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

RE: Docket No. FDA–2014–D–1180 – Draft Guidance for Industry on Ensuring Safety of Animal Feed Maintained and Fed On-Farm

The National Grain and Feed Association (NGFA) submits this statement in response to the Food and Drug Administration's (FDA) draft guidance for industry entitled ***"Ensuring Safety of Animal Feed Maintained and Fed On-Farm"*** (#203), whose availability was announced in the March 20, 2015 edition of the ***Federal Register***.

Established in 1896, NGFA consists of more than 1,050 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. NGFA's member companies cover the wide breadth of the grain, feed and grain processing industry, including 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. With more than 350 member companies operating feed manufacturing, feed ingredient, and integrated livestock and poultry operations, the NGFA is the nation's largest trade association representing commercial feed manufacturer and integrator interests. In addition, the NGFA has strategic alliances with Pet Food Institute and North American Export Grain Association. Further, 26 state and regional grain, feed and agribusiness organizations are members of, and affiliated with, NGFA.

The NGFA's members have a strong interest in FDA's draft guidance that is intended to help animal producers develop and implement on-farm practices to ensure the safety of feed maintained and fed to animals on the farm. As manufacturers and suppliers of feed to animal producers, our members are committed to producing and distributing safe and wholesome products. However, the continued safety of the feed depends on proper on-farm storage and feeding practices. As such, the NGFA appreciates FDA's efforts to address these important topics in its guidance.

In general, the NGFA believes the majority of recommendations made by FDA within the draft guidance represent reasonable practices and measures that animal producers may take to help ensure acquisition of safe feed products and maintenance of its safety until the feed is offered to animals in the farm environment. However, we provide the following comments

and recommended changes that we believe would enhance the document if incorporated into the agency's final guidance.

Specific Comments on Draft Guidance

Section IV. General Principles and Practices for Animal Feed Safety on the Farm

FDA in sub-section B of section IV recommends that animal producers "obtain feed from safe and reliable sources." The NGFA believes this is a prudent recommendation, since animal producers generally cannot improve the safety of feed once it is received at the farm.

However, in addition to the recommendation to "obtain feed from safe and reliable sources," the NGFA believes it also would be appropriate for FDA to specifically recommend that animal producers consider the safety aspects associated with the transportation of feed to the farm. As FDA is aware, the safety of feed products may be influenced by how the product is transported, with the safety of feed arriving at the farm being dependent both on how the product is manufactured and distributed. In addition, the feed supplier may not be responsible for transporting feed to the farm. Feed from a manufacturer may be transported to the farm by the animal producer or a contract hauler hired by either the feed manufacturer or animal producer.

Therefore, the NGFA recommends that FDA revise sub-section B as follows *[new language **boldfaced and underscored**]*: "Obtain **and transport** feed from safe and reliable sources **by considering both the feed supplier and feed transporter.**"

Section V. Application of General Principles and Practices for Animal Feed Safety on the Farm

- **Sub-section A. How can I address unacceptable feed risks at my farm?**

  - In sub-section A.1, FDA states that "Both U.S. Department of Agriculture (USDA) Cooperative Extension Service (in conjunction with land-grant universities) and FDA's Center for Veterinary Medicine (CVM) have information they can provide to help you learn more about contaminants likely to occur at your type of feeding operation."

    The NGFA believes that the term "likely to occur" within this statement infers that contaminants identified within information available from USDA or CVM have a high probability of occurrence. In contrast, the NGFA does not believe this is the case. We believe a more appropriate way to characterize USDA or CVM information is that it may provide animal producers with a listing of those contaminants that at some point have been associated with a feed safety incident.

Therefore, the NGFA recommends that sub-section A.1 be revised as follows *[deleted language ~~stricken through~~, new language **boldfaced and underscored**]*: "Both U.S. Department of Agriculture (USDA) Cooperative Extension Service (in conjunction with land-grant universities) and FDA's Center for Veterinary Medicine (CVM) have information they can provide to help you learn more about contaminants ~~likely to~~ **that may** occur at your type of feeding operation."

- FDA in sub-section A.1.b. recommends that animal producers may obtain useful information about feed contaminants by referring to FDA's Center for Veterinary Medicine's (CVM) Animal Feed Safety System articles on feed contaminants, such as its "Draft List of Potentially Hazardous Contaminants in Animal Feed and Feed Ingredients."

  In contrast, the NGFA respectfully submits that CVM's "Draft List of Potentially Hazardous Contaminants in Animal Feed and Feed Ingredients" contains numerous potential hazards whose presence in feed are not reasonably foreseeable or likely to occur, and therefore do not pose a significant risk to the safety of animal feed. As FDA is aware, this list was developed for purposes of developing a risk-ranking model as part of its Animal Feed Safety System, and at that time presented, it was done with the important caveat that the list itself should not be viewed as being appropriate for other purposes. Although we acknowledge there may be documented instances where such contaminants listed in the draft have caused a feed safety issue, we do not believe that many of the listed contaminants are of significant concern to animal producers. For example, we do not believe that animal producers would find it useful for feed safety purposes to focus on contaminants such as radionuclides, or on many of the microbiological contaminants, pesticides and other chemical contaminants listed in the draft.

  Therefore, if FDA desires to provide animal producers with examples of potential feed contaminants, the NGFA strongly recommends that FDA develop and incorporate into its final guidance a much more targeted list of potential contaminants, which considers the outcomes of deliberations in this regard currently ongoing within the animal feed- and pet food-related activities of the Food Safety Preventive Control Alliance. We believe that such a targeted list would better focus animal producers on potential contaminants that may pose a realistic risk to feed safety and serve to better accomplish FDA's goal of ensuring the safety of feed maintained and fed on-farm.

➢ Sub-section B. What feed safety practices should I follow on my farm?

- FDA in sub-section B.3 recommends that animal producers "obtain feed from safe and reliable sources." As previously expressed, the NGFA believes that the agency's guidance also should advise animal producers to consider the safety aspects of transporting feed to their farm. As such, we recommend that FDA add

to its final guidance the recommendation that animal producers ask about the practices used to ensure that feed safety is maintained during delivery of their products

To do so, we suggest sub-section B.3 be revised as follows *[new language **boldfaced and underscored**]*: "Obtain feed from safe and reliable sources. Examples of safe feed sources may include commercial suppliers known for delivering safe feed products. Ask each of your suppliers whether they are operating under an animal feed quality assurance program and if medicated feed is produced in compliance with applicable current Good Manufacturing Practice (CGMP) regulations (21 CFR part 225). **In addition, ask your feed transporters whether they have practices in place to maintain the safety of the animal feed during delivery.**"

- Sub-section B.4 outlines FDA's recommendations to animal producers that are intended to ensure the safety specifications of the feed are met. FDA states that, among other things, "There are several ways to [ensure safety], such as, reviewing the supplier's Certificate of Analysis (COA) indicating safety specifications of the feed are met, or reviewing results of analytical laboratory testing of feed samples completed by a qualified testing facility that uses appropriate analytical methods."

  The NGFA notes that feed manufacturers do not commonly provide COA's to animal producers for feed distributed to the farm. Furthermore, the NGFA believes that routinely providing COA's to animal producers is not necessary to ensure the safety of such feed products. Instead, the use of COA's is more appropriately a practice incorporated into the feed manufacturer's quality and feed safety practices to address potential safety concerns in a targeted and cost-effective manner.

  Accordingly, the NGFA recommends that sub-section B.4 be revised as follows *[deleted language ~~stricken through~~, new language **boldfaced and underscored**]*: "Ensure the safety specifications of the feed are met. There are several ways to do this, such as, ~~reviewing the supplier's Certificate of Analysis (COA) indicating safety specifications of the feed are met,~~ **becoming familiar with your supplier's feed quality and safety practices**, or reviewing results of analytical laboratory testing of feed samples completed by a qualified testing facility that uses appropriate analytical methods. In addition, a simple physical examination of the feed may identify abnormalities. Using several of these safety specification measures would help increase assurance that animal feed products you receive are safe."

- Within sub-section B.5, the NGFA believes that FDA should add a specific recommendation pertaining to storing feed away from other potential contaminants that may be present on the farm. Although this topic is addressed in sub-section F – *What should I consider when I use pesticide, fertilizer and other agricultural*

chemicals, we believe that the risk of feed becoming cross-contaminated on-farm with other agricultural chemicals is significant and warrants also being highlighted within this sub-section.

To do so, the NGFA suggests revising sub-section B.5 as follows *[deleted language ~~stricken through~~, new language **boldfaced and underscored**]*: "Store, transport, and offer the feed to animals in a manner that will prevent or significantly minimize:

a. infestation of the feed with pests (e.g., rodents and insects);
b. **contact with the feed** ~~of~~ **by** pet**s** (e.g., dogs and cats)~~ contact with the feed, and~~;
c. introduction of ~~agents~~ **contaminants** into the feed (e.g., pesticides, **fertilizers**, **agricultural chemicals**, pathogens, molds, or foreign materials); **and** ~~or~~
d. **other** conditions (e.g., elevated moisture levels) that can cause unacceptable feed risks."

- FDA in sub-section B.6 states "Implementation of an effective pest control program can prevent or eliminate contamination caused by pests." The NGFA notes that complete elimination of contamination by pests is very difficult, particularly at a farm. We believe a more accurate statement to include in the agency's final guidance would be *[deleted language ~~stricken through~~, new language **boldfaced and underscored**]*: "Implementation of an effective pest control program can ~~prevent or eliminate~~ **significantly minimize** contamination caused by pests."

- The NGFA believes that sub-section B.7 should be revised as follows so as to better indicate that not all changes in an animal's feed consumption is caused by contaminants in feed *[deleted language ~~stricken through~~, new language **boldfaced and underscored**]*: "Observe feed consumption patterns of your animals. Unexpected changes in feed consumption patterns ~~can~~ **may** be a**n** ~~good~~ indicator of the occurrence of feed contaminants or unacceptable feed risks in the feed."

➢ Sub-section J. What actions assist in identifying the origins of feed?

FDA states in the introduction of the draft guidance document that the agency's recommendations are to apply to feed obtained from commercial suppliers, or produced on the farm. Since the term "farm" may encompass a wide–range of operations, including integrated operations that produce high volumes of feed for a large number of animal producers, the NGFA believes that FDA's recommendation in sub-section J pertaining to removal of feed from the farm when necessary should be revised as follows *[deleted language ~~stricken through~~]*: "Establish and implement measures so you will know the origins of feed used on your farm. Having such information becomes particularly important in cases where feed is recalled and will

help ensure timely and effective removal from your farm and the market of feed products ~~manufactured and distributed by commercial feed establishments~~ that may have an adverse effect on animal or human health."

- **Sub-section K. If I want to have a feed sample analyzed, what should I keep in mind?**

FDA in sub-section K.2 recommends that adequate sampling procedures are necessary to provide useful analytical results and that appropriate sampling procedures may be found in the Association of American Feed Control Officials' (AAFCO) Feed Inspector's Manual. The NGFA agrees with FDA's recommendation concerning the need to use appropriate sampling procedures to achieve accurate analytical results.

However, in addition to such a recommendation, we also believe that it would be useful for FDA to specifically indicate in its final guidance that adhering to appropriate sampling procedures is particularly important if an animal producer desires to sample a product for the presence of a microbiological pathogen.

To do so, we recommend that FDA add the following sentences to the end of sub-section K.2 *[new language **boldfaced and underscored**]*: "**In addition, special sampling procedures must be followed to obtain accurate results when testing for the presence of potential microbiological contaminants in feed. This type of sampling is best done by individuals who have been appropriately trained on using aseptic (sterile) sampling procedures.**"

- **Sub-section L. What should I do if I have concerns about the safety of my animal feed?**

FDA within this sub-section of the draft guidance lists several recommendations that animal producers can follow if they have concerns about the safety of their animal feed.

Significantly, the NGFA notes that FDA's guidance does not include a recommendation that animal producers contact their feed supplier if they have concerns about the safety of the feed. The NGFA strongly believes that FDA should include such a recommendation within this section of its final guidance document. Further, we urge FDA to list this recommendation prominently, and believe the only FDA recommendation within this section of a higher priority is that the animal producer "take immediate measures to ensure the product is not fed to animals."

Therefore, the NGFA strongly recommends that FDA prominently include the following language within sub-section L *[new language **boldfaced and underscored**]*: "**Contact your feed supplier to report your concerns.**"

Conclusion

The NGFA's members are committed to producing and distributing safe and wholesome feed products. Our members also are committed to working with and providing assistance to animal producers to ensure the safe use of these products.

The NGFA appreciates FDA's consideration of the recommendations expressed in this statement, and would be pleased to respond to any questions the agency may have.

Sincerely,

David Fairfield
Vice President, Feed Services
National Grain and Feed Association