December 15, 2014

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

Via Regulations.gov

Re: Docket No. 2011-N-0922 and RIN 0910-AG10 Current Good Manufacturing Practices and Hazard Analysis Risk-Based Preventive Controls for Food for Animals

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. AFIA is also the recognized leader on international industry developments and holds membership in the International Feed Industry Federation, where AFIA's President and CEO, Joel G. Newman, serves as chair of the IFIF Policy Committee.

AFIA membership includes more than 575 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' by-products, vitamins, minerals, amino acids, yeast products and other miscellaneous/specialty ingredients are also manufactured by AFIA members.

AFIA's primary founding purposes were to promote and assure feed safety and to promote harmonization of all state feed laws with uniform labeling and regulations.

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 the Association of American Feed Control Officials (AAFCO) was formed. AFIA and AAFCO have an unbroken line of meetings for 105 years. These have resulted in many mutual programs and successes such as the AAFCO ingredient definitions, the model feed and pet food bill and rules, the model good manufacturing

practice regulations, and checklist and options for feed registration and facility licensing in the AAFCO Model Feed Bill. Today, every state except Alaska has a feed law based on AAFCO's Model 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.

Nearly all AFIA members that manufacture, process, pack or hold animal food are registered with FDA under the Bioterrorism Act. These registered facilities are very interested in these proposed rules and must comply with all final rules that FDA issues. Therefore, rules promulgated 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, supports and provides comments to FDA regarding FSMA, and belongs to the Food Safety Preventive Controls Alliance's (FSPCA) Animal Food Steering Committee. This committee is reviewing the human food training outline, which was developed by the FSPCA human food steering committee, and is adjusting it for animal food. AFIA will provide future training workshops based on the FDA-endorsed training framework developed by the alliance. AFIA has agreed to draft or be involved in a review of domestic guidance documents including those for dry and liquid feed, pet food, vitamin/mineral/specialty ingredients, miscellaneous products and guides for products derived from plants and animals.

AFIA is committed to a continuing dialogue with FDA on the FSMA rules and implementation process. We are also strongly committed to full and successful implementation of FSMA across all our varied industries. We greatly appreciate FDA's approachability, openness to new ideas, offers to discuss the rules and assistance in notifying our members of the law and rules via FDA's participation at our meetings and webinars. We also appreciate FDA issuing this supplemental proposed rule to allow the industry another opportunity to comment on the modified regulations and a first chance to comment on the newly proposed items included in the rule. We look forward to more cooperation as the rules are finalized and implemented.

AFIA is joined in support of these comments by many of the state or regional associations representing the local feed industry. Their support is listed by signature at the end of these comments.

Industry Description

The U.S. feed industry is diverse and is authorized to use more than 900 ingredients. There are more than 6,000 animal feed mills that manufacture 158 million tons of ready-to-eat feed annually. These numbers do not include on-farm mixers, which, in most cases, are exempt from Bioterrorism Act facility registration under the "farm" definition, and are exempt from the provisions of FSMA. Appendix A details the categories of the major species and amount of feed manufactured for each in 2013.

We estimate the animal feed value, including horse feed, to be approximately $45 billion, exclusive of sales of ingredients and pet food.

AFIA represents many dry dog and cat food firms in the U.S. and numerous specialty pet food manufacturers (as defined in the AAFCO Model Feed Bill found in the AAFCO *2014 Official Publication*). These include facilities that manufacture rabbit, gerbil, hamster, guinea pig, aquarium fish and other similar specialty pet food.

Some 60 million to 70 million of the total tons used in animal food includes co-products from food, beverage and ethanol production. These co-products provide valuable, cost-effective nutrients to the nation's livestock, poultry and aquaculture industries. Also, the co-product suppliers save considerable resources by providing the ingredients for animal food instead of disposing of them in the nation's landfills. Providing a market for food facility-produced co-products protects the environment and saves millions of dollars per year in disposal costs by turning these products into edible meat, milk, eggs and fish.

In 2013, the U.S. feed industry exported more than $9 billion worth of feed and feed ingredients—most of which were ingredients. Most of the complete feed trade was between the U.S. and Canada. There is also nearly $2 billion worth of feed trade with China, alone. Once FSMA is completely implemented, inspections to facilitate export certifications by both FDA and the U.S. Department of Agriculture's Agricultural Marketing Service will increase, and more exports will be realized. According to USDA's calculations, each billion dollars in agricultural exports creates 6,000 to 7,000 more U.S. jobs.

In 2004, AFIA created its hallmark Safe Feed/Safe Food Certification Program (SF/SF). For more than 10 years, over 600 facilities have been certified, and the program has grown from one basic program to several under the SF/SF umbrella. More information on these programs is available at www.safefeedsafefood.org. It is AFIA's intent to adjust the affected SF/SF programs to agree with the final animal food rules FDA publishes in 2015.

In 2010, AFIA launched its International SF/SF Certification Program (I-SF/SF) in cooperation with the FAMI-QS program (www.fami-qs.org) launched by the European Union Specialty Feed Ingredients and their Mixtures or FEFANA. This program was developed to provide compliance with the European Union Regulation (EC) 183/2005, which has a mandatory Hazard Analysis and Critical Control Points (HACCP) requirement for all feed, ingredients and pet food. FAMI-QS owns and maintains the standard for the program and provides training, while AFIA markets the program, trains independent certifying body auditors and educates facilities about the program. Recently, AFIA began issuing a newsletter with technical updates and suggestions. Next year, AFIA will begin year-round training to certified facilities in conjunction with our partner, the Safe Quality Food Institute (SQFI).

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 because they contain microbial control requirements that do not appear in the SF/SF feed programs.

In 2013, AFIA signed an agreement with the SQFI to operate and manage all the SF/SF programs except the I-SF/SF program, which is owned and maintained by FAMI-QS in the EU.

In late 2013, 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 urges FDA to issue supplementary proposed rules for accreditation of third party suppliers. This is an important issue for the animal food industries as many micronutrients are imported. In order to make the foreign supplier verification operate efficiently, AFIA believes third party certification programs offer the best opportunity for efficiency and effective, regular monitoring of suppliers. FDA should look at the collective comments it received and reissue the proposed rules with the agency's changes for review.

General Comments and Suggestions

AFIA applauds FDA for publishing the supplemental proposed rules. It appears FDA utilized some of AFIA's suggested changes and, in effect, these changes continue to reduce the cost of the final rule to the regulated animal food industries. However, the agency must do more, as comments made by AFIA in our March letter to FDA state that the benefit of such a final rule is quite low, and the agency should make greater attempts to lower the cost and better approximate the low and limited benefits.

AFIA notes that FDA has not addressed the high cost of the rules in this round of supplementary proposed rules. It merely added a poorly constructed cost-estimate of the changes and additions in this supplementary rulemaking to the poorly constructed estimated costs in the first set of proposed animal food rules. If FDA takes AFIA's recommendations, the costs will continue to decrease and better approximate the low benefit of these rules estimated by others. We strongly urge the agency to accept and adopt these recommendations.

One of the major concerns AFIA has with this rule is the subtle differences implied in the supplemental proposed rule regarding pet food and feed requirements. Although FDA has made significant, positive changes to the rule, there are still some places that need strengthening

regarding FDA's intent of the requirements. This is important to AFIA members, as they are inspected and audited by FDA's field staff. We urge FDA to further amend the rule to include such delineators as "where needed," "where appropriate" or "in accordance with the facility's animal food safety plan". This will help in defining where certain requirements should apply. AFIA has reemphasized those in our specific comments below.

One specific issue regarding the subtle rule differences is the separation between CGMPs and hazard analysis and preventive controls (PCs). AFIA believes nearly all hazards in a food animal feed plant can be controlled by adherence to CGMPs. In contrast, some hazard analysis and PCs must be applied in pet food plants to control microbial hazards. AFIA believes such an approach will significantly lessen the cost burden for both types of animal food plants and urges FDA to train its field staff in this area. AFIA will focus its strong efforts on the AFSPCA to develop both training and guidance documents that pinpoint these differences.

Compliance with the rules and the implementation period is still a large and looming issue with AFIA. We urge the agency to closely examine our request for changing FDA's one, two and three-year implementation period for regular, small and very small businesses, respectively, and consider the two, three and four-year approach AFIA has advocated in previous comments.

There likely will be some crossover concerns with firms that are in a one-year implementation period versus ingredient suppliers to those firms that are in a two year period. AFIA believes these differences will be minimal, as one-year period firms, being the largest industry facilities with sophisticated animal food safety program, will focus on their suppliers' animal safety plans and demand compliance via purchasing agreements. Moreover, depending on the final rule and the industry efforts to comply, AFIA may make additional requests to extend the compliance period in the future to assist in any costly changes and the need to develop adequate resources to comply with the final rule.

AFIA has consulted with other animal food industry organizations to make these comments as consistent as possible. While our approach in a few areas may differ, the conclusion is the same; the regulations need to be modified. How the agency modifies the regulations could result in cost savings that are necessary to provide effective regulations that will enhance the industry's production of safe animal food products without just simply driving up costs.

The medicated feed industry has complied with medicated feed rules (21 CFR Part 225) for over 40 years. FDA should ensure the final animal food rule to the extent practicable agrees with the medicated feed rules. This will insure better compliance and understanding with the final animal food rules.

Finally, AFIA agrees with FDA's public comments regarding the long-term efforts of these rules, which is promoting animal food safety. In fact, we have made suggestions in several places that would strengthen FDA's approach, such as our comments regarding § 507.42(g) (see below). We also agree that these rules and their enforcement can be fluid, in that changing industry practices, innovative technology and ingredients and better understanding of safe

practices all can contribute to the dynamism of this approach. AFIA appreciates FDA's patience and urges the agency to continue working with the regulated industries to achieve the common goals of reasonable regulation and reducing the cost burden.

Comment Overview

AFIA comments follow the flow of the proposed rule. In each of the supplementary proposed rule sections, we provide general comments and, where applicable, we note the specific proposed provision and AFIA's recommendation and rationale for the change(s). For the purposes of editing, new language is underlined and deleted language is stricken through. The use of five asterisks (* * * * *) means sections have not been included.

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Section I: Subpart A—General Provisions

§507.3 DEFINITIONS.

AFIA has reviewed the proposed new and re-proposed definitions in the supplemental proposed rulemaking and provides details below where we agree with the definition or where we offer suggestions for improvement of the definition.

Supplemental Proposed Definition

> *Environmental pathogen* means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food for animals may be contaminated and may result in foodborne illness if that animal food is not treated to significantly minimize or prevent the environmental pathogen. Environmental pathogen does not include the spores of pathogenic sporeformers.

AFIA Comments
AFIA agrees with this definition.

Supplemental Proposed Definition

> *Harvesting* applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, field coring, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm are examples of harvesting.

AFIA Comments
AFIA agrees with this definition.

Supplemental Proposed Definition

> *Hazard* means any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury in humans or animals in the absence of its control.

AFIA Comments
AFIA agrees with this definition.

Supplemental Proposed Definition

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

AFIA Comments

AFIA agrees with this definition.

Supplemental Proposed Definition

Known or reasonably foreseeable means a biological, chemical (including radiological), or physical hazard that has the potential to be associated with the facility or the food.

AFIA Comments

AFIA agrees with this definition.

Supplemental Proposed Definition

Packing means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg).

AFIA Comments

AFIA agrees with this definition.

Supplemental Proposed Definition

Pathogen means a microorganism <u>of such severity and exposure that it would be deemed</u> of public (human or animal) health significance.

AFIA Comments

AFIA believes that the significance of pathogens to public health is dependent on the organism's severity and exposure nature and the definition should be modified as such.

Supplemental Proposed Definition

Qualified auditor means a person who is a qualified individual as defined in this part and has technical expertise obtained by a combination of training, education ~~and~~or experience appropriate to perform the auditing function as required by § 507.53(c)(2).

AFIA Comments

AFIA strongly believes FDA should recognize the role of the education of a potential qualified individual or auditor as well as training and experience to meet the criteria. If FDA accepts education as training, then the final rule should say so.

Supplemental Proposed Definition

Receiving facility means a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier.

AFIA Comments

AFIA agrees with this definition.

Supplemental Proposed Definition with AFIA Recommendations

Significant hazard means a known or reasonably foreseeable hazard for which a ~~person knowledgeable about the safe manufacturing/processing, packing, or holding of animal food would, based on the outcome of a hazard analysis,~~ qualified individual would establish controls to significantly minimize or prevent the hazard in an animal food ~~and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records)~~ based on the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of a preventive control as appropriate to the animal food, the intended use of the animal food, the facility, and the control.

AFIA Comments

AFIA urges the above edits to this definition. FDA has proposed a definition for a "qualified individual," and therefore, we believe referencing the qualified individual, who will be in charge of the hazard analysis, is more appropriate in the definition instead of listing out requirements separately for this definition. Moreover, FDA should include a reference to severity and probability in the significant hazard definition. Without such reference, the use of the term in § 507.33(a)(1) could be interpreted as indicating that all identified hazards would require preventive controls equivalent to a critical control point.

Supplemental Proposed Definition

Supplier means the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.

AFIA Comments

AFIA agrees with this definition.

Supplemental Proposed Definition

Very Small Business means, for purposes of this part, a business that has less than ~~$2,500,000~~ $10,000 in total annual sales of food for animals, adjusted for inflation.

AFIA Comments

As published in 79 FR 188, page 58,502, FDA requests comment on the conclusion that "the definition of very small business should exempt from the rule only a small percent of animal food to minimize the risk of foodborne illness and, thus, are proposing a very small business definition of $2,500,000, which would exempt less than two percent of the dollar value of animal food produced in the Unites States." Specifically, the agency requests comment on whether other dollar limits should be considered.

AFIA is concerned about the proposed definition and its potential impact to industry as a whole. AFIA believes exempting very small businesses from proposed § 507.37, supplier program, will inadvertently result in large firms refusing to do business with very small businesses. Because the requirements for documentation are different depending on the size of the firm, it is likely large firms will be forced to require documentation from very small businesses that is not required by the regulation. AFIA reiterates our previous recommendation to define a very small business as one with less than $10,000 in annual sales. We believe a rule that encompasses virtually all ingredient and feed manufacturing and distribution facilities will encourage large firms to continue to do business with very small firms.

Supplemental Proposed Definition

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

AFIA Comments

AFIA agrees with this definition.

§507.5 EXEMPTIONS.

AFIA supports the recommendation from the National Grain and Feed Association to modify proposed § 507.5(g) and § 507.5(h) to exempt facilities that pack raw agricultural commodities other than fruits and vegetables intended for further distribution or processing from the CGMPs and preventive control requirements proposed in this rule.

Also, as noted below in our discussion on the human food by-product section, AFIA also supports the recommendations by the Grocery Manufacturers Association to provide an exemption in this section related to the coverage of meat and poultry products already regulated under separate federal food safety regulations.

§507.12 APPLICABILITY OF THIS PART TO THE HOLDING AND DISTRIBUTION OF HUMAN FOOD BY-PRODUCTS FOR USE IN ANIMAL FOOD.

AFIA appreciates FDA providing language here to delineate when Part 507 applies to the holding and distribution of human food by-products intended for use in animal food. There has been much confusion on this topic, and we support FDA being open and transparent in the discussion of when and how these products should be regulated under the human food and animal food CGMPs and PCs.

AFIA supports FDA listing the requirements for holding and distribution of these products in both § 507.28 and § 117.95, so the requirements are clear for both the animal food and human food facilities that may not otherwise check the other corresponding regulation for other potential requirements regarding such by-products.

In the preamble to the supplemental proposed rule, FDA discusses that § 507.28(b) does not apply to by-products from meat and poultry products for use in animal food, concluding that the hazards from these products could be more substantial. AFIA urges FDA to reevaluate this conclusion and provide an exemption as suggested by the Grocery Manufacturers Association for these products. If an exemption is not provided, the impact of this dual regulation of products regulated by both FDA and U.S. Department of Agriculture regulations could cause considerable confusion in the marketplace and limit the availability of these products.

Section II: Subpart B—Current Good Manufacturing Practices

CURRENT GOOD MANUFACTURING PRACTICES

General Comments to Subpart B

Although not directly mandated by FSMA, Current Good Manufacturing Practices, or CGMPs, are a major component of the FSMA proposed rule for animal food and represent a new requirement for most of the animal food industry, especially for the ingredient manufacturers and distributors. Currently, only medicated feed facilities operate under federal medicated feed CGMPs (21 CFR Part 225). Once the animal food rule is in effect, all facilities registered in accordance with the Bioterrorism Act—regardless of size—will be required to operate under federal CGMPs unless exempted as "farms." Therefore, it is very important that these CGMPs be appropriate for all animal food facilities, and where practicable agree with the medicated feed CGMPs. Generally, CGMPs are much less prescriptive and less costly than preventive controls.

AFIA commends FDA that the FSMA supplemental proposed animal food rule provides for additional flexibility, and more accurately agrees with practices in the current animal food industry. AFIA also appreciates that some of its original comments were taken into consideration. However, many proposed CGMPs still seem aimed toward human food manufacturing rather than animal food. AFIA urges FDA to reconsider the original comments submitted by the animal food industry. AFIA continues to support its original comments, believing them to be the most appropriate solution for animal food. Further, AFIA reiterates that the proposed CGMPs should more closely resemble current regulations (e.g. medicated feed CGMP rules), as they are more simply written, direct and already have industry acceptance and compliance for more than 40 years. Most importantly, the rarity of animal food safety issues related to medicated feed and/or residues in meat, milk, eggs or fish is evidence that current regulations are working in the feed industry.

Where FDA did not accept the original comments, and rather than submitting many of the same comments again, AFIA is proposing alternative approaches on the most concerning CGMP language. These solutions do not necessarily supersede AFIA's original comments, but are presented as minimally acceptable alternatives. AFIA has spent the last several months working closely with National Grain and Feed Association and Pet Food Institute as the collective industry builds its comments. Although the three organizations are not proposing the same modified language, AFIA has no concerns with the proposals offered by the other organizations. FDA should consider the slightly varied proposals as multiple solutions to shared concerns. Combining AFIA's original comments, these supplemental comments, and allied industry's comments, FDA has many options to ensure the final rule is appropriate for animal food.

AFIA is concerned with certain language throughout the rule that could affect compliance. For example, phrases such as "cleaned as necessary" are not clearly defined. AFIA strongly suggests that the rule state that "as necessary," as well as the requirements of the rule are related to the

facility's animal food safety plan, the products produced and type of facility (e.g., pet food or animal feed).

FDA Should Adopt the AFSS Definition of "Contaminants"

Similarly, AFIA is concerned with the use of the term "contamination" because it is not currently defined within the proposed rule. For example, § 507.25(b)(1)(ii) relates "soil" to contamination, though it is not likely to be a significant hazard. In its original comments, AFIA suggested that "contamination" be replaced with "adulteration," as this is the regulatory standard for action. AFIA continues to support replacing "contamination" with "adulteration;" however, FDA has publicly expressed concerns with doing so. Therefore, as an alternative, AFIA suggests that contaminants could be defined as in the Animal Feed Safety System (AFSS),[1] i.e., **"Contaminants are toxic or deleterious biological, chemical or physical hazards that are inadvertently present in animal feed and feed ingredients." Additionally, AFSS notes "…potentially hazardous contaminants…" which specifically do not apply to "unapproved or prohibited feed ingredients" and "expected contaminants in approved feed ingredients that are residues of starting materials or breakdown products produced during manufacture."** As this language seems to agree with FDA's intent, AFIA suggests adding the qualifier of "potentially hazardous" should "contamination" continue to be used in the final rule.

AFIA also supports the use of the NGFA's proposed definition for contamination as follows: "The occurrence of a substance in an animal food not intentionally added to such food, and which is present at a level that is reasonably likely to cause illness or injury."

In summary, should FDA choose to keep "contamination" instead of using "adulteration," AFIA believes contamination should be defined, and that such definition should be specific to potentially hazardous contamination or that which is reasonably likely to cause illness or injury to animals.

Further, in regard to contamination, the supplemental proposed rule uses the phrase "protect against" as well as "prevent" and "preclude." AFIA believes that "protect against" is the most appropriate phrase and suggests using it throughout the rule for the sake of consistency. Finally, concerning language, the term "sanitation" is used throughout the supplemental proposed rules, but lacks a clear definition. The word "sanitize" is defined as it relates generally to microbial control, but it is not an appropriate word for most animal food manufacturing facilities. Therefore, AFIA suggests "sanitation" be replaced with "clean(ing)" in order to prevent confusion. This is consistent with terminology used in the FDA's medicated feed CGMPs.

It is clear FDA is utilizing the term "sanitation," where such is not as essential or necessary, the term "cleaning" is more appropriate. In some cases the agency might use cleaning and sanitation, where the intent is to prevent or protect against microbial and other significant hazards.

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[1] AFSS Component #2 – Limits for Animal Feed Contaminants (April 2005) http://www.fda.gov/downloads/animalveterinary/safetyhealth/animalfeedsafetysystemafss/ucm054945.ppt

However, the term sanitation is not understood by feed mill personnel, as it is not used in the medicated feed CGMPs and those have been operational for 40+ years, and feed facilities have been trained to understand them. FDA should be clear in its use of these terms, which should not be interchangeable in the final rule.

As indicated in our introductory comments to the letter, AFIA believes adoption of these changes to the supplemental proposed CGMP rule will further reduce the costs and excessive burden on the industry, lead to better compliance and more closely mirror those processes and procedures currently utilized by the animal food industries. Better understanding yields better compliance.

Specific Comments on the Provisions in Subpart B

Due to the very short comment period and FDA's necessity to quickly review and draft final rules, we are not addressing each item within the CGMPs that FDA proposed in Subpart B. Instead, we are mentioning only those sections for which AFIA believes changes should be made and/or reiterating those sections for which FDA did not make the changes that AFIA suggested in our March 31 comments, but for which we strongly believe changes should be made.

Supplemental Proposed Rule with AFIA Recommendations

§ 507.14 Personnel.

(a) Plant management must take all reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against contamination of animal food, where such is indicated by the facility's animal food safety plan. The methods for maintaining cleanliness may include:

(1) Maintaining adequate personal cleanliness;

(2) Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to ~~prevent~~ protect against contamination;

(3) Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers;

(4) Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned; and

(5) Taking any other necessary precautions to protect against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(b) Personnel responsible for identifying ~~sanitation~~ housekeeping/cleaning failures or animal food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe animal food. Animal food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(c) Responsibility for ensuring compliance by all personnel working in direct contact with animal food with all requirements of this subpart must be clearly assigned to competent supervisory personnel.

AFIA Comments
It is important that the rule provide flexibility given the range of operations in animal food production facilities. AFIA suggests language such as "…may" in order to maintain this flexibility. AFIA makes this same suggested edit in several additional areas throughout these supplemental proposed CGMPs for the same reason. As stated previously, "protect against" is more appropriate language than "prevent." While "sanitation" could be used to describe sweeping and other dry cleaning activities, AFIA is concerned that the language will be confusing to those employees charged with this work with instances where "sanitizing" is required. The terms "housekeeping" and/or "cleaning" are more appropriate to the animal food industry. In part (c), AFIA believes it is the personnel "working in direct contact with animal food" that must be supervised in order to maintain food safety and therefore suggests this edit to make this point clearer to the facility.

"Cleaning" is the term used in the current FDA medicated feed CGMP rule in Title 21, Part 225.20 Buildings., as follows: "…ease of cleaning of equipment and work areas;…" (§ 225.20(a)). Similarly, in the subsequent subparagraph as follows: "The building(s) shall be maintained in a reasonably clean and orderly manner." (§ 225.20(b)(1)). The term "reasonably" is understood to mean that a "reasonable" person visiting a feed mill would understand that it is a dusty environment and will not have the expectation that surfaces in said feed mill will be free of dust. Even the U.S. Occupational Safety and Health Administration recognizes this and has an eighth inch allowance for grain dust in feed mills.

Also, in § 225.120 Buildings and grounds., the rules use similar vernacular: "Areas shall include access for routine maintenance and cleaning of equipment." The terms "sanitize" and "sanitation" do not occur. Cleaning and housekeeping are the terms with which major feed manufacturers are most familiar as they have been in use for over 40 years. AFIA strongly urges the use of this language in the final animal food rule.

Supplemental Proposed Rule with AFIA Recommendations
§ 507.17 Plant and grounds.

(a) The grounds surrounding an animal food plant under the control of the operator must be kept in a condition that will protect against the contamination of animal food. Maintenance of grounds ~~must~~ should include:
(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests;
(2) Maintaining driveways, yards, and parking areas so that they do not constitute a source of contamination in areas where animal food is exposed;
(3) Adequately draining areas that may contribute to contamination of animal food; and
(4) Treating and disposing of waste so that it does not constitute a source of contamination in areas where animal food is exposed.
(b) Buildings, structures, fixtures, and other physical facilities of the plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest

control to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food-packaging materials. This may include~~s~~:
(1) Providing adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment;
(2) Being constructed or maintained in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of potentially hazardous contamination;
(3) Providing adequate ventilation or control equipment to minimize potentially hazardous vapors ~~(for example, steam)~~ and fumes in areas where they may contaminate animal food; and locating and operating fans and other air-blowing equipment in a manner that minimizes the potential for contaminating animal food;
(4) Providing adequate lighting in hand-washing areas, toilet rooms, areas where animal food is received, manufactured/processed, packed, or stored, and areas where equipment or utensils are cleaned;
(5) Providing safety-type light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, to protect against animal food contamination in case of glass breakage; and
(6) Protecting animal food stored outdoors in bulk by any effective means, including:
(i) Using protective coverings;
(ii) Controlling areas over and around the bulk animal food to eliminate harborages for pests; and
(iii) Checking on a regular basis for pests and pest infestation.

AFIA Comments
The addition of "or maintained" allows for the continued use of functioning facilities that might be otherwise constructed under these rules, while continuing to preserve the intent of protecting against hazards. As stated previously, AFIA suggests that the addition of "potentially hazardous" where "contamination" appears, better defines FDA's intent in controlling "contamination." For example, steam is often a key manufacturing component, and is not likely to be a potentially hazardous contaminant in animal food.

AFIA is also concerned with references to "animal food contact surfaces," when the focus should be on animal food, not the contact surface. Facilities should protect against the contamination of animal food contact surfaces only when it is potentially hazardous and/or was reasonably likely to cause illness or injury.

Supplemental Proposed Rule with AFIA Recommendations
§ 507.19 ~~Sanitation~~ Housekeeping/Cleaning.
(a) Buildings, structures, fixtures, and other physical facilities of the plant must be kept clean and in good repair to prevent animal food from becoming contaminated to the point of adulteration, where appropriate or in accordance with the facility's animal food safety plan.

(b) Animal food-contact and non-contact surfaces of utensils and equipment must be cleaned and maintained and utensils and equipment stored as necessary and appropriate to protect against contamination of animal food, animal food-contact surfaces, or animal food packaging materials. When necessary, equipment must be disassembled for thorough cleaning. In addition:
(1) When it is necessary to wet-clean animal food-contact surfaces used for manufacturing/processing, or holding low-moisture animal food, the surfaces must be thoroughly dried before subsequent use.
(2) In wet processing, when cleaning and sanitizing is necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated.
(c) Cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use.
(d) The following applies to toxic materials:
(1) Only the following toxic materials may be used or stored ~~in a plant~~ where animal food is manufactured/processed or exposed <u>to the environment</u>:
(i) Those required to maintain clean and sanitary conditions;
(ii) Those necessary for use in the plant's operations;
(iii) Those necessary for plant and equipment maintenance and operation; and
(iv) Those necessary for use in laboratory testing procedures.
<u>(2) Areas used for storage of other toxic materials must be physically separated from areas where animal food is manufactured/processed or exposed to the environment.</u>
~~(2)~~ (3) Toxic materials described in paragraph (d)(1) <u>and (2)</u> of this section (for example cleaning compounds, sanitizing agents, and pesticide chemicals) must be identified, used, and stored in a manner that protects against <u>potentially hazardous</u> contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.
(e) Effective measures must be taken to exclude pests from the manufacturing/processing, packing, and holding areas and to protect against the contamination of animal food by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food packaging materials.
(f) Trash and garbage must be conveyed, stored, and disposed of in a way that protects against contamination of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces, and minimizes the potential for the trash and garbage to become an attractant and harborage or breeding place for pests.

AFIA Comments

As in previous sections, AFIA suggests the removal of the word “sanitation” as it can be confused with “sanitize.” As mentioned earlier, the medicated feed CGMP rule uses the terms “clean” and “cleaning,” which are well understood by the feed industry. At appropriate points in the rule, AFIA suggests the addition of “to the point of adulteration” to modify “contaminated.”

This suggestion originates from existing language in § 507.25(a)(8)[2], and is in accordance with the intent of protecting food safety.

As proposed, § 507.19(d) would not allow for the storage of potentially toxic materials that are not used in the facility. Examples may be fertilizers and pesticides that are commonly for sale in regional feed mills, cooperatives or grain elevators that also mix feed. The medicated feed CGMPs allow for storage of such items as long as they are physically separated from the manufacturing of animal food[3]. AFIA originally suggested removing the proposed language and replacing it with language similar to that found in the medicated feed CGMPs. AFIA continues to strongly support those comments, and asserts that they are the most appropriate solution for animal food. NGFA is proposing similar language to those original comments, which AFIA supports. However, as FDA did not adopt the recommended approach in the supplemental proposed rule, AFIA is very concerned the final rule will not reflect these suggested changes. As mentioned in AFIA's general comments, we are urging the agency to make the final rule agree with what the feed industry has known and is familiar with in the medicated feed CGMPs. Those rules are understood, practiced and have excellent compliance. Is that not the goal of agency for these rules?

Supplemental Proposed Rule with AFIA Recommendations
§ 507.20 Water supply and plumbing.

(a) The water supply must be adequate for the operations and must be derived from a suitable source. Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where required for the manufacturing/processing of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee hand-washing facilities. Water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe for its intended use. Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food.
(b) Plumbing must be designed, installed, and maintained to:
(1) Carry adequate quantities of water to required locations throughout the plant;
(2) Properly convey sewage and liquid disposable waste from the plant;
(3) Avoid being a source of contamination to animal food, animal food-contact surfaces, or animal food-packaging materials, water supplies, equipment, or utensils, and avoid creating an unsanitary condition;

[2] Section 507.25(a)(8) states that "[a]nimal food that has become contaminated **to the extent that it is adulterated** is rejected,…." (emphasis added).
[3] 21 CFR § 225.35 (b) states that "Work areas and equipment used for the manufacture or storage of medicated feeds or components thereof shall not be used for, and **shall be physically separated from, work areas and equipment used** for the manufacture of fertilizers, herbicides,…" (emphasis added).

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and
(5) Ensure that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for animal food or animal food manufacturing/processing.
~~(c) Sewage must be disposed of through an adequate sewerage system or through other adequate means.~~
(d) As appropriate, each ~~Each~~ plant must provide its employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.
(e) As appropriate, each ~~Each~~ plant must provide ~~hand-washing~~ facilities designed to ensure that an employee's hands are not a source of potentially hazardous contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

AFIA Comments
AFIA suggests the addition of "as appropriate" in order to provide the necessary flexibility for existing facilities. Subsection (c) should be deleted, as it is already required by (b)(2) in this subsection. AFIA believes much of this section is redundant, more appropriate as a guidance document, and will be difficult to enforce. Subsections (a)-(b) are too prescriptive. The water supply certainly needs to be adequate for the operations, but AFIA is concerned with the level of specificity FDA is proposing. Is the industry expected to re-design or re-install plumbing? This would drastically increase the cost of providing animal food. AFIA still supports our original comments on this section as submitted on March 31. AFIA strongly encourages FDA to revise subsections (a)-(b) as noted in those comments.

Regarding subparagraph (e), AFIA believes that "hand-washing" is overly prescriptive and the term "facilities" could include hand-cleaning stations.

Supplemental Proposed Rule with AFIA Recommendations
§ 507.22 Equipment and utensils.
(a) The following apply to plant equipment and utensils:
(1) All plant equipment and utensils must be designed and of such material and workmanship to be adequately cleanable, and must be properly maintained to protect against potentially hazardous contamination;
(2) The design, construction, and use of equipment and utensils must ~~preclude~~ protect against the contamination of animal food with nonfood-grade lubricants, fuel, metal fragments, contaminated water, or any other potentially hazardous contaminants;
(3) Equipment should be installed and maintained in such a way as to facilitate the cleaning of the equipment and adjacent spaces as necessary;
(4) Animal food-contact surfaces must be:

(i) Made of materials that withstand the environment of their use and the action of animal food, and, if applicable, the action of cleaning compounds and ~~sanitizing~~ cleaning agents;
(ii) Made of nontoxic materials; and
(iii) Maintained to protect animal food from being contaminated.
(5) Equipment in the animal food manufacturing/processing area that does not come into contact with animal food ~~must be designed and constructed in such a way that it can~~ should be kept in a reasonably clean condition.
(b) Holding, conveying, and manufacturing/processing systems, including gravimetric, pneumatic, closed, and automated systems, ~~must be designed, constructed, and~~ should be maintained in a way that ~~does not contaminate~~ protects against potentially hazardous contamination of animal food.
(c) Where necessary to protect against adulteration, the temperature of each ~~Each~~ freezer and cold storage compartment used to hold animal food must be monitored ~~fitted~~ with an accurate temperature ~~monitoring~~ measuring device.
(d) Instruments and controls used for measuring, regulating, or recording temperatures, pH, a_w, or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate, precise, adequately maintained, and adequate in number for their designated uses.
(e) Compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be used in such a way that animal food is protected from potentially hazardous contamination.

AFIA Comments
In some processes (e.g., pelleting), animal food comes into direct contact with lubricated equipment. AFIA suggests that only "nonfood-grade" lubricants should be specified in the rule as potentially hazardous contaminants.

In proposed (a)(3), existing equipment can be cleaned and maintained as necessary to protect against potentially hazardous contamination, but it cannot be redesigned or reconstructed; therefore, AFIA suggests the addition of "as necessary" in order to provide flexibility for all facility types and products produced. FDA has repeatedly said that this rule is not intended to force firms to rebuild their facilities (nor does FDA account for the cost of doing so in the cost/benefit analysis). AFIA suggests modifying the proposed rule to allow for the continuing use of existing equipment and to reduce costs.

Animal food may be placed into cold storage for reasons other than food safety. AFIA suggests that temperature monitoring is only required where freezing and/or cold storage is necessary to prevent adulteration of the product.

Supplemental Proposed Rule with AFIA Recommendations
§ 507.25 Plant operations.

(a) Plant management must ensure that:
(1) All operations in the manufacturing/processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with the current good manufacturing practice requirements of this subpart;
(2) The contents of containers (such as carts, totes, drums) ~~Containers~~ holding animal food, including raw materials, ingredients, or rework, are accurately identified ~~y~~ ~~the contents~~;
(3) The labeling for the finished animal food product conforms to all applicable regulatory requirements ~~contains information and instructions for safely using the product for the intended animal species~~;
(4) Animal food-packaging materials are safe and suitable for the intended use;
(5) The overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function;
(6) Reasonable precautions are taken so that plant operations do not contribute to contamination of animal food, animal food-contact surfaces, and animal food packaging materials;
(7) Chemical, microbial, or extraneous-material testing procedures are used where necessary to verify established controls ~~identify sanitation failures or possible animal food contamination~~; and
(8) Animal food that has become contaminated to the extent that it is adulterated is rejected, disposed of, or if permissible, treated or processed to eliminate the adulteration. If disposed of, it must be done in a manner that protects against the contamination of other animal food; and
(9) All animal food manufacturing/processing, packing, and holding is conducted under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms or for the potentially hazardous contamination of animal food.
(b) Raw materials and ingredients:
(1) Must be inspected on a frequency as appropriate and necessary to ensure that they are suitable for manufacturing/processing into animal food and must be handled under conditions that will protect against contamination ~~and minimize deterioration~~. In addition:
(i) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles holding raw materials and ingredients must be inspected upon receipt on a frequency as appropriate and necessary to determine whether potentially hazardous contamination ~~or deterioration~~ of animal food may have ~~has~~ occurred;
(ii) Raw materials must be cleaned as necessary to minimize ~~soil or other~~ potentially hazardous contamination; and
(iii) Raw materials and ingredients must be stored under conditions that will protect against contamination ~~and deterioration~~.

(2) Susceptible to contamination with mycotoxins or other natural toxins must be ~~evaluated and~~ used in a manner that does not result in animal food that can cause injury or illness to animals or humans;
(3) And all rework, must be held ~~in containers designed and constructed~~ in a ~~way that protects against contamination, and must be held under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and in a~~ manner that prevents the animal food from becoming adulterated; and
(4) If frozen, must be kept frozen. If thawing is required prior to use, it must be done in a manner that minimizes the potential for the growth of undesirable microorganisms.
(c) For the purposes of manufacturing/processing operations, the following apply:
(1) Animal food must be maintained under conditions that will protect against potentially hazardous contamination ~~, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms~~ and prevent the animal food from becoming adulterated during manufacturing/processing, packing, and holding;
~~(2) Measures taken during manufacturing/processing, packing, and holding of animal food to significantly minimize or prevent the growth of undesirable microorganisms (for example, heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling aw) must be adequate to prevent adulteration of animal food~~;
~~(3)~~ (2) Work-in-process and rework must be handled in such a way that it is protected against contamination and the growth of undesirable microorganisms unless mitigated by further processing;
~~(4)~~ (3) Steps such as cutting, drying, defatting, grinding, mixing, extruding, pelleting, and cooling, must be performed in a way that protects animal food against contamination;
~~(5)~~ (4) Filling, assembling, packaging, and other operations must be performed in such a way that the animal food is protected against contamination and growth of undesirable microorganisms;
~~(6) Animal food that relies on the control of aW for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level;~~
~~(7) Animal food that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at the appropriate pH; and~~
~~(8)~~ (5) When ice is used in contact with animal food, it must be made from water that is safe and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this subpart.

AFIA Comments

AFIA suggests language clarifying that it is the contents of containers that should be identified, and that labeling should conform to all applicable regulatory requirements. AFIA suggests that the addition of "for the intended use" adds specificity relating to materials being safe and suitable. Regarding testing procedures, it is reasonable that these methods be used where necessary to ensure product safety (as defined by the facility's food safety plan) or to investigate a known failure. It is not reasonable to require that continuous testing occur as a preventive measure. AFIA suggests that testing may be necessary to "verify established controls."

AFIA urges removal of "and minimize deterioration," in (b)(1) and other references to "deterioration" in this subpart as it is not defined and goes to a product's "quality"—not product safety. As long as product does not become adulterated by deterioration, which begins as soon as it is packaged and held, then the emphasis should be on protecting the product against contamination.

The inspection of containers can only identify if potentially hazardous contamination of animal food "may have" occurred, and is not in itself able to provide a definitive conclusion.

"Soil" should not be specified, as it does not represent a significant hazard. Section 507.25 (b)(2) can be interpreted to mean that every load of incoming cereal grain will need to be assessed for mycotoxins. This would certainly be cost prohibitive, and in many cases have little or no impact on animal food safety. AFIA suggests removing the word "evaluated" as this would allow facilities to make their own determination on how to manage potential mycotoxin contamination, based on the facility's CGMPs or animal food safety plan. AFIA suggests that the language regarding the holding of re-work is overly prescriptive, and can be simplified by focusing directly on protecting against adulteration.

AFIA urges the removal of subparagraph (c)(2) as this item will be handled in a facility's animal food safety plan and the requirements under Subpart C. The rest of this subparagraph would need to be renumbered accordingly.

Similarly, the requirements for maintaining animal food can be made clearer by focusing directly on potentially hazardous contamination and adulteration. The rule does not distinguish between "significantly minimize" and "minimize;" therefore, AFIA suggests removing "significantly" for the sake of clarity. In animal food manufacturing, further processing (cleaning, screening, thermal processing) can be effective at mitigating the impacts of potentially hazardous contaminants present in re-work. AFIA requests that language be considered to allow for this possibility. Control of water activity and pH are more appropriate for inclusion in the animal food safety plan rather than in the CGMPs.

Supplemental Proposed Rule with AFIA Recommendations
§ 507.27 Holding and distribution.

(a) Animal food held for distribution must be held under conditions that will protect against potentially hazardous contamination ~~and minimize deterioration~~, including the following:

(1) Containers used to hold animal food before distribution must be fit for purpose ~~designed, constructed of appropriate material~~, cleaned where necessary, and maintained to ~~prevent~~ protect against the contamination of animal food;

(2) Animal food held for distribution must be held in a way that ~~prevents~~ protects against contamination ~~from sources such as trash and garbage~~; and

(3) ~~Labeling identifying the product by the common and usual name must be affixed to or accompany the animal food.~~ Products must be reasonably identified.
(b) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected on a frequency as appropriate and necessary ~~prior to use~~ to ensure the container or vehicle will not contaminate the animal food to the point of adulteration.
(c) Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed.
(d) Unpackaged or bulk animal food must be held in a manner that does not result in cross contamination with other animal food to the point of adulteration.

AFIA Comments
AFIA suggests that "fit for purpose" is a term recognized by the feed industry, and is more appropriate than such terms such as "designed" and "constructed of appropriate material," which are subject to various interpretations. "Containers used to hold animal food" may include bins, totes or other intermediate storage containers, each of which may require differing levels and frequency of cleaning. AFIA suggests that "where necessary" be added after "cleaned" to provide the necessary flexibility.

As written, the supplemental proposed rule states that animal food being held for distribution must be labeled. However, doing so while the feed is stored in bulk is impractical. Such is not required in the medicated feed CGMPs. Plants may use a central computer system or other method to identify animal food location. AFIA suggests that animal food held for distribution may be "reasonably identified," which would include labeling as required by regulations for finished products. AFIA believes FDA is concerned about identification and not necessarily labeling of in-plant products, thus our suggestion can accomplish that goal.

Again, AFIA suggests that, while contamination is undefined, it is appropriate to call out "adulteration" as the standard measure for ensuring animal food safety. We also suggest deleting references to deterioration as noted in our comments on § 507.25.

Supplemental Proposed Rule with AFIA Recommendations
§ 507.28 Holding and distribution of human food by-products for use as animal food.
(a) Human food by-products held for distribution as animal food must be held under conditions that will protect against potentially hazardous contamination, including the following:
(1) Containers used to hold ~~animal food~~ human food by-product before distribution must be fit for purpose ~~designed, constructed of appropriate material~~, cleaned if necessary, and maintained to ~~prevent~~ protect against the contamination of the human food by-product ~~animal food~~;
(2) ~~Animal food~~ Human food by-product held for distribution must be held in a way to prevent contamination ~~from sources such as trash and garbage~~; and

(3) ~~Labeling identifying the product by the common and usual name must be affixed to or accompany animal food~~ Products must be reasonably identified.
(b) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected on a frequency as appropriate and necessary ~~prior to use~~ to ensure the container or vehicle will not contaminate the ~~animal food~~ human food by-product to the point of adulteration.
(c) The labeling for the human food by-product being distributed conforms to all applicable regulatory requirements.

AFIA Comments
AFIA recommends using "human food by-product" throughout this section to distinguish this section from § 507.27. AFIA suggests (a)(3) be modified to require that products being held are reasonably identified, but products that are not yet ready for distribution should not be required to bear labels with their common or usual name. Once the by-products are ready for distribution, then they should be labeled as such to conform to all applicable regulatory requirements. Therefore, AFIA is proposing to add such a requirement in (c) that states for consistency the same requirement AFIA proposed for animal food under § 507.25(a)(3).

RECALL PLAN ADDITION TO THIS SECTION

AFIA recommends a new section to be added to subpart B as noted in our comments below.

§ 507.XX Recall plan.

(a) For animal food with a significant hazard you must:
(1) Establish a written recall plan for the animal food; and
(2) Assign responsibility for performing all procedures in the recall plan.
(b) The written recall plan must include procedures that describe the steps to perform the following actions as appropriate to the facility:
(1) Directly notify direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;
~~(2) Notify the public about any hazard presented by the animal food when appropriate to protect animal and human health;~~
(~~3~~2) ~~Conduct effectiveness checks (as described in part 7 of this chapter) to v~~Verify the recall has been carried out; and
(4) Appropriately dispose of recalled animal food (e.g., reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying).

AFIA Comments

As stated in our March 31 comments on the original proposed rule, AFIA believes the recall plan should also be included in Subpart B. Therefore, we recommend the language above to be included in subpart B, so every animal food facility will have a recall plan in place. Also, we do not support the notification provision as it is a duplicate of the voluntary requirements in 21 CFR Part 7 and FDA's Reportable Food Registry (RFR) in Section 417 of the Federal Food, Drug & Cosmetic Act (FD&C Act), and therefore, it should be deleted. FSMA also did not require this notification. AFIA believes that no references to 21 CFR Part 7 should be made in this provision since Part 7 is currently a voluntary regulation. Referencing it here would make it mandatory, and AFIA does not support that change without rulemaking.

Section III: Subpart C—Hazard Analysis and Risk-Based Preventive Controls

General Comments on This Subpart
AFIA applauds FDA's adoption of many of the suggested changes we made for this subpart. These include the change to "hazards known or reasonably foreseeable" and removal of most references to critical control points, except those attributed to the statute. We believe these changes return the rules to the primary intent of the statute.

Recall Plan is a Necessity for all Facilities
AFIA continues to believe that it is very important for each facility to have a recall plan, and FDA should require such a plan be part of both Subparts B and C or referenced therein.

Part 11 Requirements Should Be Deleted
Of particular concern are the recordkeeping requirements for each facility to be 21 CFR Part 11 compliant with any electronic/computerized records that a facility maintains as part of this predicate rule. AFIA has previously detailed its concern with this provision in its March 31 comments. AFIA believes such a requirement is extremely counterproductive to the intent of Congress, made clear in several sections of the statute, that the agency should accept and encourage electronic records. Specifically, § 418(n)(4) prohibits the agency from "…prescribe(ing) specific technologies, practices or critical controls for an individual facility." We believe the intent of Congress in several other sections is not to require new buildings or infrastructure, such as that required by Part 11. Integrated computing systems are an inherent part of animal food facilities, and are therefore "infrastructure." Therefore, AFIA believes FDA cannot require animal food facilities to comply with Part 11 requirements for documenting compliance with this section.

The cost to validate/certify systems at animal food facilities makes it necessary to maintain paper records to be in compliance with this unintentionally counterproductive rule. Each firm must create the records in a computer, print and sign the reports and file them in a cabinet for future inspections and access. These must be maintained for two years; and the number of records at feed mills, pet food plants and ingredient facilities that will need to be maintained will be considerable. This was clearly not Congress' intent, as is elucidated in other FSMA sections.

Such paper record maintenance and control will take enormous time and resources and require FDA investigators/auditors considerable time to access and review such clumsy paper records. Of particular concern is the necessity of finding, printing and sending records to FDA in the event of an unlikely adulteration event. Is this prudent given the current state of computerized records and access of such records? AFIA believes it is not.

AFIA urges the agency to amend Part 11 to exempt FSMA and medicated feed records from its requirements in order to streamline recordkeeping and access. Alternatively, the agency should exempt from this rule the Part 11 requirements for recordkeeping to be in accord with § 418(n)(4).

The Role of Product Testing and Environmental Monitoring in FSMA

AFIA continues to agree with FDA that product testing and environmental monitoring can form an important component of an animal food safety plan, and that the role and need for these testing measures will vary depending on the type of product and activities of each facility. While AFIA believes that the agency should not require either mandatory product testing or environmental monitoring across the entire animal food industry, and we appreciate the agency's attempt to limit the applicability of these provisions and that testing is a tool that a facility may utilize to verify that control measures are operating when an appropriate hazard has been identified.

AFIA appreciates that FDA has not proposed prescriptive mandates or requirements on the products to be tested, number and location of samples or frequency. When proper testing or environmental monitoring programs are designed, much care is taken to consider the variability in product types and processes used in the particular facility. Flexibility, as required by § 418(3)(A) is necessary to implement product testing or environmental monitoring programs that are appropriate for a facility, the type of product produced and the intended use of the product. Providing prescriptive requirements in the regulation or guidance could limit the effectiveness of testing programs if a facility only worked to meet the requirements in the regulation, rather than implement the proper program for their product(s) and facility, or adapt the testing program to further enhance animal food safety. This has occurred with licensed medicated feed facilities, which do not, as a matter of routine practice sample medicated feed for animal drugs, except as required by 21 CFR § 225.58.

We urge the agency to keep the regulation general in nature and utilize future guidance documents as a means to provide recommendations on the design of testing programs that can be specific to the type of facility and animal food products produced.

In the supplemental notice to the proposed rule, FDA has not addressed whether "product testing" is limited to "finished" product testing and instead allows flexibility for the facility to make a risk-based decision on when testing would apply based upon the facility, the animal food and the nature of the preventive control. AFIA believes a product testing program for animal food should focus on finished products that are consumed by animals in accordance with their intended use as described in the facility's animal food safety plan, and not include individual ingredients used in the production of the finished products. AFIA encourages FDA to keep the language flexible, yet we propose some modifications to § 507.49(a) and § 507.49(a)(2) as detailed below that would provide clarity when testing is necessary.

In public forums, agency personnel have stated that they intend for the environmental monitoring provisions to apply only to pet foods and not to all of animal food. While the supplementary proposed regulatory text does not imply this limitation, some limitation should occur with a properly conducted hazard analysis to identify an environmental pathogen when the product does not receive a treatment after packaging. AFIA is aware that there may be ingredients where an

environmental pathogen is identified and a treatment to that individual product is not rendered. However, when incorporated into a finished animal food product, the ingredient will most likely receive a treatment to significantly minimize or eliminate the environmental pathogen. Guidance documents will play an important role as to inform when and to what products the agency expects environmental monitoring to be conducted for both investigators and regulated industry.

Product Testing and Environmental Monitoring Are Verification Activities—Not Preventive Control Measures

As stated in our comments to the original proposed rule, testing, in Section 418(f) of the FD&C Act, is discussed as a means to verify implementation of preventive controls. AFIA believes testing programs can identify failures or adverse trends in CGMPs or preventive controls; however, testing cannot prevent, reduce or eliminate microbial or chemical hazards from animal foods. Therefore, testing—whether product testing or environmental monitoring testing—is ineffective if designated as a preventive control measure.

Any test is only reflective of the sample or sample location evaluated at the time the sample was collected. Any reliance on testing as the sole means of controlling a hazard would be irresponsible. Testing must be paired with a proper, effective and validated process, as well as environmental and cleaning controls.

Product testing and environmental monitoring better functions as verification tools, when necessary and appropriate, rather than measures that directly control a hazard. For example, AFIA believes that environmental monitoring is an appropriate means to verify the effectiveness of specific environmental controls, such as cleaning, facility maintenance, zoning and personnel practices. Environmental monitoring programs play an important role in an animal food safety plan for a facility that has determined an environmental pathogen is a hazard that needs to be controlled in their facility. Effective environmental monitoring programs are designed to find and address likely issues before they could potentially lead to product adulteration.

FDA should not require that a receiving company be responsible for testing ingredients to verify supplier controls. FDA should acknowledge that verification of information in certificates of analysis (COAs) generated by suppliers, based upon their own testing, can be an appropriate component of a receiving company's verification program. FDA should indicate that while testing programs for ingredients may be part of a receiving company's verification program, a testing component should only be required when necessary and appropriate for the material, process and supplier performance based on an assessment of risk.

AFIA believes that the necessity for, and the design and implementation of, an effective product testing or environmental monitoring program must be adapted to the specific situation of the animal food product and respective manufacturing facility. FDA should recognize reputable existing guidance on relevant programs and, where necessary and appropriate, develop guidance in conjunction with industry stakeholders, rather than promulgate regulatory requirements. AFIA also believes a facility should not be punished by an investigator/inspector for finding potential problems through verification testing or monitoring if appropriate corrective actions and

preventive measures are taken. This will be a difficult concept for inspectors to grasp; retraining of FDA's inspection staff will be necessary. The "command and control" approach of by-gone years will no longer satisfy audits under the proposed rules.

Specific Comments on the Provisions in Subpart C

Due to the very short comment period and FDA's necessity to quickly review and draft final rules, we are not addressing each section that FDA proposed in Subpart C, instead, we are mentioning only those sections for which AFIA believes changes should be made and/or reiterating those sections for which FDA did not make changes that AFIA suggested in our March 31 comments, but for which we strongly believe changes should be made.

HAZARD ANALYSIS

AFIA appreciates the agency's consideration of our previous comments and effort to clarify and improve the flow of § 507.33 Hazard analysis. We were pleased to see the acceptance of the removal of reasonably likely to occur and the grouping of radiological hazards with chemical hazards along with our other minor suggestions. However, we continue to have some outstanding concerns along with the need to clarify some of the new additions to the section, and have proposed the following suggestions.

Supplemental Proposed Rule with AFIA Recommendations

§ 507.33 Hazard analysis.

(a) You must:

(1) Identify and evaluate, based on experience, illness data, scientific reports, ~~and~~ or other information, known or reasonably foreseeable hazards for each type of animal food manufactured/processed, packed, or held at your facility to determine whether there are significant hazards; and

AFIA Comments

AFIA understands the need to identify acceptable information to utilize in a hazard evaluation and appreciates the agency recognition of our comments regarding "reasonably likely to occur" by utilizing "known or reasonably foreseeable" in this section. AFIA believes "or" is the most appropriate qualifier in this listing of information as not every hazard in animal food may have all of these types of information to include in the hazard analysis.

This proposed provision also has a new reference to significant hazards—causing us to have two main concerns. First, the definition for significant hazards states they are "known or reasonably foreseeable," which is circular logic in the context of § 507.33(a)(1). Second, without including a reference to the severity and probability in the significant hazard definition, this section could be interpreted to indicate that all identified hazards would require preventive controls equivalent to a critical control point. Therefore, AFIA strongly urges FDA to modify the definition of significant hazard as noted above in Section I.

* * * * *

Supplemental Proposed Rule with AFIA Recommendations
§ 507.33 Hazard analysis.

(b) The hazard identification must consider:
(1) Hazards that include:
(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;
(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, ~~decomposition~~, unapproved food or color additives, and nutrient ~~imbalances~~ deficiencies or toxicities; and
(iii) Physical hazards; and

AFIA Comments
AFIA thanks the agency for including radiological hazards within the chemical hazard categorization, as we believe this simplifies the preparation of animal food safety plans. However, we re-emphasize our previous request to remove decomposition and to replace "nutrient imbalances" with "nutrient deficiencies or toxicities."

Removal of Decomposition
Many products used in the animal food industry, including hydrolyzed proteins, palatants and rendered materials have begun decomposition but are processed in a controlled system to halt decomposition before harmful toxins are formed. Based on FDA's broad description in the original preamble, these products may need to be identified as hazards within a facility manufacturing or utilizing these materials as ingredients even though they are demonstrably safe for use in animal foods.

AFIA is concerned that these types of materials may be subject to unnecessary regulatory scrutiny. From the examples cited within the original preamble, AFIA understands the agency's intent was to identify hazards associated with uncontrolled decomposition or spoiled foods that result from chemical changes induced by the microbial breakdown that subsequently releases potentially hazardous natural toxins. The original proposed rule and the supplemental proposal already identify natural toxins as a subgroup of chemical hazards. Thus, it is redundant and unnecessary to reference decomposition when some (lower) levels of decomposition do not pose an animal food safety risk. Accordingly, AFIA recommends that "decomposition" be deleted from the list of chemical hazards in this provision.

Nutrient Imbalances
FDA's inclusion of nutrient imbalances to the definition of chemical hazards is surprising, because the term "nutrient imbalance" is broad and encompasses nutritional design rather than just animal safety. Typically, animal safety is related to established nutrient deficiencies and toxicities. In fact, nutritional design and formulation must consider multiple factors including all sources of nutrients. Furthermore, adjustments are necessary to insure the animal does not receive too much or too little of a nutrient based on the total consumed ration. AFIA continues to

urge FDA to replace "nutrient imbalances" with "nutrient deficiencies or toxicities" and utilize the definitions for each consistent with our March 31 comments.

* * * * *

Supplemental Proposed Rule with AFIA Recommendations
§ 507.33 Hazard analysis.

(2) Hazards that may be present in the animal food for any of the following reasons:
(i) The hazard occurs naturally;
(ii) The hazard may be unintentionally introduced; or
(iii) The hazard, based on historical precedent, may be intentionally introduced for purposes of economic gain.

AFIA Comments

Based on the preamble published with the supplemental proposed rule, it seems the agency's intent is that facilities consider hazards that have been found to be introduced for economic gain in the past, such as melamine in protein sources. However, the codified language could be interpreted to mean that facilities should consider all potential economic adulterants. While we do not believe a specific notation for identification of economic adulterants is needed, AFIA recommends that language be added to clarify the agency's expectation that only known economic adulterants that pose a safety risk be considered. With this addition and the requirement provided under § 507.50(a)(3) for a reanalysis of your food safety plan when new information becomes available on potential new hazards, AFIA believes that economic adulteration would be sufficiently addressed in a robust animal food safety plan.

* * * * *

Supplemental Proposed Rule with AFIA Recommendations
§ 507.33 Hazard analysis.

(c)~~(1)~~ The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

~~(2) The hazard evaluation required by paragraph (c)(1) of this section must 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 that would significantly minimize the pathogen.~~

AFIA Comments

There is significant new language in § 507.33, and AFIA is uncertain of the agency's intent with the inclusion of environmental pathogens. A robust hazard identification process must include an evaluation of where hazards can be introduced as referenced in § 507.33(d), throughout the lifespan of the product and not just prior to packaging. Additionally, once an environmental pathogen is identified, a facility should establish a robust environmental monitoring program that would address any potential environmental exposure points and establish controls for those areas. Thus, this addition is redundant and unnecessary, as it will already be covered in the

hazard identification process and subsequently addressed in an appropriate environmental monitoring program. If the agency believes this should be specifically addressed, AFIA would recommend capturing the concept within a guidance document where it can be expanded upon for the various types of animal foods. If the item is kept, a clear description or definition is necessary for what "exposed to the environment" means for the animal food industry.

PREVENTIVE CONTROLS

Supplemental Proposed Rule with AFIA Recommendations

§ 507.37(a)(1)(ii) Supplier Program.

(B) The CGMP's or preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards; or

AFIA Comments

CGMP's are reasonable controls that may be implemented to prevent or control hazards. Thus, CGMP's should be listed as a tool to support the control of hazards.

* * * * *

Supplemental Proposed Rule with AFIA Recommendations

§ 507.37(a)(1)(ii) Supplier Program.

~~(C) The receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.~~

AFIA Comments

It is not practical to expect a customer to provide a receiving facility (which is the customer's supplier) written documentation that it is controlling a potential hazard for a material. This is beyond what a customer/supplier relationship should be.

In § 507.37(f), FDA clearly states that if a receiving facility identifies a hazard that a supplier does not control, the receiving facility is responsible for the control the hazard. Thus, § 507.37(a)(1)(ii)(C) is not necessary as the requirements for controlling the hazard are clearly identified in § 507.37(f). Requiring such documentation is redundant and unnecessary, which is costly to the industry.

Intended use of a material by a customer determines the potential hazards from a material. The customer is in the best position to assess these hazards through their own risk assessment. They can to determine whether they want to control the hazard or require the supplier to control. Documentation from the customer to the receiving facility is irrelevant and not needed.

* * * * *

Supplemental Proposed Rule with AFIA Recommendations

§ 507.37(a)(3)(iii) Supplier Program.

(C) The incoming raw material or ingredient is ~~produced in compliance with the requirements of applicable FDA food safety regulations.~~ appropriately labeled or identified.

AFIA Comments

Not all incoming raw materials or ingredients are considered finished products. The definition of raw material can imply unprocessed product. The statement above is also redundant to what is stated in (B). AFIA recommends adding "appropriately labeled or identified" to cover additional FDA or other agency food safety regulations. As an example, USDA inspected meat that has been rejected for human consumption is considered human inedible. When shipped to pet food or feed plants such products are considered by regulation to be denatured and may not reenter the human food chain.

* * * * *

Supplemental Proposed Rule with AFIA Recommendations

§ 507.37(c)(3) Supplier Program.

~~(3) If a supplier is a qualified facility as defined by § 507.3, the receiving facility need not comply with paragraphs (c)(1) and (2) of this section if the receiving facility:~~
~~(i) Documents, at the end of each calendar year, that the supplier is a qualified facility as defined by § 507.3; and~~
~~(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act. The written assurance must include a brief description of the processes and procedures that the supplier is following to ensure the safety of the animal food.~~

AFIA Comments

AFIA recommends that qualified facilities follow the same requirements as other suppliers and that this provision therefore be deleted. All facilities that have aspirations to be suppliers need to follow the same supplier requirements. Having more onerous supplier verification requirements for qualified facilities will limit their ability to compete in the marketplace, which should not be FDA's primary intent.

A receiving facility will be reluctant to use qualified facilities as suppliers due to the additional records and documentation that are required as compared to other suppliers. The additional documentation requirements will be an undue burden for receiving facilities and increase their costs when suppliers are qualified facilities. There is also a perception that qualified facilities have the potential to be higher risk suppliers due to fewer regulatory requirements and less governmental oversight.

* * * * *

Supplemental Proposed Rule with AFIA Recommendations

§ 507.37(c)(4) Supplier Program.

~~(4) If a supplier is a farm that is not subject to the requirements established in part 112 of this chapter in accordance with § 112.4 regarding the raw material or ingredient that the receiving facility receives from the farm, the receiving facility does not need to comply with paragraphs (c)(1) and (2) of this section if the receiving facility:~~

~~(i) Documents, at the end of each calendar year, that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and~~

~~(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.~~

AFIA Comments

"Farms" are exempt from FSMA requirements as they are not required to register. In addition, § 507.37(f) clearly states that the receiving facility is responsible for controlling hazards that are not controlled by a supplier. Thus, it is redundant and costly to require additional documentation and activities relative to materials from farms and this provision should be deleted.

* * * * *

Supplemental Proposed Rule with AFIA Recommendations

§ 507.37(e)(1) Supplier Program.

(e)(1) Instead of an onsite audit, a receiving facility may rely on the results of an inspection of the supplier by FDA ~~or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has recognized as comparable or has determined to be equivalent to that of the United States~~, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted; and

AFIA Comments

The reference to audits for foreign suppliers is redundant, as there is a separate rule for foreign supplier verification, and therefore, this section should be deleted.

Supplemental Proposed Rule with AFIA Recommendations

§ 507.37(e)(2) Supplier Program.

~~(2) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the animal food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.~~

AFIA Comments

As stated above, the reference to audits for foreign suppliers is redundant, as there is a separate rule for foreign supplier verification, and this entire provision should be deleted.

* * * * *

Supplemental Proposed Rule with AFIA Recommendations

§ 507.37(g) Supplier Program.

(g) The receiving facility must document the following in records and review such records in accordance with § 507.49(a)(4):

(1) The written supplier program;

(2) Documentation of the appropriate verification activities;

~~(3) The annual written assurance that a receiving facility's customer who is controlling a significant hazard has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard;~~

~~(4)~~(3) Documentation demonstrating that products are received only from approved suppliers;

~~(5)~~(4) Documentation of an onsite audit, if applicable. This documentation must include:

(i) Documentation of audit procedures;

(ii) The dates the audit was conducted;

(iii) The conclusions of the audit;

(iv) Corrective actions taken in response to significant deficiencies identified during the audit; and

(v) Documentation that the audit was conducted by a qualified auditor.

~~(6)~~(5) Records of sampling and testing. These records must include:

(i) Identification of the raw material or ingredient tested (including lot number, as appropriate) and the number of samples tested;

(ii) Identification of test(s) conducted, including the analytical method(s) used;

(iii) The date(s) on which the test(s) were conducted;

(iv) The results of the testing;

(v) Corrective actions taken in response to detection of hazards; and

(vi) Information identifying the laboratory conducting the testing.

~~(7)~~(6) Records of the review by the receiving facility of the supplier's relevant food safety records. These records must include:

(i) The date(s) of review;

(ii) Corrective actions taken in response to significant deficiencies identified during the review; and
(iii) Documentation that the review was conducted by a qualified individual.
~~(8)~~(7) Records of other appropriate supplier verification activities based on the risk associated with the ingredient.
~~(9)~~(8) Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled;
~~(10)~~(9) Documentation of an alternative verification activity for a supplier that is a qualified facility, including:
(i) The documentation that the supplier is a qualified facility as defined by § 507.3; and
(ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.
~~(11)~~(12) Documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or ingredient that is not subject to part 112 of this chapter, including:
(i) The documentation that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and
(ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.
~~(12)~~(11) Evidence of an inspection of the supplier by FDA or the food safety authority of another country.
~~(13)~~(12) Documentation of actions taken with respect to supplier non-conformance.

AFIA Comments
Please see comments above for § 507.37(a)(1)(ii) as why this activity in § 507.37(g)(3) should not be required.

This section should be renumbered when deleting provision (3).

The addition of “if applicable” in current § 507.37(g)(5) is necessary based upon proposed § 507.37(c)(2)(ii) that states an onsite audit may not be necessary if the receiving facility has documented its determination that other verification activities provide adequate assurance that the hazards are controlled. Therefore, if an onsite audit is not needed, this provision should state that documentation from an onsite audit should only be done if necessary.

* * * * *

Supplemental Proposed Rule with AFIA Recommendations

§ 507.42 Corrective actions and corrections.

a) As appropriate to the preventive control, except as provided by paragraph (c) of this section:

(1)(i) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented or found to be ineffective.

* * * * *

(b)(1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraph (b)(2) of this section if any of the following circumstances apply:

(i) A preventive control is not properly implemented or found to be ineffective and a specific corrective action procedure has not been established;

AFIA Comments

AFIA believes that failing to properly implement effective controls is synonymous to finding one or more controls to be ineffective, and this subsection should reflect that change.

* * * * *

Supplemental Proposed Rule with AFIA Recommendations

§ 507.49 Verification of implementation and effectiveness.

(a) You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards. To do so, you must conduct activities that include the following, as appropriate to the facility, the animal food, the intended use of the animal food, and the nature of the preventive control:

(1) Calibration of process monitoring and verification instruments;

(2) Product testing for a significant hazard (pathogen (or appropriate indicator organism) or other hazard);

AFIA Comments

In provision (a), FDA has proposed adding in the sentence "To do so, you must conduct activities that include the following, as appropriate to the facility, the animal food, and the nature of the preventive control." AFIA appreciates FDA adding this statement to provide clarity regarding when the activities that are listed below are applicable based upon the facility, the animal food and the nature of the preventive control. However, AFIA believes FDA should add the additional factor of the "intended use of the animal food" to help further clarify that these activities should be conducted based upon the appropriate end use of the animal food as it was intended by the manufacturer, and not upon any potential use of the product not originally intended. The suggested change will further clarify the intent of the requirement and is consistent with FDA's changes elsewhere.

The language as originally drafted in (a)(2) directs product testing based upon any pathogen or other hazard. In the supplemental notice to the proposed rule, FDA focuses on the need to identify significant hazards in the hazard analysis conducted by the facility and also takes care to limit the environmental monitoring provision in § 507.49(a)(3) to an environmental pathogen that is a significant hazard. Therefore, AFIA recommends that significant hazard be included in (a)(2) for product testing to clarify that the testing is being conducted because of a significant hazard found in the hazard analysis, which could include pathogens, appropriate indicator organisms or other hazards.

* * * * *

Supplemental Proposed Rule with AFIA Recommendations

§ 507.50 Reanalysis.

(a) You must conduct a reanalysis of the animal food safety plan:

AFIA Comments

Throughout these rules, AFIA urges FDA to differentiate between human food and animal food, especially with respect to the facility's "animal" food safety plan. There are separate rules for each, and each set of rules defines by title the type of food for which the rules are intended. AFIA only asks for such differences within the animal food rule. This will assist long-term in development of guides that apply to specific food segments of the regulated industries. Moreover, FDA differentiates between animal and human food, by referring to this rule as the animal food rule. The agency should do the same within its rules.

* * * * *

Supplemental Proposed Rule with AFIA Recommendations

§ 507.53 Requirements applicable to a qualified individual and a qualified auditor.

(a) One or more qualified individuals must do or oversee the following:
(1) Preparation of the food safety plan (§ 507.31(b));
(2) Validation of the preventive controls (§ 507.47(b)(1));
(3) Review of records (§ 507.49(a)(4)); and
(4) Reanalysis of the food safety plan (§ 507.50(d)).
(b) A qualified auditor must conduct an onsite audit (§ 507.37(d)).
(c)(1) To be a qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience or by education to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum or by education. This individual may be, but is not required to be, an employee of the facility.
(2) To be a qualified auditor, a qualified individual must have technical expertise obtained by a combination of training, education and experience appropriate to perform the auditing function.

(d) All applicable training must be documented in records, including the date of the training, the type of training, and the person(s) trained.

AFIA Comments
AFIA strongly believes FDA should recognize the role of education of a potential qualified individual or auditor as well as training and experience to meet the criteria. If FDA accepts education as training, then the final rule should say so.

Section IV: Summary and Conclusions

The high cost of compliance remains AFIA's major concern with respect to this rule and its predicted impact. AFIA strongly believes that changes suggested here will lower the costs and more closely approximate the limited (if any) benefits of the rule. We urge FDA to adopt these changes to lower the costs.

Of continuing concern is the subtle difference in the structure of the text of the rules as to how FDA expects facilities to comply with either microbial and/or chemical controls. A clearer approach should be outlined in future guidance documents for compliance with FSMA rules.

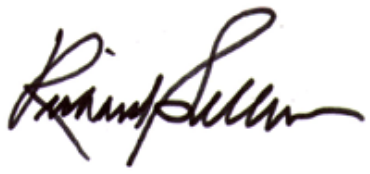
Training and adequate understanding of the final rule and industry practices are long-term concerns of AFIA due to the completely new approach of the CGMPs and PCs for animal food facilities. As AFIA has stated numerous times, these rules are a new approach to the majority of facilities manufacturing animal food. FDA needs to adopt AFIA's suggested time lines of one, two and three years for compliance with the CGMP rule, and two, three and four years for compliance with the PC rule for firms that are regular size, small businesses and very small businesses, respectively.

Continued support by FDA is strongly urged for the joint industry/agency efforts in the FSPCA Animal Food Steering Committee. This group should spend quality time on developing relevant, clear and practical guidance documents for the following animal food industry segments: dry feed liquid feed, pet food, animal-derived products, plant-derived products, vitamin/mineral/amino acid trace ingredients and miscellaneous/special purpose ingredients. AFIA pledges it support and technical assistance in developing these guides.

Finally, AFIA is grateful for FDA's cooperation in offering a number of public sessions, providing speakers for industry seminars and listening to industry concerns about this massive rulemaking process. AFIA pledges its continuing support to developing sound industry practices for compliance with this rule.

We appreciate the agency's consideration of these comments.

Sincerely,



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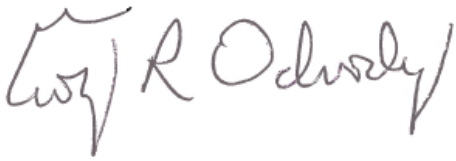
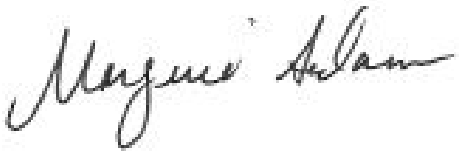


Troy Odvody
President
Oregon Feed & Grain Association, Inc.



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Kathleen M. Zander
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Texas Grain & Feed Association

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Executive Director
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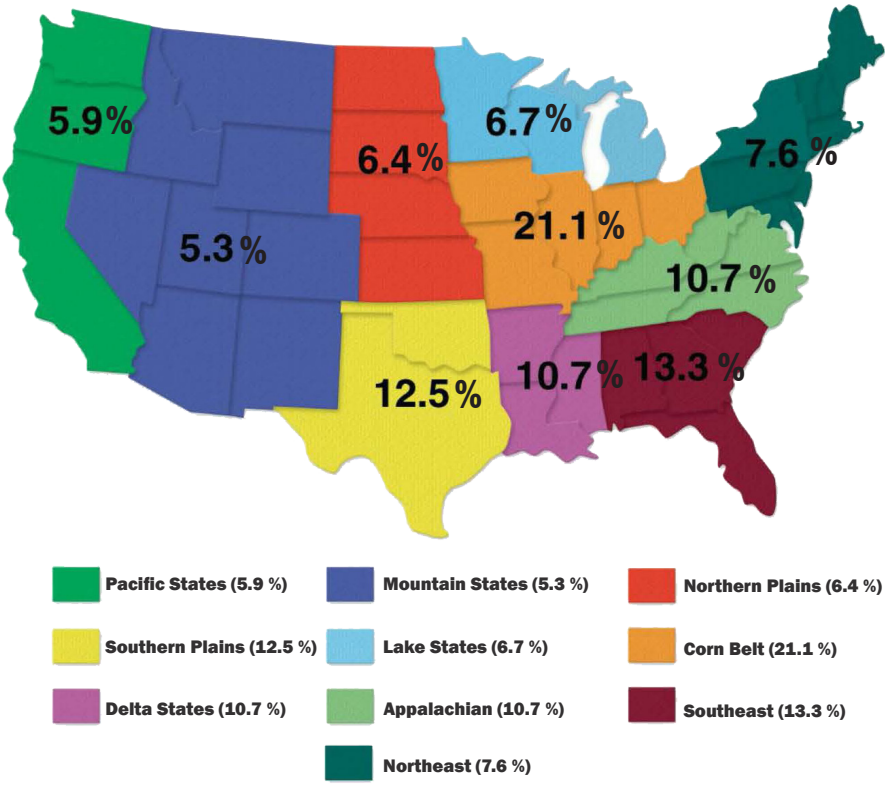
U.S. FEED INDUSTRY STATISTICS

Updated March 31, 2014

ESTIMATED PRIMARY FEED PRODUCTION REQUIRED TO SUPPORT ANIMAL INVENTORY • PERCENT OF TOTAL (2007-2012 BY REGION)

SOURCE: *Feedstuffs*, 2013 Reference Issue and Buyers Guide, Sept. 11, 2013, Number 39, Page 6



ECONOMIC IMPACT OF ANIMAL AGRICULTURE, 2012

- 1.8 million jobs to the economy
- $346 billion in gross domestic product
- $60 billion to household incomes

SOURCE: United Soybean Board

AN INDUSTRY BUILT ON RECYCLING

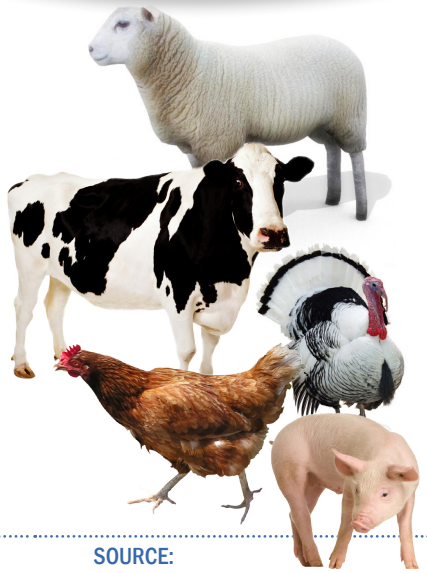
A number of animal feed ingredients are the coproducts of production systems designed to yield something else. Originally, these feed ingredients were the results of regional commodity processing. Examples include citrus molasses, cottonseed hulls, peanut skins and dried apple pomace. AFIA and the Association of American Feed Control Officials (AAFCO), partners for over 100 years, worked together to define these ingredients during the feed industry's earliest days, and the partnership continues to this day.

AN INDUSTRY BUILT ON GIVING BACK

During 2013 the U.S. feed industry donated $3 million toward local communities and volunteered 46,500 man-hours toward various causes. According to survey results, AFIA members most-frequently invest in community development activities or charitable giving towards education (schools, scholarships and research grants), FFH/4H, health-related organizations, local fire/police branches and environmental clean-up projects. Donations and volunteer hours toward hunger and disaster relief organizations/efforts also ranked highly.

TOTAL NUMBER OF FEED MILLS IN THE U.S.: 6,718

SOURCE: Jan. 15, 2014 FDA List: 1,012 facilities producing medicated feed and 491 pet food facilities



TOTAL NUMBER OF HEAD:

	2012	SOURCE:
Broilers	8.515 billion head	*National Chicken Council: March 2014*
Layers	351 million head	*USDA-NASS, as of Feb. 2014*
Market Hogs	60.2 million head	*USDA-NASS, as of March 2014*
Breeding Hogs	5.76 million head	*USDA-NASS, as of March 2014*
Dairy Cattle - Cows that calved	9.2 million head	*USDA-NASS, as of Jan. 2014*
Beef Cattle - Cows that calved	29.0 million head	*USDA-NASS, as of Jan. 2014*
Cattle on Feed	10.8 million head	*USDA-NASS, as of Feb. 2014*
Sheep & Lambs	5.21 million head	*USDA-NASS, as of March 2014*
Turkeys	242 million head	*USDA-NASS, as of Sept. 2013*

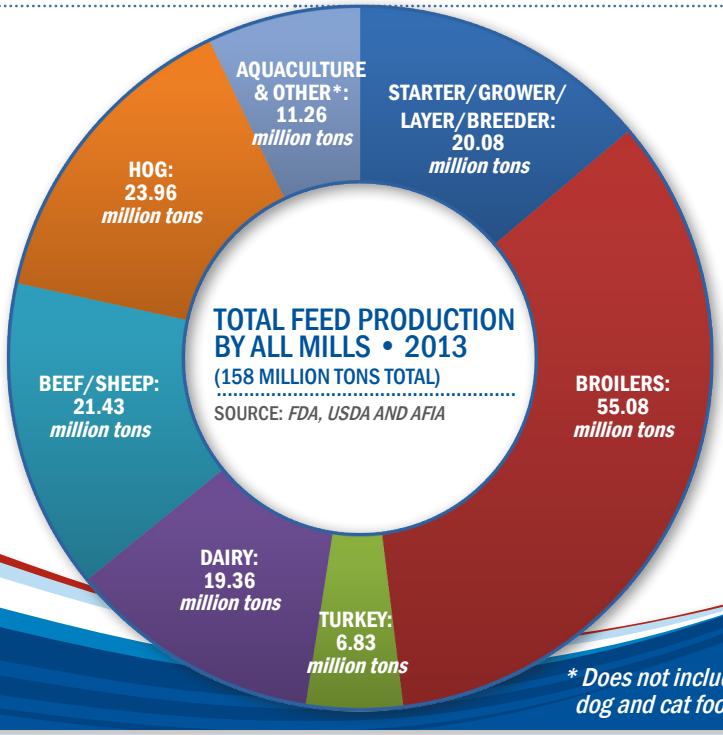
RAW MATERIALS USED IN FEEDS:

	2013	SOURCE:
Corn	4,335 million bushels	*USDA/WASDE Report, March 2014*
Wheat	388 million bushels	*USDA/WASDE Report, March 2014*
Barley	59 million bushels	*USDA/WASDE Report, March 2014*
Oats	98 million bushels	*USDA/WASDE Report, March 2014*
Soybean Meal (Domestic Use)	29,031 thousand short tons	*USDA/WASDE Report, March 2014*
Sorghum/Milo	93 million bushels	*USDA/WASDE Report, March 2014*
DDGS	35.5 million metric tons	*RFA, 2014 Annual Report*
Total Forage Production	281,810 thousand tons	*2013 Summary Report, USDA-NASS*
Alfalfa Production	57,581 thousand tons	*2013 Summary Report, USDA-NASS*
Corn Silage Production	117,851 thousand tons	*2013 Summary Report, USDA-NASS*
Other Hay Production	78,365 thousand tons	*2013 Summary Report, USDA-NASS*

LIQUID FEED TONNAGE SURVEY SUMMARY

SOURCE: AFIA Annual Tonnage Survey, 2013

	2011	2012
Beef Feedlot	602,549	594,236
Dairy Rations	698,683	830,223
Range Supplementation	335,357	315,419
Feed Mill Blends	380,678	361,571
Poured Blocks	245,045	234,387
Total Tons Manufactured	2,262,312	2,335,836



** Does not include dog and cat food.*