AMERICAN SEED TRADE ASSOCIATION

March 31, 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-0922 (RIN 0910-AG10); Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; 78 Fed. Reg. 64736 (Oct. 29, 2013)

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 proposed rule addressing Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.[1] 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. 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.

Our comments focus on the proposed regulations as they would affect the seed industry. Seed conditioning facilities[2] prepare seeds for commercial sale with the intent of their use for planting; however, some seeds are diverted for animal consumption when the intended use cannot be achieved. In large part because the seed industry presents a low-risk for food safety, our members certainly were not the intended target of this regulation when FSMA was developed by Congress. However, as a threshold matter, we are concerned that FDA may expect our members to comply with the proposed rule based on an outdated FDA guidance document interpreting the agency's facility registration regulations. This guidance imposes an overly broad registration expectation, which is particularly significant now that registration drives the applicability of the Animal Food Rule. The facility registration requirement aside, the proposed Animal Food Rule is wide-reaching, applying an expansive view of the meaning of "animal food" and treating every party in the entire supply chain as if they are a finished, processed animal food manufacturer.[3] This approach needs careful reconsideration by the agency.

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[1] 78 Fed. Reg. 64736 (Oct. 29, 2013), sometimes referred to herein as the "Animal Food Rule."

[2] By "seed conditioning facility" we mean the person or entity that cleans, grades, sizes, disinfects, or engages in other activities (e.g., drying, sorting, screening, fumigating, blending) to prepare seed for commercial sale

[3] For consistency with the preamble, our comments generally use the phrase "animal food" rather than "animal feed" to refer collectively to food consumed by animals.

As discussed in more detail in our comments that follow:

- Both the Good Manufacturing Practices (GMPs) and food safety plan-related requirements in the proposed Animal Food Rule present considerable compliance challenges and costs for seed conditioning facilities, without providing any significant benefit for the safety of animals or humans.

- FDA should exempt seed conditioning facilities from the requirement to register with the Agency under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act"). This action by FDA, if adopted, would render our FSMA-related concerns moot, as only registered facilities are required to comply with the preventive controls regulations. In particular, our comments explain why the activities performed at seed conditioning facilities are low risk and consistent with other facility registration exemptions.

- Although establishing an exemption from registration would be the clearest and most straightforward solution to the unnecessary regulatory burden that would be placed on the seed industry under the Animal Food Rule, there are several alternative approaches FDA could use to achieve the same result of exempting seed conditioning facilities from compliance with this regulation. These include:

    - Recognizing that the only activity seed conditioning facilities engage in regarding "food" is "storage" for a raw agricultural commodity (RAC) for further distribution or processing,
    - Exempting seed conditioning facilities as "solely engaged" in animal food production because they do not also engage in activities regarding human food production, or
    - Promulgating an exemption using FDA's legal authority to interpret the Federal Food, Drug, and Cosmetic Act (FFDCA) in a reasonable manner.

- The proposed "very small business" exemption would not provide relief to the seed industry because most of our members would not qualify. This is because the statute aggregates the value of sales company-wide rather than applying it on a facility-by-facility basis. Even for companies that would qualify as exempt, however, the exemption only would apply to preventive controls but not for GMPs, which also are a concern for our members and are not necessary in to assure the safety of materials from seed conditioning facilities.

- FDA has not adequately considered the economic and environmental impacts of the proposal, particularly regarding how our industry would be affected.

In summary, we urge FDA to exempt our members from compliance with the animal food preventive controls regulation, either through modifying the facility registration requirements (our preferred approach) or establishing a specific exemption for seed conditioning facilities as part of this rulemaking. These comments refer to this request collectively as our request for an exemption, even though technically the exemption would be implicit under the facility registration approach.

In light of the fact that the proposed rule requires significant revisions and reconsideration, we request that FDA re-propose the regulation, and provide an opportunity for public comment, before proceeding to issue a final rule. This is appropriate given that the impact on our industry, and many similarly situated agricultural industries, were not specifically considered or addressed as part of the proposal. This re-proposal should include an economic analysis comparing the costs and benefits associated with applying the regulation to our members, unless we are affirmatively exempted. We believe the significant costs to our industry have not been justified by the agency on the basis of preventing food safety risks.

I. Background

Our members condition seed for planting purposes. However, not all of the seed that our members condition is suitable for planting, as seeds can become cracked or damaged during the process (referred to as "screenings") or may not prove to be suitable for cultivation (e.g., low germination rate).[4] Additionally, sometimes our members condition more seed than the market demands, resulting in oversupply that easily can exceed storage capacity.[5] (Collectively, our comments refer to screenings, culls, and overstock as "discarded seed materials" or "discards.")

Untreated[6] discarded seed materials sometimes are sent or made available for animal consumption, which our members have found to be an environmentally and economically sound way to manage the materials (compared with the alternatives of incineration or landfilling). That said, the economic value of discarded seed materials is significantly lower than it would be if they were sold for cultivation, as initially intended. Cultivation is always the goal. Additionally, it is not a universal practice for seed conditioning facilities to send their discards for animal consumption.

When they are diverted into the animal food supply chain, discards typically are sent in bulk to an intermediary such as a grain elevator or feed mill prior to being used for feed. However, some discarded seed materials are sent directly to farmers or feedlots, where we understand they are used to supplement livestock diets. Other discards are provided to a broker or coop, so their end use is not known but could reasonably involve animal consumption. Discarded seed materials are never sold as a "complete feed." Additionally, these materials represent a tiny percentage of the total grain that is directed to animal food in the U.S. in any given year.

Seed conditioning facilities already are highly regulated on the federal and state levels, but the regulations are focused on seed quality and seed safety rather than food safety.[7] As seed is not

[4] Materials like corn husks and hulls also can be diverted for animal consumption (sometimes referred to as "culls").

[5] Seed conditioning facilities typically take delivery of 130 – 160% of sales inventory to guard against business risks such as demand uncertainty, long production cycles, and variables due to weather issues (e.g., drought, hail).

[6] Treated seeds are not diverted for animal consumption. Our members have carefully controlled processes in place to separate treated and untreated seeds.

[7] 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. 7 U.S.C. § 1551, et seq. There also are robust voluntary industry guidelines in place, which supplement Federal

conditioned in facilities that are currently regulated by FDA, our members' facilities do not follow GMPs for food production. Similarly, to the best of our knowledge, none of our members has ever voluntarily developed or implemented a food safety-focused hazard analysis and critical control points (HACCP) plan in their facilities. Discarded seed materials from seed conditioning facilities also are not typically regulated as commercial animal feed on the state level.[8]

There is no evidence that Congress ever intended for the seed industry to be covered by FSMA, but now the industry is facing the potential of being regulated under the proposed Animal Food Rule because it applies to all FDA registered facilities. Based on FDA's earlier interpretation of its registration guidance, we are concerned that the Agency could take the position that seed conditioning facilities are required to register with the Agency and, therefore, must comply with the preventive controls for animal food regulation. FDA should take all necessary actions to avoid this result. In our comments that follow, we discuss potential solutions FDA can implement to avoid capturing seed conditioning facilities under the significant regulatory requirements of this regulation.

II. The Proposed Requirements are not Feasible for Seed Conditioning Facilities to Implement

If FDA does not exempt seed conditioning facilities from compliance with the proposed rules, as advocated below, there will be considerable compliance challenges and burdens for our members. Rather than attempting to quantify specific costs, we are providing illustrative examples of the types of changes that would be needed to come into compliance with both the GMP and food safety plan requirements. This is because there are many questions about how the proposed GMPs would be interpreted and applied in our members' facilities, and because our members are not able to quantify values in an area in which they have no experience.

Before going into more detail, we want FDA to understand that application of food GMPs and food safety plans does not make sense in seed conditioning facilities and would be an entirely new concept. Seed conditioning facilities have no practical experience in this area because their activities are focused on their intended end product—seed for planting—rather than the discards that may end up as animal food. All activities are focused on maintaining varietal purity and product uniformity. Sites are clean and orderly, in part because it is required by law,[9] but the proposal expects the facilities to be maintained in a very different manner than they are today.

Additionally, our members do not have personnel in management or other roles that are educated or trained in food safety such that they could readily develop, implement, and manage these programs.

Seed Act requirements, as explained in our Guide to Seed Quality Management Practices, *available at* http://www.amseed.org/pdfs/resources/guide-to-seed-quality-management.pdf.

[8] The Association of American Feed Control Officials (AAFCO) exempts many discarded seeds from the definition of "commercial feed": "Unmixed whole seeds and physically altered entire unmixed seeds, when such whole or physically altered seeds are not chemically changed or are not adulterated within the meaning of Section 7(a) of this [AAFCO Model] Act, are exempt." AAFCO Model Bill and Regulations, § 3(b).

[9] Notably, the Occupational Safety and Health Administration (OSHA) "housekeeping rule," 29 C.F.R. § 1910.22, already requires places of employment to be kept in a clean, orderly, and sanitary condition.

In addition to needing to hire a "qualified individual" under the proposal to develop and implement a food safety plan,[10] other personnel also would require training in animal food production, food handing techniques, and food-protection principles.[11] Moreover, facilities would need to develop and implement many new procedures and also may require capital investments to reconfigure their facilities.

A. Concerns from Application of the GMPs

With respect to the proposed GMPs, the following are a few illustrative examples of the compliance challenges our members face:

- **§ 507.14 (Personnel):** Our members have training programs in place, but these programs do not relate to food safety. Additional training would be required to provide employees with the skills to develop, implement, and manage these programs.

- **§ 507.17 (Plant and Grounds):** Seed conditioning facilities are maintained in a clean manner, but there sometimes are loose materials around the facility environment (e.g., corn husks). Our members are concerned that FDA investigators will expect the same level of cleanliness as is required for food manufacturers, which would be difficult to achieve (and is unnecessary for food safety). Additionally, parts of some facilities are exposed to the elements and therefore factors are introduced that cannot be controlled like they would be in a traditional food production facility, but, again, this does not pose a food safety concern.

- **§ 507.19 (Sanitary Operations):** Our members clean their facilities, but their cleaning practices are focused on maintaining seed quality rather than on disinfection for food safety purposes. For example, facilities often clean off dust and "kernel clean" between different seed batches in order to maintain seed purity. Cleaning is done with a broom and air nozzle—not with sanitizing agents. Another challenge is that the systems that carry the discards are not always accessible for cleaning and may need to be redesigned to enable access (involving significant capital investments at some facilities). The requirements for cleaning animal food-contact surfaces also are nebulous in this context and could pose a major challenge, as well as an additional investment for many facilities.

  Additionally, proposed section 507.19(c) would specify requirements for the use and storage of toxic materials in animal food facilities. Numerous seed conditioning facilities are responsible for applying chemicals like fungicides and insecticides on seed. These facilities are operated in accordance with Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), and state regulations for handling the chemicals in question. The proposed rule could be read to require separation between treated and untreated seed conditioning facilities, which would be a huge disruption to our members' businesses and require a significant investment. Our members do engage in segregation

[10] Proposed § 507.50.
[11] Proposed § 507.14(b).

and have processes in place to prevent comingling of treated and untreated seeds, but activities involving treated and untreated seeds often occur in the same building.[12]

Notably, all of these changes that would require capital investments would not add any value for our members' core business of seed conditioning. We also question whether any of the process changes that would be required will add any value for food safety. Regarding proposed requirements for personnel hygiene in particular, we refer FDA to the expert report submitted to this docket by the American Feed Industry Association (AFIA), which concludes that "it is unlikely that animals would get sick from pathogens spread from humans involved in feed manufacturing to livestock through animal feed."[13]

To the extent that FDA requires compliance with GMPs by seed conditioning facilities, we urge the Agency to significantly revise the regulation. We understand that the GMPs in the proposed rule are significantly similar to the GMPs for human food, but this simply does not seem like the right fit. The regulations need to be "right sized" for the diverse animal food industry. FDA should conduct a careful analysis of the impact of the GMPs throughout the animal food supply chain by visiting facilities that would be covered by the rule to understand firsthand the challenges that they would face from being obligated to comply with processed food-type rules. FDA also should recognize the inherent uncertainty that results from questions about how individual investigators will apply the GMPs and, therefore, should issue internal guidance to direct the investigators to take a practical approach fit to the nature of the facility. Although not itemized above, there are numerous areas of the proposed GMPs that could either be reasonable or onerous depending on how they are interpreted by the Agency. For additional detail on the challenges of applying the proposed GMPs, we refer FDA to the comments submitted to this docket by the National Grain and Feed Association.

B. Concerns from Application of the Food Safety Plan Requirements

The challenges posed by application of the food safety plan requirements in seed conditioning facilities underscore the fundamental reason why FDA should exempt our members from this regulation. The first step in developing a food safety plan is to conduct a hazard analysis, but our members lack the information necessary to achieve this requirement because they typically do not know what type of animals will consume the seed discard materials and have no practical way to trace them (in particular, seeds are fungible and typically are commingled further down the supply chain, such as at a grain elevator).

Even if the type of animals could be identified, our members have no experience assessing the risks associated with seed consumption by these animals. Presumably mycotoxins and foreign material are hazards that would need to be considered, as these are already controlled today (though not

[12] Seed conditioning facilities also engage in considerable efforts to ensure there are no chemicals in diverted seeds (i.e., that only untreated seeds are diverted).

[13] *See* report submitted with AFIA comments (prepared by Timothy J. Goldsmith DVM, MPH, DACVPM and Aim Prasarnphanich, DVM, Center for Animal Health and Food Safety, University of Minnesota).

necessarily with monitoring, verification, and corrective actions as FDA would require). Outside consultants or additional staff would be needed to conduct a viable hazard analysis.[14]

Preventive controls then would need to be developed from the ground up, as there are no food safety-focused HACCP plans in place at seed conditioning facilities today. Activities like monitoring, verification, and corrective actions related to food safety would be entirely new processes to be developed, as would be the corresponding documentation requirements. Validation could present a significant challenge and expense, depending on FDA's expectations, especially considering the broad range of further processing activities that may occur. There also are no supplier verification or microbiological testing programs in place for discards.[15] Additionally, a recall plan would be quite challenging to execute because diverted materials are mixed and blended once they leave a seed conditioning facility.

Moreover, all of these actions would be unnecessary to improve food safety. Our members' customers already have processes in place to assess incoming seed discard materials and make sure that they are safe for their intended use (e.g., assessing mycotoxin levels) and our members do not discard materials that are not safe (e.g., treated seed). To the extent that seed discard materials are considered "food," the processes in place today are adequate to prevent adulteration under the FFDCA. In short, application of the food safety plan requirements would require considerable effort without providing corresponding benefits to improve animal or human health.[16]

III. FDA Should Exempt Seed Conditioning Facilities from the Facility Registration Requirement

A. FDA's Facility Registration Guidance Should Be Updated in Light of FSMA

When the FDA facility registration requirements initially were developed after enactment of the Bioterrorism Act, there were minimal legal obligations that attached as the result of registering with FDA. For the most part, facility registration was a one-time act that created a "phone book" of sorts for FDA so that the Agency had a means of identifying FDA-regulated facilities in the event of an emergency, such as a food safety outbreak or terrorist attack. As a result, both the agency's and the industry's initial application of the registration requirement was quite broad. But, the consequence of facility registration changed dramatically with FSMA, when Congress provided that the preventive controls obligations apply for all registered facilities (unless specifically exempted by FSMA or by FDA in promulgating regulations under FSMA). Accordingly, the impact to the seed industry of FDA facility registration has gone from nominal to extremely significant in terms of the accompanying regulatory obligations.

[14] Notably, FSMA specifically prohibits FDA from requiring a facility to hire a consultant or other third party "to identify, implement, certify, or audit preventive controls." FFDCA § 418(n)(3)(D); FSMA § 103). Although the proposed rule does not expressly mandate hiring a consultant, such a requirement would be the functional result when considering that the our industry lacks expertise in animal health issues.
[15] The microbiological testing conducted today is related to phytosanitary concerns for export certificates.
[16] *See* AFIA expert report, *supra* note 14.

The Agency's facility registration regulations do not specifically address the need for seed conditioning facilities to register.[17] Rather, the regulations simply state that a facility must register if it is "engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States," unless the facility qualifies for an exemption.[18] The Agency's guidance documents expand considerably about the Agency's expectations regarding the scope of the registration requirement.

In its facility registration guidance, including the most recent edition entitled *Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition)* (hereinafter "Registration Guidance"), FDA includes the following discussion:

> 9.1 Q: Is an establishment that manufactures/processes and sells seed to farmers a facility that is required to be registered if the seed is intended to be used as animal food? What if the seed is for cultivation?
>
> A: FDA requires registration of any facility that manufactures/processes, packs, or holds food for consumption in the U.S. "Food" is defined in section 201(f) of the FD&C Act (21 U.S.C. 321(f)) to include articles used for food or drink for man or other animals. The establishment that manufactures/processes and sells seed to farmers is a facility that must be registered 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. (See Comment 62 in the preamble to the Interim Final Rule).[19]

Seed conditioning facilities should not be required to register with FDA because they do not *intend* to manufacture, process, pack, or hold food for animal consumption and, therefore, are not in the animal food business. Rather, these facilities only intend to produce seed that can be used for planting—but sometimes they cannot achieve that goal and some materials must be discarded. Thus, the "substance" is not "reasonably expected to be directed to food use" because the discards

[17] 21 CFR Part 1, Subpart H (§§ 1.225 – 1.243).

[18] For example, farms (facilities "devoted to the growing and harvesting of crops") are exempted from facility registration. 21 CFR § 1.227(b)(3).

[19] *Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition)*, December 2012 (emphasis added). *See also* 68 Fed. Reg. 58893, 58910-11 (October 10, 2003) (Comment 62 in the preamble to the Interim Final Rule (IFR)). This discussion in the IFR preamble responded to comments that suggested facilities producing bulk ingredients that have both food and non-food uses should only be required to register if the commodity has been sufficiently refined to be directly added to food. The agency responded that under FFDCA section 201(f), "food" means "articles used for food or drink," so the determination of whether a substance is "food" is not a question of intended use. "Thus, FDA believes that a facility that manufactures/processes, packs, or holds food must be registered (unless subject to one of the exemptions in [21 CFR §] 1.226) even if the food is not yet in the form in which it will be used for food. FDA will consider a product as one that will be used for food if the owner, operator, or agent in charge of the facility reasonably believes that the substance is reasonably expected to be directed to a food use."

are not processed, designed, or marketed for animal consumption. Rather, diversion for animal consumption is simply one of several alternatives that can be used as a means of discarding the seeds (along with incineration and landfilling).

Although individual companies may conclude that it is appropriate not to register based on their interpretation of this guidance, our members feel considerable uncertainty because of the potential that FDA could broadly interpret the Registration Guidance to require seed conditioning facilities to register. The significant impact of this interpretation was not contemplated when it was originally issued and, therefore, should be reexamined in light of FSMA. FDA should provide greater clarity about the registration obligations for seed conditioning facilities now that facility registration is accompanied by considerable compliance obligations.

Specifically, ASTA urges FDA to revise its facility registration guidance to expressly exempt seed conditioning facilities from the facility registration requirements. The Agency should delete question 9.1 from this guidance document or revise it to provide that seed conditioning facilities are not expected to register. We note that as guidance this statement can be revised by FDA at any time without the need to engage in rulemaking, especially when the statute in question (Bioterrorism Act) does not speak to the issue directly.[20]

Alternatively, in the preamble to the animal food final rule or another document issued during the FSMA rulemaking process, FDA should interpret its registration guidance to mean that seed conditioning facilities are not required to register if their primary business intent is to produce seed for planting. Under this interpretation, any use of seeds for animal consumption would be merely incidental when the intended purpose (cultivation/planting) cannot be achieved, and therefore diversion for animals would not trigger registration. That is, agricultural seed is never "reasonably expected to be directed to a food use" because it always is expected to be planted.

We urge the Agency to revise the Registration Guidance to provide clarity and consistency, particularly given that companies are free to take their own approach other than what is recommended in guidance if they determine it is consistent with the legal standards. FDA guidance documents "do not establish any legally enforceable rights or responsibilities" and "[t]hey do not legally bind the public or FDA."[21] Under the law, use of an alternative approach is permitted if it complies with the relevant statute and regulations.

Following a discussion of why seed discard materials are low risk and akin to other materials that do not trigger facility registration, our comments in section IV below suggest several other alternative legal approaches FDA could take to mitigate the impact of the proposed rule for the seed industry. However, a simple change to the facility registration guidance would be the most straightforward and direct solution and, therefore, is our favored approach.

[20] We also would support an express exemption through the facility registration regulations, but recognize that such action requires notice and comment rulemaking and therefore is more difficult to achieve than revising guidance.
[21] 21 C.F.R. § 10.115.

B. Seed Discard Materials Used for Animal Food Should Be Exempt from Registration Because they are Inherently Low Risk and Subject to Minimal Handling

In addition to the other reasons discussed above, perhaps the most important reason to exempt seed conditioning facilities from the full reach of the proposed Animal Food Rule is that the activities in which most are engaged with respect to seeds used for animal food are inherently low risk.

In general, seed conditioning facilities subject seed to minimal handling in order to preserve seed quality. While specific crops require different handling, the general process is to receive seed via a bulk truck, remove foreign material such as sticks and leaves, dry the seed if needed, and sort the seed by size, shape or color. Neither water nor chemicals are used during these stages of handling.

The following provides more specific examples of the handling of corn and soybean seed, two products that often are discarded through the animal food supply chain:

- Corn is detasseled and harvested in the production field, then brought in bulk to seed conditioning facilities. Upon receipt, the seed conditioning facility uses basic manual or mechanical processes to remove the husk, shell the corn, remove kernels and screen the seed in order to size it. Corn discards may be diverted to animal food at harvest (from the field), or during husking/shelling or sizing.

- Soybean is received by seed conditioning facilities with most plant material already removed. It is cleaned through a conditioning process in order to remove any remaining plant material such as pods, stem pieces, split seed and low density seed. The conditioning process may include screen cleaners, color sorters, spiral separators, and/or gravity tables.

These processes are low risk, and they are much more akin to farming and harvesting than the manufacturing or processing of food. For example, the processes described above for corn and soybean are nearly identical to the harvesting and drying of peppermint described in FDA's Registration Guidance.[22] In item 9.18 of the guidance document, FDA clarifies that such low risk activity does not constitute manufacturing and therefore does not trigger the registration requirement. The only significant difference between the activity conducted by seed conditioning facilities and the activity described in 9.18 is that seeds are trimmed, sorted, and dried in a building that is not part of a farm.

In the case of minimal processing, the agency also has demonstrated a willingness to read common sense into the registration requirement law based on risk. For example, in 21 CFR § 1.227, FDA defines manufacturing and processing to include trimming, washing, and packaging foods. Yet, in its Registration Guidance, the agency explicitly allows producers to trim, wash and pack product in certain instances without triggering registration.[23] In justifying this approach, FDA cites the low health risk associated with the activity. FDA acknowledges in item 9.10 of the Registration Guidance

[22] Registration Guidance at 9.18.
[23] *See* Registration Guidance, 9.6, 9.10, and 9.11.

that placing harvested products directly into consumer-ready packages is likely to provide better protection for them than transporting them without such packaging.

FDA has also clarified that certain low risk activities conducted in facilities co-located on farms should be exempted from the requirements of FSMA for small businesses.[24] Insofar as the exemption is based on risk, the justification for it applies to seed conditioning facilities as well, regardless of size. To this end, we note that the modest handling described above closely resembles the processes that FDA deemed low risk in its Draft Qualitative Risk Assessment, such as cracking, crimping, flaking, shelling, crushing, grinding, milling, pulverizing, or dry rolling.

Accordingly, seed conditioning facilities should be exempt from registration under 21 CFR §1.225. Should FDA feel it does want a registration filed so the agency is aware of these establishments and their locations, at a minimum seed conditioning facilities should be exempted from the proposed preventive control and GMP requirements in the Animal Food Rule because there is virtually no risk associated with their discarded seed materials. Legal approaches for establishing such an exemption are discussed below.

FSMA was intended to protect humans and animals from high risk food products, such as wet cat food and dried pig ears. There is no reason to target seed conditioning facilities with this proposed rule, and those same facilities should not be required to put in place, at great cost and business interruption, GMPs and a food safety plan that serves no conceivable value.

IV. Alternative Legal Approaches to Exempt Seed Conditioning Facilities

In the event that FDA elects not to take the simple approach we recommend above and revise its facility registration guidance, we are offering three alternative legal bases the Agency could use to affirmatively exempt seed conditioning facilities from compliance with the Animal Food Rule:

1) FDA could recognize that seed conditioning facilities are "solely engaged in . . . the storage of [RACs] (other than fruits and vegetables) intended for further distribution or processing" and thereby fall within one of FSMAs' express exemptions.

2) To the extent that FDA concludes seed conditioning facilities "process" animal food, FDA could exempt the facilities on the basis that they are "solely engaged in the production of food for animals other than man."

3) FDA could exempt seed conditioning facilities from compliance with the Animal Food Rule under its authority to interpret the FFDCA in a manner consistent with Congressional intent.

The legal and policy rationales for these approaches are explained in the sections that follow.

[24] *See* Draft Qualitative Risk Assessment Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm, February 2013. http://www.fda.gov/downloads/animalveterinary/products/animalfoodfeeds/ucm366906.pdf.

A. Seed Conditioning Facilities Should Be Exempt Because They Only Store Food

If seed conditioning facilities are required to register, they should be exempt from compliance with the preventive controls regulation because their activities related to animal food only involve "storage." FSMA provides FDA with the legal authority to exempt facilities that are "solely engaged in . . . the storage of [RACs] (other than fruits and vegetables) intended for further distribution or processing."[25]

The activities engaged in by seed conditioning facilities are not related to food, but rather are related to production of seed for cultivation purposes. Our members engage in activities such as stabilization, foreign matter removal, moisture control, shelling, cleaning, temperature stabilization, conditioning, and sizing solely for the purpose of preparing seeds for cultivation/planting. None of these activities are conducted to manufacture or process food for animal food consumption.

Unfortunately some seed, screenings, and culls cannot be used for planting, so instead these discard materials may be diverted for animal consumption. It is only at this point in the process that the seed discard materials arguably become "food," which is defined in the FFDCA as "articles used for food or drink for man or other animals," or "articles used for components of any such article."[26] But even once these discards become "food," no manufacturing or processing activities occur. The seed discard materials simply are held (stored) before being shipped to the next party in the animal food supply chain. That is, to the extent that seed conditioning facilities perform any activities related to "food," they are only engaged in "storage" of food for further distribution and processing.[27]

To the extent that FDA views seed discard materials as "food" earlier in the process, which we contest, it should recognize a broader definition of "storage" that also encompasses the activities that our members conduct related to seeds. Seed conditioning facilities do not change the physical nature of these discard materials such that their activities may be considered manufacturing or processing. All of the activities in these facilities, other than "holding," are not related to food consumption but rather are for cultivation purposes. Thus, seed conditioning facilities are not manufacturing or processing seed for animal consumption or converting a RAC into a processed food. The FFDCA defines "processed food" as "any food other than a [RAC] and includes any [RAC] that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling."[28] The activities performed on RACs to prepare seeds for cultivation are not analogous to these examples.

Thus, FDA should recognize seed conditioning facilities as exempt from preventive controls under FSMA on the basis that they are only engaged in "storage" of food because at the point in the process when materials are discarded and become "food" they are simply held/stored before shipment. Alternatively, FDA should reconsider the definition of "storage" to be more than just

[25] FSMA § 103(a); FFDCA § 418(m).
[26] FFDCA § 201(f).
[27] Our members' facilities also are not engaged in packing these materials. The diverted materials may be transported in a bulk container, but this is not "packaging."
[28] FFDCA § 201(gg).

holding food, but also to include activities performed for the safe and effective storage of RACs intended for further distribution and processing. Our members' facilities are analogous to grain elevators that also perform activities like drying, screening, conditioning, fumigating, and blending.[29]

Congress intended for grain elevators to be exempt from FSMA as solely engaged in "storage" of animal food for further processing. Given that seed discard materials often are sent to grain elevators, it does not make practical sense to require seed conditioning facilities to comply with the preventive controls regulation. Any benefits from application of the preventive controls and GMPs regulations in seed conditioning facilities may be nullified by the next party in the supply chain because grain elevators are exempt. That is, our members should not have to follow the regulation to ensure materials are safe if the next entity in the supply chain does not have to follow the regulation. We are not suggesting that grain elevators should not be exempt, but rather only make this point to illustrate why it would be consistent with the overall regulatory scheme to exempt seed conditioning facilities.

We also note that many of the activities our members engage in would be exempt if conducted by farms—which, like grain elevators, are exempt from the preventive controls regulation. For a farm, "holding" would include activities traditionally performed for the safe and effective storage of raw agricultural commodities grown on the same farm or raised on another farm under the same ownership—but the definition does not include activities that transform a RAC into a processed food. This similarity is yet another reason seed conditioning facilities should be exempt.

Finally, to the extent FDA recognizes seed conditioning facilities as exempt from the Animal Food Rule on this basis, we request that the Agency make this intent explicit in the preamble to the final rule.

B. Seed Conditioning Facilities Also Could Be Exempt as "Solely Engaged in the Production of Food for Animals Other than Man"

To the extent that FDA concludes that seed conditioning facilities are engaged in "processing" "food" for animal consumption and therefore are not exempt from the Animal Food Rule on the basis we explained above, FDA has other legal authority it can use to establish an exemption. Specifically, FSMA provides that FDA may, by regulation, "exempt or modify" the preventive controls requirements with respect to "facilities that are solely engaged in the production of food for animals other than man."[30]

"Solely engaged" in this context should be read to refer to the activities that trigger FDA facility registration. That is, seed conditioning facilities only are required to register because their discarded seed materials may be consumed by animals. The other activities in these facilities that are not related to food for animal consumption (i.e., activities related to preparing seeds for cultivation) are

[29] For example, our members engage in the analogous activities of sorting, grading, husking, shelling, culling, and sizing.
[30] FSMA § 103(a); FFDCA § 418(m).

not relevant for purposes of assessing the applicability of this exemption. Rather, what matters is that the sole activities relating to "food" involve production of food for animals.

Further, our comments above explained why it does not make practical sense to require seed conditioning facilities to comply with the Animal Food Rule, especially given that farms performing analogous activities are exempt and the grain elevators where much of the diverted material is sent also are exempt. Given that there is no practical food safety benefit from requiring seed conditioning facilities to comply, the Agency could use this provision as a basis for exempting seed companies from compliance.

C. An Exemption Also Could Be Promulgated Under FDA's Authority to Reasonably Interpret the Statute

Another alternative approach FDA could take is to exempt seed conditioning facilities under its legal authority to reasonably interpret the statute in a manner consistent with legislative purpose.[31] On this basis, FDA should exempt seed conditioning facilities from the Animal Food Rule because compliance with this regulation is inconsistent with the intent of FSMA and is not a good use of the Agency's resources. There is no indication in the legislative record that Congress intended to regulate the seed industry through FSMA. The preventive controls regulation was intended to cover facilities that make food or ingredients intended for food or feed – not seed discards that incidentally are used as an ingredient in animal food.

Exempting seeds is consistent with the legislative intent, as the facilities before and after seed companies in the supply chain both are exempt. The activities performed on seed would be exempt under the "farm" definition if performed on a farm. Seed is a RAC that is grown on the farm, but then is prepared for planting elsewhere. It is an unintended anomaly that seed is not entirely exempted from preventive controls given that it is a RAC. Just as growing an ear of corn in the field is not manufacturing feed subject to preventive controls, deriving and conditioning seed from the individual kernels of that corn should not be manufacturing subject to preventive controls.

Requiring compliance with the Animal Food Rule will not improve food safety for animals. As discussed above, there are no known or suspected food safety problems as a result of seed consumption by animals. This means that covering seed conditioning facilities through this regulation will result in added costs with no public health benefits. Further, much of the material is further processed before animal consumption. For materials provided directly to farmers, the risk is the same as when farmers feed their livestock discards they produced themselves—which are not covered by the regulation. Additionally, as explained above, it does not make sense to require compliance by seed conditioning facilities when the grain elevators where they send their materials are exempt.

[31] FDA has the discretion to make a reasonable interpretation of the statute (i.e., to interpret the law in a manner that is not arbitrary and capricious) that reviewing courts are bound to uphold. *See, e.g., Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

Furthermore, FDA has limited resources for enforcing the Act. These resources should be used to focus on the areas presenting the most risk for public health. Requiring FDA inspections of seed conditioning facilities that may discard seeds for animal consumption is not a good use of Agency resources.

V. The Very Small Business Exemption Will Not Apply for Most of Our Members

FDA co-proposes three definitions of "very small business" for purposes of the "qualified facility" exemption from Subpart C (preventive controls), with limits of $500,000, $1,000,000, or $2,500,000 in total annual sales of animal food. During FDA's first stakeholder call regarding the proposed rule, the Agency discussed its expectation that seed conditioning facilities would be exempt under the "very small business" exemption. We appreciate that FDA attempted to exempt the seed industry through this approach, particularly because it shows the Agency's recognition that a solution is needed to solve for the overreach of the proposal. Unfortunately, however, the proposed "very small business" exemption will not encompass most of the seed industry.

Under the statute, this provision is applied in the aggregate, across all facilities owned by a company. Even if FDA selects the highest proposed dollar value ($2,500,000), it would be surpassed by many of our members that operate multiple facilities. That said, diverted seed production materials provide a small amount of revenue compared to the value of seed sales and our members' intent is to sell their seeds for cultivation whenever possible. Furthermore, even if a company does meet the "very small business" definition, it would still be required to comply with the GMP regulations. Our comments above explain why compliance with GMPs would require considerable commitment of resources (without commensurate health benefits to animals or humans) and may not be compatible with the operations related to our members' intent related to developing seed for planting.

VI. FDA Must Consider the Economic and Environmental Impact of the Proposed Rule for the Seed Industry

Application of the proposed rule would have a significant negative economic impact on the seed industry and the farmers that rely on this source of feed for their livestock. It also would have very detrimental effects for the environment. Neither of these important issues was adequately addressed by FDA as part of the proposal.

First, regarding the economic impact, we are disappointed that the Preliminary Regulatory Impact Analysis (PRIA) did not consider or quantify the costs for seed conditioning facilities.[32] We are unable to estimate specific costs from coming into compliance because there are so many unanswered questions about what would be required of our members to achieve compliance, but we are certain that the costs would be significant. There will be either major costs from developing and

[32] The PRIA states: "FDA has not accounted for the facilities that produce ethanol from grain crops and distribute the byproducts to animal feed mills or other animal food producers, but expects them to be subject to this proposed rule. FDA request[s] public comment and data on the number of these facilities and their expected compliance actions." PRIA at 30. FDA did not calculate the compliance costs or economic impact for the seed industry as part of the PRIA.

applying GMPs and food safety plans or significant losses from abandoning the animal food business for discards. For example, each year one of ASTA's larger members conditions 500,000 bushels of corn seed, with discards valued at $2 million per year. If the seed conditioning facility was not able to channel the discards into the animal food stream, they would incur an additional expense to dispense these discards through an alternative means (likely a landfill). This would mean a total loss of over $2 million for this one company alone. Another member reported that switching to a landfill at two of its facilities would cost $118,000 per year and result in a loss of $450,000 in annual revenue.

If seed companies had to alter their production processes to minimize overages because of the costs associated with a new diversion channel, this also would fundamentally alter the economics of seed production and lead to fewer seed choices for farmers. The costs for farmers should not be overlooked, as diverted seed production materials provide a low-cost, highly-nutritious source of feed that would need to be replaced by more expensive sources.

Second, with respect to the environmental impact, we expect that many companies will no longer divert seed discard materials into the animal food supply chain if the proposal is finalized as-is and, therefore will need to incinerate discards or send discards to a landfill. Both of these activities have significant environmental impacts compared with diversion of discards to animals, which is an environmentally friendly and efficient means of managing these materials. FDA should take account of this likely impact when further considering the proposed rule, as onerous regulatory obligations should be avoided in order to mitigate these likely environmental consequences.

In summary, to the extent that FDA does not exempt the seed industry in the final rule, it should consider the impact for our members as part of the final economic analysis. Further, FDA should recognize the proposed rule in light of its potential environmental impacts across the supply chain.

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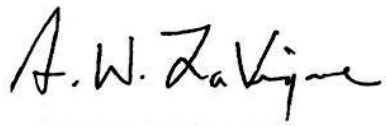
In conclusion, we encourage FDA to take a risk-based approach in the preventive controls for animal food regulation and exempt seed conditioning facilities from its scope. Our comments explain several legally viable approaches for doing so. We also urge FDA to issue a re-proposal of this regulation that specifically considers the impact for our industry so that we can have another opportunity for dialog during the rulemaking process. ASTA appreciates the opportunity to provide these comments.

Sincerely,



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