December 12, 2018

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

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No. FDA-2018-D-1861; Hazard Analysis and Risk-Based Preventive Controls for Food for Animals: Supply-Chain Program; Draft Guidance for Industry; Availability

Dear U.S. Food and Drug Administration:

The American Feed Industry Association (AFIA) is the world’s largest organization devoted exclusively to representing the business, legislative and regulatory interests of the U.S. animal feed industry and its suppliers. Founded in 1909 as the American Feed Manufacturers Association, the name changed to the American Feed Industry Association in 1985 to recognize the importance of all types of companies involved in the feed manufacturing industry—from ingredient suppliers, equipment manufacturers to commercial and integrated feed manufacturers. The association merged with the National Feed Ingredients Association in 1992 to create a more seamless industry group. AFIA is also the recognized leader on international industry developments and holds membership in the International Feed Industry Federation.

AFIA’s membership includes nearly 700 domestic and international companies and state, regional and national associations. Member companies are livestock feed and pet food manufacturers, integrators, pharmaceutical companies, ingredient suppliers, equipment manufacturers and companies which supply other products, services and supplies to feed manufacturers.

The feed industry makes major contributions to food and feed safety, nutrition and the environment, and it plays a critical role in the production of healthy, wholesome meat, milk, fish and eggs. More than 75 percent of the commercial feed in the U.S. is manufactured by AFIA members. Approximately 70 percent of the non-grain ingredients, including soybean meal, distillers’ co-products, vitamins, minerals, amino acids, yeast products and other miscellaneous/specialty ingredients are also manufactured by AFIA members.

A recent economic study found that the U.S. animal food manufacturing industry produced roughly 238 million tons of feed in the U.S. in 2016, representing nearly $300 billion in contribution to the economy, while employing nearly 1 million workers.

AFIA’s primary founding purposes were to promote and assure feed safety and to promote the harmonization of all state feed laws with uniform labeling and regulations. Today, every state
American Feed Industry Association

except Alaska has a feed law based on the Association of American Feed Control Officials’ (AAFCO) Model State Feed Bill. AFIA and its predecessor organizations have developed a number of animal food safety programs, the latest of which is AFIA’s Safe Feed/Safe Food Certification Program, which is described in more detail below.

Several state feed regulators met at the association’s founding meeting in May 1909 and followed up with a meeting in September 1909, in which AAFCO was formed. AFIA and AAFCO have held annual meetings for 109 years. These have resulted in many mutual programs and successes, such as the AAFCO ingredient definitions, the model feed and pet food law and rules, the model good manufacturing practice regulations, and checklists for inspections and options for feed registration and facility licensing in the AAFCO Model Feed Bill.

Nearly all AFIA members that manufacture, process, pack or hold animal food are registered with the FDA under the Bioterrorism Act. These registered facilities are very interested in this guidance document and must comply with all final rules that the FDA issues relative to animal food under the Food Safety Modernization Act (FSMA). Therefore, rules promulgated and guidance documents created under FSMA impact AFIA members, and these comments represent their views.

AFIA strongly supported the development and passage of FSMA and has provided many comments to the FDA regarding its implementation. AFIA has also provided a number of resources to help its members comply with FSMA, including providing: more than 40 preventive controls qualified individual training sessions; a qualified individual training video; an example Animal Food Safety Plan; and a generic hazard analysis tool detailing illness reports and scientific data on hazards.

AFIA is committed to a continuing dialogue with the FDA on FSMA rules and implementation. We are also strongly committed to a full and successful implementation of FSMA across all our varied industries.

Industry Description
The U.S. animal food industry is diverse and is authorized to use more than 900 ingredients. According to research conducted by the Institute for Feed Education and Research, there are nearly 6,000 animal feed mills that manufacture 238 million tons of ready-to-eat feed annually, and over 500 pet food manufacturing facilities that manufacture over 30 million tons of pet food. These numbers do not include on-farm mixers, which, in most cases, are exempt from the Bioterrorism Act facility registration under the “farm” definition, and therefore, are exempt from the provisions of FSMA. Appendix A details the categories of the major species and amount of feed manufactured for each in 2016.

In 2004, AFIA created its hallmark Safe Feed/Safe Food Certification Program (SF/SF). Since that time, more than 600 facilities have been certified, and the program has grown from one basic program to five programs under the SF/SF umbrella. More information on these programs is available at www.safefeedsafefood.org.
In 2012, AFIA created two new programs for the pet food industry. These are the Pet Food Manufacturing Facility Certification Program (PFMFCP) and the Pet Food Ingredient Facility Certification Program (PFIFCP). Both of these new programs and all the SF/SF programs are designed as hazard identification and preventive controls programs based on a facility’s animal food safety plan. Both pet food programs are different from the basic SF/SF feed programs in that they contain microbial control requirements that do not appear in the SF/SF feed programs.

In late 2013, the Safe Quality Food Institute announced that the Global Food Safety Initiative (GFSI) had benchmarked the enhanced SF/SF Certification Program (FSC 34) and the PFMFCP (FSC 32). This provides an assurance that these two programs meet the highest standards of animal food safety on a global basis and are compared favorably to other food safety programs. These are the only two animal food-specific safety programs benchmarked by GFSI.

The development and benchmarking of these programs is consistent with AFIA’s founding principles and highest goals to promote and ensure animal food safety throughout the animal food supply chain.

AFIA Comments on the Guidance Document
While AFIA agrees with the agency’s opinion that there will likely be limited use of supply-chain-applied-controls in animal food facilities, we appreciate the opportunity to provide comments on this draft guidance for industry. The comments that follow include text from the draft guidance document and AFIA’s edits follow this format: Text to be deleted will be shown stricken through and suggested added text will be underlined.

Draft Guidance with AFIA Recommendation

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I. Purpose

The purpose of this guidance is to help a receiving facility comply with the requirements of 21 CFR part 507, subpart E of the preventive controls for animal food (PCAF) regulation for establishing and implementing a supply-chain program for its suppliers. Because of the varied supply-chains in the animal food industry, we do not expect to see many supply-chain-applied controls in animal food safety plans. This guidance document is applicable to food safety plans that contain a supply-chain-applied control. See section III.B and the list of terms in Appendix A for the definition of a “receiving facility.” This guidance also is intended to help an entity other than the receiving facility conduct certain activities on behalf of a receiving facility, provided that the receiving facility complies with applicable requirements in subpart E to review and assess the entity’s applicable documentation, and document that review and assessment.

AFIA Comments
While AFIA agrees with everything stated in the purpose statement, we believe further clarification on the applicability of this guidance would be helpful to the industry. Adding the statement that the FDA expects to see few supply-chain-applied controls in animal food safety plans, which the agency has stated publicly on many occasions, would be both appropriate as well as help industry better understand when a supply-chain-applied control is applicable to their facility.
Draft Guidance with AFIA Recommendation

(Page 7) IV. Understand the Hazard
Part 507 defines “supply-chain-applied control” as a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt. See 21 CFR 507.3 and the glossary of terms in Appendix A. For background and details about hazards, including hazards that could require a supply-chain-applied control, see Chapter 3 of draft guidance #245 – Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (Ref. 2). Because of the varied supply-chains in the animal food industry, we do not expect to see many supply-chain-applied controls in animal food safety plans. Although supply-chain-applied controls are acceptable, these instances are rare and should be only be considered in unique circumstances.

AFIA Comments
Discussions within our industry leaders have led AFIA to believe that there will be very limited application of supply-chain-applied controls in animal food safety plans. Clarification of this in the guidance will be helpful to industry.

Draft Guidance

(Page 8) B. How Your Corporate Parent Can Participate in Establishing and Implementing Your Supply-Chain Program
As discussed in the final rule establishing part 507, your corporate parent (as the owner, operator, or agent in charge) can be active in developing and implementing your food safety plan (see responses 239, 439, and 461 in 80 FR 56170 at 56240, 56297, and 56308, respectively). For example, an individual at the corporate level may be the preventive controls qualified individual (PCQI). See 21 CFR 507.3 and Appendix A for the definition of “PCQI”

AFIA Comments
AFIA appreciates and supports the agency acknowledging the corporate parent can participate in establishing and implementing supply-chain programs.

Draft Guidance with AFIA Recommendation

(Page 12) 2. Sampling and testing of the raw material or other ingredient (21 CFR 507.110(b)(2)), first paragraph
Subpart E provides that sampling and testing of a raw material or other ingredient is an appropriate supplier verification activity (see 21 CFR 5076.110(b)(2)). Such sampling and testing can be on a periodic basis or on a lot-by-lot basis. We recommend that you establish the frequency of such testing by first conducting the sampling and testing on a relatively frequent basis (e.g., monthly) until the supplier establishes a good history of supplying an acceptable raw material or other ingredient, after which time you could sample and test less frequently, such as quarterly. The facility should consider the nature of the hazard and preventive control when determining sampling and testing frequency.
AFIA Comments
AFIA recommends the added language to clarify that the facility has flexibility to determine sampling and testing frequency, which should be based on the nature of the hazard and preventive control.

Draft Guidance with AFIA Recommendation
(Page 14) D. Considerations in Approving Suppliers and Determining the Appropriate Supplier Verification Activities and the Frequency with Which They Are Conducted
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) for products that have been identified as containing a hazard requiring a supply-chain-applied control. See 21 CFR 507.110(a)(1) and 21 CFR 507.110(a)(2). Section 21 CFR 507.110(d)(1) specifies factors that you must consider in approving suppliers and determining appropriate supplier verification activities (including determining the frequency of conducting the activity). We discuss these factors in sections VI.D.1 through VI.D.4. With one exception, the requirement to consider each of these factors applies every time you approve a supplier for a raw material or other ingredient, and every time that you determine the appropriate supplier verification activity for an animal food received from that supplier. See a discussion of the exception in 21 CFR 507.110(d)(2) and in section VI.D.5.

AFIA Comments
Approving suppliers and determining appropriate supplier verification activities are only required for products that have been identified as containing a hazard requiring a supply-chain-applied control. This should be clarified in the guidance.

Draft Guidance with AFIA Recommendation
(Page 14) 1. Hazard analysis, second paragraph
Part 507 requires that you conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control. See 21 CFR 507.33(a). The intended use of the animal food must be considered when determining known and reasonably foreseeable hazards and whether the hazard requires a preventive control. If you determine that there are any hazards that require a preventive control, with few exceptions part 507 further requires that you must identify and implement a preventive control. See 21 CFR 507.34(a). When the preventive control will be applied to a raw material or other ingredient before receipt, part 507 requires that you establish and implement a risk-based supply-chain program for that raw material or other ingredient. See 21 CFR 507.105.
AFIA Comments
AFIA believes that careful consideration of the intended use of the animal food is a very important element of a properly performed hazard analysis, and it should be stated in the guidance to provide further clarification for industry.

Draft Guidance with AFIA Recommendation

(Page 15) 1. Hazard analysis, fourth paragraph
As part of your hazard analysis, you also would may be required to evaluate environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen. See 21 CFR 507.33(c)(2). If, for example, you are purchasing a flavor enhancer that will be applied to a pet food post heat treatment, and you expect that a sanitation control will be applied to address the environmental pathogen Salmonella, you could ask to review the flavor enhancer producer’s written procedures for the environmental monitoring it does to verify the sanitation controls. See 21 CFR 507.49(b)(3). You also could periodically verify your supplier’s controls by sampling and testing the flavor enhancer for Salmonella. Because Salmonella is a hazard for which there is a reasonable probability that exposure to the hazard will cause serious adverse health consequences or death to humans or animals, you also would conduct an annual onsite audit to verify that your supplier controls Salmonella when it manufactures the flavor enhancer by using a kill step such as heat treatment of liver digest used to make the flavor enhancer and sanitation controls to significantly minimize contamination from Salmonella in the environment, with environmental monitoring to verify controls for Salmonella.

AFIA Comments
Not every facility will need to consider environmental pathogens. The agency has stated as such in several public fora. Qualification needs to be given to this paragraph in order for facilities to understand when the PCQIs must include an evaluation of environmental pathogens and when it is not applicable.

Draft Guidance with AFIA Recommendation

(Page 18) 1. Supplier Performance, Supplier’s food safety history, second paragraph
You should focus your consideration of the supplier’s food safety history on the hazard that the supplier is controlling because that is the most relevant information. However, you should also consider other information about the supplier, e.g., information regarding recalls or regulatory actions. For example, you obtain a meat meal for use in pet food from a supplier that is controlling biological hazards (e.g., Salmonella) and become aware that meat meal from this supplier has been associated with a physical hazard (e.g., large bone fragments). If the particular physical hazard was identified in your food safety plan as a hazard requiring a preventive control, you should consider whether you should implement verification activities related to the control of physical hazards to prevent bone fragments in the meat meal you receive for a period of time adequate to demonstrate that problems that could lead to the presence of bone fragments have been resolved.
AFIA Comments
Verification activities are only required by the rule when a facility identifies a hazard requiring a preventive control. The added qualifying language clarifies when verification activities should be implemented.

Draft Guidance with AFIA Recommendations
(Page 25) B. Written Procedures for Receiving Raw Materials and Other Ingredients, second paragraph
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. We anticipate that the time period for use of an unapproved supplier on a temporary basis will typically range from a few weeks to a few months, however, the time may vary more significantly depending on the circumstances.

AFIA Comments
AFIA believes this clarification is necessary to prevent any misinterpretation that the use of an unapproved supplier may last no longer than a few months.

Draft Guidance with AFIA Recommendation
(Page 26) A. Requirement to Conduct Supplier Verification Activities, first paragraph
With some exceptions, 21 CFR 507.130(a) requires that one or more supplier verification activities (i.e., onsite audit, sampling and testing, review of food safety records, and other supplier verification activities) must be conducted for each supplier before using the raw material or other ingredient from that supplier and periodically thereafter. The main goal of supplier verification activities is to verify that the supplier(s) is/are properly implementing the preventive control and that the control is effective in controlling the hazard. The exceptions to this requirement are specified in 21 CFR 507.130(c), (d), and (e). See the discussion of the exceptions to this requirement in sections X.C through X.E.

AFIA Comments
AFIA feels it is appropriate to clarify the purpose of verification activities within the food safety plan.

Draft Guidance with AFIA Recommendation
(Page 27) B. Specific Requirements When the Hazard Requiring a Preventive Control is a SAHCODHA Hazard, 1. Requirement for an onsite audit when the hazard requiring a preventive control is a SAHCODHA hazard, second paragraph
SAHCODHA hazards are those for which a recall of a violative product posing such a hazard is designated as “Class 1” under 21 CFR 7.3(m)(1) (i.e., a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death). Examples of such hazards that, in some circumstances, have resulted in serious adverse health consequences or death.
or animals include pathogens (e.g., *Salmonellae* in pet food) and nutrient deficiencies and toxicities (e.g., copper toxicity in food for sheep). These are only examples, and we are not implying that all pathogens and nutrient deficiencies and toxicities are always SAHCODHA hazards. Animal food containing a SAHCODHA hazard is considered reportable food, subject to the Reportable Food Registry requirements prescribed by the Food and Drug Administration Amendments Act of 2007. See our “Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007” and the annual reports of the Reportable Food Registry for examples of animal food that we have considered to contain SAHCODHA hazards (Refs. 10, 11, and 12).

**AFIA Comments**

Not all pathogens and nutrient deficiencies and toxicities in animal food are always considered to be SAHCODHA hazards. The added language clarifies this concept and will help eliminate confusion.

**Draft Guidance with AFIA Recommendation**

(Page 35) B. Consideration of Food Safety Regulations, fourth paragraph

A supplier that is subject to the PCAF requirements must have a food safety plan (see 21 CFR 507.31). If your supplier is subject to the PCAF requirements, the onsite audit would focus on the supplier’s food safety plan and assess the implementation of the preventive controls applied by the supplier to address the known or reasonably foreseeable hazards that you have determined to require a supply-chain-applied control. For example, before you obtain mineral premix for which you had *may have* identified copper toxicity as a hazard requiring a supply-chain-applied control from a supplier subject to the PCAF requirements, you *may elect* to audit the supplier (or obtain documentation of an audit performed by a third party) to determine whether the supplier’s manufacturing process adequately controlled the level of copper in the mineral premix. This audit would determine whether the product was formulated to contain a level of copper that is safe for the intended specie(s) and that this level was met and not significantly exceeded in the mineral premix during the manufacturing process. Because the supplier was subject to the PCAF requirements, the onsite audit should include a review of the supplier’s food safety plan. The auditor should review whether the manufacturing process had been validated to significantly minimize excess levels of copper in the mineral premix and should examine whether the supplier had implemented the manufacturing procedures in accordance with its food safety plan (e.g., through observing the establishment’s procedures and reviewing records).

**AFIA Comments**

It is important to keep in mind that verification activities covered in this draft guidance for industry only apply to hazards requiring a supply-chain-applied control. The added language helps eliminate any possible confusion.
Draft Guidance with AFIA Recommendation
(Page 37) XII. Records Documenting the Supply-Chain Program, Table 2
Table 2 lists the records required for the supply-chain program if you have a supply-chain-applied control. See 21 CFR 507.175(c).

AFIA Comments
Records documenting the supply-chain program are only required in the food safety plan if a facility has identified a hazard requiring a supply-chain-applied control. The added language helps eliminate any possible confusion.

Draft Guidance with AFIA Recommendation
(Page 51) Other Terms Used in This Guidance, Approved supplier
Approved supplier: A supplier that has met the criteria of the receiving facility’s supply-chain program, is controlling the identified hazard using an appropriate preventive control and has been approved by the receiving facility.

AFIA Comments
AFIA recognizes the purpose of this draft guidance for industry is to provide guidance in the area of supply-chain-applied controls. Since a supply-chain-applied control is a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt, we feel the added language will eliminate any possible confusion.

We appreciate your consideration of these comments and are willing to answer any questions or add clarification as needed.

Sincerely,

[Signature]

Gary Huddleston
Director of Feed Manufacturing and Regulatory Affairs and FSPCA Lead Instructor in Preventive Controls for Animal Food
American Feed Industry Association
America’s animal food manufacturing industry is at the intersection of plant and animal agriculture. More than 5,715 animal feed and 517 pet food facilities take farm-grown crops and ingredients as well as food coproducts and develop high-quality, nutritious and safe animal food. Just as farmers and ranchers depend on our industry for the healthy growth and development of more than 9.6 billion food-producing animals annually, pet owners entrust us to feed the over 144 million dogs and cats they call their companions.

But feeding America’s livestock and pets is not all that we do—our industry also significantly contributes to the national economy. A recent report commissioned by the Institute for Feed Education and Research found the animal food manufacturing industry generated $297.1 billion in total U.S. sales in 2016, including roughly $102 billion in benefits to associated industries (e.g., transportation industry). The industry employed over 944,000 people that year—paying nearly $56 billion in wages—and contributed roughly $22.5 billion in cumulative local, state and federal taxes.

The demand for animal food is strong, and the industry is expected to continue to thrive as it develops innovative solutions that meet consumer demands, reduces its environmental impact, and increases productivity.

### THE U.S. BY THE NUMBERS:

- **Total Sales**: $297.1 billion
- **Value-Added**: $102.0 billion
- **Labor Income**: $55.9 billion
- **Jobs**: 944,227
- **Taxes**: $22.5 billion

**TOTAL SALES**: The broadest measure of economic activity—often referred to as “output”; **VALUE-ADDED**: A component of “total sales,” which includes the sales minus the cost of inputs (e.g., grains); **LABOR INCOME**: A component of “value-added,” which includes the sum of employee compensation (i.e., wages) and proprietor income (self-employed); **EMPLOYMENT (JOBS)**: A measure of part- and full-time job positions, including contract workers; **TAXES**: The sum of taxes paid at the local, state and federal levels by all directly and indirectly affected industries as a result of the animal feed and pet food industry existing.

Decision Innovation Solutions prepared the data for this economic contribution study. For more information, visit afia.org.