July 23, 2018

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

Re: Docket No. FDA–2016–D–2343; Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; Draft Guidance for Industry; Availability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 AFIA 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 there was 238 million tons of feed manufactured in the U.S. in 2016. Together the feed and pet food manufacturers represent nearly $300 billion (see Appendix A) 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 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 AFMA/AFIA’s founding meeting in May 1909 and followed up with a meeting in September 1909 in which AAFCO was formed. AFIA and AAFCO have an unbroken line of 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. Therefore, rules promulgated and guidance documents created under the Food Safety Modernization Act (FSMA) impact AFIA members, and these comments represent their views.

AFIA strongly supported the development and passage of FSMA and continues to support and provide comments to the FDA regarding FSMA. AFIA has provided over 40 preventive controls qualified individual (PCQI) training sessions; offered a free generic hazard analysis detailing illness reports and scientific data on hazards; and continues to offer a free qualified individual video and a free example Animal Food Safety Plan to members.

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. feed industry is diverse and is authorized to use more than 900 ingredients. 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 plants 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. This information was the result of a funded study by the Institute for Feed Education and Research and performed by Decision Innovation Solutions.

In 2004, AFIA created its hallmark Safe Feed/Safe Food Certification Program (SF/SF). Since that time, over 600 facilities have been certified, and the program has grown from one basic program to four 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 control 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 Qualify Food Institute (SQFI) 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 can be favorably compared to other food safety programs. These are the only two animal food 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’s comments, listed below, will follow this format: if it includes text from the draft guidance document, the text to be deleted will be stricken through, and suggested added text will be underlined.

**General Comments and Suggestions**

While AFIA is pleased to see this draft guidance document, we are aware that “large facilities” have already been in compliance with the regulations since September 2017 without the benefit of this guidance document. With the addition of small facilities, most of the animal food facilities must comply by September 17 of this year. With a July 23 comment date, and another few months to develop the final document, firms will not have FDA’s final expectations until probably sometime in 2019. Thus, AFIA urges the FDA to extend inspection dates by at least a year in order to properly train inspectors and educate industry.

Also, this is said to be the first five chapters, which means there are more chapters to come and more delays. If all the final documents are not out in reasonable time, AFIA will be requesting more inspection delays.

**Inspections**

As for the use of this document, we trust the FDA will rigorously train its own and state investigators in the use of the document, as it’s the primary guide to the industry. AFIA has yet to see any FSMA inspection forms used by FDA or state inspectors, in spite of nearly a year long Freedom of Information Act (FOIA) request.

AFIA finds the draft document has a paucity of examples, and the few examples that are included should be considered just that—examples by the inspection staff. We strongly urge FDA to preach “flexibility” to its investigators, and the investigators to adhere to that doctrine.

AFIA urges the agency to create an inspection checklist to accompany this document for use by the investigators. Through the years, AFIA members have found the checklists to be very beneficial in assisting facilities to prepare for inspections, not in the sense of having just what’s on the list but knowing what an investigator will be requesting for efficiency of the inspection. We realize that an inspection may go deeper than any checklist, when warranted.
References
We find some of the references, and reference to those references, to be either archaic or unrelated, such as linking heavy metal contamination in river otters to a food safety concern for dogs and cats. Scientific relevance should be a hallmark of any agency document. The agency appears to have failed here.

Further to references, we find references back 30 plus years are likely irrelevant. Our discussions with the agency when AFIA was developing its generic, example hazard analysis noted that we would use data back 10 years for illness reports and scientific data. We believed the agency concurred with that reasonable assumption, i.e. data beyond 10 years is probably not relevant, unless in a National Research Council report that has not been updated, such as the Mineral Tolerances of Domestic Animals (2007).

In this draft, the agency gave no justification for using such outdated references.

AFIA believes the lengthy list of references in the appendix amounts to a list of references for which a facility should examine hazards mentioned in those references. FSMA places all that burden on the facility, and such a list of references will likely be used by investigators as a de facto checklist of hazards for which facilities must address. We believe that approach is faulty for a number of reasons: 1) Many of the references are outdated. 2) Facility PCQI’s are in the best position to determine the hazards related to their facilities. 3) FSMA places the burden on developing a hazard analysis on the facility, not on a list generated from outdated references. AFIA strongly believes use of such a list in inspections is neither justified, nor scientifically defensible.

Pet Food
AFIA believes it would be beneficial for both the agency and industry to clearly delineate what portions of this guidance document apply to pet food. Alternatively, the FDA could create a pet food only section. It is clear from the animal food rule that all sections do not apply to all animal food. Any agency guidance should be designed to be effective; unfortunately, the inability to delineate what applies to pet food and what does not renders the guidance less effective.

It would make the guidance more effective, if the agency clearly indicated in many areas that some sections are “not applicable to every situation or product.”

AFIA-NGFA Example Hazard Analysis
AFIA and the National Grain and Feed Association’s (NGFA) foundations funded the development of an interactive hazard analysis for each association’s members. In doing so, both organizations realized the requirements in 21 CFR §507.33 go far beyond the abilities for most facilities, and that we could create an interactive system based on “illness data and scientific reports” as required by the rule.

The associations selected the University of Minnesota’s Center for Animal Health and Food Safety (CAHFS) in the College of Veterinary Medicine to develop the FSMA tool. CAHFS assembled a team of six experts under the leadership of Dr. Tim Goldsmith to create parameters, key words and key phrases for searching scientific literature databases and reviewing scientific
literature identified as relevant. The team waded through over 4,000 pieces of scientific literature to search for hazards related to feed.

After deciding which articles were of importance, the team developed a ranking system and an interactive Excel spreadsheet into which the information from the selected articles was downloaded along with information on illness data from FDA’s Reportable Food Registry and other scientific literature sources, such as clinical reports. The team and AFIA and NGFA staff decided that literature greater than 10 years was not likely significant if such occurrences or hazards had not been repeated since that time. Also, only data from North America was deemed relevant as we concluded that hazards outside North America would likely be considered local unless literature documented their occurrence within North America.

The spreadsheet was distributed to all members of both associations in 2017 with two general workshops and a sponsored symposium at the American Society of Animal Science annual meeting in 2017. All told, it was a year-long effort.

Member firms were alerted that this was not a complete hazard analysis, but only a tool to be used in developing each facility’s hazard analysis. They were instructed to include experiential data, including hazards experienced at each facility, for the facility’s hazard analysis to be deemed in compliance with the FSMA requirements in 21 CFR §507.33.

**Items in the Introduction of the Draft Guidance**

Horses should not be considered “companion animals,” as listed in an example (Chapter 1, page 7). AFIA and other federal agencies consider horses to be livestock. AFIA urges the FDA to follow the AAFCO definitions for “pet” and “specialty pets,” as this will allay any confusion about the terms.

In the same paragraph, the text seems to make a leap to subpart C, and there’s no mention of subpart B, which AFIA believes is the most important subpart for feed manufacturers. The FDA should insert the following at the start of the paragraph: **Current Good Manufacturing Practices and other prerequisite programs play an important role in hazard reduction/mitigation in animal food facilities and may adequately preclude the necessity of having preventive controls.**

However, preventive controls may be necessary for pet food and other food production facilities.

In the bulleted list on the same page, AFIA recommends the agency add the following:

- a written food safety plan
- hazard analysis
- preventive controls
- monitoring*
- corrective actions and corrections *
- verification (including validation)*
- recall plan*
- associated records

*Required only for those facilities with preventive controls
The sentence (Chapter 1, page 7), “We do not expect that all known or reasonably foreseeable hazards for an animal food require a preventive control in all facilities.” is a very important statement. AFIA strongly shares that view and believes the agency should further explain that in the absence of preventive controls, facilities should rightly utilize other pre-requisite programs, such as current good manufacturing practices and other such programs. This should be explained in the facilities’ animal food safety plans (AFSP).

AFIA appreciates the second paragraph on page 8 of the draft and believes this comment, albeit common in FDA guidance documents, should be highlighted or italicized, as our members’ experience with other inspections frequently report that investigators treat the guidance documents as rules, when in fact, they are truly guides, and the agency should impress upon the inspection staff that firms may do things differently than that listed but can still be in compliance with the animal food rule.

AFIA also appreciates the last paragraph on page 8 and urges the agency to weave this idea throughout the document. The importance of a flexible rule and guidance document cannot be underestimated in our dynamic, very diverse industry.

Chapter 1—The Food Safety Plan
AFIA agrees with the first bullet point on the page and believes the thought expressed here, “Some facilities may not identify any known or reasonably foreseeable hazards associated with animal food at their facilities…” is a critical statement for many, if not all, feed facilities. More importantly, the phrase following this one is likely the case in most facilities, that is, “…or after evaluation may determine there are no known or reasonably foreseeable hazards requiring a preventive control.” AFIA believes preventive controls will be rare in feed facilities.

In section 1.8 on page 14, the draft states that, “You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.” AFIA is curious if the FDA has plans for announcing when new scientific understanding will result in such an action to be taken by a facility. Perhaps, the FDA could provide examples of past instances, such as the promulgation of the bovine spongiform encephalopathy rule (21 CFR Section 589).

Chapter 2—Conducting a Hazard Analysis

Draft guidance with AFIA recommendation
2.2 Overview of a Hazard Analysis, third paragraph
Use your completed hazard analysis to determine what hazards require preventive controls. Your completed hazard analysis will be useful in determining the appropriate preventive control(s) to use in your facility. Based upon the results of your hazard analysis, you may not identify any preventive controls or you may identify several. These outcomes are very dependent upon the types of products produced and their intended use. The hazard identification and evaluation in your hazard analysis should help provide justification for your decisions.
AFIA Comments
As stated earlier, AFIA believes, and the agency has stated on multiple occasions, not every facility will identify preventive controls that need to be implemented. The agency should state this clearly throughout the document, and this is one suggested spot.

The statement, “if any,” should follow all references to the establishment of preventive controls.

Draft guidance
2.2 Overview of a Hazard Analysis, fourth paragraph
You may group animal food products together for your hazard analysis if the animal food safety hazards and controls are essentially the same for all animal food products in the group, but you should clearly identify any product or process differences. We suggest you refer to your written hazard analysis when you reanalyze or modify your food safety plan. Your written hazard analysis can be a resource for you if inspectors, investigators, auditors, or your customers ask you to explain how you determined that a preventive control is not required for a known or reasonably foreseeable hazard.

AFIA Comments
AFIA supports the concept of grouping animal food products together in the hazard analysis and identifying any product or process differences, as is stated in the first sentence of this paragraph. As noted later in section 2.3.1, we are concerned the guidance is implying a full listing of products which is overly burdensome and unnecessary.

Draft guidance with AFIA recommendation
2.2 Overview of a Hazard Analysis, fifth paragraph
Your food safety plan will not be effective in protecting consumers and preventing food safety issues if you do not conduct the hazard analysis correctly and do not identify hazards that require a preventive control. A proper analysis of biological, chemical (including radiological), and physical hazards associated with your animal food and your facility calls for good judgment, detailed knowledge of the properties of the raw materials and other ingredients, detailed knowledge of your manufacturing, processing, packing, and holding processes, and access to relevant scientific expertise.

AFIA Comments
As stated earlier, not every facility will identify hazards that require a preventive control. Therefore, to avoid confusion, we propose to delete the portion stating such at the end of the first sentence as shown above.

Draft guidance with AFIA recommendation
2.3.1 Conduct Preliminary Steps, fourth paragraph
A description of the animal food and how the animal food will be distributed and used helps the PCQI understand elements of, or handling of, the animal food that may impact animal food safety such as proper storage conditions and any required
labeling information (e.g., “Do not feed to cattle or other ruminants”). The description should include the full name of the finished animal food, species and life stage or production class, the packaging type and material, and storage and distribution details. Finished animal food could be ready-to-eat animal food or it could be an ingredient or mixture of ingredients that will be further processed, mixed, or blended before the food is suitable for feeding to animals.

**AFIA Comments**

AFIA is concerned that the language in the second sentence of this paragraph is onerous and burdensome on the facility. A proper hazard analysis can be completed without having to include the entire list of products manufactured in that facility, which can be hundreds or thousands. Facilities should be able to group products by the type of animal food, species/life stage and packaging type. The list of specific product names may change frequently and allowing categorization or grouping would limit the need to update that section of the hazard analysis just so the product names are correct. We do note that it says “should include” and it is not mandatory, however, clearly stating upfront in this guidance what is expected will hopefully eliminate issues during inspections.

**Draft guidance with AFIA recommendation**

**2.3.1 Conduct Preliminary Steps, sixth and seventh paragraphs**

The purpose of a process flow diagram is to provide a clear, simple description of the steps involved in the processing of your animal food and its associated ingredients as they flow through your facility from receipt to distribution. The process flow diagram should cover all steps in the process that the facility performs, including receiving and storage steps for each raw material or other ingredient, preparation, processing, packaging, storage, and distribution of the product. Additionally, the process flow diagram should identify the equipment (e.g., bins, legs, mixers, extruders, and pellet mills) used in the operations. An accurate process flow diagram serves as a useful organization format by identifying each of the process steps that you need to assess for the hazard analysis. You should verify the process flow diagram onsite in order to ensure no steps have been overlooked.

The purpose of a detailed process description is to explain what happens at each of the process steps. Information such as where and when micro ingredients are added to an animal food mix, whether an ingredient is handled manually, or whether rework is incorporated into an animal food can be important for an accurate hazard analysis.

**AFIA Comments**

As stated in the draft guidance, the agency is seeking a very detailed process flow diagram. According to the Food Safety Preventive Controls Alliance (FSPCA) curriculum, the process flow diagram should consider all components and steps of the process but does not need to go into detail specifically identifying the equipment, number of bins or how each step works. The purpose of the process flow diagram is to describe the flow of the facility on one page. It does
not need to tell its entire story. AFIA believes the deletions we recommend are consistent with FSPCA training.

Draft guidance with AFIA recommendation
2.3.2 Hazard Analysis Worksheet
Once your PCQI (and food safety team if applicable) gathers the information you will use to conduct your hazard analysis, we recommend that you set up a method to organize your hazard analysis. The Hazard Analysis Worksheet (HA worksheet) we provide in this guidance can be a useful tool to organize your written hazard analysis, although, as stated in section 2.2, you may use any method that results in a written hazard analysis. An example of a HA worksheet can be found in Appendix D. In this section, we discuss how to set up the HA worksheet (see Box 2-3, which contains a form adapted from the FSPCA model food safety plan (Ref. 1)).

[Delete rest of this section, including Box 2-3]

AFIA Comments
All of the information provided in section 2.3.2 is already provided in Appendix D. There is no need to repeat the information on how to set up the HA worksheet. We suggest adding a sentence directing people to the example worksheet in Appendix D and then deleting the rest of the section, including Box 2-3.

Draft guidance with AFIA recommendation
2.4.1 Identifying Known or Reasonably Foreseeable Hazards (Hazard Identification), sixth bullet
- Housekeeping and/or sanitation Sanitation practices. You should consider the sanitary conditions within the facility (e.g., cleanliness of equipment and processing environment) and employee hygiene. Hard-to-clean equipment may result in pathogen harborage sites. Producing medicated and nonmedicated animal food on the same line may result in an unsafe drug in a nonmedicated animal food, which may result in animal illness or death.

AFIA Comments
We believe the item to consider is really dealing with housekeeping and/or sanitation and propose that change. We also support deleting the last two sentences in this bullet. The sentence about hard-to-clean equipment should be deleted as it is covered in the prior bullet on equipment. The sentence on producing medicated and nonmedicated feed on the same line should also be deleted as it does not relate to housekeeping or sanitation practices.

Draft guidance with AFIA recommendation
2.4.1 Identifying Known or Reasonably Foreseeable Hazards (Hazard Identification), last paragraph
It is your responsibility to identify known or reasonably foreseeable hazards (if any) for each type of animal food manufactured, processed, packed or held at your facility. Chapter 3, Appendix E and other industry sources are available.
recommend that you consult Chapter 3 and Appendix E of this guidance to help you identify known or reasonably foreseeable hazards for your animal food. Chapter 3 provides a review of biological, chemical, and physical hazards and Appendix E provides tables describing ingredient-related and process-related hazards. The hazards described in Chapter 3 and Appendix E do not represent all possible hazards. You are responsible for identifying known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility, even if they are not listed in Chapter 3.

AFIA Comments
The paragraph as originally drafted provides too much reliance on Chapter 3 and Appendix E. This re-write notes that Chapter 3 and Appendix E are not the only sources that can be used to identify known or reasonably foreseeable hazards. It is important to point out these other sources since we do not want Appendix E to be the only thing that inspectors look for or that it is necessary to respond to each hazard that is listed in Appendix E.

Draft guidance with AFIA recommendations
2.4.2 Evaluate Known or Reasonably Foreseeable Hazards (Hazard Evaluation)
Each known or reasonably foreseeable animal food hazard must be evaluated to assess the following (see 21 CFR 507.33(c)(1)):

- Severity of the illness or injury to humans or animals if the hazard were to occur.
- The probability of occurrence of the hazard in the absence of a preventive control.

Your written hazard analysis also must:

- When appropriate, include an evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged animal 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)). Not every animal food facility will need to be concerned with environmental pathogens. Facilities manufacturing pet foods and some other feeds should evaluate the intended use of the products and make a proper determination.
- Consider the effect of certain factors on the safety of the finished animal food for the intended animal such as design of the facility and storage and distribution (see 21 CFR 507.33(d)).

AFIA Comments
Not every facility needs to concern themselves with 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 facilities must include an evaluation of environmental pathogens and when it is not applicable.

Draft guidance with AFIA recommendations
2.4.2 Evaluate Known or Reasonably Foreseeable Hazards (Hazard Evaluation)-last paragraph under “Assessing severity of the illness or injury”
If your facility does not have the expertise to assess the severity of an illness or
injury that could result from a known or reasonably foreseeable hazard, you (and your PCQI) should consult with outside experts.

AFIA Comments
AFIA recommends that the last paragraph in the section “Assessing severity of the illness or injury” be deleted. This paragraph is the first and only time throughout the guidance to make reference to consulting with outside experts. We question why this is here. If there is a particular requirement under assessing severity, then a citation should be given.

Draft guidance with AFIA recommendations
2.4.2 Evaluate Known or Reasonably Foreseeable Hazards (Hazard Evaluation)-third paragraph under “Assessing probability the hazard will occur”
You also could consider your facility’s implementation of prerequisite programs when evaluating the probability that a hazard will occur in the absence of a preventive control. Proper implementation of an adequate prerequisite program may decrease the probability the hazard will occur. This probability may decrease to such a level that you determine the hazard does not require a preventive control. If you rely on a prerequisite program in your evaluation of probability of occurrence of a hazard, adequate information about the prerequisite program, such as a copy of your standard operating procedures (SOPs), must be included in your hazard analysis as part of your evaluation. FDA could determine that your prerequisite program does not adequately reduce the probability of the hazard occurrence and that a preventive control and associated preventive control management components may be necessary for the hazard.

AFIA Comments
AFIA greatly appreciates the insertion of this paragraph into the guidance document. AFIA fully supports the belief that properly implemented prerequisite programs will decrease the probability the hazard will occur in most animal food facilities. The first three sentences are very important and are highly supported by AFIA.

In the fourth sentence, AFIA proposes to delete the reference to requiring a copy of the standard operating procedures. We agree that adequate information about the prerequisite program must be included in your hazard analysis but adequate information can be provided by means other than simply supplying a copy of the SOP. It is not appropriate to call out just one method of what could constitute adequate information in this context. AFIA believes the rule and statute do not support the FDA’s mention of including a prerequisite program in a facility’s hazard analysis or animal food safety plan.

In the last sentence, we propose to change the qualifier provided as to when the FDA could determine a prerequisite program is inadequate. The FDA may make this determination at any time based upon qualifying information. We believe it is more appropriate to eliminate the qualifier.
2.4.2 Evaluate Known or Reasonably Foreseeable Hazards (Hazard Evaluation)

“Assessing severity of the illness or injury”

Facility’s historic information

You may already have considerable information on your products from various laboratory tests on finished animal food, ingredients, in-process materials, or environmental monitoring. In addition, you may have experienced an event contamination problem in the past that suggests a hazard is known or reasonably foreseeable, or received consumer complaints about certain hazards, such as physical hazards. You should consider your facility’s historical data when conducting your hazard evaluation.

AFIA Comments
This paragraph is an important paragraph for proper completion of the hazard analysis by the facility. Taking into account that specific facility’s historical information should be a main component of the hazard analysis, as every facility is unique. We suggest the second sentence be edited to keep the type of information they review broad in nature and not be limited to just looking at contamination or consumer complaints.

2.4.4 Evaluating Environmental Pathogens When Animal Food is Exposed to the Environment

For certain animal food facilities, if the animal food you make is exposed to the environment in your facility before packaging, the animal food could be contaminated with environmental pathogens such as Listeria monocytogenes (L. monocytogenes) or Salmonella. You must then include an evaluation of environmental pathogens in your hazard evaluation if the animal food you make is exposed to the environment before packaging and does not receive a treatment or include a control measure that would significantly minimize the pathogen. See 21 CFR 507.33(c)(2). Not every animal food facility will need to be concerned with environmental pathogens. Facilities manufacturing pet foods and some feeds should evaluate the intended use of the products and make a proper determination.

AFIA Comments
As stated earlier, not every facility needs to concern themselves with 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 facilities must include an evaluation of environmental pathogens and when it is not applicable.

2.4.5 Evaluation of Other Factors (second bullet)

The condition, function, and design of the facility and equipment: The condition, function, or design of a facility or its equipment could potentially result in hazards in finished animal food. For example, older some equipment in a pet food facility (e.g., older extruders, dryers, and conveying equipment) may be more difficult to
clean (e.g., because of close fitting components or hollow parts) and thus provide more opportunities for pathogens to become established in a niche environment than modern equipment designed to address the problem of pathogen harborage in niche environments. Equipment designed with metal-to-metal contact may generate metal fragments (a physical hazard). A facility that manufactures, processes, packs, or holds animal food such as raw pet food may have cold, moist conditions that are conducive to the development of a niche where the pathogen *L. monocytogenes* can become established and contaminate animal food-contact surfaces and finished animal food.

**AFIA Comments**

AFIA proposes deleting references specific to specific equipment, whether old or new, as more difficult to clean. By referencing old equipment or facilities, a bias could be put upon those facilities when in fact they can be properly operated and cleaned with understanding of how your facility works.

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**Chapter 3 – Hazards Associated with the Manufacturing, Processing, Packing and Holding of Animal Food**

**General Comments on This Section**

Because of the bifurcated nature of the animal food industry, AFIA strongly urges the FDA to create two additional chapters: 1) Biological Hazards and 2) Chemical Hazards. Physical hazards can be included in this general chapter. With these changes in mind, AFIA proposes the following changes for this chapter:

**Draft guidance with AFIA recommendations**

**Chapter 3, Pg. 31, 3.1 Introduction**

It is important for you to understand the hazards that may be associated with your products using the raw materials and other ingredients, processes, and equipment specific for those products, as well as the environment of your specific facility. Careful consideration should be given to the intended use of the animal food before deciding which hazards are applicable. This guidance document does not provide an exhaustive compilation of hazards or details about each hazard. Where possible, we cite scientific literature, regulations, or guidance that may provide useful detailed discussion or analysis of hazards.

**AFIA Comments**

AFIA recommends the addition of the sentence to help enhance the consideration of the intended use of the animal food product in this chapter.

**Draft guidance**

**Chapter 3, Pg. 31, Table 3.1**

Delete Table 3.1. In the Hazard Category, “Chemical—Drug residues and drug carryover, these should be deleted.
AFIA Comments
Drug residues and drug carryover should not be included in this guidance, as these are covered by the CGMPs for medicated feed (21 CFR Part 225), and FSMA deals specifically with foods.

All of Section 3.3 should be moved to a new chapter titled, Chapter 4 – Biological and Physical Hazards Associated with the Manufacturing, Processing, Packing and Holding of Animal Food. The opening paragraphs in each of these sections appear to be sufficient for the new chapters.

The following are some specific comments on Section 3.3 for the new chapter.

Draft guidance with AFIA recommendations

Chapter 3, Pg. 33, end of Biological Hazards section 3.3.
Table 3-2 is a Quick Reference Guide to help you identify bacteria and parasites and potential sources or entry points in your facility. The hazards listed in Table 3-2 will not apply to all animal food at all facilities. For additional examples of hazards in animal food by food category see Appendix E – Aid to Identifying Animal Food Hazards. Specific biological hazards that may need to be considered are discussed in more detail later in Chapter 3. Many of the biological hazards discussed in this section and later in Chapter 3 are not applicable to food safety plans for facilities that manufacture animal food intended for livestock and poultry production. Careful consideration must be given to the intended use of the animal food before deciding which biological hazards are applicable.

AFIA Comments
The additional sentences to the paragraph above are necessary. AFIA believes this section contains solid information but most of it is not applicable to food safety plans outside of pet food products and some additional language will help clarify when these biological hazards are appropriate for the intended use. AFIA recommends that the added paragraph above will be the end of the Biological Hazards section (3.3) of chapter 3. All other material in this section will be removed and added as a separate chapter. AFIA agrees that this section contains solid information but most of it is not applicable to food safety plans outside of the pet food industry. The extensive discussion of biological hazards in chapter 3 creates confusion and has the potential to make the document less user friendly.

Draft guidance with AFIA recommendations

Chapter 3, Pg. 36, L. monocytogenes section
Listeria monocytogenes (L. monocytogenes) is the bacterium responsible for listeriosis in humans and animals. Clinical signs of listeriosis in dogs and cats can range from the non-specific such as vomiting, diarrhea, and fever to the more specific such as neurological (imbalance or circling), or abortion in a pregnant animal. If the animal becomes septicemic (an infection throughout its body), the clinical signs can range from high fever and lethargy to shock or death. There have been recalls of L. monocytogenes contaminated pet food (mostly raw dog and cat food) due to the potential to cause listeriosis in humans or pets (Refs.
8, 9 and 10). We are not aware of any confirmed cases of humans becoming ill after handling L. monocytogenes contaminated pet food or from contact with infected dogs and cats. However, transmission of L. monocytogenes from contaminated pet food to humans or pets could be similar to transmission of Salmonella.

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*Listeria monocytogenes* (*L. monocytogenes*) is the bacterium responsible for listeriosis in humans and animals. Clinical signs of listeriosis in dogs and cats can range from the non-specific such as vomiting, diarrhea, and fever to the more specific such as neurological (imbalance or circling), or abortion in a pregnant animal. If the animal becomes septicemic (an infection throughout its body), the clinical signs can range from high fever and lethargy to shock or death.

**AFIA Comments**
Reversing the order of the two paragraphs brings the tie to raw pet food earlier in the section and thus highlights the association of *L. monocytogenes* and raw dog and cat food.

**Draft guidance with AFIA recommendations**

*Chapter 3, Pg. 36, Pathogenic Strains of* *Escherichia coli* (*E. coli*)

Pathogenic Strains of *Escherichia coli* (*E. coli*) are bacteria associated with foodborne illness in humans and animals. Dogs and cats with foodborne illness caused by pathogenic *E. coli* can be asymptomatic or have symptoms ranging from mild gastroenteritis to hemorrhagic diarrhea. A study conducted to evaluate the prevalence of microbial organisms in various types of pet food found strains of non-O157:H7 Shiga toxin-producing *E. coli* in some raw pet food and jerky type treats (Ref. 11). We are not aware of any confirmed cases of humans becoming ill after handling pathogenic *E. coli* contaminated pet food. However, transmission of pathogenic *E. coli* from contaminated pet food to humans could be similar to transmission of *Salmonella*.

Pathogenic Strains of *Escherichia coli* (*E. coli*) are bacteria associated with foodborne illness in humans and animals. We are not aware of any confirmed cases of humans becoming ill after handling pathogenic *E. coli* contaminated pet food. However, transmission of pathogenic *E. coli* from contaminated pet food to humans could be similar to transmission of *Salmonella*. Dogs and cats with foodborne illness caused by pathogenic *E. coli* can be asymptomatic or have symptoms ranging from mild gastroenteritis to hemorrhagic diarrhea. A study conducted to evaluate the prevalence of microbial organisms in various types of pet food found strains of non-O157:H7 Shiga toxin-producing *E. coli* in some raw pet food and jerky type treats (Ref. 11).
AFIA Comments
AFIA believes the reordering of sentences in the above paragraph will highlight the disconnect between E. coli in pet food and human illness.

Draft guidance with AFIA recommendations
Chapter 3, Pg. 36, Clostridium
*Clostridium spp.* are spore-forming bacteria, found, mostly in raw and canned dog and cat food, that grow best in low oxygen conditions and can produce toxins (e.g., neurotoxins or enterotoxins).

AFIA Comments
AFIA believes the addition of the wording in the above sentence will highlight the tie between clostridium and raw and canned pet food.

Draft guidance
Chapter 3, Pg. 37, *Toxoplasma gondii* and Transmissible Spongiform Encephalopathy Agents

AFIA Comments
AFIA recommends removing the two sections above as each is either not applicable to this guidance or covered in another regulation.

Draft guidance with AFIA recommendations
Chapter 3, Pg. 38, 3.3.3 Process-Related Biological Hazards
Other process-related biological hazards are not related to something going wrong with a process control. For example, if you use a process control that significantly minimizes pathogens in a pet food and then add flavoring after the control, pathogens in the flavoring could be introduced into the pet food after the process control step. Also, pathogens could be introduced into animal food after packaging if there is a lack of container integrity. This is true for canned products.

AFIA Comments
The last sentence in the above paragraph implies that lack of container integrity is a known and reasonably foreseeable hazard. That would not be the case in all types of animal food production, so we believe the explanatory statement should be added for canned products.

Draft guidance with AFIA recommendations
Chapter 3, Pg. 41, 3.3.4 Facility-Related Biological Hazards
Facility-related biological hazards in animal food could occur from exposure or contact with contaminated equipment during procedures such as conveying, mixing, cooling, or packaging. In addition, animal food that is subjected to a preventive control (e.g., heat treatment, high pressure processing) to significantly minimize pathogens identified as hazards requiring a preventive control, may be recontaminated through exposure to a facility environment that contains these pathogens (Ref. 19).
AFIA Comments
The use of reference 19 in this context is inappropriate as reference 19 is not related to recontamination.

Draft guidance with AFIA recommendations
Chapter 3, Pg. 41, 3.3.4 Facility-Related Biological Hazards
The PCAF requirements specify that your hazard evaluation must include an evaluation of environmental pathogens whenever an animal food is exposed to the environment outside of facility equipment prior to packaging and the packaged animal 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). In the following sections, we provide information on potential sources of facility-related environmental pathogens in different types of animal food facilities.

AFIA Comments
AFIA sees the need for further clarification of the phrase “exposed to the environment prior to packaging.” The addition of the underlined phrase above adds clarity.

Draft guidance
Chapter 3, Pg. 41, 3.3.4 Facility-Related Biological Hazards
Effectively designed and implemented CGMPs are key to keeping biological hazards out of your animal food.

AFIA Comments
AFIA appreciates and applauds the mention of CGMPs as key to mitigating risks due to biological hazards.

Draft guidance with AFIA recommendations
Chapter 3, Pg. 42, Sources of Facility-Related Biological Hazards
The likelihood of product contamination with a facility-related environmental pathogen increases as the prevalence of the environmental pathogens in the processing environment increases. Many of these hazards can be addressed through your SOP/prerequisite programs. Careful consideration must be given to the intended use of the animal food before deciding which hazards are applicable. The prevalence of the environmental pathogens in the processing environment can be influenced by the raw materials used in the process, the type of process, and the hygienic practices applied to keep the processing area clean and, as necessary, sanitized.

AFIA Comments
AFIA sees the need for a reminder of the intended use of this section and language about prerequisite programs.
Draft guidance with AFIA recommendations
Chapter 3, Pg. 42, Table 3-3, Air and water
Lack of appropriate air filtration for cooling, drying, air conveying, when appropriate.

AFIA Comments
AFIA sees the need for clarification in the air and water portion of this table.

Draft guidance with AFIA recommendations
Chapter 3, Pg. 43, Transient contamination
Bacterial pathogens, including environmental pathogens, are typically introduced into the processing facility through incoming raw materials and other ingredients, personnel, or pests. It is important to ensure that these microorganisms remain transient and do not become established in the environment where they can grow and multiply. Transient contaminants can, however, result in a diversity of pathogens in the processing environment that can show up in the processing lines and finished animal food. This phenomenon could occur in animal food operations using a wide variety of raw materials and other ingredients (e.g., raw meat, meat and bone meal, canola meal) because these materials can contain very diverse microflora. In general, routine cleaning and sanitizing in accordance with CGMPs is adequate to protect against contamination by transient bacteria in the processing facility.

In general, routine cleaning and sanitizing in accordance with CGMPs is adequate to protect against contamination by transient pathogens in the processing facility. Bacterial pathogens, including environmental pathogens, are typically introduced into the processing facility through incoming raw materials and other ingredients, personnel, or pests. It is important to ensure that these microorganisms remain transient and do not become established in the environment where they can grow and multiply. Transient contaminants can, however, result in a diversity of pathogens in the processing environment that can show up in the processing lines and finished animal food. This phenomenon could occur in animal food operations using a wide variety of raw materials and other ingredients (e.g., raw meat, meat and bone meal, canola meal) because these materials can contain very diverse microflora.

AFIA Comments
Moving the last sentence in the paragraph to the first helps highlight the important role CGMPs play in controlling transient contamination and further emphasizes that importance.

Draft guidance with AFIA recommendations
Chapter 3, Pg. 43, Resident Contamination
When appropriate, sanitation controls, including proper personnel practices, and good equipment and facility design are important in preventing transient bacterial pathogens from becoming resident strains.
AFIA Comments
The last two sentences of the paragraph seem to imply that a preventive control is necessary. Adding “when appropriate” before the last sentence seems to help clarify that this may not always be the case.

Draft guidance with AFIA recommendations
Chapter 3, Pg. 45, Wet Processing Environments
The most effective strategy to prevent the contamination of finished animal food with *L. monocytogenes* is to maintain an environment as dry as possible. *Listeria monocytogenes* is generally not an issue in dry processing environments.

AFIA Comments
AFIA sees the need for more distinction between wet and dry pet food in this context and justification for dry pet food not to routinely test for *L. monocytogenes*.

Draft guidance with AFIA recommendations
Chapter 3, Pg. 46, Dry Processing Environments
Careful consideration must be given to the intended use of the animal food before deciding if *Salmonella* is a known and reasonable foreseeable hazard. Environmental moisture control is critically important in preventing *Salmonella* contamination in low-moisture products (Ref. 21). Water in the dry processing environment is one of the most significant risk factors (perhaps the single most important factor) for *Salmonella* contamination because water allows for pathogen growth, significantly increasing the risk for animal food contamination. Water, present even in very small amounts for short, sporadic time periods, may allow *Salmonella* to grow in the environment. Moisture may be obvious from sources such as water droplets or puddles from wet cleaning, but not so obvious from sources such as high relative humidity or moisture accumulating inside equipment.

AFIA Comments
AFIA recommends adding the clarifying sentence above as this section (*salmonella* spp.) applies only to pet food unless a firm’s hazard analysis indicates otherwise.

Draft guidance with AFIA recommendations
Chapter 3, Pg. 47, 3.4 Chemical Hazards
In the remainder of this section on chemical hazards, we briefly describe characteristics of some chemical hazards that can be present in animal food and processing environments, including ways they can be introduced into animal food. Effectively designed and implemented CGMPs can be key to keeping many process-related chemical hazards and facility-related chemical hazards out of your animal food. Specific chemical hazards that may need to be considered are discussed in more detail in Chapter 5. Careful consideration must be given to the intended use of the animal food before deciding which chemical hazards are applicable.

AFIA Comments
The added paragraph will be the end of the Chemical Hazards section (3.4). AFIA recognizes there is a lot of valuable information here, but most is not applicable to most animal food safety
plans. All of the extensive discussion of the chemical hazards creates confusion and has the potential to make the document less user friendly. Everything after the “facility related hazards bullet point on page 47 should be removed from chapter 3 and added as a separate chapter titled, “Chemical Hazards.”

**Draft guidance with AFIA recommendations**

**Chapter 3, Pg. 47, 3.4 Chemical Hazards, fourth paragraph**

FDA has set action levels and tolerances for some chemical contaminants in animal food (Ref. 28). These levels represent limits at or above which FDA may take legal action to remove products from the market. Where no established action level or tolerance exists, FDA may take legal action against the product at the minimal quantifiable (or in some cases detectable) level of the contaminant. Action levels and tolerances are established based on the unavoidability of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable. FDA has established temporary tolerances for polychlorinated biphenyls (PCBs) in animal food and food packaging material (see 21 CFR 509.30).

**AFIA Comments**

AFIA suggests the sentence above be deleted as it pertains to minimal quantifiable action levels. AFIA believes that in instances where there is no established tolerance, the level should be tied to instances of food safety issues only.

**Draft guidance**

**Chapter 3, Pg. 48, 3.4 Chemical Hazards, third paragraph**

In the remainder of this section on chemical hazards, we briefly describe characteristics of some chemical hazards that can be present in animal food and processing environments, including ways they can be introduced into animal food. Effectively designed and implemented CGMPs can be key to keeping many process-related chemical hazards and facility-related chemical hazards out of your animal food.

**AFIA Comments**

AFIA appreciates the inclusion of the last sentence of this paragraph as recognition of the important role CGMPs can play in mitigating the risk of chemical hazards in your facility.

**Draft guidance with AFIA recommendation**

**Chapter 3, Pg. 48, 3.4 Chemical Hazards, fourth paragraph**

Table 3-5 is a guide to help you identify some of the most common sources of chemical hazards; however, this is not an exhaustive list. Not every example in table 3-5 applies to every animal food type so the table should not be viewed as a checklist. Consideration must be given to the intended use of the animal food before determining whether the hazard is applicable.

**AFIA Comments**

AFIA proposes the addition of the sentence above. Without it, one could conclude that the examples listed in the table would apply to every animal food type and that is not the case.
Draft guidance with AFIA recommendation

Chapter 3, Pg. 49 3.4.1 Ingredient-Related Chemical Hazards – Pesticides, second paragraph

All pesticide chemicals sold or distributed in the United States must be registered by the Environmental Protection Agency (EPA). See 40 CFR part 180. The EPA also establishes tolerances (maximum amounts) for pesticide chemical residues in or on food. Pesticide chemical residues in or on food render the food adulterated under section 402(a)(2)(B) of the FD&C Act unless EPA has set a tolerance for that residue in or on that food and the residue quantity is within that tolerance limit or there is an exemption from the tolerance requirement for that residue (see FD&C Act, § 408(a)(2)(B)). FDA and the USDA enforce tolerances in food under their jurisdiction, using a memorandum of understanding to coordinate activities among FDA, USDA, and EPA (Ref. 30). A detailed description of how FDA enforces tolerances for pesticide chemical residues in animal food is available in FDA’s Compliance Policy Guide Sec. 575.100 (Ref. 31). While these are all concerns, USDA and FDA pesticide surveillance suggests that a very miniscule amount of animal food ingredients have pesticide levels that exceed permitted levels or had very low levels for where no tolerance was established (add Ref.).

Reference to add:
https://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Pesticides/UCM582721.pdf

AFIA Comments
AFIA recommends the addition of this sentence here to demonstrate that pesticide residues are very unlikely in the United States. This sentence is similar to language that is included in the FSPCA curriculum.

Draft guidance with AFIA recommendation

Chapter 3, Pg. 49 3.4.1 Ingredient-Related Chemical Hazards – Heavy Metals, first paragraph

Heavy metals are naturally occurring elements such as lead, arsenic, cadmium, and mercury. Increased levels of heavy metals in the environment are often a result of industrial and agricultural practices (e.g., use of pesticides containing heavy metals, use of manure as a fertilizer, or release of industrial waste) (Ref. 32). Mercury is known to accumulate in certain fish species. One study of food found mercury concentrations in tested cat and dog food that ranged from 1 to 604 nanograms per gram (ng/g) (Ref. 33). Though not environmental, another potential source of contamination of animal food during manufacturing is the leaching of heavy metals from containers or utensils that come in contact with the animal food.

AFIA Comments
AFIA recommends deleting arsenic from the list of naturally occurring heavy metals to be consistent with the list provided in Table 3-1.
Ref 33 is a study on river otters that ate contaminated fish and is being inappropriately correlated to dogs and cats. This reference is not relevant and should be removed.

Draft guidance with AFIA recommendation

Chapter 3, Pg. 52 3.4.1 Ingredient-Related Chemical Hazards – Tissue Toxins, first paragraph
Cases of exogenous thyrotoxicosis in dogs have been associated with pet treats that contained detectable thyroid hormones (Ref. 50). In early 2017, FDA received reports of ill dogs that, upon further investigation, resulted in the recall of two different brands of dog food because of elevated levels of thyroid hormone (Refs. 51 and 52). Laryngeal tissue (gullets) obtained from beef and lamb slaughter establishments used in the manufacture of pet treats could be a potential source of thyroid tissue that could result in thyrotoxicosis in pets. Because of this potential hazard, New Zealand restricts the use of tissue from the thyroid gland or surrounding structures (larynx) in pet food (Ref. 53). When identifying known or reasonably foreseeable hazards, pet food and pet treat manufacturers should determine whether laryngeal tissue (gullet) is included in their source material and thus could result in thyrotoxicosis in pets consuming treats derived from this material. Removal of the thyroid gland does not ensure that all thyroid tissue is eliminated.

AFIA Comments
The intent of this paragraph to identify potential tissue toxins follows along with the purpose of FSMA and putting responsibility in the hands of the facility to prevent contamination via hazard analysis and preventive control implementation. However, we believe FDA’s recent statements and letters on this topic are essentially regulation put in place without the opportunity for notice and comment. AFIA supports the agency’s ability to regulate the industry based upon proper scientific evidence and following the appropriate Administrative Procedure Act protocol. Such a prohibition seems to be an overreaction to a manageable problem well suited for FSMA by proper hazard analysis and mitigation via CGMPs.

Draft guidance

Chapter 3, Pg. 52 3.4.1 Ingredient-Related Chemical Hazards – Animal Drugs

AFIA Comments
This section contains many incidences unrelated to the manufacture of medicated feed, and AFIA finds it to be helpful.

Draft guidance with AFIA recommendation

Chapter 3, Pg. 52 3.4.1 Ingredient-Related Chemical Hazards – Chemical hazards that may be intentionally introduced for purposes of economic gain, last paragraph
Sources for information about economically motivated adulteration include an online food fraud database and food fraud mitigation guidance made available by the U.S. Pharmacopeia Convention (Ref. 68), and a report from the Congressional Research Service (Ref. 69).
AFIA Comments
References 68 and 69 should not be used as they are human food focused papers and do not include animal food and therefore, are irrelevant.

Draft guidance with AFIA recommendation
Chapter 3, Pg. 55 3.4.1 Ingredient-Related Chemical Hazards – Chemical hazards that may be intentionally introduced for purposes of economic gain, last paragraph
Although very rare and unlikely, radiological hazards can become incorporated into animal food during animal food production through the use of water that contains the radionuclides. This water may be an ingredient in the animal food, or used during the manufacturing process such as for washing ingredients or equipment. There are areas in the United States where high concentrations of some radionuclides, such as radium-226, radium-228, and uranium, can be detected in well water (Refs. 70 and 71). In those regions, radiological hazards should be considered a known or reasonably foreseeable hazard for animal food operations using well water.

AFIA Comments
AFIA recommends the addition of language stating that radiological hazards are rare and very unlikely to qualify the reality of these hazards.

Draft guidance with AFIA recommendation
Chapter 3, Pg. 56 3.4.2 Process-Related Chemical Hazards – Animal drug carryover in animal food, last paragraph
When conducting your hazard analysis, you should identify whether an animal drug used in your facility is a known or reasonably foreseeable hazard to another species, production class (e.g., layers versus broilers), or life stage (e.g., calf versus adult dairy cow) for which you manufacture animal food. If you identify a carryover drug hazard, you must evaluate it to determine if the carryover drug hazard requires a preventive control (see 21 CFR 507.33). Your preventive control might include sequencing of animal food production and flushing of equipment. You should also consider whether further preventive controls are needed to prevent the accidental addition of animal drugs to the wrong animal food that could result in unsafe animal food.

AFIA Comments
This paragraph, specifically the third sentence, implies that if you manufacture medicated feed, that facility will automatically need preventive controls. By including this sentence, the implication is that procedures that are a normal part of a facility’s medicated feed CGMPs, such as sequencing and flushing, are to be considered as preventive controls. AFIA strongly disagrees with this and urges the deletion of this sentence. We believe sequencing drugs and flushing equipment are CGMPs for medicated feed and not preventive controls.
**Draft guidance with AFIA recommendation**

Chapter 3, Pg. 56 3.4.2 Process-Related Chemical Hazards – *Nutrient deficiencies or toxicities as chemical hazards*, fourth paragraph

Nutrient deficiency or toxicity hazards can be the result of incorrect levels of nutrients in incoming raw materials or ingredients, incorrect recipe/formulation, errors in manufacturing, or a combination of these. If the raw materials or other ingredients do not contain nutrients at the expected levels, this may result in either a nutrient deficiency or toxicity hazard when the ingredient is incorporated into the animal food based on a preset formulation. For information on control strategies risk mitigation strategies for nutrient deficiency or toxicity hazards, see Chapter 4, section 4.6.1.

**AFIA Comments**

The use of the phrase “control strategies” can be interpreted as every facility will require a preventive control when in reality, that will not be the case with every animal food facility. It should be replaced with a more appropriate reference to “risk mitigation strategies.”

**Draft guidance**

Chapter 3, Pg. 58 3.4.4 Facility-Related Chemical Hazards

Industrial chemicals or other contaminants from the animal food processing environment can contaminate animal food during production – e.g., if chemicals used to clean a production line are not adequately removed from the production line, if heavy metals are leaching from containers or utensils, or if a non-food-grade lubricant comes in contact with animal food. In this guidance, we do not discuss preventive controls for facility-related chemical hazards such as cleaning chemicals and the leaching of heavy metals from containers or utensils, because such hazards are usually addressed through CGMPs (Ref. 79).

**AFIA Comments**

AFIA appreciates the inclusion of the last sentence in this paragraph as it reiterates the important and proper role of CGMPs addressing specific hazards.

**Draft guidance with AFIA recommendation**

Chapter 3, Pg. 58 3.4.5 Physical Hazards

Physical hazards are broadly classified as sharp hazards, choking hazards, and conditions of animal food hazards such as size and hardness. Injuries from physical hazards may include oral cavity damage (e.g., tooth damage or laceration of the mouth or throat), laceration or perforation of the gastrointestinal tract, and choking. In this section, we describe common physical hazards, i.e., metal, glass, hard plastic, and conditions of animal food. Physical hazards in animal food are typically process related hazards and can usually be addressed through CGMPs.

**AFIA Comments**

AFIA proposes the inclusion of the last sentence in this paragraph as it reiterates the important and proper role of CGMPs addressing specific hazards.
Chapter 4 – Preventive Controls

Draft guidance with AFIA recommendations

Chapter 4, Pg. 69, 4.1 Introduction

The guidance provided in this chapter is intended to help you identify and implement preventive controls if your firm’s hazard analysis has determined the need for a preventive control(s). This chapter provides an overview of common preventive controls, if any are required, that you could use to significantly minimize or prevent the occurrence of biological, chemical, and physical hazards in animal food and the animal food production environment when the outcome of your hazard analysis is that one or more known or reasonably foreseeable hazards requires a preventive control. The guidance provided in this chapter also is intended to help you determine pertinent parameters to use when monitoring the preventive controls that you may identify and implement. This chapter does not provide all the details needed for identifying and implementing preventive controls and is only relevant if you have preventive controls as part of your animal food safety plan. You have the flexibility to identify and implement preventive controls from among all procedures, practices, and processes that are available to you and that would provide assurances that the hazard is controlled (i.e., significantly minimized or prevented).

AFIA Comments

AFIA recommends emphasizing, in this guidance, the fact that a firm may conduct its hazard analysis and find preventive controls to be unnecessary. AFIA suggests clarifying this and showing that some of Chapter 4 may only be relevant if/when it is determined that a preventive control is warranted. Without the above additions and clarification, the guidance may indicate that all animal food safety plans must contain preventive controls.

Draft guidance with AFIA recommendations

Chapter 4, Pg. 69, 4.2 Overview of Preventive Controls

The Preventive Controls for Animal Food (PCAF) regulation defines “preventive controls” as those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis (21 CFR 507.3). Preventive controls include: (1) controls at critical control points (CCPs), if there are any CCPs; and (2) controls, other than those at CCPs, that are also appropriate for animal food safety (21 CFR 507.34(a)(2)(i) and (ii)).
AFIA Comments
AFIA recommends the use of a blue line box around the definition of preventive controls for emphasis and ease of reader to find the definition.

Draft guidance with AFIA recommendations
Chapter 4, Pg. 69, 4.3 Preventive Control Considerations (and throughout this chapter)
When identifying When If preventive controls are appropriate for to control your animal food hazards, you should consider:

AFIA Comments
Again, not all animal food safety plans will have preventive controls. The above recommended language will make that clarification throughout this chapter.

Draft guidance with AFIA recommendations
Chapter 4, Pg. 71, 4.3 Preventive Control Considerations (and throughout this chapter)
For example, if you use an alarm system on your ovens, you may set the alarm on your oven so if your oven temperature drops to 352°F (178°C), the alarm will sound and you can adjust the oven temperature to ensure that the temperature does not drop below the minimum parameter value of 350°F (177°C). However, if you are finding that the alarm is sounding often because your oven temperature drops below your operating limit, we recommend you conduct a correction to address the problem.

AFIA Comments
Alarms are not used at all facilities. We believe the clarification above makes clear that this is an example.

Draft guidance with AFIA recommendation
Chapter 4, Pg. 71-2 4.4.1 Use of Parameter Values and Operating Limits in Process Controls

AFIA Comments
This section discusses more about corrective action than implementing a preventive control. While AFIA understands that monitoring may be part of a preventive control, it is recommended that this section and Figure 4-1 be moved to the area of PC Management Component Example – Monitoring 5-3a. This will be more consistent with the way monitoring is taught in the FSPCA PCQI course.

Draft guidance with AFIA recommendations
Chapter 4, Pg. 72 last paragraph
…Information also can be obtained from peer-reviewed scientific literature…
**AFIA Comments**

AFIA recommends removing this and other references to peer reviewed or peer-review as it pertains to scientific literature. It is somewhat limiting and not all peer-reviewed literature is sound science and not all non-peer reviewed literature is inadequate.

**Draft guidance**

**Chapter 4, Pg. 73 last paragraph**

This chapter does not address heat treatments that lead to commercial sterility of low-acid canned foods.

**AFIA Comments**

AFIA appreciates and applauds this portion of the guidance where a point is made to emphasize what this portion of the chapter does NOT do.

**Draft guidance with AFIA recommendations**

**Chapter 4, Pg. 75-77 Tables 4-2 and 4-3, and the sentences referring to them**

Table 4-2 shows the relative heat resistance of common types of microorganisms. Table 4-3 lists the most common factors that you should consider when designing a heat treatment as a process control for biological hazards.

**AFIA Comments**

AFIA recommends removing tables 4-2 and 4-3, and the two sentences that refer to the tables. The information in the tables is too general in nature and does not help with the concepts of applying and implementing preventive controls.

**Draft guidance with AFIA recommendations**

**Chapter 4, Pg. 77 and other instances of use of “eliminate”**

Lethal heat treatments (heat treatments) such as baking, rendering, roasting, pelleting, extrusion, and other conventional heating methods are used for processing a wide variety of animal food (e.g., cereal-grain products, pet food kibble, jerky treats, and fish food). Heat treatments may be performed for a variety of reasons, such as to make animal food safe by eliminating significantly minimizing foodborne pathogens such as *Salmonella* and *L. monocytogenes*, to improve palatability, to increase nutrient bioavailability, and to inactivate anti-nutrient factors.

**AFIA Comments**

AFIA recommends changing the word “eliminating” to “significantly minimizing” as this follows the definition of preventive controls and recommends doing so, where appropriate, throughout this guidance.
Draft guidance with AFIA recommendations
  Chapter 4, Pg. 78 second paragraph
The location of the coldest-point and time/temperature history can be predicted through simulation software, and we expect that animal food processors—manufacturers may be able to use these emerging technologies in the future.

AFIA Comments
AFIA recommends using “manufacturers” rather than “processors” as it adds clarity, is more widely accepted, and better fits this context.

Draft guidance
  Chapter 4, Pg. 80 Table 4-4
Delete Table 4-4

AFIA Comments
AFIA recommends the removal of table 4-4 and references, as it is irrelevant. The readers cannot deduce the assumed conditions for these values. This reference seems to have been pulled from the human food arena and likely should not be used without further justification.

Draft guidance with AFIA recommendations
  Chapter 4, Pg. 90 4.6.2 and 4.6.3 Headings
  4.6.2 Drying and Storage Conditions when used as Preventive Controls for Mycotoxins
  4.6.3 Sequencing and Flushing when used as Preventive Controls for Drug Carryover

AFIA Comments
Without the addition of the clarifying phrase “when used,” these subsection headings imply that a CGMP will be a preventive control. These CGMP steps may or may not be a preventive control depending on a firm’s hazard analysis and subsequent determinations.

Draft guidance with AFIA recommendations
  Chapter 4, Pg. 90 4.6.2, first paragraph
Thus, proper drying and maintaining appropriate storage conditions are may be used as CGMPs or preventive controls that can significantly minimize or prevent the growth of mold and production of mycotoxins in storage.

AFIA Comments
Activities such as proper drying and maintaining appropriate storage conditions may be included in a firm’s CGMPs and may be used as preventive controls but may not always be preventive controls.

Draft guidance with AFIA recommendations
  Chapter 4, Pg. 91 first sentence
You must comply with the validation requirements in 21 CFR 507.47 for your flushing method for use when used as a preventive control.
AFIA Comments
Flushing may be used as a CGMP or preventive control, but may not always be a preventive control.

Draft guidance with AFIA recommendations
Chapter 4, 4.7.1 Preventive Controls for Metal Hazards
X-ray devices can also be used for metal detection. One advantage of using such a device is that X-rays can detect non-metal foreign objects, such as glass fragments.

AFIA Comments
X-ray will not catch all glass and other method(s) should be employed for glass and glass fragments.

Draft Guidance
Chapter 4, Pg. 92, 4.7.2, last sentence on CGMP
If you identify glass fragments as a known or reasonably foreseeable physical hazard at your facility, you could address them through the use of prerequisite programs (e.g., CGMPs).

AFIA Comments
AFIA applauds the verbiage above demonstrating that a prerequisite program (CGMP) can be used to control a hazard such as potential presence of glass fragments.

Draft guidance with AFIA recommendations
Chapter 4, Pg. 92, 4.7.3 Preventive Controls for Hard Plastic Hazards
Hard plastic can be introduced into animal food at any time during processing when tools and equipment (e.g., scoops, buckets, paddles, sieves, and screens) wear down. Normal use and processing may wear down these tools or equipment over time resulting in fatigue, cracking, and breaking. As a preventive measure, it is important to regularly examine plastics for cracks throughout your facility. Plastic can also be present in incoming ingredients (e.g., animal identification tags in rendered products, or packaging material from products originally intended for human food used for animal food). Preventive controls that can be used to significantly minimize or prevent hard plastics in animal food at receiving or during manufacturing include visually inspecting animal food and using physical separation techniques (e.g., sieves and screens). A thorough CGMP program can be used to do hazard mitigations as well.

AFIA Comments
Without the addition of the proposed last sentence, the paragraph implies that the potential presence of hard plastics must be controlled with a preventive control. The paragraph does use “tools and equipment,” which AFIA believes in this context to be more appropriate than “utensils.”
Draft guidance with AFIA recommendations
Chapter 4 4.7.4 Preventive Controls for Conditions of Animal Food That Can be Hazards

AFIA Comments
FDA’s statements here should be consistent with the Hazard Analysis chapter.

Draft guidance with AFIA recommendations
Chapter 4 Pg. 93, 4.8 Sanitation Controls

AFIA Comments
AFIA recommends making a clearer distinction between sanitation and housekeeping. In this section, the definitions of each are below the discussion of the activities. AFIA suggests moving them earlier in the text. Give definitions for sanitation, sanitize, sanitation control, and cleaning at the beginning of 4.8 with the objective of helping the reader distinguish between each. Place a blue shaded box around each definition for clarity and a visual cue.

Draft guidance
Chapter 4 Pg. 93, 4.8 Sanitation Controls
For your sanitation controls to be effective, you should first assess the cleaning procedures, practices, and processes that you will have in place to comply with the CGMP requirements. Equipment design that ensures that all surfaces can be accessed and cleaned (see 21 CFR 507.22(a)(1)) is essential for the effective application of sanitation controls. Refer to subsection 4.8.1 for further clarification regarding the differences in definitions for cleaning, sanitation, sanitize and sanitation control in this chapter. Considerations for equipment design include factors such as whether equipment includes hollow bodies or poorly developed welds and seams, as well as whether ease of disassembly allows adequate access to all animal food-contact surfaces to ensure thorough cleaning and sanitation. Design considerations also apply to animal food facility structures (e.g., floors, walls, piping, and ceilings) to facilitate cleaning and sanitation practices. Due to this link between your CGMP procedures, practices, and processes and your sanitation controls, your CGMP procedures, practices, and processes are sometimes called prerequisite programs. See our Guidance for Industry #235: Current Good Manufacturing Practice Requirements for Food for Animals (Ref. 26). Sources of scientific and technical information also can be useful in establishing sanitation controls (Refs. 27, 28 and 29).

AFIA Comments
AFIA recommends referencing subsection 4.8.1 in the introduction to sanitation controls. We believe this will help clarify the differences among sanitation, sanitize, sanitation control, and cleaning, which is consistent with previous comments.

Draft guidance
Chapter 4 Pg. 95, 4.8 Table 4-10. Types of Cleaning Strategies
Delete Table 4-10
AFIA Comments
AFIA recommends removing Table 4-10, as all the topics contained in the table are covered in the subsequent text.

Draft guidance with AFIA recommendations
Chapter 4 Pg. 97, 4.8.2 Use of Sanitation Controls to Prevent Cross-Contamination
AFIA Comments
For ease of use, AFIA recommends reordering the paragraphs in this subsection. We suggest moving the third paragraph to the first, and the first paragraph to the third.

Chapter 5 – Overview of Preventive Control Management Components
Draft guidance with AFIA recommendations
Chapter 5, Pg. 104, 5.4 Recordkeeping Requirements for Preventive Control Management Components (if established)
For example, the records must contain the actual values and observations obtained during monitoring and as appropriate during verification; be created concurrently with the activity documented including the date and if necessary the time; and, be signed or initialed by the individual performing the activity (see 21 CFR 507.202(a) and (b)). It is recognized that your firm may not have identified a hazard requiring a preventive control, as such, the scenarios are simplified for purposes of this guidance and focus on a single hazard and preventive control for each facility.

AFIA Comments
As stated early, AFIA believes, and the agency has stated on multiple occasions, not every facility will identify hazards requiring preventive controls. This suggested sentence is a reminder of that position and explains the focus of the rest of the chapter.

Appendices Comments Follow
Appendix C – Flowchart – Hazard Analysis
AFIA appreciates the agency including a suggested flowchart that walks through the steps of conducting a hazard analysis. We question why the agency is using a different format than the step-wise approach provided by the FSPCA curriculum for animal food. Consistency should be maintained with the training provided via the FSPCA curriculum to avoid confusion with why the agency is recommending a different format than the FDA-approved curriculum.

Appendix D – Example Hazard Analysis Worksheet
Similar to the comment on Appendix C, there are differences in the example hazard analysis worksheet provided in Appendix D from what is offered in the FSPCA curriculum. We urge consideration of using the FSPCA curriculum worksheet for consistency and to avoid confusion.
If the agency supported the worksheet in the curriculum, it should suffice for use in this guidance document.

In lieu of making that change, language should be added that this is just an example and other formats can be used, similar to language found in Section 2.2.

Appendix E – Aid to Identifying Animal Food Hazards

Draft guidance with AFIA recommendations

Appendix E, Pg. 138, Introduction

These tables of hazards are intended to provide a starting point for an individual facility’s identification of known or reasonably foreseeable hazards in various categories of animal food. The tables do not list all possible animal foods or hazards, nor do all hazards listed in these tables apply to all animal food. Careful consideration of the intended use of the animal food is necessary for identifying known and reasonably foreseeable hazards. These tables are not intended to be used as a “checklist” of hazards that must be evaluated. The Appendix E tables are numbered and titled as follows:

AFIA Comments

AFIA proposes the addition of the language above to give a clearer understanding for industry on how to use Appendix E.

Draft guidance with AFIA recommendations

Appendix E, Pg. 146, Table 5

Relating to the use of References 62 and 63 for Distillers’ By-products

AFIA Comments

AFIA is particularly concerned about inclusion of Ref. 62 and 63 implying that the animal drug residues are a hazard in ethanol co-products. We see by the references that it has been the case in the past and the agency took no regulatory actions and did not concern itself with the bioactivity of the drugs in these products. AFIA’s concern is how might a PCQI address severity of such a hazard without the inclusion of extensive product testing. Some of our membership have residue testing programs and are keenly aware of the burden of cost associated with the analysis, especially considering the disparate analytical methodology used in assessments and the lack of published tolerance values.

We believe that the agency’s approach to the antibiotic residue survey work shared in the provided references reasonably leads to the determination that such residues are very low in severity and can be addressed through pre-requisite programs, such as purchasing agreements, or that they are not hazards at all.

If this item is to be included in Appendix E, we encourage the agency to provide additional references which support the concerns associated with animal drug residues, specifically antibiotics.
References for Appendix E
As stated in the introductory comments, AFIA believes some references provided to be either archaic or inappropriate. Below is a list of references in Appendix E that AFIA believes should be removed from the document along with our justification their removal. AFIA’s rationale is bolded.


16. Dubey, J. P. 2000. “Sources of Toxoplasma gondii Infection in Pregnancy. Until Rates of Congenital Toxoplasmosis Fall, Control Measures are Essential”. British Medical Journal 321 (7254): 127-128. DOI: 10.1136/bmj.321.7254.127. **This reference is 18 years old and it also refers to human food rather than animal food. It is not appropriate to be included in this document.**

18. Ruegg, P. “Salmonella, Listeria, E. coli and Mycobacterium paratuberculosis in Milk – Is There Cause for Concern?”. Accessed January 8, 2018. **This reference refers to human food rather than animal food and is not appropriate to be included in this document.**


23. Food and Drug Administration. 2015. “Murphy Farm Hay and Feed Company Issues Recall of Alfalfa Hay Due to Possible Health Risk”. Accessed January 11, 2018. **This reference refers to products that are exempt from subparts C&E in 507.5(e). It is not appropriate to be included in this document.**
25. Undersander, D., et al. 2009. “Moldy Hay”. Accessed January 8, 2018. This reference refers to products that are exempt from subparts C&E in 507.5(e). **It is not appropriate to be included in this document.**

28. Kinney, K.K., et al. 2010. “Blister Beetles in Forage Crops”. Accessed January 8, 2018. This reference refers to products that are exempt from subparts C&E in 507.5(e). **It is not appropriate to be included in this document.**

45. Mazen, M. B., et al. 1990. “Survey of the Mycoflora and Mycotoxins of Cotton Seeds and Cotton Seed Products in Egypt”. Mycopathologia 110 (3): 133-138. **This reference is 28 years old. It is not appropriate to be included in this document.**


74. Hiney, K. 1990. “Use of By-Product and Nontraditional Feeds for Horses”. Accessed December 13, 2017. **This reference is 28 years old. It is not appropriate to be included in this document.**

75. Palumbo, J. D., et al. “Isolation of Bacterial Antagonists of Aspergillus flavus from Almonds”. *Microbial Ecology* 52 (1): 45-52. DOI: 10.1007/s00248-006-9096-y. **This reference discusses using a bacterially derived product to control aflatoxin in almonds. It should focus on the sources of and potential detriment to animals from aflatoxin. It is not appropriate to be included in this appendix.**

83. Food and Drug Administration. 2003. “Dioxin Found in Animal Feeds”. Accessed December 21, 2017. **This reference is 15 years old. It is not appropriate to be included in this document.**

87. Food and Drug Administration. 1995. “CPG Sec. 685.100 Recycled Animal Waste”. Accessed December 19, 2017. **This reference is 15 years old. It is not appropriate to be included in this document.**

100. Maqsood, A. 2012. “Salmonella prevalence in the poultry feed industry in Pakistan”. Accessed December 28, 2017. **This reference outlines the presence of Salmonella in feeds in Pakistan. Due to differences in food safety regulations, a reference to the United States should be used. This reference is not appropriate for inclusion in this appendix.**

101. Food and Drug Administration. 2014. “Burkmann Feeds, Danville, KY RECALLS 656-Layer Ration 20% Pellets Because of Possible Monensin Sodium Contamination”. Accessed December 28, 2017. **This reference refers to drug carryover from manufacture of medicated feeds. Such is covered in medicated feed CGMPs and is not appropriate to be included in this appendix.**

103. Markus, C. K., et al. 1989. “Pet Food-Derived Penicillin Residue as a Potential Cause of Hypersensitivity Myocarditis and Sudden Death”. *American Journal of Cardiology* 63 (15): 1154-1156. DOI: 10.1016/0002-9149(89)90102-1. **This reference is 29 years old. It is not appropriate to be included in this document.**

104. Food and Drug Administration. 2015. “Western Milling LLC Voluntarily Recalls Western Blend Horse Feed, Lot 5251 Due to Potential Monensin Contamination”. Accessed January 11, 2018. **This reference refers to drug carryover from manufacture of medicated feeds. Such is covered in medicated feed CGMPs and is not appropriate to be included in this appendix.**
Summary and Conclusion

AFIA believes this draft guidance is comprehensive and will be of assistance to the industry with our suggested changes. We continue to express our concern about any lists in the document that could be construed by both investigators and industry employees as “checklists” to be followed.
We are also very concerned about the overly large list of outdated references, which we strongly urge FDA to remove as per our suggestions. A recent and germane listing of references will be more helpful than the “kitchen sink” approach. We remember our suggestion of 10 years or less of scientific reports and the agency’s tacit agreement.

Finally, we continue to urge the agency to extend its flexibility rationale and approach to its inspection staff, both state and federal. Companies will have many ways of reaching the same goal of animal food safety and should be allowed to use a variety of approaches. We also caution the agency to train the inspection staff to not share facilities’ approaches at other facilities. Firms consider their approaches to food safety to be proprietary.

AFIA appreciates the opportunity to review this draft and consideration of our comments. We may make additional comments in the future as the practical nature of this draft is fully digested.

Sincerely,

Richard Sellers, PAS, Dipl. ACAN
Sr. Vice President, Public Policy & Education
AFIA

Leah Wilkinson
Vice President of Public Policy & Education
AFIA
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.

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.
THE DEMAND FOR ANIMAL FOOD IS STRONG

In 2016, over 236 million tons of animal food were consumed by nine animal species.

Around the country, animal nutritionists work with farmers and ranchers to develop the right diets for the healthy growth and development of America’s livestock and poultry. With more than 900 agricultural ingredients on the market, nutritionists have a lot of choices when working with feed manufacturers to determine diets that have the right nutrients and are the most cost effective for farmers and ranchers.

What ingredients are most commonly used in animal diets? Although the answer is relatively simple, the way of determining it is a bit complex, given diets vary by region and animals require different nutrients at various stages of their lives. IFEEDER recently commissioned an analysis of the ingredients most commonly consumed in the United States and found that in 2016, approximately 236.3 million tons of animal food were fed to nine animal species. This novel data shows how important major agricultural commodities, coproducts (i.e., soybean oil, dried distiller's grains, or bakery meal) and other ingredients (e.g., enzymes, vitamins and minerals) supplements are in supporting animal agriculture.

**TOP 5 FEED INGREDIENTS:**

- **Corn**
  118,767,563 tons

- **Soybean Meal**
  30,103,264 tons

- **DDGs**
  29,777,439 tons

- **Wheat Products**
  4,003,061 tons

- **Animal Proteins**
  1,335,551 tons