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: Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Docket No. 02N-0277

Dear Sir or Madam:

The National Institute of Oilseed Products (NIOP) appreciates this opportunity to provide comments on the proposed requirements for Establishment and Maintenance of Records under the Public Health Security and Bioterrorism Preparedness and Response Act (the Act). While NIOP strongly supports the purposes of the Act, NIOP has two principal concerns about the proposed rule.

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.

NIOP respectfully submits that the proposed rule exceeds the statutory authority upon which it is based in two respects: (1) section 306 of the Bioterrorism Act does not apply to foreign facilities and therefore provides no basis for imposing recordkeeping or records inspection requirements on foreign establishments; and (2) the records inspection authority of section 306 is generally more limited than the attempted reach of the proposed rule.

1. Section 306 of the Act Does Not Extend to Foreign Facilities.

Section 306 of the Act adds a new section 414 to the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. § 350c, which contains recordkeeping and records inspection provisions. There is nothing in section 306 or its legislative history that indicates these

recordkeeping and records inspection provisions are to apply beyond the territorial jurisdiction of the United States. Absent an express Congressional intent to assert extraterritorial jurisdiction, there is a presumption that laws of the United States only apply within the territorial jurisdiction of the United States. *Sale v. Haitian Centers Council, Inc.*, 509 U.S. 155, 188 (1993).

For policy reasons relating to reciprocity and international trade relationships advocated by the United States, it would be unwise to assume that Congress intended extraterritorial application of these recordkeeping requirements. Extraterritorial application of these U.S. requirements would open the records of every U.S. exporter of food in all of the same detail to extraterritorial inspection by the government agencies of the more than 150 foreign nations to which United States companies sell food and agricultural commodities. This would create a recordkeeping nightmare for domestic food processors and exporters, and the potential for terrorists to use their relationships with a foreign country to access detailed information regarding food shipments from the United States. Without some record that Congress explicitly considered the implications of such reciprocal records inspection, there is no guidance that Congress intended that agencies of the United States and its trading partners should have reciprocal jurisdiction to require and inspect detailed records of each other's food processing and shipment, especially where such authority could be misused to make U.S. food exports a tool for terrorists.

2. The Recordkeeping Authority Asserted by the Proposed Rule Exceeds the Authority Contained in Section 306 of the Bioterrorism Act.

The new legislative language added to the FDC Act by section 306 of the Bioterrorism Act authorizes FDA to have access to records where FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. This statute provides FDA with records access only for the purpose of determining whether an article of food is so adulterated as to present a threat of serious adverse health consequences and, under those circumstances, authorizes the use of those records for a tracing investigation with respect to such an article of food. These limitations were made clear by the floor managers during consideration of this legislation:

> "[T]he Secretary would have authority to gain access to and copy only those records needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences... The managers envision procedures whereby no agency personnel will have access to records without a specific need for such access.... *Congressional Record* H2858 (May 22, 2002) (managers' report).

The proposed regulations appear to assert authority to access and copy records whenever the agency believes an article of food is adulterated so as to present the level of threat to health

that justifies a Class I recall. We believe that the legislation only provides authority to access and copy records for the purpose of determining whether a food believed to be so adulterated is actually so, and for conducting a tracing investigation in regard to such an adulterated food.

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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,

Richard E. Cristol/pco

Richard E. Cristol
Executive Director
National Institute of Oilseed Products