AMERICAN SEED TRADE ASSOCIATION, INC.

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December 23, 2003

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

Submitted via courier

RE: Requested Public Comment on Proposed Federal Regulations Promulgated Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act"); Dockets 02N-0276 and 02N-0278

Dear Sir or Madam:

Founded in 1883, the American Seed Trade Association (ASTA) is one of the oldest trade organizations in the United States. Its membership consists of over 800 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 importance. Its mission is to enhance the development and free movement of quality seed worldwide.

The seed industry has been an active partner with a number of federal and state government agencies and scientific organizations on several fronts to protect the integrity of our nation's agricultural homeland from foreign threats, either intentional or accidental. ASTA appreciates the opportunity to comment on the U.S. Food and Drug Administration's (FDA) interim final rules dated October 10, 2003 on *Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (68 Fed. Reg. 58894) and on *Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (68 Fed. Reg. 58974) (the "Interim Final Rules").

We wish to point out that seed companies are engaged primarily in the breeding, production and marketing of seed for planting purposes. As discussed in depth below, only a small portion of crops used for the production of such seed or seed itself may directly enter the human and other animal food chain. Such discarded seed remains in its natural state and has not undergone any manufacturing or processing, as defined in the Interim Final Rules. We believe that seed for planting, *i.e.*, planting seed, does not have a direct impact on the safety of the U.S. food supply. Therefore not all

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U.S. facilities of seed companies should be required to register. Foreign facilities that ship seed to the U.S. solely for planting purposes should also be excluded from FDA's registration requirements. Moreover, all seed research facilities should be exempted from registration requirements. Furthermore, we believe the definitions of "Farm" and "Harvesting" should be revised, taking into account seed production practices and modern farm business structures, to address certain difficulties in applying the current definitions. Finally, seed shipped to the U.S. solely for planting purposes should be expressly exempted from FDA's prior notice requirements.

Applicability of FDA's Registration Regulations to the Seed Industry's Research and Import Activities

The seed industry, particularly those companies located in the United States, Canada, and Mexico, have received erroneous, inconsistent and contradictory information from a number of government officials regarding the applicability of FDA's new bioterrorism regulations. We believe that this is partly due to language in the preambles to the registration and prior notice interim final rules regarding "multiple use" products. For example, to determine the applicability of the new rules, FDA articulates a novel standard for "multiple use" products that have food and non-food uses. The agency states that the rules apply if certain persons associated with the facility or shipment in question "reasonably believe the [multiple-use product] is reasonably expected to be directed to a food use." *See, e.g.,* 68 Fed. Reg. at 58910 and *id.* at 58987.

This "reasonably believes" and "reasonably expected" language, sometimes referred to herein as the "double reasonably" standard, is very unclear and difficult, if not impossible, to apply to the seed industry's varied research and development activities. This is because very small amounts of seed from research activities may be found "unsuitable" for planting and end up in the food supply. Moreover, since the quantities of such "discarded" seed are very, very small, any potential safety or security risks associated with such small quantities are very low. This is particularly true because research facilities routinely tightly control access to and the disposition of their seed for proprietary and security reasons. Staffs of professionally trained scientists, who constantly monitor the entire research process, continually manage research seed and research sites and maintain detailed records regarding all aspects of seed research, production, harvest, and shipment. Any small quantities from research facilities that may eventually be directed to food use come from highly supervised and controlled environments.

ASTA believes that a research seed facility owned by a seed company that merely packs or holds seed (that may later be sold as food) that is grown on a farm

owned by the seed company is exempt from the registration requirements according to the farm exemption in the Interim Final Rules. Some research facilities, however, receive very small quantities of seed from other companies collaborating in research that may be commingled with seed grown by the seed company. ASTA is concerned that given the current language defining FDA's farm exemption, this activity could cause a research seed facility to lose its exemption. It further believes the amount of seed that could be commingled at a research facility is so negligible and the seed is planted, grown, and harvested under such controlled conditions, as described above, that all such research facilities should be exempted from the registration requirements.

More generally, we should further emphasize that the confusion that exists regarding the applicability of the interim final rules to seed industry activities already is affecting seed movement. In situations where the industry believes their facilities are exempt from registration using FDA's confusing "double reasonably" standard mentioned above, at least one international express courier has already rejected a shipment bound for the U.S. unless the foreign facility supplies a registration number because of the risk that FDA or Customs and Border Protection (CBP) may hold or refuse the shipment due to inadequate prior notice. We have received other reports of difficulties our members are encountering clearing imports of shipments of planting seed through FDA and CBP at the border.

Accordingly, ASTA asks FDA to explicitly state that no prior notice is required for imported seed that is imported for planting purposes and that seed research facilities are exempt from registration, even if *de minimis* amounts might later be discarded into food channels. An explicit statement exempting such imported seed shipments and research facilities will minimize the current confusion that will contribute to unnecessary and costly delays at the borders or result in inconsistent regulatory enforcement.

Problems Regarding Implementation of Prior Notice Using FDA-Flagged HTS Codes

Another area that presents significant problems to the seed industry is FDA's adoption and application of its so-called Harmonized Tariff Schedule (HTS) code flagging system to imported articles subject to prior notice requirements. ASTA would like to work with FDA and other government agencies to minimize any likelihood of shipments being delayed at the border because of the misapplication of prior notice requirements to seed. To understand our concerns in this area, we first discuss FDA's complex flagging system and the use of it in the context of the prior notice interim rule.

In November 2003, FDA issued guidance to industry regarding the agency's cross linking, or "flagging", of the Harmonized Tariff Schedule (HTS) codes for articles for which FDA prior notice is, or may be, required. *See Guidance to Industry, Prior Notice of Imported Food: Harmonized Tariff Codes Flagged with Prior Notice Indicators*, Nov. 11, 2003, http://www.cfsan.fda.gov/~dms/htsguide.html (last viewed Dec. 16, 2003). Since the development of FDA's Operational and Administrative System for Import Support (OASIS), FDA has "flagged" various HTS codes in Customs and Border Protection's (CBP) electronic systems to ensure FDA receives electronic notice of imported articles regulated under the Federal Food, Drug and Cosmetic Act (FDCA). Historically, FDA flagged certain selected HTS codes with "FD0", "FD1", or "FD2". *See Import Operations/Actions, Subchapter: Import Procedures,* Regulatory Procedures Manual (RPM), Ch. 9, http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9imp.html, (last viewed Dec. 16, 2003).

FDA assigns "FD2" flags to HTS codes for articles that FDA predetermines are subject to FDA's jurisdiction and, therefore, entry data must be declared electronically to FDA during the declaration to CBP. The FD2 flag seems analogous to FDA's new "FD4" flags for HTS codes, a flag for goods that FDA has now predetermined in the context of the bioterrorism interim rule to require prior notice. Moreover, FDA states in recent guidance that CBP entry cannot even be made on "FD4" flagged HTS codes if FDA has not received a prior notice. *See Prior Notice of Imported Food Questions and Answers,* http://www.cfsan.fda.gov/~pn/pnqaguid.html (last viewed Dec 16, 2003) (answer to question 57 stating no CBP entry may be made for articles subject to prior notice requirements if those requirements have not been complied with). Therefore, if any imported seed entry is classified, whether properly or not, with an HTS code flagged by FDA as "FD4", the entry must be preceded or accompanied by prior notice, even if the seed is for planting purposes and no one associated with the shipment has any reasonable belief or expectation that the seed will be directed to a food use.

Another complication exists. During the development of OASIS, FDA assigned "FD1" flags to HTS codes for categories of goods that may be subject to FDA jurisdiction. The person electronically transmitting the entry data associated with an "FD1" flagged HTS code (ordinarily a customs broker or self-filer) must decide when filing the entry whether the article is FDA regulated, depending partly upon the article's "intended use". *See Import Operations/Actions, Subchapter: Import Procedures,* RPM Ch. 9. If the article is not intended for a use within FDA's jurisdiction, the person making the declaration may "disclaim" the entry in the electronic systems. There is no requirement to transmit entry data to FDA for "disclaimed" FD1-flagged HTS codes. This FD1 flag category is similar to FDA's new "FD3" flag for prior notice, which FDA has used to indicate HTS codes that "may" be subject to prior notice. FDA has not, however, clarified that a similar "disclaim" process is available for FD3 codes with respect to prior notice.

In light of the foregoing difficulties and confusion, ASTA requests that FDA exempt planting seed entries from prior notice requirements and remove FD3 flags from HTS codes that cover seed for sowing or planting. Alternatively, FDA should clarify that FD3-flagged HTS codes may be "disclaimed" at entry as described above for other goods based upon information available to the importer, owner, or consignee of the shipment at the time of importation.

Furthermore, irrespective of whether an HTS code is flagged by FDA, the agency should not rely solely upon HTS flags to implement its prior notice requirements. ASTA recommends that FDA issue further guidance recognizing statements on shipping documents or invoices, such as "seed covered by this invoice is for planting purposes only," to alert border officials that planting seed shipments do not require prior notice submissions.

Under the current system, importers may file prior notices simply to prevent possible delays due to FDA's HTS-flagging process. This over-reporting will create an undue burden on the seed industry and on FDA and CBP, and may create additional confusion and cause additional border delays. ASTA believes FDA's implementation of the requested actions would effectively prevent over-reporting where prior notice clearly is not required or appropriate.

Need for Revision of the Registration Definition of "Farm"

ASTA believes that the language FDA has chosen to define the boundaries of its exemption for "farms" from the registration requirements is also problematic. FDA added language to the originally proposed farm definition in order to expand its scope and bring within the exemption activities that traditionally occur on "farms." It appears that the farming operations FDA had in mind in developing the revised definition were those that grow fresh produce; however, comparable harvesting activities incidental to seed farming were not addressed.

The interim final rule expanded the definition of the term "farm" to "a facility in one general location that is devoted to the growing and harvesting of crops . . . [including] facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or on another farm under the same ownership." *See* 68 Fed. Reg. at 58961 (to be codified at 21 C.F.R. § 1.227(3)(i)). The "same ownership" language, however, does not recognize that many seed activities conducted on farms are the result of contracts and do not involve ownership. A seed company may contract with a landowner to grow seed and perform some harvesting activities but then the company may conduct additional activities at different locations

owned by the company. ASTA believes that given the nature of such seed operations, the phrase "under the same ownership" is at least ambiguous and, in any event, does not reflect current seed operations and activities that are closely associated with seed farming. These activities are part of "harvesting" discussed in the next section. The double "reasonably" standard that FDA asks ASTA members to apply to determine whether their "facility" should be registered further complicates these matters.

To try to alleviate these difficulties, ASTA recommends that FDA revise the definition of "farm" at 21 C.F.R. § 1.227(3)(i) to include "facilities that pack or hold food, provided that all food used in such activities is grown, harvested, raised, or consumed on that farm or on another farm that is operated by or under the same ownership or control as the facility conducting the activities" (tracked changes reflect proposed revision). This revision, in conjunction with the recommendations that follow, would grant the "farm exemption" to some facilities operated by many of ASTA's members that conduct seed activities but may not be recognized within the current definition of "farm." It would also ensure the exemption extends to all breeding operations. The proposed revision is also consistent with FDA's expansion of "farm" to include "facilities" that pack or hold. *See* 21 C.F.R. § 1.227(3)(i).

ASTA believes that Congress fully intended to exempt farms and all of the traditional activities that are incidental to farming activities and not to mandate a registration requirement that fails to take into account current seed operations. In addition, seed companies keep detailed records regarding all aspects of seed production, harvesting, and shipment and have in place various control measures in order to meet regulatory requirements, ensure product quality, and prevent cross-contamination. Therefore, exempting seed farming and harvesting operations from the regulation by revising the definition of "farm" as ASTA proposes would not increase safety or security risks of the nation's food supply.

Corollary Need for Revised Definition of Activities Included in "Harvesting"

For similar reasons as those described above pertaining to the lack of recognition of seed operations in the registration exemption for farms, ASTA also requests a review and revision of FDA's definition of farm "harvesting" activities. According to the registration interim rule, "harvesting" activities include only "washing, trimming of outer leaves of, and cooling produce." *See* 68 Fed. Reg. at 58910 (to be codified at 21 C.F.R. § 1.227(3)(i)). Seed farming operations, however, routinely conduct different activities that are in fact incidental to the "harvesting" of seeds for planting purposes, such as shucking, sizing, coating, and treating seed. These seed harvesting activities may occur, for example, at locations owned, operated by, or under the control of entities for which the seed was grown under contract on other lands.

In light of the traditional and incidental nature of current seed farming activities, ASTA therefore further requests that FDA revise the definition of "harvesting" to include "shucking, sizing, coating, and treating seed." This change would extend the farm exemption to seed facilities that would not be exempt under our proposed expansion of the "ownership or control" language discussed above. ASTA believes this expansion is justified by the same reasoning FDA used to exempt "washing, trimming the outer leaves of, and cooling produce." The additional proposed activities are traditional and incidental to seed farming operations but were overlooked by FDA because the "farms" FDA clearly had in mind in expanding the farm exemption did not involve facilities that conduct seed operations.

Additional Needed Change to Definition of "Food In Its Natural State"

Furthermore, planting seeds harvested in these additional ways remain in their natural state. *See* 68 Fed. Reg. at 58977 (describing activities that will not render food "not in its natural state" for determining whether a "grower" or "manufacturer" should be identified in prior notice submissions). Consequently, if FDA determines that imported seed should be subject to prior notice, the foreign sources of the imported seed would be properly classified in prior notice as "growers," which are not required to register with FDA, even if they are direct exporters to the U.S. The result is that FDA's registration requirements would be applied consistently to domestic and foreign planting seed operations, especially if FDA decides that prior notice may be required for imported seed shipments.

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In summary ASTA asks FDA:

- To explicitly state that no prior notice is required for imported seed that is destined solely for planting purposes.

- To remove "FD3" flags from HTS codes that cover seed for sowing or planting, to avoid confusion at the border regarding applicability of prior notice requirements; or alternatively, clarify that "FD3" flagged HTS codes may be "disclaimed" at entry based upon information available to the importer, owner, or consignee of the shipment at the time of importation.

- To issue further guidance recognizing the use of statements on shipping documents or invoices, such as "Seed covered by this

invoice is for planting purposes only," to alert border officials that planting seed shipments do not require prior notice submissions.

- To explicitly state that seed research facilities and operations are exempt from registration with FDA.

- To revise the definition of "farm" under the farm exemption at 21 C.F.R. § 1.227(3)(i) to include "facilities that pack or hold food, provided that all food used in such activities is grown, harvested, raised, or consumed on that farm or on another farm that is operated by or under the same ownership or control as the facility conducting the activities."

- To revise the definition of "harvesting" to include "shucking, sizing, coating, and treating of seed."

- To explicitly state that seed for sowing or planting that are shucked, sorted, sized, coated, and treated remain "in their natural state" for purposes of prior notice.

ASTA again wishes to convey our appreciation for the opportunity to provide comment on FDA's interim rule. We remain at your disposal for any information and assistance that will facilitate the smooth implementation of FDA's regulatory oversight under the Bioterrorism Act.

Sincerely,

Richard T. Crowder
President and CEO