



November 2003 International Trade Newsletter

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BDG Website Additions

We have just added tracking for Import/Export FCL shipments as well as Rail moves. Visit our web site at: www.bdginternational.com to track your freight.

BDG International, Inc. New World Headquarters

We have recently completed construction on our new World Headquarters in Elgin, IL USA. Our new facility provides BDG with the latest in communication and computer networking technologies. Our offices in Bensenville will remain open until mid 2004. While our current phone and fax numbers still function we will be getting new phone and fax numbers to provide direct dialing/faxing to our departments and team members. We will provide more information in our December newsletter.

Beware of Freight Payment Companies

Recently there have been a number of Freight Payment Companies that have declared bankruptcy. If you have not been a customer of one of these firms thank your lucky stars. These firms collected freight payments from their clients but never paid the transportation companies money that was due them. The Transportation firms recollected the outstanding balance from the shippers. Many shippers that paid twice have filed law suits against the freight payment firms. However since the Freight Payment Firms have declared bankruptcy it will be some time, if ever, before they collect on their claims.

Before entering into any agreements with Freight Payment Firms we suggest that extensive due diligence is completed. In addition we recommend continuing to perform your due diligence on an annual basis.

Re: New Food and Drug Administration Regulations
(1) Registration of Food Facilities and
(2) Prior Notice of Imported Food

On October 10, 2003 the Food and Drug Administration (FDA) issued Interim Final Regulations implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). The Bioterrorism Act requires domestic and foreign food facilities to register with the FDA by December 12, 2003 and mandates prior notification of imported food beginning on the same date. For this reason, these Interim Final Rules are effective on December 12, 2003. The FDA still wants to receive public comment on both these rules, however, which is why they are labeled "interim." Anybody wishing to submit comments may do so before December 24, 2003.

Registration of Food Facilities

All domestic and foreign facilities engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States are required to register with the FDA. This requirement does not apply to the following types of facilities:

1. a foreign facility, if food from such facility undergoes further manufacturing/processing (including packaging) by another facility outside the United States unless the processing by that other facility consists of simply adding labeling or a similar activity of a very minor nature;
2. farms (both domestic and foreign);
3. retail food establishments;
4. restaurants;

5. non-profit food establishments in which food is prepared for, or served directly to, the consumer;
6. fishing vessels engaged in harvesting and transporting fish and which also may engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvester vessel. (Other types of fishing vessels engaged in processing operations are required to register.); and
7. facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act, Poultry Products Inspection Act, or Egg Products Inspection Act.

For purposes of this regulation, "food" includes "fruits, vegetables, fish, dairy products, eggs, raw agriculture commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, 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."

"Manufacturing/processing" is defined in the rule as "making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients."

"Holding" is defined as "storage of food." "Packing" is defined as "placing food into a container other than packaging the food ("Packaging" means "placing food into a container that directly contacts the food and that the consumer receives.")"

The person responsible for registering each facility is the owner, operator, or agent in charge of the facility. The FDA is encouraging all facilities to register electronically on the FDA website at <http://www.fda.gov/furls>, which is available for registration 24 hours a day, 7 days a week. All electronic registrants will receive their registration numbers immediately upon submission of the electronic registration. Registration may also be accomplished by mail or facsimile or via CD-ROM, but FDA will not be able to process these as quickly. If you wish to use one of these alternate forms of registration, please contact us for the details of how to do so.

Each separate facility must be separately registered. The registration requires the following information for the facility:

- a. the name, full address, and phone number of the facility;
- b. the name, address and phone number of the parent company, if the facility is a subsidiary of a parent company;
- c. for domestic and foreign facilities, the name(s), address(es), and phone number(s) of the owner, operator, and agent in charge;
- d. for a foreign facility, the name, address, phone number, and emergency contact information of its U.S. agent (or, alternative emergency contact information if the registrant so desires and informs the FDA);
- e. for a U.S. domestic facility, an emergency contact phone number;
- f. all trade names the facility uses;

- g. applicable food product categories that are manufactured/processed, packed, or held by the facility (these categories will appear on the registration form as choices to check);
- h. a statement in which the owner, operator, or agent in charge certifies that the information submitted is true and accurate.
- The identity of registered facilities and the registration information above is not available for public disclosure.

As noted above, all foreign facilities must have a U.S. agent. As far as the FDA is concerned, the role of the U.S. agent "is to act as the communication link between the facility and the FDA." The FDA has further stated that it "generally does not intend to hold the U.S. agent responsible for violations of the Bioterrorism Act that are committed by a foreign facility." There are no restrictions on who may be appointed as the U.S. agent except that it (or he/she) must reside or maintain a place of business in the United States. There are a number of companies offering their services on the Internet to serve this function. It would be better, of course, if you are operating a foreign facility, to choose somebody you already know and trust to act as your U.S. agent.

As also noted above, the FDA will consider a foreign facility's U.S. agent as the emergency contact unless the facility designates another person to serve this function. The emergency contact person must be accessible 24 hours a day, 7 days a week.

Facilities that fail to register may be subject to injunctions by the U.S. government, criminal prosecution, or debarment from entering into contracts with the U.S. government. In addition, food products shipped from an unregistered facility to the United States are like to be refused entry by the FDA and Customs. In its discussion of the Interim Final Rule, the FDA addressed numerous comments that it had received from the public. Some of the following responses by the FDA may have relevance to your operations:

1. Manufacturers/processors, packers, or holders of food that is transshipped through the United States to other countries for consumption are not required to register.
2. Facilities that manufacture/process, pack or hold food for consumption in Hawaii and other U.S. states in possessions are required to register.
3. Even if the food handled by a facility does not enter interstate commerce, that facility must register if it otherwise meets the registration requirements.
4. There is no exemption in the Bioterrorism Act or in the Interim Final Rule for government-owned facilities that manufacture/process, pack, or hold food.
5. There are no exemptions from registration for port storage and inspection facilities if the facilities are used to hold food.
6. There is no exemption for facilities that handle food the destination of which is unknown at the time of handling. So long as there is a reasonable possibility the food may be consumed in the United States, the facility should register.
7. There is no exemption from the registration requirements for

facilities that export solely to their subsidiaries in the United States.

8. Vehicles used to transport food are exempt from registration unless such vehicles manufacture/process, pack, or hold food beyond the usual course of business as a carrier. However, certain vehicles are required to register such as rail cars, which are used as grain storage bins, trucker-dealers who purchase and take title to grain from producers and hold the grain in a transportation conveyance until it can be sold. Also, a vehicle engaging in the artificial ripening of food while in transit is required to register.

9. A parent company may register all of its facilities; however, each facility must be registered separately and each will receive a separate registration number.

10. The "farm" definition and exemption applies to both domestic and foreign farms. As an example, a vineyard that only grows grapes would be a farm exempt from registration unless it also processes the grapes into wine, or engages in any of the other activities qualifying for registration.

11. While each registered facility must have only one U.S. agent for FDA registration purposes, it may continue to have a variety of other agents for other types of purposes.

Prior Notice of Imported Food

The prior notice requirements apply 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, 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." The requirements do not apply to:

1. food for an individual's personal use accompanying that individual to the United States;
2. food made by an individual in his/her residence and sent by that individual as a personal gift to another individual in the United States;
3. food that is imported then exported without leaving the port of arrival;
4. meat food products, poultry products, and egg products subject to the exclusive jurisdiction of the U.S. Department of Agriculture under relevant statutes.

The prior notice may be submitted by anybody who has the required information. This person is known as the "submitter." The submitter may give the information to another person who transmits it to the FDA. In such a case, this other person is known as the "transmitter."

The prior notice must be submitted no more than 5 calendar days before the anticipated date of arrival of the food at the anticipated port of arrival. The prior notice must be submitted: (a) for food arriving by

motor carrier, no less than 2 hours before arrival at the port of arrival; (b) for food arriving by rail carrier or air carrier, no less than 4 hours before arrival at the port of arrival; or (c) for food arriving by sea, no less than 8 hours before arrival at the port of arrival. The prior notice must be submitted electronically to the FDA in the English language. The FDA will provide notification of receipt along with a Prior Notice Confirmation Number at the time of the electronic submission. The approved electronic systems for submission of the prior notice are:

1. The Customs and Border Protection (CBP) Automated Broker Interface of the Automated Commercial System (ABI/ACS); or
2. The FDA Prior Notice System Interface (PN System Interface) at <http://www.access.fda.gov>.

Prior notice may be submitted by email or fax only when the FDA makes a determination and public announcement that electronic submission is not working or unavailable.

The following information must be included in the prior notice:

1. The name of the individual submitting the prior notice and his/her business address, phone number, fax number, and email address, and the name and address of the submitting firm, if applicable. Business registration numbers may be provided in which case the city and country may be shown instead of the full address.
2. The name of the individual and firm transmitting the prior notice, if different from the submitting individual and firm. In addition, the transmitter's business address and telephone number, fax number and email address should be provided.
3. The entry type (e.g., consumption, warehouse, immediate transportation, etc.);
4. The CBP entry identifier (e.g., CBP entry number or in-bond number), if available;
5. The identity of the article of food, including (i) the complete FDA product code; (ii) the common or usual name or market name of the food; (iii) the estimated quantity of food that will be shipped, described from the largest container to smallest package size (e.g., "one container with 421 packages"); and (iv) the lot or code numbers or other identifiers of the food if required by statute or FDA regulations.
6. For an article of food that is no longer in its natural state: the name and address of the manufacturer and the registration number assigned to the facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported for transshipment, storage, and export, or further manipulation and export.
7. For an article of food that is in its natural state: the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower, it may provide the name and address of the firm that has consolidated articles of food from different growers or different growing locations.
8. The FDA Country of Production (i.e., the country where the food was grown, in the case of food in its natural state, or where the

article of food was made, for food that is no longer in its natural state. If the article of food is wild fish, the FDA Country of Production is the country in which the vessel catching the fish is registered.);

9. The name and address of the shipper and, if the shipper is required to register its facility, the registration number assigned to the shipper's facility that is associated with the article of food. A registration number is not required for a facility if the article is imported for transshipment, storage and export, or further manipulation and export.

10. The country from which the article of food is shipped;

11. Anticipated arrival information about the article of food, including (i) the anticipated port of arrival and border crossing at that port; (ii) the anticipated date of arrival at the port; and (iii) the anticipated time of arrival.

12. The name and address of the importer;

13. The name and address of the owner, if different from the importer or ultimate consignee;

14. The name and address of the ultimate consignee.

Note: For food that is imported for transshipment through the United States under a Transportation and Exportation Entry, there is no need to submit the name and address of the importer, owner, or ultimate consignee.

15. The mode of transportation;

16. The Standard Carrier Alpha Code (SCAC) or International Air Transportation Association (IATA) code of the carrier or, if such codes are not applicable, the name and country of the carrier;

17. Planned shipment information for the food including (i) the airway bill number or bill of lading number(s); (ii) for food arriving by ocean vessel, the vessel name and voyage number; (iii) for food arriving by air carrier, the flight number; (iv) for food arriving by truck, bus or rail, the trip number; (v) for food arriving as containerized cargo by water, air or land, the container number(s); (vi) for food arriving by rail, the car number; (vii) for food arriving by privately owned vehicle, the license plate number and state or province; and (viii) the six-digit harmonized tariff schedule (HTS) code.

The rule does not permit amendments to a prior notice. If the information on the prior notice changes after the prior notice has been submitted to the FDA, in most cases an entirely new prior notice must be submitted with the correct information and the first prior notice must be cancelled. However, if the only changes in information have to do with quantity, anticipated arrival information or planned shipment information, a new prior notice is not required.

There are consequences for failure to file proper prior notices for food. In the case of no prior notice, inaccurate prior notice, or untimely prior notice, the food may be refused. Refused food may be exported with CBP approval and supervision. Otherwise, refused food must be held at the port of entry. If food is refused for no prior notice or inaccurate prior notice, a prior notice must be submitted or the inaccurate prior notice must be cancelled and a new, accurate,

prior notice must be submitted. Alternatively, the submitter, importer, owner or ultimate consignee may request the FDA to review the refusal of the food if such request for review is filed within 5 calendar days of the refusal. The FDA will review and respond within 5 calendar days of receiving such a request. In the meantime, food subject to a refusal order may not be delivered to the importer, owner or ultimate consignee until the FDA releases it. In addition, violations of the prior notice requirements may result in civil or criminal actions by the United States or by a debarment proceeding.

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This is a relatively detailed overview of both of these regulations. There are other aspects of the rules that pertain to specific, limited situations. If you have any questions about these rules, or believe that your situation has not been covered by this discussion, please do not hesitate to contact us. We will endeavor to provide you with quick and accurate answers to any of your follow up questions regarding these new rules. We would also be happy to assist in preparing comments on either of these interim rules, if you desire to file them.

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BDG International is an International Freight Forwarder, NVOCC, Custom House Broker, and Duty Drawback Specialist. We provide international transportation worldwide via air or ocean. Our services include complete export/import documentation support.

We invite you to contact our offices with any questions you may have.

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