



December 12, 2018

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

**RE: Hazard Analysis and Risk-Based Preventive Controls for Food for Animals:  
Supply-Chain Program; Draft Guidance for Industry; Availability - Docket No.  
FDA-2018-D-1861**

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(NGFA) submits this statement in response to the Food and Drug Administration's (FDA) notice of availability of a draft guidance for industry entitled "Hazard Analysis and Risk-Based Preventive Controls for Food for Animals: Supply-Chain Program, #246" published on June 15, 2018 in the *Federal Register*.

FDA's draft guidance, when finalized, is intended to assist animal food facilities comply with the requirements of 21 Code of Federal Regulations (CFR) Part 507, Subpart E of the agency's final rule for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (Animal Food Rule) for establishing and implementing a supply-chain program for their suppliers.

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 29 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 commends FDA for the open and collaborative process used to solicit input from stakeholders during the rulemaking process that resulted in the agency's final Animal Food Rule. We also appreciate the agency's on-going commitment to providing a variety of resources – including guidance documents – to assist the industry in understanding and meeting regulatory expectations. We believe that, once finalized, FDA's Supply-Chain Program Guidance for Industry will be valuable to facilities when developing compliance strategies and assuring animal food safety.

Prior to providing specific recommendations pertaining to the draft supply-chain program guidance, the NGFA wishes to express support for the following elements currently present in the document.

- **Role of Corporate Parents in Establishing and Implementing a Supply-Chain Program.** The NGFA strongly supports content in the draft guidance that acknowledges corporate headquarters may develop and implement a facility’s supply-chain program and retain associated records, so long as they can be retrieved and provided onsite within 24 hours of request for official review. This language in the draft guidance appropriately reflects flexibility provided by the Animal Food Rule for corporate entities with multiple locations to implement programs in an efficient and effective manner.
- **Timing of Annual Audits.** The NGFA supports language in the draft guidance that clarifies there is flexibility in the timing of annual audits when conducted as a supplier verification activity. The draft guidance acknowledges that there could be practical reasons which preclude meeting the annual audit timeframe, e.g., if a third-party auditor needs to delay a previously scheduled audit, and that the agency does not intend to take action if the timeframe between the annual audits is reasonably close to one year, e.g., within 13-14 months. We appreciate this interpretation of the annual audit requirements and believe it represents a practical approach, while still providing assurances concerning the safety of raw materials and ingredients that may be subject to such a verification activity.
- **Financial Conflicts of Interest.** The NGFA supports the language in the draft guidance that clarifies there must not be any financial conflicts of interests that influence the results of supply-chain program verification activities. We believe the content also appropriately describes circumstances when an employee of a supplier or a third-party auditor hired by the supplier may conduct verification activities.

### **Comments Pertaining to Specific Content within FDA’s Draft Guidance**

The NGFA offers the following specific comments and recommendations pertaining to FDA’s draft Supply-Chain Program Guidance.

#### **I. Purpose (page 4)**

Even with the outreach activities conducted by FDA, the Food Safety Preventive Controls Alliance (FSPCA) and industry trade associations, confusion still remains within the animal food industry about the supply-chain program regulatory framework as established by the Animal Food Rule, and how the provisions interface with existing supply-approval programs. As such, the NGFA recommends that FDA specifically note within the Purpose section of its final guidance how the supply-chain program as detailed in Subpart E differs from how the industry historically has defined and used supplier programs.

Further, we also believe it is important to note at the outset of the final guidance that the Animal Food Rule requires implementation of a supply-chain program only when a facility has determined that a hazard requiring a preventive control in a raw material or

ingredient is to be controlled by the supplier prior to receipt by the facility.

To emphasize these important elements of the supply-chain program regulatory framework, the NGFA suggests the following language patterned after content in the FSPCA Preventive Controls for Animal Food Participant Manual be added to the Purpose section of the final guidance:

*“The Supply-Chain Program detailed in Subpart E is not the same as a supply-chain program typically thought of by the animal food industry. A Supply-Chain Program as defined by Subpart E is required only when a facility has identified a hazard requiring a preventive control in a raw material or ingredient and determined that it is necessary for the supplier of the raw material or ingredient to apply the preventive control (supply-chain-applied control).”*

## **II. Considerations to Keep in Mind if You Establish and Implement a Supply-Chain Program (page 4)**

This section of the draft guidance discusses how FDA has aligned the provisions for supplier verification in its regulation entitled “Foreign Supplier Verification Programs for Importers of Food for Humans and Animals” that apply to importers with the provisions for a supply-chain program in subpart E such that importers and receiving facilities do not have to duplicate verification activities.

The NGFA believes this content and discussion is valuable to the animal food industry, but also recommends that FDA add the agency’s definition of “importer” to this section of its final guidance to better inform readers whether the subsequent section in the guidance that explains importer exceptions applies to them.

## **III. Overview of the Requirements for a Supply-Chain Program**

### **B. “Receiving Facilities” and “Suppliers” (page 5)**

FDA in this section of the draft guidance provides definitions for a “receiving facility” and “supplier,” and offers useful examples to describe types of operations that may meet the definitions.

However, given that the definition of a “receiving facility” references the term “manufacturing/processing,” the NGFA also recommends that FDA in its final guidance include the definition for “manufacturing/processing” from 21 CFR 507.3 within this section or refer readers to Appendix A for the definition.

## **V. Requirement to Establish and Implement a Supply-Chain Program (21 CFR 507.105)**

### **C. Exceptions to the Requirement to Establish and Implement a Supply-Chain Program**

## **2. Exception for animal food supplied for research or evaluation use (page 9)**

Within this section of the draft guidance, FDA lists the criteria for animal food supplied for research or evaluation uses that when met provide an exception from the requirements for a supply-chain program. While the NGFA appreciates the additional clarity provided in this section concerning the scope and application of the exception from the supply-chain program for raw materials and ingredients used for research or evaluation, we believe the final guidance should more appropriately describe the requirement that animal food used for research or evaluation is to be supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose (21 CFR 507.105(a)(3)(iii)).

Although the language within the draft guidance aligns with the regulatory text in the Animal Food Rule, the NGFA believes the use of the term “small” to describe an appropriate quantity of animal food that is eligible for an exception is not consistent with the intent of the provision.

By definition, the term “small” when used as an adjective means “of a size that is less than normal or usual.” In contrast and within the context of FDA’s Animal Food Rule and this related guidance, we believe the intent of this provision is to provide an exception from the supply-chain program for animal food to be used for research or evaluation when supplied in a quantity that does not exceed what is normal or usual for the research, analysis, or quality assurance procedures to be performed.

The NGFA agrees with FDA’s statements in this section of the draft guidance indicating that the appropriate quantity of animal food used in research or for evaluation may vary based on the type of animal food, the nature of the research or evaluation, and other factors such as the number of repetitions required for the research or evaluation process. However, we believe FDA’s final guidance should not use the term “small” to describe such an appropriate quantity because its meaning is contradictory to the intent and purpose of the provision.

## **VI. General Requirements Applicable to a Supply-Chain Program (21 CFR 507.110)**

### **B. Appropriate Supplier Verification Activities**

#### **2. Sampling and testing of the raw material or other ingredient (21 CFR 507.110(b)(2)) (page 12)**

Within the first paragraph of this section, FDA indicates facilities using sampling and testing as a verification activity in a supply-chain program can conduct such sampling and testing on a periodic basis or on a lot-by-lot basis.

The NGFA recommends that FDA revise this language to explain that the frequency of testing should be based on factors such as ingredient volume, the nature of the

hazard, and the preventive control, and not calendar days or lots alone. We support other existing language within this paragraph that illustrates the concept that sampling frequency may change over time as more history with a given supplier is established.

In addition, FDA within the second paragraph of this section states that if sampling and testing is performed as a supplier verification activity, scientifically-based sampling plans are to be used that provide reasonable assurance that the hazard has been significantly minimized or prevented, and that address known limitations of sampling and testing animal food as a verification activity.

Related to the design of sampling plans, when issuing the final Animal Food Rule, FDA declined to elaborate on the frequency and/or number of samples that would be adequate to verify that a hazard has been significantly minimized or prevented, indicating instead that circumstances in a given facility would influence decisions about sampling and testing programs.

While the NGFA agrees that each facility and its operations are unique, and that sampling and testing plans need to be tailored to the individual facility and its animal food, as well as the nature of the preventive control and its role in the facility's food safety system, we also recommend that FDA in its final guidance provide additional information about how facilities may demonstrate that sampling plans are "scientifically-based." We also believe such information would be beneficial to facilities when they conduct sampling and testing as a verification activity for a preventive control implemented within their own operations.

#### **D. Considerations in Approving Suppliers and Determining the Appropriate Supplier Verification Activities and the Frequency with Which They Are Conducted (page 14)**

As previously expressed, there still is confusion within industry about the supply-chain program regulatory framework as established by the Animal Food Rule and when a supply-chain program is required. As such, the NGFA recommends that the first sentence of the first paragraph within this section be revised as follows [*new language **boldfaced and underscored***]:

*"As noted in section VI.A, subpart E specifies that you must approve suppliers and determine appropriate supplier verification activities (including determining the frequency of conducting the activity) **when you have identified a hazard requiring a preventive control in a raw material or ingredient and determined that it is necessary for the supplier of the raw material or ingredient to apply the preventive control.**"*

#### **2. Entity controlling the hazard (page 15)**

The NGFA believes this section of the draft guidance accurately explains that there is flexibility in the requirements regarding which entity in the supply chain applies the

preventive control. To further demonstrate this fact, the NGFA recommends that FDA in its final guidance add an example that illustrates how another entity other than the supplier may apply the preventive control. To do so, we recommend the following language be added as the first full paragraph on page 16:

*“As an example, if you purchase an ingredient requiring a supply-chain-applied control from a broker or distributor, you may rely on documentation from the broker or distributor that demonstrates the supplier of the ingredient is adequately applying the control. The broker/distributor would provide this documentation to you to review, assess and gain assurance that the supplier is effectively controlling the hazard.”*

### **3. Supplier performance (page 16)**

The second bullet within this section discusses reviewing, as applicable, a supplier’s compliance with relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States. Related to this topic, the NGFA recommends FDA add information to indicate, if accurate at the time of publication of the final guidance, that the agency has not developed a systems recognition process for animal food, and, therefore, there are no signed systems recognition arrangements with any foreign food safety authority related to animal food. We acknowledge that such information already is included in the draft guidance on page 18, but also believe it would be appropriate to add similar language to this section of the guidance.

#### **Supplier’s procedures, processes, and practices (page 16)**

Related to understanding the supplier’s procedures, processes, and practices associated with the safety of the raw material and other ingredients, FDA within the first paragraph of this section on page 16 states, “*Methods to do so include,*” and then lists four potential assessment methods.

The NGFA believes that the listing of potential assessment methods is appropriate, but recommends that FDA revise its final guidance to make clear that the identified methods are not mandatory steps that must be taken by a facility to be in compliance. To do so, we recommend that the initial sentence used to introduce the potential methods be modified to [*new language **boldfaced and underscored***]: “*Mechanisms to do so **could** include:*”

#### **Applicable food safety regulations (pages 17 and 18)**

Similarly, related to assessing compliance of food safety regulations by suppliers, FDA within the second paragraph of this section on page 17 of the draft guidance states, “*Methods to do so include,*” and then describes three potential evaluation methods. Accordingly, the NGFA recommends this language also be revised to: “*Mechanisms to do so **could** include.*”

Also related to these mechanisms, the NGFA recommends that FDA’s final guidance include the hyperlink to the agency’s Supplier Evaluation Resources within this section of the guidance, in addition to providing it within the Reference section.

Pertaining to evaluation of foreign suppliers, the NGFA has reviewed the sections 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 these sections of the website, as currently maintained and structured, readily provide information about all of the foods covered under the systems recognition arrangements. As such, we recommend that FDA revise its website to provide such information in a clearer and more concise format.

#### **4. Other factors**

Within this section of the draft guidance, FDA describes other factors, such as storage and transportation practices, that a facility is to consider when approving suppliers and determining appropriate supplier verification activities. In doing so, the agency provides an example that a facility should consider how a supplier ensures adequate control of temperature of the animal food during transportation when control of temperature is necessary to keep the product safe.

Regarding assuring food safety during transportation activities, the NGFA recommends that FDA’s final guidance also reference the requirements established by the agency’s final rule for Sanitary Transportation of Human and Animal Food, and that a facility should evaluate supplier conformance to these requirements as appropriate.

### **VII. Responsibilities of the Receiving Facility (21 CFR 507.115)**

#### **A. Your responsibility to Approve Suppliers (page 20)**

As previously expressed, there still is confusion within industry about the supply-chain program regulatory framework as established by the Animal Food Rule and when approval of suppliers is required. As such, the NGFA recommends that the first sentence of the first paragraph within this section be revised as follows [*new language boldfaced and underscored*]:

**“Section 507.115(a)(1) specifies that the receiving facility must approve suppliers when they have identified a hazard requiring a preventive control in a raw material or ingredient and determined that it is necessary for the supplier of the raw material or ingredient to apply the preventive control.”**

## VIII. Using Approved Suppliers (21 CFR 507.120)

### B. Written Procedures for Receiving Raw Materials and Other Ingredients

On page 24 of the draft guidance, when describing an approach to a written procedure for ensuring that raw materials and other ingredients are only received from approved suppliers when it is necessary for the supplier to implement a supply-chain-applied control, FDA describes the use a computer system that has a safeguard mechanism to prevent the acceptance of a raw material or other ingredient from an unapproved supplier. In response, the NGFA notes that some facilities may utilize such computer systems, while other facilities may not.

To avoid creating a perception among FDA investigators that facilities likely will have such systems in place, the NGFA recommends the first sentence of the first full paragraph of page 24 be revised as follows [*new language **boldfaced and underscored***]:

*“Another **potential** approach to a written procedure **that a facility may use** for ensuring that raw materials and other ingredients are only received from approved suppliers is a computer system or specific supply-chain management software that manages the procurement, receipt, and usage of raw materials and other ingredients.”*

In addition, on page 25 of the draft guidance, the first sentence of the first full paragraph states, “*You should use unapproved suppliers only on a temporary basis until you are able to fully evaluate and approve a different supplier, or until the problem with your previously approved supplier has been corrected and, as appropriate, you reevaluate your approval of that supplier. An appropriate time period for use of an unapproved supplier on a temporary basis might vary, depending on the circumstances, from a few weeks to a few months.*”

The NGFA believes this language could be misinterpreted as a requirement that use of an unapproved supplier may last no more than a few months, and there is a risk that FDA investigators may attempt to enforce such a limit without regulatory support for doing so. As such, the NGFA recommends the text be revised as follows to make clear that this language is not mandatory [*new language **boldfaced and underscored**, deleted language ~~struck through~~*]:

*“You should use an unapproved supplier only on a temporary basis until you are able to fully evaluate and approve **that supplier or** a different supplier, or until the problem with your previously approved supplier has been corrected and, as appropriate, you reevaluate your approval of that supplier. ~~An appropriate~~ **FDA anticipates that the** time period for use of an unapproved supplier on a temporary basis ~~might vary, depending on the circumstances, from~~ **typically will range from** a few weeks to a few months, **though the time may vary more significantly depending on the circumstances.**”*

Further, the last sentence of the first full paragraph on page 25 states, “*Having multiple suppliers approved for each raw material or ingredient you receive can reduce the use of temporary suppliers when one supplier experiences an emergency.*”

While the NGFA agrees that having multiple approved suppliers may be beneficial to a facility, it is not always feasible or possible to approve more than one supplier. To avoid creating a perception among FDA investigators that facilities are to approve more than one supplier for each raw material or ingredient, the NGFA recommends this sentence be revised as follows [*new language **boldfaced and underscored***]:

*“**When feasible**, having multiple suppliers approved for each raw material or ingredient you receive can reduce the use of temporary suppliers when one supplier experiences an emergency.”*

## 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 the Food Safety Modernization Act.

Respectfully submitted,



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