AMERICAN FEED INDUSTRY ASSOCIATION

July 8, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Docket No. 02N-0275

Dear Sir or Madam:

The American Feed Industry Association (AFIA) appreciates this opportunity to submit comments regarding the Food and Drug Administration's (FDA) proposed rule on administrative detention of food for human or animal consumption. 68 Fed. Reg. 25,242 (May 9, 2003).

AFIA is the national, not-for-profit trade association for animal feed and pet food manufacturers, ingredient manufacturers and suppliers, equipment manufacturers, and other firms that supply goods and services to the animal feed and pet food industry. AFIA's nearly 600 corporate members manufacture 75 percent of the nation's primary commercial feed. Because AFIA members would be subject to the proposed rule, AFIA offers these comments on their behalf.

AFIA supports the detention of food upon credible evidence of a threat of serious adverse health consequences as established by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). However, we are concerned that some of the proposed requirements do not anticipate the realities of product detention and will burden AFIA members unnecessarily without furthering the goals of the Bioterrorism Act.

We ask that FDA make a few recommended changes and/or clarify certain issues when it issues the final rule.

1. The final rule should allow for the immediate off-loading of detained food to secure storage.

Proposed section 1.380 discusses where and under what conditions a detained article of food may be held. The proposed rule would allow FDA to determine whether it is appropriate for the detained article of food to be moved to a secure facility. Such movement would be based, in part, on whether "there is a danger of the detained article entering the stream of commerce."

Under the proposed rule, an article of food could be detained pursuant to a detention order until such time as an authorized FDA representative releases the article or the detention period expires. Proposed section 1.381 would require the submission of a detailed, written request for a "limited conditional release" in order for the detained product to be moved to a secure storage facility. Further, according to proposed section 1.381, the limited conditional release would be granted only in "rare circumstances" that the agency finds appropriate.

AFIA believes FDA should avoid detaining articles of food on conveyances without first allowing the articles to be offloaded to secure storage. It is contrary to the interests of biosecurity to allow detained food to remain on a mobile conveyance. Detained food should be offloaded immediately to secure storage to avoid its movement into commerce. Additionally, detaining food on a truck, rail car, or vessel for a time approaching the proposed maximum of 30 days could have a disastrous effect upon businesses that are depending upon these conveyances to make timely deliveries on tight schedules.

FDA should clarify in the final rule that where food is detained on a conveyance, the detention order will specifically provide for the product's removal to secure storage. Should the agency determine that a written request for limited conditional release is required, transferring an article of food from a conveyance to secure storage should be one of the "rare circumstances" specified in the regulation as a ground on which FDA shall grant a conditional release.

2. The detention order should identify the timeframes the recipient has to challenge the order and the procedures the recipient must follow.

Proposed section 1.393 would require the detention order to include a statement that, with certain exceptions, an informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under 21 C.F.R. Part 16. AFIA believes that the administrative detention order issued by FDA should include additional information concerning the rights of the affected parties. The order should provide a statement that the potential claimant of the detained article has the right to appeal that order and seek a hearing. The order should identify that the appeal and/or request for hearing must be in writing and to whom the appeal and/or request must be directed. The order should also state the number of days the claimant has to appeal the order or to seek a hearing, and the date by which such appeal and/or request must be filed.

3. If one part of a shipment is detained, FDA should allow the remainder of the shipment to proceed.

The proposed rule does not address what would transpire if a particular product that is part of a larger shipment were detained. Assuming that suspect product has not contaminated the conveyance or any other product in the shipment, AFIA believes that the article of food that is the subject of the detention should be segregated from the balance of the shipment, and the remainder of the shipment should be allowed to proceed. We ask that final rule explicitly state that FDA will not interfere with the distribution of the part of the shipment that is not covered by the detention order.

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AFIA thanks FDA for this opportunity to comment on the proposed rule.

Sincerely,

Richard Sellers/dah

Richard Sellers
Vice President -- Feed Control and Nutrition
American Feed Industry Association