus on the sprouting process for sprouts that will not be subject to commercial processing, which includes the procurement of only seeds that were produced with the express intent to be used for sprouting.

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[6] These comments are attached as a reference.

[7] Of course, cooked sprouts must be manufactured in compliance with the preventive controls regulation, proposed 21 C.F.R. Part 117, so they are safe to eat.

[8] Additionally, FDA should define "sprout" in the regulation to make clear what types of foods are covered. Sprouts are foods where the visible seed is part of the consumed product. There are a wide range of sprouted products available on the market, from alfalfa sprouts to wheatgrass sprouts. It is important to have clarity about what foods must comply with the regulation.

ASTA Supports Requiring Sprout Seed Producers to Take "Measures Reasonably Necessary" for Safety

FDA proposes to require facilities that produce seeds for sprouting to make sure the seeds are safe for that purpose. Section 112.141(a) of the proposed rule states: "If your farm grows seeds or beans for use to grow sprouts, you must take *measures reasonably necessary* to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you will use for sprouting" (emphasis added). We support this proposed language because of its flexible approach.[9]

FDA's proposed regulation provides much-needed flexibility to seed producers so they can individually determine the appropriate steps to prevent contamination. We agree with FDA's approach of not prescribing specific measures that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that will be used for sprouting.

This flexible approach is appropriate because there are many different ways to achieve the same goal of preventing the introduction of known or reasonably foreseeable hazards into or onto seeds that are intended to be used for sprouting. Methods are constantly evolving with development of new technology. FDA's FSMA regulations should not be static but, rather, should be written in a flexible manner that allows for development of new technologies and techniques over time. We support the proposed codified language as taking such an approach.

Recognizing that some companies may need assistance in developing programs that meet the regulation's requirements, we support the use of guidance to provide suggested approaches seed companies may follow to be in compliance. The level of detail that will be needed is more appropriate for guidance, which is more readily updated for new developments, than for the regulation itself which requires notice and comment rulemaking to revise.

From our members' experience, we believe that two steps are necessary to ensure sprouting seed safety. First, seed producers should ensure that their seed growers engage in good agricultural practices (GAPs) The GAPs that should be used for growing seeds that are intended to be used in sprouting (and are appropriate to include in guidance on this issue but not in the regulation itself) include the following:

- Sprout seeds should be grown on well drained fields;
- Sprout seed fields should not have animal manure applied or grazing materials in the field;
- Sprout seed fields should not be in close proximity to animal feed lots, so as to prevent water runoff from feed lots into fields;
- Irrigation water should be clean;
- Equipment should be clean; and
- Only appropriate treatments (e.g., chemical seed treatments; crop protectant chemicals) should be applied to the plants that will be used to produce seed.[10]

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[9] We interpret this requirement as applying only if the seeds produced will be used to produce sprouts for raw consumption. If the seeds will be used to grow sprouts that will be further processed to adequately reduce the presence of microorganisms of public health significance and the seed producer can document this fact, proposed section 112.141 should not apply.

[10] These GAPs are intended as examples, not as an exhaustive list.

Second, seed producers should implement Good Manufacturing Practices (GMPs) and sanitation programs.

In addition to requiring their seed growers to follow GAPs and implementing GMPs and sanitation programs in their own facilities, some of our members that produce seed have developed proprietary disinfection techniques to reduce the viability of pathogens on sprout seeds without significantly affecting germination rates. For example, a process may include a combination of modified atmosphere and extended "heat treatment" within closely defined limits. It may be possible to validate such a process to show up to a 3 log reduction in pathogens. We encourage the agency to maintain flexibility (i.e., using the language "measures reasonably necessary" rather than prescribing specific measures in the regulation) so that companies following their own proprietary processes can continue such an approach.

Finally, we encourage the agency to clarify the use of the terms "you" and "your" in the language of the regulation. In the phrases "your farm" and "you will use," it is unclear if the agency intends to apply section 112.141(a) only to farms that produce their own seeds for sprouting or also to seed production facilities that intend to sell their seeds to be used for sprouting purposes by others. We support broader application of this provision to seed production facilities that intend to sell their seeds to others, provided that the agency recognizes that facilities should only be covered by this regulation if they intend for their seeds to be used for sprouting (i.e., the seeds are (1) specifically produced for this purpose and (2) sold directly to sprouters or to third-parties that will then sell the seed to sprouters).

The Final Rule Should Require Supplier Verification by Sprouters

In the preamble to the proposed rule, FDA explains that it considered proposing a supplier approval and verification program for seeds and beans received by sprouters for sprouting purposes. However, the agency declined to take that approach.[11] We encourage FDA to reconsider this issue and require sprouters to engage in supplier verification under the final rule. We believe that requiring supplier verification by sprouters would greatly enhance food safety.

Such a requirement should direct sprouters to verify and document that the seed producer took measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that were intended to be used for sprouting.[12] This approach would provide assurance that seeds received from a third party are appropriately grown, harvested, stored, and handled such that they are acceptable to use for sprouting.

We also support two new labeling requirements for seed producers who intend for their seeds to be used for sprouting. First, these seed producers should be required to label their seeds to state that

[11] 78 Fed. Reg. 3504, 3595-96 (Jan. 16, 2013).

[12] In the alternative, we would support a requirement that the sprouter verify that the seeds were produced for sprouting purposes. This could be achieved by requiring seed companies producing seeds for sprouting to label their seeds with a statement such as "Meets FDA requirements for use in sprouting." Sprouters could be required to use seeds with such labeling.

Another alternative to consider is requiring supplier verification unless the sprouter uses a validated process of their own to control any hazards presented by the seeds and ensure that the sprouts are not adulterated. We are not aware of any such processes, but recognize that they could be developed in the future.

the seeds are appropriate for use in sprout production (e.g., "Seed intended for sprout production"). This labeling would give sprouters a clear indication that the seeds can be used for sprouting and would allow them to infer that seeds that lack such labeling cannot be used for sprouting. Second, seed producers who intend for their seeds to be used for sprouting should be required to include their full name and address on the label.[13] This would give the sprouter the information needed to identify the seed producer so that they can engage in supplier verification.[14]

We disagree with the agency's tentative conclusion that a supplier verification program may not be practical or effective because only a small percentage of harvested seeds go to sprout production. Regardless of whether distributors are used or seeds may be held in storage for some period of time before use, ensuring that they came from an appropriate source will go a long way to improving food safety. Special attention to whether seeds were expressly intended to be used for sprouting is necessary if the system is to work effectively in a way that protects consumers and public health.[15]

A supplier verification requirement also will provide some protection for seed producers who are not producing seed with the intent of sprouting. If a sprouter engages in verification of seeds and the seed producer informs them that the seeds are not intended for sprouting, the sprouter will know that these seeds are not safe to use for that purpose and will not use them. In this case, the sprouter will know it needs to source its seeds elsewhere.

FDA Should Recognize the Term "Treat" Has a Different Meaning under the Federal Seed Act and Should Use a Different Term in the Final Rule

Proposed section 112.142(c) states: "You must treat seeds or beans that will be used to grow sprouts . . . . Prior treatment conducted by a grower, handler, or distributor of seeds or beans does not eliminate your responsibility to treat seeds . . . ." (emphasis added). We support the intent of this requirement (to disinfect seeds before use), but are concerned by use of the term "treat." The word "treat" is a term of art in the seed context, with a different meaning than FDA intends here. Seed treatments are chemical or biological substances that are applied to seeds to control disease organisms, insects, or other pests. Seed treatment pesticides include bactericides, fungicides, and insecticides. Treated seeds generally are not safe for human consumption.

The Federal Seed Act defines the term "treated" to mean seeds "given an application of a substance or subjected to a process designed to reduce, control, or repel disease organisms, insects or other pests which attack seeds or seedlings growing therefrom." Federal Seed Act § 101(a)(23); 7 USC §

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[13] Currently, the Federal Seed Act regulations require seeds to be labeled with the full name and address of either the shipper or consignee. 7 C.F.R. § 201.23. These regulations also require traceability to identify the source of the seed. *See* 7 C.F.R. §§ 201.4, 201.5.

[14] Third-party audits of a supplier's facility that produces seed for sprouting may be a helpful resource for sprouters when conducting supplier verification.

[15] We also note that although this supplier verification requirement may require sprouters to go more than "one step back," which is the traceability limitation under the Bioterrorism Act, FDA has proposed through FSMA requiring supplier verification that goes further back than an immediate supplier. Under the Foreign Supplier Verification Program proposed rule, FDA proposes defining "foreign supplier" to mean, in part, "the establishment that . . . harvests the food." 78 Fed. Reg. 45772 (July 29, 2013) (proposed § 1.500). Oftentimes there are several intermediate parties between an importer and the entity that harvests the food. Therefore, there is precedent in the FSMA rulemakings for requiring sprouters to go more than "one step back" as part of supplier verification.

1561(a)(23).[16] It could be confusing to use the word differently in this regulation. Furthermore, "treated seeds" (using the term as defined in the Federal Seed Act) may not be safe to use for sprouting because such treatments are aimed at a different endpoint: plant health and not human health. We also note that FDA has not proposed a definition for "treat" in the produce safety proposed rule.

In place of the word "treat," we suggest using the term "disinfect." This could be defined as "inactivating human pathogens that may be associated with the seed."

Facility Registration Should Only be Required When Seeds are Expressly Intended for Sprouting

With respect to facility registration, ASTA urges FDA to continue to distinguish between seeds produced for agronomic uses (i.e., to be used in fields and greenhouse vegetable production) versus seeds produced to be used for the development of sprouts. Seed facilities should only be required to register with FDA if they make seeds expressly intended for sprouting. That is, registration should only be required if the facility affirmatively decides that its seeds will be sold to sprout producers and grows and processes them with this intent in mind.[17]

If seed producers are producing seeds intended for agronomic use, they should not be required to register with FDA. Such facilities' activities do not meet the registration trigger in the Bioterrorism Act because they are not producing food for consumption. Furthermore, producers of seed for agronomic use should not be penalized if their seeds are unintentionally used for sprouting based on later diversion by a third-party. Furthermore, we understand such diversion is, at most, trivial in amount.

To make it clear that a seed producer's intent is a key consideration when determining whether facility registration is required, FDA should revise its Compliance Policy Guide (CPG) on this issue.[18] FDA's CPG Sec. 555.750 states: "FDA is of the opinion that all seeds used for sprouting are foods." We respectfully request that FDA revise this CPG to clarify that seeds used for sprouting are foods if the seeds are produced with that intent.[19] This would be consistent with the exemption in the CPG for "mung beans used solely for the purpose of developing mature plants in order to harvest a crop of mung beans." Seed producers should not be penalized or held to food-producing standards simply because a third-party later uses their seeds for an unintended use such as sprouting. If the intent for the seeds is planting, the facility should not have to register.[20]

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[16] Treated seeds are labeled to indicate that they are not safe for producing food for human consumption. Federal Seed Act § 201(i); 7 C.F.R. § 201.31a.

[17] Consistent with FDA's treatment of "mixed type facilities" under FSMA, if a facility produces both seeds intended for sprouting and seeds intended for agronomic purposes only the operations relating to sprout seed production should be required to comply with the produce safety regulation.

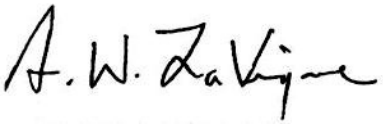
[18] FDA CPG Sec. 555.750, *Seeds for Sprouting Prior to Food Use, i.e., Dried Mung Beans, Alfalfa Seeds, Etc.* We note that this CPG was last updated in 1989, long before the Bioterrorism Act's facility registration requirement and FSMA were adopted.

[19] Specifically, the CPG should be revised to state: "FDA is of the opinion that all seeds produced with the intention of being used for sprouting are foods" (new text underlined).

[20] ASTA is filing separate comments with the agency's docket on the preventive controls for animal feed proposed rule regarding a similar registration-related issue.

In conclusion, we encourage FDA to take a risk-based approach in the produce safety regulation, as applied to sprouts, so that seed companies are only affected if they intend to make seeds for use in sprouting. ASTA appreciates the opportunity to provide these comments.

Sincerely,



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