

AMERICAN SEED TRADE ASSOCIATION



May 30, 2014

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Re: Food and Drug Administration Docket No. FDA-2011-N-0179; Draft Guidance for Industry: Prior Notice of Imported Food Questions and Answers (Edition 3); 79 Fed. Reg. 17947 (Mar. 31, 2014)

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(ASTA) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) regarding its revised draft guidance addressing prior notice of imported food. 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. 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.

The draft guidance includes an updated discussion about the applicability of prior notice requirements for seeds. This section of the draft guidance states:

4.1 Are seeds subject to prior notice requirements?

[Response updated March 2014] The answer depends on whether the seeds meet the definition of food. FDA considers a seed to be food if it is reasonably likely to be directed to a food use (73 FR 66294 at 66301; November 7, 2008). For example, if the seed is for use in animal feed, the seed is food and prior notice is required (21 CFR 1.276(b)(5); 21 CFR 1.277(a)). Similarly, if the seed is to be used for human food, such as sesame seeds to be used in baking or oilseeds for processing into edible oil, then prior notice must be submitted to FDA before the seed is imported or offered for import into the U.S.

If the seed will be used for the production of edible sprouts, such as alfalfa seeds for production of alfalfa sprouts, then you must provide prior notice to FDA before the seeds are imported or offered for import. By contrast, if the seed is only for cultivation (even if it is used to grow a plant that may subsequently be consumed as food), then prior notice is not required.

FDA has an enforcement discretion policy regarding seeds for planting. Under the policy, FDA and CBP would typically consider not taking any regulatory action regarding seeds that will be used for cultivation. The policy applies when no more than a small portion of that seed is diverted from cultivation to animal feed or other food use. It does not apply, however, where the seed is used for the production of edible sprouts, such as alfalfa

seeds for the production of alfalfa sprouts. For further discussion, see FDA's Compliance Policy Guide on FDA's website at:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm>


ASTA supports this revision to the guidance. Notably, the updated guidance explains that a seed is considered "food" (thus, triggering the need to file prior notice) "is reasonably likely to be directed to a food use." ASTA views this language as an improvement over the second edition of the guidance, which assessed "food" status based on whether the importer "reasonably believes that the substance is reasonably expected to be directed to a food use." The updated language is simpler and easier to understand. We also support the reference to FDA's enforcement discretion policy in the updated guidance. Although that policy is not new, FDA's use of cross-references between agency documents in this manner is helpful for industry.

In the same vein, we encourage FDA to revisit its guidance document regarding facility registration, to make updates consistent with the changes proposed for the prior notice guidance document. In particular, the facility registration guidance states that registration is required if "the owner, operator, or agent in charge of the establishment reasonably believes that the seed is reasonably expected to be directed to a food use, including animal food use or as an ingredient in animal food. However, if the seed is reasonably expected only to be cultivated, the establishment is not required to be registered."¹ This uses the same, confusing language that FDA is deleting from the prior notice guidance. We encourage the agency to revise the registration guidance in a manner consistent with the updated prior notice guidance (e.g., registration is required only if the seed is reasonably expected to be directed to a food use). This would provide needed clarity for industry, which is particularly important now that registered facilities face considerable compliance obligations under the FDA Food Safety Modernization Act (FSMA).²

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In conclusion, we encourage FDA to finalize the prior notice draft guidance as-is and to revise the facility registration guidance in a consistent manner. ASTA appreciates the opportunity to provide these comments.

Sincerely,



Andrew W. LaVigne
President & CEO

¹ Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition) (Dec. 2010) at C.9.1.

² That said, ASTA's preferred course of action is for FDA to entirely exempt seed conditioning facilities from the requirement to register with the Agency. See ASTA Comments on Docket No. FDA-2011-N-0922 (Animal Food Preventive Controls Proposed Rule) (submitted March 31, 2014).