October 2003

FDA Actions on New Bioterrorism Legislation

Fact Sheet on FDA'S New Food Bioterrorism Regulation: Interim Final Rule -- Prior Notice of Imported Food Shipments

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) requires that FDA receive prior notice of food imported into the United States, **beginning on December 12, 2003**. Most of the prior notice information required by the interim final rule is data usually provided by importers or brokers to the Bureau of Customs and Border Protection (CBP) when foods arrive in the United States. Now, the Bioterrorism Act requires that this information also be provided to FDA in advance of an imported food's arrival to the United States. FDA will use this information in advance of the arrival to review, evaluate, and assess the information, and determine whether to inspect the imported food. FDA and CBP have collaborated on the implementation of the prior notice interim final rule. Nearly all of the current imported food shipments can comply by using CBP's Automated Broker Interface of the Automated Commercial System (ABI/ACS). **Prior notice can be submitted either through ABI/ACS or FDA's Prior Notice (PN) System Interface beginning December 12, 2003.**

When must prior notice be submitted? Prior notice must be received and confirmed electronically by FDA no more than 5 days before arrival and, as specified by the mode of transportation below, no fewer than:

1. 2 hours before arrival by land by road
2. 4 hours before arrival by air or by land by rail
3. 8 hours before arrival by water
4. The time consistent with the timeframe established for the mode of transportation for an article of food carried by or otherwise accompanying an individual if it is subject to prior notice (The food must also be accompanied by the FDA confirmation.)

In addition, prior notice must be received and confirmed electronically by FDA before food is mailed by international mail. (The parcel must be accompanied by confirmation of FDA receipt of prior notice.)

How must the prior notice be submitted? Prior notice must be submitted electronically. FDA estimates more than 80 percent of prior notice of imported food shipments submissions can be transmitted through ABI/ACS. Prior notice for international mail food shipments, other transaction

types that cannot be made through ABI/ACS, or articles of food that have been refused admission under section 801(m)(1) of the Federal Food, Drug, and Cosmetic Act must be submitted to the FDA PN System Interface at www.access.fda.gov. **Beginning on December 12, 2003, for technical assistance in submitting prior notice:**

- **For the United States, call 1-800-216-7331 or 301-575-0156**
- **From all other countries and locations, call 301-575-0156**
- **Send a fax to 301-210-0247**

This technical assistance will be available on business days from 7 AM until 11 PM U.S. Eastern Time. Requests for assistance also may be emailed to furls@fda.gov. For assistance with ABI/ACS transmission, contact your CBP client representative.

Both the CBP and FDA systems for prior notice will be available 24 hours a day, 7 days a week for information submission beginning December 12, 2003.

If the ABI/ACS is not working, then prior notice must be submitted using the FDA PN System Interface. If the FDA PN System Interface does not appear to be working properly, the online Help Desk should be contacted first. If the system is not working, then the required prior notice information, which appears in the interim final rule and will be listed on FDA's website, must be submitted by fax or email. The fax number(s) and email address(es) where they can be sent will be posted on the FDA website (www.fda.gov).

Who must submit prior notice? Any individual with knowledge of the required information may submit the prior notice, including, but not limited to, brokers, importers, and U.S. agents.

What food is subject to the requirement for submitting prior notice? Prior notice applies to food for humans and other animals that is imported or offered for import into the United States. For purposes of the interim final rule, "food" is defined by reference to section 201(f) of the Federal Food, Drug, and Cosmetic Act. Section 201(f) defines "food" as articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such articles.

Examples of "food" include:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack food, and candy (including chewing gum)

- Live food animals
- Animal feeds and pet food

What foods are excluded from the prior notice requirement? Foods that are excluded from the prior notice requirement are: (1) food carried by or otherwise accompanying an individual arriving in the United States for that individual's personal use (i.e., for consumption by themselves, family, or friends, and not for sale or other distribution); (2) food that is exported without leaving the port of arrival until export; (3) meat food products, poultry products and egg products that are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act; and (4) food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for non-business reasons) to an individual in the United States.

Will FDA provide confirmation of receipt of prior notice? Yes. FDA will issue a confirmation of prior notice to the transmitter upon successful receipt of the prior notice information.

What information must be included in the prior notice? The prior notice must be submitted electronically and contain the following information:

- Identification of the submitter, including name, telephone and fax numbers, email address, and firm name and address
- Identification of the transmitter (if different from the submitter), including name, telephone and fax numbers, email address, and firm name and address
- Entry type and CBP identifier
- The identification of the article of food, including complete FDA product code, the common or usual name or market name, the ***estimated*** quantity described from the smallest package size to the largest container, and the lot or code numbers or other identifier (if applicable)
- The identification of the manufacturer
- The identification of the grower, if known
- The FDA Country of Production
- The identification of the shipper, except for food imported by international mail
- The country from which the article of food is shipped or, if the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed
- The anticipated arrival information (location, date, and time) or, if the food is imported by international mail, the U.S. recipient (name and address)
- The identification of the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States
- The identification of the carrier and mode of transportation, except for food imported by international mail
- Planned shipment information, except for food imported by international mail

Does the carrier need the prior notice confirmation upon arrival? It is prudent to have the confirmation. For a prior notice that is submitted through the ABI/ACS interface, the prior notice confirmation number together with a "PN received" message will be made available to the filer through the ACS/ABI interface. If prior notice is submitted through the FDA PN System Interface, then the transmitter will receive a confirmation online as soon as the submission is confirmed. To make it easier for the carrier or individual at the port, the carrier should have a copy of the confirmation, which includes a prior notice confirmation number in his/her possession. For international mail packages, the Prior Notice Confirmation Number must accompany the package. For food carried by or otherwise accompanying an individual arriving in the United States, the Prior Notice Confirmation Number must accompany the food.

Can an incomplete prior notice be corrected? Yes. If the transmission fails the validation, it will be rejected and the transmitter will have an opportunity to make corrections.

The FDA PN System Interface has Help features and interactive feedback to assist the submitter and minimize spelling mistakes and omissions. In addition, the online Help Desk will be available to assist users, beginning December 12, 2003. The Help Desk will be staffed on business days from 7 AM until 11 PM U.S. Eastern Time.

Confirmation means the information has been received and is facially complete. Subsequent system and manual review by FDA staff may result in inspection of the imported food upon arrival.

What must be done if information changes after prior notice confirmation has been received? If any of the following required information changes after confirmation, then a new prior notice must be submitted:

- Identification of the submitter, including name, telephone and fax numbers, email address, and firm name and address
- Identification of the transmitter (if different from the submitter), including name, telephone and fax numbers, email address, and firm name and address
- Entry type and CBP identifier
- The identification of the article of food, except the estimated quantity
- The identification of the manufacturer
- The identification of the grower, if known
- The FDA Country of Production
- The identification of the shipper
- The country from which the article of food is shipped or, for food imported by international mail, the anticipated date of mailing
- The U.S. recipient (name and address) if the food is imported by international mail
- The identification of the importer, owner, and consignee
- The identification of the carrier and mode of transportation
- Planned shipment information unless the food will not be imported

Does food that has been refused for inadequate prior notice require any additional information in prior notice? Yes. The prior notice for food that has been refused for inadequate prior notice also must include the port of arrival, the location where the refused food is being held, the date it arrived or will arrive at that location, and the identification of the contact person at that location.

What are the consequences of failing to submit adequate prior notice information of an imported food shipment? Food that is imported or offered for import with inadequate prior notice is subject to refusal and holding at the port or in secure storage. FDA will provide its staff with enforcement guidance containing the Agency's policies on injunctions, prosecution, and debarment related to failure to provide timely and accurate prior notice, as well as the Agency's policies regarding refusals under § 801(m)(1) and holds under § 801(l). FDA intends to include a transition period in this guidance, during which it will emphasize education to achieve compliance. While FDA will nonetheless be authorized to take various types of enforcement action for violations of the prior notice requirements, this planned transition period will allow FDA to focus its resources on the most appropriate circumstances. FDA also intends to provide guidance to its staff on enforcing the prior notice requirements after a transition period. FDA's guidance documents will be available to the public, and FDA will publish a notice of availability in the *Federal Register*.

Will additional comments be accepted on this interim final regulation? FDA is providing a 75-day comment period on this interim final rule. In addition, to ensure that those commenting on this interim final rule have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of this interim final rule, the Agency intends to reopen the comment period in March 2004 for an additional 30 days. This date will coincide with the issuance of the plan by FDA and CBP relating to timeframes. Regularly updated information on this interim final rule and how to comment on it can be accessed electronically at http://www.fda.gov/oc/bioterrorism/bioact.html.

How will FDA enforce this interim final rule during the comment period? FDA will actively consider the exercise of its discretion in the enforcement of the prior notice interim final rule while at the same time ensuring public health protection, both during initial implementation of the interim final rule and thereafter. The prior notice interim final rule takes effect on December 12, 2003, and covered entities are responsible for complying with the requirements in the interim final rule at that time. FDA recognizes that a number of affected parties still may need assistance understanding the interim final rule's requirements and how to comply even after the extensive outreach and educational activities that FDA will be conducting before December 12th. Accordingly, for this and other reasons, FDA intends to put into place, during the initial months following the effective date, a policy that emphasizes assisting covered entities in understanding the requirements and how to comply. FDA will shortly publish a notice of availability for a Compliance Policy Guide that will outline how FDA generally intends to exercise its enforcement discretion. This guidance, however, will not affect FDA's ability to take actions that may be necessary, including conducting inspections for food safety and security concerns or taking any other action under the Federal Food, Drug, and Cosmetic Act.

This policy will also not affect the ability of the Bureau of Customs and Border Protection to assess penalties under 19 U.S.C. 1595a(b) or to take enforcement action under any other authority.

For more details and information on the specific requirements of this interim final rule, please refer to the interim final rule itself. The interim final rule is available at http://www.cfsan.fda.gov.
