

July 1, 2005

Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**CITIZEN PETITION**

The National Institute of Oilseed Products (NIOP) submits this petition under §§ 414, 701(a), and 801(m) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 350c, 371(a), and 381(m), to request the Commissioner of Food and Drugs to revise the Food and Drug Administration's (FDA) policy regarding the applicability of the FDA's prior notice and recordkeeping requirements (21 C.F.R. Part 1, subparts I and J) to food samples for quality assurance, research, or analysis purposes.

NIOP submits this petition with the endorsement of the undersigned associations: **the National Oilseed Processors Association, the Institute of Shortening and Edible Oils (ISEO), Palm Oil Refiners Association of Malaysia (PORAM), and the Canola Council of Canada.**

***A. Action requested***

NIOP requests that the Commissioner exempt food samples that are for quality assurance, research, or analysis purposes and not for commercial sale or distribution from the FDA regulations requiring prior notice of imports (21 C.F.R. Part 1, subpart I) and establishment and maintenance of records (21 C.F.R. Part 1, subpart J).

NIOP requests that 21 C.F.R. § 1.277 be amended to add a new paragraph (b)(7) to read as follows (new language underlined):

**§ 1.277      What is the scope of this subpart?**

- (a) This subpart applies to all food for humans and other animals that is imported or offered for import into the United States for use, storage, or distribution in the United States, including food for gifts and trade and quality assurance/quality control samples (except as provided in paragraph (b)(7) of this section), food for transshipment through the United States to another country, food for future export, and food for use in a U.S. Foreign Trade Zone.

(b) Notwithstanding paragraph (a), this subpart does not apply to:

- (1) Food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States;
- (2) Food that was made by an individual in his/her personal residence and by that individual as a personal gift (i.e., for non-business reasons) to an individual in the United States;
- (3) Food that is imported then exported without leaving the port of arrival until export;
- (4) Meat food products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.);
- (5) Poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 et seq.);
- (6) Egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 et seq.); and
- (7) Samples of food for quality assurance, research, or analysis purposes and that are not for commercial sale or distribution. To qualify for this exemption, the sample must be clearly marked as a sample not for commercial sale or distribution and must be in a quantity appropriate to the intended analysis.

The requested exemption from the recordkeeping rule may be made in an informal policy document and does not require amendment of an existing FDA regulation.

## ***B. Statement of grounds***

### **1. Current FDA Policy**

FDA's interim final rule requiring prior notice of food imports (21 C.F.R. Part 1, subpart H) and its final rule requiring establishment, maintenance, and availability of records (21 C.F.R. Part 1, subpart J) do not distinguish between food samples and other foods. However, FDA has announced that food samples that are for quality assurance, research, and analysis purposes only will be treated differently than other foods under both regulations as a matter of policy:

- Under the prior notice interim final rule, FDA has announced that a sample of food that is imported for quality assurance, research, or analysis purposes only does require submission of prior notice to FDA, but the prior notice may omit the FDA registration number of the foreign manufacturing facility. A "reason code" (i.e., the letter "I" for "samples – quality assurance, research or analysis purposes only") must be provided to explain why the prior

notice does not include the manufacturing facility's registration number. In determining whether a food sample qualifies for this limited exemption, FDA will consider the sample's size, whether it is used up by the analysis or destroyed after analysis, and whether the shipping documents indicate that the sample is for quality assurance, research, and/or analysis only. FDA Compliance Policy Guides (CPG) § 110.310.

- Under the records rule, FDA has announced that a sample of food for quality assurance, research, and analysis purposes only is exempt from the requirement to retain records identifying the immediate previous sources and immediate subsequent recipients of such food, provided the sample is not consumed by humans or animals. A sample that is used for sensory examination (*e.g.*, organoleptic examination for tea quality or detection of histamines) is exempt from recordkeeping, but a sample that is consumed is not exempt. In determining whether a food sample qualifies for this exemption, FDA will consider the sample's size, whether it is used up by the analysis or destroyed after analysis, and whether the shipping documents indicate that the sample is for quality assurance, research, and/or analysis only. This exemption is set forth in the preamble to the final rule. 69 Fed. Reg. 71562, 71574 (Dec. 9, 2004).

FDA also has indicated that a sample that is not an article of food is not subject to either of these regulations. For example, FDA has stated that a slurry of lettuce for pesticide analysis or a sterile container of juice for heavy metal analysis would not be considered articles of food, and therefore their importation would not require prior notice to FDA. CPG § 110.310; Prior Notice of Imported Foods Questions and Answers (Edition 2) (May 2004), 17.2. FDA also has stated that a substance in "such early stages of research and development that it cannot yet be considered food," such as a substance being tested for possible preservative qualities before being tested in food, is not a "food" and not subject to these regulations. 68 Fed. Reg. at 58993. A substance that has both food and non-food uses, but that is not intended to be used for food (*e.g.*, vegetable oil for use in cosmetics), would also not be covered by these regulations.<sup>1</sup>

## **2. Background on Role of Samples in International Trade**

Food samples serve an important commercial purpose for the food industry. In the oil and oilseeds industry, a company importing oil will almost invariably request and analyze a sample before ordering a shipment of product. We believe the same is true in other segments of the food industry. Consequently, the volume of traffic in food samples is enormous. Since the decision whether to purchase a shipment of vegetable oil is based on analysis of the sample of oil, time is of the essence in the movement of samples.

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<sup>1</sup> If a substance has both food and non-food uses, it is considered a "food" for purposes of the prior notice requirement if any of the persons involved in its importation "reasonably believes that the substance is reasonably expected to be directed to a food use." 68 Fed. Reg. 58974, 58987 (Oct. 10, 2003). Conversely, if none of the persons involved in its importation reasonably believe the substance is reasonably expected to be directed to a food use, it is not a "food."

### **3. Requiring prior notice for imported food samples is unnecessary and would disrupt the flow of commerce.**

We believe there is no public health benefit to be derived from requiring prior notice of food samples. An article of food that is earmarked for laboratory analysis is the least likely target of bioterrorism for the simple reason that it will be analyzed by a laboratory. Moreover, because of its small quantity and because it is not likely to be blended with other food, a sample for analysis generally is not capable of contaminating large quantities of food and therefore is unlikely to be viewed by terrorists as a promising target.

We believe that an exemption for samples could be narrowly tailored. We also note that samples pose less risk than other foods already exempt from the prior notice regulation. For example, food accompanying individual travelers entering the United States could easily arrive in greater quantities than the typical sample. Articles that are not reasonably expected to be directed to a food use are also exempt from the prior notice requirement, even though such articles (*e.g.*, artificial colors intended for use in cosmetic products) could be the target of tampering.

Requiring prior notice for imported samples of food also has the potential to disrupt the international trade in food. Congress explicitly directed that implementation of this provision of the Bioterrorism Act should not “unnecessarily disrupt the flow of commerce.”<sup>2</sup> The purpose of the prior notice requirement is to give FDA the opportunity to inspect a food offered for import prior to its admission into the United States.<sup>3</sup> For vegetable oils and many other foods, FDA inspection means lab testing. However, if FDA tests a sample of food, the food may lose its value as a sample. For example, if the article of food is in a sterile container (which is typically the case with samples of vegetable oil) or other packaging, opening of the container or packaging will ordinarily mean the sample can no longer serve its commercial purpose.<sup>4</sup>

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<sup>2</sup> Statement of Rep. John Shimkus, House of Representatives, Dec. 20, 2001 Congressional Record, p. E2388.

<sup>3</sup> “The prior notice provision furthers this goal [protecting the United States from bioterrorism and other public health emergencies] by enhancing the agency’s ability to inspect imported food upon arrival in the United States.” 68 Fed. Reg. at 58991.

<sup>4</sup> If the U.S. buyer claims that the sample is deficient in any way, the foreign seller is likely to claim that FDA handling and testing altered the sample’s taste, nutrient values, or other relevant characteristics. While the parties theoretically could agree to accept the results of any FDA testing, there is no guarantee that FDA will subject the sample to the same tests that the parties consider important. For example, FDA may test a sample of vegetable oil for chemical contaminants when the U.S. buyer may be equally interested in the vegetable oil’s taste and nutrient values. In that case, the FDA test results would be insufficient.

**4. Requiring recordkeeping for samples that are consumed imposes a substantial burden on the food industry in return for an insignificant public health benefit.**

As discussed above, FDA has stated that food samples for quality assurance, research, or analysis purposes are exempt from the recordkeeping rule, but only if they will not be consumed by humans or animals. We believe this qualification virtually nullifies the exemption. Food samples, including most vegetable oil samples, which are intended for quality assurance, research or analysis, may also be tasted by the receiving company's employees as part of their organoleptic analysis.

If food samples that are "consumed," as part of organoleptic analysis are subject to FDA's new recordkeeping rule, then the source that sends the food sample (unless it is a foreign person), the transporter that delivers the sample, and the recipient that receives the sample will each be required to establish and maintain FDA compliant records regarding that sample. We believe that very few companies that ship or receive samples retain such records. These companies would be required to create an entirely new kind of record for these small sample shipments because these samples are typically shipped through different channels, using different carriers than those which are used for the bulk commodities and products which they represent.

The costs to the food industry would far outweigh any benefits. Shippers and receivers of food samples would need to create and maintain new documents containing the required information for samples. The benefits of such recordkeeping, which FDA measures in terms of number of illnesses averted, are likely to be minimal or non-detectible.<sup>5</sup> By definition, a sample is a food that is not in commercial distribution and that will not be "consumed," although it may be tasted in minute amounts to confirm its organoleptic characteristics. A sample's potential to cause illness or to be a vector for bioterrorism is extremely limited. Therefore, the number of illnesses that can be avoided by recordkeeping with respect to samples is essentially zero.

**5. Samples of food for quality assurance, research, or analysis should be exempt from prior notice and recordkeeping.**

Samples of food for quality assurance, research, or analysis purposes only, and clearly marked as such, should be exempt from both the prior notice and recordkeeping regulations.

***C. Environmental impact***

The requested action is categorically excluded from the requirement for an environmental assessment by 21 C.F.R. § 25.30(h), because it involves the issuance or amendment of administrative guidance documents.

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<sup>5</sup> FDA's regulatory impact analysis for this rule assumes that recordkeeping will avert illnesses by accelerating the agency's tracing investigation (and thereby shortening the duration of the foodborne illness outbreak caused by the contaminated food) and preventing future outbreaks caused by the same source.

*D. Economic impact*

Information concerning economic impact will be submitted upon request.

*E. Certification*

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Richard Cristol". The signature is written in a cursive style with a large initial "R".

Richard Cristol  
Executive Director  
National Institute of Oilseed Products