March 31, 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 co-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. Today, every state except Alaska has a feed law based on the Association of American Feed Control Officials' (AAFCO) Model State Feed Bill. AFIA and its predecessor organizations have developed a number of animal food safety programs, the latest of which is AFIA's Safe Feed/Safe Food Certification Program, which is described in more detail below.

Several state feed regulators met at AFMA/AFIA's founding meeting in May 1909 and followed up with a meeting in September 1909 in which AAFCO was formed. AFIA and AAFCO have an unbroken line of meetings for 105 years. These have resulted in many mutual programs and successes such as the AAFCO ingredient definitions, the model feed and pet food law and rules, the model good manufacturing practice regulations, and checklist and options for feed registration and facility licensing in the AAFCO Model Feed Bill.

Nearly all AFIA members that manufacture, process, pack or hold animal food are registered with 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 development and passage of FSMA, supports and provides comments to FDA regarding FSMA, and belongs to the Food Safety Preventive Controls Alliance's Feed Steering Committee. This committee is reviewing the human food training outline and is adjusting it for animal food. AFIA will provide future training workshops based on the FDA-endorsed training outline 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, and guides for products derived from plants and animals.

AFIA is committed to a continuing dialogue with FDA on FSMA rules and implementation. We are also strongly committed to a 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 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.

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 food and other similar specialty pet food.

Some 60 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 co-products protects the environment and saves millions of dollars per year.

In 2013, the U.S. feed industry exported more than $9 billion worth of feed and ingredients—most of which was ingredients. Most of the complete feed trade is 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 results in 6,000 to 7,000 more U.S. jobs.

In 2004, AFIA created its hallmark Safe Feed/Safe Food Certification Program (SF/SF). Since that time, over 600 facilities have been certified, and the program has grown from one basic program to several under the SF/SF umbrella. More information on these programs is available at www.safefeedsafefood.org.

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 auditors and educates facilities about the program.

In 2012, AFIA created two new programs for the pet food industry. These are the Pet Food Manufacturing Facility Certification Program (PFMFCP) and the Pet Food Ingredient Facility Certification Program (PFIFCP). Both of these new programs and all the SF/SF programs are designed as hazard identification and preventive control programs based on a facility's animal food safety plan. Both pet food programs are different from the basic SF/SF feed programs in that it contains microbial control requirements that do not appear in the SF/SF feed programs.

In 2013, AFIA signed an agreement with the Safe Quality Food Institute (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.

General Comments and Suggestions

The Animal Food Rule Needs Delineation from the Human Food Rule

AFIA believes the proposed animal food Current Good Manufacturing Practices (CGMP) and hazard analysis preventive controls are well-organized. However, AFIA is concerned that FDA has failed to clearly delineate the human food rules from the animal food rules as Congress intended. Both the intent and sometimes the language used in the statute require a separation of the rules. FDA has created separate rules physically, but they are both philosophically driven by a human food approach, using language such as "sanitary" and "hand-washing" and "utensils." These terms are not common in the vernacular of the feed industry.

FDA Should Remove CGMPs that Imply Disease Transmission from Employee Illness Via Animal Food to Animals

AFIA is concerned about the reference in § 507.14 regarding employees' illnesses being transmitted to animals via handling of the animal food by such employees. AFIA is not aware of any valid scientific literature that would support such an assumption, and FDA does not reference any in the *Federal Register* notice of these proposed rules. AFIA commissioned Dr. Tim Goldsmith, Center for Animal Health and Food Safety, University of Minnesota, to review the scientific literature and provide his professional opinion. His report is in Appendix B of these comments. He determined that the scientific literature has not documented such transmission, and it is unlikely.

AFIA believes this is another example of FDA's attempts to force human food regulations on the animal food industry without adequate scientific justification. AFIA urges removal of such requirements.

HACCP References Should be Removed

Having reviewed the comments submitted by the Grocery Manufacturers Association (GMA) for the human food preventive control proposed rule, AFIA finds that many of their issues and concerns are appropriate for our comments as well, and we provide them below with GMA's permission. Of particular concern is FDA's focus on "reasonably likely to occur" language, whereas the statute uses the term "known or reasonably foreseeable hazard."

We agree with GMA's statements regarding this issue. In particular, the agency's proposed approach would require all preventive controls be subject to management elements usually reserved for critical control points (CCPs) in HACCP systems, unless FDA has noted a specific exemption. This is because the proposed rule focuses on hazards "reasonably likely to occur," which are generally interpreted to require CCPs in HACCP programs. AFIA is concerned about this approach, because CCPs are only one component of an effective animal food safety system.

The term "preventive controls," as defined under FSMA, is much broader than CCPs under HACCP programs. Food safety plans under FSMA must focus more broadly on food safety systems, including a foundation of "prerequisite" programs, like CGMPs. As GMA suggested and AFIA agrees, FDA should propose that "preventive controls" include the spectrum of controls that food safety experts consider necessary to achieve the FSMA food safety goals, consistent with the statute. Thus, we propose changing "hazards reasonably like to occur" to "known or reasonably foreseeable hazards," removing the perception that a CCP is required.

One of the basic principles FDA has espoused in this proposed rule is found in § 507.33 - Hazard Analysis. AFIA believes this section does not express the intent of FSMA and focuses on a more HACCP-type approach. FSMA does not take that specific approach; although it adopts similar principles, it does not mention HACCP. AFIA has no concerns with HACCP as an animal food safety approach, just as we have no concern with statistical process control, or the myriad approaches to food/feed safety promoted and utilized by firms in the marketplace. In fact, AFIA sponsors HACCP trainings two or more times each year at our members' request.

However, AFIA does oppose FDA requiring specific programs and approaches where the statute did not identify a specific process. Therefore, AFIA recommends the same rewrite for the animal food proposed rule that was proposed by GMA for the human food proposed rule:

> (a) The owner, operator, or agent in charge of a facility is responsible to ensure that ~~must identify and evaluate~~ known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility are identified and evaluated by a qualified individual to determine, based on their probability and severity, ~~whether there are hazards that are reasonably likely to occur~~ the hazards that are of such a nature that control measures to significantly minimize or prevent them are necessary for the production of a safe animal food and therefore must be addressed in the animal food safety plan.

AFIA believes this language is more consistent with the intent and approach provided in the statute. This will appear in our specific comments below and we urge adoption of this language in the final rule.

FDA Investigators Need Specified Training and Requirements

As noted above, the animal food industry is very diverse and produces a broad range of products. AFIA has serious concerns that FDA's investigators will encounter difficulty in performing the same type of inspection in a feed mill as a pet food manufacturing plant or an ingredient manufacturing facility. Our members' experience with audits of medicated feed facilities has demonstrated that FDA investigators oftentimes do not fully comprehend the feed industry or feed manufacturing processes. This leads to inaccurate assessments and assumptions by the investigators and an inefficient use of companies' resources devoted to addressing unrealistic or false concerns by the investigator.

The agency needs to develop and implement strong training programs for its field staff that clearly distinguishes between the different types of facilities, and provides clear guidance regarding which parts of these rules are applicable to a particular type of plant. Otherwise,

regulatory and industry resources will be wasted in facility managers' attempts to explain to each investigator the differences between the types of animal food facilities, and what portions of the rule apply to the particular type of facility based upon the product produced and the facility's animal food safety program.

As national policy, FDA should establish requirements for training investigators on the new FSMA requirements. With the implementation of the new FSMA rules, it is imperative that investigators are trained and qualified to perform inspections in all types of animal food facilities which they are assigned to inspect or audit.

Thus, AFIA recommends that inspections are conducted by "qualified investigators." AFIA is suggesting a new definition in Section I for a qualified investigator. The suggested definition states a "*qualified investigator* means a FDA investigator that has successfully completed a formal training course on aseptic sampling inspections, CGMPs and preventive controls for animal food facilities, both animal feed and pet food and has demonstrated an understanding of the differences between pet food and animal feed manufacturing facilities. It also means that this investigator has successfully participated in two complete inspections with supervisory or trained investigators in the facilities that s/he will be responsible for inspecting. Qualified investigators must also have successfully completed formal training in aseptic technique for sterile sampling to minimize risk of sample adulteration for *Salmonella* and other microbial testing."

Quality References Should be Removed

One term that appears throughout the proposed rule is the word "quality." While AFIA members view animal food safety as a part of a quality program, a quality program is not wholly an animal food safety program. Many feed and pet food firms have very large quality programs, of which the animal food safety section is a small subset.

Many firms consider their quality programs as proprietary programs developed over years of research and which provide the basis for producing quality products. For that reason, firms generally will allow no outside organization access to those programs for potential competitive and marketing reasons. AFIA informs its members that they should protect these programs by creating a detailed and specific animal food safety program subject to government review (i.e., the animal food safety plan) and never provide any inspector access to the complete quality manual to which they may not be entitled.

Therefore, AFIA urges the agency to remove references to "quality" in the final rules, for instance, in § 507.3 – Definitions, as it is not relevant to FSMA. *Quality control operation* (78 Fed. Reg. at 64824) should be deleted.

Consistency Between FSMA Rules is Necessary

Another concern that has arisen among AFIA's members is the differences between these rules and the foreign supplier verification program (FSVP) rules. AFIA strongly believes both rules need to be identical, as well as have an inspection approach that is identical. This is important as it is necessary (1) for the U.S. to maintain an identical system for foreign and domestic facilities and (2) to create a seamless system that meets the nation's international treaty obligations.

Moreover, inconsistency makes it difficult for domestic facilities to review operations of foreign suppliers when a different system is used to evaluate/audit/inspect these facilities.

Subjective Language will be Difficult to Implement Across the Animal Food Industry

An additional major concern is the subjective language utilized in the proposed rules that could apply equally for pet food, ingredients and animal feed. AFIA believes that was not FDA's specific intent, but public comments by agency officials indicated there would not be separate rules for pet food, ingredients or animal feed, in spite of different approaches to animal food safety by FDA.

In public statements by agency officials, the human food rule has been characterized as "microbial control rule," while the animal food rule (except for pet food) has been characterized as a chemical control rule. AFIA believes this is true, especially for *Salmonella* control. Pet food manufacturing facilities operate under a *Salmonella* reduction and control system, whereas animal feed plants believe *Salmonella* is not a reasonably foreseeable hazard based on previous surveys—at least for the eight serotypes FDA has identified in its compliance policy guide, "690.800 *Salmonella* in Food for Animals." AFIA will embark on a national survey of feed and ingredients in the near future to further document this belief. It is our intent, with other organizations, to sample feed and ingredients throughout the U.S.; assay for *Salmonella*; if positive, serotype; and submit the survey findings for publication in a peer-reviewed scientific journal.

This separation is important from both a compliance standpoint and an inspector training and understanding standpoint. FDA should clearly advise its investigators when inspecting a feed mill or feed ingredient operation that a *Salmonella* reduction and control standard should not apply to animal feed plants unless that firm has identified *Salmonella* as a known or reasonably foreseeable hazard.

The issue subjective language in these proposed rules is clearly evident in § 507.20 - Sanitary Facilities and Controls, where the proposed rules speak of water that "…must be safe and of adequate sanitary quality" (78 Fed. Reg. at 64827). This phrase can have varying interpretations in a feed plant versus a pet food manufacturing facility. AFIA is concerned how FDA or state inspectors will know how to apply such a phrase to plants with vastly differing control processes. For instance, animal feed mills do not need potable water for processing feed if they are not making pet food and microbial hazards have not been identified in the facility's animal food safety plan. Requiring potable water in remote areas of the U.S. may impose a significant cost for operations with no identifiable benefits for animal feed manufacturing. Animal feed manufacturing facilities in these areas may not list water as carrying potential hazards in the facility's animal food safety plan.

Compliance Dates Should Phase-in CGMPs First and then Preventive Controls

According to FDA's economic analysis of the feed industry, approximately 47 percent of the facilities manufacture roughly 80 percent of the finished, ready-to-eat feed and pet food, measured by dollar value. However, this means there are many, perhaps the majority of facilities in the U.S, small to medium-sized mills that make less feed and are less sophisticated in their operations. AFIA believes these mills will have the greatest difficulty and require more time in

implementing these new FSMA animal food rules. For that reason, AFIA believes that FDA's proposal for delayed compliance dates based on size (one year for regular mills, two years for small businesses (SBs) and three years for very small businesses (VSBs)) for both the CGMP rule *and* preventive control rule is impractical.

AFIA believes many of the small to medium-sized feed mills and even ingredient operations should be allowed more time to implement the CGMPs first and even more time to implement the hazard analysis and preventive controls. We strongly urge FDA to adopt a one, two and three-year time frame, respectively for CGMPs and two, three and four-year, respectively for the preventive controls. This will ensure that firms are familiar with these basic animal food safety programs (i.e., the CGMPs) before they implement the more complicated requirements of the hazard analysis and preventive control rule.

After the final rules are published and efforts are made in earnest to comply, AFIA will have a better grasp at how small to medium-sized firms are adjusting. If more time is needed to comply, AFIA will petition the agency with adequate justification to request more time.

The multi-year compliance approach may be dismissed by some groups which have indicated to AFIA that such a diversity of dates for various facilities, especially of ingredient facilities, will make feed and pet food manufacturing facilities' operation of animal food safety plans difficult. For instance, if a feed mill has only one year to comply with the rules but buys from one or more ingredient facilities that have two or more years, it becomes difficult to ensure compliance with the feed mill's animal food safety plan. This is because components of supplier verification control are dependent on facilities that do not need to be in compliance for another year or more. However, a phased approach as proposed by FDA, along with AFIA's suggested modifications is more consistent with the underlying statute's intent of phased-in compliance for small and very small business. We urge FDA to provide the additional time necessary for CGMPs and preventive controls as indicted above by allowing a one, two, three year approach for CGMPs and a two, three, four year approach for the preventive controls.

<u>The Estimated Cost for this Rule Far Outweighs the Benefits</u>

AFIA appreciates the attempt FDA made to estimate the costs and benefits of this rule in the Preliminary Regulatory Impact Analysis (PRIA). However, we believe the PRIA greatly underestimates the cost to the regulated industry. AFIA supports the filing to this docket of an economic analysis performed by George Mason University's Mercatus Center. This analysis stated the benefit of these rules was $30 million—several factors shy of the $87-$129 million in costs to the animal food industry that FDA estimated. It is clear FDA failed to reduce the estimated costs of this rule to more reasonably approximate the potential benefits. FDA should more carefully assess the costs of implementing the proposed changes and any new additional requirements that could be proposed in the future.

<u>FDA Should Renumber the Rule to Parallel the Human Food Rule</u>

One modification that would assist with comparing the human food rule and animal food rule is consistent numbering between the two. AFIA notes that the numbering systems for many of the human food rules in Title 21, C.F.R are located in the 100s whereas the animal food rules are located in the 500s section. These rules are generally parallel numbered. For example, the

Generally Recognized as Safe (GRAS) section is located in section 182 for human food and section 582 for animal food. Moreover, the food additives are in sections 173 and 573, respectively. AFIA suggests renumbering the animal food rules to correspond directly with applicable human food rules in the proposed 114 section.

Comment Overview

AFIA has written our comments to follow the flow of the proposed rule. In each of those sections we provide general comments and, where applicable, we note the specific proposed provision, AFIA's recommendation and then the rationale for the change. For the purposes of editing, new language is underlined and deleted language is stricken through.

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Section I: Subpart A—General Provisions

§507.3 DEFINITIONS.

AFIA has reviewed the proposed definitions and provides in detail below where we agree with the definition, where we offer suggestions for improvement of the definition or where AFIA is proposing a new definition for consideration.

Proposed Definition

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

AFIA Comments

AFIA agrees with this definition.

Proposed Definition

Affiliate means any facility that controls, is controlled by, or is under common control with another facility.

AFIA Comments

AFIA agrees with this definition.

Proposed Definition

Animal food means food for animals other than man and includes pet food, animal feed, and raw materials and ingredients.

AFIA Comments

AFIA is concerned with the addition of "raw materials" for a number of reasons. Currently, the AAFCO Model Regulations exempt raw materials (such as meat scraps or the initial mined material) from regulation as they are not suitable for feed without further processing. If FDA expects the firms producing raw materials for animal food to register and create animal food safety plans, we believe many of these firms will merely dispose of the products in landfills due to the high cost of developing and maintaining such animal food safety plans. We also believe FDA did not factor this significant loss into its economic analysis, which is likely to significantly raise the cost of feed in the U.S. AFIA estimates that 50 million tons of food co-products, not including industrial ethanol co-products, are utilized in the animal food industry each year. We do not have a good estimate on how many of these tons are from sources deemed "raw materials" and hence, ones that might disappear from animal food production. We believe it would be substantial.

The term raw materials may also be interpreted to cover the ingredients used to safely manufacture feed ingredients (such as amino acids, vitamins, minerals, technical additives, enzymes and additives) that assure the safety and usefulness of agricultural based products. These same raw materials are used in the manufacturing of many non-food products, for example

drugs, plastics, solutions and building materials. It is costly and ill-conceived to require raw materials to be covered under these regulations. Manufacturers of feed ingredients use raw materials that meet internal specifications to assure that the final ingredients are safe. Requiring feed ingredient manufactures to only use raw materials that are intended for food or animal food use (for example, manufactured under food or animal food CGMPs) may require changes in manufacturing processes or abandonment of certain ingredients that will not have a source of raw materials necessary for their manufacture, and will certainly add significant cost to production.

FDA should seriously consider exempting many of the low risk raw material industries, as the processing of these materials into feed ingredients will remove many, if not all of the hazard associated with the raw materials.

Proposed Definition

> *Batter* means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

AFIA Comments

AFIA agrees with this definition.

Proposed Definition

> *Blanching*, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

AFIA Comments

AFIA agrees with this definition.

Proposed Definition

> *Calendar day* means every day shown on the calendar.

AFIA Comments

AFIA agrees with this definition.

Proposed Definition with AFIA recommendations

> *Critical control point* means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate an animal food safety hazard or reduce such hazard to an acceptable level.

AFIA Comments
Although FSMA mentions this phrase in several places, AFIA is opposed to its use in the preventive control rules, as it is very confusing and not understood by this industry in the context of FSMA and the required preventive controls. This term is a HACCP term and is not appropriate for use in these rules where the scope is defined differently by the statute.

Proposed Definition with AFIA recommendations

> *Environmental Pathogen* means a microorganism that is of animal or human public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment where it may result in product adulteration with the potential for serious adverse health consequences or death if the product is consumed.

AFIA Comments
It is important to make the change to the definition as noted above to clarify that a foodborne pathogen is only an environmental pathogen when it exists in the animal food processing environment where product adulteration could potentially occur and only at levels that may cause serious adverse health consequences or death if the product is consumed. AFIA also recommends that environmental pathogens in animal food be limited to *Salmonella* that has the potential to cause illness via animal food contaminated from the production environment, because controlling *Salmonella* will control other pathogens.

Proposed Definition

> *Facility* means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR part 1, subpart H.

AFIA Comments
AFIA agrees with this definition.

Proposed Definition

> *Farm* means farm as defined in Sec. 1.227(b) of this chapter.

AFIA Comments
AFIA agrees with this definition.

Proposed Definition

> *FDA* means the Food and Drug Administration.

AFIA Comments
AFIA agrees with this definition.

Proposed Definition

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

AFIA Comments

AFIA is concerned with the addition of "raw materials" for a number of reasons. Currently, the AAFCO Model Regulations exempt from regulation raw materials (such as meat scraps or the initial mined material) as they are not suitable for feed without further processing. If FDA expects the firms producing raw materials for animal food to register and create animal food safety plans, we believe many of these firms will merely dispose of the products in landfills due to the high cost of developing and maintaining such safety plans. We also believe FDA did not factor this significant loss into its economic analysis, which is likely to significantly raise the cost of feed in the U.S. AFIA estimates that 50 million tons of food co-products, not including industrial ethanol co-products, are utilized in the animal food industry each year. We do not have a good estimate on how many of these tons are from sources deemed "raw materials" and hence, ones that might disappear from animal food. We believe it would be substantial.

The term raw materials may also be interpreted to cover the ingredients used to safely manufacture feed ingredients (such as amino acids, vitamins, minerals, technical additives, enzymes and additives) that assure the safety and usefulness of agricultural based products. These same raw materials are used in the manufacturing of many non-food products, for example drugs, plastics, solutions and building materials. It is costly and ill-conceived to require raw materials to be covered under these regulations. Manufacturers of feed ingredients use raw materials that meet internal specifications to assure that the final ingredients are safe. Requiring feed ingredient manufactures to only use raw materials that are intended for food or animal food use (for example, manufactured under food or animal food CGMPs) may require changes in manufacturing processes or abandonment of certain ingredients that will not have a source of raw materials necessary for their manufacture, and will certainly add significant cost to production.

FDA should seriously consider exempting many of the low risk raw material industries, as the processing of these materials into feed ingredients will remove many, if not all of the hazard associated with the raw materials.

Proposed Definition with AFIA recommendations

Food-contact surfaces are those surfaces that contact animal food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" include food-contact surfaces of ~~utensils~~ tools and equipment.

AFIA Comments

AFIA believes the rules should use the vernacular of the animal food industry to maximize understanding and compliance. We suggest replacing the term "utensils," more of a food industry term, with "tools."

Proposed Definition

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by 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 the farm on which they were grown or raised, or another farm under the same ownership. 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). Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting.

AFIA Comments

AFIA agrees with this definition.

Proposed Definition with AFIA recommendations

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

AFIA Comments

In the comments below regarding §507.33 (b)(2) &(4), AFIA recommends including radiological hazards as a subcategory of chemical hazards, as that is how they are scientifically categorized. Additionally, there is no evidence that the risk warrants its own specific category in the U.S. It is redundant and unnecessary.

Proposed Definition with AFIA recommendations

~~*Hazard reasonably likely to occur* means a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls.~~

AFIA Comments

As noted in other sections, the language of "hazard reasonably likely to occur" is common in HACCP systems and most often associated with CCPs. The statute specifically avoided HACCP and related terminology to allow a broader definition of preventive controls and permit appropriate actions to minimize animal food safety risk based on the severity and probability of a hazard within a specific facility and process. AFIA recommends applying the statutory framework by using language in the statute regarding hazards "known or reasonably foreseeable" as the basis for hazard analysis. This should include an evaluation of probability and severity of a hazard occurring to determine how hazards are controlled within the animal food safety system.

AFIA requests removal of all references to "hazards reasonably likely to occur" in the final rule and there is no need for a definition if the phrase does not appear in the stature or rule.

Proposed Definition with AFIA recommendations

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For facilities, holding also includes activities performed for the safe or effective storage of raw agricultural commodities other than fruits and vegetables intended for further distribution or processing, 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. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, 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

As drafted by the agency, the definition does not recognize activities such as drying, screening, conditioning, fumigating and blending which are done by facilities, such as grain elevators, for the safe or effective storage of raw agricultural commodities other than fruits and vegetables. These activities are routinely performed by grain elevators to effectively and safely store grain commodities. Therefore AFIA has recommended the additional language to the definition to clarify that these types of processes should be allowed under the definition of *holding*.

Proposed Definition

Lot means the food produced during a period of time indicated by a specific code.

AFIA Comments

AFIA agrees with this definition.

Proposed Definition with AFIA recommendations

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding. For holding facilities, manufacturing/processing does not include activities performed for the safe or effective holding or storage of raw agricultural commodities.

AFIA Comments
AFIA recommends the addition of the sentence above referring to how this definition applies to "holding" facilities. This addition would mirror the language already in the definition related to "farm and farm-mixed type" facilities.

Proposed Definition

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having animal or human health significance. The term "undesirable microorganisms" includes those microorganisms that are of animal or human health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

AFIA Comments
AFIA agrees with this definition.

Proposed Definition

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

AFIA Comments
AFIA agrees with this definition.

Proposed Definition

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

AFIA Comments
AFIA agrees with this definition.

AFIA Proposed New Definitions

Nutrient Deficiency means the absence or insufficient amount of an essential nutrient at such a level and being consumed over a time frame that is scientifically documented that would result in a serious adverse health effect or death.

Nutrient Toxicity means the over-abundance or excess of a nutrient at such a level and being consumed over a time frame that is scientifically documented that would result in a serious adverse health effect or death.

AFIA Comments
FDA's inclusion of nutrient imbalances in the definition of chemical hazards was surprising, because nutrient imbalances are broad and may encompass nutritional design rather than animal safety. The agency references nutrient imbalances within the codified language, yet no definition is provided. While an imbalance of nutrients is less than ideal for an animal, it may not create an animal food safety risk. Typically, animal safety is related to established nutrient deficiencies and toxicities. Therefore, AFIA suggests these two definitions and recommends removal of references to nutrient imbalances from the final rule. The final rule should include nutrient deficiencies and nutrient toxicities in §507.33(b)(2).

Proposed Definition

> *Packaging* (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

AFIA Comments
AFIA agrees with this definition.

Proposed Definition

> *Packing* means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, 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.

Proposed Definition

> *Pest* refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

AFIA Comments
AFIA agrees with this definition.

Proposed Definition

> *Plant* means the building or establishment, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food.

AFIA Comments
AFIA agrees with this definition.

Proposed Definition

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

AFIA Comments

AFIA agrees with this definition.

Proposed Definition

Qualified end-user, with respect to an animal food, means the consumer of the food (where the term does not include a business); or a restaurant or retail food establishment (as those terms are defined in Sec. 1.227(b) of this chapter) that:

(1) Is located:

(i) In the same State as the qualified facility that sold the food to such restaurant or retail food establishment; or

(ii) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

AFIA Comments

AFIA agrees with this definition.

Proposed Definition

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the animal food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the animal food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all animal food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

AFIA Comments

AFIA agrees with this definition.

Proposed Definition with AFIA recommendations

Qualified individual(s) or *qualified animal food safety team* means a person or persons who ~~has~~ have successfully completed education and/or 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 is otherwise qualified through job experience to develop and apply an animal food safety system.

AFIA Comments

We concur that the animal food safety plan must be prepared by individuals with appropriate training, education and/or experience. However, in practice this is typically achieved with an animal food safety team consisting of experts in different areas. We therefore suggest adding "or qualified animal food safety team" to the definition. Additionally, we request that formal education be recognized as a qualification in addition to the training option.

AFIA Proposed New Definition

Qualified investigator means a FDA or state commissioned investigator that has successfully completed a formal training course on inspections; CGMPs; hazard analysis and preventive controls for animal food facilities, both animal feed and pet food, and has demonstrated an understanding of the differences between pet food and animal feed manufacturing facilities. It also means that this investigator has successfully participated in two complete inspections with supervisory or trained investigators in the facilities which s/he will be responsible for inspecting. Qualified investigators must also have successfully completed formal training in aseptic technique for sterile sampling to minimize risk of sample adulteration for *Salmonella* and other microbial testing.

AFIA Comments

As national policy, FDA should establish training requirements for investigators on the new FSMA requirements before conducting inspections. The animal food industry is very diverse in terms of facility, equipment and product types. AFIA is seriously concerned that FDA's investigators will encounter difficulty in performing the same type of inspection in a feed mill, a pet food manufacturing plant or an ingredient manufacturing facility. Our members' experience with audits of medicated feed facilities has demonstrated that FDA investigators oftentimes do not fully understand the feed industry or feed manufacturing processes and apply many human food rules to their inspections. This leads to inaccurate assessments by the investigators and an inefficient use of companies' resources devoted to addressing unrealistic or false concerns raised by FDA investigators.

On numerous occasions, knowledgeable animal food industry personnel have observed investigators taking samples for microbial testing without sterile gloves and sterile sample packaging, or contaminating samples with their hands and sample probes during the sampling process. Most animal food industry personnel will also benefit from formalized training in sterile sampling technique. AFIA is preparing training in this area for our members.

With the implementation of the new FSMA rules, it is imperative that investigators are qualified. Thus, AFIA recommends that inspections under this rule be completed by qualified investigators as defined above.

Proposed Definition with AFIA recommendations

~~*Quality control operation* means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.~~

AFIA Comments

"Quality control operation" is a very broad term used within the animal food industry that applies to various processes and procedures throughout the manufacturing system and may not be specific to animal food safety. Thus, AFIA believes FDA should maintain the focus on animal food safety. Accordingly, we recommend the removal of the references to quality control, including the definition of a "quality control operation." Our member's facilities will continue to have quality systems and controls, but these should not be part of the requirements or definitions FDA is proposing.

Proposed Definition with AFIA recommendations

Reasonably foreseeable hazard means a ~~potential~~ probable biological, chemical, or physical~~, or radiological~~ hazard that may be associated with the facility, or the food.

AFIA Comments

AFIA recommends that FDA replace "potential" with "probable," as the definition of probable as stated in the *Merriam-Webster Dictionary* is "supported by evidence strong enough to establish presumption but not proof" and is more consistent with "foreseeable." "Potential" is much broader and could be anything that is possible, even if unlikely. Also, per our comments in §507.33 (b)(2) & (4), we are making the same suggested edit regarding "radiological" in this definition.

AFIA Proposed New Definition

Receiving firm means, for an article of animal food, a facility or corporate parent of 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 believes it is important to draw a distinction between the firm that owns the receiving facility and the facility receiving an ingredient or raw material. A firm may have multiple sites or facilities with different type of manufacturing capabilities.

AFIA Proposed New Definition

Receiving facility means, for an article of animal food, an individual location or 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 believes it is important to draw a distinction between the facility receiving an ingredient or raw material from the company. A company may have multiple sites or facilities with different type of manufacturing capabilities.

Proposed Definition with AFIA recommendations

Rework means ~~clean, unadulterated~~ animal food that has been removed from processing for reasons other than ~~insanitary~~ unclean conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as animal food.

AFIA Comments

AFIA recommends replacing "insanitary" with "unclean," as the former term is not utilized in the animal food industry and has little meaning.

AFIA Proposed New Definition

Risk assessment is a scientifically based process consisting of hazard identification, hazard characterization, exposure assessment, and risk characterization.

AFIA Comments

AFIA requests that FDA include a definition for a risk assessment. This is defined within the preamble (78 Fed. Reg. at 64752) and it clearly includes an exposure assessment, which is vital in an effective animal food safety plan. AFIA is recommending the inclusion of risk assessment into §507.33 (c) and this definition clarifies the expectation.

Proposed Definition

Safe moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given aw will not support the growth of undesirable microorganisms.

AFIA Comments

AFIA agrees with this definition.

Proposed Definition

Sanitize means to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of animal or human health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for animals or humans.

AFIA Comments

AFIA is concerned about the use of this term, as it's not commonly used in the animal food industry. We have removed all instances of its use in this proposal and replaced it with clean.

Proposed Definition

Should is used to state recommended or advisory procedures or identify recommended equipment. Should denotes non-binding guidance.

AFIA Comments

AFIA agrees with this definition.

Proposed Definition

Significantly minimize means to reduce to an acceptable level, including to eliminate.

AFIA Comments

AFIA agrees with this definition.

Proposed Definition with AFIA recommendations

Small business means, for purposes of this part, a business employing fewer than 500 persons <u>involved in the animal food portion of a firm, including all facilities</u>.

AFIA Comments

It is unclear in the proposed definition for this category if FDA intends the "…fewer than 500 persons" to mean those involved in the entire business or those only involved in the animal food-related portions of the business. The preamble to the proposed rules states that it means "…a business employing fewer than 500 persons." The term "business" is unclear. Does it mean a corporation and all its subsidiaries or only the portion of the business related to animal food, be it animal feed, pet food and/or ingredients? AFIA believes this needs clarification and suggests the threshold means companies with 500 persons employed in the animal food portion of the firm only. This would be consistent with the definition for *very small business*, where FDA proposes a dollar threshold limited to a firm's animal food product sales.

Proposed Definition

Subsidiary means any company that is owned or controlled directly or indirectly by another company.

AFIA Comments
AFIA agrees with this definition.

AFIA Proposed New Definition

Supplier means, for an article of animal food, the establishment that manufactures/processes the animal food, raises the animal or harvests the animal food that is provided to a receiving firm 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 believes it is important that FDA define "supplier" as it prepares requirements for a supplier verification program. This will assist in avoiding confusion or misunderstandings of the scope of a supplier verification program.

Proposed Definition with AFIA recommendations

Validation means ~~that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards~~ obtaining evidence that a control measure or combination of control measures, when properly implemented, is capable of effectively controlling the hazard to a level necessary for product safety.

AFIA Comments
AFIA believes FDA has confused the two definitions of validation and verification in the proposed rule. The proposed edits here more appropriately define validation to contain the meaning that is intended in FSMA.

Proposed Definition with AFIA recommendations

Verification means ~~those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to plan.~~ the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.

AFIA Comments
AFIA believes FDA has confused the two definitions of validation and verification in the proposed rule. The proposed edits here more appropriately define verification to contain the meaning that is intended in the statute.

AFIA Proposed New Option for Very Small Business
Option 4: *Very small business* means, for purposes of this part, a business that has less than $10,000 in total annual sales of animal food, adjusted for inflation.

AFIA Comments
AFIA believes no facility should be exempt from these rules because of size alone. Animal food safety is every firm's responsibility. The extension of the compliance period to three years for CGMPs and four years for PCs, as proposed by AFIA, should provide sufficient time for facilities to comply with these rules.

Moreover, if FDA adopts the highest level (option 3), some ingredient manufacturers may be exempt from developing animal food safety plans. Because of the requirements for feed and pet food manufacturers in the rule, those suppliers without animal food safety plans would eventually disappear from the marketplace. However, if FDA is determined to use a threshold level, AFIA recommends $10,000 in annual sales, so that all facilities would be required to comply with these rules.

Proposed Definition

> *Water activity (a_w)* means a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

AFIA Comments
AFIA agrees with this definition.

Section II: Subpart B—Current Good Manufacturing Practices

CURRENT GOOD MANUFACTURING PRACTICES

AFIA supports FDA establishing CGMPs for the animal food industry. Currently, only medicated feed facilities operate under federal CGMPs in 21 CFR, Part 225. According to FDA, as of January 2014, there were 1,012 licensed medicated feed mills in the U.S. out of 18,627 domestically registered animal food facilities as of February 19, according to FDA's facility registration website. While some non-medicated animal food facilities participate in industry certification programs such as Safe Feed/Safe Food Certification Program or the Pet Food Manufacturing Facility Certification Program, the majority remains unfamiliar with CGMPs and will need adequate time to adopt those proposed in their facilities. AFIA notes that the human food industry had several decades in which human food CGMPs were provided in a "Guidance for Industry" document by the agency. This allowed for consistent implementation and enforcement across the human food sector before human food CGMPs were moved into regulation. Animal food will not be afforded that "grace" period; therefore, our comments strive to make these CGMPs as easily understood as possible for the varied products and size of facilities in our industry.

Below, AFIA provides overarching comments regarding the proposed CGMPs. We then follow with specific recommendations and edits for consideration by the agency.

Other CGMP Sources are More Appropriate as the Starting Point than the Human Food CGMPs
AFIA strongly believes that the human food CGMPs do not provide an appropriate starting point for animal food CGMPs. There are several resources that are more suitable. For example, the "Codex Animal Production and Health Manual of Good Practices" and the "Prerequisite Programmes for Food Safety in the Manufacturing of Food and Feed for Animals" (PAS 222), both international standards, are better suited as a starting point for animal food CGMPs.

There are also two domestic standards. In fact, both were developed with the benefit of FDA's technical expertise. The medicated feed CGMPs (21 CFR, Part 225) were made final rules by FDA in 1976. The "Model Good Manufacturing Practice Regulations" published by AAFCO also benefited from FDA as well as state regulators' expertise. Although AAFCO's model good manufacturing practices were not published until 2010, development actually began in 1999. During this time, part of AAFCO's strategic plan was to "…develop a feed safety program in coordination with FDA's Animal Feed Safety System initiative and existing programs."[1] FDA played an important role in developing AAFCO's model good manufacturing practices; yet FDA chose not to use this as a starting point for the proposed animal food CGMPs. AFIA believes the AAFCO model good manufacturing practices, which were developed in concert with industry and regulators for the U.S. feed industry, would have been more appropriate as a starting point than the human food CGMPs.

Outside of medicated feed mills, implementing CGMPs in the production of animal food has always been voluntary. AFIA believes FDA erred by expecting that all animal food

[1] July 10, 2007 Memo from Eric Nelson to AAFCO membership, printed in the 2008 AAFCO OP

manufacturers follow CGMPs based on human food CGMPS versus the limited animal food manufacturers currently following medicated feed CGMPs. AFIA recognizes the importance of CGMPs in ensuring a safe food supply, and embraces implementation of CGMPs for animal food. It is critical, however, that they are done correctly, which means implementing CGMPs intended for animal food and not human food.

AFIA encourages FDA to utilize CGMPs from AAFCO, the medicated feed rules, or PAS 222, where indicated below, on the specific provisions. However, our comments provide edits in an attempt to make the CGMPs proposed herein appropriate for animal food instead of human food, and the suggestions are based on our more than a century of working with the collective feed industry.

Every Animal Food Facility Does Not Have the Same Hazards; Flexibility is Necessary
It is important to understand there are different risks among animal food manufacturers. While the distinction is not as extreme as the difference between animal food and human food, it is vital to understand when determining risk in animal food production. Risk is handled separately because of these differences.

Instead of different sets of CGMPs for every category of animal food produced, AFIA believes CGMPs should be written to accommodate the diversity among animal food manufacturers. Including phrases such as "as appropriate" or "as necessary" allows the differences in risk among animal food the manufacturers produce to be addressed. This allows for separation between animal food production that may or may not need to comply with a specific CGMP for the purpose of animal food safety. It is also important to note that animal food may have different purposes. AFIA strongly believes that "for intended use" should be included in many CGMPs because it allows the process to be risk-based without any loss in food safety. While some of these additions may seem minor, AFIA believes they are very important for the final rule and for proper implementation by the industry and enforcement by the agency.

AFIA agrees with FDA's decision to propose several non-binding ("should") CGMP provisions instead of required ("must") provisions. This allows qualified individuals to determine risk-appropriate and site-specific controls for potential risks.

When Appropriate, FDA Should Remove "Sanitize," "Contamination," and "Utensils" and Replace with "Clean," "Adulteration" and "Tools"
AFIA has significant concerns regarding the applicability of the proposed CGMPs to the production of food for animals. Most of these concerns center on two areas. First, the prescriptive nature of the proposed CGMPs does not allow for a risk-based assessment and restricts innovative approaches to addressing site-specific animal food safety concerns. Second, many of the proposed CGMPs use the terms "sanitary" and/or "sanitize," which are defined as processes leading to the destruction of microorganisms.

In many instances, requirements to sanitize processing and contact surfaces in animal food production facilities are unrealistic and unnecessary. This places an undue burden on the facilities in the absence of scientific evidence demonstrating the necessity of such practices in preserving animal and/or human health. "Sanitizing" is not always the correct control for a

potential hazard. Additionally, AFIA believes FDA should focus on the "adulteration of animal food," rather than the "contamination of animal food, animal food contact surfaces or animal food packaging materials." "Adulteration" of food is the regulatory standard for action, whereas contamination is currently undefined by FDA. AFIA has provided several revisions to the proposed CGMPs as detailed below.

AFIA suggests the use of "tools" instead of "utensils" to better fit the terminology used in the animal food industry. "Scoops" or "shovels," for example, are either called by these names, or could be referenced as a "tool," but they are not referred to as a "utensil." This example is why the human food CGMPs were not an ideal starting point for the animal food CGMPS. Section 11 of PAS 222 uses the term "tools" while AAFCO uses "equipment." Below, AFIA recommends deleting "utensils" and replacing it with "tools" in the proposed CGMPs.

Specific Comments on the Provisions in Subpart B
AFIA provides the following comments regarding FDA's proposed current good manufacturing requirements.

Proposed Rule with AFIA Recommendations

§ 507.14 Personnel

(a) Plant management must take all reasonable measures and precautions to ensure that, where appropriate:
~~(1) Any person who, by his own acknowledgement, by medical examination, or by supervisory observation, is shown to have, or appears to have any illness, open skin lesion, or other source of abnormal microbial contamination by which there is a reasonable possibility of animal food, animal food-contact surfaces, or animal food-packaging materials becoming contaminated, is excluded from any operations which may be expected to result in such contamination until the condition is resolved;~~
~~(2) Personnel have been instructed to report such health conditions to their supervisors;~~
(~~3~~1) Where appropriate and necessary given the intended use of the animal food, a~~A~~ll persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices while on duty to the extent necessary to protect against ~~contamination~~ adulteration of animal food. The methods for maintaining cleanliness include:
(i) Maintaining adequate personal cleanliness;
(ii) Washing hands thoroughly ~~(and sanitizing if necessary to protect against contamination with undesirable microorganisms)~~ in an adequate hand-washing facility ~~before starting work and~~ at ~~any other~~ time~~s~~ when ~~the hands may have become soiled or contaminated~~ appropriate and necessary to prevent adulteration;
(iii) As necessary, ~~Removing all unsecured~~ remove or secure jewelry and other objects ~~that might fall into animal food, equipment, or containers~~ to minimize the risk of adulteration;
(iv) As necessary, s~~S~~toring clothing or other personal belongings in areas other than where animal food is exposed or where equipment or tools ~~utensils~~ are cleaned ~~washed~~; and

(v) Taking any other necessary precautions to protect against ~~contamination~~ adulteration of animal food~~, animal food-contact surfaces, or animal food-packaging materials with microorganisms or foreign substances~~.

(b) Personnel responsible for identifying ~~sanitation failures or animal food contamination~~ departures from CGMPs 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. As necessary for the intended use of the animal food, ~~Animal food~~ handlers and supervisors should receive appropriate training in proper animal food handling techniques and animal food-protection principles and should be informed of the danger of poor personal hygiene and ~~unsanitary~~ housekeeping practices.

(c) Responsibility for ensuring compliance by all personnel with all requirements of this subpart must be clearly assigned to competent supervisory personnel.

AFIA Comments

AFIA believes it is more appropriate for FDA to adopt currently accepted language reflected in the medicated feed CGMPs, AAFCO and/or PAS 222 models for this section rather than the proposed language. For example, the AAFCO model states: "(P)ersons working in direct contact with feed and/or feed ingredients shall conform to good hygienic practices to minimize the risk of adulteration." This statement upholds animal food safety without the human food microbial elements found in currently-proposed section (a)(1-2). Therefore, AFIA has recommended deleting (a)(1) and (2). AFIA also has concerns as to the legality of asking employees about illnesses. Supervisory personnel do not have the authority or typically the knowledge to make these determinations.

To justify the removal of proposed (a)(1), AFIA commissioned a report by Dr. Tim Goldsmith, Center for Animal Health and Food Safety at the University of Minnesota, to evaluate and provide an opinion on the potential spread of a communicable disease from humans to animals through animal food. A literature review was conducted on documented cases of transmission of disease from humans to animals, the potential for transmission from humans to animals and the major recognized zoonotic pathogens. The review found no documented cases of disease spread from humans to animals through animal food from humans involved in the manufacturing of the feed. Potential transmission routes could exist via human excrement or bodily fluids, however, the toilet and hand washing facilities provided in animal food facilities and required in these CGMPs should render these routes as negligible. The final opinion of the report was that "it is unlikely that animals would get sick from pathogens spread from humans involved in feed manufacturing to livestock through animal feed." The full report is provided in Appendix B.

Proposed Rule with AFIA Recommendations

§ 507.17 Plant and grounds.

(a) The grounds about an animal food plant under the control of the operator must be kept in a condition that will protect against the ~~contamination~~ adulteration of animal food. The methods for adequate maintenance of grounds ~~must~~ should include:

(1) Properly storing equipment, ~~removing~~ limiting the presence of 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 roads, yards, and parking lots under the control of the operator so that they do not constitute a source of ~~contamination~~ adulteration in areas where animal food is exposed;
(3) Adequately draining areas that may contribute to ~~contamination~~ adulteration of animal food ~~by seepage, foot-borne filth, or providing a breeding place for pests~~; and
(4) Treating and disposing of waste so that it does not constitute a source of ~~contamination~~ adulteration in areas where animal food is exposed. ~~If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a)(1) through (a)(3) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of animal food contamination.~~
(b) The plant's buildings and structures must be suitable in size, construction, and design to facilitate maintenance and ~~sanitary~~ clean operations for animal food-production purposes (i.e., manufacturing, processing, packing, and holding). The plant ~~must~~ should:
(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for ~~the maintenance of sanitary operations and~~ the production of safe animal food.
(2) As appropriate and necessary for the intended use, ~~P~~ permit the taking of proper precautions to reduce the potential for ~~contamination~~ adulteration of animal food~~, animal food-contact surfaces, or animal food-packaging materials~~ with undesirable microorganisms, hazardous chemicals, filth, ~~and~~ or other ~~extraneous~~ hazardous material. ~~The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, air flow, enclosed systems, or other effective means.~~
(3) As appropriate and necessary for the intended use, ~~P~~ permit the taking of proper precautions to protect animal food in outdoor bulk vessels by any effective means, which may include ~~ing~~ but are not limited to:
(i) Using protective coverings;
(ii) Controlling areas over and around the vessels to eliminate harborages for pests; and
(iii) Checking on a regular basis for pests and pest infestation~~; and~~
~~(iv) Skimming fermentation vessels, as necessary.~~
(4) Be constructed in such a manner that ~~floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts, and pipes does not contaminate~~ protects against the adulteration of animal food~~, animal food-contact surfaces, or animal food-packaging materials~~; and that ~~aisles or~~ working spaces are ~~provided between equipment and walls and are adequately unobstructed and of~~ adequate ~~width~~ to permit employees to perform their duties effectively. ~~and to protect against contaminating animal food, animal food-contact surfaces, or animal food-packaging materials.~~
(5) Provide adequate lighting in hand-washing areas, toilet rooms, areas where animal food is examined, processed, or stored, and areas where equipment or ~~utensils~~ tools are cleaned; and provide safety-type light bulbs, fixtures, and skylights, or other glass items

suspended over exposed animal food in any step of preparation, or otherwise protect against animal food ~~contamination~~ adulteration in case of glass breakage.
(6) Where appropriate and necessary, p~~P~~rovide adequate ventilation or control equipment to minimize hazardous ~~odors and~~ vapors ~~(including steam and noxious fumes)~~ in areas where they may ~~contaminate~~ adulterate animal food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for ~~contaminating~~ adulterating animal food~~, animal food-packaging materials, and animal food-contact surfaces~~.
(7) Provide, where appropriate and necessary, adequate ~~screening or other~~ protection against pests.

AFIA Comments

AFIA proposes the following edits to this section:

- "Adulteration" of the food is the regulatory standard for action. AFIA recommends FDA use "adulteration" instead of "contamination" as noted in our comments above.
- AFIA suggests deleting part of (a)(4) as it is redundant with provisions in (a)(1-3).
- "Sanitizing" is not appropriate for all animal food plants. In some facilities, "sanitation" may be the appropriate standard, but not in all cases. Therefore, the rule must be written in a manner that allows for risk/hazard specific controls.
- AFIA believes the second sentence of (b)(2) belongs in a guidance document, and is not an issue appropriate for the codified rule. It appears to provide suggestion for compliance.
- AFIA suggests using the currently accepted and less prescriptive language found in medicated feed CGMPs (Part 225.2(b)(4)), PAS 222 (5.6) instead of the language currently proposed in section (b)(5). This would allow for consistency of regulations for those firms already required to comply with the Part 225 rules.
- In (b)(6), odors are not an animal food safety issue, and AFIA recommends deleting this reference. "Steam" is only used in some animal food processing and should not be called out within the rule. Alternate language to consider can be found in PAS 222 (5.4).
- AFIA believes that protecting against pests is the ultimate goal of (b)(7). FDA should not limit the types of protection plants can use for this purpose. AFIA does not believe "screening" should be called out as it is only one potential pest control option. Removing the mention of this option makes the provision general enough for a facility to apply the appropriate protection against pests based on their facility.

Proposed Rule with AFIA Recommendations

§ 507.19 ~~Sanitary~~ Clean operations.

(a) Buildings, fixtures, and other physical facilities of the plant must be maintained in a ~~sanitary~~ clean condition and must be kept in repair sufficient to prevent animal food from becoming adulterated. Cleaning ~~and sanitizing~~ of ~~utensils~~ tools and equipment must be conducted in a manner that protects against ~~contamination~~ adulteration of animal food~~, animal food-contact surfaces, or animal food-packaging materials~~.
(b) Cleaning compounds ~~and sanitizing agents must be free from undesirable microorganisms and~~ must be safe and adequate under the conditions of use. ~~Compliance~~

~~with this requirement may be verified by any effective means, including purchase of these substances under a supplier's guarantee or certification or examination of these substances for contamination.~~

~~(c) The following applies to toxic materials:~~

~~(1) Only the following toxic materials may be used or stored in a plant where animal food is processed or exposed:~~

~~(i) Those required to maintain clean and sanitary conditions;~~

~~(ii) Those necessary for use in laboratory testing procedures;~~

~~(iii) Those necessary for plant and equipment maintenance and operation; and~~

~~(iv) Those necessary for use in the plant's operations.~~

(~~2~~c) All cleaning materials must be identified, held, and stored in a manner that protects against adulteration of animal food. ~~Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.~~

(d) Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the ~~contamination~~ adulteration of animal food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the ~~contamination~~ adulteration of animal food~~, animal food-contact surfaces, and animal food-packaging materials~~.

(e) ~~All a~~Animal food-contact surfaces, including ~~utensils~~ tools and animal food-contact surfaces of equipment, ~~must~~ should be cleaned ~~as frequently~~ as appropriate and necessary to protect against ~~contamination~~ adulteration of animal food.

(1) As appropriate and necessary for the intended use, ~~A~~animal food-contact surfaces used for manufacturing, processing or holding low-moisture animal food ~~must~~should be in a clean~~,~~ and dry~~, sanitary~~ condition at the time of use. When the surfaces are wet-cleaned, they ~~must~~ should~~, when necessary,~~ be ~~sanitized~~ cleaned and thoroughly dried before subsequent use, when appropriate and necessary.

(2) In wet processing, when cleaning is necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food-contact surfaces must be cleaned as necessary ~~and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated~~. Where equipment and ~~utensils~~ tools are used in a continuous production operation, the ~~utensils~~ tools and animal food-contact surfaces of the equipment must be cleaned ~~and sanitized~~ as necessary.

(3) Single-service articles (such as ~~utensils~~ tools intended for one-time use, paper cups, and paper towels) that may present a hazard to animal food should be stored in appropriate containers and must be handled, dispensed, used, and disposed of in a manner that protects against ~~contamination~~ adulteration of the animal food~~, animal food-contact surfaces, or animal food-packaging materials~~.

(f) Non-animal food-contact surfaces of equipment used in the operation of an animal food plant should be cleaned in a manner and as frequently as necessary to protect against ~~contamination~~ adulteration of animal food~~, animal food-contact surfaces, and animal food-packaging materials~~.

~~(g) Cleaned and sanitized portable equipment with animal food-contact surfaces and utensils should be stored in a location and manner that protects animal food-contact surfaces from contamination.~~

AFIA Comments:
AFIA disagrees with FDA's prescriptive approach in §507.19 to describe proper handling and classification of cleaning materials. As an example, proposed (c) refers to compounds as "toxic," which implies all cleaning or sanitation materials are toxic. Any substance may be considered "toxic" if handled or used inappropriately. Therefore AFIA recommends removing references to "toxic" and instead referring to them as "cleaning materials" as the more appropriately identified substances of concern in this section. In addition, the agency also describes which cleaning or sanitation materials may be stored. Activities, such as "storage," should be described in its appropriate section, such as §§ 507.25 or 507.28. In essence, manufacturing facilities should be concerned about the control of all materials not approved for inclusion in animal feeds. Such activities should be properly described in the most appropriate section rather than creating confusion with the prescriptive text used by FDA in § 507.19

AFIA recommends the following edits to this section:

- Instead of the currently proposed item (c), AFIA suggests FDA adopt the currently accepted language in medicated feed CGMPs (Part 225.35) as it relates to the storage of cleaning and/or non-food materials.
- If the agency insists on using the current language, then AFIA suggests deleting (c)(1)(i-iv), because it is too prescriptive and limiting.
- As proposed, (c)(2), creates confusion through the use of "toxic" and therefore AFIA suggests focusing on cleaning materials and preventing adulteration.
- AFIA recommends deleting part (g) as it is redundant because all equipment (both portable and stationary) is covered in proposed § 507.22 Equipment and utensils.

Proposed Rule with AFIA Recommendations

§ 507.20 ~~Sanitary facilities and controls.~~ Housekeeping.

(a) The water supply must be adequate and sufficient for the operations intended ~~and must be derived from an adequate source~~ and must be provided in all areas where necessary. ~~Any water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee sanitary facilities.~~
~~(b) Plumbing must be of adequate size and design and adequately installed and maintained to:~~
~~(1) Carry sufficient quantities of water to required locations throughout the plant;~~
~~(2) Properly convey sewage and liquid disposable waste from the plant;~~
~~(3) Avoid constituting a source of contamination to animal food, water supplies, equipment, or utensils or creating an unsanitary condition;~~

~~(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) Provide that there is not 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.~~

(~~e~~b) Sewage must be disposed of through an adequate sewage system or through other adequate means.

(~~d~~c) Each plant must provide its employees with adequate~~, readily accessible~~ toilet facilities. ~~Toilet~~ Restroom facilities must be kept clean and must not be a potential source of ~~contamination~~ adulteration of animal food~~, animal food-contact surfaces, or animal food-packaging materials~~.

(~~e~~d) Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of ~~contamination~~ adulteration of animal food~~, animal food-contact surfaces, or animal food-packaging materials~~, by providing facilities that are adequate~~, convenient, and furnish running water at a suitable temperature~~.

(~~e~~f) Rubbish must be conveyed, stored, and disposed of in a way to ~~minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination~~ protect against the adulteration of animal food~~, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces~~.

AFIA Comments

AFIA suggests several edits to this section as detailed below:

- As mentioned before, "sanitation" is not appropriate for all animal food facilities. AFIA recommends changing this section to "Housekeeping." The animal food industry does not refer to toilets as "sanitary facilities" or "toilet facilities" and therefore we changed these references to "restrooms."
- If the water supply *is* sufficient for the operations intended, what would constitute an "inadequate source" in (a)? AFIA agrees that the "the water supply must be sufficient for the operations intended," which implies it must come from an "adequate source."
- Item (b) is overly prescriptive and is redundant with respect to (a). Further, who would be considered qualified to determine adequacy of plumbing? The majority of FDA's inspectors are not knowledgeable enough to make this determination. Therefore, AFIA suggests deleting this provision and renumbering the rest of the section.
- In proposed item (d), "adequate" is sufficient to delineate the toilet facilities. "Readily accessible" is undefined and could be construed to have different meanings by different investigators. AFIA suggests deleting it.
- "Convenient" in proposed item (e) is undefined and AFIA recommends deleting it.
- Further, proposed item (e) is redundant, as hand washing is previously addressed in § 507.14(a)(3)(ii).
- AFIA suggests edits to proposed item (f) to clarify that the goal is preventing the production of adulterated product. The recommended edits relate the provision more to the animal food facility rather than a human food facility.

Proposed Rule with AFIA Recommendations:

§ 507.22 Equipment and ~~utensils~~ tools.

(a)(1) ~~All~~ Where appropriate and necessary given the intended purpose of the animal food, plant equipment and ~~utensils~~ tools must be designed and of such material and workmanship to be adequately cleanable, and must be properly maintained;
(2) The design, construction, and use of equipment and ~~utensils~~ tools must preclude the adulteration of animal food with lubricants, fuel, metal fragments, contaminated water, or any other potential adulterants~~contaminants~~;
(3) ~~All~~ Animal food equipment should be installed and maintained in such a way to facilitate the cleaning of the equipment and all adjacent spaces;
~~(4) Animal food-contact surfaces must be made of materials that resist corrosion when in contact with animal food;~~
(~~5~~4) Animal food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of animal food, and, if applicable, the action of cleaning compounds and sanitizing agents; and
(~~6~~5) Where appropriate and necessary given the intended purpose of the animal food, a~~A~~nimal food-contact surfaces must be maintained to protect animal food from being ~~contaminated~~ adulterated.
~~(b) Seams on animal food-contact surfaces must be maintained so as to minimize accumulation of food particles, dirt, and organic matter, and thus minimize the opportunity for growth of microorganisms.~~
~~(c) Equipment in the animal food manufacturing or handling area that does not come into contact with animal food must be constructed in such a way that it can be kept in a clean condition.~~
~~(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate sanitary condition.~~
(~~e~~b) Each freezer and cold storage compartment used to store and hold animal food capable of supporting growth of undesirable microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device installed to show the temperature accurately within the compartment.
(~~f~~c) 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 and precise and adequately maintained, and adequate in number for their designated uses.
(~~g~~d) As appropriate and necessary for the intended use, c~~C~~ompressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment ~~must~~ should be treated in such a way that protects against the adulteration of animal food ~~is not contaminated~~.

AFIA Comments:
AFIA recommends several edits to this section as detailed below:

- AFIA believes FDA's proposal for (a)(4) is not feasible or appropriate. Furthermore, any animal food safety concerns are covered by language in proposed item (a)(5).
- Proposed items (b), (c) and (d) are redundant and unnecessary given the language in (a). Therefore, AFIA suggests deleting them and renumbering the section.
- AFIA believes FDA should consider PAS 222 (5.5) for alternate language in this section.

Proposed Rule with AFIA Recommendations

§ 507.25 Processes and controls.

(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 adequate ~~sanitation principles~~ good manufacturing practices;
(2) Containers holding animal food, raw materials, or ingredients ~~are labeled to accurately~~ identify the contents;
(3) The labeling for the finished animal food product contains the ~~specific~~ information and instructions ~~needed~~ so the food can be safely used for the intended animal species;
(4) ~~Appropriate quality control operations are employed so that a~~Animal food-packaging materials are safe and suitable;
(5) The overall ~~sanitation~~ cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function;
(6) All reasonable precautions are taken so that production procedures do not contribute to ~~contamination~~ adulteration of animal food ~~from any source~~;
(7) Chemical, microbial, or extraneous-material testing procedures are used where appropriate and necessary to identify ~~sanitation failures or possible animal food contamination~~ adulteration; and
(8) All animal food that has become ~~contaminated to the extent that it is~~ adulterated is rejected, or if permissible, treated or processed to eliminate the ~~contamination~~adulterant.
(b) Raw materials and ingredients:
(1) Must be inspected and ~~segregated or otherwise~~ handled as necessary to ensure that they are ~~clean and~~ suitable for processing into animal food and must be stored under conditions that will protect against adulteration~~contamination and minimize deterioration~~. In addition:
~~(i) Raw materials must be washed or cleaned as necessary to remove soil or other contamination;~~
~~(ii) Water used for washing, rinsing, or conveying animal food must be safe and of adequate sanitary quality;~~
~~(iii) Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food; and~~
(~~iv~~i) As necessary for the intended use, c~~C~~ontainers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to ~~contamination~~

~~or deterioration~~ adulteration of animal food that will not be mitigated by the manufacturing process.

(2) Must not contain levels of undesirable microorganisms that may render the food injurious to the health of animals or humans, or they must be treated (e.g., heat) during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated;

(3) Susceptible to ~~contamination with afla~~ mycotoxins or other natural toxins must comply with current FDA ~~regulations~~ rules or guidance/action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished animal food;

(4) Including rework, must be held in bulk, or in containers designed and constructed in a way that protects against ~~contamination~~ adulteration, and must be held ~~at a temperature and relative humidity and~~ in a manner that prevents the animal food from becoming adulterated. Material scheduled for rework must be identified as such;

(5) If frozen, must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and ingredients from becoming adulterated, or possible adulteration should be mitigated by the manufacturing process; and

(6) Whether liquid or dry, received and stored in bulk form must be held in a manner that protects against ~~contamination~~ adulteration.

(c) For the purposes of manufacturing operations, the following apply:

(1) Equipment, ~~utensils~~ tools, and finished animal food containers must be maintained in an acceptable condition through appropriate cleaning ~~and sanitizing,~~ as necessary. ~~When necessary, equipment must be taken apart for thorough cleaning;~~

(2) All animal food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are appropriate and necessary to minimize the potential for the growth of undesirable microorganisms or for the ~~contamination~~ adulteration of animal food;

~~(3) Animal food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding;~~

(~~4~~3) As appropriate and necessary for the intended use, m~~M~~easures taken to destroy or prevent the growth of undesirable microorganisms, such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w, must be adequate under the conditions of manufacture, handling, and distribution under owner/operator control to prevent animal food from being adulterated;

(~~5~~4) Work-in-process and rework must be handled in a manner that protects against ~~contamination~~ adulteration and the growth of undesirable microorganisms that will not be mitigated by the manufacturing process;

(~~6~~5) Effective measures must be taken to protect finished animal food from ~~contamination~~ adulteration by raw materials, ingredients, or refuse. ~~When raw materials, ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated animal food. Animal food transported by conveyor must be protected against contamination as necessary~~;

(~~7~~6) Equipment, containers, and ~~utensils~~ tools used to convey, hold, or store raw materials, work-in-process, rework, or animal food must be constructed, handled, and

maintained during manufacturing, processing, packing, or holding in a manner that protects against ~~contamination~~ adulteration of animal food;
(~~8~~7) Effective measures must be taken to protect against the inclusion of metal or other extraneous material in animal food that result in an unsafe product;
(~~9~~8) Adulterated animal food, raw materials, and ingredients must be disposed of in a manner that protects against the ~~contamination~~ adulteration of other animal food or, if the adulterated animal food, raw materials, or ingredients are capable of being reconditioned, they must be reconditioned using an effective method ~~that has been proven to be effective~~;
(~~10~~9) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, defatting, and forming must be performed in a way that protects animal food against ~~contamination~~ adulteration. Animal food should be protected from unsafe materials ~~contaminants~~ that may drip, drain, or be drawn into the animal food that will not be mitigated by the manufacturing process;
(~~11~~10) Heat blanching, when required in the preparation of animal food, should be ~~effected~~ affected by heating the animal food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the animal food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning;
(~~12~~11) Batters, breading, sauces, gravies, dressings, and other similar preparations must be treated or maintained in such a manner that they are protected from~~against contamination~~ adulteration;
(~~13~~12) Filling, assembling, packaging, and other operations must be performed in such a way that the animal food is protected from~~against contamination~~ adulteration ~~and growth of undesirable microorganisms~~;
(~~14~~13) Where appropriate and necessary, a~~A~~nimal food, including dry mixes, nuts, intermediate moisture animal food, and dehydrated animal food, that relies on the control of a_w for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level;
(~~15~~14) 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
(~~16~~15) When ice is used in contact with animal food, it must be made from water that is safe ~~and of adequate sanitary quality~~, and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part, where appropriate for the finished animal food product.

AFIA Comments:
The intent of the CGMPs and FSMA is to ensure animal food safety. AFIA supports this proactive approach. As noted in our introductory comments, AFIA concludes it is unnecessary to incorporate quality control measures in the scope of the regulation. Quality control operations are only mentioned within § 507.25 - Processes and Controls, and only in regards to ensuring animal food packaging materials are safe and suitable. “Quality control operation” is a very broad term used within the animal food industry. It applies to various processes and procedures throughout the manufacturing system and may not be specific to animal food safety. Thus, AFIA desires

maintaining a focus on animal food safety. Accordingly, we recommend removing the references to quality control, including the definition of "quality control operation," as noted in our comments on the definitions in Section I. Because the term "quality control operations" only appears in the definitions and §507.25 (a)(4), it appears FDA's intent is not to widen the scope of the regulation. Our recommendation clarifies FDA's intent to focus on the safety of the foods and associated materials.

AFIA recommends several edits to this section as detailed in the following:

- In (2), some containers, such as storage bins, may not be labeled, but instead, designated within an automated system or in a central location.
- Several portions of (b) are overly prescriptive. Ensuring that finished animal food is safe and not adulterated is the primary purpose of this regulation. Many of the listed items offer very specific items that are more appropriate for a guidance document. Removing soil from raw ingredients (in item (b)(1)(i)) is not a practical, realistic animal food safety issue. Should every soybean or corn kernel be washed? Items (b)(1)(ii-iii) are already addressed in § 507.20, which makes this provision redundant. AFIA suggests edits to reflect our concerns.
- While (b)(3) is acceptable, why is it necessary if it is covered in other regulations?
- Regarding proposed (c)(3), there are some ingredients (e.g., liquids) that must be held at high temperatures, but any potential hazards associated with higher temperature conditions will be controlled during manufacturing. It is more appropriate for human foods. AFIA recommends its removal.
- Proposed items (c)(11-12) will not likely apply to the majority of animal food facilities. AFIA has retained these provisions, but urges FDA to consider whether it is appropriate for animal food.
- In proposed item (c)(13), "undesirable microorganisms" would be considered an adulteration, so it is not necessary to repeat it as an example in this item.
- It is unlikely that the ice mentioned in proposed (c)(16) will be applicable to the animal food industry. While AFIA has retained this provision, we urge FDA to consider whether it is appropriate for animal food.

Proposed Rule with AFIA Recommendations:

§ 507.28 Warehousing and distribution.

Storage and transportation of animal food must be conducted under conditions that will protect against ~~biological, chemical, physical, and radiological contamination~~ adulteration of animal food ~~as well as against deterioration of the animal food and the container~~.

AFIA Comments

As noted in our earlier comments in this section, "contamination" is not defined as a regulatory term. An unadulterated finished product is the overall goal. The rule should reflect that goal instead of listing specific types of hazards. Warehousing and distribution should be conducted in a way that prevents adulteration of any type.

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 for animal food with a hazard that is known or reasonably foreseeable ~~likely to occur~~.

(a) The owner, operator, or agent in charge of a facility must develop a written recall plan for animal food with a hazard that is known or reasonably foreseeable ~~likely to occur~~ and assign responsibility for performing all actions in the plan.
(b) The written recall plan must include procedures for:
(1) Directly notifying direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;
~~(2) Notifying the public about any hazard presented by the animal food when appropriate to protect animal and human health;~~
(~~3~~2) ~~Conducting effectiveness checks (as described in part 7 of this chapter) to v~~Verify the recall has been carried out; and
(~~4~~3) The proper disposition (e.g., destroying, reprocessing, or diverting to another use that would not present a safety concern) of the recalled animal food.

AFIA Comments
As stated in our comments on § 507.30-Requirement for a food safety plan, AFIA believes the recall plan should be included in subpart B. Therefore, we recommend the language above to be included in subpart Bm so every animal food facility will have a recall plan in place. Also, as noted in our comments below, 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

HAZARD IDENTIFICATION

FDA Should Replace "Reasonably Likely to Occur" with "Known and Reasonably Foreseeable"
FDA's proposal to use "reasonably likely to occur" would make all preventive controls subject to management elements usually reserved for CCPs in HACCP systems. In HACCP, a hazard "reasonably likely to occur," is generally perceived to require a CCP. AFIA is concerned by this approach because CCPs are only one component of an effective animal food safety system. FSMA defines preventive controls as much broader than only a CCP under a HACCP program. Robust animal food safety plans must address broader issues in the animal food safety system, including a foundation of CGMPs. AFIA believes that preventive controls include the entire spectrum of controls that food safety experts consider necessary to achieve the FSMA food safety goals, consistent with the statute. Thus, AFIA recommends replacing "hazards reasonably like to occur" with "known and reasonably foreseeable hazards" for consistency with the statute, removing the perception that a CCP is required.

FDA Should Adjust the Final Rule to Reflect the Appropriate Management Oversight for Preventive Controls and not CCPs
With such a wide range of preventive controls under FSMA, the regulations should not require all preventive controls to be managed in the same way. Each facility is able to determine the level of management oversight necessary to significantly minimize and prevent any animal food safety hazards. Like CCPs under HACCP, the proposed rule requires full management oversight and subjects all preventive controls to monitoring, corrective actions and verification. However, not every preventive control is a CCP. The nature of the risk/hazards and the controls employed should determine the level of management oversight. FDA suggests this type of flexibility in various places in the preamble, and we urge the agency to modify the proposed codified language to more directly reflect this principle in the content of the final rule.

The Final Regulation Should Encompass Controls in the Entire Animal Food Safety System, be Risk-Based and Allow for Effective Enforcement
The regulation should address all controls within the context of an animal food safety system necessary to produce safe food and meet the animal food safety standards required in FSMA. Qualified animal food safety experts recognize that this requires management beyond critical control points. The regulation should recognize that facilities must select controls and determine how the controls are managed based on a fact-based, risk-based hazard analysis. This hazard analysis should address animal food safety needs that take specific products, processes, the nature of the controls involved and other relevant factors into account.

The regulation should provide for effective enforcement. This requires a regulatory verification approach that assesses the evaluation and management of risk within an animal food safety system. It should not merely rely on a prescriptive list of regulatory requirements. The final rule's preamble and agency guidance should include examples to assist in implementation. However, FDA should ensure that all examples are treated as instructional and not binding requirements.

Guidance Documents are Necessary to Provide Clarity and Assist with Implementation

We also encourage FDA to use guidance documents to add greater clarity about ways in which FDA finds it acceptable to achieve compliance. AFIA strongly supports guidance documents to assist facilities with implementing the FSMA regulations, provided that guidance is appropriately treated as illustrative but non-binding. Guidance documents are also an important tool to explain the agency's expectations and help companies with limited resources understand specific steps they can follow to develop compliant programs. AFIA welcomes the opportunity to assist the agency with guidance document development. Together, risk-based regulations and thoughtful guidance will ensure the regulation is enforceable and not overly burdensome for the agency or the industry.

Specific Comments on the Provisions in Subpart C

AFIA provides the following comments regarding requirements of the animal food safety plan and the hazard analysis.

Proposed Rule with AFIA Recommendations

§ 507.30 Requirement for a<u>n animal</u> food safety plan.

(a) The owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written <u>animal</u> food safety plan.

(b) The written <u>animal</u> food safety plan must be prepared by (or its preparation overseen by) a qualified individual <u>or qualified animal food safety team.</u>

AFIA Comments

AFIA acknowledges that it is the responsibility of the owner, operator, or agent in charge to insure the written animal food safety plan is successfully established and implemented. However, we would like to clarify for the agency that the owner, operator or agent in charge may not be directly involved in the preparation of the written animal food safety plan. In fact, the qualified individual, as allowed by the proposed definition, may not reside at the facility. We concur that the animal food safety plan must be prepared by individuals with appropriate training, education and/or experience; however, we also understand that in practice this is typically achieved with animal food safety team members with expertise in different areas of the facility. We request the final regulation acknowledge this practice by including "animal food safety team" within this provision and the definition of qualified individual as noted in our comments on the definitions in Section I.

Proposed Rule with AFIA Recommendations

§ 507.30 Requirement for a<u>n animal</u> food safety plan.

(c) The written <u>animal</u> food safety plan must include <u>as applicable</u>:

(1) The hazard analysis as required by § 507.33;

(2) The preventive controls as required by § 507.36;

(~~3~~) ~~The recall plan as required by § 507.38;~~

(~~4~~<u>3</u>) The procedures and the frequency with which these procedures will be conducted for monitoring the performance of the preventive controls as required by § 507.39;

(~~5~~4) The corrective action procedures as required by § 507.42; and
(~~6~~ 5) The verification procedures and the frequency with which they will be performed as required by § 507.45.

AFIA Comments

Required Contents of Animal Food Safety Plans

AFIA agrees with FDA's intentions for an animal food safety plan as stated in the preamble to the proposed rule (78 Fed. Reg. at 64750) "We propose to require that the owner, operator, or agent in charge of a facility have and implement a written food safety plan that includes *as applicable*:…"

AFIA notes that unlike the preamble language, the proposed regulation § 507.30(b) removed the words "as applicable" and replaced them with the words "must include." This change from the proposed text found in the preamble could be interpreted as creating requirements that may not be applicable, appropriate, or pertinent to all individual preventive controls. Therefore, AFIA recommends the addition of "as applicable" in part (c).

The list of management elements listed in § 507.30(c)(2, 4, 5 and 6), as proposed, are traditionally associated with CCPs. These activities do not apply to hazards for which CCPs have not been established and, therefore, preventive controls are not necessary. Thus, the inclusion of the terminology "as applicable" is more germane and a better description of both the agency's stated intentions and the development of effective animal food safety plans that will fully protect public health and veterinary public health. Statements in the agency's preamble support this position:

- "We do not expect that all possible preventive measures and verification procedures would be applied to all foods at all facilities." 78 Fed. Reg. at 64737
- "Although there are some differences between HACCP systems and the preventive control system established by section 418 of the FD&C Act. It differs in part in that preventive controls may be required at points other than at CCPs and critical limits would not be required for all preventive controls. " 78 Fed. Reg. at 64785

The risk-based nature of the FSMA statute allows companies to manage controls with the management activities necessary to achieve FSMA's food safety goals. Following the statute preserves the key elements of successful animal food safety systems. This includes consideration of the analytical frameworks and necessary thought processes, such as: (1) how science is evaluated and applied to specific products and circumstances; (2) the way management activities are customized to fit diverse animal food safety needs; and (3) the use of CCPs and enhanced and general controls only in circumstances where a qualified individual or animal food safety team determines that general controls are not adequate to manage a hazard.

Grouping of Animal Food Safety Plans

AFIA agrees with agency statements in the preamble to the proposed rule that facilities shall be able to group food types or production method types if the hazards, control measures, parameters and required procedures such as monitoring are essentially identical.

Accordingly we concur with:

- The statement from 78 Fed. Reg. at 64779 that says, "proposed § 507.30 would provide flexibility for facilities in the development of their food safety plans by allowing facilities to group animal food types or production method types if the hazards, control measures, parameters, and required procedures such as monitoring are essentially identical." and
- The statement from 78 Fed. Reg. at 64780 that states, "Federal HACCP regulations...allow the HACCP plan to group food types or production method types if the hazards, critical control points, critical limits and required procedures such as monitoring are essentially identical, provided that any required features of the plan that are unique to a specific product or production method are clearly delineated in the plan and are observed in practice.... *This type of grouping would be allowed under proposed §507.30* and, thus, would provide flexibility for facilities in the development of their HACCP plans." (Emphasis added).

It is important to emphasize that while HACCP plans may be part of animal food safety plans; animal food safety plans are broader and cover control measures that are not managed with CCPs alone.

Inclusion of the Recall Plan in Animal Food Safety Plans

AFIA strongly believes that the requirement for a recall plan should be moved to subpart B (CGMPs). The recall plan requirements should apply to every facility regardless of size. This modification to the proposed rule is justified because:

- Recall plans are often tailored to a given facility or company, not to a given product, process or production line.
- In cases where a company has multiple production facilities, recall plans are often prepared by the corporate office. Furthermore, recall activities are often administered by the corporate office.
- Recall plans are a crisis management tool and are used after an adulterated product is released into the marketplace. In contrast, the animal food safety plan's goal is to prevent a potentially adulterated product from being produced and/or entering commerce.
- A facility may process several categories of food in one building and have several animal food safety plans to do so. However, such a facility typically has only one recall protocol.

FSMA holds all food processors responsible for recalling their goods when the public health may be threatened. The recall plan requirement is included in subpart C of the proposed rule. However, certain firms are exempt from the provisions of subpart C. These exempted firms would not be required to maintain recall plans. If the requirement for a recall plan is part of the CGMPs, no firm will be exempt from developing and maintaining a recall plan. Better public and veterinary public health outcomes will result if all facilities can conduct effective recalls.

FDA should make the appropriate changes throughout the regulations (such as § 507.30) to reflect this modification to clarify the requirements of an animal food safety plan and move the requirement for a recall plan to subpart B, CGMPs.

Proposed Rule with AFIA Recommendations

§ 507.33 Hazard analysis.

(a) The owner, operator, or agent in charge of a facility is responsible to ensure that ~~must identify and evaluate~~ known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility are identified and evaluated by the qualified individual or qualified food safety team to determine, based on their probability and severity, ~~whether there are hazards that are reasonably likely to occur~~ the hazards that are of such a nature that control measures to significantly minimize or prevent them are necessary for the production of a safe animal food and therefore must be addressed in the animal food safety plan and develop a written hazard analysis.

AFIA Comments

AFIA agrees that the owner, operator or agent in charge is responsible for the animal food safety plan and the hazard analysis; however, FDA's proposal in § 507.30(c) calls for a qualified individual to prepare or oversee preparation of the animal food safety plan, including the hazard analysis. While we agree that the owner, operator or agent in charge is responsible for ensuring that this task is completed, the qualified individual or team conducting these activities may be someone besides the owner, operator or agent in charge. AFIA recommends utilizing language to separate responsibilities for managing and administering an animal food safety plan from the task of preparing and overseeing components of the plan.

As noted in the summary of our comments, the proposed language "hazards reasonably likely to occur" is common in HACCP systems and most often associated with CCPs. The statute specifically avoided HACCP and related terminology. FSMA's language allows a broader definition of preventive controls and permits appropriate actions to minimize animal food safety risk that is based on the severity and probability of a hazard within a specific facility and process. AFIA believes it is important to consider both the severity of a hazard and the probability it will occur. This is consistent with FDA's Center for Veterinary Medicine's Animal Feed Safety System developed over the last eight years. AFIA recommends applying the statutory framework by using hazards "known or reasonably foreseeable" as the basis for hazard analysis. This approach should include an evaluation of the probability and severity of a hazard's occurrence to determine how hazards are controlled within the animal food safety system.

Proposed Rule with AFIA Recommendations

§ 507.33 Hazard analysis.

(b) The hazard analysis must consider hazards that may occur naturally or may be unintentionally introduced including:

(1) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other undesirable microorganisms of animal or human health significance;

AFIA Comments

The proposed rule defines microorganisms as "yeasts, molds, bacteria, viruses, protozoa and microscopic parasites and includes species having animal or human health significance," which is very broad and could, if not more clearly defined, encompass materials utilized in animal foods to provide a positive nutritional benefit (i.e., yeast products, direct fed microbials). AFIA is concerned that confusion will result if the definition is not limited to microorganisms that have a negative impact on animal food safety. This is especially the case if investigators are not familiar with the animal food industry and its products. AFIA suggests inserting the term "undesirable" to describe microorganisms to clarify the negative impact of concern. This qualifier is based on FDA's inclusion of the term "undesirable microorganisms" within the microorganism definition that identified undesirable microorganisms as those "that are of animal or human health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated." 78 Fed. Reg. at 64756

Proposed Rule with AFIA Recommendations

§ 507.33 Hazard analysis.

(b) The hazard analysis must consider hazards that may occur naturally or may be unintentionally introduced including:

(2) Chemical hazards, including substances such as pesticide and drug residues, natural toxins, ~~decomposition~~, unapproved food or color additives, <u>radiological hazards</u> and ~~nutrient imbalances~~ <u>nutrient deficiencies or toxicities</u>;

AFIA Comments

<u>Removal of Decomposition</u>

Decomposition is only referenced in the preamble to the proposed rule. Even that discussion is broad and subjective. The description provided on 78 Fed. Reg. at 64782 reads:

> Decomposition of animal food consists of microbial breakdown of the normal food product tissues and the subsequent enzyme-induced chemical changes. These changes are manifested by abnormal odors, taste, texture, color, etc., and can lead to reduced food intake or rejection of the food by the intended animal species, resulting in illness or death.

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 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. Acknowledging that chemical changes can be manifested by abnormal odors, taste and texture is true, but that is subjective.

AFIA is concerned that these types of materials may be unfairly criticized. From the examples cited within the 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 releases potentially hazardous natural toxins.

The proposed rule already identifies natural toxins as a subgroup of chemical hazards. 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.

Radiological Hazards

In our comments below regarding §507.33 (b)(3) & (4), AFIA recommends including radiological hazards as a subcategory of chemical hazards. This is the appropriate categorization from a scientific standpoint, and there is no evidence that radiological hazards deserve a special classification in the U.S. It is redundant and unnecessary. Therefore, AFIA recommends radiological hazards be added to the chemical hazard 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 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.

Specifically regarding livestock feeds, there are certain geographic areas where naturally occurring minerals in the soil, water and plants, especially forages, require nutrient supplementation that, if taken out of context, would certainly appear to be an "imbalance." Examples include:

- Central and northwestern U.S. states, where molybdenum levels in plants require copper supplementation at levels that would, under "normal" circumstances, be considered to be in the range to negatively affect animal health.
- Ohio-Pennsylvania areas where soil selenium is very deficient, and selenium deficiency is common in animals supplemented to the maximum legal level, and injectable selenium is commonly used, especially in dairy cattle.
- High phosphorus levels (and high fluorine levels) in southeastern U.S. states, that require a lower level of phosphorus and maximum level of selenium in animal feeds.
- Areas in California and the Dakotas, where no selenium is added, which could be construed as a "deficiency" on paper in areas where soil selenium is high.
- Pastures in oil-producing states where the brine used in oil drilling is the primary water supply for livestock, in which case, salt is not added, or added at very low levels, to supplements.
- Use of phytase enzymes creates situations where, to those that lack adequate understanding of phytase enzymes, diets appear to be deficient in phosphorus and low in calcium.

These examples illustrate that there are many instances where animal food formulations may appear nutritionally deficient, but are formulated for a specific situation where these factors are

taken into account by professional nutritionists and formulators. AFIA strongly recommends that "nutrient imbalances" be deleted and replaced with "nutrient deficiencies and toxicities." See our comments on the definitions in Section I for proposed definitions for "nutrient deficiencies" and "nutrient toxicities."

Proposed Rule with AFIA Recommendations

§ 507.33 Hazard analysis.

(b) The hazard analysis must consider hazards that may occur naturally or may be unintentionally introduced including:

(3) Physical hazards~~; and~~

(4) ~~Radiological hazards~~.

AFIA Comments

FSMA requires FDA to develop regulations consistent with existing domestic and international programs. Creating a specific hazard category for radiological hazards is inconsistent with established guidelines. The National Advisory Committee Microbiological Criteria for Foods (NACMCF) HACCP guidelines, the Codex HACCP Annex, and federal HACCP regulations for seafood, juice, meat and poultry do not require examinations of radiological hazards as a separate and distinct hazard subject. AFIA does not believe the animal food rule should differ from these established programs in this regard.

As FDA concluded in its own assessments, radiological contamination occurs very infrequently:

- "Radiological contamination of foods is a rare event." 78 Fed. Reg. at 3667
- In *FDA's Qualitative Risk Assessment Risk of Activity/Food Combinations for Activities Conducted in a Facility Co-Located on a Farm* it states, "...the Hazard Identification section of this document does not include radiological hazards because they are too rare in food to be considered associated with any food category other than water."
- In the same document, FDA states, "The presence of radiological hazards in foods is a rare event and consumer exposure to harmful levels of radionuclide hazards is very low (United Nations Scientific Committee on the Effects of Atomic Radiation, 2008). Use of water that contains a radionuclide to manufacture a food is not reasonably likely when using water from a domestic municipal source subject to regulation by EPA (40 CFR § 141.66; see 65 FR at 76708)."

In the Preliminary Regulatory Impact Analyses for the proposed rule, FDA states that the proposed preventive controls rule would not impose additional costs on large animal food companies. We expect, however, that all large animal food companies will incur significant expenses if they revise their animal food safety plans to address radiological hazards in their hazard analyses. Considering radiological hazards as a separate hazard will result in developing new templates for ingredient and process step assessments and the re-documentation of all existing plans. This is an undue burden that will lack an animal food safety gain; these issues are already considered as part of chemical hazard analysis.

Event-based hazards are handled separately from the animal food safety plan in programs such as crisis management. Changing every hazard analysis currently employed in the industry would

require a major dedication of resources, both financial and otherwise. We recognize that FSMA requires consideration of radiological hazards; however, consideration of these risks as part of chemical hazards is not inconsistent with the statute. Therefore, AFIA recommends deleting "radiological" hazards and adding it in §507.33 (b)(2) as a chemical hazard.

Proposed Rule with AFIA Recommendations

§ 507.33 Hazard analysis.

(c) The hazard analysis must contain an evaluation of the hazards identified in paragraph (b) of this section to determine whether the hazards are ~~reasonably likely to occur~~ known or reasonably foreseeable, including ~~an~~ a risk assessment of the severity of the illness or injury if the hazard were to occur.

AFIA Comments

As noted in the summary of our comments, the language "hazards reasonably likely to occur" is common in HACCP systems and is associated with CCPs. The statute specifically avoided HACCP and related terminology. This allows for a broader definition of preventive controls and permits appropriate action to minimize animal food safety risks based on the severity and probability of a hazard occurring within a specific facility and process. AFIA recommends applying the statutory framework by using hazards "known or reasonably foreseeable" as the basis for hazard analysis. This would include an evaluation of the probability and severity of a hazard to determine how hazards are controlled within the animal food safety system.

In addition to utilizing the reasonably foreseeable language, AFIA recommends that the definition of "reasonably foreseeable hazard" be changed to include probable rather than potential hazards. Considering all potential hazards is unrealistic and the probability and severity must be considered in hazard analysis. AFIA recommends the addition of a "risk" assessment of the severity to further clarify that an animal food safety plan must consider the likelihood and severity of an animal food safety risk.

Proposed Rule with AFIA Recommendations

§ 507.33 Hazard analysis.

~~(d) The hazard analysis must consider the effect of the following on the safety of the finished animal food:~~

~~(1) The formulation of the animal food;~~
~~(2) The condition, function, and design of the facility and equipment;~~
~~(3) Raw materials and ingredients;~~
~~(4) Transportation practices;~~
~~(5) Manufacturing/processing procedures;~~
~~(6) Packaging activities and labeling activities;~~
~~(7) Storage and distribution;~~
~~(8) Intended or reasonably foreseeable use;~~
~~(9) Sanitation, including employee hygiene; and~~
~~(10) Any other relevant factors~~

(d) Assessments of the probability of a hazard may take into account the following factors, among others that may be relevant:

(1) The effectiveness of existing programs, such as CGMPs or other general controls, such as third-party certification programs;
(2) The frequency with which a potential hazard is associated with an animal food, ingredient, process, or other component of an animal food safety system;
(3) Method of preparation of the animal food;
(4) Formulation of the animal food;
(5) Storage and transportation conditions;
(6) Historical experience within the facility or with the product category; and
(7) Design of processing system.

AFIA Comments

AFIA agrees the evaluation of items stated in proposed §507.33(d)(1-10) can affect the outcome of the hazard analysis. The preamble discussion suggests that only *risks* posed by these factors should be considered, but AFIA strongly recommends that processors should also consider the benefits, advantages, augmentations or contributions to animal food safety from these items. Therefore we recommend deleting the language proposed in §507.33(d)(1-10). It should be replaced with a new d(1-7) as detailed above. AFIA believes this revised section on the assessments of a hazard at a facility is more consistent with FDA's Animal Feed Safety System. Again, AFIA supports using guidance documents to demonstrate appropriate and more specific expectations.

PREVENTIVE CONTROLS

Implementation of the Preventive Controls Requirements will be Difficult

This proposed rule presents a substantial burden to the animal food industry. Without a cost/benefit analysis to refute, and an unreasonably short timeframe to review the proposed rule, AFIA believes the cost is extremely high for the limited benefit provided to the animals fed in the U.S. This is highlighted in the report of the Mercatus Center regarding this rulemaking, which is referenced earlier in these comments. However, we understand that FSMA requires promulgation of this rule. Our goal is to provide comments that include recommendations which make the rules reasonable, and provide a distinction between the different segments of the large, diverse animal food industry in the U.S.

The varied segments of the animal food industry will need substantial time to fully implement the preventive control requirements. Many hours of training, much documentation, and many guidance documents will need to be developed to encircle this industry with the details and knowledge necessary to comply in all instances. AFIA will annually assess compliance efforts with this rule, when final, and make suggestions for changes and request extensions to the compliance schedule, where needed. Such requests will be accompanied by economic assessments and timeline analysis.

AFIA reiterates its commitment to continue providing training venues, working with the Food Safety Preventive Controls Alliance and developing guidance documents to assist in integrating this diverse industry into this new dawn of regulation to the maximum degree possible. Our formal FSMA training courses will begin this summer and continue for the next year with focuses on hazard analysis, CMGPs and preventive controls.

We strongly urge FDA to provide updated training for its inspection staff. As an example, our experience with medicated feed CGMP rules and implementation has been less than gratifying. There are still too many inspections conducted by inadequately trained FDA investigators that do not have sufficient familiarity with the medicated feed industry and its practices. We are gratified that FDA has chosen to sign agreements with state feed regulatory agencies that have trained inspectors who are commissioned FDA officers. AFIA members say these inspections and inspectors are far superior to those provided by FDA, primarily because they are near full-time feed inspectors, whereas many FDA inspectors spend limited time addressing animal food or have never been in a feed mill.

Finally, we reiterate our long-standing belief that the “C” in CGMPs represents what is current at a given point in time. Our industry is innovative and changes processes regularly. FDA investigators need to know about these changes by regularly attending training and industry expositions and meetings.

AFIA provides the following comments regarding FDA’s proposed preventive control requirements.

Proposed Rule with AFIA Recommendations

§ 507.36 Preventive controls for hazards that are ~~reasonably likely to occur~~known or reasonably foreseeable.

For hazards identified in the hazard analysis as ~~reasonably likely to occur~~ known or reasonably foreseeable:
(a) The owner, operator, or agent in charge of a facility must identify and implement preventive controls, including at critical control points, if any to provide assurances that hazards identified and evaluated in the hazard analysis ~~as reasonably likely to occur~~ that should be addressed in the animal food safety plan will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.
(b) Preventive controls must be written.
(c) Preventive controls must include, as appropriate to the facility and animal food:
(1) Parameters associated with the control of the hazard, such as parameters associated with heat processing, irradiating, and refrigerating animal foods; and
(2) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical~~, or radiological~~ parameters must be controlled to significantly minimize or prevent ~~a~~ hazards addressed in the facility's animal food safety plan ~~that is reasonably likely to occur~~.
(d) Preventive controls must include, as appropriate:
(1) Process controls that include those procedures, practices, and processes performed on ~~an~~ animal food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are ~~reasonably likely to occur~~ addressed in the facility's animal food safety plan
(2) Sanitation controls:
(i) Where necessary to significantly minimize or prevent hazards ~~that are reasonably likely to occur~~ addressed in the facility's animal food safety plan, procedures for the:
(A) Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of ~~utensils~~ tools and equipment; and
(B) Prevention of ~~cross-contamination~~adulteration from ~~insanitary~~ objects and from personnel to animal food, animal food packaging material, and other animal food-contact surfaces and from raw product to processed product, if such hazards are addressed in the animal food safety plan and risk of those hazards from these items are a potential and significant risk.
(ii) The owner, operator, or agent in charge must take action to correct, in a timely manner, conditions and practices that are not consistent with the procedures in paragraph (d)(2)(i)(A) or (d)(2)(i)(B) of this section
(iii) The owner, operator, or agent in charge of the facility is not required to follow the corrective actions described in § 507.42(a) and (b) when the owner, operator, or agent in charge of a facility takes action, in accordance with paragraph (d)(2)(ii) of this section, to correct conditions and practices that are not consistent with the procedures in paragraph (d)(2)(i)(A) or (d)(2)(i)(B) of this section.

(iv) All corrective actions taken in accordance with paragraph (d)(2)(ii) of this section must be documented in records that are subject to verification in accordance with Sec. 507.45(b)(2) and records review in accordance with § 507.45(c)(1)(i) and (c)(2).
~~(3) A recall plan as required by Sec. 507.38;~~ and
~~(4)~~ (3) Any other controls necessary to satisfy the requirements of paragraph (a) of this section.
(e)(1) Except as provided by paragraph (e)(2) of this section, the preventive controls required under this section are subject to:
(i) Monitoring as required by § 507.39;
(ii) Corrective actions as required by § 507.42; ~~and~~
(iii) Validation required by § 507.44; and [newly created section by AFIA]
(iv) Verification as required by § 507.45.
~~(2) The recall plan established in § 507.38 is not subject to the requirements of paragraph (e)(1) of this section.~~

AFIA Comments
AFIA firmly believes FDA should focus on language that will clearly differentiate between functions, processes and controls for facilities with animal food safety plans that identify microbial hazards and those that do not identify microbial hazards, and other known or reasonably foreseeable hazards. Sanitation of objects and surfaces may be appropriate for the former, but not necessarily for the latter.

As noted in our comments below, AFIA proposes removing the recall plan from inclusion in the proposed preventive controls animal food safety plan, and moving it to subpart B. Therefore it is deleted here. AFIA does not believe that FDA should add a requirement for facilities to conduct mock recalls as a verification activity in the final rule. Mock recalls are an industry best practice that is used as a training tool to improve upon the firm's ability to conduct efficient recalls and should not be mandated on how or when to complete one by FDA.

AFIA also has suggested a new section 507.44 on validation as discussed below. We are recommending it be added to the listing in this section.

Proposed Rule with AFIA Recommendations

~~§ 507.38 Recall plan for animal food with a hazard that is reasonably likely to occur.~~

~~(a) The owner, operator, or agent in charge of a facility must develop a written recall plan for animal food with a hazard that is reasonably likely to occur and assign responsibility for performing all actions in the plan.~~
~~(b) The written recall plan must include procedures for:~~
~~(1) Directly notifying direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;~~
~~(2) Notifying the public about any hazard presented by the animal food when appropriate to protect animal and human health;~~
~~(3) Conducting effectiveness checks (as described in part 7 of this chapter) to verify the recall has been carried out; and~~

~~(4) The proper disposition (e.g., destroying, reprocessing, or diverting to another use that would not present a safety concern) of the recalled animal food.~~

AFIA Comments
As stated in the comments on § 507.30 Requirement for a food safety plan, AFIA believes the recall plan should be included in subpart B. Therefore, we recommend deleting it here under subpart C. AFIA also does not support the notification requirement proposed here as it is duplicative of existing regulations for which the animal food industry should follow when conducting a recall in 21 CFR, Part 7 and the reporting requirements in the RFR.

Proposed Rule with AFIA Recommendations

§ 507.39 Monitoring.

(a) The owner, operator, or agent in charge of a facility must establish and implement written procedures for monitoring the preventive controls or cause these to be established where required by the facility's animal food safety plan. These procedures must include:
(1) What preventive controls will be monitored;
(2) Who will perform the monitoring;
(3) How the monitoring will be performed;
(4) What parameter will be measured, if applicable;
(5) Frequency with which the monitoring will be performed; and
(6) Any additional information needed to ensure appropriate monitoring of the preventive controls.
(b) Where required by the facility's animal food safety plan, ~~T~~the owner, operator, or agent in charge of a facility must monitor the preventive controls with sufficient frequency to provide assurance that the preventive controls are consistently performed.
(c) Where required by the facility's animal food safety plan, ~~M~~monitoring of preventive controls in accordance with this section must be documented in records that are subject to verification in accordance with § 507.45(b)(1) and records review in accordance with § 507.45(c)(1)(i) and (c)(2).

AFIA Comments
AFIA believes monitoring preventive controls is an important safeguard in a facility's animal food safety program, but only where the animal food safety plan requires performing such monitoring. Therefore, AFIA has recommended the addition of "where required by the facility's animal food safety plan" to § 507.39 (b) and (c) to clarify this requirement for FDA investigators and the animal food industry.

Proposed Rule with AFIA Recommendations

§ 507.42 Corrective actions.

(a) The owner, operator, or agent in charge of a facility must establish and implement written corrective action procedures that must be taken if preventive controls are not

properly implemented or found to be ineffective. The corrective ~~active~~ action procedures must describe the steps to be taken to ensure:
(1) Appropriate action is taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur;
(2) All affected animal food, if any, is evaluated for safety; and
(3) All affected animal food, if any, is prevented from entering into commerce if the owner, operator, or agent in charge of the facility cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.
~~(b) If a preventive control is not properly implemented and a specific corrective action procedure has not been established, or a preventive control is found to be ineffective, the owner, operator, or agent in charge of a facility must:~~
~~(1) Take corrective action to identify and correct the problem to reduce the likelihood that the problem will recur;~~
~~(2) Evaluate all affected animal food for safety;~~
~~(3) As necessary, prevent affected animal food from entering commerce as would be done following the corrective action procedure under paragraph (a)(3) of this section; and~~
~~(4) Reanalyze the food safety plan in accordance with Sec. 507.45(c) to determine whether modification of the food safety plan is required.~~
(~~c~~b) When corrective actions are taken for animal food safety issues, the corrective actions should be documented and verified~~they must be documented in written records~~. These records are subject to verification in accordance with § 507.45(b)(2) and records review in accordance with § 507.45(c)(1)(i) and (c)(2).

AFIA Comments
Corrective actions are important in the animal food safety plan and required by the statute. However, subsection (b) is not in the statute and should be deleted. If FDA keeps (b)(1-4) then the term "problem" should be replaced with "animal food safety issue" in (b)(1).

AFIA recommends that documentation be maintained for corrective actions only if the correction was made to address an animal food safety issue. The animal food safety plan should outline when a corrective action is required as well as the procedure to be followed. It is impossible to outline all unforeseeable animal food safety issues. The requirement should only focus on animal food safety issues and not quality issues. AFIA believes quality control is outside the scope of the statute and has recommended its removal elsewhere in our comments.

Proposed Rule with AFIA Recommendations

§ 507.44 Validation.

Where required by the facility's animal food safety plan, the owner, operator or agent in charge of a facility must validate that the preventive controls are identified and implemented in accordance with § 507.36. The validation of the preventive controls:
(a) Must be performed (or overseen) by a qualified individual:
(1) Prior to implementation of the animal food safety plan or, when necessary, during the first six months of production (a longer period requires written justification); and
(2) Whenever a reanalysis of the animal food safety plan reveals the need to do so;

(b) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazard(s) identified in the facility's animal food safety plan; and
(c) Need not address:
(1) The sanitation controls in § 507.36 (d)(2); and
(2) The recall plan in § 507.38.

AFIA Comments
AFIA recommends that FDA separate the "Validation" requirements from the "Verification" section and create a new "Validation" section. These processes are distinct, and the separation allows plant personnel to focus on each functional section. AFIA also recommends a modified definition for validation as discussed in our comments in Section I.

Proposed Rule with AFIA Recommendations

§ 507.45 Verification.

~~(a) Except as provided by paragraph (a)(3) of this section, the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented in accordance with Sec. 507.36 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:~~
~~(1) Must be performed (or overseen) by a qualified individual:~~
~~(i) Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production; and~~
~~(ii) Whenever a reanalysis of the food safety plan reveals the need to do so;~~
~~(2) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur; and~~
~~(3) Need not address:~~
~~(i) The sanitation controls in Sec. 507.36(d)(2); and~~
~~(ii) The recall plan in Sec. 507.38.~~
(~~b~~a) Where required by the facility's animal food safety plan, ~~T~~the owner, operator, or agent in charge of a facility must verify that:
(1) Monitoring is conducted as required by § 507.39;
(2) Appropriate decisions about corrective actions are being made as required by § 507.42;
(3) The preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are ~~reasonably likely to occur~~ identified in the facility's animal food safety plan; and
(4) The activities conducted must include, as appropriate to the facility and the animal food, calibration and/or accuracy checks of process monitoring and verification instruments.

(c) The owner, operator, or agent in charge of a facility must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards identified in the facility's animal food safety plan ~~that are reasonably likely to occur~~ by ensuring that a qualified individual is conducting (or overseeing):
(1) A review of the following records in the timeframe specified:
(i) Monitoring and corrective action records within 1 week after the records are made; and
(ii) Records of calibration of instruments where necessary, based on the control, within a reasonable time after the records are created.
(2) A review of the records in paragraphs (c)(1)(i) and (c)(1)(ii) of this section to ensure:
(i) The records are ~~complete~~adequate and contain the information required in subpart F;
(ii) The activities reflected in the records occurred in accordance with the facility's animal food safety plan;
(iii) The preventive controls are effective; and
(iv) Appropriate decisions were made about corrective actions.
(d) The owner, operator, or agent in charge of a facility must establish and implement written procedures, as appropriate to the facility and the animal food, for the frequency of calibrating process monitoring and verification instruments.
(e) The owner, operator, or agent in charge of a facility must:
(1) Conduct a reanalysis of the animal food safety plan:
(i) At least once every 3 years;
(ii) Whenever a significant change is made in the activities conducted at the facility operated by such owner, operator, or agent in charge if the change creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;
(iii) Whenever the owner, operator, or agent in charge becomes aware of new information about potential hazards associated with the animal food;
(iv) Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established;
(v) Whenever a preventive control is found to be ineffective; and
(vi) Whenever FDA requires a reanalysis in response to newly identified hazards and developments in scientific understanding.
(2) Complete the reanalysis and implement any additional preventive controls needed to address the hazard identified before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production;
(3) Revise the written animal food safety plan if a significant change is made, or document the basis for the conclusion that no additional or revised preventive controls are needed; and
(4) Ensure the reanalysis is performed (or overseen) by a qualified individual.
(f) All verification activities taken in accordance with this section must be documented in records.

AFIA Comments
AFIA believes this is a very complicated section for animal feed facilities, and in some cases unnecessary, based on the past history of this industry. This is the primary reason AFIA asks for

two, three, and four years to implement the animal food preventive control section of the proposed rule. There will be an urgent need for many training sessions (which AFIA is beginning to plan) and guidance documents (for which AFIA is cooperating with the Food Safety Preventive Controls Alliance) once the final rules are issued.

As indicated in the "Validation" comments, AFIA urges FDA to separate this section to better clarify what is required. At the same time, AFIA urges FDA to modify the terms *Validation* and *Verification* as recommended by AFIA in Section I.

Proposed Rule with AFIA Recommendations

§ 507.48 Modified requirements that apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.

(a) The owner, operator, or agent in charge of a facility solely engaged in the storage of packaged animal food that is not exposed to the environment must conduct the following activities for any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin formation by, microorganisms of animal or human health significance, where appropriate for the facility's animal food safety plan:
(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin formation by, microorganisms of animal or human health significance, as determined by the animal food manufacturer or qualified individual or qualified animal food safety team;
(2) Monitor the temperature controls with sufficient frequency to provide assurance they are consistently performed;
(3) Take appropriate corrective actions if there is a problem with the temperature controls for such refrigerated packaged animal food to:
(i) Correct the problem and reduce the likelihood that the problem will recur;
(ii) Evaluate all affected animal food for safety; and
(iii) Prevent the animal food from entering commerce, if the owner, operator, or agent in charge of the facility cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;
(4) Verify that temperature controls are consistently implemented by:
(i) Calibrating temperature monitoring and recording devices;
(ii) Reviewing records of calibration within a reasonable time after the records are made; and
(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within a week after the records are made;
(5) Establish and maintain the following records:
(i) Records documenting the monitoring of temperature controls for any such refrigerated packaged animal food;
(ii) Records of corrective actions taken when there is a problem with the control of temperature for any such refrigerated packaged animal food; and
(iii) Records documenting the verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

AFIA Comments
AFIA agrees with this proposed section with the addition noted in (a)(1) to clarify that temperature controls should be implemented when determined necessary by the facility or qualified individual.

Proposed Rule with AFIA Recommendations

§ 507.50 Requirements applicable to a qualified individual or qualified animal food safety team members.

(a) One or more qualified individuals must do or oversee the following:
(1) Prepare the animal food safety plan (§ 507.30));
(2) Validate the preventive controls (§ 507.45(a));
(3) Conduct a review of records for implementation and effectiveness of preventive controls and appropriateness of corrective actions (§ 507.45(c));
(4) Perform a reanalysis of the animal food safety plan (§ 507.45(e)).
(b) To be qualified, an individual or individuals on a team 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 education to develop and apply an animal 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. This individual may be, but is not required to be, an employee of the facility.
(c) 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 that "education" should be considered when determining whether an individual is "qualified." If FDA considers "education" to be part of "training," it should be included in this section as part of the definition of a "qualified individual." AFIA recommends the addition of "education" in this section and in the definition of "qualified individual" in our comments in Section I.

Proposed Rule with AFIA Recommendations

§ 507.55 Records required for this subpart C.

(a) The owner, operator, or agent in charge of a facility must establish and maintain the following records:
(1) The written animal food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures~~,~~ and verification procedures~~, and recall plan~~;

(2) Records that document the monitoring of preventive controls;
(3) Records that document corrective actions;
(4) Records that document validation;
(5) Records that document verification, including, as applicable, those related to:
~~(i) Validation;~~
(~~ii~~i) Monitoring;
(~~iii~~ii) Corrective actions;
(~~iv~~iii) Calibration of process monitoring and verification instruments;
(~~v~~iv) Records review; and
(~~vi~~v) Reanalysis; and
(~~5~~6) Records that document applicable training for the qualified individual or qualified animal food safety team.
(b) The records that the owner, operator, or agent in charge of a facility must establish and maintain are subject to the requirements of subpart F of this part.

AFIA Comments
AFIA agrees with the agency that companies must be required to maintain records. The above list seems appropriate with AFIA's suggested edits to separate out the sections on *validation* and *verification*. Our recommended edits reflect that *validation* and *verification* are different processes, and appropriately clarifies which records relate to *verification*.

As noted later in our comments, AFIA believes the required records are specific to each facility and should not be provided to the agency beyond a review during an agency inspection. The submission of hazards associated with each product and respective preventive controls offers little to no value in determining the level of risk in a review of records outside of the facility.

Section IV: Subpart F—Requirements Applying to Records That Must Be Established and Maintained

RECORDS AND REGISTRATION

Introduction and Overall Comments on this Section

AFIA understands that strong documentation and recordkeeping programs are an essential function of an animal food safety program. However, many items FDA has proposed are prescriptive in nature and could place an undue burden on some facilities to gather and maintain the information requested. AFIA members have also expressed concerns whether FDA will treat this information as confidential or not; we believe it should be treated in that manner. Many AFIA members consider their animal food safety programs as proprietary and confidential. This includes the design of the program, the hazard analysis and scientific assessment of those hazards, the preventive controls, testing times and frequency and the facilities' design and layouts. Providing this to FDA means the firms need a clear protection from disclosure to the public, as provided by the protections afforded facilities in the applicable exemptions of the Freedom of Information Act.

Flexibility is Necessary

Any recordkeeping requirements in the final rule should allow flexibility as the types of records, storage and maintenance of such records will vary by company and from facility to facility. For companies that have multiple production facilities, the storage of the animal food safety records will likely be maintained in centrally-located corporate files with easy access or at each facility. For example, records relating to suppliers, raw materials, consumer comments, validation and similar topics that are relevant to multiple facilities are routinely kept in a central location. Requiring such records to be kept at individual facilities for a period of time would not enhance public or veterinary public health. Keeping these records at individual facilities solely to allow FDA timely access when on-site would be duplicative and unnecessary. Also, FDA should not prescribe the types of records that are necessary, where appropriate, to accommodate the different forms of recordkeeping methods used in the animal food industry. These often vary by the type of facility and products produced.

Records are Best Understood when Shared On-site

AFIA believes that facility records are best understood when reviewed on-site and discussed between the facility personnel and the investigator during an inspection/audit. This facilitates better understanding regarding the records' meaning, significance and context. Facilities should not be required to provide records remotely (e.g., submit records to FDA through mail or electronically) because this practice will not enhance animal food safety oversight, and records could be taken out of context when not viewed at the facility with appropriate management personnel. Instead, remote sharing will likely lead to confusion and misunderstandings. Furthermore, FSMA does not provide a legal basis for a remote access requirement, and AFIA does not support such a requirement.

Specific Comments on the Provisions in Subpart F

AFIA provides the following comments regarding FDA's proposed records and registration requirements.

Proposed Rule with AFIA Recommendations

§ 507.50 Requirements applicable to a qualified individual.

(a) One or more qualified individuals or the qualified animal food safety team must do or oversee the following:

(1) Prepare the animal food safety plan (§ 507.30));

(2) Validate the preventive controls (§ 507.45(a));

(3) Conduct a review of records for implementation and effectiveness of preventive controls and appropriateness of corrective actions (§ 507.45(c));

(4) Perform a reanalysis of the animal food safety plan (§ 507.45(e)).

(b) To be qualified, an 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 education and/or job experience to develop and apply an animal 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. This individual may be, but is not required to be, an employee of the facility.

(c) 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 agrees with the language used by the agency in the above portion of the proposed rule. It is important to recognize that job experience could qualify a person to meet the requirements of the rule without having formalized training. AFIA does recommend adding "education and/or" language in (a) and (b) to reflect the similar edits made to the definition of *qualified individual* in our comments in Section I. A team of qualified individuals should be allowed and recognized as capable to handle the requirements of the qualified individual. Formal education should be recognized as a qualification in addition to the training or job experience options.

Proposed Rule

§ 507.100 Records subject to the requirements of this subpart F.

(a) Except as provided by paragraphs (d) and (e) of this section, all records required by this part are subject to all requirements of this subpart F.

(b) Records required by this part are subject to the disclosure requirements under part 20 of this chapter.

(c) All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services upon oral or written request.

(d) The requirements of § 507.106 apply only to the written animal food safety plan.

(e) The requirements of § 507.102(a)(2), (a)(4), and (a)(5) and (b) do not apply to the records required by § 507.7(e) pertaining to qualified facilities.

AFIA Comments
AFIA believes facilities should have the ability to submit records in electronic format during or after an inspection exclusive of Part 11 requirements. However, AFIA believes that all records should be reviewed on-site and FDA should not request those records prior to, or in lieu of, an inspection. The on-site review and discussion of the records with the appropriate personnel should not – and cannot – be replaced with an electronic submission or records. Because of the inherent risk of copying confidential documents, FDA should make every effort to refrain from doing so. A cooperative relationship can quickly deteriorate should FDA fail to protect confidential information.

Proposed Rule with AFIA Recommendations

§ 507.102 General requirements applying to records.

(a) Records must:

(1) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records~~, which must be kept in accordance with part 11 of this chapter~~;

(2) Contain the actual values and observations obtained during monitoring;

(3) Be accurate, indelible, and legible;

(4) Be created concurrently with performance of the activity documented; and

(5) Be as detailed as necessary to provide history of work performed.

(b) All records must include:

(1) The name and location of the plant or facility;

(2) The date and time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the production code, if any.

AFIA Comments
As a whole, AFIA disagrees with the agency's prescriptive approach to records management. The agency should not decide what the records should look like and what information should be in the records. This should be left to the discretion of the facility and outlined in the facility's animal food safety plan. A prescriptive approach limits the development of new technologies for recordkeeping. However, AFIA has no specific suggestions as to what should be required.

FDA's acceptance of electronic records for satisfaction of records requirements is appreciated. However, AFIA believes that compliance with 21 CFR Part 11 will be a significant burden to the industry and is unnecessary. The spirit, and in some places, the language of FSMA, encourages FDA not to require new business practices or specific requirements with respect to records. The industry currently has many types of records that will support FSMA requirements but do not meet the requirements of Part 11. Part 11 is very complex and few, if any, facilities would be able to meet the requirements for the rules proposed here without lasting and significant costs. The industry-wide cost of compliance would outweigh any benefit. Therefore, we are urging its removal from (a)(1).

Proposed Rule

§ 507.106 Additional requirements applying to the animal food safety plan.

The animal food safety plan must be signed and dated by the owner, operator, or agent in charge of the facility upon initial completion and upon any modification.

AFIA Comments

AFIA agrees that a signature is necessary, but would like clarification on "the agent in charge" in either the registration or definition section. The definition should be broad enough to encompass all individuals identified by the facility to perform the function. It should not be limited to the "agent in charge" as referenced within the actual FDA Facility Registration.

Proposed Rule

§ 507.108 Requirements for record retention.

(a) All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.

(b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained at the facility for at least 2 years after their use is discontinued (e.g., because the facility has updated the written animal food safety plan (§ 507.30) or records that document validation of the written animal food safety plan (§ 507.45(a)).

(c) Except for the animal food safety plan, offsite storage of records is permitted after 6 months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review. The animal food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.

(d) If the plant or facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location, but must be returned to the plant or facility within 24 hours for official review upon request.

AFIA Comments

AFIA understands that the FSMA statute requires retaining documents for two years after they are prepared. In the case of animal food, the two-year time frame may be an extremely long period of time when most of the animal feed is consumed by the animal within days after the feed is produced.

AFIA urges FDA to consider utilizing its authority under § 418 (m) of FSA to modify animal food recordkeeping from the two-year recordkeeping requirement to a one-year requirement. This would be consistent with the recordkeeping requirements for both CGMPs for medicated feed and what FDA is proposing for the veterinary feed directive (VFD) records.

FDA stated in the VFD proposed rulemaking preamble (78 Fed. Reg. at 75520) the following:

> "Based on our experience, FDA does not believe the extra 1 year of recordkeeping for VFD drugs is warranted for any of the involved parties. The value added by the second year of record retention has not been shown to justify

> the associated paperwork burden. FDA compliance investigations regarding violative drug residues in edible animal tissues are normally completed within the first year of their detection and nearly all of these are associated with dosage form drugs (i.e., non-feed use drugs). Therefore, FDA is proposing to reduce the recordkeeping requirement for copies of VFDs for all involved parties, and for manufacturing receipt and distribution records for VFD distributors, from 2 years to 1 year. Because the usual and customary records of purchase and sales kept by distributors to comply with the cGMP regulations in part 225 adequately support the VFD inspection program, we have not included the VFD receipt and distribution recordkeeping requirement found in current § 558.6(e) in this proposed rule."

AFIA believes the record-keeping traceback issues would be similar for FDA in the CGMP, preventive control and hazard analysis rules and would likely result in the same conclusion as stated above. AFIA, therefore, believes a one-year recordkeeping requirement for FSMA records would be adequate for animal food and urges FDA to use its § 418 (m) authority to change the recordkeeping requirements for hazard analysis and preventive controls. As the CGMP proposed rules are not authorized under FSMA, and FDA is using existing authority, the agency could require only one-year recordkeeping for CGMP records.

Section V: Appendix and Other Additional Issues FDA is Seeking Comments

PRODUCT TESTING AND ENVIRONMENTAL MONITORING

AFIA agrees 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 the facility. AFIA believes that the agency should not require either mandatory product testing or environmental monitoring across the entire animal food industry. Instead, the agency should recognize testing as a tool that a facility can utilize to verify that control measures are operating when an appropriate hazard has been identified. Flexibility should remain with the facility to implement the appropriate product testing or environmental monitoring program for their type of facility and products produced. The regulations and guidance documents should not dictate sampling frequency, locations, etc.

Comments Regarding Testing and Environmental Monitoring

FDA Must Provide for Additional Comment Period if Proposing Codified Language
AFIA appreciates the opportunity to provide feedback in response to the many questions FDA posed relative to the scope and specificity of requirements for product testing and environmental monitoring. In this proposed rule, FDA did not propose any codified language. AFIA requests that prior to FDA issuing a final regulation that may attempt to require testing, FDA provide an opportunity to comment on specific proposed codified language. It is important that FDA be transparent in providing a clear indication of what it would propose in order to meet the Administrative Procedure Act requirements, and to allow full and open public comment by all stakeholders.

Testing is a Verification Activity—Not a Preventive Control Measure
Testing, in Section 418(f) of the FD&C Act, is discussed as a means to verify implementation of preventive controls. 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. Thus, testing is ineffective as a preventive control measure.

Testing 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.

Testing better functions as a verification tool, when necessary and appropriate, rather than a measure that directly controls a hazard. 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.

In finished animal food products, if adulteration is present, it is often not possible for testing programs to detect adulteration due to statistical sampling limitations. Thus, finished product testing results can provide a false sense of reassurance as to the acceptability of a product. This proposed rule covers all types of animal foods, with a large variety of potential hazards, meaning that finished product testing will likely not be the most appropriate method to verify the effectiveness of a preventive control. In animal food, finished product testing, even as a verification tool, likely has limited applications in verifying acceptability.

AFIA believes that the necessity for, and the design and implementation of, an effective testing 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 testing 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 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.

Flexibility is Necessary

Although FDA is not proposing the product testing or environmental monitoring provisions at this time, the agency asked several questions in the preamble that lead AFIA to believe FDA would be prescriptive in any potential requirements. The level of specificity asked in the questions – if written into the regulations – likely could not be achieved in a general animal food rule to cover all product and facility types. 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 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 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.

If a facility implements a testing program, FDA should expect that such programs are appropriate and necessary to verify the effectiveness of CGMPs or process controls. However, it

is inappropriate for FDA to try to mandate specific program designs. Guidance documents can provide recommendations on the design of testing programs that can be specific to the type of facility and animal food products produced.

FDA Needs to Rework the Cost Estimates for Product Testing and Environmental Monitoring
If FDA proposes requiring product testing or environmental monitoring as a verification tool to ensure controls measures are adequate, the cost estimates must be recalculated as part of any proposal of testing requirements.

AFIA believes the projected costs FDA presented in this rulemaking notice for product testing are grossly underestimated, as it appears that the agency only considered biological testing. A mandatory chemical testing program for products for verification likely would be much more, and would depend upon the specific chemical or nutrient involved, the frequency of the tests, and the number of chemicals or nutrients tested. AFIA believes the costs outlined in the proposed rule do not take into account the additional costs associated with the labor to perform the tests and/or take samples, the inventory—carrying costs for product on hold awaiting test results, the costs of scrapping product that expires while waiting for delayed testing, the cost incurred when a false positive result is issued from a laboratory, and other related costs—all of which can add up to a much greater financial exposure to the manufacturer than contemplated in the current projected product testing costs presented in the rulemaking notice.

In the preamble to the rule, FDA estimates an annual cost of $3,500 per facility to implement an environmental monitoring program for *Salmonella* spp. This cost estimate assumes only 15 environmental samples are taken per month at the cost of $19.20 per sample tested. AFIA believes the number of environmental samples that could be taken would likely be much higher than 15 per month in some facilities. Current industry estimates also set the cost per sample for *Salmonella* spp. between $25 to $50 per sample. Clearly, FDA's consultant economist(s) did not explore this economic assessment with existing animal food facilities.

Specific Comments Regarding Product Testing

FDA Should Refer to "Finished Product Testing" Instead of "Product Testing"
In establishing section 418 of the FD&C Act, Congress used the phrase "product testing" and did not stipulate finished product testing or ingredient testing. In the preamble and appendix to the proposed rule, FDA has acknowledged that "product" could mean "ingredient" or "finished product." However, in much of its discussion, FDA has chosen to generally interpret "product testing" as "finished product testing." The statute also did not indicate the specific circumstances under which product testing is required, or the specific manner in which such testing should be performed.

While AFIA does not support FDA-mandated finished product testing, if FDA decides to pursue such testing, AFIA believes a product testing program for animal food should focus on finished products that are consumed by animals in accordance with the facility's animal food safety plan. A product testing program should not focus on the ingredients or raw materials used in making the finished products. A preventive control for ingredients and raw materials should be

implemented through a supplier verification program by the finished product manufacturer, where appropriate controls can be determined to ensure finished product safety.

Risk-Based Assessment Should Define Product Testing

AFIA agrees with the agency that the role of, and need for, finished product testing programs varies depending on the type of products, the activities performed at the manufacturing facility, and the potential hazards related to the intended use of the product. We appreciate FDA's understanding that the regulations should take a risk-based and flexible approach to the design of testing programs. To that end, AFIA believes finished product testing should be a tool for the hazard analysis process and respective risk assessment, as needed, and not mandated via regulation. Product manufacturers are best positioned to understand their customers' needs, the intended use of products and any potential hazards that could be introduced. A tremendous amount of flexibility should be allowed in a testing program to accommodate all the variations in the animal food industry. Thus, the manufacturer of the finished product should determine what is appropriate and necessary to ensure the product is safe and does not present a serious, adverse health consequence to animals. AFIA believes it would be impossible to prescribe specific testing requirements for all scenarios in the animal food industry in a regulation.

AFIA recommends that the agency should not mandate finished product testing and instead, FDA should recognize that finished product testing is a useful verification tool when determined to be appropriate and necessary based upon product risk and the facility's animal food safety plan.

Product Testing Should Include Biological and Chemical Preventive Controls

AFIA agrees with the agency that a product testing program encompasses biological and chemical testing. However, the preamble and proposed codified regulation focuses primarily on biological concerns, and does not draw a distinction between biological and chemical testing. For most animal foods, biological hazards are not a risk in manufacturing facilities.

Facilities that manufacture pet foods are the exception where biological hazards are closely controlled due to the potential risks associated with human handling. Historical perspective has shown biological risks from animal foods have not created animal food safety risks, excluding pet food. Animal foods should focus on concerns (such as mycotoxins) and nutrient toxicities or deficiencies that could result in animal food safety risks related to the animals consuming such animal food.

Chemical testing is complex, as it entails approved testing methods as well as personnel and facilities for a broad range of nutrients and/or compounds. The agency should avoid requiring product testing that is not clearly defined and unnecessary for the respective finished product.

Finished Product Testing Should Apply No Matter the Company Size

Given that the focus of FSMA is improving the overall safety of the animal food supply, AFIA does not believe the size of the company should be a factor in determining which companies are required to complete finished product testing. CGMPs are essential for all manufacturers to ensure the food supply is safe, and finished product testing should be considered a tool in the hazard analysis and risk assessment for any company manufacturing animal food—regardless of

the company's revenue stream or the number of people it employs. If a finished product is prone to the introduction of a hazard, the manufacturing company should conduct a thorough risk-based hazard analysis to determine what level of finished product testing it needs to incorporate into its verification program, if any. This is consistent with AFIA's approach to very small businesses, i.e., the threshold for a VSB should be animal food sales of less than $10,000 annually.

Use "Technically Sound" Rather than "Scientifically Valid"

Analytical methods for testing of products and ingredients need to be validated to confirm that they are capable of detecting and/or quantifying the item being tested. "Validated" is an appropriate term when referring to analytical methods where scientific validation is possible. However, certain aspects of sampling and testing can be scientifically validated while others cannot, but all aspects need to be based upon sound technical and practical considerations. AFIA recommends using the term "technically sound" instead of "scientifically valid" when referring to sampling and testing to account for the various aspects of testing programs and to avoid confusion with formal validation procedures.

Program Design Should be Flexible and not Mandated by FDA

FDA asks several questions in the preamble as to whether FDA should specify that certain requirements be included in a finished product testing program. **While AFIA does not support FDA mandating finished product testing**, we want to convey to the agency that any program proposed should allow for implementation appropriate to the facility, the product type and the intended use of the animal food product, and not be prescribed by FDA.

AFIA provides the following responses to the preamble questions below:

Preamble Comment Request #1:

- Specifying particular hazards, situations or product types for which finished product testing would be required

AFIA Comments

FDA should not attempt to predict every possible scenario where finished product testing would be required in animal food. If FDA sets one standard, a firm could simply design its program to only meet those regulatory requirements, and not implement a program that would best verify its actual animal food safety plan controls.

Preamble Comment Request #2:

- Specifying the frequency of testing and, if so, whether this frequency should depend on the type of product

AFIA Comments

Setting a specific frequency for testing in general or for specific product types should not be dictated by regulation. Instead, frequency should be determined by an appropriate hazard analysis and risk assessment – and subsequently-designed program – as determined by the qualified individuals at the facility.

Preamble Comment Request #3:

- Identifying appropriate sampling plans for finished product testing

AFIA Comments

FDA should recognize current industry best practices and guidance documents that provide facilities with a framework for establishing an appropriate sampling plan. FDA could recognize these documents by reference in a guidance document.

Preamble Comment Request #4:

- Requiring periodic testing for trend analysis and statistical process control

AFIA Comments

FDA should not be prescriptive in requiring a set amount of testing to conduct a trend analysis or to establish a statistical process control. A facility that chooses to implement finished product testing as a verification measure, where appropriate, will conduct regular analysis of the data as a means to determine trends indicating where loss of control may occur. FDA could write guidance to allow the agency flexibility in updating this recommendation based upon industry best practices and scientific knowledge.

Preamble Comment Request #5:

- Requiring written procedures for conducting finished product testing and, if so, also require that procedures for finished product testing be scientifically valid and include the procedures for sampling and the sampling frequency

AFIA Comments

AFIA believes it is reasonable for FDA to require written procedures regarding product testing if a facility is utilizing such a program as a verification tool. This documentation should include the procedures for sampling, the frequency of sampling and how this is determined. The finished product test that is used should also be documented. However, AFIA does not support FDA prescribing the exact procedure and frequency in the regulation as this can be dependent on the product being tested as well as the actual test to be used.

AFIA also urges the use of "technically sound" instead of "scientifically valid" as detailed in our comments above.

Specific Comments Regarding Environmental Monitoring

<u>FDA Should Allow Flexibility and Not be Prescriptive</u>

As noted above, AFIA urges FDA to allow facilities that utilize environmental monitoring as a verification tool to implement a program appropriate to their facility and product type. FDA should not be prescriptive in the requirement as indicated by the questions asked in the preamble.

AFIA provides the following responses to the questions below:

Preamble Comment Request #1:

- How and when environmental testing is an appropriate means of implementing the FSMA statutory directives?
- If included, at what appropriate level of specificity? For example, should the agency simply require the performance of environmental monitoring, for an appropriate microorganism of public health significance or for an appropriate indicator organism, if contamination of animal food with an environmental pathogen is a hazard reasonably likely to occur?

AFIA Comments

Environmental monitoring can be a useful verification tool utilized for measuring cleanliness and control measures in animal food facilities where environmental pathogens are determined to be a hazard. The animal food industry covers a wide range of product types and production facilities; therefore it would be very difficult for the agency to detail in regulation every possible scenario where environmental monitoring would be appropriate. AFIA opposes FDA mandating a specific requirement for environmental monitoring programs in animal food facilities in the final rule. The industry needs flexibility to utilize industry best practices regarding when and how to establish an environmental monitoring program for their facility, processes and product types. This should be a voluntary tool used by any facility within the context and requirements of the facility's animal food safety plan.

AFIA also believes the term "reasonably likely to occur," as used in the second bullet point above, is not appropriate for use in the rule as it does not appear in the statute. Please see AFIA's comments regarding this topic in the Introduction and Section III.

Preamble Comment Request #2:

- Specifying the environmental pathogen or the indicator organism for which the samples must be tested.

AFIA Comments

AFIA believes that FDA should not specify the environmental pathogen or the indicator organism for which an animal food facility must test. Each facility should have the ability to establish their own specific monitoring plan if an environmental pathogen is determined to be a hazard that needs to be controlled in that facility, as per the facility's animal food safety plan. If the agency is prescriptive in the regulation regarding the specific pathogen or organism, it could potentially limit the ability to enforce the regulation if new science indicates other organisms should be the focus of such monitoring. FDA should work with industry to recognize current industry guidance and best practices, or to develop guidance where necessary, to assist the animal food industry in the proper design and utilization of environmental monitoring programs if one is used as a verification tool.

Preamble Comment Request #3:

- Specifying the corrective actions that should be taken if environmental testing identifies the presence of an environmental pathogen, such as:

- Conducting microbial sampling and testing of surrounding surfaces and areas to determine the extent of the contamination and the potential source of the contamination;
- Cleaning and sanitizing the contaminated surfaces and surrounding areas to eliminate the test organism;
- Conducting additional microbial sampling and testing to determine whether the contamination has been eliminated; and
- Conducting finished product testing.

AFIA Comments
AFIA recommends that FDA not mandate specific corrective actions that should be taken upon the finding of an environmental pathogen. Corrective actions should be implemented where appropriate and necessary when environmental monitoring indicates a process control is not working as per the facility's animal food safety plan. However, the specific corrective action that should be put in place will vary by the facility, the process utilized, and the products produced by that facility. The corrective action should be based on the actual cause of the issue.

The examples of corrective actions that FDA has listed here are indeed, very likely the next steps a facility utilizing environmental monitoring could be expected to take; however, they are not the only ones. Mandating just one or a set of specific corrective actions will also limit the ability of the industry to adapt and adopt new technologies and strategies that may be developed as a means of industry best practices.

Regarding FDA's suggestion to require finished product testing as a corrective action when an environmental pathogen is found, AFIA believes this step should not be mandated. When an environmental pathogen is identified, the facility should evaluate data from their environmental monitoring and process controls and also the risk of the pathogen being transferred to the finished product. If the risk is high, then a facility may choose to conduct finished product testing, but finished product testing should not be mandated for every instance.

As noted previously in AFIA's comments for the proposed CGMPs, AFIA also urges FDA to move away from using the term "sanitation" with regards to animal food facilities, and instead rely upon "cleaning" as the appropriate term. For more explanation, see our comments in Section II.

Preamble Comment Request #4:
- Specifying the locations within the facility at which samples must be collected;

AFIA Comments
FDA should not mandate the specific locations within the facility for collecting samples. The qualified individual or qualified animal food safety team establishing the monitoring program should be allowed the flexibility to establish the sampling locations based upon the risk and the features of that specific facility. One problem with mandating specific sampling locations is that facilities could interpret it as detailing the only locations that need to be sampled.

Preamble Comment Request #5:

- Specifying the frequency of collection of environmental samples (e.g., weekly or monthly depending on risk). For example, should the frequency of collection:
    - Be greatest for animal foods that are likely to be handled by certain vulnerable populations, such as children, the elderly, and individuals with compromised immune systems after a minimal treatment that may not adequately reduce the environmental pathogen?
    - Be greater for an environmental pathogen that is frequently introduced into a facility (e.g., Salmonella spp., which is ubiquitous in the environment and can be continually introduced into a facility from many routes, including ingredients, people and objects (Ref. 94)) than for an environmental pathogen that is less frequently introduced?
    - Be greater for products that undergo significant handling and exposure to the environment than for products that undergo limited or no handling or have little exposure to the environment?
    - Increase as a result of finding the environmental pathogen or an indicator of the environmental pathogen or as a result of situations that pose an increased risk of contamination, e.g., construction? (Refs. 94 and 95).

AFIA Comments

The frequency for environmental sampling should be decided upon by the animal food facility based on a risk analysis, and results of sampling data and process control activities in accordance with the facility's animal food safety plan. FDA could provide a list of factors to consider when establishing sampling frequency; however it would be nearly impossible for the agency to prescribe specific frequencies given the breadth of facility types and products in the animal food industry. Again, if a specific frequency is prescribed, there is a risk that facilities could interpret the regulation as meaning only that specified number of samples needs to be collected – no matter how appropriate based on actual risk.

Preamble Comment Request #6:

- Requiring written procedures for conducting environmental testing and, if so, also requiring that procedures for environmental testing be scientifically valid and include the procedures for sampling and the sampling frequency;

AFIA Comments

AFIA believes it is reasonable for FDA to require written procedures on environmental testing procedures if a facility is utilizing such a program as a verification tool. This documentation should include the procedures for sampling and the frequency. However, AFIA does not support that the exact procedures and frequency of testing be prescribed in the regulation.

AFIA also urges the use of "technically sound" instead of "scientifically valid" as detailed in our comments above regarding product testing.

Preamble Comment Request #7:

- Requiring data analysis to detect trends.

AFIA Comments
Analyzing data from a facility's environmental monitoring program is a valuable tool in verification of process controls, especially in determining trends where loss of control may occur. However, the manner and frequency in which a facility must conduct such analysis should not be prescribed in the regulation. Instead, guidance should be written to allow the agency flexibility in updating this recommendation based upon best industry practices and scientific knowledge.

Preamble Comment Request #8:
- The agency further requests comment on whether there is benefit in conducting routine environmental monitoring for other organisms in addition to, or instead of, the environmental pathogen of concern.

AFIA Comments
When a specific animal food facility has determined an environmental pathogen is a hazard that needs to be controlled, AFIA believes there may be benefit in conducting routine environmental monitoring for other organisms in addition to, or instead of, the environmental pathogen of concern. Routine environmental testing for pathogen index organisms or other indicators can be useful in providing a broad picture of the facility's sanitation status. However, this broadened sampling will be dependent upon the facility and processing situation, and should not be prescribed in the regulation.

<u>AFIA Agrees with the Identified Indicator Organisms</u>
FDA Proposal
"FDA's current thinking is that *Listeria* spp. may be an appropriate indicator organism for *L. monocytogenes*, because tests for *Listeria* spp. will detect multiple species of *Listeria*, including *L. monogytogenes*. However, FDA's current thinking is that there are no currently available indicator organisms for *Salmonella* spp."

AFIA Comments
AFIA agrees that no indicator organism for *Salmonella* spp. has been identified in the animal food manufacturing environment. AFIA would like to note that the industry currently utilizes several other cleanliness indicators (i.e., *Enterobacteriaceae* or Total Plate Count) as a mechanism to monitor the processing environment. While these indicators may not always directly correlate with *Salmonella*, they are useful tools to monitor whether the cleaning program is effective. Often these indicators are found before other pathogenic microorganisms, like *Salmonella*, and can play an important role in an environmental monitoring program.

AFIA agrees that *Listeria* spp. is an appropriate indicator organism for *L. monocytogenes* when it has been identified as an environmental pathogen of concern for a specific processing facility where *Listeria* growth is of concern.

<u>FDA Should Not Focus on *Listeria* in Ruminant Animals</u>
FDA makes a statement that listeriosis occurs in a number of animals species, especially ruminant animals. AFIA agrees that listeriosis does occur in some animals; however, since *Listeria* occurs naturally in the soil and environment, animal feed is likely not a significant

source of this disease. We acknowledge that it may be a concern for certain ruminant feeds that may contain certain ingredients (i.e., raw milk or contaminated silage). AFIA notes that in most cases, raw milk and silage are typically used on-farm and do not enter into commerce. Therefore, they are not generally regulated as a commercial feed and would be outside the scope of this regulation.

Again, each facility, when identifying potential hazards, would make a determination if this is a hazard and put a control mechanism in place. Environmental monitoring is a verification tool that can be utilized by a facility where an environmental pathogen is determined to be a hazard that needs to be controlled. AFIA believes it is very likely that this concern or risk could be addressed by other means in a facility's animal food safety plan and/or proper supplier verifications on incoming ingredients, and/or checking the pH of the silage product before use in ruminant rations, and likely would not require environmental monitoring.

SUPPLIER APPROVAL AND VERIFICATION

AFIA supports establishment of supplier verification requirements as part of the CGMPs for animal foods. AFIA believes FDA's approach to supplier verification should incorporate the current leading practices in place today that result in successful animal food safety programs. The regulation should be carefully developed with input from supply chain management experts to ensure the new requirements are practical to implement and will improve animal food safety. It is important for FDA to conduct further research on current leading supplier verification practices to ensure any proposed rule is not a significant diversion from these well-established, effective programs. Furthermore, FDA's supplier verification requirements should not place an undue cost burden on this industry. The individual facility or corporation should retain the flexibility to implement any such program, and any regulations should not be prescriptive.

Below, AFIA provides overarching comments regarding the role of supplier verification in the animal food industry and in this regulation. AFIA also addresses specific questions raised by FDA in the preamble. To provide further clarity and understanding by industry and FDA, AFIA also proposes definitions for *receiving firm*, *receiving facility* and *supplier* in our comments in Section I.

<u>FDA Must Provide a Formal Comment Period for Additional Comment if it Proposes Codified Language</u>

AFIA appreciates the opportunity to provide feedback in response to the many questions FDA asked regarding the scope and specificity of requirements for supplier verification. In this proposed rule, however, FDA did not propose any codified language. AFIA requests that FDA provide an opportunity to comment on specific codified language before it issues a final regulation that may attempt to require supplier verification. FDA should be transparent and provide a clear indication of what it will propose to meet the Administrative Procedure Act requirements and allow full and open public comment by all stakeholders. It should also provide a reasonable economic analysis by contacting AFIA and requesting estimated costs for such an effort.

<u>FDA Needs to Rework the Cost Estimates for Supplier Verification</u>

When FDA provides for that additional opportunity to comment on proposed codified language, the cost estimates must be recalculated. AFIA believes FDA's projected costs for supplier verification are grossly underestimated.

AFIA agrees with FDA's assertion that the vast majority of costs related to a supplier approval and verification program are due to verification activities, such as audits and testing of raw materials and ingredients. Such verification activities should be based on the hazard associated with the raw material or ingredient, and where the hazard is controlled. Although the agency is not including a provision for such a program in this proposed rule, AFIA feels the agency grossly underestimated the costs of implementing a supplier verification program. Additional staffing will be required, mostly to maintain and manage the documentation, as well as implementing the verification activities, such as testing and audits. Many animal food facilities work with several

hundred suppliers, which are not considered in FDA's estimates. Therefore, we urge FDA to reconsider the cost estimate for this provision in any subsequent rulemaking. AFIA would be pleased to discuss these cost estimates and collect appropriate data and costs.

Flexibility in Program Design is Necessary to Continually Improve Animal Food Safety

A regulation that imposes regulatory requirements without encouraging thoughtful analysis and dialogue within a company or facility will miss an important opportunity to improve animal food safety in the industry. Details, such as requiring mandatory annual supplier audits versus only a detailed review of a supplier's regulatory compliance documentation, versus a one-size-fits-all approach, will cause firms to focus on compliance with the regulation rather than prevention and continuous animal food safety improvements. This is not FSMA's primary goal, and it should not be FDA's.

Supplier Verification is a Foundational Program Already in Place Today

AFIA recognizes the importance of supplier verification within an animal food safety system. Our experience teaches us that supplier verification *verifies* whether the animal food has been produced under a strong animal food safety program. It does not, *itself,* make animal food safe. Rather, it is a foundational program – one component of an integrated system of controls that operate collectively to deliver safe animal food. Many of our members manage their supplier verification programs at the corporate level and apply them to the entire company.

Under HACCP, which FSMA does not mandate, supplier verification is a prerequisite program. Like CGMPs, pest control, or other programs, supplier verification establishes the foundation for a sound hazard analysis program. Supplier verification is a foundation in any sound animal food safety program. Therefore, our members believe it is critical to have a level of visibility into their supply chains. This allows them to perform some degree of supplier due diligence for most ingredients.

Animal food safety issues can be created by various hazards. Our experience teaches us that animal food safety programs are most effective when applied across the board because both the largest and smallest suppliers are still subject to the same risks if appropriate controls are not in place. Companies engage in some level of supplier verification for most suppliers, no matter their supplier's size or sophistication. There are some limited, very low-risk situations where a company does not typically engage in supplier verification. One particular instance is intra-company shipments between business units owned by the same corporate parent. Also, certain commingled raw agricultural commodities should be exempt from supplier verification, because of the complex nature of the supply chain and the low animal food safety risk, which we discuss later in this section.

An Effective Supplier Verification Program Includes Both Supplier and Ingredient Risks

The level of risk associated with both a supplier and the incoming ingredient need to assessed before determining verification activities. The severity and probability of the risk, as well as the intended use of the ingredient, are considered by our members to determine the most appropriate verification activities. Basing the risk assessment on both the supplier and incoming ingredient provides a more robust verification program for higher risks to the animal food safety program. Due to the large number of suppliers and various types of ingredients used by our members,

some companies group supplier or ingredients into categories based on the type of risk (severity and probability). This provides more efficient preventive controls for potential risks.

Audits can Play an Important Role but Limitations Apply

The scope of an audit typically determines the type and depth of a supplier audit. Our members need the flexibility to determine what is most appropriate for their suppliers. This allows them to implement a tailored, animal food safety risk-based program. Regardless of the type of audit (second-party or third-party), AFIA agrees that it is important that audits are conducted by an appropriately qualified individual and the appropriate checks are in place to account for conflicts of interest.

Many third-party audits completed by our members are conducted under the Safe Feed/Safe Food or Pet Food Manufacturing Facility Certification Programs managed by AFIA and SQFI. AFIA strongly recommends recognizing third-party certifications. This supports receiving companies' supplier verification program.

AFIA agrees that third-party audits will prevent duplication by companies, as a single third-party audit of a supplier can satisfy the requirements of multiple customers. Our members assess the information provided by third party audits and determine if additional verification activities are needed, and may conduct their own second-party audit.

Although supplier audits are an important verification activity, they do not control hazards or change the inherent risk of an ingredient. Supplier audits are only a "snapshot" of a supplier's performance. Nevertheless, audits are a valuable tool because they provide insight into a supplier's animal food safety system. They assist purchasers in deciding if a supplier has an adequate animal food safety program, if the facility is following the program at the time of the audit and the likelihood it will be followed in the future.

Audit Information Should be Considered Confidential

Confidentiality protections are necessary for effective supplier audits. Confidentiality encourages robust scrutiny and an open dialog without causing fears about consequences from an FDA review of the resulting paper trail. Currently, companies may experience push-back from suppliers that seek to conduct second-party audits, because some suppliers are hesitant to allow customers into their facilities. For an effective second-party audit, information gathered during the audit must remain confidential. Suppliers oftentimes will not allow their customers sufficient access to their facilities and records without an adequate assurance of confidentiality from the receiving company (nondisclosure agreements). Confidentiality is a key prerequisite for a comprehensive animal food safety audit. Thus, it is essential that FDA not have routine access to the underlying audit reports.

Brokers or Distributors Should be Responsible for Supplier Verification

AFIA is concerned that its members will be accountable for the supplier verification of ingredients or raw materials from brokers or distributors. AFIA recommends that brokers and distributors be responsible for developing a supplier verification program for the ingredients/materials provided to receiving companies. The broker or distributor should be responsible for ensuring its suppliers meet internally defined supplier verification requirements. The receiving company is responsible for ensuring the broker or distributor meets the receiving

company's specifications for ingredients/materials it receives. As a supplier to the receiving company, the broker/distributor will be required to comply with the receiving company's supplier verification requirements also. The two parties should work together to ensure the requirements for the receiving company are met. A recognized third-party certification program for the animal food industry, such as Safe Feed/Safe Food Certification Program, should be considered a viable tool for an effective supplier verification program.

Supplier Verification is Typically Managed on the Corporate Level

It would be tremendously inefficient if FDA inspects a supplier verification program at the facility level. This could mean a company with 20 facilities has its supplier verification program inspected 20 different times. Instead, inspection of these programs should be addressed at the corporate level if the company manages the program in such a manner. The regulatory language should provide the flexibility to allow for supplier verification at the corporate level.

COMPLAINT FILES AND FACILITY PROFILES

Starting on 78 FR at 64809, FDA asks for comment on other potential provisions that are not explicitly included in Section 418 of the FD&C Act. As in our comments on other provisions that are not proposed in the rule, AFIA respectfully requests that FDA propose codified language for comment before making these provisions part of the final rule. Specific responses to the two potential issues are below.

FDA Should Not Require Complaint File Review to Verify the Preventive Controls
AFIA believes that an animal food facility or corporation should have a procedure in place to accept and review complaint files. In fact, this is a provision required in the AFIA certification programs of SF/SF and PFMFCP. However, AFIA does not agree that this should be mandated in the preventive control rule for animal food.

The procedure for receiving and handling complaints will vary by company and facility across the scope of the animal food industry. FDA should not try to mandate a one-size-fits-all approach when firms should have the flexibility to utilize the system that is best for their situation. As the agency has noted, complaints received cover a broad set of topics related to the product beyond the complaints related to animal food safety. These other complaints can and do include complaints on packaging, fines, color, odor and many other parameters. These non-animal food safety complaints comprise the overwhelming majority of complaints received by firms. Only those issues pertinent to animal food safety are important for FSMA purposes.

Because of the short comment period, AFIA has not completed a full economic analysis of the agency's estimated annual cost of $2,800 per facility. However, AFIA has heard feedback from our members that this figure is absurdly low. Also, on quick review, FDA estimates that the total annual cost for domestic facilities would only be $1,767,000. This figure, when divided by the average cost per facility ($2,800) is only 631 facilities. In other words, FDA's estimates do not correlate with the actual number of domestic facilities. There are far more than 631 domestic facilities that will be affected by this rule. FDA has inadvertently utilized the foreign facilities number and reduced it by a factor of 10 fold.

If the actual number were utilized based on FDA's February 19 registration website numbers, the number of domestic facilities which would require a complaint file would be 18,627. This would amount to a total domestic cost of $52,155,600 based on an FDA estimated cost of $2800 per facility. AFIA believes that the number of facilities and the estimated cost per facility proposed by FDA is extremely low. If FDA proposes adding this provision, the economic impact must be reassessed and be realistic. Furthermore, AFIA would be pleased to provide more realistic costs to maintain complaint files at a domestic animal food facility.

Facility Profile Information Should Remain as Basic Information
FDA requests comments on whether additional data elements should be submitted with the facility profile information at time of reregistration. Such additional information would include the hazards identified for each product, the preventive controls established, any third-party certification information and training conducted. FSMA does not provide the agency with the authority to require the submission of such information. AFIA also believes that proper

interaction is necessary between the facility and investigator to properly understand the components of its animal food safety plan, specifically (1) the hazards identified and (2) the preventive controls established. Therefore, AFIA does not agree that this information should be required for submission in a facility profile at reregistration. Nor should this information be sent to the FDA in advance of an inspection. As an industry practice, animal food safety plans are not disclosed beyond the firm. In many cases, it is company policy not to make these types of documents (e.g., preventive controls) available beyond the facility.

Additionally, the maintenance of such facility information, specifically the product list, the hazards and preventive controls, frequently change depending upon the product and processing facility. Keeping this information current would create an undue burden. Any facility profile information that is not properly maintained would not be useful to FDA.

This concludes AFIA's specific comments to the proposed rules and specific questions and issue raised by FDA in this rulemaking.

Section VI: Summary and Conclusions

AFIA's efforts in responding to this proposed rule have been related to five major areas:

- Refocusing the rule to better comply with the statutory intent and requirements, which includes removing HACCP references and requirements. This includes removing references to "hazards that are reasonably likely to occur" and returning to the statutory language "known or reasonably foreseeable hazards."
- Redefining and redrafting the CGMPs to make them more practical and less prescriptive, thereby allowing for innovation and better understanding by the animal food industry.
- Making clear references to requirements that should be related to different types of facilities (e.g., pet food or ingredient), so that inspections/audits of the facility are related to the facility's animal food safety plan and not some predetermined idea about the expectations of a plant related to the highly subjective language of the proposed rules. An example would be a requirement by an investigator for potable water, where the facility's animal food safety plan has not identified any hazards in the well water the plant may be utilizing.
- Simplifying the language, such that terms and concepts used in the animal food industry are utilized. For example, replacing terms such as "utensils" by "tools."
- Ensuring that the intent and language of the rules are truly dedicated to the animal food industry and not the human food industry from which they originated.

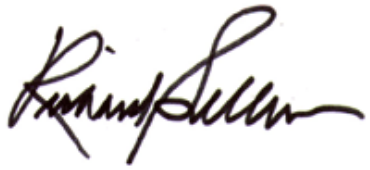
In these comments, AFIA has provided its best efforts to respond to a massive set of proposed rules with more than 44 questions for which FDA has requested comments. We are very disappointed that there was insufficient time to review FDA's economic analysis, as AFIA believes the estimated costs were very low and unrealistic. This is primarily because FDA utilized what AFIA believes is faulty data in assessing costs. Moreover, the lack of a cost/benefit analysis further concerns AFIA. While agreeing that Congress mandated the development and publication of these rules; AFIA believes FDA failed to follow statutory intent required by the Administrative Procedure Act by its failure to estimate a cost/benefit of these rules. AFIA believes the benefits of these rules are low, with very high costs placed upon the industry as indicated in the George Mason University's Mercatus Center study.

Several FDA officials have indicated publicly that the agency is considering filing additional proposed rules governing issues OMB removed from the proposed rules before publication. This will likely raise the costs if they are related to supplier verification, environmental testing and/or product testing. Further burdens to the animal food industry are not justified given the limited benefits.

AFIA will continue reviewing the proposed rules, estimating costs of the rules and filing comments throughout the year. Our goal is to continue to provide FDA with the best information on the animal food industry, develop non-prescriptive rules that promote innovation and push FDA to reduce the costs and to better approximate the benefits.

AFIA appreciates FDA's consideration of these comments.

Sincerely,



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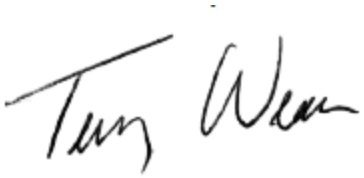

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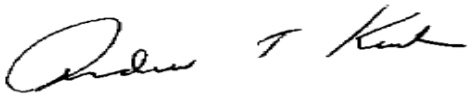

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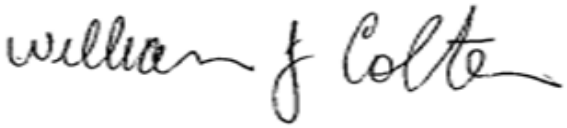

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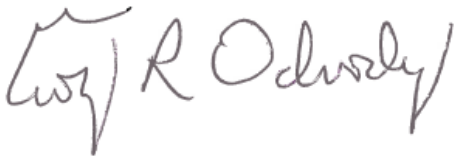

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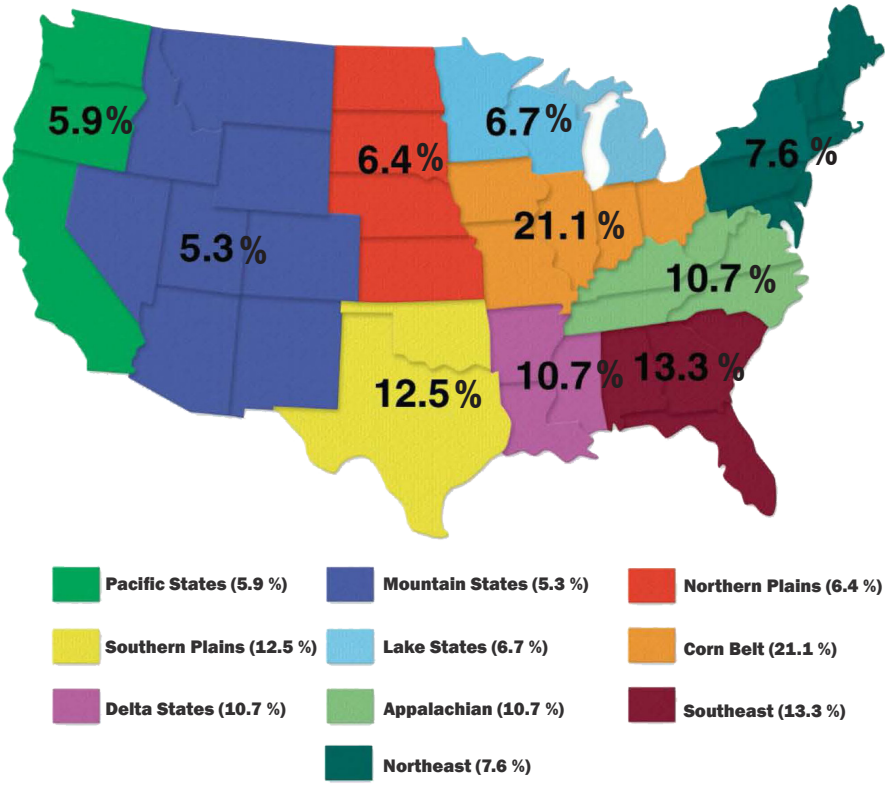
U.S. FEED INDUSTRY STATISTICS

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

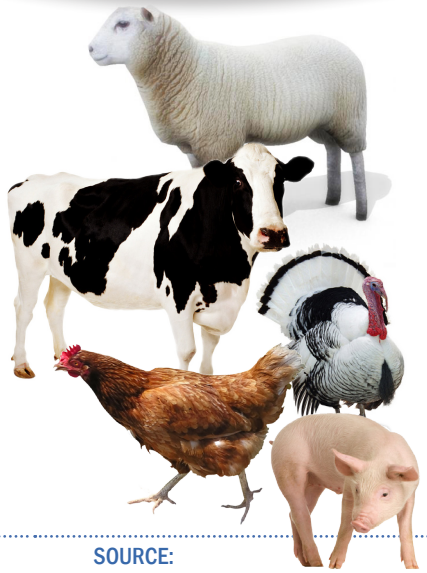
During 2013 the U.S. feed industry donated $3 million toward local communities and volunteered 46,500 man-hours toward various causes. According to survey results, AFIA members most-frequently invest in community development activities or charitable giving towards education (schools, scholarships and 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*



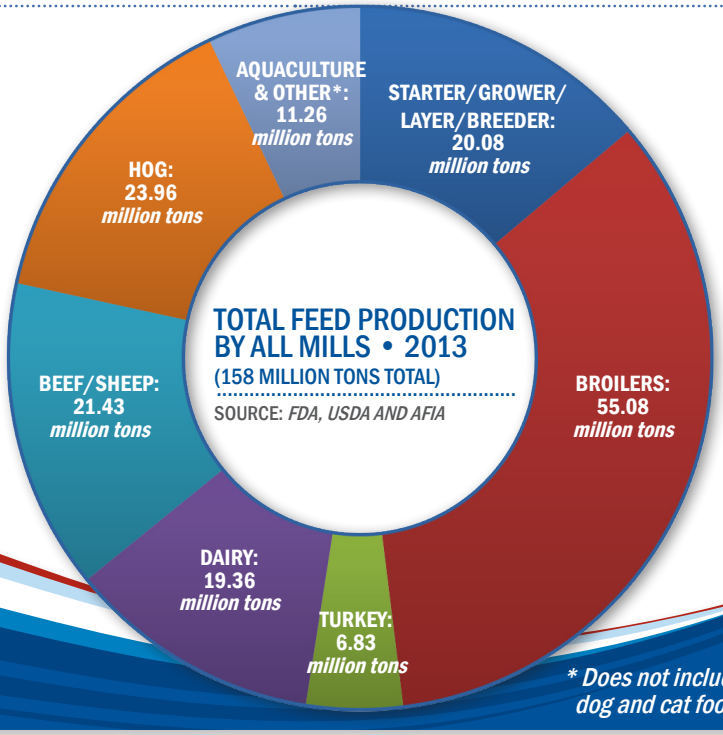
RAW MATERIALS USED IN FEEDS:

	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.*

This report was generated by the authors at the request of AFIA to provide evaluation and opinion of the potential spread of a communicable disease from humans to animal through animal feed. What is the "risk" of animals getting sick from pathogens spread by human through animal feed?

Summary conclusion

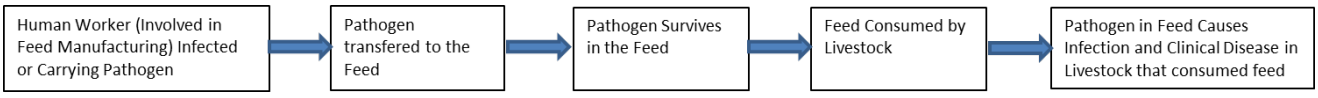
The above question was considered in the context of disease spread from humans involved in the preparation of feed to livestock through the animal feed, thus the feed would be acting as a fomite for the disease spread. Literature review on documented cases of transmission of diseases from human to animal as well as potential transmission from human to animal was completed. In addition a review on major recognized zoonotic pathogens was completed. These reviews were summarized in Table 1 and Table 2.

Key findings:

1. No documented cases of human to animal spread of disease through animal feed from humans involved with the manufacturing of the feed in peer reviewed literature.
    a. 2 studies ([14, 21]) reviewed showed the feed as a source of reported zoonotic pathogens, however no studies showed a relationship form human contact in the feed manufacturing with the contamination of the feed with zoonotic pathogens
2. Potential relevant transmission routes for spread via the proposed situation exist, however the significance of these transmission routes and likelihood for disease spread is unknown.
    a. Fecal-oral, or fecal contamination of feed
    b. Feed contaminated by urine or secretions
    c. Fomites (feed) contaminated with body fluids

In the opinion of the authors of this report, based on the information available **it is unlikely that animals would get sick from pathogens spread from humans involved in feed manufacturing to livestock through animal feed**. This is based on the understanding that basic sanitation facilities are available at feed manufacturing facilities, accepted pathways for known zoonotic pathogens and documented cases of reverse zoonosis in peer reviewed publications available, applied to question addressed.

Basic Pathway Steps for Pathogen Spread:



Methods

A literature review was conducted through scientific databases such as PubMed, University of Minnesota Library (MNCAT Discovery and Libraries catalogue), Google Scholar and Google search engines including only English journal articles and books. Search terms included: *reverse zoonosis, zooanthroponosis, human-to-animal transmission, human-to-animal disease transmission, human-to-animal AND feeds, reverse zoonosis AND feed, reverse zoonosis AND livestock, anthroponosis.* A recently

published article *Reverse Zoonotic Disease Transmission (Zooanthroponosis): A Systematic Review of Seldom-Documented Human Biological Threats to Animals*[1], which provides an overview of published literature on reverse zoonoses, was also explored and all relevant references for the article were reviewed.

Table 1. Documented Reverse Zoonoses in Livestock: summarizes the main findings related to livestock species and documented cases and possible cases of reverse zoonoses. Reports of non-disease-causing agents (e.g. common gastrointestinal bacteria) and reports showing little evidence or association on human-to-animal transmission were excluded.

Table 2. Zoonoses in six livestock species: summarizes zoonoses in 6 livestock species, namely horse, cattle, goat, sheep, swine and poultry, extracted from *Human-Animal Medicine: Clinical Approaches to Zoonoses, Toxicants, and Other Shared Health Risks*[2]. An assumption on bidirectional transmission was made assuming that if a disease can transmit from animals to humans, the spread in the other direction (human-to-animal) could occur. This was done to conservatively evaluate the potential risk of these known zoonoses for the purpose of opinion development.

Conclusion on the likelihood of infection of animals through feed contaminated by human contact was then drawn based on the information in Table 1 and Table 2.

Definitions

Reverse zoonoses: as defined in Saunders Comprehensive Veterinary Dictionary, 3 ed. © 2007, infections transmitted from humans to animals.

Zoonoses: diseases of non-human animals that may be transmitted to humans or may be transmitted from humans to non-human animals (National Institute of Health MEDLINE database).

Tables

Table 1 contains the following elements:

1. The **agent** as identified in the literature(s)

2. The **disease** caused by that particular agent in humans and animals: These listed diseases have been documented to be specifically transmissible from humans to animals. Other diseases or illnesses resulted from infection of the agent in humans or animals but have not been documented on human-to-animal transmission are excluded. *No reported* is indicated when the agent could result in a number of diseases and the report did not mention specifically what disease infected humans and animals had.

3. **Types of infected animals** focusing only on livestock species.

4. **Mode of transmission**: Specific mode of transmission of each peer-reviewed publication is reported. If mode of transmission for that particular instance of reverse zoonosis was not mentioned; *Not reported* is used. *Unclear* is used when reports clearly stated the transmission method is unclear.

5. **Reference** for publication organized by number is provided at the end of the table. References are in the same order found in the "References" section at the end of the report.

Table 2 contains the following elements:

1. The causative **agent** for that particular zoonotic disease

2. The **disease** caused by that particular agent

3. **Types of animals**: As this report has a focus on livestock, six species- horse, cattle, goat, sheep, swine and poultry, are selected in this table. A cross mark is given when animals in that species can contract that specific disease and pass it to humans.

4. **Zoonotic transmission route** summarized from *Human-Animal Medicine: Clinical Approaches to Zoonoses, Toxicants, and Other Shared Health Risks*[2].

5. **Likelihood that feed would act as a Fomite;** authors' opinion on likelihood for disease spread from humans involved in the preparation of feed to livestock through the animal feed.

Table 1. Documented Reverse Zoonoses in Livestock

Confirmed cases of reverse zoonosis					
Agent	**Human disease**	**Animal disease**	**Type of infected animal**	**Mode of transmission**	**Reference**
Staphylococcus aureus	Chronic sinusitis	Bovine mastitis	Cattle	Not reported	3
Staphylococcus aureus	Not reported	poultry skeletal infections	poultry	Not reported	4
Streptococcus pyogenes	Pharyngitis, scarlet fever	Mastitis	Cattle	Not reported	5
Corynebacterium diphtheria	Not reported	Bovine Mastitis, dermatitis with pyrexia	Cattle	Not reported	6
Mycobacterium tuberculosis	Tuberculosis	Tuberculosis	Deer	Not reported	5
Mycobacterium tuberculosis	Tuberculosis	Tuberculosis	Swine	Inhalation of aerosolized droplets	7
Mycobacterium bovis	Pulmonary and renal tuberculosis	Tuberculosis	Cattle	Not reported	8
Hepatitis E virus (HEV)	Hepatitis	Experimentally infected	Pig	Intravenously (experimentally inoculated)	9
Cryptosporidium parvum	Acute gastroenteritis	watery diarrhea	Calf	Orally (experimentally infected)	10
Influenza A (pH1N1) virus	Influenza	Influenza	Swine	Not reported	11
Influenza A (pH1N1)	Respiratory	egg production	Turkey	Direct contamination during	

virus	disease	drop, reduced egg quality and respiratory distress		insemination procedure	12
Reverse zoonotic potential					
Mycobacterium bovis	Genito-urinary tuberculosis	Tuberculosis	Cattle	Human urine	13
Blastocystis spp.	Intestinal disease	Not reported	Guinea pig, chicken	Fecal-oral, food-borne, waterborne	14
Giardia duodenalis	Enteric illness	Enteric illness	Cattle	Sewage contaminated drinking water or feed, direct contact with infected animal handlers, direct fecal-oral	15, 16
Cryptosporidium spp.	Enteric illness	Enteric illness	Cattle	Sewage contaminated drinking water or feed, direct contact with infected animal handlers, direct fecal-oral	15, 16
Extended-spectrum-β-lactamese (ESBL)-producing *Escherichia coli*	Urinary tract infection (UTI), bacteremia	Various diseases, e.g. UTIs, wound infection, urogenital tract infection and diarrhea	Equine	Not reported	17
Methicillin-Resistant *Staphylococcus aureus (MRSA)*	No clinical signs	Skin infection	Pig	Not reported	18

Methicillin-Resistant *Staphylococcus aureus (MRSA)*	Not reported	Subclinical mastitis	Cattle	Not reported	19
Methicillin-Resistant *Staphylococcus aureus (MRSA)*	Not reported	postprocedural infection	Equine	Unclear	20

Table 2. Zoonoses in six livestock species

		Types of animals						Zoonotic transmission route	Likelihood that feed would act as a Fomite
Agent	**Disease**	**Horses**	**Cattle**	**Goats**	**Sheep**	**Swine**	**Poultry**		
ARTHROPOD									
Sarcoptes scabiei	Scabies		X	X	X	X		Sustained direct skin-to-skin contact	NA
Dermanyssus gallinae	Acariasis						X	Sustained direct skin-to-skin contact	NA
BACTERIAL									
Bacillus anthracis	Anthrax	X	X	X	X	X		Direct contact with sick/dead animals or spore contaminated animal products	NA
Toxin produced by *Clostridium botulinum*	Botulism	X	X		X		X	Foodborne, wound infection	NA

Brucella spp.	Brucellosis	X	X	X	X	X	X	Direct contact with infected tissue or secretions, enter the body by breaks in the skin or contact with mucous membranes, ingestion of dairy products, infected meat, inhalation of aerosol	Unlikely
Campylobacter spp.	Campylobacteriosis	X	X	X	X	X	X	Consumption of contaminated food, fecal-oral, waterborne	Unlikely
Chlamydophilia spp.	*Chlamydophilia* infection	X	X	X	X		X	Fecal-oral, direct contact to mucous membrane, aerosol	Unlikely
Ehrlichia spp. and *Anaplasma spp.*	Ehrlichiosis and anaplasmosis	X	X	X	X			Tickborne infection	NA
Escherichia coli 0157	*Escherichia coli* 0157 infection		X	X	X		X	Direct contact with feces, ingestion of contaminated food or water	Unlikely
Leptospira spp.	Leptospirosis	X	X	X	X	X		Exposure to water, moist soil, food or feed contaminated by urine or secretions, direct contact with infected animals	Unlikely
Borrelia spp.	Lyme disease	X	X					Tick vector	NA
Pseudomonas pseudomallei	Meliodosis	X		X	X	X		Acquired from environment	Unlikely

Staphylococcus aureus	Methicillin-resistant *Staphylococcus aureus* (MRSA) infection	X			X	X	X	Direct Contact with contaminated Individuals, Fomites contaminated with body fluids	Unlikely
Mycobacterium spp.	Mycobacteriosis other than TB		X		X			Respiratory aerosolization, ingestion of infected materials	Unlikely
Mycobacterium tuberculosis and *Mycobacterium bovis*	TB		X			X		Respiratory aerosolization, ingestion of infected materials	Unlikely
Coxiella burnetii	Q fever	X	X	X	X	X		Inhalation of droplets and/or aerosols containing organisms from infected placental tissue, foodborne (unpasteurized milk)	Unlikely
Salmonella spp.	Salmonellosis	X	X	X	X	X	X	Fecal-Oral, Direct Contact with Feces	Unlikely
Francisella turarensis	Tularemia	X			X	X		Arthropod vector, a bite or scratch or conjunctival contact from an infected animals, inhalation of aerosols, ingestion of contaminated food or water	Unlikely
Yersinia enterocolotica	Yersiniosis					X		Ingestion of undercooked (pork) meat	NA

FUNGAL									
Epidermophyton spp., Microsporum spp., Trichophyton spp.	Dermatophytosis	X	X	X	X	X		Skin-to-skin, skin-to-hair, indirect contact (environment, fomite	NA
Sporothrix schenckii	Sporotrichosis	X	X	X		X		Cat bites and scratches, squirrel bite	NA
PARASITIC									
Taenia solium, Taenia saginata	Cysticercosis (*Taenia* infection)					X		Ingestion of undercooked meat (Fecal-oral to cattle from Humans)	Unlikely
Cryptosporidium spp.	Cryptosporidiosis	X	X	X	X	X	X	Ingestion of oocysts: faecal-oral, via drinking water or food	Unlikely
Echinococcus spp.	Echinococcosis (tapeworm)	X	X	X	X	X		Ingestion of contaminated food, direct contact with definitive hosts	NA
Giardia spp.	Giardiasis	X	X	X	X	X		Fecal-oral, ingestion of contaminated water	Unlikely
Leishmania spp.	Leishmaniasis	X						Vector-borne (sand fly)	NA
Toxoplasma gondii	Taxoplasmosis	X		X	X	X		Ingestion of raw or undercooked meat	NA
Trichinella spp.	Trichinellosis					X		Consumption of undercooked meat	NA

PRION									
PrP^{sc} of PrP^{C} cellular prion proteins	Transimissible spongioform encephalopathy	X		X			X	Ingestion of contaminated animal products	NA
VIRUS									
Influenza viruses	Influenza (avian)					X	X	Contaminated-hand-to-mucous membrane contact, inhalation of contaminated dust particles or aerosols	Unlikely
Parapoxvirus ovis	Other orthopox infection (ORF)			X	X			Direct contact with broken skin or mucous membranes	Unlikely
Lyssavirus spp.	Rabies	X	X	X	X	X		A bite, an open wound, contact with mucous membranes	NA
Phlebovirus spp.	Rift Valley fever		X	X	X			A bite from an infected mosquito, mechanical transmission from other insects	NA
Flavivirus spp.	West Nile virus infection	X		X	X			Mosquito bites	NA

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