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Food and Drug Administration
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RE: Application of the ‘‘Solely Engaged’’ Exemptions in Parts 117 and 507; Draft Guidance for Industry; Availability: Docket No. FDA–2017–D–6133

The National Grain and Feed Association (NGFA) submits this statement in response to the Food and Drug Administration's (FDA) notice of availability of a draft guidance for industry entitled "Application of the "Solely Engaged" Exemptions in Parts 117 and 507; Draft Guidance for Industry," published on Oct. 20, 2017 in the ***Federal Register***.

FDA's draft guidance, when finalized, is intended to assist establishments and facilities determine whether they are ‘‘solely engaged’’ in certain activities that are exempt from some or all requirements established within two regulations implemented by the agency as part of the Food Safety Modernization Act (FSMA) – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 Code of Federal Regulations Part (CFR) 117) and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR Part 507).

The NGFA, established in 1896, consists of more than 1,000 grain, feed, processing, exporting and other grain-related companies that operate more than 7,000 facilities and handle more than 70 percent of all U.S. grains and oilseeds. Its membership includes grain elevators; feed and feed ingredient manufacturers; biofuels companies; grain and oilseed processors and millers; exporters; livestock and poultry integrators; and associated firms that provide goods and services to the nation's grain, feed and processing industry. The NGFA also consists of 34 affiliated State and Regional Grain and Feed Associations, and has strategic alliances with Pet Food Institute and the North American Export Grain Association.

The NGFA appreciates this opportunity to provide comments on FDA's draft guidance. As indicated in the comments that follow, we believe that FDA should make several changes to its current interpretations and the draft guidance so that Part 117 and Part 507 requirements are applied in a manner that better reflects risks posed to food and feed safety. We believe our recommendations, if implemented, would result in meaningful regulatory burden reduction while allowing FDA to fulfill its public health mission and statutory obligations.

FDA's Current Interpretation of "Solely Engaged" Should be Modified to Better Reflect Risks Posed to Food and Feed Safety

Federal Food Drug and Cosmetic (FD&C) Act Section 418 (m) provides FDA the authority to exempt or modify preventive controls requirements for certain facilities:

> *(m) Authority With Respect to Certain Facilities - The secretary may, by regulation, exempt or modify the requirements for compliance under this section with respect to facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment.*

Although FDA did in some respects exempt from or modify the preventive controls requirements for certain facilities solely engaged in certain activities during rulemaking that established Parts 117 and 507, the NGFA believes the agency has authority to provide additional exemptions and modifications so that the requirements are further applied in a risk-based manner while still assuring food and feed safety.

The relevant solely engaged exemptions refer to the primary subparts that contain current good manufacturing practice (CGMP) and preventive controls requirements – subparts B (animal food and human food CGMP), subparts C and G (human food preventive controls) and subparts C and E (animal food preventive controls) – and are as follows:

- Exemption from human food CGMP requirements - Part 117, subpart B does not apply to the following:
  - Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities (RACs) (117.5(k)(1)(iii))
  - Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing, such as roasting nuts) (117.5(k)(1)(v))

- Exemption from human food preventive controls requirements - Part 117, subparts C and G do not apply to:
  - Facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (117.5(j))
  - Facilities solely engaged in the storage of unexposed packaged food (117.7(a))

- Exemption from animal food CGMP requirements - Part 507, subpart B does not apply to the following:
  - Establishments solely engaged in the holding and/or transportation of one or more RACs (507.5(h)(1))
  - Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts) (507.5(h)(2))
  - Establishments solely engaged in ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed) (507.5(h)(3))

- Exemption from animal food preventive controls requirements - Part 507, subparts C and E do not apply to:
  - Facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (507.5(g))
  - Facilities solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens (507.10(a))

Of particular relevance to the exemptions is FDA's definition for "facility," which, as stated in 21 CFR 1.227, means, in relevant part, "any establishment, structure, or structures under one ownership at one general physical location…that manufactures/processes, packs, or holds food for consumption in the United States….A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership....".

In general, FDA's draft guidance states that the "solely engaged" exemptions provided within the regulations apply when the entire facility is only engaged in specified food-related activities for which a "solely engaged" exemption exists. More specifically, FDA states that a facility can be exempt from both CGMP and preventive controls requirements, for Parts 117 or 507 or both parts, only so long as it is engaged in any combination of activities that are exempt from CGMP and preventive controls requirements, and not engaged in activities that would be subject to those requirements.

Significantly, FDA states in the draft guidance that if any part of a facility is engaged in an activity subject to CGMP and/or preventive controls requirements, then the entire facility is subject to the CGMP requirements, the preventive controls requirements, or both.

As an example, FDA's draft guidance states that a facility consisting of both a grain elevator that stores RACs for animal food use and a feed mill that manufactures animal food is not "solely engaged" in activities exempt from either its CGMP or preventive controls requirements and therefore the entire facility is subject to the Part 507 CGMP and preventive controls requirements. Using the same logic, FDA would not consider a grain elevator storing RACs to be exempt from Part 117 CGMPs or preventive controls requirements if it is located at the same facility as a human food processing plant, such as a flour mill.

To justify its current interpretation, FDA has stated its view that the plain meaning of "solely" is "only, completely, entirely; without another or others; singly; alone." Therefore, FDA has asserted a position that all food-related activities that are covered by food facility registration requirements at the entire facility must be covered by a "solely engaged" exemption for any food-related activity that is covered by food facility registration requirements at the facility to be exempt from the specified requirements.

To the contrary, NGFA believes that FDA's current interpretation and application of the "solely engaged" exemptions are not consistent with congressional intent, are illogical and do not represent a risk-based approach to food safety.

The NGFA was intimately involved during the drafting of the legislative language for the "solely engaged" exemptions provided in Section 418 (m). During that process, it clearly was the intent of the congressional drafters that such exemptions were to be applied to ***operations*** that are solely engaged in the specified activities, such as holding and distributing RACs (other than fruits and vegetables) intended for further distribution or processing, and ***not just when the entire facility was conducting such an operation***. That is, Congress intended the exemptions to be applied in a risk-based manner based on the food and type of activity being conducted regardless of what other food-related activities might occur within other operations at the same facility. This intent represents a risk-based approach to food safety, which is the cornerstone of FSMA.

Specifically related to the RAC exemptions, during the rulemaking process that established Parts 117 and 507, FDA concluded that "outbreaks of illness associated with…agricultural commodities…have not been traced back to storage facilities solely engaged in the storage of raw agricultural commodities" and that "there would not be significant public health benefit to be gained by subjecting facilities that solely store non-fruit and vegetable raw agricultural commodities intended for further distribution or processing [to such] requirements." Indeed, FDA's economic impact analysis for the requirements was predicated on that basis.

The NGFA agrees with FDA's own conclusions. We are not aware of recalls or market withdrawals that have been linked to operations that hold RACs other than fruits and vegetables and subjecting such operations to the Part 117 and/or Part 507 requirements is unnecessary to protect public health. Further, and as FDA is aware, such operations remain subject to the requirements of the FD&C Act and experience routine surveillance inspections under FSMA's inspection mandate to assure the safety of products being held and distributed.

Accordingly, the NGFA believes it is well established that the activity of holding RACs other than fruits and vegetables for further distribution or processing does not pose a significant risk to public health and does not warrant being subject to Parts 117 or 507 requirements.

FDA's current interpretation of how the "solely engaged" exemptions should be applied also creates illogical and unfair regulatory disparities, as well. For example, under FDA's current interpretation, a grain elevator that holds and distributes RACs other than fruits and vegetables that is co-located at a facility with a feed mill is subject to both the CGMP and preventive controls requirements established by Part 507. However, a grain elevator performing the ***exact same*** food-related activities that is potentially located across the street at a different facility is exempt from Part 507 requirements. The NGFA contends that this regulatory outcome simply does not make sense and is unnecessary, is not risk-based and does not contribute to protecting public health. It only adds considerable costs and unnecessary regulatory burden.

Given the extremely limited risk to public health, it appears that FDA's definition for "facility" is the primary basis for the agency's current interpretation for how the solely engaged exemptions provided for RACs other than fruits and vegetables should be applied. In contrast, the NGFA respectively submits that FDA's interpretation of the "solely engaged" exemptions should not simply be dependent on the agency's definition for "facility" that does not appropriately recognize and acknowledge that different food-related activities may occur within distinct and

separate parts of the same "facility." Such a reliance on the existing "facility" definition results in regulatory burdens being imposed on industry that: 1) do not enhance food safety; 2) create regulatory disparities; 3) cause both industry and FDA to expend finite resources to deal with regulatory requirements for activities that do not pose a risk to animal health or public health; and 4) add exponentially to regulatory costs without commensurate benefit.

To alleviate these unnecessary outcomes, the NGFA strongly recommends that FDA initiate notice-and-comment rulemaking to make modifications to its "facility" definition so that the definition acknowledges the distinct and separate food-related activities that may occur at a given "facility" and more appropriately directs regulatory requirements based on risks to food safety. When the existing "facility" definition was established in 2003, we do not believe that it was foreseen that the definition would be so intricately used to establish compliance obligations associated with FSMA. Therefore, we believe it is proper to revisit the definition and make necessary modifications to make it more suitable for use in establishing regulatory obligations.

FDA Should Characterize Pulse Crops as "Grain"

Parts 117 and 507 exempt from preventive controls requirements facilities solely engaged in the storage of RACs other than "fruits and vegetables" intended for further distribution or processing. Further, Parts 117 and 507 exempt establishments solely engaged in the holding and/or transportation of one or more RACs from CGMP requirements.

In addition, FDA on Jan. 4 announced that holding and other specified farm-related activities performed by certain facilities on both "fruits and vegetables" (or "produce") and "non-produce" RACs will be the subject of enforcement discretion for preventive controls requirements established in Parts 117 and 507. Further, FDA on Jan. 25 issued guidance that extends enforcement discretion for Part 1, Subpart L – Foreign Supplier Verification Programs – requirements to certain importers of grain. The NGFA commends the agency for these decisions and strongly agrees that enforcement discretion should be extended to facilities and importers that are the subject of the announcement and guidance document.

However, FDA's announcement and guidance document also indicated that the agency was not yet extending enforcement discretion for Part 117 CGMPs or Part 1, Subpart L to "produce" RACs, but that "produce" RACs will be granted enforcement discretion for Part 507 CGMPs.

When promulgating the final Part 117 and Part 507 rules, FDA chose to define "grains" to mean the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of RACs designated as food grains by FDA include barley, dent- or flint-corn, sorghum, oats, rice, rye, wild rice, wheat, amaranth, quinoa, buckwheat, cotton seed, and oilseeds for oil extraction (such as cotton seed, flax seed, rapeseed, soybeans, and sunflower seed).

In contrast, examples of RACs that FDA has designated as "fruits and vegetables" or "produce" and therefore not subject to the agency's enforcement discretion for Part 117 CGMPs or Part 1, Subpart L include peas, peanuts and beans (such as coffee beans, cocoa beans, kidney beans, lima beans, and pinto beans), tree nuts and seeds for direct consumption (such as pumpkin seeds, sunflower seeds, and flax seeds).

Pertaining to the designation of various RACs as "fruits and vegetables," the NGFA believes the clear intent of Section 418 (m) within FSMA was to exclude from the preventive controls exemption fruits and vegetables that were known or could be reasonably foreseen to be associated with outbreaks of foodborne illness. As such, we do not believe that FDA's current designation of certain RACs as "fruits and vegetables" meets this risk-based intent.

Specifically, the NGFA strongly disagrees with the agency's current position that pulses (dry peas, lentils, chickpeas, and dry beans) should be designated within the category of "fruits and vegetables" or "produce," which under FDA's current enforcement policies make facilities holding or performing specified farm-related activities with such products subject to Part 117 CGMPs and importers of such products subject to Part 1, Subpart L.

Contrary to FDA's position, pulses are the edible hard seeds of plants from the legume family, which makes their origin consistent with the terminology used by the agency to define "grains." In addition, pulses are further processed after holding and/or packing prior to consumption, which makes their use consistent with the terminology used by FDA to define "grains." Further, pulses are not "processed food," but typically dry in the field and are harvested in the same manner as "grains." Finally, the NGFA is not aware of food safety risks that have been associated with the holding of and/or performing farm-related activities with pulses, which, again, is consistent with the limited food safety risks related to holding or performing farm-related activities with "grains."

Accordingly, the NGFA urges FDA to characterize pulses as "grains" to avoid imposing unnecessary and inappropriate regulatory requirements on facilities and importers that are involved with such products.

FDA Should Include Additional Examples in the Final Guidance to Illustrate Application of the Exemptions to Mixed-Type Facilities

The NGFA believes FDA should add additional examples within its final solely engaged guidance to further illustrate how the exemptions are to be applied. Specifically, we believe the final guidance should address mixed-type facility scenarios. As such, we offer the following proposed content and examples for inclusion into Section III - Discussion of the final guidance.

Application of Exemptions to Mixed-Type Facilities

The term "mixed-type facility" is defined in 21 CFR 117.3 and 507.3 and means an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a

farm, but also conducts activities outside the farm definition that require the establishment to be registered. Activities performed at a mixed-type facility that do not require registration under section 415 of the FD&C Act need not be considered when determining whether the facility is solely engaged in the activities specified in the exemptions.

Examples

1. A facility consists of the following operations: 1) a grain elevator that holds RACs other than fruits and vegetables intended for consumption by humans and other animals in the United States; and 2) an operation where non-RAC animal food ingredients are transferred (transloaded) from one transportation conveyance to another transportation conveyance that does not involve "holding" the animal food ingredients for purposes other than for transloading. At this facility, the grain elevator operation performs a "holding" activity on RACs that is subject to registration under section 415 of the FD&C Act. However, the transloading activity does not require registration under section 415 because it does not involve the activities of manufacturing, processing, packing, or holding food. Therefore, the transloading operation need not be considered when determining whether the facility is solely engaged in activities specified in the exemptions provided for facilities that hold and distribute RACs.

2. A facility consists of the following operations: 1) a grain elevator that holds RACs other than fruits and vegetables intended for consumption by humans and other animals in the United States; and 2) an operation that stores and distributes fertilizer for use by farmers during crop production. At this facility, the grain elevator operation performs a "holding" activity on RACs that is subject to registration under section 415 of the FD&C Act. However, the activities related to the fertilizer operation are not subject to registration under section 415 because they do not involve food intended for consumption by humans and/or other animals in the United States. Therefore, the fertilizer operation need not be considered when determining whether the facility is solely engaged in activities specified in the exemptions provided for facilities that hold and distribute RACs.

FDA Should Modify the Animal Food Preventive Controls Requirements to Better Reflect Low-Risk Activity/Food Combinations

The NGFA believes that it would be appropriate for FDA to reconsider and provide additional exemptions from the preventive controls requirements established in Part 507 Subparts C and F for facilities only engaged in low-risk packing/holding activity/animal food combinations and low-risk manufacturing/processing activity/animal food combinations. The NGFA believes FDA has authority to provide additional exemptions for low-risk activity/food combinations, and doing so would significantly lessen the regulatory burden at affected facilities without compromising animal food safety or public health. An example of a facility that could benefit from such additional exemptions for low-risk activity/food combinations would be one that stores and distributes grain, but also cracks/grinds and distributes some grain for further use as animal food.

While promulgating Part 507, FDA conducted a risk assessment to satisfy FSMA requirements to complete a science-based risk analysis and to consider the results of that analysis in determining whether to exempt small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing or holding activities involving certain foods that FDA determines to be low risk from the requirements of FD&C Act sections 418 (preventive controls) and 421 (targeting inspection resources), or whether to modify such requirements for such facilities. As an outcome, FDA established that farm mixed-type facilities that are small or very small businesses and only conduct low-risk activity/animal food combinations specified in 507.5(e) and (f) are exempt from the requirements of Part 507 subparts C and E, including the requirement for a food safety plan.

During the Part 507 rulemaking process, FDA declined to extend the exemptions provided to farm mixed-type facilities that are small or very small businesses and only conduct specified low-risk activity/animal food combinations to all facilities that are small or very small businesses. Nevertheless, the NGFA respectively requests that FDA reconsider this previous decision and provide the same exemptions to such facilities. Extending the exemptions would represent a science- and risk-based approach to food safety, provide consistency in the regulatory framework, lessen the regulatory burden at affected facilities, and allow both industry and FDA to focus resources in a more effective and appropriate manner to protect human and animal health. We believe FDA has the authority to provide such exemptions under FD&C Act Section 418 (m).

Conclusion

The NGFA appreciates FDA's consideration of its views expressed in this statement, and would be pleased to respond to any questions the agency may have. The NGFA also again commits to being a fully engaged and constructive participant during FDA's implementation of FSMA.

Respectfully Submitted,

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