

Therefore, FDA tentatively concludes that all food would be subject to administrative detention under section 304(h) of the act, whether or not the food enters interstate commerce. Because a bioterrorist threat involving food or other food-related emergencies would have the same effect on the public health regardless of whether the food had originated from an out of State source, FDA believes that administrative detention should apply to all food, whether or not the food was in interstate commerce. FDA recognizes, however, that section 304(h) of the act is not clear in this regard. For example, section 304(h) includes references to certain enforcement provisions of the act, such as section 304(a) of the act, an enforcement provision that includes an interstate commerce requirement. Because this is an important and controversial issue, the agency is seeking comment on whether its tentative conclusion that it has authority to administratively detain food in intrastate commerce is correct and, if so, whether FDA should use that authority. FDA also seeks comments on the amounts and types of food that would only be in intrastate commerce.

This proposed rule complies with section 315 of the Bioterrorism Act entitled "Rule of Construction," which states that nothing in title III of the Bioterrorism Act, or an amendment made by title III, shall be construed to alter the jurisdiction between the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services under applicable statutes and regulations. Accordingly, this proposed rule does not apply to food regulated exclusively by the USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*). However, food that is jointly regulated by FDA and USDA would be subject to this proposed rule. An example of a food that is jointly regulated by FDA and USDA is frozen TV dinners containing both meat and fish.

In addition to section 303 of the Bioterrorism Act, which amends the act as described previously in section I of this document, FDA is relying on section 701(a) of the act (21 U.S.C. 371(a)) in issuing this proposed rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the act.

II. Preliminary Stakeholder Comments

On July 17, 2002, FDA sent an open letter to members of the public interested in food issues outlining the

four provisions of title III of the Bioterrorism Act which require FDA to issue regulations in an expedited time period, and FDA's plans for implementing them (see <http://www.cfsan.fda.gov/~dms/sec-ltr.html>). In the letter, FDA invited stakeholders to submit comments to FDA by August 30, 2002, for FDA's consideration as it developed this proposed rule. FDA also held several meetings with representatives of industry, consumer groups, other Federal agencies, and foreign embassies after sending out the July 17, 2002, letter in order to solicit stakeholder comments. In response to these solicitations, FDA received a number of comments regarding section 303 of the Bioterrorism Act.

FDA has considered all the comments received by August 30, 2002. FDA will consider all comments we have received so far with the comments we receive during the public comment period for this proposed rule in developing the final rule.

Some of the significant comments FDA received on or before August 30, 2002, include the following:

- The regulations should apply to all foods within FDA's jurisdiction, (e.g., processed food, fresh agriculture, and dietary supplement products).
- The written notice of detention should describe the article of food that has been detained, the quantity of the food, its location, and the basis for the detention. A written notice of detention also should include a written explanation of the appeal right and information that will enable a person entitled to appeal to understand how to file such an appeal.
- FDA's regulations should ensure that if a detained article of food is moved to a secure facility, the food will be maintained under temperature, humidity, and other conditions that will maintain the value and quality of the food.
- A period of 24 to 48 hours from the time of request to the time of holding a hearing is the appropriate timeframe given the short life of many perishable foods.
- Any regulations with respect to detention of food should specify how disputes and resolutions will be handled in order to help prevent spoilage of detained food.
- When an appeal against the detention is filed, FDA should deal with it expeditiously within a fixed period of time to minimize the impact on private businesses.
- An appellant should be entitled to file a written statement of his or her position. The findings of the Secretary after the hearing should be set forth in

writing since the Bioterrorism Act provides that the Secretary's decision is "final agency action" under the Administrative Procedure Act, which is judicially reviewable.

- A sanction should be imposed if the detained product is moved before the detention period has expired or has been terminated.

III. The Proposed Regulation

This proposed rule implements the administrative detention provision in section 303 of the Bioterrorism Act. If the regulation is made final as proposed, administrative detention, together with the proposed rules implementing section 305 (registration), section 306 (recordkeeping), and section 307 (prior notice) of the Bioterrorism Act, will enable FDA to act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies.

In establishing and implementing this proposed rule, FDA will comply fully with its international trade obligations, including applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement. For example, FDA believes this proposed rule is not more trade-restrictive than necessary to meet the objectives of the Bioterrorism Act. The criteria FDA would use to order a detention are taken directly from the Bioterrorism Act and are the same for both domestic and foreign articles of food.

A. Highlights of Proposed Rule

The key features of this proposed rule are as follows:

- An officer or qualified employee of FDA may order the detention of domestic or imported food for up to 30 days if FDA has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals.
- The FDA District Director in the district in which the article of food is located or an FDA official senior to such director must approve a detention order.
- FDA may require that the detained article of food be labeled or marked as detained with official FDA tags or labels. The FDA tag or label will include, among other information, a statement that the article of food must not be consumed, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative.
- A violation of a detention order or the removal or alteration of the tag or label is a prohibited act.