

# NATIONAL INSTITUTE OF OILSEED PRODUCTS

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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 National Institute of Oilseed Products (NIOP) appreciates this opportunity to provide comments on the proposed requirements for Administrative Detention of Food For Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act (the Act). While NIOP strongly supports the purposes of the Act, NIOP respectfully submits that the proposed rule needs to be clarified so that detention of product does not delay or interfere with the orderly movement of oceangoing vessels.

The National Institute of Oilseed Products is an international organization of companies engaged in all facets of edible oil and oilseed commerce. Members range from producers of oilseeds to multi-national food processors and also represent the distribution and marketing network, which includes ocean carriers, storage facilities, brokers and dealers. One of NIOP's major goals is to facilitate international trade in edible oils. In pursuit of that goal, NIOP members devote significant resources to processes and procedures to assure the safety of these products and their timely movement in commerce.

The Administrative Detention Rule, implementing section 303 of the Bioterrorism Act, as proposed, could allow FDA to detain a bulk cargo on board a ship, thereby delaying the ship from leaving port for up to 30 days. Ships carrying vegetable oils hold these oils in individual parcel tanks. For example, a ship might transport many parcel tanks of vegetable oil (e.g., palm oil, palm kernel oil, coconut oil and their derivatives) intended for many different buyers up and down the East Coast, West Coast and U.S. gulf with each parcel in a separate, self-contained tank. A single ship could carry in excess of 50 separate cargoes. If FDA should receive intelligence that a particular parcel tank could be contaminated and decide to detain it, that parcel tank should be removed to shore storage and the ship should be allowed to proceed with deliveries of the remaining parcel tanks.

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In promulgating the final regulations, FDA should make clear that the detention of cargo should always be managed so as to minimize delay or interference with the orderly movement of an oceangoing vessel or other conveyance. This clarification will be consistent with the structure and intent of the Bioterrorism Act and with FDA's relationship with the U.S. Customs Service for the following reasons:

1. The Bioterrorism Act grants FDA limited detention authority. This authority should not be read as expanding the agency's authority to inspect and detain imported food on a vessel at a port of entry when this authority belongs, in the first instance, to the U.S. Customs Service (Customs).
  - a. FDA acknowledges in the proposed regulations that it intends, primarily, to continue to regulate imported food in conjunction with Customs and pursuant to section 801 of the Federal Food, Drug, and Cosmetic Act. Thus, the proposal confirms that principal detention authority over imported food on vessels at ports of entry remains with Customs.
  - b. Section 303 (c) of the Bioterrorism Act also authorizes FDA to request that Customs institute a temporary hold for up to 24 hours on an article of food offered for import at a U.S. port of entry if FDA has credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals, and FDA is unable immediately to inspect, examine or investigate such article. Because section 303(c) of the Bioterrorism Act authorizes FDA to obtain a hold on product from Customs, it further confirms that the authority to detain a cargo on board a vessel remains primarily with the Customs Service and not FDA.
2. If FDA believes it does have the authority to board vessels and detain articles of food at a port of entry, the final rule must allow for the immediate off loading of detained food to secure storage.
  - a. Keeping detained food on a vessel for up to 30 days will have disastrous effects upon commerce. Huge ocean going vessels run on tight schedules, where business livelihood depends upon a vessel being in service and able to make timely deliveries. FDA's exercise of its detention authority must consider the economic harms that may result if the detention prohibits a vessel from resuming its normal shipping activities.

- b. Allowing detained food to remain on a vessel undermines the security concerns that underlie the Bioterrorism Act and the proposed regulations.

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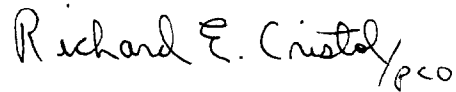
For all of these reasons, NIOP urges that the final regulations provide:

- FDA will not detain product on vessels at ports without first allowing the product to be offloaded to secure storage.
- FDA detention orders will specifically provide for the removal of products from vessels to secure storage.
- Moving detained product from the vessel should be specified as a basis for a conditional release, permitting the movement of detained product to secure storage.

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NIOP appreciates the opportunity to present these comments and hopes that they will be of assistance in shaping the final regulations.

Very truly yours,

Handwritten signature of Richard E. Cristol in cursive script, with the initials 'pco' written at the end.

Richard E. Cristol  
Executive Director  
National Institute of Oilseed Products