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

RE: Docket No. FDA–2015–N–0797 - FDA Food Safety Modernization Act: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards

The National Grain and Feed Association (NGFA) submits this statement in response to the Food and Drug Administration's (FDA) request for comments published in the March 24, 2015 ***Federal Register*** regarding its implementation strategy for the prevention-orientated food safety standards being promulgated under the Food Safety Modernization Act (FSMA).

Established in 1896, the NGFA comprises more than 1,000 member companies that operate more than 7,000 facilities and handle more than 70 percent of the U.S. grain and oilseed crop. The NGFA's membership encompasses all sectors of the industry, including country, terminal and export grain elevators; commercial feed and feed ingredient manufacturers; biofuels producers; cash grain and feed merchants; end-users of grain and grain products, including processors, flour millers, and livestock and poultry integrators; commodity futures brokers and commission merchants; and allied industries. The NGFA also has strategic alliances with the North American Export Grain Association and Pet Food Institute. In addition, affiliated with the NGFA are 26 state and regional grain and feed trade associations. Canadian and Mexican firms also are NGFA members.

At the outset, the NGFA commends FDA for the extensive public outreach it is conducting to implement the various provisions of FSMA. We appreciate the time and effort FDA is expending to host public meetings, speak at meetings hosted by public and private-sector organizations, and conduct smaller group sessions to solicit a wide range of stakeholder input. Such outreach, we believe, is essential to implementing this complex and far-reaching law in a manner that further enhances what already is a safe and wholesome food and animal feed supply, without adding unnecessary regulatory burdens and costs that would undermine the industry's ability to provide an abundant and affordable food supply to U.S. and world consumers.

The NGFA has participated in each of the public meetings FDA has hosted to date concerning its implementation of FSMA. The industry segments within the NGFA's membership recognize the paradigm shift FSMA represents in terms of placing the principal focus on prevention of hazards that can pose a risk to human or animal health. The law also codifies a fundamental principle that the grain, feed and grain processing industry has long held – that the industry bears the principal responsibility for producing and distributing safe products. That is a responsibility our industry embraces and takes very seriously.

General Comments on FDA's Operational Strategy and Framework for Risk-Based Industry Oversight

The NGFA, American Feed Industry Association, and Pet Food Institute appreciated the opportunity to provide joint perspectives during the stakeholder panel session conducted at the April 23-24 public meeting in which FDA sought public comments on its plans to further implement FSMA. In addition to remarks provided during that session, the NGFA wishes to offer the following general comments on issues related to FDA's operational and inspectional strategy.

- **A Common Understanding of Responsibilities and Obligations Must Be Developed:** The NGFA believes that both regulatory officials and industry will need a clear and common understanding of responsibilities and obligations under the new FSMA-related rules. For such an understanding to be achieved, FDA will need to issue multiple guidance documents for various industry sectors in a timely manner after final rules are issued. We urge FDA to work closely with the regulated industry while developing such documents so that content reflects the realities of industry practices, aligns with regulatory requirements and serves to further enhance the safety of human food, animal feed and pet food. To do so, we strongly recommend that FDA engage with the regulated industry at the outset of its guidance development process so that valuable and essential dialogue can occur pertaining to these important documents.

  In addition, FDA's investigators will need to undergo comprehensive training to ensure uniformity of inspection and compliance efforts. While FDA has indicated that it intends to develop metrics to measure industry's compliance with FSMA requirements, the NGFA also believes that the agency must establish clear metrics to accurately measure its investigators' understanding and application of the regulations. Consistent and reasonable inspectional activities will play an essential role in establishing the constructive relationship between regulators and industry that is necessary to advance food and feed safety.

- **FDA Should Use an "Educate before Regulate" Approach:** The NGFA strongly supports FDA's stated FSMA-compliance philosophy of "educate before it regulates." Appropriate time will need to be provided so that industry can understand and come into compliance with the new and far-reaching requirements to be established under the FSMA-related rules. For example, the forthcoming animal feed and pet food rule will establish new requirements for both good manufacturing practices (CGMPs) and preventive controls for facilities involved in the animal feed and pet food industries. As such, we believe it is necessary and appropriate for FDA to provide such facilities with adequate time to come into compliance with the CGMP requirements before being expected to comply with the preventive controls requirements. To do so, we request that FDA provide facilities one year after being required to be in compliance with the CGMPs 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 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.

- **FDA Should Use a Risk-Based Approach When Setting Inspection Priorities:** The NGFA believes that FDA should rely upon currently collected and publicly available information and data obtained over the course of many years when determining whether a facility or its products should be subject to more frequent inspections as mandated under FSMA. Such data sources include, but are not limited to: 1) results of FDA and state inspections of food and feed facilities; 2) recall information; 3) reports submitted to the Reportable Food Registry; 4) identifiable trends in foodborne illnesses, as evidenced by public health data maintained by the Centers for Disease Control; and 5) data available through the OASIS computer system and prior notices received by the FDA under the Bioterrorism Act. We strongly believe that FDA's inspectional resources should be focused on facilities that have a higher risk of affecting human and animal health.

- **FDA Should Provide Regulatory Incentives for Compliance:** Just as the agency rightfully should focus its inspection and enforcement resources where they are most needed and will have the greatest impact on facilitating food safety, the NGFA also believes that FDA should provide regulatory incentives for those firms that demonstrate good compliance. We strongly support the concept of FDA conducting less frequent and/or targeted inspections of a more limited duration at firms with good compliance histories. Using such an approach, FDA would be able to direct its resources in such a manner that maximizes benefits to food safety.

- **FDA Should Continue to Use State Regulatory Officials for Inspections:** The NGFA strongly supports FDA's continued use of state feed regulatory officials to conduct FDA-credentialed inspections of animal feed and pet food facilities. The use of state regulatory officials who are familiar with and knowledgeable about animal feed and pet food facilities and the types of products manufactured and distributed will result in more meaningful inspections being conducted. In contrast, inspections conducted by investigators who are not familiar with animal feed and pet food facilities can result in undesirable outcomes for both industry and FDA. This is not a theoretical concern, as such negative outcomes unfortunately have occurred in the past. Use of state regulatory officials for FSMA-related inspections will require additional training and inspector calibration to ensure consistency in inspectional approaches and execution. We urge FDA to work closely with states to ensure that state regulatory officials are appropriately trained to conduct FSMA-related inspections.

- **The Food Safety Preventive Controls Alliance Serves an Essential Role in Effectively Implementing the Preventive Control Regulations:** The NGFA is fully committed to the animal feed- and pet food-related activities occurring within the Food Safety Preventive Controls Alliance. 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 in implementing the preventive controls regulation. We strongly believe it is through the cross-cutting interaction provided for within the Alliance that effective training and guidance materials may be made available that will enable both FDA and industry to implement the preventive controls regulation in a consistent and practical manner that maximizes benefits to animal feed and pet food safety.

- **FDA Should Develop a System to Resolve Disputes about Inspectional Observations:** Even with industry and regulator training programs and agency-issued guidance documents, the NGFA believes that it is inevitable that disagreements will arise pertaining to inspectional observations under the agency's new FSMA regulations. Therefore, we strongly support development of a timely appeals mechanism so companies that disagree with an investigator's conclusion can readily bring the issue to the attention of FDA experts. We believe that an appropriate and transparent inspection and dispute resolution process will be essential to effective implementation of the regulations.

Evaluating Food Safety Culture

During the April 22-23 public meeting on FSMA implementation, FDA indicated that the agency's regulator training would include the topic of food safety culture. In addition, FDA has approached the NGFA and other animal feed- and pet food-related trade associations to provide thinking about how the agency might evaluate a company's food safety culture.

While the NGFA agrees that a company's culture affects the performance of its food safety system, we caution the agency to not place an excessive emphasis on this area during its inspection and compliance activities. As the agency is well aware, FDA's FSMA-related rules will establish a multitude of new and expansive requirements for all sectors of the human food, animal feed and pet food industries. Many of these sectors have had minimal interaction with FDA in the past, and have limited experience with the agency's inspection and compliance activities. Therefore, we believe the agency should expect there will be cases when facility personnel are somewhat cautious in their responses and reactions to an FDA investigator during the inspection process. In such situations, we believe that evaluating the facility's food safety culture may prove to be particularly difficult until there is an appropriate level of mutual trust fostered between FDA and the facility.

Further, the NGFA believes that a company's food safety culture may be challenging to measure even at companies that are familiar with FDA and its inspection activities. Conventionally, culture is evaluated by reviewing documentation associated with a company's management commitment to food safety. This documentation may take the form of written food safety mission statements, objectives, policies and review procedures. However, FSMA does not mandate that companies establish and document such management commitment nor do we believe it would be appropriate for the agency to require companies to do so. Clearly, the degree to which food safety culture needs to be formalized to facilitate food safety depends upon the

specific company and the nature of its operations. A one-size-fits-all approach will not guarantee a "good" food safety culture or ensure food safety. As such, FDA investigators should not expect to experience the same degree of food safety culture within every facility, nor is it necessary for every facility to express a given level of food safety culture to have a successful food safety program.

The NGFA is concerned that FDA's attempts to evaluate food safety culture may largely depend on subjective criteria that do not correlate to the facility's actual compliance with regulatory requirements. If FDA does place undue emphasis on attempting to evaluate food safety culture, this could result in the unintended consequence of causing companies to direct limited resources away from important food safety practices and towards creating a program to simply satisfy FDA's interests in this area. We urge FDA to carefully avoid such an outcome.

Two-Tiered Inspection Approach

FDA has indicated that the agency is considering a two-tier inspection for companies with corporate-wide programs and policies. Under FDA's proposed approach, an initial inspection would first assess the adequacy of food safety plans developed on the corporate level. Then, FDA would conduct a subsequent inspection to assess implementation of the plans on the facility level. FDA also has indicated that the agency likely would do a feasibility/pilot study to evaluate this approach.

FDA states that utilizing such an inspection approach could help the agency better allocate inspection resources – for example, by helping investigators prepare for facility-level inspections (potentially reducing inspection time), and possibly resolving any questions about the food safety plan by having better access to corporate food safety management.

While the NGFA supports the agency's goal of making inspections more efficient and effective, we strongly believe that industry's participation in any two-tiered inspection program implemented by FDA should be strictly voluntarily. As FDA is aware, its inspectional authority under the forthcoming preventive controls rules is provided for firms registered with the agency as a food facility under the Bioterrorism Act. Therefore, FDA has authority to inspect at reasonable times and in a reasonable manner domestic and foreign facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States. Often corporate offices for food and feed companies do not have an obligation to register with FDA as a food facility because the corporate office does not manufacture, process, pack or hold food or feed for consumption in the United States. As such, we believe that any inspectional activities conducted at such corporate offices would need to occur on a voluntary basis.

The NGFA also believes that accurately accessing the adequacy of a food safety plan at a corporate level would be difficult. We believe that the adequacy of a plan is best evaluated within the context of a facility's operation, where an investigator can readily observe how various aspects of the plan interact to control identified hazards. Indeed, this concept is embodied in FDA's general authority to inspect and access records as detailed in section 704 § 374 (a) of the Food, Drug and Cosmetic Act, which plainly provides that FDA's inspection activities are to

occur at the establishment in which the food is manufactured, processed, packed or held for introduction into interstate commerce. FDA's inspection authority is provided for in this manner for good reason. It is not possible to make accurate inspectional observations without being able to observe and understand the context of the facility's operations.

In addition to these overarching views, the NGFA provides the following comments pertaining to FDA's proposed two-tier inspection approach:

- Since FDA's inspection authority at corporate offices likely is limited, we believe a more appropriate terminology to describe the proposed approach would be "Pre-Inspection Program Review."

- We reiterate our previously expressed belief that industry's participation in any corporate review program must be voluntarily. As such, visits to corporate offices by FDA would need to be scheduled in advance to ensure that company subject matter experts are available. In addition, firms should have the option to specify which components of their food safety programs would be made available for review.

- While the review of corporate programs may be helpful for FDA inspection planning purposes, the review should not be used for enforcement actions. FDA authority to inspect exists at the food facility level, and any necessary enforcement actions rightfully are to occur at the food facility.

- We believe in many cases it is unlikely that the same FDA investigator would visit both the corporate office and the company's facilities. This disparity has the potential to cause differences of interpretation and calibration during the facility inspection. We believe FDA should carefully consider this possibility as it evaluates the two-tier inspection concept.

Conclusion

The NGFA appreciates FDA's consideration of the recommendations expressed in this statement, and pledges to continue to be a fully engaged and constructive participant in future discussions with the agency concerning its operational strategy and the risk-based industry oversight framework that is a core component of FSMA.

Sincerely,

David Fairfield
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