

notify U.S. Customs Service and a general order warehouse. Generally, at that point the warehouse must arrange to take and store the food at the expense of the consignee. The disposition of this merchandise is governed by 19 U.S.C. 1491 and the implementing regulations at 19 CFR part 127.

Typically, after 6 months, unentered merchandise is deemed unclaimed and abandoned and can be disposed of by the United States. Before this 6 month period runs, however, such merchandise can be re-exported. FDA and U.S. Customs Service plan to develop additional guidance to explain how the agencies will handle food when it must be placed in general order warehouses due to failure to register.

Even though delivery is not allowed, FDA believes that importers, owners, and consignees of food that has been refused under section 801(l) of the act can make arrangements for food to be held: these arrangements can be made without taking possession of the food. FDA recognizes that food may be shipped in the same container or truck with nonfood items. Since articles that are not food are not subject to these regulations, when mixed or consolidated imported freight contains articles of food that must be held at the port of entry or moved to a secure facility, those articles under hold must be dealt with before the rest of the shipment proceeds.

FDA also is proposing in § 1.241(h) that determination that an article of food is no longer subject to hold under section 801(l) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer subject to hold under section 801(l) of the act does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

3. What Does Assignment of a Registration Number Mean? (Proposed § 1.242)

FDA is proposing in § 1.242 to state that assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way denote FDA's approval or endorsement of a facility or its products. Therefore, any representation in food labeling that creates an impression of official approval, endorsement, or apparent safety because a facility that manufactures/processes, packs, or holds the food is registered by FDA would be misleading and would misbrand the food under section 403(a)(1) of the act (21 U.S.C. 343(a)(1)).

4. Is Food Registration Information Available to the Public? (Proposed § 1.243)

The Bioterrorism Act provides that registration information and any information contained therein that would disclose the identity or location of a specific registered facility is not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act). This provision does not apply to information obtained by other means or that has previously been disclosed to the public as defined in 21 CFR 20.81. FDA is proposing to codify this provision in § 1.243.

IV. Analysis of Economic Impacts

A. Benefit-Cost Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

B. Need for the Regulation

The purpose of this regulation is to ensure FDA has knowledge of all domestic and foreign facilities that manufacture/process, pack, or hold food for consumption in the United States. In the event of an actual or threatened bioterrorist attack on the U.S. food supply or other food-related public health emergency, such information will help FDA and other authorities determine the source and cause of such an event, and allow FDA to communicate with potentially affected facilities. The benefits of this regulation would be realized by accomplishing this purpose, as well as other, related benefits. For example, FDA is developing a regulation, 21 CFR part 1, subpart I, to implement prior notice provisions in section 307 of the Bioterrorism Act. Information provided

to FDA in a facility's registration would be helpful in FDA's assessment of whether a shipment may present a threat of serious adverse health consequences or death to humans or animals.

C. Reason for the Regulation

FDA is proposing three regulations that will work in harmony to improve food safety. Food safety is mostly a private good. Establishments have powerful incentives to ensure that the ingredients they purchase are not contaminated and that their production processes are protected from unintentional and intentional contamination. Deliberate (intentional) contamination of food linked to a particular product or facility—particularly if the facility is considered negligent—would be extraordinarily costly to a firm. Indeed, the private incentives to avoid deliberate contamination should be similar to the private incentives for food safety. Deliberate food contamination events nonetheless differ from ordinary outbreaks of foodborne illness in that they are more likely to be low probability events with severe public health consequences.

Although private incentives lead to private efforts to protect against deliberate contamination at the facility level, there are external effects associated with privately produced protection. Private incentives fail to provide the optimal amount of information about the food production and distribution system. Getting food from the farm or sea to the plate involves a complex system of production and distribution. The system works using local knowledge and information; each participant needs to know only as much about the overall system as is necessary for his or her business. Market prices convey most of the information necessary for the ordinary production and distribution of food. In the event of an actual or suspected contamination of the food supply, however, more complete information is needed where it can be centrally used. The suspect food must be traced backward and forward through the distribution chain, both to protect consumers and to find the source and cause of the event.

No individual firm or organization has sufficient financial incentive to establish a central information system relating to food safety for the entire economy. The nation's food processors and importers as a whole would benefit from such a system because it would be easier to uncover and solve problems, but the private costs to create the system