

us to characterize such cooks as “manufacturers” for purposes of § 801(m) of the FD&C Act.

(Comments) Several comments suggest that the final rule should not apply to foods that arrive by international mail or express carriers.

(Response) FDA disagrees. Except for the exclusions already described for food for personal use that is carried by or otherwise accompanying a traveler and homemade gifts, section 801(m) of the FD&C Act applies to food regardless of the method of importation. Thus, foods that arrive by international mail and by express carriers (e.g., Federal Express, United Parcel Service, etc.) are subject to section 801(m)’s prior notice requirements. Indeed, FDA notes that foods, drugs, devices, and cosmetics that arrive by mail or express carriers are currently subject to admissibility determinations under section 801(a) of the FD&C Act, which also uses the phrase “imported or offered for import.” Finally, were we to adopt such an exemption, it would create a potentially significant loophole, which could defeat the purpose of prior notice. Those who did not want to or could not comply with prior notice requirements would be able to bring articles of food in by mail or express carrier. While this might not be practical for all kinds of foods, many foods are regularly imported by mail or express carrier, e.g., dietary supplements and specialty foods ordered by U.S. consumers from foreign firms. For example, one commenter states its company provides, through Internet sales, special dietary foods and fresh baked foods that are shipped via express carriers directly to consumers at the rate of around 1,000 home deliveries per week.

(Comments) Several comments suggest that the final rule should not apply to various kinds of samples, including trade and market research samples (i.e., samples sent or carried in for the purpose of selling products or conducting market research), trade show samples, samples for testing for nutritional, safety, quality control, or quality assurance reasons, and samples for basic research. These comments reason that samples used for marketing are not intended for retail consumption and generally do not enter commercial trade and, thus, are not intended for use as food. In the case of samples for testing, comments reason that these samples are for the individual’s specific and limited personal use and not for further distribution to others and should be exempted as samples are under federal poultry and meat inspection regulations.

(Response) FDA agrees in part. If the samples are items that are in such early stages of research and development that they cannot yet be considered food under § 1.276(b)(5) of the interim final rule, they would not be subject to prior notice requirements. An example of such an item is a substance being tested for possible preservative qualities before being tested in any food. However, samples of food, including those for test marketing, are clearly subject to prior notice as they are “articles of food imported or offered for import” as stated in section 801(m) of the FD&C act. For example, in the summer of 2003, FDA received a report from a poison control center in country T concerning the acute poisoning of 9 men (one died) from ingestion of an herbal fermented wine. Symptoms occurred within minutes. Reports indicated that this product may have been exported to the United States in small quantities for test marketing in restaurants. This underscores the importance of FDA receiving prior notice of all food imported or offered for import.

(Comments) One comment suggests that food for research and development purposes sent directly to facilities that are registered under section 415 of the FD&C Act should be exempt.

(Response) If the item is indeed food under this subpart and it is not otherwise excluded under § 1.277(b), prior notice is required. There is no basis in the statute for an exemption based on the fact that an article of food is being sent to registered facilities.

(Comments) Comments ask that articles of food that are of *de minimis* value (i.e., less than \$200) be exempt from prior notice. The comments argue that such small shipments for personal use could hardly qualify as a risk to the domestic food supply. They also point out that enforcing prior notice on such articles would be difficult and burdensome to FDA. In addition, they state that prior notice for these items would be a burden on consumers as they usually do not have an agent in the United States to represent them.

(Response) FDA notes that it has removed the restrictions on who can submit prior notice. Thus, foreign sellers or shippers can file prior notices for these kinds of shipments under the interim final rule. Low-value food items are clearly subject to the terms of section 801(m) of the FD&C Act as they are “articles of food imported or offered for import” as stated in section 801(m). Moreover, we do not agree that low value shipments are always imported for personal use or would present only *de minimis* risks, such that an exemption can be justified under the *de*

minimis doctrine. First, a low value is not necessarily a good indication that the article is for personal use. Many food items (e.g., produce) can have a low invoice value at importation, especially if the shipment is not large. Moreover, in our experience, many specialty, gourmet, ethnic, and exotic foods are often imported for commercial purposes in very small amounts. Thus, a shipment of bottled cooking oil or a beverage contaminated with toxic chemicals may be represented as low-value or low-volume but could have a wide, and very negative, public health impact. In addition, we note that misdeclaration of value of articles of food at entry can be a problem. Finally, any burden such an exemption might relieve would likely be offset by the burden of administering it.

(Comments) Comments ask for an exemption for food imported into the United States for sale in duty free stores.

(Response) FDA disagrees. Unless the food is imported and exported without leaving the port of arrival until export, as set out in § 1.277(b)(2), there is no basis in section 801(m) of the FD&C Act for such an exemption.

(Comments) Some comments recommend that prior notice be waived for foods in situations that they characterize as “low risk.” These situations were identified in the comments as any one of the following:

- Exported from U.S.-owned foreign companies;
- Transferred between commonly owned facilities (intra-company transfers);
- Subject to high quality control standards and/or produced in highly-regulated businesses;
- Shipped under seal or in bond;
- Entered as high-volume, repetitive shipments;
- Processed through CBP’s Border Release Advanced Selectivity Screening (BRASS); and
- Associated with a program of assessment of low risk, such as the Customs-Trade Partnership Against Terrorism (C-TPAT); Free and Secure Trade program (FAST); or food safety and security programs of foreign government regulatory authorities.

(Response) FDA disagrees. As explained previously, section 801(m) of the FD&C Act applies to all food imported or offered for import into the United States except as outlined in § 1.277(b). Nothing in section 801(m) of the FD&C Act authorizes an exemption for articles of food that are “low risk” or covered by programs of other agencies, such as CBP or foreign government regulatory authorities.