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Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Compliance Policy Guide, Guidance for FDA and CBP Staff

May 2009

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U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine

Department of Homeland Security
U.S. Customs and Border Protection

May 2009

**Compliance Policy Guide
Guidance for FDA and CBP Staff**

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Compliance Policy Guide

Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

This guidance represents the Food and Drug Administration's (FDA) and U.S. Customs and Border Protection's (CBP) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA, CBP, or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION:

The purpose of this document is to provide guidance on enforcing the requirements for submitting prior notice for food imported or offered for import into the United States (21 CFR 1.276 - 1.285).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND:

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), section 307, added section 801(m) to the Federal Food, Drug, and Cosmetic Act (the act) to require that FDA receive prior notice for food imported or offered for import into the United States. Section 801(m) also provides that if an article of food arrives at the port of arrival with inadequate prior notice (e.g., no prior notice, inaccurate prior notice, or untimely prior notice), the food is subject to refusal of admission under section 801(m)(1) of the act and may not be delivered to the importer, owner, or consignee. If an article of food is refused under section 801(m)(1) of the act, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless otherwise directed by CBP or FDA.

The Bioterrorism Act, section 305, also added section 415 to the act to require domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA. The implementing regulations are at 21 CFR 1.225 - 1.243. Under section 801(l) of the act, if an article of food is imported or offered for import and it is from a foreign facility for which a registration has not been submitted under section 415, then the article of food is subject to being held until the foreign facility has been registered. If an article of food is held under section 801(l) of the act, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless otherwise directed by CBP or FDA.

It should be noted that the consequences for the failure to provide timely and/or adequate notice as required by the act and implementing regulations does not otherwise preclude other appropriate and available enforcement actions, including seizure and referral for criminal prosecution.

In October 2008, FDA and CBP issued final regulations requiring that FDA receive prior notice of the importation of food. For the purposes of prior notice, "food" has the meaning given in section 201(f) of the act, and is defined as (1) articles of food or drink for man or other animals,

(2) chewing gum, and (3) articles used as components of any such article, except that it does not include food contact substances or pesticides. The requirements for prior notice do 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 sent by that individual as a personal gift 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. Articles of food subject to Art. 27(3) of The Vienna Convention on Diplomatic Relations (1961), i.e., shipped as baggage or cargo constituting the diplomatic bag.

FDA may consider the failure to provide adequate prior notice as a factor in determining whether and where to examine an article of food. However, if FDA decides not to refuse an article of food under 21 CFR 1.283, this decision has no bearing on whether the article of food is admissible or will be granted admission under other provisions of the act or other U.S. laws. Thus, for food that is imported or offered for import, FDA and CBP will continue normal review, investigative, and enforcement activities for food safety and security concerns to determine whether the food is subject to refusal under section 801(a) of the act or other appropriate action. If FDA decides not to refuse an article of food under 21 CFR 1.283, this decision does not affect FDA's ability to initiate other types of actions -- such as seizures, injunctions, prosecutions, or debarments under sections 302, 303, 304, and 306 of the act -- that may be appropriate. Likewise, it does not affect CBP's ability to initiate other types of actions such as seizure, assessment of civil penalties, and referral to U.S. Immigration and Customs Enforcement (ICE) for investigation and prosecution under any laws enforced by Customs and Border Protection that may be appropriate.

III. POLICY:

This policy provides guidance to FDA and CBP staff when they encounter the situations described within this section. FDA and CBP staff may take different or additional actions if they believe particular circumstances warrant them.

1. No Prior Notice:

FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import and there is no prior notice in the following situations:

A. Food imported or offered for import for non-commercial purposes with a non-commercial shipper, irrespective of the type of carrier

FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for non-commercial purposes with a non-commercial shipper. Generally, staff should consider a non-commercial purpose to be when the food is purchased or otherwise acquired by an individual for non-business purposes and the shipper is an individual (e.g., the individual delivers the food to a post office or common carrier for delivery to self, family member, or friend for non-business purposes, i.e., not for sale, resale, barter, business use, or commercial use).

Examples of foods imported or offered for import that may be covered by this non-commercial category are:

- food in household goods, including military and civilian transfers;
- food purchased by a traveler and mailed or shipped to the traveler's U.S. address by the traveler, not the commercial establishment; and
- gifts purchased at a commercial establishment and shipped by the purchaser, not the commercial establishment.

Note that the shipper and the carrier are different entities, and the carrier is likely to be a commercial entity even when the shipper is an individual. Thus, the food for non-commercial purposes may arrive by international mail or any other mode of transportation, but must be shipped by one individual to another individual (self, family member, or friend) to be considered for non-commercial purposes. For example, when an individual ships his or her own household goods, even when the goods are delivered to a mover or carrier for international movement, the individual is the shipper, e.g., the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail to the United States (see 21 CFR 1.276(b)(14)). In another example, when an individual purchases food at Store A and sends that food to an individual by mail, the individual is the shipper and the carrier is the mail service. If the individual uses an express courier, the result is the same: the individual is the shipper and the express courier is the carrier. However, if Store A ships the food, Store A is the shipper. Since Store A is not an individual, this last example is not covered by the guidance described above because the food was not imported or offered for import with a non-commercial shipper. (Although a "person" may be an individual, partnership, corporation, or association, see section 201(e) of the act, by "individual" we mean a sole human being, not a partnership, corporation, or association.)

B. Food imported or offered for import for quality assurance, research or analysis purposes only, not for human or animal consumption or resale

FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for quality assurance, research or analysis purposes only, not for human or animal consumption and not for resale.

For the purpose of this CPG, samples of food are considered to be imported or offered for import for quality assurance, research or analysis purposes when they are imported in small quantities (i.e., quantities consistent with the quality assurance, research, or analysis purposes) and the entire sample is used up by the analysis or is destroyed after analysis or a reasonable retention period after analysis. The analysis may include sensory analysis or evaluations such as those organoleptic analyses for testing the quality of tea or for testing for histamines. Evidence that an article of food is imported for quality assurance, research, or analysis purposes only might include, among other evidence, that the food and shipment documents are marked accordingly. The policy in this section does not apply to samples intended for test marketing, such as tasting at trade shows or product promotional tasting events. However, this guidance may apply to samples submitted by consumers in response to a complaint.

Information about when samples are "food" for the purposes of prior notice is provided in the 2nd Edition of Guidance for Industry, Prior Notice of Imported Food, Questions and Answers, May 2004 (Q&A). This guidance states that, in general, prior notice is required for samples of food, including animal feed, for research and development and test marketing.^[1] However, if the samples are items that are in such early stages of research and development that they cannot yet be considered food for the purposes of prior notice, then they would not be subject to prior notice requirements.^[2] In addition, if the sample is in a form that is not an article of food, such as a slurry of lettuce for pesticide analysis or a sterile sample container filled with juice for heavy metal analysis, then prior notice would not apply.^[3]

C. Food imported or offered for import only for "in vivo" testing in non-food producing laboratory animals:

FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for "in vivo" testing in non-food producing laboratory animals only. For the purposes of this CPG, food is considered to be for in vivo testing in non-food producing laboratory animals if there are adequate assurances that the laboratory animals will never enter the human or animal food chain (e.g., rendering the laboratory animal means it would likely enter the animal food chain) and the entire amount is used up by the in vivo testing.

D. Foreign-to-foreign mail and courier

Mail: FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import via international mail and there is no U.S. recipient/consignee, i.e., the article is not consigned for delivery to a U.S. party/address.

Courier: FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import and the carrier is an express consignment operator or carrier and the importer, owner, or recipient/consignee is not located in the United States.

E. Official U.S. federal government shipments

FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for an official government purpose, provided that a Federal Government agency is the importer of record. "Official government purpose" includes, but is not limited to, evidence for investigative purposes, research, and testing.

F. Imported food arriving from and exiting to the same country

FDA and CBP staff should typically consider not taking any regulatory action if there is no prior notice and each of the following conditions is met:

- The food is exported to the same country from which it was imported (i.e. Canada-United States-Canada or Mexico-United States-Mexico).
- Due to the geography, the only practical transportation route available for the shipment is through the United States.
- The importing conveyance is physically sealed before it enters the United States and the integrity of the aforementioned seal is maintained during the time the shipment is in-transit through the United States. FDA and CBP should randomly examine the shipments to ensure that the food imported from the country is the same food that is exported back to that country.
- The food being imported or offered for import is for shipment by land through the United States, and will not be manufactured, processed, packaged, unloaded or transferred from conveyance to conveyance, or modified in any other way while in transit.
- The food being imported or offered for import represents a relatively regular/routine shipment by land that arrives at and exits from specific border crossings, such that FDA and/or CBP are sufficiently familiar with the typical shipment.
- The number of the regular/routine shipments by land between the two border points is relatively low, e.g., an average of one or less shipments per day.
- The transportation route through the United States is relatively short, e.g., less than 100 miles.
- Before the import or series of imports, the FDA Prior Notice Center is contacted regarding the above. The public can contact the Prior Notice Center at 866-521-2297.

G. Seed imported or offered for import for cultivation

FDA and CBP should typically consider not taking any regulatory action when seed is imported or offered for import for cultivation. Generally, staff should consider seed to be for cultivation when no more than a small portion of that seed is likely to be diverted from cultivation to animal feed or other food use. The policy in this section does not apply to seeds for sprouting, such as seeds for alfalfa sprouts.

2. Gift Pack purchased or otherwise acquired by an individual and imported or offered for import for non-business purposes

FDA and CBP staff should typically consider not taking any regulatory action if there is a prior notice violation because a single prior notice is submitted for a gift pack and the identity of the facility that packed the gift pack is submitted in lieu of the identity of the manufacturer(s) and/or grower(s) for each article of food within the gift pack, provided that the gift pack is purchased or otherwise acquired by an individual and imported or offered for import for non-business purposes.

Food is considered to be for non-business purposes when it is not for sale, resale, barter, business use, or commercial use. The policy described in this section applies irrespective of where the individual who purchased or otherwise acquired the gift pack lives and irrespective of the type of carrier. While the policy also applies irrespective of whether it involves a commercial or non-commercial shipper, please note that the guidance contained in section III.1.A of this CPG applies to gift packs, and other foods, that are imported or offered for import for non-commercial purposes with a non-commercial shipper. More information about non-commercial purposes, the difference between shippers and carriers, and the difference between commercial and non-commercial shippers is contained in section III.1.A of this CPG.

For the purpose of this CPG, gift packs are considered to be food that is described with FDA Product Code 37Y--01 (human food) or FDA Product Code 72E--99 (animal food). Examples of gift packs are:

- A gift basket containing fresh fruit and/or vegetables.
- A gift box containing crackers and cheeses and canned condensed soups.
- A gift basket of crackers, cheeses and fresh fruit.
- A wicker basket with champagne, port, scotch whisky, smoked salmon, cheese, tea, coffee, chutney, pistachio nuts, biscuits, marmalade, honey, butter biscuits, crackers, cake, mustard, olive oil, and olives.
- Tote bag with infant clothing, bib, booties, and coffee and candy for the parents; or a toy dispenser with hard candy and powdered candy.
- A gift bag with multiple pet food items such as rawhide chews and dog biscuits, with or without non-food items

3. Registration Numbers and Registration Status

21 CFR 1.281 (a)(6), (b)(5), and (c)(6) requires "for an article of food that is no longer in its natural state, the identity of the manufacturer, as follows: (i) The name of the manufacturer; and (ii) Either the registration number, city, and country of the manufacturer or both the full address of the manufacturer and the reason the registration number is not provided." One of the following reasons may be submitted when no manufacturer registration number is provided:

- Situations where the facility is out of business, as stated in 21 CFR 1.235(a)
- Private residence, as stated in 21 CFR 1.227(b)(2)

- Facility is a restaurant, as defined in 21 CFR 1.227(b)(10), and qualifies for the restaurant exemption in 21 CFR 1.226(d)
- Facility is a retail food establishment, as defined in 21 CFR 1.227(b)(11), and qualifies for the retail food establishment exemption in 21 CFR 1.226(c)
- Facility is a non-processing fishing vessel, as stated in 21 CFR 1.226(f)
- Non-bottled drinking water collection and distribution establishment, as stated in 21 CFR 1.227(b)(2)
- Manufacturer satisfies the definition of "farm" in 21 CFR 1.227(b)(3), and qualifies for the farm exemption in 21 CFR 1.226(b)
- Submitter is unable to determine the registration number of the manufacturer. Full address of the manufacturer has been provided.

We intend to reject prior notice submissions unless the prior notice includes a valid registration number *or* an appropriate reason selected from among those listed above. The requirement that FDA provide confirmation of receipt of Prior Notice does not apply to rejected submissions.

When a reason is provided in lieu of a registration number, FDA staff should verify that the reason is valid.

If the reason provided is that the submitter is unable to determine the registration number of the manufacturer, FDA should nonetheless verify the identity of the manufacturing facility and its registration status. Without the registration number, it will be more difficult and/or may take more time for FDA to verify the identity of the manufacturing facility and its registration status and to determine whether the article of food is subject to being held under section 801(l) of the act. As a result, if an article of food is imported or offered for import and the registration number is not provided, and if FDA has concerns that the food may pose a serious health threat, then physical movement of the food shipment beyond the arrival port may be delayed until the verification is completed.

If the registration number of the facility that manufactured the food is not submitted as part of prior notice, FDA may also consider this in determining whether and where to examine the article of food.

IV. ACTION IN RESPONSE TO VIOLATIONS

FDA and CBP's strategy for enforcing violations of sections 801(m) and 801(l) of the act is to take into account the severity of the violations, whether they are flagrant, and whether the person has had previous violations, particularly if they were similar types of violations. Thus, FDA and CBP staff should take into consideration the circumstances surrounding each violation prior to making a decision whether and how to pursue any particular action.

When it is consistent with the public protection responsibilities of the Agency and depending on the nature of the violation, FDA gives individuals and firms an opportunity to take voluntary and prompt corrective action before initiating regulatory actions. Accordingly, FDA may elect to

refuse prior notices or send Compliance letters to give the responsible parties warning prior to pursuing other regulatory actions, e.g., Injunction, Prosecution, etc.

The regulatory actions for violations include:

- Refusal under section 801(m) of the act for no prior notice, inaccurate prior notice, or untimely prior notice
- Hold under section 801(l) of the act importing or offering for import food from a foreign facility that is not registered under section 415 of the act

- Injunction under section 302 of the act
- Prosecution under sections 301 and 303 of the act
- Debarment under section 306 of the act

- CBP seizure and assessment of Civil Monetary Penalties for violation of any laws enforced by Customs and Border Protection, including but not limited to 19 U.S.C. 1595a. Civil monetary penalties may be assessed against any person who directs, assists, financially or otherwise, or is in any way concerned in the importation of any merchandise contrary to law

^[1] Q&A, Section C., Question 1.3: Are there exceptions from prior notice for any of the following:

- a. Food items of small value or quantity;
- b. Food samples for research and development or for testing purposes only and not for consumption; or
- c. Food samples for test marketing?

There are no exemptions from prior notice requirements for:

- a. Food based on the size or value of the shipment (68 FR 58993);
- b. Samples of food, including animal feed, for research and development. (However, if the samples are items that are in such early stages of research and development that they cannot yet be considered food under 21 CFR 1.276(b)(5), 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); or
- c. Samples of food, including animal feed, for test marketing.

^[2] See Footnote 1 (Q&A, Section C., Question 1.3)

^[3] Q&A, Section C., Question 17.2: Are samples of food that are intended for analytical testing for contaminants exempt from prior notice?

If the samples are articles of food, such as a head of lettuce or a can of juice, then prior notice is required. However, if the sample is in a form that is not an article of food, such as a slurry of lettuce for pesticide analysis or a sterile sample container filled with juice for heavy metal analysis, then prior notice would not apply.

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