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The National Grain and Feed Association submits this statement in response to the Food and Drug Administration’s (FDA) supplemental notice in which the agency proposes to amend its 2013 proposed rule for current good manufacturing practices (CGMPs) and hazard analysis and risk-based preventive controls for animal feed and pet food.

The NGFA, established in 1896, consists of more than 1,050 grain, feed, processing, exporting and other grain-related companies that operate more than 7,000 facilities and handle more than 70 percent of all U.S. grains and oilseeds. Its membership includes grain elevators; feed and feed ingredient manufacturers; biofuels companies; grain and oilseed processors and millers; exporters; livestock and poultry integrators; and associated firms that provide goods and services to the nation’s grain, feed and processing industry. With more than 350 member companies operating feed manufacturing, feed ingredient, and integrated livestock and poultry operations, the NGFA is the nation’s largest trade association representing commercial feed manufacturer and integrator interests. In addition, the NGFA has strategic alliances with Pet Food Institute and North American Export Grain Association.

In response to the agency’s proposed rule issued Oct. 29, 2013, the NGFA submitted extensive comments in which it recommended many significant changes so that the proposed requirements would conform to the Food Safety Modernization Act’s (FSMA) statutory language and provide sufficient flexibility to allow facilities to adopt animal feed and pet food safety practices that are practical and effective for their specific, individual operations. In addition, the NGFA recommended that FDA make available a second draft of the proposed regulations reflecting the agency’s views after reviewing stakeholders’ initial comments on its proposed rule, given the very significant nature of these regulations and the extent of revisions being recommended by the NGFA and other stakeholders. We commend FDA for issuing the supplemental notice and providing this additional opportunity to make comments on key provisions of the proposed rule.

In this statement, the NGFA begins by providing comments on the revisions proposed by FDA within the supplemental notice pertaining to how FDA has chosen to exercise the authority provided to the agency by FSMA to, by regulation, exempt or modify the requirements for
compliance under the hazard analysis and risk-based preventive controls section with respect to facilities that are solely engaged in the storage of raw agricultural commodities other than fruits and vegetables intended for further distribution or processing. Similarly, the NGFA also provides comments on how FDA proposes to apply its CGMPs regulation to such facilities. Next, we provide comments and recommendations regarding aspects of the proposed regulations for CGMPs and hazard analysis and risk-based preventive controls for animal feed and pet food. We conclude by providing comments pertaining to the economic impact of the proposed requirements on affected facilities.

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Executive Summary

The NGFA shares FDA’s goal of promoting and ensuring the production and distribution of safe and wholesome animal feed and pet food. We believe FSMA embodies many of the well-recognized, science- and risk-based principles already employed through much of the industry to ensure the safety of such products. However, the NGFA remains very concerned that in many important instances, FDA’s proposed regulations are not realistic and do not align with the flexibility provided by FSMA for the agency’s use when developing regulatory requirements. Although the provisions proposed by FDA within the supplemental notice represent an improvement in comparison to those issued previously, we believe they still would add unnecessary requirements that would cause industry to direct scarce resources toward complying with regulatory obligations that will not benefit the safety of animal feed and pet food.

Therefore, the NGFA urges FDA to actively address the following issues to ensure that its final rule will allow facilities to adopt animal feed and pet food safety practices that are practical and effective for their specific, individual operations.

FDA’s Final Rule Must Provide a Clear Exemption for Low-Risk Holding and Packing Activities of Raw Agricultural Commodities Other than Fruits and Vegetables

The NGFA strongly supports FDA’s revised definition for “holding” as proposed within the supplemental notice. We agree with the agency that “holding” rightfully should encompass activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity).

We believe that FDA’s revised “holding” definition and proposed exemptions from the agency’s CGMPs and preventive controls regulations for facilities holding raw agricultural commodities other than fruits and vegetables appropriately reflect the limited public health risk pertaining to such facilities and the fact that outbreaks of foodborne illness have not been traced back to facilities solely engaged in the storage of non-fruit or vegetable raw agricultural commodities. Therefore, we urge FDA to codify the supplemental notice’s proposed definition for “holding” and proposed exemptions for such “holding” facilities within its final regulation.

However, by contrast, FDA’s supplemental notice fails to address provisions within the agency’s 2013 proposed rule that would not provide a clear exemption for facilities engaged in packing of raw agricultural commodities other than fruits and vegetables that are intended for further distribution or processing. The NGFA strongly believes that such packing activities are inherent to the distribution process associated with raw agricultural commodities, such as grains and oilseeds, and represent a negligible risk to public health.

Accordingly, the NGFA urges FDA to modify its final regulations to clearly state that facilities solely engaged in the storage and packing of raw agricultural commodities other than fruits and vegetables intended for further distribution or processing are exempt from the regulations’ requirements.
FDA’s Final Rule Must Establish Realistic and Practical CGMPs Requirements for Animal Feed and Pet Food

FDA’s proposed rule would establish an overarching set of CGMP requirements that generally would apply to all facilities required to register with the agency under the Bioterrorism Act that are involved in manufacturing and distributing animal feed and pet food. In proposing to do so, FDA stated within its 2013 proposed rule that it believed that CGMPs similar to those for human food are appropriate for animal feed and pet food.

In contrast, the NGFA strongly believes that CGMPs similar to those established for human food are not appropriate for animal feed and pet food. We believe that a clear distinction between necessary manufacturing and distribution practices and conditions for human foods – in comparison to those for animal feed and pet food – is proper and has a sound scientific basis. Clearly, the innate hygienic standards of humans far exceed the hygienic standards of livestock, poultry and other animals. Further, animal feed typically is fed in such a manner that exposes the product to the environmental and hygienic conditions associated with animals’ domicile. As such, it is obvious and reasonable that the hygienic safety standards necessary for the manufacture and distribution of human foods rightfully should exceed the hygienic safety standards necessary for the manufacture and distribution of animal feed and pet food. Therefore, the requirements within FDA’s final CGMPs for animal feed and pet food must appropriately reflect this fact.

In addition, the NGFA believes the provisions established within FDA’s CGMPs regulation should be appropriate and reasonable for the full range and scope of facilities that will be required to comply with the requirements. While the revised CGMPs proposed within FDA’s supplemental notice are an improvement over those originally issued, we remain concerned that many of the requirements are neither applicable nor appropriate for the vast majority of firms that will need to comply with the final rule. As such, we believe that FDA must make significant revisions to the proposed CGMPs so that the final regulation does not add unnecessary requirements that would cause industry to expend millions of dollars towards complying with regulatory obligations that are not needed to ensure the safety of animal feed and pet food.

FDA’s Final Rule Must Allow for Hazards to be Controlled in a Manner Commensurate with Risk

FSMA instructs FDA to implement preventive controls regulation applying to facilities registered with the agency under the Bioterrorism Act that require such facilities to conduct an analysis of hazards associated with their operations that are “known or reasonably foreseeable” and to use appropriate preventive controls to minimize or eliminate identified hazards so that food products are not adulterated or misbranded. As such, FSMA provides for the use of various types of preventive controls commensurate with the nature of the risk associated with the hazard. Significantly, FSMA also expressly provides that FDA may exempt from or establish modified preventive controls requirements for facilities solely engaged in the production of food for animals other than man (i.e., animal feed and pet food).

Pertaining to the preventive controls regulation, the NGFA supports revisions made by FDA within the supplemental notice that would establish the term “significant hazard” and the process to be used by facilities to determine whether such a hazard exists within their operations. We
strongly believe that only “significant hazards” should be subject to FDA’s preventive control regulations, which would require the use of management controls that may include monitoring, corrections or corrective actions, validation, verification and recordkeeping.

The NGFA believes the agency’s proposed approach as reflected in the supplemental notice better acknowledges the safety benefits derived from the use of prerequisite programs, such as CGMPs, and provides for a framework whereby appropriate decisions may be reached regarding hazards that may need more extensive management controls. However, we urge FDA to make additional revisions to its regulation, as recommended in this statement, to provide further flexibility to facilities to control potential hazards in a manner that is both effective and efficient for their operations.

In addition, since determinations about whether a given hazard rises to the level of being a “significant hazard” will be so integral in establishing compliance obligations under the regulations, the NGFA urges FDA to work closely with industry to develop sound guidance on how such determinations are to be made. In that regard, the NGFA is an active participant within the Food Safety Preventive Controls Alliance that was established to assist in developing guidance on how to comply with FDA’s preventive control regulations. We strongly believe that the Alliance, which consists of human food and animal feed/pet food safety experts from FDA and other regulatory bodies, industry and academia, is the best forum to identify what constitute “significant hazards” in animal feed and pet food, and to develop appropriate guidance and training for addressing such hazards, as well as other issues.

**FDA’s Final Rule Must Contain Revised Requirements to Reduce Compliance Costs**

Assuming very small businesses are defined as having animal feed and pet food sales of less than $2.5 million per year, FDA’s Preliminary Regulatory Impact Analysis (PRIA) for the proposed rule estimates an annualized compliance cost of $93.45 million for the entire animal feed and pet food industries. FDA’s annualized compliance cost per facility ranges from $13,200 to $18,300.

In contrast, NGFA’s economic analysis of the proposed rule, which focused exclusively on the cost to animal feed facilities, resulted in an estimated annualized cost of $430.33 million to $722.65 million, which equates to an annual cost per facility ranging from $56,385 to $127,715.

Importantly, the lower dollar amount of NGFA’s estimate represents the anticipated cost for complying with the proposed CGMPs requirements and only the provisions of the preventive controls regulation that would require a hazard analysis to be conducted. The higher dollar amount of NGFA’s estimate represents the anticipated cost for complying with the proposed CGMPs requirements and all aspects of the preventive control regulations when control of “significant hazards” would be required.

Therefore, NGFA’s analysis quantifiably demonstrates how the compliance costs of the proposed rule will be influenced dramatically based upon FDA’s regulatory decisions as to whether a given hazard reaches the threshold of being classified as a “significant hazard.” This is the case since, under FDA’s proposal, a facility that identifies a “significant hazard” within its operation would be required to comply with all aspects of the preventive control regulations. In contrast, a facility that identifies no “significant hazards” only would be required to perform the hazard analysis requirements of the preventive controls regulation.
Further, NGFA’s economic impact analysis also clearly demonstrates how the compliance costs of the proposed rule will be influenced significantly by FDA’s final CGMPs requirements. Within the proposed rule, FDA would establish numerous CGMPs requirements based upon human food safety standards that would compel the industry to redesign or reconstruct facilities and equipment. To make such changes, the NGFA estimates that the annualized capital cost to the animal feed industry would be $297.63 million, or an annual capital cost of $38,998 for each affected facility. In contrast, if FDA accepts the NGFA’s recommendations that would make its final CGMPs regulations more appropriate and reasonable for animal feed facilities, we believe such capital costs for the animal feed industry would be eliminated.

Accordingly, the NGFA analysis estimates the annualized cost for animal feed facilities to comply with the proposed preventive control regulation with no “significant hazards” and to comply with the proposed CGMPs regulations with no need for capital expenditures to be $132.70 million, or $17,387 per facility.

Significantly, FDA’s PRIA does not quantify the benefits of the proposed rule. As such, the NGFA urges FDA to produce empirical evidence of the benefits associated with the requirements before issuing a final rule. We believe empirical evidence will prove the costs of the proposed rule far exceed the anticipated benefits. In addition, we strongly believe that a more limited regulation would accomplish the goals of FSMA more effectively, while imposing a significantly lower economic burden upon the regulated industry.

**FDA’s Final Rule Should Stagger Compliance Dates for CGMPs and Preventive Controls**

The NGFA strongly believes that FDA should provide a sufficient time period following publication of its final regulations to allow affected facilities to come into compliance with the rule. We believe that affected facilities – both large and small – will need to expend considerable effort and resources to implement practices and procedures to comply with requirements to be established by both the final CGMPs and preventive controls regulations.

Since the CGMPs regulations will establish new baseline requirements for all affected animal feed and pet food facilities – many of which previously have not been subject to such requirements – we believe it is necessary and appropriate for FDA to provide facilities with adequate time to come into compliance with the CGMPs regulation before being expected to comply with the preventive controls regulation. We believe that such a staggered compliance schedule for the two regulations would serve to provide necessary time for affected facilities to fully implement programs to comply with the CGMPs regulation that, in turn, will serve as the foundation by which facilities successfully may implement the written animal feed/pet food safety plans to be required under the preventive controls regulation.

Therefore, the NGFA strongly recommends that FDA provide the following time periods for affected businesses to come into compliance with the CGMP requirements after publication of the final rule: 1) one year for businesses other than small and very small businesses; 2) two years for small businesses; and 3) three years for very small businesses.

In addition, to provide for staggered implementation of the two regulations, the NGFA recommends that FDA establish the following time periods for affected businesses to comply
with the requirements of the agency’s final preventive controls regulation: 1) two years for businesses other than small and very small businesses; 2) three years for small businesses; and 3) four years for very small businesses.

**FDA’s Proposed Requirements for Facilities Solely Engaged in the Storage of Raw Agricultural Commodities Other than Fruits and Vegetables**

The NGFA provides the following comments and recommendations on provisions of FDA’s supplemental notice that apply to raw agricultural commodities other than fruits and vegetables that are intended for further distribution or processing.

**Rulemaking Authority Provided to FDA**

As amended by FSMA, Section 418(m) of the federal Food, Drug and Cosmetic Act (FD&C Act) provides in relevant part that FDA may by regulation “exempt or modify the requirements for compliance under [Section 418 - hazard analysis and risk-based preventive controls] with respect to facilities that are engaged solely in … the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.”

The NGFA strongly believes this authority applicable to raw agricultural commodities other than fruits and vegetables intended for further distribution or processing represents a sound risk-based approach, and clearly reflects the view of Congress that both industry and FDA should focus their finite resources on segments of the animal feed and pet food production and distribution system where the greatest benefits to product safety can be achieved. This same risk-based approach is embraced by food safety experts who widely recognize that the use of HACCP principles (like those that would be required under Section 418) are applied most appropriately and effectively during processing activities associated with foods. It is at this step of the food supply chain that effective controls are most readily available to eliminate or minimize significant hazards so as to ensure product safety.

**FDA’s Proposed Exemptions for “Holding” Raw Agricultural Commodities**

Within its proposed rule, FDA recognizes the appropriateness of a risk-based approach and uses the authority provided to the agency when proposing certain provisions that would apply to raw agricultural commodities as follows:

- Proposed § 507.5(g) states, “subpart C [hazard analysis and risk-based preventive controls] of this part does not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.”

- Proposed § 507.5(h) states, “subpart B [CGMPs] of this part does not apply to the holding or transportation of one or more raw agricultural commodities as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.”

The NGFA strongly agrees with FDA’s intent to exempt facilities engaged in the storage of raw agricultural commodities other than fruits and vegetables intended for further distribution or
processing from requirements that would be established within its proposed regulations for CGMPs and preventive controls. We strongly concur with FDA’s tentative conclusion expressed within the preamble of its 2013 proposed rule for human food that “there would not be significant public health benefit to be gained by subjecting facilities that solely store non-fruit and vegetable raw agricultural commodities intended for further distribution or processing [to such] requirements.”

To clarify the scope of the intended exemptions, FDA within its supplemental notice has revised the proposed definition for “holding.” The agency’s proposed definition for “holding” now states, “Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.”

The NGFA strongly supports FDA’s revised definition of “holding.” We agree that “holding” rightfully should encompass activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity). We also concur with statements made by FDA within the preamble of the supplemental notice that, either for the purposes of safe or effective storage or for meeting customer specifications, a variety of activities incidental to “holding” of raw agricultural commodities may be performed, including:

- Drying grain;
- Fumigating grain;
- Cleaning grain;
- Treating stored grain with protectant chemicals and pesticide alternatives (other than by fumigation) to control infestation;
- Using modified atmosphere treatments to control pests;
- Using biological controls for pests;
- Applying chemical preservatives to grain to prevent growth of mycotoxin-producing molds;
- Weighing grain;
- Blending grain;
- Sampling and grading grain; and
- Aerating grain to control temperature.

The NGFA believes that FDA’s revised “holding” definition and proposed exemptions for facilities holding raw agricultural commodities other than fruits and vegetables appropriately reflect the limited public health risk pertaining to such facilities and the fact that outbreaks of foodborne illness have not been traced back to facilities solely engaged in the storage of non-fruit or vegetable raw agricultural commodities. Therefore, we urge FDA to codify the proposed definition and exemptions within its final regulation.
Proposed Requirements for “Packing” Raw Agricultural Commodities

As proposed in FDA’s 2013 rule, the exemptions under § 507.5(g) and § 507.5(h) would not apply to facilities engaged in “packing” raw agricultural commodities. FDA’s definition of “packing” within the 2013 proposed rule stated, “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).”

In contrast to FDA’s proposal, current 21 CFR § 110.19(a) does provide an exemption from CGMPs regulation for establishments “… engaged solely in the harvesting, storage, or distribution of one or more raw agricultural commodities, as defined in Section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.” As a matter of application from a regulatory standpoint, the activity of packing has been encompassed within the term “distribution,” and, therefore, has not been subject previously to CGMPs regulation.

In attempting to justify its proposal to exclude from exemption “packing” of raw agricultural commodities from requirements proposed within the CGMPs and preventive controls regulations, FDA within its 2013 proposed rule for preventive controls for human food cited examples of foodborne illness outbreaks and contamination events associated with fresh produce and other raw agricultural commodities, and stated that the agency continues to be concerned about sanitation practices at establishments that pack raw agricultural commodities. In addition, FDA stated that packing of raw agricultural commodities has been implicated as a likely source of contamination in multi-state foodborne illness outbreaks associated with such products.

The NGFA respectively submits that FDA’s proposal to exclude from exemption “packing” of all raw agricultural commodities from requirements proposed within its CGMPs and preventive controls regulations represents a one-size-fits-all approach that is not risk based. The examples and concerns cited by FDA as justification to exclude from exemption packing of raw agricultural commodities from its regulations pertain to produce, such as fruits and vegetables, but not other raw agricultural commodities, such as grains and oilseeds. Indeed, as cited previously within this statement, FDA has noted the minimal public health risk associated with those activities that pertain to the storage of raw agricultural commodities other than fruits and vegetables that are intended for further distribution or processing.

Further, the NGFA believes that FDA has authority to provide such an exemption from CGMPs regulation for packing of raw agricultural commodities other than fruits and vegetables that are intended for further distribution or processing. As expressed previously in this statement, the current exemption provided in 21 CFR § 110.19(a) includes distribution activities that inherently encompass packing. In addition, Section 418(m) of the FD&C Act authorizes FDA to exempt or modify its preventive controls requirements with respect to facilities that are engaged solely in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing. Clearly, facilities solely engaged in the storage of raw agricultural commodities other than fruits and vegetables also distribute such commodities. In
many situations, packing inherently is involved in this distribution process. Therefore, the NGFA believes it is reasonable to conclude that the authority granted to FDA to exempt such facilities from regulation justifiably extends and may be applied to all activities that are inherent to storing raw agricultural commodities, other than fruits and vegetables, that are intended for further distribution or processing.

Moreover, FDA within its supplemental notice proposes to revise the definition of “farm” and “packing” to:

- Provide for on-farm packing and holding of raw agricultural commodities to remain within the farm definition regardless of ownership of the raw agricultural commodities;
- Clarify that packing also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food); and
- Provide that activities performed incidental to packing a food would apply to all establishments that pack food, not just to farms and farm mixed-type facilities.

Therefore, under FDA’s newly proposed definitions, the agency proposes to differentiate requirements associated with packing between establishments that are “facilities” and those that are “farms.” A “farm” that packs raw agricultural commodities other than fruits and vegetables, regardless of ownership of such commodities, would not be subject to CGMPs and preventive control regulations because the establishment still would meet the definition of a “farm.” In contrast, a “facility” that packs raw agricultural commodities other than fruits and vegetables, regardless of ownership of such commodities, would be subject to CGMPs and preventive control regulations under FDA’s proposed regulations. The NGFA believes that this proposed regulatory distinction between two types of operations that perform identical activities lacks sound reasoning and is not justified when a risk-based approach to food safety is applied.

Based upon the minimal level of public health risk and the authority provided to the agency, the NGFA strongly recommends that FDA expressly exempt facilities that pack raw agricultural commodities, other than fruits and vegetables intended for further distribution or processing, from the CGMPs and preventive controls requirements to be established under its regulations.

To achieve this outcome, the NGFA recommends that FDA modify proposed § 507.5(g) and § 507.5(h) to read as follows [new language boldfaced and underscored]:

- § 507.5(g): “Subpart C of this part does not apply to facilities that are solely engaged in the storage or packing of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.”
- § 507.5(h): “Subpart B of this part does not apply to the holding or transportation of one or more ‘raw agricultural commodities,’ or the packing of ‘raw agricultural commodities’ (other than fruits and vegetables), as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.”
FDA’s Proposed Requirements for Facilities Solely Engaged in the Production of Food for Animals Other than Man

The NGFA provides the following overarching comments and recommendations pertaining to how FDA has chosen to exercise the authority provided by FSMA to exempt from or modify the requirements for compliance under its proposed preventive controls regulation with respect to facilities that are engaged solely in the production of animal feed and pet food.

FDA’s Proposed Requirements for CGMPs for Animal Feed and Pet Food

Although not specifically required by FSMA, FDA indicated within its 2013 proposed rule that, for a variety of reasons, it believes baseline CGMPs should be established for facilities required to register under the Bioterrorism Act that are involved in manufacturing and distributing animal feed and pet food. In addition, FDA requested comment on the agency’s current thinking that CGMPs similar to those for human food are appropriate for animal feed and pet food.

Pertaining to this issue, the NGFA extensively was involved and supported the development of the Association of American Feed Control Official’s (AAFCO) Model Good Manufacturing Practice Regulations for Feed and Feed Ingredients. AAFCO’s model GMPs provide basic requirements for the production of animal feed and pet food, and address the following areas: personnel; establishments, including construction, design, and grounds; maintenance and housekeeping, including pest control; equipment, including construction and design; receiving and storage for further manufacture; manufacturing; labeling; storage of finished feed and/or feed ingredients; inspection, sampling, and testing of incoming and finished feed and/or feed ingredients for adulterants; transportation of feed and/or feed ingredients; and voluntary recall/withdrawal.

As such, the NGFA believes the AAFCO model GMPs contain practical and reasonable provisions to establish that animal feed and pet food is manufactured and distributed under conditions and practices that protect against the adulteration of such products. The AAFCO model GMPs were the outcome of a long, collaborative process between AAFCO, FDA and various industry stakeholders and represent baseline conditions and practices that were deemed acceptable to all parties, including FDA. Accordingly, we believe the AAFCO model GMPs represent sound practices and conditions that could be used for establishing FDA’s CGMPs regulation.

In addition, the NGFA actively provided input to the Safe Supply of Affordable Food Everywhere (SSAFE) public-private partnership during its development of the Prerequisite Programmes for Food Safety in the Manufacturing of Food and Feed for Animals (PAS 222:2011). We believe that PAS 222, which was published by the British Standards Institute, also contains effective and prudent concepts that could be used when establishing appropriate CGMPs requirements for animal feed and pet food.

In contrast, the NGFA strongly believes that FDA-promulgated CGMPs similar to those for human food are not appropriate for animal feed and pet food. We believe that a clear distinction between necessary manufacturing and distribution practices and conditions for human foods in comparison to animal feed and pet food is proper and has a sound scientific basis. Clearly, the
innate hygienic standards of humans far exceed the hygienic standards of livestock, poultry and other animals. Further, animal feed typically is fed in such a manner that exposes the product to the environmental and hygienic conditions associated with animals’ domicile. As such, it is obvious and reasonable that the hygienic safety standards necessary for the manufacture and distribution of human foods should rightfully exceed the hygienic safety standards for animal feed and pet food, and raw materials and ingredients used in such products. Therefore, we firmly believe the requirements within the CGMPs regulation for animal feed and pet food should appropriately reflect this fact.

In addition, the NGFA believes the provisions established within FDA’s CGMPs regulation should be appropriate and reasonable for the full range and scope of facilities that will need to comply with the requirements. While the revised CGMPs within FDA’s supplemental notice are an improvement over those originally proposed, we remain concerned that many of the proposed requirements are neither applicable nor appropriate for the vast majority of firms that will be required to comply with the final rule.

Our comments and recommendations pertaining to specific provisions proposed within the CGMPs regulation further address NGFA’s views pertaining to the scope and application of the proposed requirements.

**FDA’s Proposed Requirements for Preventive Controls for Animal Feed and Pet Food**

Section 418(m) of the FD&C Act authorizes FDA, by regulation, to modify the requirements for compliance under the section with respect to facilities that are engaged solely in the production of food for animals other than man. As such, FDA stated within its 2013 proposed rule that the agency tentatively concluded the differences between human food and animal feed and pet food are best addressed through separate rulemakings. Further, FDA stated it has tentatively concluded that the requirements of section 418 of the FD&C Act are needed to ensure the safety of animal feed and pet food, and in turn the health of animals, the health of humans who are exposed to animal food, and the safety of animal-derived products for human consumption. Therefore, FDA proposed requirements to implement section 418 of the FD&C Act for animal feed and pet food with only few modifications (e.g., no allergen controls).

The NGFA continues to agree with FDA’s tentative conclusion that the differences between human food and animal feed and pet food are addressed best and most appropriately through separate rulemakings when implementing section 418(m). For reasons previously expressed, the NGFA strongly believes there are fundamental differences between the manufacturing and distribution practices and conditions necessary to ensure the safety of human food in comparison to those necessary to ensure the safety of animal feed and pet food. We also agree with the agency’s conclusion that allergens are not a safety concern that need to be addressed within FDA’s regulations for animal feed and pet food.

However, as indicated in its previous statement to FDA, the NGFA believes the agency’s 2013 proposed rule would have establish an extremely burdensome regulatory framework that is not necessary to ensure the safety of animal feed and pet food. As proposed, we believe the preventive controls provisions would have required excessive and unnecessary management control and oversight of potential product safety hazards that are not commensurate with the risk posed by the vast majority of potential hazards associated with animal feed and pet food. Further,
the proposed requirements would have diverted finite resources away from industry practices that have and continue to effectively ensure the safety of such products.

In NGFA’s previous statement submitted in this rulemaking, we strongly recommended that FDA not use the term “reasonably likely to occur” within its regulation when defining hazards that are to be addressed within a facility’s written animal feed/pet food safety plan. We did so for two reasons. First, FDA uses this term within its mandatory seafood and juice HACCP regulations. However, FSMA clearly does not mandate that facilities implement regulatory HACCP plans. In fact, FSMA does not use the phrase “reasonably likely to occur” to define a threshold for determining preventive controls. Nor does it provide any other basis for using such a phrase to differentiate among various hazards and associated preventive controls. Second, we believe using the term “reasonably likely to occur” when defining hazards would be interpreted as requiring all such hazards be addressed in the same manner as a critical control point within a HACCP program. Such an outcome clearly is inconsistent with FSMA, which explicitly provides for the use of a range of preventive controls commensurate with the risk of the hazard.

Instead, the NGFA recommended that FDA closely follow FSMA’s statutory language that provides for consideration of “known or reasonably foreseeable” hazards to make an appropriate distinction between mandatory HACCP regulations and the preventive controls regulation as required by FSMA. Further, the NGFA recommended that FDA’s regulation provide that when evaluating hazards, both likelihood and severity need to be considered in a scientific hazard analysis, consistent with international standards. Considering both severity and probability is necessary to evaluate successfully the significance of potential hazards on a case-by-case basis, determine the appropriate control measures, and decide how such measures need to be managed.

We also strongly recommended that FDA within its regulations acknowledge the safety benefits derived from the use of prerequisite programs, such as CGMPs, so as to avoid the unnecessary and untenable outcome of every hazard and control being subject to the burdensome requirements of monitoring, corrective actions, validation and verification, and recordkeeping.

In response to comments made by the NGFA and other organizations, FDA within its supplemental notice proposes to use the new term “significant hazard” and, in general, use this new term instead of “hazard reasonably likely to occur” throughout the proposed preventive controls regulation. FDA proposes to define “significant hazard” as “a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in an animal food, and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the control.”

As proposed by FDA, determining whether a “significant hazard” exists within a facility would involve a two-part analysis. First, the facility would narrow potential “hazards” to those hazards that are known or reasonably foreseeable – i.e., those biological, chemical (including radiological), or physical hazards that have the potential to be associated with the facility or the food. Second, the facility would narrow the known or reasonably foreseeable hazards to those that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in an animal food, as well as components to manage those
controls. The hazard analysis also would require an evaluation of known or reasonably foreseeable hazards to assess two key aspects of risk – i.e., the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

The NGFA generally supports FDA’s use of the term “significant hazard” within its proposed regulation and the process to be used by facilities to determine whether such a hazard exists within their operations. We believe the agency’s proposed approach acknowledges the safety benefits derived from the use of prerequisite programs, such as CGMPs, and provides for a framework whereby appropriate decisions may be reached regarding hazards that require management controls that may include monitoring, corrections or corrective actions, verification, and records. However, as expressed later within this statement, the NGFA does have suggested revisions to the proposed definition of “significant hazard,” which we believe will enhance the meaning and application of the term.

Although FDA’s use of the term “significant hazard” will help to clarify the types of hazards to be subject to rigorous management oversight (i.e., monitoring, corrective actions, verification and recordkeeping), the NGFA believes for compliance purposes a baseline understanding between industry and regulatory officials will need to be established as to what constitutes a “significant hazard” and what preventive controls will be deemed to be adequate to control such a hazard.

In general, the NGFA believes that a “significant hazard” is one that poses the threat of a high degree of illness or injury severity and high probability of occurrence, and to which a specific process step (i.e., “kill step”) can be applied to minimize to eliminate the significant hazard or reduce it to an acceptable level. Therefore, the NGFA generally believes physical and chemical hazards are not “significant hazards” for the animal feed and pet food industries, and that such hazards may appropriately be controlled through CGMP programs. Regarding biological hazards, the NGFA generally believes the only potential “significant hazard” is Salmonella that may be present in products that are stored and fed to animals in the home.

Pertaining to the issue of developing a common understanding between industry and FDA about “significant hazards,” the NGFA believes the Food Safety Preventive Controls Alliance provides the best forum to identify what constitute “significant hazards” in animal feed and pet food, and to develop timely and appropriate guidance and training for addressing such hazards, as well as other issues for use by both industry and FDA/State investigators. The NGFA was very pleased to be invited to serve on the organizing committee and steering committee of the Alliance, and has been an active participant in its on-going activities. We believe the Alliance, which appropriately consists of human food and animal feed/pet food safety experts from regulatory bodies, industry and academia, is uniquely positioned to serve in this essential role under the preventive controls regulation. We strongly believe it is through the cross-cutting interaction provided for within the Alliance that effective guidance may be made available that will enable both FDA and industry to implement the preventive controls regulation in a consistent manner that maximizes benefits to animal feed and pet food safety.

Our comments and recommendations presented subsequently pertaining to specific provisions proposed within the preventive controls regulation further address NGFA’s views pertaining to the scope and application of the proposed requirements.
**Proposed Requirements for Product Testing, Environmental Monitoring, Supplier Programs and Economically Motivated Adulteration**

FDA requests comment on potential requirements that would be included within its preventive controls regulation for product testing, environmental monitoring, supplier programs, and hazards that may be introduced intentionally for purposes of economic gain.

The NGFA offers the following overarching perspectives pertaining to these topics, and provides further comments and recommendations concerning specific proposed regulatory provisions later in this statement.

**Product Testing**

The agency’s proposed product testing provisions would require that a facility conduct product testing as an activity for verification of implementation and effectiveness as appropriate to the nature of the preventive control used to control a significant hazard, facility, and the animal feed and/or pet food. Under FDA’s proposal, a facility, as appropriate, would be required to have written procedures for product testing, corrective action procedures to address the presence of a pathogen that is a significant hazard, appropriate indicator organism, or other significant hazard in finished animal feed or pet food detected as a result of product testing, and records of product testing.

Pertaining to such potential requirements, section 418 of the FD&C Act states that a facility shall verify that “the preventive controls implemented under [section 418(c) of the FD&C Act] are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means.” Concerning this language, FDA has acknowledged that “the statute does not indicate the specific circumstances where product testing would be required or the specific manner in which such testing should be performed” and “the role and need for these measures varies depending on the type of products and activities of a facility.”

The NGFA agrees that in some circumstances product testing may be used as an appropriate verification activity, and that the nature and extent of testing needs to be adapted to the particular circumstances of each facility and product. In general, each kind of product testing has its own role and purpose. Testing of incoming raw materials may have an appropriate role in certain manufacturing situations. But finished product testing is a beneficial verification activity only in limited circumstances. Because of the statistical limitations of finished-product testing, lot-by-lot testing generally does not help improve animal feed and pet food safety.

Accordingly, the NGFA believes FDA’s regulations should provide facilities the flexibility to determine if there are circumstances in which product testing is necessary to ensure that any identified significant hazards are being effectively controlled, to explain the basis for making such determinations, and to incorporate such testing, if any, within its written animal feed/pet food safety plan. Such regulatory flexibility would allow facilities to use product testing in a manner that is commensurate with the particular circumstances associated with the facility and its products.
Environmental Monitoring

If a facility identifies an environmental pathogen as a significant hazard, FDA’s proposed provisions would require environmental monitoring in the specific circumstances where the affected product is exposed to the environment prior to packaging and the packaged product does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the product when it is exposed. However, the potential requirements would not otherwise specify circumstances where environmental monitoring would be required and would instead require that the facility conduct environmental monitoring as appropriate to the facility, the product and the nature of the preventive control.

The NGFA believes the nature and extent of environmental testing appropriately should be adapted to the particular circumstances of each facility and product. In this regard, FDA’s proposal would specify one situation where environmental monitoring would be required: when a facility’s hazard analysis determines that an environmental pathogen is a significant hazard to a product and the product is exposed to the environment prior to packaging and the packaged product does not receive a treatment that would significantly minimize an environmental pathogen.

The NGFA generally agrees that environmental monitoring under this specific situation would be appropriate. However, to further clarify the scope of the proposed requirement, we recommend that FDA define within its regulations what is meant by “exposed to the environment.” Based upon previous statements made by FDA, we understand the phrase “exposed to the environment” to mean the product is in a form that is exposed and/or subject to direct human contact. We believe providing a definition for “exposed to the environment” is necessary to avoid confusion over what is meant by this phrase.

Supplier Programs

FDA’s supplier program would, if included in a final rule, require supplier controls when the receiving facility’s hazard analysis identifies a significant hazard for a raw material or ingredient, and that hazard is controlled before the facility receives the raw material or ingredient. Further, FDA proposes a receiving facility would not need to establish supplier controls if it controls the significant hazard, or if its customer controls that hazard.

FDA proposes that with one exception, the receiving facility would have flexibility to determine the appropriate supplier verification activity (e.g., onsite audit; sampling and testing of the raw material or ingredient; review of the supplier’s food safety records; or other appropriate verification activity). The one exception would be when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (SAHCODHA). In this circumstance, FDA proposes to require the receiving facility to have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter, unless the receiving facility determines and documents that other verification activities and/or less-frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled. FDA also proposes that instead of an onsite audit, a receiving facility would be able to rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA officially has recognized as comparable.
or has determined to be equivalent to that of the United States, provided that the inspection was conducted within one year of the date that the onsite audit would have been required to be conducted.

The NGFA offers the following views pertaining to any potential requirements for supplier programs:

- **The role of audits should not be overemphasized.** The NGFA believes that potentially requiring facilities to conduct mandatory audits of suppliers would be much too prescriptive and not allow the necessary flexibility for a facility to tailor an effective supplier program based upon risk. Although the NGFA believes that audits may be an effective verification tool, they only offer a “snapshot” of a supplier’s performance at a given time. The value of audits within any potential requirements for supplier programs should not be overemphasized or prescribed in a narrow manner. Rather, effective audits are risk-based, assess a supplier’s food safety system as a whole, and occur at a frequency tailored to the risks presented by both the supplier and food or feed.

  In addition, for audits to facilitate animal feed and pet food safety, the NGFA strongly believes that any potential regulations must include provisions to ensure the confidentiality of audit findings. The vast majority of information included in audit reports and that would be available for review by FDA under its proposed regulations would be process- and facility-specific. Therefore, the results contain such information as facility and equipment design, and processing and monitoring parameters based on product formulas. We believe that these design parameters and process and monitoring plans fall within the bounds of trade secret or commercial confidential business information, and must be protected from public disclosure.

  Moreover, confidentiality protections are necessary to encourage robust scrutiny and an open dialog during the audit process without creating fears about consequences from subsequent FDA review of the resulting report. We believe FDA’s potential records access to audit findings should be limited, and primarily focus on information that demonstrates appropriate actions were taken in response to the audit as needed to ensure product safety.

- **Any potential requirements must conform with international standards and agreements.** Section 404 of FSMA expressly states the provisions of FSMA are not to be construed in a manner inconsistent with U.S. international obligations. As a World Trade Organization (WTO) member, the United States is to act consistently with its WTO obligations, including those contained in the Agreement on the Application of Sanitary and Phytosanitary Measures.

  As such, the NGFA generally agrees with FDA’s position, as explained in the preamble of its 2013 proposed Foreign Supplier Verification Program rule, that the agency is obligated to take a parallel approach to domestic supplier verification within its preventive controls regulations to enhance compliance with WTO obligations and ensure trade access.
Therefore, the NGFA believes that FDA should take a cautious and balanced approach when implementing the requirements associated with foreign and domestic supplier programs, recognizing such requirements have potential trade implications and that foreign countries likely will impose similar obligations on domestic suppliers that export products. Such requirements must be flexible in application and commensurate with both the risk associated with the product and the supplier itself so as to avoid unnecessary and burdensome costs.

- **The complex and comingled nature in which raw agricultural commodities and other bulk ingredients move through the supply chain must be recognized.** Within the agency’s proposed regulation, FDA proposes to define “supplier” to mean, “the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.”

Therefore, FDA’s proposed definition of “supplier” does not include firms that only hold or pack the food, animal feed or pet food, regardless of whether such a facility is required to register with FDA under Section 415 of the FD&C Act. As justification, FDA previously has stated that it tentatively concludes Congress intended for the importer (or receiving facility) to verify a single supplier for a particular shipment of a food or feed.

The NGFA agrees with FDA’s tentative conclusion. The agency’s proposed requirements cannot feasibly be applied to all of the potential establishments that may have been involved in the production and distribution of the animal feed or pet food. Attempting to do so would result in a situation that would be extremely complex, burdensome, costly and counterproductive to enhancing food and feed safety. Rather, the requirements should reflect a risk-based approach and rightfully focus on the supplier, as appropriate, that has the greatest impact on the safety of the product.

Further, any potential supplier program requirements should appropriately reflect the complexities associated with the origination and movement through the supply chain of raw agricultural commodities and many other bulk ingredients used by the animal feed and pet food industries. A wide variety of bulk ingredients are handled and distributed in a comingled nature, thereby making it infeasible to determine the specific identity of each ingredient manufacturer whose product may be present in a given lot or shipment of the ingredient. The NGFA strongly believes any potential requirements pertaining to supplier programs must reflect the realities of the bulk ingredient supply chain by not attempting to impose untenable pedigree traceability standards and appropriately considering the risk posed by the raw agricultural commodity or ingredient.

- **Substitution of a regulatory inspection (e.g., by FDA or a comparable state regulatory agency, or food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States) should be allowed:** The NGFA strongly believes that FDA should not prescribe mandatory and rigid requirements for any potential supplier program. However, when a facility determines through an appropriate assessment of risk...
that verification activities of a supplier are necessary, we believe it would be appropriate for the facility to rely on the results of an inspection of the supplier conducted by FDA, a comparable state regulatory agency, or food safety authority of a country whose food safety system FDA officially has recognized as comparable or has determined to be equivalent to that of the United States. We believe this approach would accomplish adequately the required verification activity, and avoid costly and unnecessary redundancy.

**Economically Motivated Adulteration**

In FDA’s 2013 proposed rule for preventive controls, the agency announced its intent to implement the statutory requirements for hazards that may be intentionally introduced, including by acts of terrorism, in a separate rulemaking, rather than include them in the requirements for preventive controls. However, when FDA developed its 2013 proposed intentional contamination rule, the agency tentatively concluded that economically motivated adulteration would be addressed best through the approach in the preventive controls rules for human food and for animal food, rather than through the vulnerability assessment-type approach for intentional adulteration, where the intent is to cause wide-spread public health harm, such as by acts of terrorism. Therefore, FDA seeks comment on whether to add provisions to its preventive controls regulation specifically to address the potential for economically motivated adulteration.

FDA states that provisions proposed within its supplemental notice pertaining to economically motivated adulteration would require the hazard analysis to consider hazards that may be introduced intentionally for purposes of economic gain. Further, FDA states the focus of the potential requirement would be on those economically motivated adulterants that are reasonably likely to cause illness or injury in the absence of their control, not on economically motivated adulterants that solely affect quality and value with little or no potential for public (human or animal) health harm. Therefore, FDA notes that it would not expect facilities to consider hypothetical economically motivated adulteration scenarios for their animal feed and pet food products, but instead focus on circumstances where there has been a pattern of such adulteration in the past.

The NGFA strongly agrees that FDA should not require facilities to consider hypothetical economically motivated adulteration scenarios. To do so would subject the industry to a costly, unreasonable and unproductive exercise of trying to identify and assess any hazard – foreseeable or not – that conceivably could be introduced into the food or feed supply.

If FDA establishes within its final regulation that an affected facility’s hazard analysis is to consider economically motivated adulterants, we strongly believe the facility should only need to consider those adulterants for which there has been an historical pattern of occurrence. In addition, we believe that such an analysis should solely focus on inbound products, since it is obvious that intentional economic adulteration of products by the facility itself will not be prevented via a hazard analysis. Further, we believe that for facilities involved in the animal feed and pet food industries, adulterants intentionally added to products that are identified through the hazard analysis likely would not meet the threshold of a “significant hazard” and therefore would be appropriately addressed through supplier agreements and/or CGMPs.
In addition, the NGFA believes that guidance for both industry and FDA’s investigators would need to be developed and provided to ensure that regulatory obligations associated with any final requirement to consider economically motivated adulterants during required hazard analyses are defined clearly. As expressed previously, the NGFA believes the Food Safety Preventive Controls Alliance is the best forum through which such guidance may be developed.

**Very Small Businesses and Feed Mills Associated with Contract and Integrated Farming Operations**

FDA seeks comment on whether feed mills associated with fully vertically integrated farming operations, including cooperatives that fit this model, that meet the farm definition should be required to register as a food facility under section 415 of the FD&C Act, and therefore be subject to FDA’s CGMPs and preventive control regulations. In addition, FDA requests comment on how to value the animal feed manufactured at such operations that have no annual sales for purposes of determining whether the feed mill would be a “very small business,” which generally would be exempt from the preventive controls regulation.

As stated within NGFA’s comments submitted in response to FDA’s 2013 proposed rule, we believe FDA’s CGMPs and preventive controls regulations should be applied uniformly across facilities that produce and distribute animal feed and pet food products, and that no facilities should be exempted from the regulations because of size alone. Producing safe animal feed and pet food is a responsibility that every firm bears. In addition, regulatory exemptions create an uneven playing field for industry participants, providing a competitive advantage to some firms, but not others.

Nonetheless, FDA clearly has signaled that it intends to establish a “very small business” definition that generally will exempt such businesses from its preventive controls regulations. Accordingly, the agency within its supplemental notice proposes to define a “very small business” as one that has less than $2.5 million in total annual sales of animal feed and/or pet food, adjusted for inflation.

Given FDA’s intentions, the NGFA recommends the following definition for “very small business:”

**Very Small Business** means, for purposes of this part, a business that has less than $1 million in total annual sales of animal food, adjusted for inflation, and distributes less than 5,000 tons of animal food annually.

We believe such a definition for “very small business” would more appropriately limit the number of facilities that would qualify for an exemption from FDA’s preventive controls regulation. Further, such a definition would establish that integrated farm operations that do meet the farm definition, and therefore are required to register with FDA as a food facility, would only be provided an exemption if the business distributes less than 5,000 tons of animal feed and/or pet food annually. We believe that distributing 5,000 tons or more of animal feed and/or pet food annually is an appropriate threshold for determining whether to exclude an integrated farm operation from being classified as a “very small business” because if such a quantity of animal feed was sold commercially, its value very likely would be $1 million or more.
Pertaining to farms, the NGFA acknowledges the challenges in attempting to modify the farm definition in manner that would not result in unintended consequences and potentially have a negative impact on traditional farming operations. As such, we make no recommendations concerning revisions to the farm definition.

**Detailed Comments on Proposed Part 507 Provisions**

The NGFA provides the following comments and recommendations on FDA’s revised provisions proposed within part 507 – Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals. In many instances, we propose revisions to the draft codified language. In such cases, text that is recommended as being deleted is noted with a strikethrough (strikethrough) and text that is recommended as being added is noted by being boldfaced and underscored (boldfaced and underscored) for emphasis.

**Subpart A - General Provisions**

Following are NGFA’s comments and recommendations on the general provisions proposed within Part 507 Subpart A for which FDA seeks comment.

**§507.12 Applicability of this part to the holding and distribution of human food by-products for use in animal food.**

FDA proposes revisions on how the CGMPs and preventive controls regulations for animal feed and pet food would apply to holding and distribution of human by-products for use as a feed and pet food ingredient. FDA states it tentatively concludes that a human food facility’s compliance with human food CGMPs and all other applicable human food requirements are sufficient to help provide animal feed and pet food safety until the point of separation from the human food. Further, FDA proposes that once the by-product is separated from the human food and is merely packed and/or held by the facility for distribution, the facility would only be required to comply with CGMPs proposed at §507.28 that would apply to holding and distribution of the by-product, i.e., that facility would be exempt from animal feed and pet food preventive controls regulation. In addition, FDA proposes that a human food facility that further processes human food by-products (i.e., does more than solely hold and distribute) after the point of separation from the human food would be subject to animal feed and pet food preventive controls for those by-products. Examples provided by FDA of further processing include drying, pelleting, or heat treatment.

The NGFA generally supports FDA’s proposed approach on how human food by-products used in animal feed and pet food would be addressed within the agency’s regulations. We generally agree with FDA’s tentative conclusion that a human food facility’s compliance with proposed human food preventive controls and other applicable human food safety requirements are sufficient to help provide the safety of animal feed and pet food by-products until the point of separation from the human food. We also generally agree that provisions proposed within §507.28 that would apply to the holding and distribution of the by-product are sufficient to further ensure its safety.
However, in the preamble to the supplemental notice, FDA discusses that §507.12(b), which provides that human food by-products are not subject to the proposed rule’s requirements except those to be established within §507.28, would not apply to by-products from meat and poultry products for use in animal feed and pet food since the hazards from these products could be more substantial. Accordingly, the NGFA finds FDA’s discussion and intentions pertaining to this issue unclear, since it appears such an outcome would completely exempt by-products from meat and poultry products for use in animal food from the proposed rule’s requirements. If FDA’s tentative conclusion is to require facilities distributing by-products from meat and poultry products for use in animal feed and pet food to comply with all of the rule’s proposed requirements, we request that FDA carefully evaluate this conclusion and consider the impact that this potential dual regulation of products regulated by both FDA and the U.S. Department of Agriculture would have upon the industry, the availability of these products and the associated compliance costs.

§507.3 Definitions

The NGFA provides the following comments on the revised definitions proposed within §507.3. For proposed definitions in which we are in agreement with FDA, we generally offer no comments. However, we do offer comments in areas in which we wish to emphasize support for constructive changes made by FDA in its supplemental notice.

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

  The NGFA believes that FDA’s proposed definition for “environmental pathogen” is too general, as it would include any pathogen that is capable of surviving or persisting in the environment. Instead, we believe the definition should be limited to pathogenic bacteria that are more relevant when protecting animal feed and pet food safety. As such, we recommend the definition be revised as follows:

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

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

  The NGFA agrees with FDA’s proposed revision to include radiological hazards as a subset of chemical hazards in the definition of “hazard.”
- **FDA proposed definition:** *Known or reasonably foreseeable hazard* means a potential biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with a food or the facility in which it is manufactured/processed.

The NGFA agrees with FDA’s proposed revision because it provides for the proper consideration of both the food and the facility when making determinations pertaining to a “known or reasonably foreseeable hazard.”

- **FDA proposed definition:** *Pathogen* means a microorganism of public (human or animal) health significance.

The NGFA believes the significance of pathogens to public health is dependent on the organism’s severity and exposure nature and, as such, recommends the definition be modified as follows:

**NGFA recommended definition:** *Pathogen* means a microorganism of such severity and exposure that it would be deemed of public (human or animal) health significance.

- **FDA proposed definition:** *Significant hazard* means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing/processing, packing, or holding of animal food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

As expressed previously, the NGFA generally supports FDA’s new term “significant hazard” and the process to be used by facilities to determine whether such a hazard exists within their operations. However, because the evaluation of severity and probability are so integral in making a proper determination as to whether a hazard is “significant,” the NGFA recommends that FDA revise its proposed definition to include these concepts. In addition, for the purpose of clarity and consistency, we also recommend the definition be modified to state that determinations of significant hazards are to be made by a “qualified individual.” Further, we suggest the definition include the concept of intended use of the animal food because it is essential to making appropriate determinations about hazards. As such, we recommend the proposed definition be revised as follows:

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

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

  The NGFA strongly supports FDA’s revised definition for “holding.” We agree that “holding” rightfully should encompass activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity).

- **FDA proposed definition: Qualified auditor** means a person who is a qualified individual as defined in this part and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function as required by §507.53(c)(2).

  The NGFA strongly supports FDA’s proposal that would allow audits to be conducted by a “qualified auditor” that is a receiving facility’s employee or by a third-party “qualified auditor” that need not be accredited under the requirements to be established under the agency’s forthcoming third-party certification regulation. We believe such an approach would provide for appropriate flexibility for conducting audits when necessary, while still ensuring the audits are performed with the required rigor to verify the safety of raw materials and ingredients.

  In addition, the NGFA believes that a “qualified individual” may appropriately acquire the technical expertise to become a “qualified auditor” by training, education or experience. As such, we recommend the definition of “qualified auditor” be revised as follows.

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

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

  The NGFA supports FDA’s proposed definition for “receiving facility.”
• **FDA proposed definition:** *Supplier* means the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.

The NGFA supports FDA’s proposed definition for “supplier.”

• **FDA proposed definition:** *Very Small Business* means, for purposes of this part, a business that has less than $2,500,000 in total annual sales of animal food, adjusted for inflation.

The NGFA believes FDA’s CGMPs and preventive controls regulations should be applied uniformly across facilities that produce and distribute animal feed and pet food products, and that no facilities should be exempted from the regulations because of size alone. Producing safe animal feed and pet food is a responsibility that every firm bears. In addition, regulatory exemptions create an uneven playing field for industry participants, providing a competitive advantage to some firms, but not others.

Nonetheless, as expressed previously, we recommend the following definition for “very small business,” given FDA’s intent to establish such a definition.

**NGFA recommended definition:** *Very Small Business* means, for purposes of this part, a business that has less than $2,500,000 in total annual sales of animal food, adjusted for inflation and distributes less than 5,000 tons of animal food annually.

As noted in NGFA’s statement submitted in response to FDA’s 2013 proposed rule, we also recommend that the term “nutrient imbalances” within the preventive controls regulation be replaced with the terms “nutrient deficiency” and “nutrient toxicity,” and offer the following proposed definitions for these terms.

• **NGFA recommended definition:** *Nutrient deficiency* means the absence or insufficiency of an essential nutrient at such a level and being consumed over a timeframe that is scientifically documented that would result in a serious adverse health effect or death to animals.

• **NGFA recommended definition:** *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 to animals.

§507.5(g) and §507.5(h) – Exemptions for Raw Agricultural Commodities Other than Fruits and Vegetables

Although not specifically addressed within FDA’s supplemental notice, the NGFA reiterates its belief that, based upon the minimal level of public health risk and the authority provided to the agency, FDA should modify its proposed rule and expressly exclude packing activities associated with raw agricultural commodities other than fruits and vegetables intended for
further distribution or processing from the CGMPs and preventive controls requirements to be established under its regulations.

As such, we restate our recommended revisions to §507.5(g) and §507.5(h):

- §507.5(g): “Subpart C of this part does not apply to facilities that are solely engaged in the storage or packing of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.”

- §507.5(h): “Subpart B of this part does not apply to the holding or transportation of one or more ‘raw agricultural commodities,’ or the packing of ‘raw agricultural commodities’ (other than fruits and vegetables), as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.”

**Subpart B - Current Good Manufacturing Practice**

As previously expressed, the NGFA believes the provisions established within FDA’s CGMPs regulation should be appropriate and reasonable for the full range and scope of animal feed and pet food facilities that will be required to comply with the requirements. While the revised CGMPs within FDA’s supplemental notice are an improvement over those originally proposed, we remain concerned that many of the proposed requirements are neither applicable nor appropriate for the vast majority of firms that will be required to comply with the final rule, and would add to the industry’s compliance costs.

In principle, the NGFA believes that FDA’s CGMPs requirements generally should be non-prescriptive and reflect desired outcomes, thereby allowing facilities to use practices and procedures effective for their operations to achieve animal feed and pet food safety. As such, we believe the provisions need to provide sufficient flexibility so as to not prohibit or require certain practices or conditions when other equally effective and appropriate controls can be implemented to achieve the same desired outcome. Pertaining to this concept, we note that many of FDA’s proposed requirements focus on the design or construction of equipment and/or facilities, instead of the desired outcome of protecting against the adulteration of products. We strongly believe that such provisions are not appropriate, and, if included with FDA’s final rule, could compel the animal feed and pet food industry to spend millions of dollars redesigning or replacing equipment and facilities with no benefit to animal feed and pet food safety.

Further, we question how FDA will evaluate for compliance purposes many of the proposed CGMPs requirements pertaining to design and construction of equipment and facilities. While the agency’s proposed preventive control regulations specify documentation and recordkeeping requirements, no such proposed requirements are included with the proposed CGMPs. As such, we believe that many of the proposed provisions would create open-ended compliance obligations, and potentially establish the need to establish and maintain extensive and costly documentation, again with no commensurate benefit to animal feed and pet food safety.

Finally, as expressed previously in our comments submitted in response to FDA’s 2013 proposed rule, the NGFA urges FDA to replace the term “contamination” throughout its proposed regulation with the term “adulteration.” As FDA is aware, the term “contamination” is not
defined and has no legal meaning. We strongly believe that FDA’s regulation cannot rightfully focus on avoiding and preventing “contamination,” when that term has no defined meaning in a regulatory context. In addition, the desired outcome of FDA’s requirements is to prevent adulteration of animal feed and pet food. As such, we believe that proposed language pertaining to the “contamination of animal food, animal food-contact surfaces, and animal food-packaging” should be deleted and generally be replaced with “adulteration of animal food.”

Nonetheless, if the agency chooses to not replace within its regulation the term “contamination” with the term “adulteration,” we recommend FDA define the term “contamination” to mean “the occurrence of a substance in an animal food not intentionally added to such food, and which is present at a level that is reasonable likely to cause illness or injury.”

Further, in regard to the use of the term “contamination,” the supplemental proposed rule uses the phrases “protect against” as well as “prevent” and “preclude.” The NGFA believes that “protect against” is the most appropriate phrase and suggests using it throughout the rule for the sake of consistency.

In accordance with these views, the NGFA provides the following specific comments and recommendations pertaining to the agency’s codified language proposed within its supplemental notice for Subpart B, Current Good Manufacturing Practice.

§507.14 Personnel

Proposed § 507.14 would establish requirements that personnel in animal feed/pet food facilities conform to specified hygienic practices and recommends that responsible personnel and employees be trained to protect against contamination of animal feed and pet food.

The NGFA provides the following comments pertaining to provisions proposed within §507.14:

- The term “utensils” is not widely used or understood within the animal feed and pet food industry. Therefore, the NGFA recommends the term “tools” be used in its place.

- We believe §507.14(a) adequately establishes that facilities have an obligation to keep the facility’s grounds in a condition that will protect against the adulteration of animal feed and pet food. As such, we believe that provisions listed under (a)(1) should be made recommendations, rather than requirements. Further, we believe that making such provisions recommendations still would provide FDA ample authority to take compliance action when it finds conditions associated with such provisions as being violative.

- The NGFA believes the term “thoroughly” used within §507.14(a)(2) is ambiguous, and, as such, should be deleted because it would establish vague compliance obligations.

- The NGFA believes the terms “clean” or “housekeeping” generally are more appropriate than the term “sanitary” for use in FDA’s regulations for animal feed and pet food. The term “sanitary” is not commonly used within the animal feed and pet food industry to describe conditions at facilities, and conveys strong connotations pertaining to health, factors affecting health, and precautions against disease, all of which primarily relate to
the control of undesirable microorganisms. We strongly believe the vast majority of facilities that will be required to comply with FDA’s CGMPs regulation do not need to implement controls for undesirable microorganisms to ensure the production and distribution of safe products. Instead, if the presence of undesirable microorganisms is a hazard associated with a particular facility’s operation, we believe that such a hazard appropriately should be addressed within the facility’s animal feed/pet food safety plan developed under the agency’s preventive controls regulation.

- We believe that proposed §507.14(a)(3) that specifically addresses the potential for jewelry and other objects to fall into animal feed and pet food is unnecessary. The proposed CGMPs contain numerous other provisions that require facilities to protect against the adulteration of products. The NGFA believes the special focus placed on jewelry and other items that potentially might fall into products and cause adulteration is unwarranted because of the limited risk posed by such a possibility. In addition, we believe enforcement of the proposed provision would be highly subjective and cause undue emphasis to be placed on an area of limited significance to the production and distribution of safe animal feed and pet food.

- The NGFA believes that proposed §507.14(a)(4) that would specifically require storing of clothing or other personal belongings outside of areas other than where animal food is exposed or where equipment or utensils are cleaned is not practical nor necessary to ensure the safety of animal feed and pet food. As FDA is aware, the temperature conditions within various areas of an animal feed mill may vary considerably, especially during winter months when some areas are heated and others are essentially at ambient temperatures. While performing duties, a typical employee will pass in and out of the various areas of the plant frequently. As such, we believe it would be completely unreasonable to require that an employee store necessary protective clothing outside of areas where animal food is exposed or where equipment or tools are cleaned. Further, we believe that storing such clothing within areas where animal feed is exposed poses no risk to product safety. As such, we strongly recommend this proposed provision be deleted.

- The NGFA believes that FDA should not require that personnel responsible for identifying the status of the CGMPs within a facility somehow be able to demonstrate their competency in doing so. Instead, we believe that FDA through its inspectional observations should be able to make appropriate determinations regarding the animal feed/pet food safety conditions present within a facility, and the ability of responsible personnel to direct the facility’s operations to ensure the production and distribution of safe products. Therefore, we strongly believe that proposed § 507.14(b) should recommend, but not require, that responsible personnel have an appropriate background of education or experience.

Further, the NGFA agrees that FDA’s regulation should recommend, but not require, that appropriate employee training occur for the production and distribution of safe animal feed and pet food. We believe that the scope and format of appropriate employee training may vary dramatically according to the type and size of a given facility, and the range of products that it manufactures, packs or holds. For example, in some facilities, employee training that is highly structured and conducted at preset intervals may be appropriate,
while at other facilities on-the-job employee oversight that is provided by the employer is sufficient to achieve the goal of safe animal feed/pet food. Therefore, the NGFA believes that FDA’s regulations should allow facilities to conduct employee training in a flexible manner, with the facility determining the training content and frequency that is appropriate for the duties of a given employee as they relate to ensuring the safe production and distribution of animal feed and pet food. As such, we believe that proposed § 507.14(b) that recommends, but does not require, employee training provides facilities with flexibility to direct and oversee employees in a manner appropriate to their own operations.

Accordingly, the NGFA recommends that proposed § 507.14 be revised as follows:

§507.14 Personnel

(a) Plant management must take all reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against contamination adulteration of animal food. The methods for maintaining cleanliness should include:

1. Maintaining adequate personal cleanliness;
2. Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to prevent contamination protect against adulteration;
3. Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers;
4. Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned; and
5. Taking any other necessary precautions to protect against contamination adulteration of animal food, animal food-contact surfaces, or animal food-packaging materials.

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

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

§507.17 Plant and Grounds

Proposed §507.17 would establish required conditions and practices pertaining to a facility’s plants and grounds. Plant, as defined in proposed §507.3, means the building or establishment or parts thereof used in connection with the manufacturing, processing, packing or holding of animal feed and pet food.

The NGFA provides the following comments and recommendations pertaining to the proposed provisions:
- As previously expressed, the NGFA believes that the terms “clean” or “housekeeping” generally are more appropriate than the term “sanitary” for use in FDA’s regulations for animal feed and pet food.

- The NGFA believes §507.17(a) adequately establishes that facilities have an obligation to keep the facility’s grounds in a condition that will protect against the adulteration of animal feed and pet food. As such, we believe that provisions (a)(1) through (a)(4) should be made recommendations, rather than requirements. Further, we believe that making such provisions recommendations still would provide FDA with ample authority to take compliance action when it finds conditions associated with such provisions are violative.

- Likewise, we believe §507.17(b) adequately establishes that facilities have an obligation to keep the facility’s buildings and structures in a condition that will protect against the adulteration of animal feed and pet food. Accordingly, we believe provisions (b)(1) through (b)(6) should be made recommendations, rather than requirements.

- The NGFA believes that §507.17(b)(1) represents a provision that focuses on facility design rather than the necessary outcome of protecting against the adulteration of animal feed and pet food. As such, we believe the provision should be revised to allow for other means to accomplish adequate cleaning and maintenance of equipment in equally effective manners.

- We believe proposed §507.17(b)(2) pertaining to the potential for drips or condensate from fixtures, ducts, and pipes is generally not relevant and redundant with §507.17(b), and therefore should be deleted.

- The NGFA believes that requirements proposed within §507.17(b)(3) pertaining to ventilation equipment and controls are not relevant for the vast majority of animal feed and pet food facilities, and therefore the provision should be qualified with the phrase “where necessary.” In addition, we believe the parenthetical reference to steam being a potentially hazardous vapor is confusing, unnecessary and should be deleted.

- We believe §507.17(b)(6) should be revised to provide that protecting bulk animal feed stored outdoors may include the criteria specified in items (i) through (iii).

Accordingly, the NGFA recommends that proposed §507.17 be revised as follows:

§507.17 Plant and grounds

(a) The grounds surrounding an animal food plant under the control of the operator must be kept in a condition that will protect against the contamination adulteration of animal food. Maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests;

(2) Maintaining driveways, yards, and parking areas so that they do not constitute a source of contamination adulteration in areas where animal food is exposed;
(3) Adequately draining areas that may contribute to contamination adulteration of animal food; 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.

(b) Buildings, structures, fixtures, and other physical facilities of the plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control to reduce the potential for contamination protect against adulteration of animal food, animal food contact surfaces, and animal food packaging materials. This should includes:

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

§507.19 Sanitation

Within §507.19, FDA proposes to establish requirements that buildings, fixtures, and other physical structures be maintained in sufficient sanitary condition and repair to prevent animal food from becoming adulterated. In addition, the agency proposes that equipment and utensils would need to be cleaned and sanitized to protect against contamination of animal food, animal food contact surfaces, and animal food packaging materials.

The NGFA provides the following comments on requirements proposed within §507.19:

• We believe this section would be more appropriately titled as, “Housekeeping and Cleaning.”
• The NGFA believes the second sentence within §507.19(b) pertaining to disassembling equipment for cleaning is much too prescriptive and unnecessary because of the general
requirement proposed within the first sentence of the provision. Therefore, we recommend the second sentence be deleted.

- We believe §507.19(b)(1) should be a recommendation, and not a requirement, as the potential presence of some moisture on animal food-contact surfaces does not pose a significant risk to the adulteration of products.

- The NGFA believes §507.19(b)(2) should not prescribe a required cleaning and sanitizing frequency, but instead provide facilities flexibility in establishing an appropriate frequency that protects against products from being adulterated.

- The NGFA strongly believes the absolute prohibition of a given material due to its potential risk within a plant as proposed within §507.19(d) does not provide for sufficient flexibility to control the risk in a different, but equally effective manner. In addition, the vast majority of animal feed plants hold and distribute materials that FDA likely would consider “toxic.” Therefore, such facilities either would be required to stop distributing such materials or construct additional, separate storage areas if the requirements specified in §507.19(d) are included in FDA’s final rule. As detailed in the economic impact section of this statement, the NGFA estimates that construction of additional storage areas would cost the animal feed industry hundreds of millions of dollars.

Instead, the NGFA urges FDA to establish a reasonable provision to allow facilities flexibility in appropriately controlling substances within a plant that are not approved for use in animal feed and pet food.

Therefore, the NGFA recommends that proposed §507.19 be revised as follows:

§507.19 Sanitation-Housekeeping and Cleaning

(a) Buildings, structures, fixtures, and other physical facilities of the plant must be kept clean and in good repair to prevent protect against adulteration. animal food from becoming contaminated adulterated.

(b) Animal food-contact and non-contact surfaces of utensils tools and equipment must be cleaned and maintained and utensils tools and equipment stored as necessary and appropriate to protect against contamination adulteration of animal food, animal food-contact surfaces, or animal food-packaging materials. When necessary, equipment must be disassembled for thorough cleaning. In addition:

(1) When it is necessary to wet-clean animal food-contact surfaces used for manufacturing/processing, or holding low-moisture animal food, the surfaces must should be thoroughly dried before subsequent use.

(2) In wet processing, when cleaning and sanitizing is necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated as necessary to protect against adulteration of animal food.

(c) Cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use.
Substances not approved for use in animal food must be identified, held, stored and used or distributed in a manner that protects against adulteration of animal food. The following applies to toxic materials:

(1) Only the following toxic materials may be used or stored in a plant where animal food is manufactured/processed or exposed:
   (i) Those required to maintain clean and sanitary conditions;
   (ii) Those necessary for use in the plant’s operations;
   (iii) Those necessary for plant and equipment maintenance and operation; and
   (iv) Those necessary for use in laboratory testing procedures.

(2) Toxic materials described in paragraph (d)(1) of this section (for example cleaning compounds, sanitizing agents, and pesticide chemicals) must be identified, used, and stored in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

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 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.

Trash and garbage must be conveyed, stored, and disposed of in a way that protects against contamination adulteration of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces, and minimizes the potential for the trash and garbage to become an attractant and harborage or breeding place for pests.

§507.20 Water Supply and Plumbing

The NGFA provides the following comments pertaining to proposed §507.20 that would establish requirements for a plant’s water supply and plumbing:

- FDA in §507.20(a) proposes detailed requirements for water. However, the NGFA is unaware of any animal feed or pet food safety incident that has occurred due to an inadequate water supply. As such, the NGFA believes the general required condition for water used in facilities should be that it is adequate for the operations intended. We therefore strongly recommend the additional terms used to prescribe water requirements within the proposed provision be deleted.

- We believe proposed §507.20(b) that would establish requirements pertaining to plumbing are not necessary to prevent the adulteration of animal feed and pet food and should be deleted entirely. The NGFA is unaware of any animal feed or pet food safety incident that has occurred due an inadequate plumbing system that would potentially provide justification for such requirements. Further, we believe the proposed provisions generally would establish requirements that pose ambiguous compliance obligations. For instance, we have strong concerns about how facilities would be expected to demonstrate compliance, and how FDA investigators would evaluate such provisions.

- The NGFA believes the addition of “as appropriate” to §507.20(d) and §507.20(e) is necessary to provide flexibility for existing facilities.
Accordingly, the NGFA recommends that proposed §507.20 be revised as follows:

§507.20 Water supply and plumbing

(a) The water supply must be adequate for the operations and must be derived from a suitable source. Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where necessary, required for the manufacturing/processing of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee hand-washing facilities. Water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe for its intended use. Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food.

(b) Plumbing must be designed, installed, and maintained to:
   (1) Carry adequate quantities of water to required locations throughout the plant;
   (2) Properly convey sewage and liquid disposable waste from the plant;
   (3) Avoid being a source of contamination to animal food, animal food-contact surfaces, or animal food-packaging materials, water supplies, equipment, or utensils, and avoid creating an unsanitary condition;
   (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and
   (5) Ensure that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for animal food or animal food manufacturing/processing.

(c) Sewage must be disposed of through an adequate sewerage system or through other adequate means.

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

§507.22 Equipment and Utensils

Within §507.22, FDA proposes requirements associated with the design, construction and maintenance of equipment and utensils used by animal feed and pet food facilities.

The NGFA provides the following comments pertaining to proposed §507.22:

- The NGFA believes the requirement proposed within §507.22(a)(5) pertaining to the construction and design of equipment that does not contact animal feed and pet food would establish a highly prescriptive requirement that is not performance based, nor necessary. In this case, the desired outcome is to keep the animal feed or pet food manufacturing area clean so as to prevent adulteration of products. Instead, the provision
would establish subjective criteria about whether the equipment’s design and construction allows it to be kept in clean condition. We strongly believe FDA’s regulatory focus should be on whether the area is adequately clean, and not on attempting to mandate and evaluate equipment construction and design. In addition, FDA has indicated that it is not the agency’s intent to establish requirements that compel firms to rebuild their facilities, nor does FDA account for the cost of doing so in its economic analysis. Further, we believe this provision is redundant with §507.22(a)(1). Therefore, we urge FDA to delete this provision.

- We believe the requirement proposed within §507.22(b) pertaining to the design of specific equipment should be deleted because it is redundant with §507.22(a)(1) through (a)(4).

- The NGFA believes that §507.22(c) implies the need for a continuous temperature monitoring device. We believe continuous temperature monitoring devices should not be required, and that facilities should have flexibility in controlling temperatures in freezers and cold storage compartments.

- Pertaining to proposed requirements within §507.22(e), we are not aware of any evidence to indicate that compressed air used to clean product contact surfaces or equipment needs to be treated in some manner to prevent the adulteration of animal feed and pet food. Therefore, we request that that portion of the proposed requirement be deleted.

Accordingly, the NGFA recommends that proposed §507.22 be revised as follows:

§507.22 Equipment and utensils tools

(a) The following apply to plant equipment and utensils tools:

(1) All 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 contamination protect against adulteration of animal food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants adulterants;

(3) Equipment should be installed and maintained in such a way as to facilitate the cleaning of the equipment and adjacent spaces;

(4) Animal food-contact surfaces must be:

(i) Made of materials that withstand the environment of their use and the action of animal food, and, if applicable, the action of cleaning compounds and sanitizing agents;

(ii) Made of nontoxic materials; and

(iii) Maintained to protect against animal food from being contaminated adulterated.

(5) Equipment in the animal food manufacturing/processing area that does not come into contact with animal food must be designed and constructed in such a way that it can be kept in a clean condition.

(b) Holding, conveying, and manufacturing/processing systems, including gravimetric, pneumatic, closed, and automated systems, must be designed, constructed, and maintained in a way that does not contaminate animal food.
(b) **The temperature of each** freezer and cold storage compartment used to hold animal food must be **monitored**, fitted with an accurate temperature monitoring **measuring** device.

(c) **Instruments and controls used for measuring, regulating, or recording temperatures, pH, aw, or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate, precise, adequately maintained, and adequate in number for their designated uses.**

(d) Compressed air or other gases mechanically introduced into animal food or used to **clean animal food-contact surfaces or equipment** must be used in such a way that protects against animal food is not contaminated from being adulterated.

§507.25 Plant Operations

FDA proposes within §507.25 to establish requirements for various processes and controls to be used by facilities producing and distributing animal feed and pet food.

The NGFA provides the following comments pertaining to proposed §507.25:

- We believe that §507.25(a)(2) should be revised to clarify that bulk silos and bins are not required to be physically placarded as to their contents, and that the provision provides flexibility in establishing the identity of materials placed in containers.

- The NGFA believes §507.25(a)(3) should be revised to require labeling to conform with applicable regulatory requirements.

- We believe the potential for “sanitation failures” referenced in §507.25(a)(7) would only apply to facilities that have identified a pathogen as a significant hazard within their operations. Accordingly, we believe the use of any testing to identify “sanitation failures” would occur in accordance with the facility’s written animal feed/pet food safety plan established under the preventive control regulations. Therefore, we recommend the reference to “sanitation failures” within this provision be deleted.

- Pertaining to proposed §507.25(a)(8), current 21 CFR §110.80(b)(9) requires that food, raw materials and other ingredients that are adulterated must be disposed of in a manner that protects against the contamination of other food. It further requires if the adulterated food is capable of being reconditioned, it be reconditioned using a method that has been proven to be effective or it be reexamined and found not to be adulterated within the meaning of the FD&C Act before being incorporated into other food.

Within its 2013 proposed human food CGMPs regulation, FDA proposed to delete the option for reexamination so that adulterated food only can be disposed of or reconditioned if the food is capable of being reconditioned. FDA stated that it is proposing this deletion because a food may test positive for a contaminant in one test and negative in one or more additional tests although the food continues to be contaminated. Therefore, under FDA’s proposal, a food found to be adulterated must be reconditioned before it is reexamined.
The NGFA notes that FDA’s proposal is in conflict with provisions of the U.S. Grain Standards Act (USGSA) found at 7 CFR §800.125 and §800.135. These provisions currently permit a review inspection of grains by the USDA for either official grade/factors or official criteria. Specifically, these provisions provide for review inspection services for the presence of aflatoxin in grains on either a new sample or the file sample in accordance with regulations without reconditioning.

The USDA promulgated these provisions for a review process in 1985 as a result of inherent sampling and inspection variability associated with determining official grade/factors or official criteria of grains. As such, users of USDA’s official grain inspection system have an opportunity to obtain another inspection service when certificated results are questionable.

The NGFA believes the current review inspection process serves an important function for both USDA and industry in ensuring that official grade/factors and/or official criteria are determined accurately. Therefore, we request that, if FDA proceeds to promulgate within its final CGMPs regulation a requirement that a food found to be adulterated must be reconditioned before it is reexamined, the agency clarify such a requirement does not apply to grains subject to the review inspection provisions provided for by 7 CFR §800.125 and § 800.135.

- The NGFA strongly opposes use of the phrase “minimize deterioration” introduced in §507.25(b)(1) and the subsequent uses of the term “deterioration” within other proposed provisions. The interpretation of “minimize deterioration” and “deterioration” would be highly subjective, and the use of such a phrase and term within the regulation would establish ambiguous compliance obligations. Further, we disagree with FDA’s assertion that such a requirement is necessary to ensure that animal feed is not adulterated. FDA and state regulatory agencies already have existing requirements establishing that the nutrient content of products be accurately and truthfully labeled. Therefore, we strongly recommend the use of the term “deterioration” be deleted from the proposed regulation.

- The NGFA believes the requirement proposed in §507.27(b)(1)(i) that would require shipping containers and bulk vehicles holding raw materials and ingredients be inspected upon each receipt is unnecessary. Instead, FDA’s regulation should establish that inspection of shipping containers and bulk vehicles be conducted as appropriate and necessary to ensure products are not adulterated. For example, a shipping container or bulk vehicle may be dedicated to transporting only one product. In this case, it is not appropriate nor necessary to require inspection of the container or bulk vehicle prior to each receipt. Therefore, we strongly recommend the proposed provision be revised to provide for flexibility in establishing an appropriate inspection frequency.

- We believe §507.25(b)(1)(ii) that pertains to cleaning raw materials would establish an ambiguous requirement, is not generally relevant to animal feed and pet food facilities, and should be deleted.

- The NGFA believes §507.25(b)(2) should be revised by deleting the term “evaluated.” As drafted, we believe the proposed provision could be interpreted to mean that all raw
materials and ingredients must be evaluated upon receipt for potential mycotoxins. Such an evaluation is not always necessary, since the potential presence of mycotoxins in grains and grain by-products is highly dependent upon the weather conditions that were present during the grain’s growing season.

- We believe the reference within §507.25(b)(3) and §507.25(c)(1) pertaining to holding and manufacturing products at temperatures and relative humidities that will minimize the potential for growth of undesirable microorganisms should be deleted because it is not relevant to the vast majority of facilities that will be subject to the CGMPs regulation. Further, we believe references to container design and construction should be deleted in §507.25(b)(3), since FDA’s requirements rightfully should be outcome based, rather than prescribe restrictive conditions.

- The NGFA believes proposed §507.25(c)(2) pertaining to the use of temperature and other measures to minimize the growth of undesirable microorganisms is not relevant to the vast majority of facilities that will be covered by the CGMPs regulation, and therefore should be deleted. If such controls are necessary, we believe they should be implemented as part of the facility’s animal feed/pet food safety plan under the agency’s preventive controls regulation.

- We believe proposed §507.25(c)(6) and §507.25(c)(7) would establish requirements for the control of undesirable microorganisms that are not a hazard for the vast majority of affected facilities. As such, we believe that if such a hazard is associated with a particular facility and product, that facility should appropriately address the hazard within its animal feed/pet food safety plan developed under the agency’s preventive controls regulation. Therefore, we recommend these provisions be deleted.

Accordingly, the NGFA recommends that proposed §507.25 be revised as follows:

§507.25 Plant operations

(a) Plant management must ensure that:

1. All operations in the manufacturing/processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with the current good manufacturing practice requirements of this subpart;

2. Containers holding animal food, including raw materials, ingredients, or rework, are accurately identified as to the contents;

3. The labeling for the finished animal food product contains information and instructions for safely using the product for the intended animal species conforms with applicable regulatory requirements;

4. Animal food-packaging materials are safe and suitable for their intended use;

5. The overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function;

6. Reasonable precautions are taken so that plant operations do not contribute to contamination protect against adulteration of animal food, animal food-contact surfaces, and animal food packaging materials;

7. Chemical, microbial, or extraneous-material testing procedures are used
where necessary to identify sanitation failures or possible animal food contamination adulteration; and

(8) Animal food that has become contaminated to the extent that it is adulterated is rejected, disposed of, or if permissible, treated or processed to eliminate the adulteration. If disposed of, it must be done in a manner that protects against the contamination adulteration of other animal food; and

(9) All animal food manufacturing/processing, packing, and holding is conducted under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms or for the contamination protect against adulteration of animal food.

(b) Raw materials and ingredients:

(1) Must be inspected to ensure that they are suitable for manufacturing/processing into animal food and must be handled under conditions that will protect against contamination and minimize deterioration adulteration. In addition:

(i) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles holding raw materials and ingredients must be inspected upon receipt at a frequency appropriate and necessary to determine whether contamination or deterioration adulteration of animal food has occurred;

(ii) Raw materials must be cleaned as necessary to minimize soil or other contamination; and

(ii) Raw materials and ingredients must be stored under conditions that will protect against contamination and deterioration adulteration.

(2) Susceptible to contamination with mycotoxins or other natural toxins must be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans;

(3) And all rework, must be held in containers designed and constructed in a way that protects against contamination, and must be held under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and in a manner that prevents protects against the animal food from becoming adulterated; and

(4) If frozen, must be kept frozen. If thawing is required prior to use, it must be done in a manner that minimizes the potential for the growth of undesirable microorganisms protects against adulteration.

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

(1) Animal food must be maintained under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent protect against the animal food from becoming adulterated during manufacturing/processing, packing, and holding;

(2) Measures taken during manufacturing/processing, packing, and holding of animal food to significantly minimize or prevent the growth of undesirable microorganisms (for example, heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling aw) must be adequate to prevent adulteration of animal food;

(2) (3) Work-in-process and rework must be handled in such a way that it is protected against contamination and the growth of undesirable microorganisms adulteration;

(3) (4) Steps such as cutting, drying, defatting, grinding, mixing, extruding, pelleting, and cooling, must be performed in a way that protects against contamination adulteration;

(4) (5) Filling, assembling, packaging, and other operations must be performed in such a
way that the animal food is protected against contamination and growth of undesirable microorganisms; and
(6) Animal food that relies on the control of aw for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level;
(7) Animal food that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at the appropriate pH; and
(5) When ice is used in contact with animal food, it must be made from water that is safe and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this subpart.

§507.27 Holding and Distribution

The NGFA provides the following comments pertaining to proposed §507.27 that would establish requirements for the holding and distribution of animal feed and pet food.

- We believe the detailed criteria proposed in §507.27(a)(1) pertaining to containers should be replaced with the general requirement that containers be “fit for purpose.”
- The NGFA believes that §507.27(a)(3) as proposed would establish a requirement associated with distributing the animal feed or pet food, rather than holding a product for distribution. As such, we recommend the provision be revised to reflect that products being held for distribution be accurately identified.
- We believe the requirement proposed in §507.27(b) that would require inspection of shipping containers and bulk vehicles prior to each use is unnecessary. Instead, FDA’s regulation should establish that inspection of shipping containers and bulk vehicles be conducted as appropriate and necessary to ensure products are not adulterated. For example, a shipping container or bulk vehicle may be dedicated to transporting only one product. In this case, it is not appropriate nor necessary to require inspection of the container or bulk vehicle prior to each shipment. Therefore, we strongly recommend the proposed provision be revised to provide for flexibility in establishing an appropriate inspection frequency.

Accordingly, the NGFA recommends that proposed §507.27 be revised as follows:

§507.27 Holding and distribution

(a) Animal food held for distribution must be held for distribution under conditions that will protect against contamination and minimize contamination and prevent the contamination of animal food; and
(1) Containers used to hold animal food before distribution must be designed, constructed of appropriate material, fit for purpose, cleaned when necessary, and maintained to prevent the contamination protect against adulteration of animal food;
(2) Animal food held for distribution must be held for distribution in a way that protects against adulteration from sources such as trash
and garbage; and

(3) **Animal food held for distribution must be accurately identified.** Labeling identifying the product by the common and usual name must be affixed to or accompany the animal food.

(b) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use at a frequency appropriate and necessary to ensure the container or vehicle will not contaminate adulterate the animal food.

(c) Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed.

(d) Unpackaged or bulk animal food must be held in a manner that does not result in cross contamination adulteration with other animal food.

§507.28 Holding and Distribution of Human Food By-products for Use as Animal Food

The NGFA recommends §507.28 be revised in accordance with our comments pertaining §507.27. In addition, we recommend the term “human food by-product” be used to further distinguish this section from §507.27.

As such, we recommend §507.28 be revised as follows:

(a) Human food by-products held for to be distribution distributed as animal food must be held under conditions that will protect against contamination adulteration, including the following:

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

(2) Animal food held for distribution Human food by-products must be held for distribution in a way to prevent contamination that protects against adulteration from sources such as trash and garbage; and

(3) **Human food by-products held for distribution must be accurately identified.** Labeling identifying the product by the common and usual name must be affixed to or accompany animal food.

(b) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food human food by-products must be inspected prior to use at a frequency appropriate and necessary to ensure the container or vehicle will not contaminate adulterate the animal food human food by-products.

(c) **Labeling that conforms with applicable regulatory requirements must accompany the human food by-product when distributed.**

Recall Plan for Animal Feed and Pet Food

The NGFA believes the requirement for a recall plan rightfully should be established in Subpart B, Current Good Manufacturing Practice. We believe that requirements for firms to maintain a recall plan should be facility-wide, not product- and process-specific. Therefore, we believe it is
appropriate to move the recall plan requirement to Subpart B. Further, recall plans are a management tool that is used after an adulterated product is released into the marketplace. Conversely, we believe the goal of the written animal feed/pet food safety plan is to prevent adulterated product from being produced and entering commerce. In addition, the NGFA believes that establishing and maintaining a recall plan is appropriate for facilities subject to FDA’s CGMPs regulation, not just those subject to FDA’s preventive controls regulation.

Pertaining to proposed §507.38 that would establish recall plan requirements, the NGFA opposes FDA’s proposed requirement in §507.38(b)(2) that facilities notify the public about any hazard presented by the animal food when appropriate to protect animal and human health. We believe that such a requirement would be highly subjective and create a nebulous regulatory burden that could subject facilities to unnecessary regulatory oversight and enforcement actions. As such, we recommend this provision be deleted:

- §507.38(b)(2): Notify the public about any hazard presented by the animal food when appropriate to protect animal and human health;

Subpart C - Hazard Analysis and Risk-Based Preventive Controls

FDA’s proposed preventive controls regulation is intended to implement the requirements of section 103 of FSMA for animal feed/pet food facilities that must register under section 415 of the FD&C Act to establish and implement an animal feed/pet food safety system that includes a hazard analysis and risk-based preventive controls.

As proposed within the supplemental notice, FDA’s preventive controls regulation would require a hazard analysis to determine whether any “significant hazards” exist within the facility. If a “significant hazard” is identified, then the facility would be required to identify and implement preventive controls to provide assurances that “significant hazards” are minimized or prevented so that animal feed and/or pet food products are not adulterated. In addition, FDA’s regulations would require that preventive controls used to minimize or eliminate “significant hazards” be subject to management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control. Therefore, the applicability of the vast majority of FDA’s proposed preventive control requirements largely will depend on whether a facility’s hazard analysis identifies a “significant hazard.”

As previously expressed, the NGFA generally supports FDA’s new defined term “significant hazard” and the process to be used by facilities to determine whether such a hazard exists within their operations. We believe the agency’s proposed approach acknowledges the safety benefits derived from the use of prerequisite programs, such as CGMPs, and provides for a framework whereby appropriate decisions may be reached regarding hazards that require management controls, which may include monitoring, corrections or corrective actions, verification, and records.

We also reiterate our general belief that physical and chemical hazards are not “significant hazards” for the animal feed and pet food industries, and that such hazards may appropriately be controlled through CGMPs programs. Regarding biological hazards, the NGFA believes the only
potential “significant hazard” within the animal feed and pet food industries is *Salmonella* that may be present in products that are stored and fed to animals in the homes of their owners.

In accordance with these views, the NGFA provides the following comments and recommendations pertaining to requirements proposed within Subpart C, Hazard Analysis and Risk-Based Preventive Controls.

§507.31 Food Safety Plan

Proposed §507.31(c)(4) would require that the written animal feed/pet food safety plan include a recall plan. As expressed previously, the NGFA believes that establishing and maintaining a recall plan is appropriate for facilities subject to FDA’s CGMPs regulation, not just those subject to FDA’s preventive controls regulation. Therefore, we believe the requirement for a recall plan rightfully should be established within Subpart B, Current Good Manufacturing Practice and that the reference to the recall plan within the section should be deleted:

- §507.31(c)(4): The written recall plan as required by §507.38(a)(1);

§507.33 Hazard Analysis

The NGFA provides the following comments pertaining to proposed § 507.33 that would establish various provisions that require covered facilities to identify and evaluate hazards associated with the types of animal feed and pet food manufactured, processed, packed or held at the facility.

- We note that FDA in its 2013 proposed rule used the phrase “experience, illness data, scientific reports, or other information” when defining criteria to be used when determining a “hazard reasonably likely to occur.” [Emphasis added.] We believe §507.33(a)(1) should be similarly revised as follows to state the hazard analysis is to consider “experience, illness data, scientific reports, and or other information” about hazards, since it is not necessary to evaluate all of the criteria specified in all cases:
  - §507.33(a)(1): You must: (1) Identify and evaluate, based on experience, illness data, scientific reports, and or other information, known or reasonably foreseeable hazards for each type of animal food manufactured/processed, packed, or held at your facility to determine whether there are significant hazards

- FDA’s position, as expressed within the preamble of the 2013 proposed rule, is the agency would consider the animal feed and pet food intended for each animal species to be a “type of animal food” that would require its own hazard analysis. However, the NGFA strongly believes that many aspects of a facility’s hazard analysis rightfully may be applied to all types of animal feed and pet food that are produced at the facility. Therefore, we believe that a completely separate and distinct hazard analysis for each animal species is not warranted. In addition, we do not believe that further subsets or differentiation of types of animal feed or pet food is necessary or appropriate when performing the hazard analysis.
The NGFA strongly recommends that the term “nutrient imbalances” in §507.33(b)(1)(ii) be replaced with “nutrient deficiencies” and “nutrient toxicities.” As previously expressed, we believe the term “nutrient imbalances” is too broad and vague, and potentially could be construed in a manner that does not pertain to the safety of animal feed and pet food. In addition, we previously have proposed definitions for both of these terms within this statement. As such, we recommend the provision be revised as follows:

- §507.33(b)(1)(ii): Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient imbalances deficiencies and nutrient toxicities;

As previously expressed, we strongly believe facilities should not be required to consider hypothetical economically motivated adulteration scenarios within their hazard analysis. To do so would subject the industry to a costly, unreasonable and unproductive exercise of trying to identify and assess any hazard – foreseeable or not – that conceivably could be introduced into the food or feed supply. If FDA establishes within its final regulation that the hazard analysis is to consider economically motivated adulterants, we strongly believe the facility should only be required to consider those adulterants associated with raw materials or ingredients for which there has been an historical pattern of occurrence. As such, we recommend that §507.33(b)(2)(iii) be revised as follows:

- §507.33(b)(2)(iii): The hazard has an historical pattern of occurrence of may be being intentionally introduced for purposes of economic gain.

Proposed §507.33(c)(2) specifically would require that the hazard analysis include an evaluation of environmental pathogens under certain circumstances. In response, the NGFA believes it is unnecessary to establish a specific provision that identifies environmental pathogens as a hazard that is required to be evaluated. During the hazard analysis, a facility already would be required to consider “known or reasonably foreseeable hazards” that have the potential to be associated with the facility or the animal feed or pet food. Therefore, we recommend this provision be deleted:

- §507.33(c)(2): The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged animal food does not receive a treatment that would significantly minimize the pathogen.

If FDA does not delete §507.33(c)(2), we strongly recommend that FDA define within its regulation what is meant by the phrase “exposed to the environment.” Based on previous statements made by FDA, we understand “exposed to the environment” to mean the product is in a form that is exposed and/or subject to direct human contact. We believe providing a definition for “exposed to the environment” is necessary to avoid confusion over what is meant by this phrase.

The NGFA believes that the proposed language in §507.33(d)(8) referencing “intended or reasonably foreseeable use” is too open ended and vague to provide clear direction to
industry and regulators pertaining to compliance obligations. Accordingly, we recommend that proposed provision be revised as follows:

- §507.33(d)(8): Intended or reasonably foreseeable Expected use;

§507.36 Preventive Controls

The NGFA provides the following comments pertaining to proposed §507.36 that would establish provisions that require covered facilities to identify and implement preventive controls to provide assurances that hazards identified as being necessary to address within the facility’s animal feed/pet food safety plan will be significantly minimized or prevented and the animal feed and pet food manufactured, processed, packed, or held by the facility will not be adulterated.

- As previously expressed, The NGFA believes references to “contamination” and “utensils” within FDA’s proposed regulations should be deleted and replaced with the terms “adulteration” and “tools,” respectively. We therefore recommend the following provisions be revised as follows:
  - §507.36(c)(2)(i): Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils tools and equipment; and
  - §507.36(c)(2)(ii): 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.

- As previously expressed, the NGFA believes provisions for recall plans should be included within the CGMPs section of the regulations, therefore we recommend that §507.36(c)(4) pertaining to recall plans be deleted:
  - §507.36(c)(4): A recall plan as required by § 507.38; and

§507.37 Supplier Program

The NGFA provides the following comments pertaining to proposed § 507.37, which would require supplier controls when the receiving facility’s hazard analysis identifies a significant hazard for a raw material or ingredient, and that hazard is controlled before the facility receives the raw material or ingredient.

- We believe §507.37(a)(5) is ambiguous and contrary to other provisions that establish the receiving facility is to conduct verification activities as necessary and appropriate. We therefore recommend the provision be deleted:
  - §507.37(a)(5): For some hazards, in some situations under paragraph (b) it will be necessary to conduct more than one verification activity and/or to increase the frequency of one or more verification activities to provide adequate assurances that the hazard is significantly minimized or prevented.
Proposed §507.37(b)(4) would require the receiving facility to consider the applicable FDA food safety regulations and information regarding the supplier’s compliance with those regulations, including whether the supplier is the subject of an FDA warning letter or import alert relating to the safety of the animal feed or pet food.

The NGFA believes that regulatory information such as FDA’s warning letters or import alerts can be a helpful tool to consider when assessing supplier risk, but that review of such information is only one benchmark that should be considered as part of such an assessment. Moreover, we believe receiving facilities should have the flexibility to determine what responsive action is appropriate based upon the significance of such regulatory actions for their intended use of the food or feed, such as the food or feed being supplied, the nature of the regulatory findings and whether the supplier has instituted effective corrective actions.

Further, we believe that a distinct and prescriptive review of regulatory information should not be required unless FDA develops a system that allows receiving facilities to efficiently monitor new regulatory enforcement actions. Currently, there is no way to ensure that warning letters and import alerts are timely when they are made available publicly, as this information is not typically posted in real time. Warning letters often are posted to FDA’s website several months after being mailed to a company. Before imposing any distinct regulatory requirement to review these materials, FDA first would need to develop an improved process to ensure that receiving facilities can obtain this information about their suppliers in an efficient manner and on a timely basis.

Proposed §507.37(c)(2)(i) and (ii) would establish that for a SAHCODHA hazard controlled by a supplier, the receiving facility must have documentation of an annual onsite audit of the supplier, unless the receiving company documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

As expressed previously, the NGFA believes audits may be an effective verification tool, but they only offer a “snapshot” of a supplier’s performance at a given time. Therefore, the value of audits within any potential requirements for supplier programs should not be overemphasized. As such, the NGFA generally supports FDA’s proposed approach of allowing receiving facilities to document determinations that instead of an annual onsite audit other verification activities and/or less frequent onsite auditing of a supplier provide adequate assurance that a SAHCODHA hazard is being controlled.

Further, as expressed previously, the NGFA strongly supports FDA’s proposal that would provide that supplier program audits may be conducted by a third-party “qualified auditor” that need not be accredited under the requirements to be established under the agency’s forthcoming third-party certification regulation.

FDA’s proposed rule specifies that if a supplier is a farm that is not subject to the produce safety regulations, the receiving facility of animal food from the supplier would not be subject to the “standard” verification requirements, but would instead be required to
obtain written assurance biennially that the supplier is producing the food in compliance with the FD&C Act.

As such, under §507.37(c)(4), if a supplier of a food is a farm that is not subject to the requirements in part 112 (the produce safety regulations) in accordance with §112.4 regarding the food being received, the receiving facility would not be subject to the supplier verification activity requirements in §507.37(c)(1) and (c)(2) if the receiving facility:

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

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

These alternative verification requirements would apply to receiving facilities of raw materials from farms that do not grow and harvest “produce,” as defined in § 112.3(c) of the proposed produce safety regulations. For example, because grains are not “produce,” the alternative verification requirements would apply to receiving facilities that receive grain.

The NGFA believes that such a proposed requirement is contrary to the traceability provisions of the Bioterrorism Act and FSMA. Under the Bioterrorism Act regulations, a facility only is required to be able to trace food “one-step back.” Requiring receiving facilities to engage in supplier verification further back to the source of the food’s production would be contrary to the Bioterrorism Act and the traceability provisions in FSMA. Significantly, FSMA specifically restricts FDA from requiring facilities to maintain records of the full pedigree of a food – even high-risk foods – and also limits trace back requirements for commingled raw agricultural commodities to the immediate previous source of the food. Any regulation that would require a receiving facility to verify a grower of grain, would be contrary to these traceability restrictions since receiving facilities typically would be required to go more than one-step back.

Further, as previously expressed, for reasons given by FDA in the preamble of its proposed Foreign Supplier Verification Program regulations, Congress intended for the importer (or receiving facility) to verify a single supplier for a particular shipment of a food or feed. Since most grain received by receiving facilities is commingled and produced by multiple growers, FDA’s proposed requirements clearly are contrary to what Congress intended.

Moreover, the NGFA opposes such provisions because FDA has not established safety standards for the growers of grain. Therefore, attempting to receive “written assurances” from growers of grain to indicate that the grain supplied was produced in compliance with applicable FDA food safety regulations is not feasibly possible. As such, we believe the proposed requirement ultimately could result in the exchange of token paperwork that would have no appreciable benefit to animal feed or pet food safety.
Therefore, the NGFA strongly urges that proposed §507.37(c)(4) be deleted:

§507.37(c)(4): If a supplier of a food is a farm that is not subject to the requirements in part 112 (the produce safety regulations) in accordance with §112.4 regarding the food being received, the receiving facility would not be subject to the supplier verification activity requirements in §507.37(c)(1) and (c)(2) if the receiving facility:

(i) Documents, at the end of each calendar year, that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and
(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

Further, the NGFA urges FDA to appropriately exempt raw agricultural commodities other than fruits and vegetables from domestic and foreign supplier verification program requirements because of the low risk that such commodities pose to food safety and because such products undergo further processing that addresses potential hazards.

- The NGFA strongly supports proposed §507.37(e)(1) that would, instead of an onsite audit, allow a receiving facility to rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within one year of the date that the onsite audit would have been required to be conducted.

- The NGFA believes §507.37(g) should be revised to clarify that documentation and review of various verification activities is only necessary when such verification activities are used within the supplier program. To do so, we recommend the provision be revised as follows:

  §507.37(g): The receiving facility, as appropriate to its supplier program, must document the following in records and review such records in accordance with §507.49(a)(4)

In addition, consistent with our recommendation that raw agricultural commodities that are not fruit and vegetables be exempted from the supplier program requirements, we believe §507.37(g)(11) should be deleted:

§507.37(g)(11) Documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or ingredient that is not subject to part 112 of this chapter, including:

(i) The documentation that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and
(ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

§507.38 Recall Plan for Animal Food

As previously expressed in this statement, the NGFA believes that requirements associated with recall plans should be relocated to Subpart B, Current Good Manufacturing Practice. As such, our recommendations pertaining to such requirements are included within the Current Good Manufacturing Practice section of this statement.

§507.39 Preventive Control Management Components

For reasons previously expressed, the NGFA believes that the proposed provision within §507.39 pertaining to recall plans should be deleted:

- §507.39(e): The recall plan established in § 507.38 is not subject to the requirements of paragraph (a) of this section.

§507.40 Monitoring

Pertaining to proposed § 507.40 that would require facilities to establish and implement written procedures for monitoring the preventive controls that are implemented to control hazards, the NGFA believes §507.40(b) is redundant with §507.40(a)(2), and therefore should be deleted as follows:

§507.40 Monitoring

(a) As appropriate to the preventive control you must:

(1) Establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls; and

(2) Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(b) You must monitor the preventive controls with adequate frequency to provide assurance that the preventive controls are consistently performed.

(c) All monitoring of preventive controls in accordance with this section must be documented in records that are subject to verification in accordance with §507.45(a)(2) and records review in accordance with §507.49(a)(4)(i).

§507.42 Corrective Actions and Corrections

The NGFA provides the following comments pertaining to proposed §507.42 that would require facilities to establish and implement written procedures for corrective action that is to be taken if preventive controls are not properly implemented.
• We believe the use of the term “all” with “affected” in §507.42(a)(2)(iii) and (iv) and §507.42 (b)(2)(iii) is redundant and may contribute to unwarranted and unnecessary regulatory emphasis being placed on the extent of products that potentially may be subject to corrective actions if a preventive control is not properly implemented, if a preventive control is not properly implemented and a corrective action procedure has not been established, or if a preventive control is found to be ineffective. Therefore, we recommend that these provisions be revised as follows:

- §507.42(a)(2)(iii): All affected animal food is evaluated for safety; and

- §507.42(a)(2)(iv): All affected animal food is prevented from entering into commerce if you cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

- §507.42(b)(2)(iii): Evaluate affected animal food for safety

• The NGFA believes that FSMA provides that procedures be required for corrective actions, as opposed to a requirement that all individual preventive controls must have a specific corrective action procedure. We believe FDA should clarify within the preamble of its final rule that it is not necessary for all individual preventive controls to each have a specific corrective action procedure. As such, we recommend § 507.42(b)(1)(i) be revised as follows:

- §507.42(b)(1)(i): A preventive control is not properly implemented and a specific corrective action procedure has not been established;

§507.47 Validation

The NGFA provides the following comments pertaining to §507.47 that proposes to establish requirements for validating that preventive controls are adequate to control significant hazards.

• §507.45(b)(1)(i) proposes to require that validation of preventive controls occur prior to implementation of the animal feed/pet food safety plan or, when necessary, during the first six weeks of production. In response, the NGFA believes that prescribing a specific timeframe for such activity is arbitrary and does not provide sufficient flexibility to facilities to always complete validation of the range of controls and/or control combinations that may be used to effectively control a hazard. We strongly recommend that FDA allow facilities to complete validation within a reasonable time, and that this provision be revised as follows:

- §507.45(b)(1)(i): Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production within a reasonable time as justified by the qualified individual;

• Rather than requiring validation of preventive controls through collection and evaluation of scientific and technical information or studies as outlined in §507.45(b)(2), the NGFA strongly recommends that FDA revise this provision to allow facilities the flexibility to
verify that preventive controls are effective in the manner prescribed by FSMA. That is, such controls should be deemed to be effective by an appropriate means, as determined and supported by the facility within its animal feed/food safety plan. In addition, we believe FDA should allow facilities the flexibility to verify combinations or systems of controls, and not require specific verification of every control. Therefore, we recommend that §507.45(b)(2) be revised as follows:

- §507.45(b)(2): Must include collecting and evaluating scientific and technical information (or, when such information is not available or is inadequate, conducting studies) evidence to determine whether the preventive controls, when properly implemented, will effectively control significant hazards;

• For reasons previously expressed, the NGFA believes that §507.45(b)(3)(iii) pertaining to recall plans should be deleted:
  - §507.45(b)(3)(iii): The recall plan in § 507.38.

§507.49 Verification and Implementation of Effectiveness

The NGFA provides the following comments pertaining to proposed § 507.49 that would require facilities to verify that preventive controls are implemented and effectively controlling significant hazards.

• We believe that §507.49(a)(2) pertaining to product testing should be revised to clarify that such testing would apply to significant hazards. As such, we recommend the provision be revised as follows:
  - §507.49(a)(2): Product testing for a significant hazard (e.g., a pathogen (or appropriate indicator organism) or other hazard);

• The NGFA believes proposed §507.49(a)(4)(i) that would require a review of monitoring and corrective action records within one week after the records are created is arbitrary, too rigid and does not provide sufficient flexibility to facilities to perform required reviews under different timeframes that may be equally or more effective in achieving animal feed and pet food safety. As such, we recommend the provision be revised as follows:
  - § 507.49(a)(4)(i): Monitoring and corrective action records within a week after the records are created a timeframe determined to be appropriate to ensure that adulterated product does not enter commerce;

§ 507.50 Reanalysis

The NGFA provides the following comments on proposed §507.50 that would establish requirements for reanalysis of written animal feed/pet food safety plans.
• We believe that §507.50(a)(3) pertaining to the need for reanalysis when “new” information becomes available is an ambiguous requirement that would establish vague compliance obligations. Further, the concept embodied by this provision does not align with FSMA’s statutory language. As such, we believe the provision should be deleted:

- §507.50(a)(3): Whenever you become aware of new information about potential hazards associated with the animal food;

• §507.50(b) proposes that any additional preventive controls identified as necessary during the reanalysis be implemented before the change in activities at the facility is operative or, when necessary, during the first six weeks of production. In response, the NGFA believes that prescribing a specific timeframe for such implementation is arbitrary and does not provide sufficient flexibility to facilities to always complete implementation of the range of controls and/or control combinations that may be used to effectively control a hazard. We strongly recommend that FDA allow facilities to complete implementation of an additional preventive control within a reasonable time, and that the provision be revised as follows:

- §507.50(b): You must complete the reanalysis required by paragraph (a) of this section and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production another timeframe determined to be appropriate to ensure that adulterated product does not enter commerce.

§507.53 Requirements Applicable to a Qualified Individual and a Qualified Auditor

Proposed §507.53 would require that one or more qualified individuals prepare the animal feed/pet food safety plan, validate the preventive controls, review records for implementation and effectiveness of preventive controls, and perform reanalysis of the animal feed/pet food safety plan. Further, it would establish criteria whereby individuals would be qualified to develop and oversee the animal feed/pet food safety plan and conduct audits used for verification purposes within supplier programs.

The NGFA generally agrees with FDA’s proposed definition for “qualified individual,” but believes that education also is an appropriate criterion by which an individual may be qualified to develop and apply an animal food safety system. In addition, we believe that a “qualified individual” may appropriately acquire the technical expertise to become a “qualified auditor” by training, education or experience.

As such, the NGFA recommends that the relevant provisions in §507.53 be revised as follows:

- §507.53(c)(1): To be a qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through education or job experience to develop and apply a food safety system. Education or job experience may qualify an
individual to perform these functions if such education or 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.

- §507.53(c)(2): To be a qualified auditor, a qualified individual must have technical expertise obtained by a combination of training, education and or experience appropriate to perform the auditing function.

§507.202 General Requirements Applying to Records

The NGFA provides the following comments pertaining to proposed §507.202 that would establish general requirements for the form, content and accuracy of required records.

- FDA proposes at §507.202(a)(1) to require that electronic records be kept in accordance with 21 CFR part 11 (Part 11). Part 11 provides criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. The proposed requirement clarifies and acknowledges that records required by the proposed CGMPs and preventive controls regulations may be retained electronically, provided that they comply with Part 11.

FDA stated in the 2013 proposed rule that it tentatively concluded that it is appropriate to apply the requirements of Part 11 to such records. However, FDA also requested comment on whether there are any circumstances that would warrant not applying Part 11 requirements within the regulation. As an example, FDA asked whether the requirement that electronic records be kept according to Part 11 would mean that current electronic records and recordkeeping systems would have to be recreated and redesigned, which the agency determined to be the case in its Bioterrorism Act recordkeeping regulation, and in other cases. In such cases, FDA has not required resulting predicate records to comply with Part 11.

The NGFA strongly urges FDA not to apply Part 11 to a facility’s electronic records that would be required under the proposed regulation because, as with the Bioterrorism Act and other cases, such a requirement is disproportionate to the regulatory need and would create a tremendous burden on industry. Electronic recordkeeping systems are widely used throughout all sectors of the animal feed and pet food industry to document and store business-related information. The requirements that FDA proposes within its regulation would require numerous and extensive documents and records to be established and maintained. The most efficient and cost-effective manner in which to establish and maintain such documents and records is with existing electronic systems. The vast majority of such systems do not meet the very stringent provisions detailed in Part 11. As such, facilities would be required to recreate and redesign their current electronic systems at an enormous cost or scrap the use of existing systems and create and maintain records in a paper format. Both of these options represent an overwhelming expense and burden that is not necessary to assure compliance with regulatory requirements or ensure animal feed or pet food safety.
Instead, the NGFA recommends FDA partner with key stakeholders to develop guidance that describes the kinds of practical principles, protocols and systems that may be used to ensure the integrity of electronic records without imposing specific technical requirements that are unnecessary and inappropriate.

- §507.202 (b)(2) proposes that all required records include the date and time of the activity performed. However, the NGFA believes such a requirement to include the time of the activity with all required records is unwarranted. While the time of the activity may be of significance to records that document the monitoring of certain preventive controls that have parameters associated with them, recording of a specific time is not relevant or practical in many other instances when records are proposed to be required. For example, corrective actions may consist of multiple steps that occur over a period of time. In such a case, we believe it would be burdensome and unnecessary to require recording of a specific time when each step of the corrective action activity occurred. Further, we believe that requiring the notation of a specific time for records associated with verification activities is unwarranted. The effectiveness of such activities is not dependent upon the hour and minute at which they are performed. Therefore, the NGFA believes that FDA should require that records include time only when necessary to ensure the effectiveness of the activity being recorded.

Therefore, the NGFA recommends that proposed §507.202 be revised as follows:

§507.202 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;
   (i) Electronic records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in 21 CFR 11.3 (b)(6) are exempt from the requirements of 21 CFR 11.
   (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, where necessary and appropriate, 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.

§507.212 Use of existing records

Proposed §507.212 would establish that facilities may use existing records to satisfy the record requirements associated with the preventive controls regulation. Further, the provision would establish that required information does not need to be kept in one set of records.
The NGFA strongly supports proposed §507.212, as it would provide flexibility to facilities to comply with the record requirements in an efficient manner.

**Compliance Dates**

The NGFA believes affected facilities will need to expend considerable effort and resources to implement practices and procedures to comply with requirements to be established by both the final CGMPs regulation and preventive controls regulation. Since the CGMPs regulation will establish new baseline product safety requirements for all affected animal feed and pet food facilities – many of which have not previously been subject to such requirements – we believe it is necessary and appropriate for FDA to provide facilities with adequate time to come into compliance with the CGMPs regulation before being expected to comply with the preventive controls regulation. We believe that such a staggered compliance schedule for the two regulations would serve to provide necessary time for affected facilities to fully implement programs to comply with the CGMPs regulation that, in turn, will serve as the foundation by which facilities may successfully implement the written animal feed/pet food safety plans to be required under the preventive controls regulation.

Therefore, the NGFA strongly recommends that FDA provide the following time periods for affected businesses to come into compliance with the CGMPs requirements after publication of the final rule: 1) one year for businesses other than small and very small businesses; 2) two years for small businesses; and 3) three years for very small businesses.

In addition, to provide for staggered implementation of the two regulations, the NGFA recommends that FDA establish the following time periods for affected businesses to comply with the requirements of the agency’s final preventive controls regulation: 1) two years for businesses other than small and very small businesses; 2) three years for small businesses; and 3) four years for very small businesses.

**Economic Impact of Proposed Regulations**

**Major Findings**

FDA’s Preliminary Regulatory Impact Analysis (PRIA) for the FSMA Supplemental Notice of Proposed Rulemaking for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (2014 proposed rule) estimates an annualized compliance cost of $93.45 million for animal feed and pet food facilities. FDA’s annualized compliance cost per facility ranges from $13,200 to $18,300. The estimates represent anticipated compliance costs for the re-proposed CGMPs and preventive controls and the newly proposed additional preventive controls.

In contrast and as subsequently discussed in greater detail, NGFA’s economic analysis of the 2014 proposed rule focuses exclusively on the cost to animal feed facilities and estimates an annualized cost of $430.33 million to $722.65 million, which equates to an annual cost per facility ranging from $56,385 to $127,715.
Importantly, the lower dollar amount of NGFA’s estimate represents the anticipated cost for complying with the proposed CGMPs requirements and only the provisions of the preventive controls regulation that would require a hazard analysis to be conducted. The higher dollar amount of NGFA’s estimate represents the anticipated cost for complying with the proposed CGMPs requirements and all aspects of the preventive control regulations when control of “significant hazards” would be required.

Therefore, NGFA’s analysis quantifiably demonstrates how the compliance costs of the 2014 proposed rule will be dramatically influenced based upon FDA’s regulatory decisions as to whether a given hazard reaches the threshold of being classified as a “significant hazard.” This is the case since, under FDA’s proposal, a facility that identifies a “significant hazard” within its operation would be required to comply with all aspects of the preventive control regulations. In contrast, a facility that identifies no “significant hazards” would only be required to perform the hazard analysis requirements of the preventive controls regulation.

Further, NGFA’s economic analysis also clearly demonstrates how the compliance costs of the 2014 proposed rule will be significantly influenced by FDA’s final CGMPs requirements. Within the 2014 proposed rule, FDA would establish numerous CGMPs requirements based on human food safety standards that would compel the industry to redesign or reconstruct facilities and equipment. To make such changes, the NGFA estimates that the annualized capital cost to the animal feed industry would be $297.63 million, or an annual capital cost of $38,998 for each affected facility. In contrast, if FDA accepts the NGFA’s recommendations that would make its final CGMPs regulation more appropriate and reasonable for animal feed facilities, we believe such capital costs for the animal feed industry could be eliminated.

Accordingly, the NGFA analysis estimates the annualized cost for animal feed facilities to comply with the proposed preventive controls regulation with no “significant hazards” and to comply with the proposed CGMPs regulation with no need for capital expenditures to be $132.70 million, or $17,387 per facility.

The primary reasons for the large difference in cost estimation between the PRIA and the NGFA analysis is because the PRIA vastly underestimates many costs, including, but not limited to, under-accounting for the number of labor hours that would be spent reviewing the new animal feed regulations, developing compliance plans, monitoring and verifying controls, and performing cleaning operations. Further, the PRIA greatly underestimates the cost of compliance for the potential new preventive controls announced in the 2014 proposed rule, if animal feed facilities are required to implement such controls because of a “significant hazard.” For example, an animal feed facility would incur significant labor costs to comply with potential requirements for product testing, environmental monitoring, controlling the potential for economically motivated adulteration and implementing supplier programs, if a “significant hazard” is identified within its operation.

Costs Identified in NGFA’s Economic Analysis

Because of the importance of distinguishing between the costs for CGMPs and the costs of the re-proposed and the newly proposed additional preventive controls, the NGFA analysis separates the 2014 proposed rule’s cost into the three following groups:
• CGMPs;
• Preventive controls that also were included within the 2013 proposed rule; and
• Additional potential preventive controls proposed within the 2014 proposed rule.

The NGFA analysis estimates the 2014 proposed rule would require 7,632 animal feed facilities to comply with CGMPs within one, two or three years after publication of the final rule, depending on the business’s number of employees and annual feed sales dollars. For such facilities, the NGFA analysis estimates the annualized cost of CGMPs beginning in the fourth year after publication of the final rule to be $419.84 million or $55,011 per facility.

Comparatively, the NGFA analysis estimates that 4,165 animal feed facilities would be part of animal feed businesses with $2.5 million or more in annual feed sales and be required to comply with preventive controls within one or two years after publication of the final rule, depending on the business’s number of employees. For such facilities, the NGFA analysis estimates the annualized cost beginning in the third year after publication of the final rule for the preventive controls that were included in the 2013 proposed rule to be $192.14 million or $46,132 per affected facility. Further, the NGFA analysis estimates an extra annualized cost beginning in the third year after publication of the final rule of $110.67 million or $26,572 per affected facility for the potential additional preventive controls announced in 2014 proposed rule.

Significantly, if it is determined animal feed facilities do not have “significant hazards” that need to be controlled using preventive controls, then the average annualized cost for preventive controls for the animal feed industry is estimated at $10.49 million (the estimated cost of conducting a hazard evaluation of the facility’s operation annually and creating a written report).

The total cost for the 2014 proposed rule for each of the three groups is shown below. The total represents the costs that animal feed facilities would incur to comply with CGMPs and implement preventive controls due to “significant hazards” within their operations.

\[
\begin{align*}
\text{\$419.84 million: CGMPs} \\
+ \text{\$192.14 million: Preventive controls that also were in the 2013 proposed rule} \\
+ \text{\$110.67 million: Additional preventive controls in the re-proposed rule} \\
= \text{\$722.65 million: Total annualized cost for the animal feed industry} \\
= \$94,687 \text{ average cost across 7,632 animal feed facilities}
\end{align*}
\]

The cost estimates in the NGFA analysis are representative of both labor and capital costs for the proposed CGMPs and only labor costs for the proposed preventive controls. Capital costs included for the proposed CGMPs are those associated with purchasing and maintaining buildings for segregating toxic materials from plant areas where animal feed manufacturing or feed exposure occurs and other CGMP provisions, such as hygienic and sanitation requirements that would require the redesign or reconstruction of facilities and equipment. Significantly, capital costs not included for preventive controls are those associated with constructing new holding bins to allow for segregating feed batches for testing programs or costs for redesigning animal feed facilities to minimize the presence of microorganisms.
Methodology

The NGFA analysis reuses results from a survey of animal feed facilities conducted by the NGFA as part of its analysis of the 2013 proposed CGMPs and preventive controls regulations. The NGFA survey was designed to parallel the approach used to estimate labor costs by the Eastern Research Group (ERG) in its April 2011 report. In addition to the survey results, the NGFA analysis relies on information gained from animal feed subject matter experts that are members of NGFA’s Biofuels and Co-Products Committee, Feed Legislative and Regulatory Affairs Committee and Feed Manufacturing and Technology Committee.

The NGFA analysis focuses on the cost of the 2014 proposed rule for animal feed facilities. Thus, the estimated cost for pet food facilities is not included in the NGFA analysis. Further, the NGFA analysis splits the cost of the 2014 proposed rule into the following groups:

- CGMPs;
- Preventive controls that also were included within the 2013 proposed rule; and
- Additional potential preventive controls announced within the 2014 proposed rule.

Key Assumptions

In the 2014 proposed rule, FDA estimates 6,287 domestic facilities and 1,843 foreign facilities or 8,130 total facilities would be affected by CGMPs. FDA estimates pet food manufacturers comprise 386 of the 6,287 domestic facilities or 6.1 percent. To estimate the number of foreign pet food manufacturers, the NGFA analysis assumes 6.1 percent or 112 facilities of the 1,843 foreign facilities are pet food manufacturers. The NGFA analysis added the 386 domestic and 112 foreign pet food manufactures and then subtracted the sum from the 8,130 total facilities to arrive at its estimate of 7,632 animal feed facilities – see Table 1.

Similarly, in the 2014 proposed rule, FDA estimates 3,143 domestic facilities and 1,182 foreign facilities or 4,325 total facilities would be affected by preventive controls. FDA estimates pet food manufacturers comprise 116 of the 3,143 domestic facilities that would be affected by preventive controls or 3.7 percent. To estimate the number of foreign pet food manufacturers that would be affected by preventive controls, the NGFA analysis assumes 3.7 percent or 44 facilities of the 1,182 foreign facilities that are affected by the preventive controls are pet food manufacturers. The NGFA analysis added the 116 domestic and 44 foreign pet food manufactures and then subtracted the sum from the 4,325 facilities to arrive at its estimate of 4,165 affected animal feed facilities – see Table 1.

However, while the NGFA chose to use FDA’s estimates for the number of facilities that would be affected by preventive controls, the NGFA is skeptical that only 4,325 total animal feed and pet food facilities would be covered by the regulation. As evidence for this skepticism, the NGFA surveyed its members pertaining to total annual feed sales and none had annual feed sales that were less than $2.5 million. Further, the average survey response indicated annual feed sales of approximately $45 million. Additionally, the NGFA notes that $2.5 million in annual sales at $200 per ton of animal feed (a very conservative price) would occur with only 12,500 tons of annual sales – a very small figure to sustain an animal feed business. Therefore, the NGFA
believes the preventive controls regulations could impact significantly more than the 4,325 total animal feed and pet food facilities estimated by FDA.

Table 1: Estimate of Number of Animal Feed Facilities Affected by Re-Proposed Rule with Very Small Business <$2,500,000 1/

<table>
<thead>
<tr>
<th>Item</th>
<th>Number of Affected Animal Feed Facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affected by CGMPs</td>
<td>7,632</td>
</tr>
<tr>
<td>Potentially Affected by Preventive Controls</td>
<td>4,165</td>
</tr>
</tbody>
</table>

1/ Based on FDA’s estimate of affected facilities less pet food manufacturers.

Table 2 indicates the hourly compensation assumptions from the PRIA 1 and the NGFA analysis. With the exception of the wage rate for food consultants, the NGFA analysis uses the same methodology as the PRIA for estimating hourly compensation, which is based on Bureau of Labor Statistics (BLS) hourly wage rates plus a 50 percent increase for fringe benefits and other overhead costs. However, the NGFA analysis uses 2013 BLS hourly wage rates, whereas the PRIA uses 2007 BLS hourly wage rates.

In addition, for the food consultant hourly labor rate, the NGFA based its $400 per hour compensation assumption (includes hourly rate, travel expense, and fixed upfront fees) on information obtained from animal feed industry contacts that have hired consultants.

Table 2: Hourly Compensation Assumptions for Analysis

<table>
<thead>
<tr>
<th>Title</th>
<th>NAICS Code</th>
<th>PRIA Labor Rates</th>
<th>NGFA Labor Rates 2/</th>
</tr>
</thead>
<tbody>
<tr>
<td>General and operations manager</td>
<td>111021</td>
<td>$72.69</td>
<td>$72.02</td>
</tr>
<tr>
<td>First line supervisor</td>
<td>511011</td>
<td>$34.26</td>
<td>$35.42</td>
</tr>
<tr>
<td>Production Occupations</td>
<td>519199</td>
<td>$22.61</td>
<td>$22.61</td>
</tr>
<tr>
<td>Inspectors, testers, sorters, samplers, and weighers</td>
<td>519061</td>
<td>$23.03</td>
<td>$23.43</td>
</tr>
<tr>
<td>Office Clerks, general</td>
<td>439061</td>
<td>$20.13</td>
<td>$18.99</td>
</tr>
<tr>
<td>Food Consultant</td>
<td>NA</td>
<td>$100.00</td>
<td>$400.00</td>
</tr>
</tbody>
</table>

1/ 2007 BLS mean hourly wage rate plus a 50% increase for fringe benefits and other overhead costs.
2/ 2013 BLS mean hourly wage rate plus a 50% increase for fringe benefits and other overhead costs.
3/ Based on discussion with feed industry contacts that have hired consultants.

**Estimated Labor Costs of CGMPs**

The 2014 proposed CGMPs still will apply to all animal feed facilities that are required to register with FDA under the Bioterrorism Act. Therefore, the NGFA analysis reuses the NGFA survey-based results from its economic analysis of the 2013 proposed rule to estimate the labor costs for CGMPs in the 2014 proposed rule.

Table 3 contains a comparison of the PRIA-assumed labor estimates that are based on Table 3-7 of ERG’s April 2011 report and the NGFA survey-based results of its members on the estimated amount of time by employment position that would be required to comply with the CGMP

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1 The PRIA for the FSMA Supplemental Notice reuses cost assumptions for CGMPs and preventive controls that were included in the PRIA for the October 29, 2013 proposed rule.
provisions. For some of the provisions, the PRIA estimate was left blank because a labor estimate was unavailable in ERG’s April 2011 report or in the PRIA.

Based on the NGFA survey results, labor estimates are underestimated in the PRIA for most provisions. For example, the amount of time to review the new regulations and develop a compliance plan appears to be significantly underestimated.

In addition, FDA estimates that only a fraction of facilities would need to spend labor on various proposed provisions, implying that such facilities already have practices in place to comply with the new proposed requirements. The NGFA strongly disagrees with this assumption, and believes based on its survey results that all types and sizes of facilities would need to devote significant labor hours towards gaining compliance. Therefore, NGFA’s labor cost estimates represent averages that would be incurred by all facilities, not just a fraction of the industry.

| Table 3: CGMP Labor Estimates from ERG/PRIA and NGFA Survey |

<table>
<thead>
<tr>
<th>Provision</th>
<th>Source of Estimate</th>
<th>First-Year Labor Hours</th>
<th>Annual Labor Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review the new animal feed rules and develop a compliance plan</td>
<td>ERG/PRIA Estimate</td>
<td>Senior Manager: 40</td>
<td>Mid-Level Manager: 79</td>
</tr>
<tr>
<td>Complete training in the development and application of sanitation controls</td>
<td>ERG/PRIA Estimate</td>
<td>Senior Manager: 18</td>
<td>Mid-Level Manager: 8</td>
</tr>
<tr>
<td>Ensure pest infestation is minimized during storage</td>
<td>ERG/PRIA Estimate</td>
<td>Senior Manager: 3</td>
<td>Mid-Level Manager: 12</td>
</tr>
</tbody>
</table>

In total, the NGFA’s average annualized CGMP labor cost estimate beginning in the fourth year after publication of the final rule is $16,013 per facility or $122.21 million for the animal feed industry – see Table 4. The average labor cost estimate of $16,013 per facility is the product of NGFA’s hourly compensation rates in Table 2 and NGFA’s survey labor hours in Table 3. This product results in estimated annual labor costs to comply with the proposed CGMP requirements of $122.21 million ($16,013 per facility x 7,632 animal feed facilities) for the animal feed industry.

| Table 4: Estimated Labor Costs for CGMPs in Re-Proposed Rule for Animal Feed Facilities |

<table>
<thead>
<tr>
<th>Item</th>
<th>Average Annualized Cost per Animal Feed Facility 1/</th>
<th>Total Annualized Cost for Animal Feed Industry (Million $) 1/</th>
</tr>
</thead>
</table>
| Labor Cost | $16,013 | $122.21 | 1/ 7% discount rate.
**Estimated Capital Costs of CGMPs**

The NGFA chose not to quantitatively estimate capital costs for the CGMPs requirements in the 2013 proposed rule because such requirements had not been differentiated from those established for human food. Therefore, the NGFA believed the proposed CGMPs lacked enough detail on FDA’s final expectations for animal feed facilities to allow for a reasonable capital cost estimation. However, the NGFA now is estimating the capital costs for CGMPs provisions within the 2014 proposed rule since such provisions strongly signal the agency’s intentions for those to be established within its final requirements.

**Storage of Toxic Materials**

Within the CGMPs regulation of the 2014 proposed rule, FDA proposes only toxic materials that fall into one of the following categories may be used or stored in a plant where animal feed is manufactured/processed or exposed:

- Those required to maintain clean and sanitary conditions;
- Those necessary for use in the plant’s operations;
- Those necessary for plant and equipment maintenance and operation; and
- Those necessary for use in laboratory testing procedures.

In comparison, 21 CFR 225.35, which applies to the manufacture of medicated feed, establishes the following requirements pertaining to storage of substances not approved for use in animal feed:

- Use of work areas, equipment, and storage areas for other manufacturing and storage purpose:
  - Many manufacturers of medicated feeds are also involved in the manufacture, storage, or handling of products which are not intended for animal feed use, such as fertilizers, herbicides, insecticides, fungicides, rodenticides, and other pesticides. Manufacturing, storage, or handling of non-feed and feed products in the same facilities may cause adulteration of feed products with toxic or otherwise unapproved feed additives.
  - Work areas and equipment used for the manufacture or storage of medicated feeds or components thereof shall not be used for, and shall be physically separated from, work areas and equipment used for the manufacture of fertilizers, herbicides, insecticides, fungicides, rodenticides, and other pesticides unless such articles are approved drugs or approved food additives intended for use in the manufacture of medicated feed.

Based on 21 CFR 225.35, the NGFA analysis assumes toxic materials in the 2014 proposed rule would include fertilizers, herbicides, insecticides, fungicides, rodenticides and other pesticides not approved for use in animal feed.

In response to the provisions for storage of toxic materials within FDA’s 2014 proposal, the NGFA has been advised by its members that one or more of the products detailed in 21 CFR 225.35 are stored in and distributed from the vast majority of plants used for commercial and
wholesale livestock feed manufacturing and processing. Such activity takes place for the benefit of the feed business’s customers who use such products during farming and animal production operations.

Therefore, the NGFA analysis conservatively assumes for the purpose of segregating toxic materials from a plant where animal feed is manufactured/processed or exposed that 75 percent of the plants used for commercial and wholesale livestock feed manufacturing or processing would be required to construct new buildings for the storage of toxic materials.

Table 5 displays the estimated one-time cost of constructing a 12-feet tall by 40-feet wide by 60-feet long metal component building to separately store fertilizers, herbicides, insecticides, fungicides, rodenticides, and other pesticides outside of the plant where animal feed is manufactured/processed or exposed. The estimated one-time purchase cost for animal feed businesses that would be required to segregate toxic materials is $67,136.

Further, FDA estimates 6,287 domestic facilities and 1,843 foreign facilities or 8,130 total facilities would be covered by the CGMPs regulation in the 2014 proposed rule. Commercial and wholesale livestock feed manufacturers comprise 5,129 of the 6,287 domestic facilities or 81.6 percent. The NGFA analysis assumes 81.6 percent or 1,504 facilities of the 1,843 foreign facilities are commercial livestock feed manufacturers and wholesale livestock feed manufacturers. The NGFA analysis added the 5,129 domestic and 1,504 foreign commercial and wholesale livestock feed manufacturers to arrive at its estimate of 6,633 animal feed facilities that would be affected by the proposed requirement to segregate toxic materials from plants where animal feed is manufactured/processed or exposed.

The NGFA analysis assumes 75 percent of the 6,633 commercial and wholesale livestock feed manufacturers or 4,975 facilities would be required to construct a new storage building to segregate toxic materials from their plants where animal feed is manufactured/processed or exposed.

Based on these assumptions, and as shown in Table 6, the NGFA analysis estimates the average building purchase cost per facility across the entire 7,632 animal feed facilities for segregating toxic materials from plants where animal feed is manufactured/processed or exposed is $43,761.
Table 6: Estimated Average Purchase Cost of Building for Use in Segregating Toxic Materials from Animal Feed that is Manufactured/Processed or Exposed

<table>
<thead>
<tr>
<th>Building Type</th>
<th>Building Cost</th>
<th>Number of Impacted Facilities</th>
<th>1-Time Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 Tall x 40' Wide x 60' Long</td>
<td>$67,136</td>
<td>4,975</td>
<td>$333,984,816</td>
</tr>
<tr>
<td>Average Purchase Cost of Building per Facility Across the 7,632 Animal Feed Facilities Subject to CGMPs</td>
<td>$43,761</td>
<td>7,632</td>
<td>$333,984,816</td>
</tr>
</tbody>
</table>

Further, Table 7 indicates the total estimated annualized cost per facility for segregating toxic materials from plants where animal feed is manufactured/processed or exposed. The annualized cost includes the average purchase price of the buildings plus the annual direct and indirect costs of the buildings. As shown, the average annualized cost per facility across the 7,632 animal feed facilities is $15,290.

Table 7: Estimated Average Cost per Animal Feed Facility for Segregating Toxic Materials from Animal Feed Manufacturing/Processing or Exposure

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase Cost</td>
<td>$43,761</td>
<td>1-Time purchase price</td>
</tr>
<tr>
<td>Annual Cost</td>
<td>$9,353</td>
<td></td>
</tr>
<tr>
<td>Annualized Cost</td>
<td>$15,290</td>
<td>7 percent of purchase cost + annual cost</td>
</tr>
<tr>
<td>Direct costs</td>
<td>$2,170</td>
<td>Direct costs = maintenance and maintenance labor</td>
</tr>
<tr>
<td>Maintenance labor</td>
<td>$1,085</td>
<td>Calculated based on:</td>
</tr>
<tr>
<td>Performed</td>
<td>1</td>
<td>time a month</td>
</tr>
<tr>
<td>Hours</td>
<td>4</td>
<td>hours an event</td>
</tr>
<tr>
<td>Labor cost</td>
<td>$22.61</td>
<td>$/hr for production occupations</td>
</tr>
<tr>
<td>Maintenance materials</td>
<td>$1,085</td>
<td>Equal to maintenance labor</td>
</tr>
<tr>
<td>Indirect Costs</td>
<td>$7,183</td>
<td>Indirect Costs = overhead, administrative, property tax, insurance, capital recovery</td>
</tr>
<tr>
<td>Admin, tax, ins.</td>
<td>$1,750</td>
<td>4% of capital cost</td>
</tr>
<tr>
<td>Overhead</td>
<td>$1,302</td>
<td>60% of maintenance labor + materials</td>
</tr>
<tr>
<td>Capital Recovery</td>
<td>$4,130.74</td>
<td>Calculated by multiplying purchase cost &amp; capital recovery factor</td>
</tr>
<tr>
<td>Capital Recovery Factor</td>
<td>0.094392926</td>
<td>Factor used by the Environmental Protection Agency for evaluating the cost of proposed regulations</td>
</tr>
<tr>
<td>Interest rate</td>
<td>7%</td>
<td>Years</td>
</tr>
<tr>
<td>lifetime</td>
<td>20</td>
<td></td>
</tr>
</tbody>
</table>

In total, the NGFA analysis indicates the average annualized capital cost of constructing and maintaining buildings for segregating toxic materials from plants where animal feed is manufactured/processed or exposed would be $15,290 per facility beginning in the fourth year after publication of the final rule across the 7,632 animal feed facilities or $116.69 million for the animal feed industry – see Table 8.
Table 8: Estimated CGMP Capital Costs in Re-Proposed Rule for Animal Feed Facilities if Toxic Materials are Required to be Segregated from Animal Feed that is Manufactured/Processed or Exposed

<table>
<thead>
<tr>
<th>Item</th>
<th>Average Annualized Cost per Animal Feed Facility 1/</th>
<th>Total Annualized Cost for Animal Feed Industry (Million $) 1/</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of Purchasing and Maintaining Buildings for Segregating Toxic Materials from Feed Manufacturing/Processing or Exposure</td>
<td>$15,290</td>
<td>$116.69</td>
</tr>
</tbody>
</table>

1/ 7% discount rate.

**Redesigning or Reconstructing Facilities and Equipment**

The NGFA also believes animal feed facilities would incur significant capital costs to comply with other CGMP provisions within the 2014 proposed rule. For example, the following list of facility- and equipment-related redesign or reconstruction activities are among those that would be required by the proposed CGMPs:

- Modifying facilities to provide additional space for cleaning warehouses, processing areas and equipment.
- Redesigning/reconstructing facilities, fixtures, ducts, and pipes so as to prevent potential condensation.
- Redesigning/reconstructing operating fans or other air-blowing equipment to “minimize the potential” of air contaminating animal feed.
- Redesigning hand-washing areas and toilet rooms to meet FDA’s compliance standards.
- Redesigning plumbing systems to demonstrate to FDA that such systems are not a “source of contamination” for animal feed.
- Reconstructing equipment that does not contact animal feed so as to demonstrate to FDA that the equipment can be “kept clean.”
- Modifying facilities so that “all conditions and controls” associated with animal feed manufacturing “minimize the potential for growth of undesirable microorganism.”

The NGFA’s economic analysis does not attempt to individually estimate the costs for specific capital projects that would be necessary to redesign or reconstruct facilities and equipment to comply with the proposed CGMPs requirements. Instead, based on input from NGFA’s members, the NGFA analysis conservatively assumes an average capital cost of $75,000 per animal feed facility for compliance. However, the NGFA notes that some NGFA members believe the capital costs for complying with the proposed CGMP provisions could far exceed this $75,000 estimate.

Accordingly, Table 9 summarizes the NGFA analysis for the estimated annualized cost per facility for redesigning or reconstructing animal feed facilities to comply with the proposed CGMP provisions. The annualized cost includes the average initial cost of the facility and/or equipment redesign or reconstruction and the annual direct and indirect costs of the modifications. As indicated, the average annualized cost per facility across the 7,632 animal feed facilities is $23,708.
Table 9: Estimated Average Cost per Animal Feed Facility for Redesign or Reconstruction of Animal Feed Facilities to Comply with CGMP Provisions

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Cost</td>
<td>$75,000</td>
<td>1-Time expense</td>
</tr>
<tr>
<td>Annual Cost</td>
<td>$13,552</td>
<td></td>
</tr>
<tr>
<td>Annualized Cost</td>
<td>$23,708</td>
<td>7 percent of purchase cost + annual cost</td>
</tr>
<tr>
<td>Direct costs</td>
<td>$2,170</td>
<td>Maintenance and maintenance labor</td>
</tr>
<tr>
<td>Maintenance labor</td>
<td>$1,085</td>
<td>Calculated based on:</td>
</tr>
<tr>
<td>Performed</td>
<td>1</td>
<td>time a month</td>
</tr>
<tr>
<td>Hours</td>
<td>4</td>
<td>hours an event</td>
</tr>
<tr>
<td>Labor cost</td>
<td>$22.61</td>
<td>$/hr for production occupations</td>
</tr>
<tr>
<td>Maintenance materials</td>
<td>$1,085</td>
<td>Equal to maintenance labor</td>
</tr>
<tr>
<td>Indirect Costs</td>
<td>$11,382</td>
<td></td>
</tr>
<tr>
<td>Admin, tax, ins.</td>
<td>$3,000</td>
<td>4% of capital cost</td>
</tr>
<tr>
<td>Overhead</td>
<td>$1,302</td>
<td>60% of maintenance labor + materials</td>
</tr>
<tr>
<td>Capital Recovery</td>
<td>$7,079.47</td>
<td>Calculated by multiplying initial cost and capital recovery factor</td>
</tr>
<tr>
<td>Capital Recovery Factor</td>
<td>0.094392926</td>
<td>Factor used by the Environmental Protection Agency for evaluating the cost of proposed regulations</td>
</tr>
<tr>
<td>Interest rate</td>
<td>7%</td>
<td></td>
</tr>
<tr>
<td>lifetime</td>
<td>20</td>
<td>Years</td>
</tr>
</tbody>
</table>

Given the average annualized capital cost for redesigning or reconstructing animal feed facilities for compliance with the proposed CGMP provisions is estimated at $23,708 per facility beginning in the fourth year after publication of the final rule, the total capital cost across all affected 7,632 animal feed facilities is $180.94 million – see Table 10.

Table 10: Estimated CGMP Capital Costs in Re-Proposed Rule for Animal Feed Facilities if Redesign or Reconstruction of Animal Feed Facilities is Required to Comply with CGMP Provisions

<table>
<thead>
<tr>
<th>Item</th>
<th>Average Annualized Cost per Animal Feed Facility 1/</th>
<th>Total Annualized Cost for Animal Feed Industry (Million $) 1/</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of Redesigning or Reconstructing Facilities</td>
<td>$23,708</td>
<td>$180.94</td>
</tr>
</tbody>
</table>

1/ 7% discount rate.

Total Estimated Capital Costs of CGMPs

To show the total estimated capital costs for the proposed CGMPs, Table 11 combines the estimated capital cost for purchasing and maintaining buildings for segregating toxic materials and the estimated capital cost of other CGMP provisions that would require the redesign or reconstruction of facilities and equipment. As indicated, the average annualized cost beginning in the fourth year after publication of the final rule per animal feed facility for the proposed CGMPs is $38,998 or $297.63 million for the animal feed industry.
Table 11: Estimated Total Capital Costs for CGMPs in Re-Proposed Rule for Animal Feed Facilities

<table>
<thead>
<tr>
<th>Item</th>
<th>Average Annualized Cost per Animal Feed Facility</th>
<th>Total Annualized Cost for Animal Feed Industry (Million $)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of Purchasing and Maintaining Buildings for Segregating Toxic Materials from Feed Manufacturing/Processing or Exposure</td>
<td>$15,290</td>
<td>$116.69</td>
</tr>
<tr>
<td>Cost of Redesigning or Reconstructing Facilities</td>
<td>$23,708</td>
<td>$180.94</td>
</tr>
<tr>
<td><strong>Total Capital Cost</strong></td>
<td><strong>$38,998</strong></td>
<td><strong>$297.63</strong></td>
</tr>
</tbody>
</table>

1/ 7% discount rate.

Estimated Total Labor and Capital Costs of CGMPs

Based upon the NGFA analysis, the average annualized labor and capital cost beginning in the fourth year after publication of the final rule per animal feed facility for the proposed CGMPs is $55,011 or $419.84 million for the animal feed industry – see Table 12. These figures are derived by combining the labor and capital estimates from Tables 4 and 11.

Table 12: Estimated Total Labor and Capital Costs for CGMPs in Re-Proposed Rule for Animal Feed Facilities

<table>
<thead>
<tr>
<th>Item</th>
<th>Average Annualized Cost per Animal Feed Facility</th>
<th>Total Annualized Cost for Animal Feed Industry (Million $)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labor Costs</td>
<td>$16,013</td>
<td>$122.21</td>
</tr>
<tr>
<td>Capital Costs</td>
<td>$38,998</td>
<td>$297.63</td>
</tr>
<tr>
<td><strong>Total Labor and Capital Cost</strong></td>
<td><strong>$55,011</strong></td>
<td><strong>$419.84</strong></td>
</tr>
</tbody>
</table>

1/ 7% discount rate.

Estimated Cost of Preventive Controls in 2013 Proposed Rule

The proposed preventive controls would apply to commercial animal feed facilities that are part of businesses with total annual sales of animal feed that are more than $2.5 million. Further, the preventive controls proposed within the 2013 proposed rule for animal feed and pet food still are included in the 2014 proposed rule.

Therefore, the NGFA analysis reuses the NGFA survey-based results for labor that were included in NGFA’s comments for the 2013 proposed rule. Table 13 contains NGFA’s labor estimates for compliance with the preventive controls that would be established under the 2013 propose rule and that remain in the 2014 proposed rule.

The NGFA maintains its position that FDA’s PRIA significantly underestimates the amount of time to establish and implement the proposed preventive controls. In addition, the NGFA believes that some provisions, such as cleaning as required under sanitation controls could require facilities to hire additional employees, further escalating the labor costs well above the estimates in the PRIA and the NGFA analysis.
Accordingly, for those preventive controls that were proposed within the 2013 proposed rule and that remain in the 2014 proposed rule, the NGFA analysis’s average annualized cost estimate for labor beginning in the third year after publication of the final rule is $46,132 per affected facility or $192.14 million for the animal feed industry – see Table 14.
**Table 14: Estimated Labor Costs for Preventive Controls in 10/29/2013 Proposed Rule for Animal Feed Facilities if Preventive Controls are Applicable to Animal Feed Facilities**

<table>
<thead>
<tr>
<th>Item</th>
<th>Average Annualized Cost per Animal Feed Facility 1/</th>
<th>Total Annualized Cost for Animal Feed Industry (Million $) 1/</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labor Cost for Preventive Controls in 10/29/2013 Proposed Rule</td>
<td>$46,132</td>
<td>$192.14</td>
</tr>
</tbody>
</table>

1/ 7% discount rate.

**However, if it is determined that animal feed facilities do not have a “significant hazard” that would be required to be controlled using preventive controls, then the average annualized cost for preventive controls is estimated to be $10.49 million for the animal feed industry.**

Significantly, for an animal feed facility with no “significant hazards,” the only labor cost for the preventive controls regulation would be the cost of conducting an annual hazard evaluation and creating a written report.

**Estimated Cost of New Preventive Controls Introduced in 2014 Proposed Rule**

The 2014 proposed rule contains the following additional preventive control provisions in comparison to those previously proposed:

- Product Testing;
- Environmental Monitoring;
- Economically Motivated Adulteration;
- Supplier Program; and
- Review of Records for these Provisions.

Based on information obtained from NGFA members, the NGFA estimates that animal feed facilities affected by the new proposed preventive control provisions would need to expend four hours of additional labor per day to comply with the requirements, if it is determined that “significant hazards” are present within the operation. Such hours would be spent obtaining test samples, performing or overseeing the testing, monitoring the test results, tracking the product batches that are on hold until the test results are known, remedying any issues that may be associated with test results, and conducting one or more of the following supplier verification activities: onsite audits, sampling and testing of raw materials or ingredients, reviewing supplier food safety records, or performing other supply verification activities as appropriate based on the risk associated with the ingredient and the supplier.

For purposes of this analysis, the NGFA assumes the four hours of additional labor would occur within the production occupation, and therefore an hourly labor rate of $22.61 per hour is used to determine labor costs. As such, the NGFA analysis estimates the average annualized cost for the preventive control provisions associated with product testing, environmental monitoring, economically motivated adulteration and supplier program provisions beginning in the third year after publication of the final rule to be $26,572 per affected facility or $110.67 million for the animal feed industry (4,165 animal feed facilities are potentially impacted by preventive controls) – see Table 15.
Since the newly proposed preventive control provisions were not included in NGFA’s previous survey, the NGFA assumes the extra labor for review of records associated with the additional preventive controls would equal the survey-based results for the 2013 proposed preventive control provision that would require affected animal feed facilities to write monitoring procedures for preventive controls and update them annually – see Table 13. As such, the NGFA analysis estimates the average annualized cost of review of records for the additional preventive control provisions beginning in the third year after publication of the final rule to be $2,887 per affected facility or $12.02 million for the animal feed industry – see Table 15.

Table 15: Estimated Labor Costs of Additional Preventive Controls in Re-proposed Rule for Animal Feed Facilities if Preventive Controls are Applicable to Animal Feed Facilities

<table>
<thead>
<tr>
<th>Item</th>
<th>Average Annualized Cost per Animal Feed Facility 1/</th>
<th>Total Annualized Cost for Animal Feed Industry (Million $) 1/</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Testing, Environmental Monitoring, Economically Motivated Adulteration and Supplier Program</td>
<td>$23,685</td>
<td>$98.65</td>
</tr>
<tr>
<td>Review of Records for these Provisions</td>
<td>$2,887</td>
<td>$12.02</td>
</tr>
<tr>
<td><strong>Total Labor Cost for Additional Preventive Controls</strong></td>
<td><strong>$26,572</strong></td>
<td><strong>$110.67</strong></td>
</tr>
</tbody>
</table>

1/ 7% discount rate.

Significantly, the NGFA analysis for the additional preventive control requirements in the 2014 proposed rule does not include capital costs. However, capital costs for these provisions could be immense, especially for segregating feed batches for a testing program or for redesigning animal feed facilities to minimize the presence of microorganisms as part of an environmental monitoring program.

For instance, if FDA were to mandate specific testing requirements, affected animal feed facilities likely would need to test and hold finished products to effectively comply with such a mandate. However, animal feed facilities currently are designed to operate in a very efficient manner, with warehouse and bulk product storage space optimized to minimize capital costs while meeting customer needs. If FDA establishes provisions that require testing and holding of products in its final rule, facilities would need significant amounts of additional storage space to hold products for up to several days while waiting for test results to be reported. If this were to occur, the NGFA believes that each affected facility would need to expend hundreds of thousands of dollars in capital costs to construct additional storage space to enable such testing and holding of products.

In addition, if environmental monitoring is required, animal feed facilities likely would need to be completely redesigned to minimize the presence of microorganisms of regulatory concern. Moreover, the NGFA believes the capital costs associated with such a redesign of animal feed facilities would be so staggering that many facilities would be shuttered.

Importantly, the NGFA estimated costs for the additional preventive controls in Table 15 are based upon animal feed facilities being required to implement preventive controls because “significant hazards” were identified within their operations. If it is determined that animal feed facilities do not have “significant hazards” that are required to be controlled using preventive controls then there would be no further cost for the proposed additional preventive controls.
Total Estimated Cost of CGMPs and All Preventive Controls in 2014 Proposed Rule

As shown in Table 16, FDA’s estimated annualized cost of the 2014 proposed rule ranges from $13,200 to $18,300 per facility. The total estimated cost to the animal feed and pet food industries is $93.45 million, an increase of $6.53 million over its estimated annualized cost of $86.92 million for the 2013 proposed rule. The $6.53 million increase is due to additional preventive controls for product testing, environmental monitoring, supplier programs, economically motivated adulteration and a review of records for such provisions. In addition, FDA’s cost estimates include the labor and capital costs for compliance.

In contrast, the NGFA analysis estimates the annualized labor and capital costs of CGMPs in the 2014 proposed rule to be $55,011 per facility or $419.84 million for the animal feed industry beginning in the fourth year after publication of the final rule.

In addition, the NGFA analysis estimates the annualized labor cost for the preventive controls that were included in the 2013 proposed rule and that remain in the 2014 proposed rule to be $46,132 per affected facility or $192.14 million for the animal feed industry beginning in the third year after publication of the final rule. Further, the NGFA analysis estimates the annualized labor cost for the new preventive control requirements in the 2014 proposed rule to be $26,572 per affected facility or $110.67 million for the animal feed industry beginning in the third year after publication of the final rule.

In combination, the NGFA analysis estimates the average annualized cost for facilities that would be required to comply with both CGMPs and preventive controls to be $127,715 per facility, with the total estimated annualized cost of the 2014 proposed rule for the animal feed industry at $722.65 million.

Therefore, the NGFA estimated average annualized cost of the 2014 proposed rule across all 7,632 animal feed facilities, assuming businesses with more than $2.5 million in annual feed sales must implement preventive controls for “significant hazards” is $94,687 per facility.

However, if it is determined animal feed facilities do not have “significant hazards” that are required to be controlled using preventive controls, then the average annualized cost for preventive controls is estimated to decrease to $10.49 million for the animal feed industry. This would occur because the only cost animal feed facilities would incur for preventive controls would be the cost of conducting a hazard evaluation annually and creating a written report.

Hence, if implementing preventive controls is not required because of no “significant hazards,” the NGFA estimated cost of the 2014 proposed rule would be $430.33 million for the animal feed industry ($419.84 million for CGMPs and $10.49 million for the annual hazard evaluation), or $56,385 per facility ($55,011 for CGMPs and $1,374 for the annual hazard evaluation).

Furthermore, if FDA eliminates provisions from its proposed rule that would compel animal feed facilities to redesign or reconstruct facilities and equipment for CGMP compliance, the NGFA estimate to comply with the CGMPs requirements would decrease by $297.63 million, or $38,998 for each affected facility.
Accordingly, the NGFA analysis estimates the annualized cost for the animal feed industry to comply with the proposed preventive controls regulation with no “significant hazards” and the CGMPs regulation with no need to incur capital expenditures to be $132.70 million, or $17,387 per animal feed facility.

Table 16: Estimated Total Costs for Re-proposed Rule

<table>
<thead>
<tr>
<th>Item</th>
<th>Average Annualized Cost per Facility 1/</th>
<th>Total Annualized Cost (Million $) 1/</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRIA for FSMA Supplemental: Includes Animal Feed &amp; Pet Food Facilities 2/</td>
<td>$13,200-$18,300</td>
<td>$93.45</td>
</tr>
<tr>
<td>NGFA - CGMPs: Includes only Animal Feed Facilities 2/</td>
<td>$55,011</td>
<td>$419.84</td>
</tr>
<tr>
<td>NGFA - Annual Hazard Evaluation: Includes only Animal Feed Facilities 3/</td>
<td>$1,374</td>
<td>$10.49</td>
</tr>
<tr>
<td>NGFA - Preventive Controls that Remain from 10/29/13 Proposal:</td>
<td>$46,132</td>
<td>$192.14</td>
</tr>
<tr>
<td>Includes only Animal Feed Facilities 3/</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NGFA - Additional Preventive Controls in the Re-proposed Rule:</td>
<td>$26,572</td>
<td>$110.67</td>
</tr>
<tr>
<td>Includes only Animal Feed Facilities 3/</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NGFA - CGMPs, Hazard Evaluation &amp; All Preventive Controls:</td>
<td>$55,011 4/</td>
<td></td>
</tr>
<tr>
<td>Includes only Animal Feed Facilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$56,385 5/</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$127,715 6/</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$94,687 7/</td>
<td>$722.65 8/</td>
</tr>
</tbody>
</table>

1/ 7% discount rate.
2/ Includes both labor and capital costs.
3/ Includes only labor costs.
4/ Businesses with total annual sales of animal feed of less than $2.5 million.
5/ Average cost across all businesses if businesses with total annual sales of animal feed that is more than $2.5 million don't have to comply with prevent controls, but must conduct an annual hazard evaluation.
6/ Businesses with total annual sales of animal feed that is more than $2.5 million. Assumes they must comply with preventive controls.
7/ Average across all animal feed facilities if businesses with total annual sales of animal feed that is more than $2.5 million must comply with preventive controls.
8/ High end of the range of the cost estimate for the re-proposed rule and is the sum of CGMPs and preventive controls. The cost of the annual hazard evaluation is already included in the cost of the preventive controls, thus it is not included again to avoid double-counting.

Analysis of Alternatives Considered - Personnel Training

Within FDA’s 2014 proposed rule, the agency is considering mandatory education and training requirements for facility personnel. Given the lack of data on education and training programs offered by animal feed facilities, FDA relies on responses compiled within a 2010 ERG survey of human food facilities to estimate training needs necessary to comply with the personnel training requirements being considered by the agency. Based upon that survey, FDA makes a variety of assumptions pertaining to the number of animal feed facilities that would need to implement training programs for various product safety and employee hygiene issues.
The NGFA strongly contends that a 2010 ERG survey of training practices conducted at human food facilities does not provide a sound basis from which to estimate personnel training costs for animal feed facilities. Further, the NGFA reiterates its strong belief that FDA’s regulation should recommend, but not require, that appropriate employee training occur for the production and distribution of safe animal feed. We believe that the scope and format of appropriate employee training may vary dramatically according to the type and size of a given facility, and the types of products that it manufactures, packs or holds. Therefore, we believe that FDA’s regulations should not attempt to prescribe specific employee training requirements.

Benefits of 2014 Proposed Rule

The NGFA generally agrees with comments submitted on the PRIA for the 2013 proposed rule by George Mason University’s Mercatus Center. In particular, the NGFA agrees with the Mercatus Center that some of the hazard and recall information presented by FDA within its benefit section actually undermines the argument that the regulation would solve a significant problem that is not already addressed by marketplace incentives and legal liability. For instance, the PRIA presents an example where the largest pet food recall in history resulted in the pet food industry spending more than $50 million to remove product from the marketplace. According to the Mercatus Center, and NGFA strongly concurs, this figure suggests the marketplace creates substantial incentives for the industry to keep animal feed and pet food safe. In addition, the PRIA itself notes that the direct cost of recalls and loss of customer goodwill provide incentives for manufacturers to reduce risks.

Animal Feed and Pet Food Facility Closures and Job Loss

The PRIA does not estimate facility closures and job loss due to the 2014 proposed rule, but the ERG April 2011 report, which is based on a similar anticipated regulation, estimates the closure of 4 to 13 small facilities, which approximately represents only 0.1 percent of the 8,130 animal feed and pet food facilities that would be affected by the regulations. In contrast, NGFA believes the ERG report dramatically underestimated facility closures because the proposed rule adds significantly to operating expense without adding revenue. For facilities already operating on tight profit margins, the cost of complying with the proposed requirements likely would cause many facilities to cease operations. For these reasons, the NGFA strongly urge FDA to reassess the impact of the 2014 proposed rule on potential facility closures and job loss before issuing its final regulations.

Summary

While the NGFA appreciates FDA’s complex task of quantifying the economic impact of the 2014 proposed rule, our analysis indicates the PRIA severely underestimates the cost for animal feed facilities to comply with proposed requirements. In particular, the NGFA challenges FDA’s estimate that the average annual implementation cost would range from $13,200 to $18,300 per facility, which is $93.45 million annually for the animal feed and pet food industries.

In contrast to FDA’s analysis, NGFA’s economic analysis focused exclusively on the cost to animal feed facilities and found an average annual cost of $430.33 million to $722.65 million for the industry, which equates to a per facility cost ranging from $56,385 to $127,715.
Importantly, the lower dollar amount of NGFA’s estimate represents the anticipated cost for complying with the proposed CGMPs requirements and only the provisions of the preventive controls regulation that would require a hazard analysis to be conducted. The higher dollar amount of NGFA’s estimate represents the anticipated cost for complying with the proposed CGMPs requirements and all aspects of the preventive control regulations when control of “significant hazards” would be required.

Further, if FDA eliminates provisions from its proposed rule that would compel animal feed facilities to redesign or reconstruct facilities and equipment for CGMP compliance, the NGFA estimate to comply with the CGMPs requirements would decrease by $297.63 million, or $38,998 for each affected facility.

Accordingly, the NGFA analysis estimates the annualized cost for animal feed facilities to comply with the proposed preventive control regulation with no “significant hazards” and to comply with the proposed CGMPs regulation with no need for capital expenditures to be $132.70 million, or $17,387 per facility.

Significantly, the PRIA does not quantify the benefits of the 2014 proposed rule. As such, the NGFA urges FDA to produce empirical evidence of the benefits associated with the requirements before issuing a final rule. The NGFA believes empirical evidence will prove the costs of the proposed rule far exceed the anticipated benefits. In addition, we strongly believe a more limited regulation would accomplish the animal feed safety goals of FSMA more effectively, while imposing a significantly lower economic burden upon the animal feed industry.

Finally, NGFA believes the costs associated with the proposed rule could lead to the closure of many facilities that already operate on tight profit margins. The NGFA urges FDA to better assess the impact of the proposed requirements on facility closures and job loss before issuing a final rule.

**Conclusion**

The NGFA wishes to again thank the FDA for issuing the supplemental notice and providing an additional opportunity to make comments on key provisions of this very significant proposed rule. As FDA is well aware, the agency’s regulations for CGMPs and preventive controls will set the regulatory landscape for the animal feed and pet food industries for decades to come. As such, we believe it is essential that requirements in the final rule are practical, achievable and demonstrably serve to ensure the safety of animal feed and pet food.

While the proposed CGMPs within FDA’s supplemental notice are an improvement over those originally issued, the NGFA remains very concerned that many of the proposed requirements are neither applicable nor appropriate for the vast majority of firms that will be required to comply with the final rule. We also have grave concerns about the economic impact of the proposed requirements, particularly those that focus on facility and equipment design and construction. Therefore, we urge FDA to carefully consider our recommended revisions to the proposed CGMPs and issue final requirements that will ensure product safety, but also reflect the realities of animal agriculture and feeding practices.
Pertaining to the preventive controls regulation, we commend FDA for responding to stakeholders’ comments by making revisions to the proposed regulatory text to better acknowledge the safety benefits derived from the use of prerequisite programs, such as CGMPs, and provide for a framework whereby appropriate decisions may be reached regarding hazards that require management controls that may include monitoring, corrections or corrective actions, verification, and records. However, we request that FDA consider additional revisions, as recommended in this statement, to provide further flexibility to facilities within its regulation to control potential hazards in a manner that is effective and efficient for their operations.

The NGFA appreciates FDA’s consideration of the recommendations expressed in this statement, and pledges to be a fully engaged and constructive participant in future discussions and rulemakings with the agency.

Sincerely,

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

cc: Dr. Bernadette Dunham, Director, Center for Veterinary Medicine, FDA
Dr. Daniel McChesney, Director, Office of Surveillance and Compliance, CVM, FDA
Ms. Jeanette Murphy, Consumer Safety Officer, Division of Animal Feeds, CVM, FDA