



National Grain and Feed
Association



North American Export
Grain Association

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NGFA, NAEGA Commend FDA for Making Major Changes in Final Bioterrorism-Preparedness Recordkeeping Rules

WASHINGTON – The National Grain and Feed Association (NGFA) and the North American Export Grain Association (NAEGA) today said a preliminary review indicates that the Food and Drug Administration (FDA) made several major improvements when issuing final regulations implementing the recordkeeping requirements under the bioterrorism-preparedness law.

The NGFA and NAEGA said several of the major changes made by FDA were consistent with the recommendations submitted by the two major grain and feed trade organizations in an extensive joint statement filed with the agency in 2003.

FDA's recordkeeping regulations require companies and facilities that manufacture, process, store, pack, transport, distribute, receive, or import food, feed or feed ingredients to maintain records sufficient to identify the immediate previous source of incoming products and immediate subsequent recipient of outbound products. The regulations encompass domestic and export grain elevators, commercial feed mills, corn and soy processing facilities, and pet food manufacturers. Under the bioterrorism-preparedness law enacted by Congress in 2002, FDA has the authority to access such records if it receives "credible threat of serious adverse health consequences or death" to humans or animals.

“Our initial analysis is that FDA has done a commendable job in revising its bioterrorism recordkeeping rules to reflect legitimate industry concerns and make them much more workable while still achieving its statutorily mandated requirement to protect the food supply in the event of a terrorism incident,” said NGFA President Kendell W. Keith and NAEGA President Gary C. Martin. “It is this kind of partnership involving security enhancements by the private sector and proactive, practical steps by federal and state governments that will ensure the safety and security of the U.S. food supply.”

The NGFA, established in 1896, consists of 900 grain, feed, processing, exporting and other grain-related companies that operate about 5,000 facilities that handle more than two-thirds of all U.S. grains and oilseeds. With more than 350 member companies operating commercial feed mills and 30 integrated livestock and poultry feed manufacturing operations, the NGFA is the nation’s largest trade association representing feed manufacturer interests. The NGFA also consists of 35 affiliated state and regional grain and feed associations, as well as two international affiliated associations.

NAEGA, established in 1912, is a not-for-profit trade association comprised of 35 private and publicly owned companies and farmer-owned cooperatives involved in and providing services to the bulk grain and oilseed exporting industry. NAEGA member companies ship practically all of the bulk grains and oilseeds exported each year from the United States.

The NGFA and NAEGA said major changes and improvements to the recordkeeping regulations made by FDA include the following:

- Acknowledgement that the specificity of information deemed to be “reasonably available” in such records will vary based upon the particular circumstances involved, such as the type of firm and the nature of its operations. Specifically, consistent with a strong recommendation made by the NGFA and NAEGA, FDA’s final rule expressly recognizes that for facilities that handle, store and ship products on a commingled basis – such as

grain elevators, feed mills and processing plants – it will be sufficient to identify all of the sources of commodities contained in the bin or conveyance, and not to link specific portions of the commingled mass to individual deliveries. FDA also said it would consider issuing additional guidance on this matter if necessary.

- Allowing up to 24 hours for companies to provide access to records, identical to the recommendation made by the NGFA and NAEGA. Previously, the agency proposed to require that companies provide access to records within four hours if requested on a weekday and eight hours on a weekend, which the NGFA and NAEGA said would not provide sufficient time in some circumstances. FDA's final regulations also responded positively to the NGFA-NAEGA suggestion that existing company records be sufficient if they contain all of the required information; there is no obligation to create an entirely new record or compilation of records. Further, FDA acknowledges that records can be maintained at the individual facility, at a company headquarters or elsewhere so long as they are made accessible within the required 24 hours.
- Exempting foreign facilities, except for foreign transporters hauling commodities or food into the United States, from the requirement to maintain and provide access to records. The NGFA and NAEGA had argued that attempting to impose such requirements on foreign facilities could trigger trade challenges within the World Trade Organization and subject U.S. companies to the same treatment by foreign governments.
- Extending the time period for firms to comply. Most firms will have 12 months after the final regulations are published to comply, double the six months originally proposed. Small firms – defined as those with 11 to 499 full-time equivalent employees – will have 18 months to comply, up from the 12 months originally proposed. Extremely small firms – those with 10 or

fewer employees – will have two years to comply, up from the originally proposed 18 months.

- Expressly including retail feed and farm supply stores in the definition of “retail establishments” that are exempt from maintaining records on finished products shipped directly to consumers and final purchasers. FDA’s final rule quotes from the NGFA-NAEGA joint statement when it notes that “many small rural feed manufacturers also have a retail outlet in their facilities that sell bagged feed, pet food and feed ingredients/additives over-the-counter directly to consumers and to final purchasers for their own animals.” FDA stated this exemption will apply unless the feed is to be used in animals that will subsequently be sold as food. “If the feed is to be fed to food-producing animals, then the purchasers are not considered consumers, since they are purchasing the food (or feed) for a business (i.e., for the food-producing operation),” FDA’s final rule states.
- Exempting companies from keeping intra-company records. The NGFA and NAEGA recommended such an exemption so that companies with multiple facilities that ship or receive commodities within their system will not be required to keep records of such intra-company transfers until possession of the commodities or products shifts to another company or entity.
- Adopting the NGFA-NAEGA recommendation that the definition of “farm” be size-neutral so as to encompass integrated livestock and poultry operations so long as such locations are limited to “growing or raising” farm animals for human food, but do not extend to further processing of food-producing animals into meat, milk or eggs. FDA’s final rule notes that the NGFA-NAEGA statement was the only one submitted to address this issue.

The NGFA and NAEGA also commended FDA for retaining its original proposal that animal feed manufacturers be required to maintain such records for one year,

consistent with the requirements under the agency's existing current good manufacturing practice regulations for medicated feed and its feed regulations designed to prevent the establishment or spread of bovine spongiform encephalopathy (BSE). Except for perishable commodities or those subject to spoilage after a short time period, most other facilities are required to maintain records for two years.

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