National Grain and Feed Association
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U.S. Food and Drug Administration
12420 Parklawn Drive
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RE: Docket Number FDA-2023-N-2393; Modernizing Recalls of FDA-Regulated Commodities

The National Grain and Feed Association (NGFA) appreciates the opportunity to submit this statement in response to the U.S. Food and Drug Administration's (FDA) request for stakeholder comments on modernizing recalls of FDA-regulated commodities.

The NGFA, established in 1896, consists of grain, feed, processing, exporting and other grain-related companies that operate more than 8,000 facilities that handle over 75 percent of U.S. grains, oilseeds and animal food products. 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. NGFA also consists of 27 affiliated State and Regional Grain and Feed Associations.

NGFA-member companies manufacture, pack and hold a variety of FDA-regulated commodities subject to FDA recall requirements, and we commend the agency for conducting a listening session on September 29 to receive public input on FDA's recall policies and practices, and how modernization could improve recall effectiveness and advance animal and public health. We also appreciate this docket through which written comments on this topic may be submitted.

Food safety is a priority shared by NGFA members and FDA, and our members are committed to protecting the health of animals and the public, and work to ensure products brought to the marketplace are safe and properly labeled. Our members are also committed to effectively and efficiently recalling food products, when necessary.

NGFA believes there are opportunities to enhance FDA's policies and practices to improve the effectiveness and efficiency of recalls. In general, we believe FDA should take several steps to enhance consistency, transparency, and communications associated with its recall processes and expectations. Related to these topics, NGFA offers the following specific

recommendations.

- **Recalls should be appropriately and consistently delineated from market withdrawals.** 21 Code of Federal Regulations (CFR) Part 7.3 defines a market withdrawal to mean "a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.". In contrast, a recall is defined to mean "a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the Agency would initiate legal action, e.g., seizure, [and] recall does not include a market withdrawal or stock recovery".

  Pertaining to appropriately distinguishing market withdrawals from recalls, NGFA believes FDA should have clear and consistent processes in place to avoid determining a recall is necessary when a given situation is, in fact, a minor violation that would not be subject to legal action by the agency. As an example, we believe FDA should not characterize a minor, out-of-tolerance result from an animal food nutrient assay as a recall situation when the assay result would not be subject to legal action by FDA and does not pose a risk to animal or public health. Characterizing such a situation as a recall would cause undue negative consequences for the affected firm, divert FDA's resources from priority activities, and create unjustified concern among consumers. FDA should modernize its recall and market withdrawal terminology to ensure that events are appropriately characterized based upon the established definitions and risk to animal and public health.

- **Consistency, timeliness and accuracy of recall classifications should be ensured.** NGFA believes industry would benefit from FDA providing clearer direction on their classification process for Class I, II, and III recalls, and establishing more definitive timelines for determining classifications. Further, we believe FDA's health hazard evaluations should be shared with affected firms to promote consistency, awareness, and transparency within FDA's processes.

  Related to timeliness of recall classifications, to satisfy FDA's expectations, a firm's recall response is tailored to the classification type determined by the agency. If the recall type is changed by FDA after the initial classification, the firm is obligated to alter its activities, which can lead to confusion and inefficiencies. For example, NGFA is aware of situations when an initial recall classification was determined, but later changed after the health hazard evaluation was completed. This type of change

creates additional burdens for the firm during an already hectic and challenging situation, and can create unwarranted negative effects.

In addition, NGFA believes that FDA should carefully consider its process to determine the need for a public warning to be part of the recall process. As noted in 21 CFR Part 7.42(b)(2), the purpose of a public warning is to alert the public that a product being recalled presents a serious health hazard and public warnings are to be reserved for urgent situations where other means of preventing use of the recalled product appear inadequate. However, NGFA members have expressed that it is common for FDA to suggest that a public warning be issued even when the situation is not urgent, and when the recall has not been classified as Class I. Instead, we believe FDA should adhere to the criteria listed in 21 CFR 7.42(b)(2), and work with firms to ensure that public notifications are issued when necessary.

Related to the need for public notifications, we urge FDA to carefully consider whether a given situation reaches the threshold of presenting a serious health event. While we acknowledge FDA has stated the agency uses an abundance of caution when making health consequence determinations associated with a recall, the unwarranted classification of an event as a Class I recall causes both FDA and industry to direct resources to activities that have minimal effect in protecting animal and public health.

- **Training on FDA directives and policies related to recalls should be provided.** While FDA has issued a variety of guidance documents related to recall topics, NGFA believes practical training provided by the agency would be helpful for all entities involved in recalls. In addition, we believe all entities involved in recalls would benefit from FDA issuing a concise recall handbook for agency staff, states, and the regulated industry that articulates a clearer and standardized interpretation of FDA requirements and expectations. Such a handbook should include updated templates, forms and model plans that accurately reflect FDA's requirements and current thinking.

- **Expectations among FDA Recall Coordinators should be more consistent.** NGFA members have indicated the application of FDA's recall process is highly dependent on the FDA Recall Coordinator, and that expectations among FDA Recall Coordinators dramatically differ. We believe FDA should take steps to ensure that all recall coordinators have consistent interpretations and expectations associated with recall requirements.

In addition, NGFA members have experienced situations in which multiple recall coordinators are involved with one recall event, which has created confusion and duplication of efforts. We believe one recall coordinator should be assigned to an event, and this coordinator should be responsible for further internal communications within FDA, as needed. Further, we believe that FDA should clearly assign a backup point-of-contact with which industry can communicate when the assigned recall coordinator is unavailable.

- **Communication between all entities involved in the recall - federal, state and industry - should be coordinated and harmonized.** Our members indicate that during a recall event they often receive multiple requests for the same information from both state regulatory agencies and FDA. Multiple requests for the same information cause undue stress on industry personnel, whose primary focus during the recall should be the removal of affected products from commerce. In addition, the occurrence of multiple information requests from regulatory authorities has the potential to lead to different versions of information being possessed by various regulatory entities, which may create confusion and generate additional, unproductive communications between industry and regulatory bodies.

  To ensure proper coordination between FDA and states during recall situations, NGFA believes FDA and states should clearly establish and communicate: 1) roles and responsibilities of FDA and the state(s) involved with the recall; 2) manners in which information will be exchanged efficiently between regulatory bodies; and 3) when the termination of the recall occurs.

  Related to coordinating and harmonizing the information exchange between FDA and state authorities, NGFA encourages FDA and states to review and update information sharing laws to allow information to be shared as necessary to respond to recall events rapidly and efficiently. FDA and states need to address current legal restrictions and state workarounds to further integrate their efforts and achieve the goal of mutual reliance and an integrated food safety system.

  To better facilitate the exchange of information between industry and regulatory entities, NGFA believes FDA should:

  – Centralize recall functions, and create an electronic portal through which required documents may be submitted and accessed.

  – Standardize the format for distribution lists used during recall events.

- Make recall Attachment A and a standardized Attachment B available to the industry.

- Eliminate the requirement for industry to submit Attachment B, when the recall event involves a Reportable Food Registry Report, since the information is duplicative.

- Enable the industry to communicate directly to FDA subject matter experts, rather than the current practice of relying on the FDA Recall Coordinator to convey information provided by the industry.

- Formalize and make more efficient processes associated with review of effectiveness checks, to avoid duplicative work being performed by industry, states, and FDA.

Conclusion

In closing, NGFA believes there are opportunities to modernize FDA's policies and practices to improve the effectiveness and efficiency of recalls by enhancing the consistency, transparency, and communications associated with its recall processes.

We again commend FDA for soliciting stakeholder comments on modernizing recalls of FDA-regulated commodities, and look forward to any future opportunities to provide additional feedback.

Sincerely,

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