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ADMINISTRATIVE AND EXECUTIVE OFFICE
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April 3, 2002

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane Room 1061
HFA-305
Rockville, MD 20852

RE: Docket No. 02N-0278 RIN 0910-AC41—Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 5428 (February 3, 2003).

Dear Sir or Madam:

The National Institute of Oilseed Products (NIOP) welcomes this opportunity to provide comments on the "Prior Notice" requirements of the Public Health Security and Bioterrorism Preparedness and Response Act (the Act). Under the Act, the Secretary is required to implement final regulations addressing Section 307 by December 12, 2003. After evaluation of the FDA proposal, NIOP submits that it needs significant clarification, particularly in regard to the import notifications required in respect to cargoes arriving on ocean-going vessels. These comments suggest appropriate clarifications to make implementation more effective and less burdensome.

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.

Proposed "Window" for Notification is Very Restrictive: The proposal for import notification requires that notice be provided by the importer to FDA "no later than noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry." Proposed 21 C.F.R. § 1.286(a), 68 Fed. Reg. 5461. The proposal also requires that the importer "may not submit prior notice more than five days before the anticipated date of arrival of the food at the anticipated port of entry." Proposed 21 C.F.R. § 1.286 (b), 68 Fed. Reg. 5461. This import notification must be updated if the actual time of arrival is subsequently anticipated to be more than three hours later or one hour earlier than the time of arrival specified in the

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original notification to FDA. Proposed 21 C.F.R. § 1.294, 68 Fed. Reg. 5462. This language indicates that the anticipated time of arrival at the port of entry is to be stated with great precision in the import notification.

Wider "Window" Needed for Ocean Going Cargoes: A wider margin of variability should be allowed for the arrival of oceangoing vessels, than is presently provided by the proposal. For ocean-going shipments, an amendment of an importer's import notification should not have to be required so long as the anticipated actual arrival at the port of entry is not more than 24 hours before or after the anticipated time of entry specified in the import notification. This 24 hour allowance takes into account the variability which will be needed in the winter months when vessels are often delayed by storms and high seas. Amended notification should not be required unless the vessel will arrive more than 24 hours before or after the anticipated arrival time specified in the original import notification.

In addition, while the five-maximum day period during which notification can be provided may be reasonable, the proposal should be amended to allow notification to be made within as little as eight hours prior to a vessel's arrival in port.

For Ocean-Going Cargoes, Time of Arrival Is Measured As the Time of Arrival at the Entrance to the Seaport: The proposal's very precise provisions for import notification are not well suited to the arrival of cargoes aboard oceangoing vessels at U.S. seaports. The application of the proposed regulations to cargoes of vegetable oil arriving in oceangoing vessels needs to be clarified. First, it should be clarified that the "time of arrival of the food at the anticipated port of entry" is the time of arrival at the entrance to the seaport at which the importer will be taking delivery. It is at this point that the vessel becomes subject to the control and regulation of U.S. Customs, and the time of arrival at this point, rather than the time of arrival at the importer's dock, should be provided in the import notification.

Products Subject to Notification: The proposed import notification regulations contain a number of exemptions for certain specific types of foods. Proposed 21 C.F.R. §1.276(b), 68 Fed. Reg. 5460. There should also be an exemption for bulk commodities which cannot be used as food ingredients without further processing or refining. This is a category that includes not only crude vegetable oils, but also crude petroleum and minerals such as phosphates which, for example, can be refined and processed into food ingredients such as glycerin and phosphoric acid. Where bulk commodities have potential food and non-food uses, there should be an exemption from import notification where these commodities have not been sufficiently refined to be directly used as food ingredients without further processing or refining.

FDA Requirements Should be Harmonized with Those of the U.S. Customs Service: Finally, FDA's import notification procedures should be harmonized with those of the Delivery Authorization Documents filed with the U.S. Customs Service. These documents provide substantially the same information which will be required in FDA's notifications and include a uniform manufacturer identification number. Not only will the failure to harmonize the

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requirements of FDA and Customs be burdensome on importers, but also it will result in a loss of clarity and efficiency in the programs of both FDA and Customs.

Thank you for your consideration of these comments.

Respectfully Submitted,

Handwritten signature of Richard E. Cristol in cursive script, including a slash and the letters 'SDP' at the end.

Richard E. Cristol, Executive Director
National Institute of Oilseed Products