

NATIONAL INSTITUTE OF OILSEED PRODUCTS
ADMINISTRATIVE AND EXECUTIVE OFFICE
1156 Fifteenth Street, N.W., Suite 900, Washington, D.C. 20005
TEL:(202)785-3232 FAX:(202)223-9741

April 3, 2003

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

RE: Docket No. 02N-0276—Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 5377 (February 3, 2003).

Dear Sir or Madam:

The National Institute of Oilseed Products (NIOP) welcomes this opportunity to provide comments on the requirements for Registration of Food Facilities under 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 305 by December 12, 2003. After evaluation of the FDA proposal, NIOP submits that it needs significant clarification, particularly in regard to the treatment of facilities which process bulk products that can be used in either food or industrial applications. Appropriate clarifications will make implementation of the Act 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.

Definition of "Food." The Act imposes registration requirements on facilities which process food, but the Act does not define "food." The proposed regulations cross reference the definition of "food" at Section 201(f) of the Federal Food Drug and Cosmetic Act, which provides:

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

02N-0276

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After cross-referencing this definition, the proposed regulations then expand it as follows:

(4) *Food* has the meaning given in section 201(f) of the act. Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients; infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods.

Proposed 21 C.F.R. § 1.227(c)(4), 68 Fed. Reg. 5418. In the face of this sweeping definition, the proposed regulations recognize that at least for food contact substances, the intended use will control whether the originating establishment must register.¹ “Basic chemicals or other components incorporated into packaging may be intended for food or nonfood uses.” 68 Fed. Reg. 5389. This same issue also arises with basic commodities of both agricultural and mineral origin which may or may not be intended for food use.

Registration: Proposed 21 C.F.R. § 1.226(a), 68 Fed. Reg. 5417, which provides a limited registration exemption for certain foreign facilities, should be clarified to confirm that foreign facilities which process or refine vegetable oils, which are not intended for direct inclusion in human food or animal feed should be exempt from registration. A substantial part of the vegetable oil import trade involves products which are imported for industrial use, such as soap stock, rather than for edible use. An example would be palm kernel oil. A foreign facility should not be required to register with FDA with respect to vegetable oils, which are brought into the United States for either industrial use or further refining and which are not intended or suited for inclusion in food and feed products when they are imported.

The importation of vegetable oils for industrial use is analogous to the importation of petroleum oils and bulk minerals, such as phosphates, in that all of these products can be further processed into a food ingredient. Where bulk ingredients have both food and non-food uses, the proper standard for facility registration and import notification should look to whether the bulk commodity has been sufficiently refined to be directly incorporated as a food ingredient without further processing or refining.

Ocean-Going Vessels Are Not “Facilities:” The definition of facility in proposed 21 C.F.R. § 1.227(c)(2), 68 Fed. Reg. 5418, covers “any establishment, structure, structures under one management at one general physical location, or in the case of a mobile facility traveling to multiple locations, that manufactures/processes, packs or holds food for consumption in the

¹ The same definitions will apply to import notification.

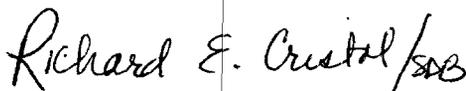
April 3, 2003
Page 3

United States.” “Holding” is defined in terms of the “storage of food,” proposed 21 C.F.R. § 1.227(c)(5), 68 Fed. Reg. 5418, which suggests that the proposal is not intended to treat vehicles or vessels in which food is being transported as “facilities.” However, there is an express exemption for fishing vessels, (proposed 21 C.F.R. 1.226(f), 68 Fed. Reg. 5417), and the final regulations should also include express language exempting vessels and barges transporting vegetable oil and other foods from registration as “facilities.”

Agent Should Be Optional: Where a foreign facility processing vegetable oil registers its facility pursuant to proposed 21 C.F.R. § 1.225(c), 68 Fed. Reg. 5417, it has the option of doing so through a U.S. agent. Since the use of the U.S. agent is optional, the final regulation should confirm that having a U.S. agent is also optional where a foreign facility chooses to handle its registration directly.

Thank you for your consideration of these comments.

Respectfully Submitted,

Handwritten signature of Richard E. Cristol in cursive script.

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