National Grain and Feed Association
www.ngfa.org ngfa@ngfa.com

1400 Crystal Drive, Suite 260
Arlington, VA 22202
P: (202) 289-0873
F: (202) 289-5388

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5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; Draft Guidance for Industry; Availability: Docket No. FDA-2018-D-0388

The National Grain and Feed Association (NGFA) submits this statement in response to the Food and Drug Administration's (FDA) notice of availability of a draft guidance for industry entitled "Hazard Analysis and Risk-Based Preventive Controls for Food for Animals," published on January 23, 2018 in the ***Federal Register***.

FDA's draft guidance, when finalized, is intended to assist animal food facilities comply with the requirements for hazard analysis and risk-based preventive controls under the agency's regulations for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (Animal Food Rule).

The NGFA, established in 1896, consists of more than 1,000 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. The NGFA also consists of 29 affiliated State and Regional Grain and Feed Associations, and has strategic alliances with Pet Food Institute and the North American Export Grain Association.

The NGFA commends FDA for the open and collaborative process used to solicit input from stakeholders during the rulemaking process that resulted in the agency's final Animal Food Rule. We also appreciate the agency's on-going commitment to providing a variety of resources – including guidance documents – to assist the industry in understanding and meeting regulatory expectations. We believe that, once finalized, FDA's Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (PC) guidance will be extremely valuable to facilities when developing compliance strategies and assuring animal food safety.

Prior to providing specific comments pertaining to the draft PC guidance, the NGFA wishes to offer the following overarching perspectives.

- **FDA's Final PC Guidance Should Not Establish Binding Compliance Obligations**

  Although the draft PC guidance contains FDA's standard language stating, "It does not establish any rights for any person and is not binding on FDA or the public," the NGFA believes this message should be amplified throughout the guidance so the final content does not imply that there are additional requirements beyond those established by the Animal Food Rule for facilities to comply when evaluating hazards and determining the need for preventive controls within their animal food safety plans. The Animal Food Rule by necessity established a flexible framework in which facilities are to develop and implement required animal food safety plans. It is our hope to see this flexibility reinforced within the PC guidance and preserved during FDA's enforcement of the regulation.

  To better acknowledge the flexibility provided by the Animal Food Rule, the NGFA believes that some sections of the draft PC guidance require further explanation or examples to allow companies to understand whether requirements and/or recommendations included in the guidance are applicable to them. We believe it is essential the final guidance makes clear that it is intended to serve as a resource for industry, and its content – both guidance on requirements and recommended suggestions – will not apply uniformly across the full spectrum of different types of animal food and facilities.

  Similarly, it is imperative that FDA investigators and FDA-credentialed state inspectors not treat the PC guidance like a checklist of requirements when conducting facility inspections. This will be particularly important when investigators conduct inspections to evaluate a facility's hazard analysis that is to address "known or reasonably foreseeable hazards." FDA should make clear that investigators should not expect to see each hazard identified in the guidance addressed in each facility's hazard analysis. More specifically, investigators should not automatically expect facilities to identify a hazard as being "known or reasonably foreseeable" simply because the facility handles an ingredient or mixed ingredient product for which Appendix E or Chapter 3 of the PC guidance identifies as being associated with a potential hazard.

  Accordingly, FDA investigators and state inspectors should be trained to understand that facilities should not be considered out of compliance with the regulation if their hazard analysis does not include a discussion of every potential hazard identified in Appendix E or Chapter 3. As the Animal Food Rule provides, each facility is to make their individual determination of whether a hazard is present for an animal food and, if so, whether it requires a preventive control based on that facility's unique situation.

- **FDA's Final PC Guidance Should Clarify Regulatory Expectations for Different Types of Animal Food**

  FDA's Animal Food Rule requirements generally apply to the full scope of animal food facilities required to register with the agency as "food facilities" under section 415 of the Federal Food Drug & Cosmetic Act established by the Public Health Security and

Bioterrorism Preparedness and Response Act of 2002. As such, a wide variety of animal food facilities (e.g., livestock feed mills, feed ingredient manufacturers, animal food warehouses and pet food manufacturers) fall under the rule's requirements.

To accommodate the full range and scope of facilities that will need to comply with the requirements, FDA rightfully has incorporated flexibility within various provisions that qualify that certain requirements are applicable "as necessary," "where necessary" and "when necessary." The NGFA commends FDA for providing this appropriate flexibility into its final requirements. However, we believe the regulated industry would benefit from additional guidance from FDA related to its compliance expectations associated with provisions that specifically address the control of pathogens.

Through FDA's past enforcement actions and previously issued compliance guidance, the agency clearly has established that it believes the potential presence of pathogens in animal food and animal food facilities pose differing health risks based upon the type of animal food and its intended use.

In accordance with the agency's established policies on the presence of pathogens, such as *Salmonella*, in animal food, the NGFA believes that FDA should provide additional information within its final PC guidance concerning its compliance expectations associated with the control of pathogens at various types of animal food facilities. When doing so, we would expect that FDA clarify that its compliance expectations associated with the potential presence of pathogens in animal foods that have a high likelihood of direct human contact differ from those associated with animal food products that do not have a high likelihood of direct human contact.

Provisions within the Animal Food Rule directed at significantly minimizing or preventing pathogens have created many questions within the animal food industry. We believe the agency's final PC guidance needs to provide additional information, based upon previously issued compliance guidance and enforcement actions, to further explain how compliance expectations related to pathogens depend upon the type of animal food and its intended use.

- **FDA's Final PC Guidance Should Clearly Acknowledge the Use of Prerequisite Programs in Controlling Known and Reasonably Foreseeable Hazards**

  The NGFA appreciates the discussion within the draft guidance – Section 2.4.2 Evaluate Known or Reasonably Foreseeable Hazards (Hazard Evaluation) – that describes how implementation of prerequisite programs may decrease the probability that a known or reasonably foreseeable hazard may occur, and contribute to a determination that the hazard does not require a preventive control.

  The discussion in Section 2.4.2 is consistent with NGFA comments previously submitted to FDA, in which we stated our belief that the vast majority of known or reasonably foreseeable hazards within animal food facilities generally may be adequately controlled through the use of prerequisite programs, and do not require preventive controls. Clearly

acknowledging the use of prerequisite programs in controlling such hazards is extremely significant because arbitrarily mandating the use of preventive controls would require excessive and unnecessary management control components that are not commensurate with the risk posed by the vast majority of potential hazards associated with animal food. Further, arbitrarily mandating the use of preventive controls would divert finite resources away from industry practices that have and continue to effectively ensure the safety of animal food products.

To emphasize this important concept further, the NGFA recommends that FDA provide additional examples in its final guidance on how known or reasonably foreseeable hazards may be adequately controlled through prerequisite programs. Such examples would be of benefit to the industry, as well as FDA investigators who will be evaluating animal food safety programs for regulatory compliance.

Comments Pertaining to Specific Content within FDA's Draft Guidance

The NGFA offers the following specific comments pertaining to FDA's draft PC guidance.

Chapter 1 – The Food Safety Plan

- **1.2 What is a Food Safety Plan? (Page 10)**

  The NGFA commends FDA for stating, "Some facilities may not identify any known or reasonably foreseeable hazards associated with animal food at their facilities, or after evaluation may determine there are no known or reasonably foreseeable hazards requiring a preventive control." We believe this statement accurately reflects the flexibility provided by the Animal Food Rule requirements, and that there should be no arbitrary compliance expectation that all animal food facilities will have preventive controls.

- **1.7 Is there a Required Format for a Food Safety Plan? (Page 12)**

  The NGFA appreciates content within this section that re-enforces that there is no standardized or required way to organize a food safety plan. Again, we believe the content accurately reflects the flexibility provided by the Animal Food Rule requirements.

  As a resource for organizing a food safety plan, the draft guidance references the availability of training material available from the Food Safety Preventive Controls Alliance (FSPCA). To further elaborate on the flexibility of organizing plans, the NGFA recommends that FDA also mention in its final PC guidance that animal food trade associations have made available materials to assist the industry.

- **1.8 What Circumstances Require Review (Reanalysis) of My Food Safety Plan? (Page 12)**

  The draft PC guidance accurately states that reanalysis of the food safety plan is to occur when FDA determines it is necessary to respond to new hazards and developments in scientific understanding. However, the NGFA believes it would be helpful to industry for the final guidance to elaborate on how FDA would communicate about new hazards or new developments in scientific understanding that may need to be considered in the future.

Chapter 2 – Conducting a Hazard Analysis

- **2.2 Overview of a Hazard Analysis (Pages 14-15)**

  The NGFA appreciates content in this section that indicates animal food products may be grouped for the hazard analysis if the animal food safety hazards and controls are essentially the same for all animal food products in the group. We believe such flexibility will streamline the required analysis, without compromising the evaluation.

  Pertaining to proper analysis of hazards, the NGFA recommends that the final guidance include that expertise available from outside the facility (e.g., land-grant universities, cooperative extension services, trade associations, raw material/ingredient suppliers or other sources) also may be beneficial.

- **2.3.1 Conduct Preliminary Steps (Pages 15-16)**

  This section provides information about recommended, non-mandatory steps that may be conducted when performing the required hazard analysis. One of the recommended steps is to develop a detailed description of the animal food and how it is processed and distributed. For this step, the draft PC guidance specifically recommends that the description include "the full name of the finished animal food, species and life stage or production class, the packaging type and material, and storage and distribution details."

  Pertaining to the "full name of the finished animal food," the NGFA strongly recommends that FDA delete this phrase from the final PC guidance. If facilities choose to incorporate a process description into their food safety plans, we believe grouping like product types together within this description provides sufficient information. Including within the description the full name of each finished animal food would be extremely burdensome at many facilities and would not enhance the effectiveness of the hazard analysis.

  Another recommended preliminary step within this section of the draft guidance pertains to developing a process flow diagram. FDA states, "The process flow diagram should cover all steps in the process that the facility performs, including receiving and storage steps for each raw material or other ingredient, preparation, processing, packaging, storage, and distribution of the product. Additionally, the process flow diagram should

identify the equipment (e.g., bins, legs, mixers, extruders, and pellet mills) used in the operations."

Based on the current language of the draft guidance, it appears FDA expects very detailed process flow diagrams to be used by facilities during the hazard analysis. In contrast, the FSPCA animal food curriculum states, "[a process flow diagram] is not the blueprint of the facility, but instead is a block flow summarizing [a facility's] manufacturing process from start to end. When flow diagrams are included, they can be as simple or complicated as desired to fit the needs of the facility. Flow diagrams are tools that can be used during the hazard identification process, so the flow diagrams should be accurate and as detailed as necessary."

The NGFA believes the language included in the FSPCA animal food curriculum more appropriately describes the level of detail that should be associated with a process flow diagram when completed as a preliminary step within an animal food safety plan. Therefore, we recommend that FDA use the FSPCA language within its final guidance.

- **2.4.1 Identify Known or Reasonably Foreseeable Hazards (Hazard Identification) (Pages 18-19)**

  The draft PC guidance states, "After reviewing all relevant information, the [preventive controls qualified individual] PCQI (with the food safety team if applicable) can develop a list of known or reasonably foreseeable hazards that may be introduced or increased (e.g., due to pathogen growth) at each step described on the flow diagram." In response, the NGFA recommends that the phrase "described on the flow diagram" be deleted from the sentence because a flow diagram is not a required element of the food safety plan.

  FDA further recommends that facilities consult Chapter 3 and Appendix E of the guidance for assistance in identifying known or reasonably foreseeable hazards. Pertaining to Chapter 3 and Appendix E, FDA emphasizes that content in these sections of the draft PC guidance does not represent all possible hazards. While this point of emphasis may be justifiable, the NGFA believes it also is warranted for the final guidance to state that a facility is not obligated to characterize a hazard as being known or reasonably foreseeable simply because the facility handles a product for which Chapter 3 or Appendix E identifies as being associated with a potential hazard.

- **2.4.2 Evaluate Known or Reasonably Foreseeable Hazards (Hazard Evaluation) (Page 20)**

  Pertaining to the control of pathogens in animal food, the draft PC guidance states, "Your written hazard analysis also 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 or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen."

The NGFA believes this requirement (21 CFR 507.33(c)(2)) should be further explained within this section of the final PC guidance in view of FDA's policies on the potential presence of pathogens in animal food. In addition, we believe that FDA should further elaborate on what constitutes "being exposed to the environment prior to packaging."

Concerning the use of prerequisite programs when accessing hazard probability, FDA states, "If you rely on a prerequisite program in your evaluation of probability of occurrence of a hazard, adequate information about the prerequisite program, such as a copy of your standard operating procedures (SOPs), must be included in your hazard analysis as part of your evaluation."

In response, the NGFA believes this sentence should be revised in the final PC guidance to state, "If you rely on a prerequisite program in your evaluation of probability of occurrence of a hazard, the program must be effectively implemented. Having procedures associated with the prerequisite program and routine recordkeeping in place are a good industry practice."

Further related to the use of prerequisite programs, FDA states, "During an inspection, FDA could determine that your prerequisite program does not adequately reduce the probability of the hazard occurrence and that a preventive control and associated preventive control management components may be necessary for the hazard."

Pertaining to this statement, the NGFA believes FDA's position is overreaching in absence of further elaboration, and that FDA should clarify within its final PC guidance under what circumstances the agency would find a prerequisite program to be inadequate. In general, we believe that a facility's compliance with current good manufacturing practice requirements and other applicable regulations, along with the absence of animal food safety incidents, should provide ample evidence that prerequisite programs are adequately controlling the hazard.

- **2.4.4 Evaluating Environmental Pathogens When Animal Food is Exposed to the Environment (Page 25)**

  The NGFA believes that additional context for requirements associated with evaluating environmental pathogens should be included within FDA's final PC guidance. Specifically, FDA should clarify compliance expectations associated with 21 CFR 507.33(c)(2) by elaborating on the agency's current policies on the potential presence of pathogens in animal food and providing additional clarity on what constitutes "being exposed to the environment prior to packaging."

- **2.4.5 Evaluation of Other Factors (Page 25)**

  Pertaining to the condition, function, and design of the facility and equipment, the draft guidance offers an example that contrasts the ability to clean "old" equipment versus "modern" equipment. The NGFA recommends that FDA in its final guidance delete such references that imply the use of "old" equipment may present greater compliance

challenges. We do not believe that it is appropriate for FDA's guidance to establish an unfavorable bias towards "old" equipment.

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

- **3.1 Purpose of this Chapter (Page 31)**

  The NGFA believes it is important to emphasize within the agency's final PC guidance that the risk posed by potential hazards is influenced by the intended use of the animal food. Specifically, we recommend that the final guidance draw distinctions for how certain hazards may be of significant concern in direct human contact animal food (e.g., animal food products used and stored in the home) versus the limited concern posed by the same hazards when present in animal food products to which human exposure is limited (e.g., livestock and poultry feeds, etc.).

- **Table 3-2. Quick Reference Guide for Common Sources of Bacteria and Parasites in Animal Food (Page 34)**

  The NGFA recommends that FDA's final PC guidance place Table 3.2 after the discussion on pages 34-37 that pertains to the agency's policies related to the potential presence of bacterial pathogens and other pathogens in animal food. Moving the table to a point in the guidance after this discussion will help reduce confusion within the industry about whether pathogens are a known or reasonably foreseeable hazard associated with their animal food and facilities.

- **3.3.1 Foodborne Pathogens Associated with Animal Food (Pages 37-38)**

  Transmissible spongiform encephalopathy agents are addressed within this section, with a short discussion about bovine spongiform encephalopathy (BSE) regulations – 21 CFR 589.2000 and 21 CFR 589.2001. The NGFA recommends that FDA include information its final PC guidance about how conformance to these existing regulations could reduce the probability of the BSE hazard to occur and, therefore, obviate the need for a preventive control for this hazard.

- **3.3.4 Facility-Related Biological Hazards (Page 41)**

  FDA states, "The [Animal Food Rule] requirements specify that your hazard evaluation 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 or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen. See 21 CFR 507.33(c)(2)."

  Consistent with previous recommendations made within our comments, the NGFA requests that FDA further elaborate the context concerning 21 CFR 507.33(c)(2) within

its final PC guidance. The industry would benefit from more clarification on when and where this provision applies.

- **3.4 Chemical Hazards (Page 48)**

  The NGFA recommends that Table 3-5 be renamed to "Examples Sources of Chemical Hazards." In addition, we recommend revising the sentence immediately preceding the table to state, "Table 3-5 has example sources of chemical hazards to assist in the hazard analysis process. This is not an exhaustive list." We believe these suggested revisions are appropriate because the use of the word "common" implies that chemical hazards are routine and widespread throughout the animal food industry.

- **3.4.1 Ingredient-Related Chemical Hazards**

  - **Pesticides (Page 49):** The NGFA believes that the following information from the FSPCA animal food standardized curriculum that illustrates the limited potential for pesticide residues should be added to this section within the final PC guidance: "FDA pesticide surveillance suggests that a very small percentage of animal food have pesticide levels that exceed permitted levels. For example, of 420 animal food samples collected in fiscal year 2013, eleven contained violative pesticide levels that exceeded an EPA tolerance or FDA action level (FDA Pesticide Monitoring Program Fiscal year 2013 Pesticide Report)."

  - **Mycotoxins (Pages 50-51):** Table 3-6 provides information about FDA guidance for mycotoxins associated with ingredients used in animal food. As FDA is aware, the agency has provided no official guidance for the presence of ochratoxin or zearalenone in animal food. Accordingly, the NGFA recommends that additional information be provided by FDA within its final guidance concerning how these two mycotoxins should be addressed within an animal food safety plan.

  - **Animal Drugs (Pages 52-53):** FDA's discussion about potential hazards associated with animal drugs within this section has no reference to FDA's medicated feed regulations – 21 CFR 225. The NGFA believes that FDA should elaborate in this section of its final PC guidance on how conformance to these existing regulations could reduce the probability of hazards associated with animal drugs from occurring and, therefore, minimize the need for a preventive control for this type of hazard.

  - **Chemical Hazards that May Be Intentionally Introduced for Purposes of Economic Gain (Pages 54-55):** The NGFA agrees with FDA's recommendation within this section that facilities should within their hazard analysis focus on a historic pattern of economic adulteration when considering chemical hazards that may be intentionally introduced for purposes of economic gain. We strongly believe 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 animal food.

In the case when a facility does identify an economically motivated chemical hazard as being known or reasonably foreseeable, the NGFA recommends that FDA in its final PC guidance include information about how an effective supplier prerequisite program may reduce the likelihood of the hazard occurring, and therefore mitigate the need for a preventive control.

- **Radiological Hazards (Page 55):** FDA suggests that radiological hazards should be considered a known or reasonably foreseeable hazard for an animal food facility if it introduces well water into animal food from areas of the United States where "high concentrations of some radionuclides", such as radium-226, radium-228, and uranium, can be detected in well water as indicated by References 70 and 71 in the draft PC guidance.

  The NGFA has reviewed References 70 and 71, which are highly technical scientific articles authored by the U.S. Geological Survey. Based on our review, we were unable to determine what level constitutes a "high concentration of some radionuclides." However, it appears that it could be concluded from these references that many areas of the United States could be characterized as having areas of "high concentrations of some radionuclides." For example, areas mentioned in the articles that could be associated with "high concentrations of some radionuclides" include, but are not limited to: Illinois, Iowa, Louisiana, Maryland, Minnesota, Missouri, Nebraska, the New England States, New Mexico, New York, Wisconsin, and the areas including the Fall Line of the southeastern States from Georgia to New Jersey.

  FDA previously has stated that radiological hazards rarely occur in the food supply. This statement is supported by the Scientific Literature Database – Food for Animals Tool published by the University of Minnesota's College of Veterinary Medicine. This tool, developed through funding provided by the National Grain and Feed Foundation and the American Feed Industry Association's Institute for Feed Education and Research, summarizes an evaluation of articles published in Canada and the United States during 2006-2016 from scientific literature databases (PubMed and CABI) to identify documented occurrences of hazards in animal food that caused or had the potential to cause adverse health consequences in animals or humans. In addition, the tool summarizes information from FDA recall information on Class I recalls from 2009-2016, and information from FDA Enforcement Reports from Class II and Class III recalls from 2012-2016. Based on this literature review, there were no documented occurrences of radionuclides in animal food that caused or had the potential to cause adverse health consequences in animals or humans.

  While FDA's draft PC guidance generally suggests that the concern of radiological hazards is limited to use of well water and accidental contamination, the NGFA strongly recommends that the agency in its final PC guidance clearly state that the potential for radiological hazards in animal food is extremely rare, and that radiological hazards are not likely to be considered known or reasonably foreseeable for the vast majority of animal food safety plans. In addition, for any facility that

FDA envisions radiological hazards to be known or reasonably foreseeable, the final PC guidance should provide clear information about FDA's compliance expectations associated with evaluating and controlling such a hazard.

- **3.4.2 Process-Related Chemical Hazards**

  - **Animal Drug Carryover in Animal Food (Pages 56-57):** Consistent with our previous comments, the NGFA believes that FDA should elaborate within this section of its final PC guidance on how conformance to 21 CFR 225 regulations may reduce the probability of hazards associated with animal drug carryover from occurring and therefore, minimize the need for a preventive control for this hazard.

- **3.5 Physical Hazards**

  - **Conditions of Animal Food (Pages 58-59)**: FDA introduces a new term – "conditions of animal food" – within this section of the draft PC guidance. The NGFA believes that other conditions of animal food mentioned in this section (e.g., particle size, hardness, surface texture, digestibility, and ability to soften when moistened) often pertain to product quality and not product safety. As such, we recommend that FDA clarify in its final guidance that such characteristics do not represent known or reasonably foreseeable hazards for all types of animal food, and that each facility should determine whether a given condition poses a hazard.

Chapter 4 – Preventive Controls

- **4.2 Overview of Preventive Controls (Page 68)**

  The NGFA recommends the discussion about the need to validate preventive controls be revised in the final PC guidance to make clear that validation is only a regulatory requirement for process controls and "other controls." As currently drafted, this section could confuse facilities by inferring that sanitation and supply chain controls also are required by regulation to be validated.

- **4.6.1 Preventive Controls for Nutrient Deficiencies and Toxicities (Pages 88-90)**

  Within this section of the draft PC guidance, FDA provides several examples of preventive controls to address potential chemical nutrient deficiencies and toxicities. The NGFA strongly recommends that FDA also include within its final guidance examples of how the use of prerequisite programs may decrease the probability that a known or reasonably foreseeable hazard may occur, and result in a determination that the hazard does not require a preventive control.

  More specifically, the NGFA strongly disagrees with FDA's recommendations made in the draft guidance that "if [a facility is] manufacturing a cat food that will undergo [low acid canned food] LACF thermal processing, [the facility] should identify thiamine deficiency as a chemical hazard requiring a preventive control" and "if [a facility

manufactures] food for cattle that requires copper at levels that would be toxic to sheep, and [the facility] manufactures food for sheep on the same equipment, [the facility] would likely identify copper excess as a known or reasonably foreseeable nutrient toxicity hazard requiring a preventive control." We believe FDA's statements about such potential chemical hazards are in direct contradiction to the Animal Food Rule's requirements, which clearly state it is up to the facility to determine whether a hazard requires the use of a preventive control based on the facility's own experience and unique situation.

Therefore, the NGFA urges FDA to not include within its final guidance the recommendations that facilities should identify that thiamine deficiency or copper toxicity are chemical hazards requiring a preventive control within these examples. Further, we strongly recommend that the copper toxicity example from the FSPCA animal food curriculum be added to this section of the final guidance to illustrate how a facility's use of prerequisite programs may appropriately influence how copper toxicity is characterized within an animal food safety plan.

- **4.6.2 Drying and Storage Conditions as Preventive Controls for Mycotoxins (Page 90)**

  Within this section, FDA states, "Growth of toxigenic fungi during storage and transportation can be enhanced by improper drying or rewetting of the crop from rain or condensation. Thus, proper drying and maintaining appropriate storage conditions are preventive controls that can significantly minimize or prevent the growth of mold and production of mycotoxins in storage."

  In response, the NGFA strongly recommends that FDA revise this section within its final PC guidance to clarify that proper drying and maintaining appropriate storage conditions **may** be a preventive control, **if** a facility chooses to characterize these activities in that manner, but more frequently are considered to be components of the prerequisite program implemented to address regulations established by the Animal Food Rule in Subpart B - Current Good Manufacturing Practice.

- **4.6.3 Sequencing and Flushing as Preventive Controls for Drug Carryover (Pages 90-91)**

  The NGFA recommends that FDA revise this section in its final PC guidance to include information about how conformance with 21 CFR 225 regulations may reduce the probability of hazards associated with animal drug carryover from occurring and, therefore, minimize the need for a preventive control for this hazard.

- **4.7.1 Preventive Controls for Metal Hazards (Pages 91-92)**

  The NGFA believes the idea of using a preventive control for metal hazards is problematic unless a facility can utilize electronic or X-ray metal detection devices for finished product evaluation. Using process preventive controls for metal hazards would

require parameter values to be set, and conducting monitoring activities to assure values are being met. Establishing meaningful parameter values for metal hazards and conducting effective monitoring of finished product may be possible if using electronic or X-ray metal detection devices, but generally is not feasible if magnets, sieves, screens, or a combination thereof, are designated as preventive controls.

Accordingly, the NGFA recommends that FDA revise this section within its final guidance to clarify that the use of electronic or X-ray metal detection devices may serve as preventive controls when used in final product evaluation and that other controls, such as magnets, sieves, screens and equipment inspection may serve as effective components of a prerequisite program to reduce the probability of metal hazards and obviate the need for a preventive control.

- **4.7.3 Preventive Controls for Hard Plastic Hazards (Page 92)**

  Similar to metal hazards, the NGFA believes the suggestion to use sieves and screens as preventive controls within animal food safety plans generally is problematic unless such controls are used at the end of the process for finished animal food evaluation. We recommend that FDA revise this section within its final PC guidance to indicate that sieves and screens typically are used as components of a prerequisite program to reduce the probability of plastic hazards and minimize the need for a preventive control.

- **4.7.4 Preventive Controls for Conditions of Animal Food That Can be Hazards (Pages 92-93)**

  As previously expressed, the NGFA believes that other characteristics of animal food mentioned in this section (e.g., particle size, hardness, surface texture, digestibility, and ability to soften when moistened) often pertain to product quality and not product safety. As such, we recommend that FDA clarify in its final PC guidance that such conditions often are addressed through quality assurance programs. In addition, we believe that FDA in the final guidance should recognize that when such conditions do relate to product safety, they typically are addressed by animal food facilities through the use of prerequisite programs.

Chapter 5 – Overview of Preventive Control Management Components

- **5.3 Who is Responsible for Conducting Preventive Control Management Component Activities? (Page 103)**

  The draft guidance states, "… PCQIs must conduct or oversee validation of preventive controls and some verification of implementation and effectiveness activities (see 21 CFR 507.53(a)). The PCQI may designate another individual to conduct some of these activities provided the individual is a [qualified individual] QI and the PCQI maintains oversight." In comparison, 21 CFR 507.53(a)) of the Animal Food Rule states, "One or more preventive controls qualified individuals must do or oversee the following [preventive control management components].

Since the rule's provision states the PCQI must do **or** oversee the specified management components, the NGFA questions why the draft PC guidance implies that the PCQI's ability to designate another qualified individual to conduct the management components associated with preventive controls is limited to "some" of these activities. We believe that FDA should clarify its intent related to "some" within the final PC guidance or eliminate the use of this qualifier.

- **Box 5-4a. PC Management Component Example – Corrective Actions**

The NGFA appreciates the example provided in the draft guidance to illustrate the application of the corrective action requirements. However, since stopping a conveyor holding biscuits within a hot oven typically is not realistic, we recommend that the example be revised in the final PC guidance as follows *[new language **boldfaced and underscored**, deleted language ~~struck through~~]*:

> Salmonella in dog biscuit treats: If your oven temperature drops below 352°F (178°C) (your operating limit), an alarm sounds. If the alarm sounds, the designated operator checks the oven to determine the problem, and does a correction if the problem is minor. If the temperature drops below 350°F (177°C) (i.e., deviates from your established minimum parameter value), **incoming biscuits are stopped from entering the oven, and biscuits within the oven are diverted and held to determine appropriate disposition**, ~~the conveyor stops~~ and the designated operator immediately initiates a corrective action per your written corrective action procedures.
>
> During production, an oven alarm sounds indicating that the oven temperature fell below 352°F (178°C). The designated operator conducts an initial inspection of the oven to see whether a minor adjustment will correct the temperature. While he is examining the oven, the temperature drops below 350°F (177°C) (the established minimum parameter value for temperature) and **incoming biscuits are stopped from entering the oven, and biscuits within the oven are diverted and held to determine appropriate** disposition ~~the conveyor stops running~~. Per your written corrective action procedures, the designated operator promptly informs the shift manager, who oversees corrective actions. The shift manager then contacts the maintenance department. The maintenance individual determines the oven air recirculation fan was not operating properly and installs a new fan. The shift manager documents this repair in the corrective action records, along with her signature and date.
>
> The shift manager also documents the lot number for the batch of biscuits that was in the oven when the oven temperature was below 350°F (177°C). **The appropriate disposition of** all biscuits in this batch **that were** ~~are~~ separated ~~from other ingredients and products and set aside for~~ **is determined to be** destruction**.** To destroy the batch, an employee puts the batch of biscuits in trash bags, adds a denaturing agent, and places the batch in the dumpster. The shift manager observes and documents the

destruction along with the lot number of the batch in the corrective action records.

- **5.8.5 Verification of Implementation and Effectiveness**

  - **Product Testing (Page 119):** The NGFA appreciates that within this section FDA states, "Product testing is not required for all facilities that identify pathogens or other hazards requiring a preventive control." We believe the Animal Food Rule appropriately provides flexibility to facilities to determine whether product testing should be used as verification of implementation and effectiveness of a preventive control.

  - **Environmental Monitoring (Pages 120):** Although this section of the draft PC guidance indicates that environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, **may** be used when a facility's hazard analysis determines that contamination of animal food with an environmental pathogen (or appropriate indicator organism) is a hazard requiring a preventive control, the NGFA recommends that FDA also include language in its final guidance that environmental monitoring is not required for all facilities that identify pathogens requiring a preventive control. Such an addition would be consistent with FDA's statement already included in the Product Testing section of the draft guidance.

  - **Box 5-11a and Box 5-11b. PC Management Component Example – Verification of Implementation and Effectiveness, Record Review (Pages 122 and 123):** The NGFA notes that both preventive control management component examples illustrate multiple verification reviews of the preventive control monitoring records, while the Animal Food Rule requires that monitoring records be reviewed once by (or under the oversight of) a preventive controls qualified individual within specified timeframes. While multiple verification reviews of monitoring records may provide additional assurance of accuracy and completeness, we believe the examples should more clearly describe to the industry how to meet requirements established by the rule.

    Further, both examples seem to imply that the PCQI must verify monitoring records within 7-working days, or provide written justification for why a longer timeframe is acceptable. Again, the NGFA does not believe this aspect of the examples is consistent with the Animal Food Rule's requirements. Instead, the rule provides flexibility that the review of monitoring records may be performed by qualified individuals under the oversight of the PCQI.

    Accordingly, the NGFA recommends that these examples be revised in the final PC guidance to better reflect regulatory requirements. If FDA desires to include within the examples the suggestion of multiple verification reviews, we believe the agency should clearly note that multiple reviews are optional and are being included to illustrate that they may provide additional assurance of accuracy and completeness of the records being reviewed.

Appendix D – How to Use the Hazard Analysis Worksheet

The NGFA agrees with FDA's statement within Section 2.2 - Overview of a Hazard Analysis of the draft guidance that facilities are not required to use a certain format for conducting their hazard analysis and that other formats may be used as long as the hazard analysis contains the elements of hazard identification and hazard evaluation and a determination of whether any of the hazards require a preventive control.

Although the worksheet in Appendix D is marked "example," the NGFA recommends that language from Section 2.2 related to no required format be reiterated at the beginning of the appendix in the final PC guidance. Further, we recommend that Appendix D also expressly reference the FSPCA curriculum for animal food for an alternate example of a hazard analysis worksheet, as previously mentioned in Section 2.5.

Appendix E – Aid to Identifying Animal Food Hazards

As previously expressed in this statement, an overarching concern the NGFA has related to Appendix E is FDA investigators may have an expectation that every facility address within its hazard analysis each identified hazard that FDA indicates has been associated with the ingredients used at the facility.

The NGFA believes this concern is justifiable given the introductory remarks in Appendix E that state, "These tables of hazards are intended to provide a starting point for an individual facility's identification of known or reasonably foreseeable hazards in various categories of animal food. The tables do not list all possible animal foods or hazards." This language leaves a clear impression that the identified hazards are, at a minimum, those that FDA has pre-determined as "known or reasonably foreseeable," and, therefore, required to be evaluated within a facility's hazard analysis when an ingredient with a designated hazard is used within its operation.

In contrast, the NGFA believes that the purpose of Appendix E should be to assist in the identification of **potential** hazards for animal food. Accordingly, we strongly urge FDA to more explicitly state in its final guidance that the purpose of the appendix is to identify **potential** hazards for a facility to consider when determining those known or reasonably foreseeable hazards associated within its animal food and operations that will be further evaluated in its hazard analysis. Further, we urge FDA to explicitly state that the identified hazards may or may not represent a potential safety concern to a given facility and that it is each facility's responsibility to evaluate the potential hazard and take appropriate actions in accordance with the Animal Food Rule's requirements. To not provide this clarification could create a tremendous burden across the industry to document and justify how each hazard identified for the various ingredients listed the PC guidance is being addressed.

Further, the NGFA urges FDA to train its investigators in such a manner so as to understand that facilities should not be considered out of compliance with the regulation if their hazard analysis does not include a discussion of every potential hazard identified in Appendix E. As established by the Animal Food Rule, each facility is to make their individual determination of whether a

hazard is known or reasonably foreseeable for their animal food and operation, and, if so, whether the hazard requires a preventive control based on that facility's unique situation.

The NGFA also offers the following specific comments pertaining to Appendix E:

- **Introduction:** On page 139 in the draft guidance FDA states, "A dash ("-") is inserted when [FDA] did not identify the hazard in the animal food at the time of issuance of this guidance document." To reinforce, as stated by FDA in an earlier section of the Introduction, that not all hazards are likely to be known or reasonably foreseeable hazards in a facility's animal food (including raw materials, ingredients, and mixed ingredient products), the NGFA recommends the following sentence be added to the final guidance: "When a dash is inserted, an animal food facility, after considering its own experience, could identify the hazard as not being known or reasonably foreseeable in the specified animal food."

- **Reference Dates:** Several references listed for Appendix E are decades old. This contributes to concern about the scope of FDA's compliance expectations related to hazard analysis. The Animal Food Rule states that facilities are to conduct a hazard analysis to identify and evaluate, **based on experience**, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control (21 CFR 507.33(a)(1)). The NGFA believes that this provision provides flexibility to facilities to determine the appropriate scope when considering the specified criteria for known or reasonably foreseeable hazards based upon their own experience. We urge FDA to review references included within the draft guidance to ensure they are relevant and meaningful to the animal food industry.

- **Plant Protein Meal (Page 146):** Appendix E indicates that economically motivated chemical hazards are associated with plant protein products (e.g., camelina meal; canola meal; coconut meal; cottonseed meal; linseed meal; peanut meal; safflower meal; soybean meal) and uses Reference 44 to substantiate this determination. However, Reference 44 refers to an import alert issued by FDA when the agency found melamine and melamine-related compounds in wheat gluten and rice protein concentrates. The import alert does not reference camelina meal; canola meal; coconut meal; cottonseed meal; linseed meal; peanut meal; safflower meal; or soybean meal. As such, the NGFA believes that this reference does not demonstrate that economically motivated chemical hazards have been associated with plant protein products and we recommend that FDA remove the designation.

- **Distillers By-Product (Page 147):** Appendix E lists animal drug residues as a hazard for distillers by-products and references FDA sampling and testing data to support this inclusion. It is NGFA's understanding that FDA's testing of distillers by-products did not assess biological activity associated with residues indicated through testing. Further, we are aware that subsequent peer-reviewed published journals have indicated that while some residue may be present, there is no biological activity associated with the residue.

Therefore, the NGFA questions whether it is appropriate to include animal drug residues as a potential hazard associated with distillers by-products. If FDA holds the position that such an inclusion in the appendix is warranted, the NGFA recommends that FDA also provide additional information in its final guidance related to the biological activity associated with potential residues.

Conclusion

The NGFA appreciates FDA's consideration of its views expressed in this statement, and would be pleased to respond to any questions the agency may have. The NGFA also again commits to being a fully engaged and constructive participant during FDA's implementation of FSMA.

Respectfully Submitted,

David A. Fairfield
Senior Vice President for Feed Services
National Grain and Feed Association