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May 25, 2018

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane
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RE: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; Draft Guidance for Industry; Availability: Docket No. FDA–2017–D–5225

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(NGFA) submits this statement in response to the Food and Drug Administration's (FDA) notice of availability of a draft guidance for industry entitled "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals," published on January 25, 2018 in the ***Federal Register***.

FDA's draft guidance, when finalized, is intended to provide the agency's thinking on how importers of human or animal food can comply with the regulation on foreign supplier verification programs (FSVP) – 21 CFR Part 1, Subpart L – issued on November 27, 2015

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The NGFA offers the following comments concerning specific sections of FDA's draft guidance. As indicated in our remarks, we recommend that FDA make several changes to its draft guidance to better inform importers on how they may comply with the FSVP regulations. We also make recommendations on certain FSVP issues that, if implemented, would result in meaningful regulatory burden reduction while allowing FDA to fulfill its public health mission and statutory obligations.

III. Questions and Answers

A. To What Foods Does the FSVP Regulation Apply? (21 CFR 1.501)

- **A. 4:** Question 4 asks what does "U.S. owner or consignee" mean.

  Within the answer, FDA indicates the FSVP importer must ensure that, for each line entry of food product offered for entry into the United States, a unique facility identifier (UFI) recognized as acceptable by FDA is provided electronically when filing entry with U.S. Customs and Border Protection.

  Related to the requirement for a UFI, the NGFA recommends FDA include within its answer that currently, the DUNS number, derived from Dun & Bradstreet's Data Universal Numbering System (DUNS) is the UFI that FDA recognizes as acceptable.

- **A. 5:** Question 5 asks about the situation when multiple entities meet the definition of "importer" for a particular food.

  Pertaining to FDA's answer, the NGFA recommends the second paragraph of the response be revised as follows to improve readability and clarity (text that is recommended as being added is noted by being boldfaced and underscored [**boldfaced and underscored**] for emphasis):

  "When there are multiple entities that meet the "importer" definition, these entities will need to determine who will be responsible for meeting the FSVP requirements for the food (and, consequently, who should be identified as the importer of the food at entry). We expect that U.S. owners and consignees will address the responsibility for FSVP compliance in their contractual agreements when they have a direct commercial relationship. If there is an agreement between or among multiple U.S. owners or consignees of a food regarding responsibility for FSVP compliance and identification of the importer at entry, the entity identified as the FSVP importer at entry would be the entity that we would ordinarily prioritize for possible review under our risk-based FSVP compliance assessment program. ***In all cases, a foreign owner or consignee of a food may not lawfully designate an importer as their U.S. agent or representative for purposes of FSVP compliance without a signed consent statement (see Question A. 14).***

  When there are multiple unaffiliated U.S. owners or consignees for the same line of an entry of a food, we anticipate that each such entity will develop an FSVP for the food and foreign supplier. However, if one of the entities were willing to serve as the FSVP importer for this food from this foreign supplier, this would be permissible under the regulation. Similarly, if someone (e.g., one of multiple U.S. owners or consignees of a food) fraudulently or unintentionally identified a U.S. owner or consignee of a food as the FSVP importer (contrary to a written agreement regarding responsibility for FSVP compliance), we would take this into account in any enforcement action we take with respect to this food."

- **A. 14:** Question 14 asks whether a foreign owner or consignee of a food may lawfully designate an importer as their U.S. agent or representative for purposes of FSVP compliance without the importer's knowledge.

FDA's answer indicates such a designation is not valid unless the importer confirms in a signed statement that they have consented to serve as the FSVP importer. FDA further states the agency will maintain on its website a list of importers subject to the FSVP regulation, and that if importers discover by reviewing this list or otherwise, that they have been inappropriately designated as the FSVP importer, they should contact the agency.

The NGFA supports FDA's actions to maintain a list of importers subject to the FSVP regulations. However, we believe that FDA should take additional steps to minimize the potential for a foreign owner or consignee of a food to inaccurately or falsely designate an importer as their U.S. agent or representative. Specifically, we recommend that FDA establish an active system to notify an importer when they have been designated as a U.S. agent or representative for purposes of the FSVP regulation. Such a proactive system would be an effective deterrent to incorrect or false designations, and would help assure that a signed consent statement between foreign owner or consignee and the importer is in place.

- **A. 20:** Question 20 asks whether food contact substances are subject to FSVP requirements.

  FDA's answer states the agency intends to exercise enforcement discretion for food contact substance with regard to FSVP requirements. The NGFA supports FDA policy decision regarding this matter.

  To further clarify that such enforcement discretion extends to animal food contact surfaces, the NGFA recommends the following sentence in the fifth paragraph of the answer be revised as follows (text that is recommended as being added is noted by being boldfaced and underscored [**boldfaced and underscored**] for emphasis):

  *"Further, we note that food contact substances are not subject to the supply-chain program requirements in the human food **or animal food** preventive controls regulation**s**"*

- **A. 21:** Question 21 asks whether grains that are raw agricultural commodities (RACs) are subject to the FSVP requirements.

  FDA's answer indicates the agency intends to exercise enforcement discretion with regard to the FSVP requirements for the following certain importers of grain RACs: 1) Those that are solely engaged in the storage of grain intended for further distribution or processing; and 2) those that do not take physical possession of the grain they import, but instead arrange for the delivery of the grain to others for storage, packing, or manufacturing/processing.
  For purposes of such enforcement discretion, FDA has designated grain RACs to include barley, dent- and flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds for oil extraction (e.g., cotton seed, flax seed, rapeseed, soybean, sunflower seed).

The NGFA commends the agency for its decision to exercise enforcement discretion with regard to the FSVP requirements for certain importers of grain RACs. We believe this decision represents a risk-based approach to food safety and fulfills the need to construct the FSVP requirements utilizing a parallel approach to domestic supplier verification requirements that were established within the human food and animal food preventive controls regulations to enhance compliance with World Trade Organization obligations and ensure trade access.

However, FDA's enforcement discretion from the FSVP requirements was not extended to RACs that FDA has designated as "produce." Among the RACs that FDA has classified as "produce" are 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).

FDA's designation of RACs as either "grain" or "produce" is significant because Section 418(m) of the Food Safety Modernization Act (FSMA) provided the agency the authority to exempt from or modify preventive controls requirements for facilities solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables (or produce)) intended for further distribution or processing. Accordingly, FDA during rulemaking did exempt from preventive controls requirements facilities solely engaged in the storage of RACs designated by the agency as "grain", but did not provide such an exemption for RACs classified as "fruits and vegetables (or produce)."

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 makes certain importers of such products subject to Part 1, Subpart L when they otherwise would be covered by FDA's enforcement discretion extended to grain RACs.

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 holding pulses, which, again, is consistent with the limited food safety risks related to holding "grains."

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

- **A. 25:** Question 25 asks what is meant by a "small quantity" of a food that is consistent with a research or evaluation purpose.

  The NGFA appreciates that FDA's answer acknowledges the amount of food used in research or for evaluation can vary based on the type of food, the nature of the research or evaluation, and other factors. However, we recommend that FDA also acknowledge within its final guidance the amount of food imported for research or evaluation purposes may not always be completely used and that this type of occurrence is not in violation of FSVP requirements so long as any remaining amount of such food is properly disposed.

D. What Hazard Analysis Must I Conduct? (21 CFR 1.504)

- **D. 9:** Question 9 asks what is meant by a hazard that is intentionally introduced for purposes of economic gain.

  FDA's answer includes the statement that importers should consider the potential for such hazards that have a history of known or attempted economically motivated adulteration (EMA).

  The NGFA agrees with FDA statements made in Response 125 of the preamble of the FSVP final rule that "as with other hazards, importers need only consider EMA hazards that are known or reasonably foreseeable." In addition, we concur with FDA's expectation that "EMA hazards will be identified in rare circumstances, usually in cases where there has been a pattern of EMA in the past."

  To better reflect FDA statements made in the preamble of the FSVP rule, the NGFA recommends the agency revise its answer within the final guidance to state that importers should consider the potential for such hazards when there has been a **pattern** of EMA in the past. We believe such a revision would convey a more appropriate compliance expectation related to EMA hazards.

- **D. 15:** Question 15 asks where guidance and other information can be found that may be useful for conducting a hazard analysis**.**

  The NGFA appreciates FDA's answer which provides a variety of resources that may be useful to importers when conducting a hazard analysis. In addition to those links provided to resources listed, the NGFA recommends that a link to the new section of FDA's Data Dashboard be added to the fourth bullet – https://datadashboard.fda.gov/ora/fd/fser.htm.

- **D. 17:** Question 17 asks where information may be found about the condition, function and design of the nature of the establishment and equipment associated with a typical entity that manufactures/processes, grows or harvests a type of food. Such information is

required to be considered by the importer when conducting their hazard analysis.

FDA's answer indicates that information may be obtained about the nature of establishments that produce a particular food and the equipment from an inspection or audit, trade journals and other publications, academic literature, and materials obtained directly from the importer's potential foreign suppliers.

The NGFA believes that Response 136 within the preamble of the FSVP final rule provides a more complete and accurate answer pertaining to Question 17. Within the preamble, FDA states, "Importers will not be required to conduct onsite audits of potential foreign suppliers as part of the hazard analysis of a food under §1.504(c)(3)(ii) of the final rule. We have revised this hazard evaluation factor from the 'condition, function, and design of the foreign supplier's establishment and equipment' to the 'condition, function, and design of the establishment and equipment of a typical entity that manufactures/ processes, grows, harvests, or raises this type of food.' This change is designed to make clear that importers must consider how a typical establishment and equipment used to manufacture/process, grow, harvest, or raise a food affect the hazards in the food, rather than the potential effect of a particular foreign supplier's operations. (The requirement to consider a particular foreign supplier's performance is located in § 1.505 of the final rule, which sets forth the requirements for evaluation for foreign supplier approval and verification.) Importers can obtain information about the nature of establishments that produce a particular food and the equipment they use by consulting a number of sources of information other than audits. These may include, for example, trade journals and other publications, academic literature, and materials obtained directly from potential foreign suppliers."

Although inspections and audits are ways of obtaining information about the nature of establishments that produce a particular food and the equipment they use, the NGFA recommends that FDA revise its answer to Question 17 when issuing its final guidance to reflect the preamble language of the final rule and clearly indicate the use of inspections and audits is not required.

E. What evaluation for foreign supplier approval and verification must I conduct? (21 CFR 1.505)

- **E. 3:** Question 3 asks how importers should consider the entity or entities that will be significantly minimizing or preventing a hazard or verifying that a hazard has been significantly minimized or prevented.

  FDA's answer provides an example to illustrate the flexibility of how a hazard requiring a control may be prevented and its control verified by an importer through the supply chain. The NGFA believes the example could be confusing in that it does not indicate Supplier X has identified *Salmonella* as being a hazard that requires a preventive control within its food safety plan. Therefore, we recommend the following revisions be made to the first section of the example when FDA issues its final guidance (text that is recommended as being deleted is noted with a strikethrough [~~strikethrough~~] and text that

is recommended as being added is noted by being boldfaced and underscored [**boldfaced and underscored**] for emphasis).

"In the following example, you obtain a seasoning mix from a foreign supplier (Supplier X). Supplier X made the seasoning mix by blending milk powder (produced by Establishment Y) and a spice blend (produced by Establishment Z). You identify Salmonella as a hazard in the seasoning mix, and you learn from Supplier X (your direct supplier) that he does not apply a control for Salmonella in the blending operation. ***Although Supplier X is your "foreign supplier" (as defined in 21 CFR 1.500), Supplier X also is a receiving facility (because Supplier X is a manufacturer) and, thus, is subject to the supply-chain program provisions of the preventive controls regulation. Supplier X, within its hazard analysis, has identified the need to control Salmonella through the use of supply-chain-applied controls. Supplier X relies on Establishments Y and Z to implement preventive controls for Salmonella that are verified through appropriate supplier verification activities, such as auditing Establishments Y and Z or sampling and testing the milk and the spices.*** ~~*Instead,*~~ ***Accordingly,*** *Establishment Y applies a process control for Salmonella in the milk powder and Establishment Z applies a process control for Salmonella in the spice blend.* ~~*Although Supplier X is your "foreign supplier" (as defined in 21 CFR 1.500), Supplier X also is a receiving facility (because Supplier X is a manufacturer) and, thus, would be subject to the supply-chain program provisions of the preventive controls regulation (and therefore would have conducted appropriate supplier verification activities, such as auditing its suppliers or sampling and testing the milk and the spices, to ensure that they have used proper controls).*~~ *You would have several options for conducting supplier verification activities for Establishment Y and Z because they are entities controlling the Salmonella hazard. You could conduct the appropriate supplier verification activities with respect to Establishments Y and Z yourself. You could rely on documentation provided to you by Supplier X regarding Supplier X's supplier verification activities for Establishments Y and Z. You could rely on documentation from Supplier X for some supplier verification activities with respect to Establishments Y and Z and conduct additional supplier verification activities for Establishments Y and Z yourself. You also would determine an appropriate supplier verification activity and associated frequency for Supplier X."*

- **E. 12:** Question 12 asks under what circumstances is an importer not required to conduct a food and foreign supplier evaluation or conduct foreign supplier verification activities.

  To provide a more complete answer, the NGFA recommends that FDA's response to question E. 12 also include information provided in the answer to question D .19 in the draft guidance. Specifically, we recommend the answer include the following information:

  "If an importer conducts a hazard analysis and determines there are no hazards requiring a control, the importer is not required to conduct an evaluation for foreign supplier approval and verification activities and the importer is not required to conduct foreign supplier verification activities (21 CFR 1.504(f)). However, this does not apply if the food is a RAC that is a fruit or vegetable that is "covered produce" (as defined in 21

CFR 112.3) subject to the requirements of the produce safety regulation (because FDA has determined that there are biological hazards associated with "covered produce" that require controls). Thus, such fruit and vegetables are subject to the FSVP requirements to conduct an evaluation for foreign supplier approval and verification and to conduct foreign supplier verification activities."

H. What Corrective Actions Must I Take Under My FSVP? (21 CFR 1.508)

- **H. 6:** Under what circumstances must I investigate to determine whether my FSVP is adequate?

  FDA's answer includes an example that describes a cheese product from a foreign supplier that was contaminated with *Listeria monocytogenes.* The NGFA recommends that FDA include in its final guidance another example that pertains to animal food.

L. What FSVP May I Have if I Am a Very Small Importer or I Am Importing Certain Food from Certain Small Foreign Suppliers? (21 CFR 1.512)

- **L. 3:** Question 3 asks under what circumstances a foreign supplier would be considered to be a qualified facility?

  FDA's answer refers to sales made to "qualified end-users," but the draft guidance does not provide the term's definition. To provide a more complete answer to the question, the NGFA recommends that FDA in its final guidance include the definition of "qualified end-users" (21 CFR 117.3 and 507.3).

- **L. 15:** Question 15 asks what foreign supplier verification activities importers must conduct if their foreign supplier is a qualified facility?

  FDA's answer includes examples about the control of potential vegetative pathogens, such as *Salmonella***,** in pepper and honey-roasted pecans. The NGFA recommends that FDA also include in its final guidance an example that pertains to animal food.

M. What FSVP May I Have if I Am Importing Certain Food from a Country with an Officially Recognized or Equivalent Food Safety System? (21 CFR 1.513)

- **M. 2:** Question 2 asks where information may be found on the countries FDA recognizes as having a food safety system that is comparable or equivalent to that of the United States.

  FDA's answer indicates that information on the countries FDA officially recognizes under its systems recognition initiative as having a comparable food safety system is available on the agency's website. In addition, FDA states that the agency will maintain on its website a listing of equivalency agreements for which food covered under the agreements will be subject to the modified FSVP requirements in section 1.513, along with the texts of those agreements.

The NGFA has reviewed the section of FDA's website that provides information related to countries the agency recognizes as having a food safety system that is comparable or equivalent to that of the United States. Based on our review, we do not believe that the website, as currently maintained and structured, readily provides information about all of the foods covered under the systems recognition arrangements. As such, we strongly recommend that FDA make revisions to its website to provide the information to importers in a clearer and more concise format.

N. What Are Some Consequences of Failing to Comply with the FSVP Requirements? (21 CFR 1.514)

- **N. 3:** Question 3 asks how FDA will determine if an importer is in compliance with the FSVP requirements.

  FDA's answer states that FDA may review the importer's records to evaluate compliance with the FSVP requirements, including as applicable to the FSVP plan:

  - Hazard analysis;
  - Evaluation and reevaluation of risk posed by a food and the foreign supplier's performance;
  - Procedures for ensuring receipt of food from approved foreign suppliers;
  - Determination and performance of appropriate foreign supplier verification activities; and
  - Documentation of eligibility as a very small importer or of a foreign supplier's "small" status.

  To better clarify the scope of records for which the FDA has authority to review when evaluating compliance with the FSVP requirements, the NGFA recommends that FDA revise its answer to Question 3 when issuing its final guidance to state that the record review may include, as applicable to the FSVP plan:

  - Hazard analysis;
  - Foreign supplier performance evaluation;
  - Procedures for approving foreign suppliers;
  - Foreign supplier approval;
  - Procedures to assure use of only approved foreign suppliers;
  - Determination of verification activities and their frequency;
  - Performance of verification activities;
  - Corrective actions;
  - Documentation of eligibility as a very small importer or of a foreign supplier's "small" status; and
  - Reevaluations of the FSVP either for cause or routinely every 3 years.

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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