



# Federal Register

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**Part IV**

**Department of  
Health and Human  
Services**

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**Food and Drug Administration**

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**21 CFR Part 1  
Registration of Food Facilities and Prior  
Notice of Imported Food Under the  
Public Health Security and Bioterrorism  
Preparedness and Response Act of 2002;  
Proposed Rules**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 1**

[Docket No. 02N-0276]

RIN 0910-AC40

**Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing a regulation that would 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 by December 12, 2003. The proposed regulation would implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which requires domestic and foreign facilities to register with FDA by December 12, 2003, even in the absence of final regulations. Registration is one of several tools that will enable FDA to act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply by giving FDA information about all facilities that manufacture, process, pack, or hold food for consumption in the United States. In the event of an outbreak of food-borne illness, such information will help FDA and other authorities determine the source and cause of the event. In addition, the registration information will enable FDA to notify quickly the facilities that might be impacted by the outbreak.

**DATES:** Submit written or electronic comments by April 4, 2003. Written comments on the information collection provisions should be submitted by March 5, 2003.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, the Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Leslye M. Fraser, Center for Food Safety and Applied Nutrition (HFS-4), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2378.

**SUPPLEMENTARY INFORMATION:**

**Table of Contents**

- I. Background and Legal Authority
- II. Preliminary Stakeholder Comments
- III. The Proposed Regulation
  - A. Highlights of Proposed Rule
  - B. General Provisions
    - 1. Who Must Register Under This Subpart? (Proposed § 1.225)
    - 2. Who Is Exempt From This Subpart? (Proposed § 1.226)
    - 3. What Definitions Apply to This Subpart? (Proposed § 1.227)
  - C. Procedures for Registration of Food Facilities
    - 1. When Must You Register? (Proposed § 1.230)
    - 2. How and Where Do You Register? (Proposed § 1.231)
    - 3. What Information is Required in the Registration? (Proposed § 1.232)
    - 4. What Optional Items are Included in the Registration Form? (Proposed § 1.233)
    - 5. How and When Do You Update Your Registration Information? (Proposed § 1.234)
  - D. Additional Provisions
    - 1. What Other Registration Requirements Apply? (Proposed § 1.240)
    - 2. What Happens if You Fail to Register? (Proposed § 1.241)
    - 3. What Does Assignment of a Registration Number Mean? (Proposed § 1.242)
    - 4. Is Food Registration Information Available to the Public? (Proposed § 1.243)
- IV. Analysis of Economic Impacts
  - A. Benefit-Cost Analysis
  - B. Need for the Regulation
  - C. Reason for the Regulation
  - D. Options
- V. Initial Regulatory Flexibility Act
- VI. Unfunded Mandates
- VII. Small Business Regulatory Enforcement Fairness Act (SBREFA) Major Rule
- VIII. Paperwork Reduction Act of 1995
- IX. Analysis of Environmental Impact
- X. Federalism
- XI. Comments
- XII. References

**I. Background and Legal Authority**

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

(“the Bioterrorism Act”) (Public Law 107-188), which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A—Protection of Food Supply, section 305, which requires the Secretary of Health and Human Services (the Secretary) to develop regulations mandating domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. The provision creates section 415 and amends sections 301 and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331 *et seq.*).

The major components of section 305 of the Bioterrorism Act are as follows:

- The owner, operator, or agent in charge of a facility is responsible for submitting the registration form to FDA;
- The registration form must include the name and address of each facility at which, and all trade names under which, the registrant conducts business. Foreign facilities also must include the name of the U.S. agent for the facility;
- FDA also may require each facility to submit the general food category (as identified under § 170.3 (21 CFR 170.3)) of the food manufactured, processed, packed, or held at the facility, if FDA determines this submission necessary through guidance. FDA plans to issue such guidance;
- Foreign facilities exporting food to the United States are required to register unless the food undergoes further processing or packaging by another facility outside the United States;
- Other facilities excluded from the registration requirement are: farms, restaurants and other retail facilities, nonprofit food establishments in which food is prepared for or served directly to the consumer, and fishing vessels (except those engaged in processing as defined in § 123.3(k) (21 CFR 123.3(k)));
- FDA shall notify the registrant when it has received the registration and assign a unique registration number to each registered facility. This number is not subject to public disclosure under section 552 of title 5, United States Code (the Freedom of Information Act);
- FDA may encourage electronic registration; and
- Registered facilities must notify FDA in a timely manner of changes to their registration information.

In addition to section 305 of the Bioterrorism Act, FDA is relying on sections 701(a) and 701(b) of the act (21 U.S.C. 371(a) and (b)) in issuing this proposed rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the act, while

section 701(b) of the act authorizes FDA and the Department of Treasury to jointly prescribe regulations for the efficient enforcement of section 801 of the act.

## II. Preliminary Stakeholder Comments

On July 17, 2002, FDA sent a letter to members of the public interested in food issues outlining the four provisions in title III of the Bioterrorism Act that require FDA to issue regulations in an expedited time period, and FDA's plans for implementing them (see <http://www.cfsan.fda.gov/~dms/sec-ltr.html>). In the letter, FDA invited stakeholders to submit comments to FDA by August 30, 2002, for FDA's consideration as it developed this proposed rule. FDA also held several meetings with representatives of industry, consumer groups, other Federal agencies, and foreign embassies after sending out the July 17, 2002, letter, in order to solicit stakeholder comments. In response to these solicitations, FDA received numerous comments regarding section 305 of the Bioterrorism Act.

FDA has considered all the comments received by August 30, 2002. FDA will consider all comments received thus far along with the comments we receive during the public comment period on this proposed rule as we develop the final rule. Some of the significant comments FDA received on or before August 30, 2002, include:

- Defining farm to include typical post-harvesting operations, if all food is grown on the farm;
- Including food product categories in a format that satisfies both the requirements of the Bioterrorism Act and stakeholder concerns;
- Allowing facilities that handle most or all of the food categories listed to check "most/all" food product categories instead of requiring them to check every product category handled by the facility;
- Maintaining flexibility regarding qualifications for a U.S. agent;
- Including dates the facility is in operation, if its business is seasonal;
- Defining "facility" to include multiple buildings on a single site, or buildings within the same general physical location;
- Allowing a corporate headquarters or other central management to submit registrations for multiple facilities;
- Providing for both electronic and paper registration;
- Providing registration numbers instantaneously, if registration is done electronically;
- Requiring only trade names of facilities, as opposed to brand names of products the facility produces;

- Defining "food" consistent with the act's definition;
- Including a model of what the electronic registration screen would look like;
- Defining "timely updates" to mean within 30 calendar days of changes to information on the registration form; and
- Requiring facilities that begin to manufacture, process, pack, or hold food for consumption in the United States on or after December 12, 2003, to register before they begin such activities.

## III. The Proposed Regulation

This proposed rule implements the food facility registration requirements in section 305 of the Bioterrorism Act. Together with the proposed rules implementing section 307 (prior notice), section 306 (recordkeeping), and section 303 (administrative detention) of the Bioterrorism Act, registration of food facilities will enable FDA to act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies. Registration will provide FDA with information about facilities that manufacture, process, pack, or hold food for consumption in the United States. In the event of an outbreak of food-borne illness, such information will help FDA and other authorities determine the source and cause of the event. In addition, the registration information will enable FDA to notify quickly the facilities that might be impacted by the outbreak.

In establishing and implementing this proposed rule, FDA will comply fully with its international trade obligations, including the applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement (NAFTA). For example, FDA believes this proposed rule is not more trade-restrictive than necessary to meet the objectives of the Bioterrorism Act. FDA has endeavored to make the registration process as simple as possible for both domestic and foreign facilities.

### A. Highlights of Proposed Rule

The key features of this proposed rule are as follows:

- Owners, operators, or agents in charge of facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States must register the facility with FDA;
- Facilities covered under this rule must be registered by December 12, 2003;

- Domestic facilities must register with FDA, whether or not food from the facility enters interstate commerce;
- A foreign facility may designate its U.S. agent as its agent in charge for purposes of registering the foreign facility;
- Foreign facilities are exempt from registering if food from these facilities undergoes further processing or packaging by another facility outside the United States. The facility is not exempted from registration if the processing or packaging activities of the subsequent facility are limited to the affixing of a label to a package or other de minimis activity. The facility that conducts the de minimis activity also must register.
- The following facilities are also exempt from registering: Farms; retail facilities; restaurants; nonprofit food facilities in which food is prepared for, or served directly to, the consumer; fishing vessels not engaged in processing, as defined in § 123.3(k); and facilities regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*);
- FDA strongly encourages electronic registration, which will be quicker and more convenient for both facilities and FDA than registration by mail.

### B. General Provisions

#### 1. Who Must Register Under This Subpart? (Proposed § 1.225)

As required by the Bioterrorism Act, the proposed rule applies to facilities engaged in the manufacturing/processing, packing, or holding of food for human or animal consumption in the United States. The proposed rule applies to both domestic and foreign food facilities. Individual homes are not subject to the regulation if the food that is manufactured/processed, packed, or held in the home does not enter commerce.

FDA is proposing in § 1.225(b) to require all domestic facilities that manufacture/process, pack, or hold food to register, whether or not the food from the facility enters interstate commerce. The Bioterrorism Act provides that "any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States" must register and defines "domestic facility" as "a facility located in any of the States or Territories." Therefore, FDA tentatively concludes that the statute requires all domestic facilities to

register, whether or not they engage in interstate commerce. Moreover, having a central database of all domestic facilities producing food would greatly assist FDA in limiting the effects of a food-related emergency covering several States. Nonetheless, because FDA recognizes that this is an important and controversial issue, the agency is seeking comment on whether the agency has authority to exempt domestic facilities engaged only in intrastate commerce from the registration requirement and, if so, whether FDA should use that authority. FDA also seeks comment on how many intrastate facilities are not covered by one of the exemptions from the registration requirement (e.g., the farm or retail exemption). Finally, FDA invites recommendations on what screening questions the agency could ask to enable the owner, operator, or agent in charge of a facility to easily determine whether the facility is an interstate or intrastate facility.

For both domestic and foreign facilities, FDA is proposing in § 1.225(a) and (b) that the owner, operator, or agent in charge, register the facility. FDA is also proposing in § 1.225(c) that the U.S. agent may register a foreign facility if the foreign facility has designated the U.S. agent as its agent in charge. If a foreign facility wants to designate its U.S. agent as its agent in charge for purposes of registering, FDA recommends that the facility and U.S. agent enter into a written agreement authorizing the U.S. agent to register the facility and specifying the U.S. agent's other responsibilities. There are other roles in the course of business that an agent in charge may fill. A formal written agreement between the facility and its U.S. agent would provide clarity for both. Because the proposed rule would require the U.S. agent to reside or maintain a place of business in the United States, allowing the U.S. agent to register the foreign facility will give foreign facilities reliable access to electronic registration that some facilities might not otherwise have. For example, within the United States, Internet access is readily available to members of the public at many local libraries and certain places of business (e.g., photocopying centers).

This process will allow a foreign facility to be registered much more quickly than requesting a paper registration form from FDA by mail, waiting to receive the registration form in the mail from FDA, completing the registration form and sending it to FDA by mail, waiting for FDA to enter the information manually into the electronic registration database—which

could take several weeks to several months depending on the number of paper registrations FDA has received previously—and awaiting a response from FDA by mail that contains the confirmation of registration and the facility's registration number.

## 2. Who is Exempt From This Subpart? (Proposed § 1.226)

In § 1.226, FDA is proposing to exempt several types of facilities from the registration requirement. First, as noted previously, FDA is proposing in § 1.226(a) to exclude foreign facilities, "if food from these facilities undergoes further manufacturing/processing (including packaging) by another foreign facility outside the United States." In other words, foreign facilities involved in the initial stages of manufacturing/processing food are not required to register if another facility further manufactures/processes or packs the food produced at that facility outside the United States.

This exemption would not apply to facilities if the "further manufacturing/processing" at the subsequent facility is of a de minimis nature, such as adding labeling to a package or adding plastic rings to the outside of beverage bottles to hold them together. The facility conducting the de minimis activity would also be required to register. This proposal is based on FDA's tentative conclusion that the statute's exclusion of labeling and "similar activity of a de minimis nature" from the definition of "further processing and packaging" applies only for purposes of the definition of "foreign facility." FDA tentatively concludes that this limitation does not apply to the term "processing" as used elsewhere in the registration provision of the Bioterrorism Act. Accordingly, facilities that label food or engage in similar activities would be required to register as processors. FDA requests comment on this interpretation of the Bioterrorism Act.

The following are examples of which foreign facilities would be subject to, or exempt from, the registration requirement, based on the activities they perform:

(1) A foreign facility would be required to register if it prepares a finished food and places it into packages suitable for sale and distribution in the United States.

(2) A foreign facility distributing food to food processors outside the United States for further manufacturing/processing before the food is exported for consumption in the United States would not be required to register, unless the further manufacturing/processing

entails adding labeling or other de minimis activity. If the further manufacturing/processing is of a de minimis nature, both the facility conducting the de minimis activity and the facility immediately prior to it would be required to register.

(3) The last foreign facility that manufactures/processes an article of food before it is exported to the United States would be required to register, even if the food subsequently is held or stored at a different facility outside of the United States. FDA is proposing to require these manufacturers/processors to register because the Bioterrorism Act exempts a foreign facility from registering only if another facility subsequently processes or packages the food.

(4) Facilities located outside the United States that take possession, custody or control of finished foods for holding, packing, and/or storage prior to export to the United States, would be required to register.

Even though the last processors and packagers of food are required to register under the proposed rule, the Bioterrorism Act also requires foreign facilities that pack and/or hold food subsequent to the processing and packaging process to register with FDA. Requiring registration of foreign facilities that conduct a significant activity with respect to the food, starting with the last manufacturer/processor involved, and ending with the last facility before the food is shipped to the United States, is consistent with the Bioterrorism Act, and ensures that FDA has contact information for foreign facilities whose operations would be expected to affect food exported for consumption in the United States. This requirement achieves a balance between protecting the U.S. food supply, and not unduly burdening foreign facilities.

Consistent with the Bioterrorism Act, FDA also is proposing in § 1.226(g) to exempt certain fishing vessels from the registration requirement. These vessels include "those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel." However, consistent with the Bioterrorism Act's reference to § 123.3(k), the proposed rule provides that "those fishing vessels otherwise engaged in processing fish, which for purposes of this section means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding

are subject to all of the regulations in this subpart.”

FDA also is proposing in § 1.226(h) to exempt facilities that are regulated exclusively, throughout the entire facility, by USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*). Such facilities include meat and poultry slaughterhouses. This section complies with section 315 of the Bioterrorism Act entitled “Rule of Construction,” which states that nothing in title III of the Bioterrorism Act, or an amendment made by title III, shall be construed to alter the jurisdiction between USDA and the U.S. Department of Health and Human Services under applicable statutes and regulations.

FDA is proposing in § 1.226 that facilities that are jointly regulated by FDA and USDA will be required to register under this rule because they are under FDA’s jurisdiction as well as that of USDA. Examples of facilities jointly regulated by FDA and USDA include slaughter facilities that slaughter cattle and deer, and food processing facilities that process meat and nonmeat products, such as frozen T.V. dinners containing both meat, which is regulated by USDA, and fish, which is regulated by FDA.

As specified in the Bioterrorism Act, FDA also is proposing to exempt several other facilities from the registration requirement. These facilities, which are discussed in the definitions section, include farms (§ 1.226(b)); retail facilities (§ 1.226(c)); restaurants (§ 1.226(d)); and nonprofit food facilities in which food is prepared for, or served directly to, the consumer (§ 1.226(e)).

### 3. What Definitions Apply to This Subpart? (Proposed § 1.227)

As specified in proposed § 1.227, the following definitions are used throughout the proposed rule:

a. *The act.* The proposed rule (§ 1.227(a)) defines “the act” as the Federal Food, Drug, and Cosmetic Act. The proposed rule applies the definitions of terms in section 201 of the act (21 U.S.C. 321) to such terms in the proposed rule.

b. *Calendar day.* FDA is proposing in § 1.227(c)(1) to define “calendar day” as every day shown on the calendar. This term includes weekend days.

c. *Facility.* FDA is proposing in § 1.227(c)(2) to define a “facility” as “any establishment, structure, or structures under one management at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes,

packs, or holds food for consumption in the United States. Individual homes are not facilities if the food that is manufactured/processed, packed, or held in the home does not enter commerce.” In response to comments that FDA received during its early outreach efforts, FDA is clarifying in the proposed rule that a facility is not limited to one building, but can consist of several contiguous structures.

The definition of “facility” also specifies that a facility must be under one management. This means that, for purposes of the proposed rule, a single building may house distinct facilities if they are under separate management. If a facility is under joint management of two or more companies, the joint management arrangement is considered one management.

A mixed-type facility performs activities of a facility that is ordinarily required to register and activities of a facility that is ordinarily exempt, such as a farm or retail facility. In order to determine whether a mixed-type facility must register, FDA will consider whether the activity that would require registration is merely incidental to the activities of an exempt facility. If these activities are merely incidental, the facility need not register. For further clarification, see the discussion of the definitions of “farm,” “retail facility,” and “restaurant” that follow.

i. *Domestic facility.* FDA is proposing in § 1.227(c)(2)(A) to define “domestic facility” consistent with the definition of “State” in section 201(a)(1) of the act (21 U.S.C. 321(a)(1)). That is, FDA is proposing to define a domestic facility as one that is located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

ii. *Foreign facility.* FDA is proposing in § 1.227(c)(2)(ii) to define a foreign facility as a facility other than a domestic facility that manufactures, processes, packs, or holds food for consumption in the United States.

d. *Farm.* FDA is proposing in § 1.227(c)(3) to define “farm” in part as “a facility in one general physical location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both.” A farm may consist of contiguous parcels of land, ponds located on contiguous parcels of land, or, in the case of netted or penned areas located in large bodies of water, contiguous nets or pens. Some examples of farms include: Apple orchards, hog farms, dairy farms, feedlots, or aquaculture facilities.

The definition of “farm” includes: (i) Facilities that pack or hold food, provided that all of the food used in

such activities is grown or raised on that farm or is consumed on that farm; and (ii) facilities that manufacture/process food, if all of the food used in such activities is consumed on that farm or another farm under the same ownership. “Farm” includes such facilities because they are activities incidental to farming that most farms engage in (e.g., holding and packing of harvested crops). Facilities that engage in manufacturing/processing, packing, or holding of food that is not described in the definition of “farm” must register because such activities are not activities that most farms engage in and are thus not included in the definition of “farm.”

A farm that manufactures/processes, packs, or holds food is not required to register with FDA, if all of the food used in such activities is consumed on that farm or another farm under the same ownership. For example, a farm that manufactures/processes animal feed from ingredients obtained off the farm for consumption by animals on the farm would be exempt because most farms that raise animals engage in this activity.

This definition does not extend to facilities that grow crops and raise animals and also manufacture/process food that is sold for consumption off the facility because such activities are not incidental to farming. For example, a facility that grows oranges and manufactures/processes them into orange juice for sale to a distributor would be required to register as a manufacturing/processing facility.

A facility could meet the definition of “farm” if all of the activities on the farm meet the description in § 1.227(c)(3)(i), (c)(3)(ii), or both. For example, one farm could meet the description in § 1.227(c)(3)(i) if all of the food packed or held on the farm was grown on that farm. A second farm could meet the description in § 1.227(c)(3)(ii) if all of the food manufactured/processed on the farm is consumed on that farm, even if some of the food was not grown or raised on the farm (e.g., animal feed processed on the farm using materials obtained off the farm and fed to cattle on that farm).

It should be noted that the proposed retail exemption also may apply to facilities that grow crops and raise animals. Thus, a facility that grows crops and raises animals and that also manufactures/processes, packs, or holds food and sells it directly to consumers would be exempt from registering as a retail facility under § 1.226(e), whether or not the food was all grown or raised on that facility. Similarly, a facility would be exempt as both a farm and a retail facility if it sold crops grown on

the farm to consumers at a roadside stand.

FDA is proposing to require co-op facilities that manufacture/process, pack, or hold food, and that are not subject to the farm exemption, to register with FDA. Co-ops are organizations formed to perform activities, including manufacturing/processing or packing food, for their members. The product of these activities is distributed to the members or the public. A farm that grows wheat for distribution to co-op members would be exempt from registration, but a processing facility owned by the co-op would be required to register if it is not located on the farm and mills the wheat into flour for consumption by co-op members off the farm.

The definition of farm does not include facilities that contract with multiple farmers to grow crops or raise animals. These facilities may manufacture/process feed and distribute it to the contract farmers for feeding to animals being raised on the farm. FDA is proposing that the facilities that manufacture/process feed for the contract farmers would be required to register. The farms that grow the crops or raise the animals would be exempt from the registration requirement.

e. *Food*. FDA is proposing in § 1.227(c)(4) to define "food" as it is defined in section 201(f) of the act. That definition is: "\* \* \* (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." FDA also is proposing to include some examples of products that are considered food under section 201(f) of the act. These examples include, but are not limited to: Fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals (such as hogs and elk); bakery goods; snack foods; candy; and canned foods. "Substances that migrate into food from food packaging" include immediate food packaging or components of immediate food packaging that are intended for food use. Outer food packaging is not considered a substance that migrates into food."

f. *Holding*. FDA is proposing in § 1.227(c)(5) to define holding as storage of food. The proposed rule gives examples of holding facilities as

including, but not being limited to: Warehouses, cold storage facilities, storage silos, grain elevators, or liquid storage tanks.

g. *Manufacturing/processing*. FDA is proposing in § 1.227(c)(6) to define manufacturing/processing as "making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients." Some examples of manufacturing/processing include, but are not limited to: Cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. FDA is defining manufacturing and processing together because the meanings of the terms overlap. For example, combining two materials into a finished product, such as macaroni and cheese, could be considered manufacturing, processing, or both. Since both manufacturers and processors are required to register with FDA, FDA does not believe it is necessary to distinguish between manufacturing and processing in the proposed rule.

h. *Nonprofit food facility*. FDA is proposing in § 1.227(c)(7) to define a nonprofit food facility as "a charitable entity that prepares, serves, or otherwise provides food to the public." Examples of these facilities include: food banks, soup kitchens, and nonprofit food delivery services. FDA is proposing that in order to qualify as a nonprofit food facility, the entity must be exempt from paying income tax under the U.S. Internal Revenue Code. This requirement serves to ensure that FDA's definition of a nonprofit facility is consistent with that of other agencies of the U.S. Government.

i. *Packing*. FDA is proposing in § 1.227(c)(8) to define packing as "placing, putting, or repacking a food into different containers without making any change to the form of the food." Facilities engaged in packing of food for consumption in the United States must register under the proposed rule, unless exempt.

j. *Port of entry*. For purposes of the proposed rule, FDA is defining "port of entry" as "the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first arrives in the United States." FDA is proposing this definition because the port where the food arrives in the United States may be different than the port where the entry of the article of food is processed for U.S. Customs

purposes, i.e., where the article is "entered." Under U.S. Customs Service statutes, products can be imported into one port, then transported to another port under a custodial bond before a consumption entry is filed. For example, food may be imported into the United States from Canada through Buffalo, NY, but not entered for consumption with U.S. Customs until it reaches St. Louis, MO, several days later. In this example, under FDA's proposed definition, the port of entry is Buffalo, NY.

The registration authority in the Bioterrorism Act is intended to give FDA better tools to deter, prepare for, and respond to bioterrorism. Given this purpose, "port of entry" must be defined as the port of arrival. Allowing food from a facility that has not registered and that is presented for importation into the United States to be shipped around the country and potentially lost to Government control simply is not consistent with the Bioterrorism Act's stated purpose. FDA believes that its ability to protect U.S. consumers from terrorism or other food-related emergencies will be strongest if food can be examined, and if necessary, held at the point where it first arrives in the United States. FDA requests comment on its proposal to define "port of entry" as the port of arrival.

k. *Restaurant*. FDA is proposing in § 1.227(c)(10) to define a restaurant as "a facility that prepares and sells food directly to consumers for immediate consumption." As defined in the rule, some examples of restaurants include, but are not limited to: Cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens. See section III.B.3.c of this document for a discussion of mixed-type facilities, which may include restaurants.

Due to possible ambiguity in the term, "catering facilities", FDA states in the proposed restaurant definition that facilities that provide food to interstate conveyances, such as airplanes, passenger trains, and cruise ships, rather than directly to consumers, are not restaurants. Facilities that provide food to interstate conveyances are not considered restaurants because they do not serve food directly to consumers for immediate consumption. For example, a facility that provides sandwiches to a passenger train for eventual sale to passengers would not be considered a restaurant. However, the snack bar on the train that sells the sandwiches to consumers would be considered a restaurant. FDA has historically

inspected these facilities that provide food to interstate conveyances and considers them processors, rather than restaurants.

Because the proposed rule also applies to facilities that manufacture/process, pack, or hold food for animal consumption in the United States, by analogy, the term "restaurants" also includes pet shelters, kennels, and veterinary facilities in which food is provided to animals.

l. *Retail facility.* In § 1.227(c)(11), the proposed rule defines a retail facility as "a facility that sells food products directly to consumers only. The term includes, but is not limited to, grocery and convenience stores, vending machine locations, and commissaries. The term includes facilities that not only sell food directly to consumers, but that also manufacture/process food in that facility solely for direct sale to consumers from that same facility."

The Bioterrorism Act does not limit the retail facility exemption to human food. However, the legislative history to the Bioterrorism Act states that the retail exemption applies to food for "human" consumption. Therefore, FDA is taking comments on whether the retail exemption should also be applied to food for animal consumption.

The proposed rule would also require facilities that sell both directly to consumers and to distributors and wholesalers to register. Examples of these facilities are warehouse clubs. Because such facilities do not sell food directly to consumers only, they do not meet the definition of a "retail facility."

m. *U.S. agent.* FDA is proposing in § 1.227(c)(12) to define a U.S. agent as "a person residing or maintaining a place of business in the United States whom a foreign facility designates as its agent." This definition is consistent with FDA's drug, biologics, and device registration regulations found in parts 207, 607, and 807 (21 CFR parts 207, 607, and 807), respectively. In order to ensure that the U.S. agent is available to assist FDA in contacting foreign facilities, the proposed definition of U.S. agent also specifies that the U.S. agent "cannot be in the form of a mailbox, answering machine, or service, or other place where an individual acting as the foreign facility's agent is not physically present." FDA also is proposing to have the U.S. agent's responsibilities include acting as a communications link between FDA and the facility, such that FDA will treat representations provided by the U.S. agent to FDA as those of the foreign facility, and will consider information FDA provides to the U.S. agent as the equivalent of providing the same

information or documents directly to the foreign food facility. As noted previously, FDA also is proposing to allow the U.S. agent to register on behalf of the foreign facility. FDA recommends that the U.S. agent and facility enter into a written agreement specifying the U.S. agent's responsibilities. The facility does not need to submit a copy of the agreement to FDA as part of its registration. If the foreign agent registers a facility without authorization from the facility, FDA will consider the registration to be a materially false, fictitious, or fraudulent statement to the U.S. Government under 18 U.S.C. 1001.

n. *You or registrant.* FDA is proposing in § 1.227(c)(13) to define "you" or "registrant" as "the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States." FDA is proposing to use "you" or "registrant" throughout the proposed rule for easier readability.

### C. Procedures for Registration of Food Facilities

#### 1. When Must You Register? (Proposed § 1.230)

The Bioterrorism Act requires facilities subject to its requirements to be registered with FDA no later than December 12, 2003. Proposed § 1.230 would require facilities that currently manufacture/process, pack, or hold food for consumption in the United States to be registered by December 12, 2003. FDA is proposing that facilities that begin to manufacture/process, pack, or hold food for consumption in the United States on or after December 12, 2003, must be registered before they begin such activities. This also would apply to facilities engaged in seasonal activities that may not be operating in December, 2003. Before these facilities could begin to manufacture/process, pack, or hold food for consumption in the United States after December 12, 2003 (or resume operations after this date), they must be registered with FDA.

FDA is planning to have both its electronic and paper registration systems operational at least 2 months before the statutory deadline of December 12, 2003. FDA will announce the exact date these systems will be available for registration in the final rule. On or before October 12, 2003, FDA will publish in the **Federal Register** either a final rule setting forth the final registration requirements, or a notice providing an address to which paper registrations should be sent, if either the final rule or the electronic system for accepting registrations has not been completed by that date.

Registrations should not be mailed to FDA before publication of that document in the **Federal Register**. Registrations mailed to FDA before the date announced in the **Federal Register** publication will not be accepted.

#### 2. How and Where Do You Register? (Proposed § 1.231)

Although FDA is proposing to allow registration by either electronic or paper means, FDA is planning to devote most of its resources earmarked for registration to building and maintaining an electronic food facility registration system. The majority of facilities, both in the United States and abroad, have access to the Internet, either within their companies or through public libraries, copy centers, schools, or Internet cafes, as well as through a foreign facility's U.S. agent if the facility makes such arrangements. If the U.S. agent does not have Internet access onsite, the agent may register the facility electronically from a local library or other public facility that offers Internet access either free or for a relatively small fee. In this manner, all foreign facilities would be able to obtain an automatic electronic confirmation of registration and the facility's registration number similar to domestic facilities that register electronically.

Registering electronically will benefit both facilities and FDA. FDA will be able to accept electronic registrations from anywhere in the world 24 hours a day, 7 days a week through a link on FDA's Internet Web site. Electronic registration also will enable a facility to be registered more quickly than registering by mail, since obtaining confirmation of registration and the facility's registration number online should be instantaneous once a facility fills in all required fields on the registration screen. In contrast, registration by mail may take several weeks to several months, depending on the efficiency of the mail system and the number of paper registrations that FDA will need to enter manually into the system. Registrations received by mail will be processed in the order in which they are received.

Regarding the electronic Internet-accessible system, the registrant will be able to fill out the entire form online. In order to ensure that the form is filled out completely, the electronic system will not accept a registration submission until all of the mandatory fields are completed. Because FDA intends to allow companies the option of filing registration forms on behalf of one or more of their facilities, FDA will give the registrant the option of completing additional registration forms for other

facilities after the first registration form, and each subsequent registration form, is completed.

FDA is proposing in § 1.231(b) that a registrant may register by mail if none of the means of electronic access mentioned previously are reasonably available. In registering by mail, a registrant also may fill out one or more forms on behalf of one or more facilities. A registrant registering by mail must pick up a copy of the form from FDA headquarters, call FDA at a toll-free number (that will be provided in the final rule) to request a copy of the form, or send FDA a written request for the form. Once the registrant receives the mailed copy of the form, the form must be filled out completely and legibly, and mailed back to FDA at the address provided in the final rule. Once FDA receives the form, an agency employee will check to make sure all mandatory fields are filled out completely and legibly. If the form is not complete or is illegible, it will be returned to the registrant for completion, provided that the registrant's mailing address is legible and valid. If the form is complete and legible, FDA will manually enter the data on the form into the system as soon as practicable, which will depend on the number of other registration forms awaiting manual entry into the system.

The Bioterrorism Act requires FDA to notify the registrant that it has received the facility's registration and to assign the facility a unique registration number. Accordingly, FDA is proposing the following: If a facility registers electronically, FDA will provide the registrant with an automatic electronic confirmation of registration, along with the facility's registration number. This notification will be similar to an automatic electronic receipt many companies provide consumers when they purchase products online (i.e., via the Internet). If the facility registers by mail, FDA will be able to provide the registrant with confirmation of registration and the facility's registration number only after FDA manually enters the registration information into the system. Depending on the number of other paper registrations FDA receives, this entry process could take several weeks to several months. After the registration information is entered into the system, FDA will mail a copy of the information entered to the registrant, along with confirmation of registration and the registration number. If any of the information that was entered into the system is incorrect, the registrant must mail an update to correct the information within 30 calendar days.

For electronic registrations, FDA is proposing in § 1.231 to consider the facility registered when FDA electronically transmits the facility's registration number. If a registration is done by mail, the facility is registered once the data are entered into the registration system and the system generates a registration number. This means that the facility information will be entered into the registration system before the facility receives its registration number, if registration is done by mail. FDA strongly encourages all facilities, both foreign and domestic, to register electronically, as that minimizes the delay in having FDA mail the registrant a form, the registrant returning the completed form to FDA, FDA entering the facility's data manually into the registration system, and FDA subsequently mailing the registration number and receipt of registration to the facility. To the extent possible, all covered facilities should make every effort to register electronically or send in their registration form as far in advance as possible of the date they are intending to import their products into the United States (but not sooner than the announced date) since the Bioterrorism Act requires FDA to hold imported products of any unregistered facility at the U.S. port of entry until the facility is registered with FDA.

The Bioterrorism Act precludes FDA from requiring facilities to register electronically. Given FDA's preference for electronic registration and the ease of electronic registration for both registrants and FDA, FDA is requesting comments regarding what other means FDA should use to encourage electronic registration. FDA also is requesting comments from facilities that believe they will be unable to register electronically, as well as comments regarding data on the number of these facilities.

No registration fee is required for either the electronic or paper registration. FDA is proposing that registrants must submit all registration information in the English language. FDA is proposing to require submissions to be in English in order for FDA to understand the content of submissions and ensure that registration data are entered accurately.

### 3. What Information is Required in the Registration? (Proposed § 1.232)

FDA is proposing in § 1.232 that registrants must submit to FDA certain information, including: The name, full address, phone number, fax number, and e-mail address of the facility (paragraph (a)); the name and address of

the parent company (paragraph (b)), if the facility is a subsidiary of the parent company; emergency contact information, including the contact's name, title, office phone, home phone, cell phone (if available), and e-mail address (if available) (paragraph (c)); all trade names the facility uses (paragraph (d)); and the name, address, phone number, fax number (if available), and e-mail address (if available) of the U.S. agent for foreign facilities (paragraph (f)). FDA is planning to include all of this information in the mandatory section of the registration form. At the end of the form, FDA is planning to provide a statement in which the registrant will certify that the information submitted is true and accurate, and that the individual submitting the registration is authorized by the facility to do so (paragraph (g)). This statement also will require the phone number, e-mail address (if available), and fax number (if available) of the person submitting the registration.

Section 305 of the Bioterrorism Act also states that FDA may require registrants to submit the general food categories of food produced at the facility, if FDA determines through guidance that such information is necessary. FDA plans to issue such guidance, and make it available for comment in accordance with good guidance practices (21 CFR 10.115). The guidance will address FDA's finding that such food categories are necessary. Section 305 of the Bioterrorism Act specifically provides that the food categories to be used are those provided in § 170.3. FDA tentatively concludes that information on the category of food manufactured, processed, packed, or held at each facility that must register is necessary for a quick, accurate, and focused response to a bioterrorist incident or other food-related emergency, because the categories will assist FDA in conducting investigations and surveillance operations in response to such an incident. These categories will also enable FDA to quickly alert facilities potentially affected by such an incident if FDA receives information indicating the type of food affected. For example, if FDA receives information indicating that soft drinks could be affected by a bioterrorist incident or other food related emergency, FDA would be able to alert soft drink manufacturers/processors, packers, and holders about this information. Additionally, the food categories, in conjunction with the prior notification requirements in 21 CFR part 1, subpart I, would aid FDA in verifying that



imported products are correctly identified by where and by when they were produced. For example, if the registration information identifies a facility as producing only dairy products and FDA receives a prior notice purportedly from the facility for the shipment indicating that the facility is shipping nuts, FDA can target that facility for verification based on the discrepancy. FDA believes, however, that information about a facility's food product categories is a key element for both FDA and industry to allow for rapid communications to facilities directly impacted by an actual or potential bioterrorist attack or other food-related emergency. FDA, therefore, is proposing in § 1.232(e) to include on the registration form as a mandatory field the categories from § 170.3. For ease of use, however, the more common categories found in FDA's product code builder at [www.fda.gov/search/databases.html](http://www.fda.gov/search/databases.html) will be listed as the main categories on the form, followed by the food product categories in § 170.3 as references for each FDA product code category. For example, the registration form includes coffee and tea as a product category, which includes the products listed in § 170.3(n)(3) and (n)(7). Categories not in § 170.3 will be listed as optional selections.

FDA believes its proposed approach will both permit the agency to collect vital information regarding usable categories of products produced at the facility, and address industry's concern that the food product categories in § 170.3 are unworkable. FDA is interested in receiving comments on whether use of FDA's product code builder categories as the primary selection, with references immediately after each entry to the food product categories in § 170.3 that apply to each selection, addresses the comments' concerns regarding use of the categories in § 170.3, while complying with the requirements of the Bioterrorism Act.

FDA also is proposing to include several other fields that relate directly to the statutory requirements. The first of these is the name, address, phone number, facsimile number (if available), and e-mail address (if available) of the U.S. agent. Because the U.S. agent will act as a communications link between the facility and FDA, it is vital for FDA to have reliable contact information for the U.S. agent.

FDA also is proposing that a mandatory section of the form include, if applicable, the name and address of the parent company, if the facility is owned by a parent corporation. This information is important for FDA in understanding the relationship between

a facility and its parent company regardless of the name under which a facility may be operating.

FDA also is proposing to include as a mandatory section the emergency contact information for a facility, which would include an individual's name, title, office phone, home phone, and cell phone (if available). If FDA receives information regarding a potential or actual threat to the nation's food supply, or other food-related emergency, it must be able to get in touch with an individual at each potentially affected facility who could respond immediately to the threat at any hour. The emergency contact person does not have to be physically located at the facility; however he or she must be accessible and able to respond in an emergency. Thus, for example, a parent corporation can list as the emergency contact the name of an individual at headquarters who has overall responsibility for responding to emergencies at any facility owned by the parent company.

FDA is planning to include at the end of the form a statement in which the person submitting the registration information will certify that the information submitted on the form is true and accurate and the person registering the facility is authorized to do so. If a person submits false information on the registration form, or if a person registers a facility without being authorized to do so, that registration will be considered a materially false, fictitious, or fraudulent statement to the U.S. Government under 18 U.S.C. 1001, which subjects the person to criminal penalties. FDA is including this language on the registration submission to deter individuals from either submitting false information, or registering a facility if they are not authorized by the facility to register it. This applies both to individuals who do not have any relationship with the owner, operator, or agent in charge of a facility, and to those who have a connection to the owner, operator, or agent in charge of a facility, such as the U.S. agent, but who do not have authorization from the facility to register on its behalf.

#### 4. What Optional Items Are Included in the Registration Form? (Proposed § 1.233)

FDA also is proposing in § 1.233 to include several optional fields on the registration form. These items are consistent with the statutory directive, and will enable FDA to communicate more quickly with facilities that may be the target of a bioterrorist attack or other food-related emergency. These proposed fields include:

(a) a preferred mailing address, which would allow a facility's corporate headquarters to serve as the primary contact with FDA instead of the facility;

(b) the type(s) of activity conducted at the facility (e.g., manufacturing/processing, packing, or holding), which would allow FDA to target its communications in emergencies to those facilities potentially impacted based on the information FDA receives (e.g., a threat to a type of food product at manufacturing facilities);

(c) food categories not included in § 170.3 (e.g., dietary supplements, infant formula, and food for animal consumption), which would be helpful to FDA for responding to a terrorist incident or other food safety emergency involving these foods;

(d) the type of storage or manufacturing/processing facility, in the event that the facility is solely a warehouse/holding facility and stores multiple types of food;

(e) a food product category of "most/all food product categories", if the facility manufactures, processes, packs, or holds foods in most or all of the categories under § 170.3; and

(f) the approximate dates of operation, if the facility's business is seasonal.

FDA encourages all facilities to submit this optional information if it applies to the facility's operations.

#### 5. How and When Do You Update Your Registration Information? (Proposed § 1.234)

FDA is proposing in § 1.234 that the owner, operator, or agent in charge must submit a timely update to FDA via the Internet (or by paper copy if no Internet access) within 30 calendar days of any change to any of the information previously submitted, including, but not limited to, the name of the owner, operator, or agent in charge. FDA is proposing 30 calendar days in order to balance the needs of both industry and FDA. In order for FDA to have accurate information for responding to terrorist threats or other food related emergencies, facilities must submit updates within an expedited timeframe. However, FDA also understands that the need to submit updates may coincide with transitions occurring at the facility in which the facility may not be able to provide updates immediately after such transitions occur. FDA believes that requiring updates within 30 calendar days of changes to the information on the initial registration submission is a reasonable balance between FDA's and industry's interests. FDA requests comments on this 30-day timeframe.

With respect to the content of the update, FDA is proposing that the

update must include any changes to any information the facility previously submitted, including, but not limited to, changes to information regarding food product categories. This information, including these categories, will assist FDA in conducting investigations and surveillance operations in response to a bioterrorist incident. If this information is outdated it will interfere with FDA's ability to quickly ascertain the nature and scope of the problem and to alert affected facilities and prevent further distribution of harmful food. Therefore, for efficient and effective implementation of the Bioterrorism Act, FDA is proposing to require registrants to update previously submitted information in both the mandatory and optional categories, if the registrant originally submitted information in both categories and that information changes. FDA requests comments on this proposed requirement and how it will affect the submission of optional information.

A facility canceling a registration must do so on a separate cancellation form electronically or by mail.

#### *D. Additional Provisions*

##### 1. What Other Registration Requirements Apply? (Proposed § 1.240)

In proposed § 1.240, FDA has included a provision reminding registrants that they must comply with all other applicable registration requirements, including those found in part 108 (21 CFR part 108), related to emergency permit control. FDA wants to ensure that registrants subject to the registration regulation being proposed to implement the Bioterrorism Act are aware that this registration does not take the place of that required in part 108, or any other registration requirements.

FDA seeks to minimize the burden of this rule on covered facilities and the submission of duplicative information. FDA is aware that existing registrations required by FDA and other federal agencies ask for information that may be duplicative of some of the information FDA is proposing be submitted under this rule. The Bioterrorism Act requires that certain facilities register with FDA. The Bioterrorism Act also specifies that certain information must be contained in the facilities' registration submissions. FDA seeks comments on whether there are registration requirements under which facilities must submit duplicative information to more than one Federal agency. If so, FDA also seeks comments on whether there is any way, consistent with the requirements and purpose of the Bioterrorism Act, to minimize the

duplication of information required to be submitted under these registration requirements. In particular, FDA is interested in comments on whether it has authority, under the Bioterrorism Act or another regulatory mandate, to grant a partial or full exemption from the FDA registration requirement to facilities that have already registered with another Federal agency. If such authority exists, FDA is also interested in whether the goals of the Bioterrorism Act could be met if FDA does not have complete registration information.

##### 2. What Happens if You Fail to Register? (Proposed § 1.241)

As provided in the Bioterrorism Act, two consequences may occur if a facility covered under these regulations fails to register. Failure of either domestic or foreign facilities to register is considered a prohibited act under section 301 of the act (21 U.S.C. 331). Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin persons who commit a prohibited act and, under section 303 of the act (21 U.S.C. 333), can bring a criminal action in Federal court to prosecute persons who commit a prohibited act. Under section 305a of the Bioterrorism Act, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.

FDA seeks comment on circumstances under which a firm's registration should be considered null and void and on circumstances under which a firm's registration should be revoked. FDA also seeks comment on the process for such determinations.

For foreign facilities that fail to register and attempt to import food into the United States, the Bioterrorism Act requires the food be held at the port of entry unless FDA directs its removal to a secure facility. FDA is proposing in § 1.241(e) that if FDA determines that removal to a secure facility is appropriate (e.g., due to a concern with the security of the article of food or due to space limitations in the port of entry), FDA may direct that the article of food be removed to a bonded warehouse, container freight station, centralized examination station, or another appropriate secure facility that has been approved by FDA. Perishables, however, may not be stored in U.S. Customs Service's bonded warehouses; thus FDA may direct fresh produce or seafood that requires storage to another facility. FDA and the U.S. Customs Service plan to issue guidance for their field offices that will identify locations of secure storage.

In order to minimize confusion about who is responsible for making arrangements if food is held under section 801(l) of the act (21 U.S.C. 381(l)), FDA is proposing in § 1.241(f) that the owner, purchaser, importer, or consignee must arrange for storage of the article of food, in an FDA-designated secure facility and must promptly notify FDA of the location. Any movement of the article to the facility must be accomplished under bond. We note that when section 801(l) of the act requires that food be held, it does not appear to mandate that the Government take actual physical custody of the goods; instead it limits both the movement of the goods and the potential storage locations, thereby making Government oversight straightforward. As described previously, U.S. Customs Service has identified a well-established network of storage facilities that are secure. When these storage facilities are used, charges are borne by the private parties. We thus believe that although Congress intended strict controls over food refused admission under section 801(l) of the act, it did not intend to require FDA or U.S. Customs Service to take custody of or pay for the holding of such food. We seek comment on this issue.

The article of food must be held at the port of entry or in the secure facility until the owner, operator, or agent in charge of the foreign facility has submitted its registration information to FDA, FDA has registered the facility, and FDA has notified the U.S. Customs Service and the person who submitted the registration that the facility is registered and the article of food no longer is subject to a hold under section 801(l)(1) of the act. Notwithstanding section 801(b) of the act, while any article of food is held at its port of entry or in a secure facility under section 801(l) of the act, it may not be delivered to any of its importers, owners, or consignees.

The Bioterrorism Act does not provide specific procedures for the disposition of food under hold under section 801(l) of the act when no subsequent registration is submitted. FDA thus believes that the general requirements of Title 19 of the United States Code and the U.S. Customs implementing regulations that apply to imports for which entry has not been made apply in these circumstances. Under 19 U.S.C. 1448 and 1484, entry of merchandise must be made within the time period prescribed by regulation, which is 15 calendar days after the food arrives in the United States. (See 19 CFR 142.2.) If entry is not made within this timeframe, the carrier or other authorized party is required to

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

probably would be prohibitive for any single firm or third party organization.

We estimate that an effective system of information would require several hundred thousand participants to gather information and provide it to a central system. The private transactions costs to bring all the participants together voluntarily and get them to agree to create such a system would be extraordinarily high. No single organization could capture additional revenue sufficient to cover the cost. Also, because the provision of information by some participants makes it available for all, there would be a tendency for establishments to try to be free riders in the information system. But the more information and participation in the system, the more effective it is.

Another way of looking at the problem of participation is in terms of marginal private benefits and marginal social benefits. By gathering and providing the information used in a food safety system, an individual establishment receives additional private benefits from enhancing the safety of its own food. In addition, participating in the system increases the effectiveness of the entire information system. In other words, the more establishments participate in the system, the better it works. The individual establishment does not capture this additional social benefit. The marginal private benefit (enhanced safety for individual establishments) is less than the marginal social benefit (the marginal private benefit plus the increased effectiveness of the entire information system). The difference between private and social benefit reduces the incentive for establishments to participate in a voluntary private system.

The events of September 11, 2001, led Congress to conclude that public creation and provision of an information system is necessary. The Bioterrorism Act and its implementing regulations would establish an information system that would allow FDA to have a more integrated picture of the food distribution system. This particular regulation addresses one important aspect of this information system: The need to know what facilities manufacture/process, pack, or hold food for consumption in the United States, what types of food each facility handles, and how each facility can be contacted. However, as stated previously, FDA is proposing three regulations to address these needs, so the costs and benefits of any one regulation will be closely associated with related provisions in other proposed rules. With the

regulations in place, the agency would have the additional tools necessary to help prevent and respond to threats to the nation's food supply as well as to other food safety problems.

#### *D. Options*

FDA analyzes the costs and benefits of eight regulatory options that address the goal of deterring or containing purposeful or accidental contamination of the U.S. food supply. Option 1 is the status quo and provides the baseline against which all the other options are measured. Option 2 has the most complete coverage of domestic and foreign facilities and required information in the registration. Options 3 through 5 are each less comprehensive than option 2. Options 6 and 7 use a different definition of mixed-type facilities and option 7 permits U.S. agents to register on behalf of the foreign facility they represent. Option 7 is the proposed option. Option 8 is a discussion of the costs and benefits of the Bioterrorism Act's registration provisions becoming requirements without FDA issuing a regulation (statutory default provision).

- Option 1 is to not impose any new regulatory or statutory requirements.
- Option 2 requires the registration of domestic and foreign facilities that manufacture/process, pack, or hold food for consumption in the United States, whether or not food from the facility enters interstate commerce. Farms, fishing vessels, nonprofit food facilities, facilities exclusively regulated by USDA, and retail facilities are exempted from the registration requirement. Mixed-type facilities that perform some activities of a farm or retail facility but that also manufacture/process food for consumption off that facility must register under this option. Foreign facilities are also required to have a U.S. agent to facilitate communication between the foreign facility and FDA.

- Option 3 has the same requirements and coverage as option 2, but excludes facilities that participate only in intrastate commerce. FDA tentatively concludes that this option is not legally viable, as the Bioterrorism Act does not seem to exempt facilities participating only in intrastate commerce.

- Option 4 has the same coverage and requirements as option 2, but excludes all mixed-type facilities, regardless of whether they also manufacture/process food for consumption off the facility or pack or hold food not grown or raised on that facility. As discussed in the following paragraphs, FDA does not believe this option is legally viable.

- Option 5 has the same requirements and coverage as option 2, but does not

require that facilities include information about the types of products they manufacture/process, pack, or hold on their registration.

- Option 6 has the same requirements and coverage as option 2, but mixed-type facilities are required to register if they pack or hold food not harvested on that facility or manufacture/process food not for consumption on that facility. However, facilities that manufacture/process food are exempted as retail facilities if they sell the food directly to consumers from that facility.

- Option 7, the proposed option, requires the same coverage of facilities as option 6. Under this option, the U.S. agent can register on behalf of the foreign facility.

- Option 8 is to allow the registration requirement of the Bioterrorism Act to be implemented without issuing a regulation. The Bioterrorism Act requires facilities to register by December 12, 2003, regardless of whether FDA issues a regulation. Due to uncertainty about how this option would be implemented, FDA does not attempt to estimate costs or benefits for this option.

#### 1. Option One: Do Not Require Facilities to Register

Option one is to maintain the status quo, i.e., no statutory or regulatory registration requirement. This option will serve as the baseline against which other options will be measured for assessing costs and benefits. OMB's cost-benefit analysis guidelines recommend discussing requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity cost of legal constraints that prevent the selection of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866.

The Bioterrorism Act requires that FDA implement through regulation registration for food facilities; therefore, this is not a legally viable option.

#### 2. Option Two: Comprehensive Registration of Domestic and Foreign Manufacturers/Processors, Packers, and Holders of Food

Option two requires domestic facilities that manufacture/process, pack, or hold food for consumption in the United States to register with FDA, including facilities engaged in interstate and intrastate commerce. Farms, fishing vessels, nonprofit food facilities, facilities exclusively regulated by USDA, and retail facilities are exempted from the registration requirement. Mixed-type facilities that perform activities of a farm or retail facility but

that also manufacture/process food for consumption off that facility must register under this option. Registration may be electronic or by mail, although FDA strongly encourages all facilities to register electronically. The information required on the registration includes the facility's name, address, parent company name and address (if applicable), emergency contact information, trade names, general food product categories under § 170.3, and certification by the owner, operator, or agent in charge of the facility as to the accuracy of the information and the submitter's authority to register the facility.

Under the Bioterrorism Act, foreign establishments are required to register if they manufacture, process, pack, or hold food for consumption in the United States without the food undergoing further processing or packaging outside the United States. In addition to registering, the Bioterrorism Act requires foreign facilities to have a U.S. agent. The U.S. agent is a person residing in or maintaining a place of business in the United States, who the owner, operator, or agent in charge of a foreign establishment designates as its agent. Only one U.S. agent per foreign establishment is permitted and the U.S. agent must reside or maintain a place of business in the United States. The U.S. agent is responsible for acting as a communications link between FDA and the facility.

a. *Coverage—i. Domestic establishments.* Consistent with the Bioterrorism Act, this proposed regulation's legal requirements apply to facilities, as opposed to firms. A firm is composed of facilities under common ownership. As a result, changes in behavior may occur at the firm- or facility-level to comply with this proposed regulation. However, for ease of analysis, FDA will focus on the facility as the unit of analysis. For a count of domestic facilities, FDA used the 2000 County Business Patterns (CBP) (Ref. 1), 1999 Nonemployer Statistics (Ref. 2), the FDA Field Accomplishments and Compliance Tracking System (FACTS) (Ref. 3), and the Census of Agriculture (Ref. 4). The Census Bureau created the 2000 CBP by analyzing data from the Business Register, the Census Bureau's file of all known single and multi-facility companies. These data for single-location firms are obtained by the Census from the Economic Censuses, the Annual Survey of Manufacturers, Current Business Surveys, and administrative records from the Internal Revenue Service, Social Security

Administration, and the Bureau of Labor Statistics.

Table 1 of this document provides a count of businesses in the relevant North American Industry Classification (NAICs) codes in the 2000 CBP. There are 103,125 affected facilities in the 2000 CBP under option two. Facilities not included in the CBP are counted in the Nonemployer Statistics, which is also from the Census Bureau (Ref. 2). Nonemployer businesses are companies with no paid employees. The Census Bureau primarily obtains data about nonemployer businesses from annual business income tax returns filed with the Internal Revenue Service. The Nonemployer Statistics dataset is less disaggregated than the CBP dataset. As a result, including entire counts of facilities in some NAICs codes in the Nonemployer Statistics would result in an overestimate of the number of facilities. For example, NAICs code 4931, warehousing and storage, includes warehouses and storage facilities that store nonfood products, and so is too aggregated for this analysis and includes facilities that would not be required to register. To estimate the number of affected warehouses in NAICs 4931, FDA assumed that the percentage of warehouses that are refrigerated and nonrefrigerated warehouses that store farm products is the same for both the 2000 CBP and the 1999 Nonemployer Statistics, and uses this as an adjustment factor for the 1999 Nonemployer Statistics. With this adjustment, there are 68,424 facilities in the relevant NAICs codes in the 1999 Nonemployer Statistics. Table 2 of this document provides a count of businesses in the relevant NAICs codes in the 1999 Nonemployer Statistics. Manufacturers/processors, packers, and holders of substances that migrate into food from food packaging or other articles that contact food do not correspond to any single NAICs code. Tables 3 and 4 of this document provide numbers of facilities in the 2000 CBP and 1999 Nonemployer Statistics, respectively. Broader NAICs codes, such as 322 and 326 that include facilities that deal only in nonfood products have only the number of facilities reported that could reasonably be expected to deal in substances that migrate into food from food packaging or other articles that contact food. For example, stationery manufacturers have been removed from the estimate. The Nonemployer Statistics have more aggregated counts than the 2000 CBP. To get a more accurate count of facilities in the Nonemployer Statistics, the count of facilities in each aggregated NAICs

codes is reduced by the percentage of facilities believed to be dealing with substances that migrate into food from packaging in the 2000 CBP. However, this number may be an overestimate as for some NAICs codes, in which it was not clear if the facilities were producing substances for food or nonfood use. For example, plastic forms may be made into food packaging or may be used for other purposes. To further adjust the number of facilities to include only facilities that manufacture/process, pack, or hold substances that migrate into food from food packaging or other articles that contact food, the numbers in each category are adjusted by data reported in The Rauch Guide to the U.S. Packaging Industry (Ref. 5). The Rauch guide reports that the packaging of consumer products accounts for 78 percent of all packaging and that 55 percent of the total used for consumer products is used for food and beverages. This means 43 percent of packaging is used to package food and beverages. To reflect this data, the NAICs categories for end, or near-end use packaging were reduced by 57 percent. NAICs categories for explicit food use, such as kitchen utensils and cutlery were assumed to have 100 percent of facilities manufacturing/processing, packing, or holding food.

Basic chemicals or other components incorporated into packaging may be intended for food or nonfood uses. FDA was unable to determine how many of these components are intended for food use. FDA also was not able to distinguish between manufacturers/processors, packers, or holders of immediate food packaging, which would be considered "substances that migrate into food from food packaging or other articles that contact food," and manufacturers/processors, packers, or holders of outer food packaging, which would not. Therefore, FDA included for purposes of this analysis: (1) Facilities manufacturing/processing, packing, or holding basic chemicals or other components incorporated into packaging for both food and nonfood use, and (2) manufacturers/processors, packers, and holders of both immediate and outer food packaging. Because this approach results in an overestimation of the number of facilities subject to this proposed rule, FDA requests comments on the number of these types of facilities that would be required to register.

Also covered under this proposed rule are slaughterhouses that process FDA regulated meats and renderers. FDA requests comments on the number of these facilities.

The Census data sets do not identify facilities engaged only in intrastate

commerce (Refs. 1 and 2). To be considered a facility engaged only in intrastate commerce, a facility must obtain all its ingredients and sell all its products within a single State. FDA assumes that facilities that participate only in intrastate commerce will be very small and are unlikely to be warehouses or wholesalers. To determine which facilities are in interstate commerce, FDA compared the number of facilities in Census data sets with the number of facilities in the FACTS database. FACTS is a database of facilities regulated by FDA that includes data on operations accomplished by the field (e.g.,

inspections, investigations, sample collections, sample analyses, etc.) (Ref. 3). FACTS and FDA's Operation and Administration System for Import Support (OASIS) identify firms as workload and nonworkload obligations for FDA. FACTS uses different product categories for facilities than the Census datasets, making a direct comparison of the number of firms within categories with the Census datasets difficult. Table 5 of this document presents a count of facilities in the FACTS database by FDA categories. The FACTS database has some facilities that appear in more than one category, so a single facility may

appear more than once in the database. This double counting is not corrected in the count of each type of facility, but is corrected in the total count of facilities. Because the FACTS database gives a count of facilities that FDA inspects, FDA assumes that all facilities in FACTS are in interstate commerce. If we take the total count of facilities from the CBP and Nonemployer Statistics, 171,549, and subtract the count of facilities in FACTS, 71,871, this gives a reasonable estimate of the number of facilities in intrastate commerce 99,678. This calculation is presented in table 6 of this document.

TABLE 1.—COUNT OF FACILITIES IN THE 2000 CBP

| NAICs Code | Type of Industry  | Number of Facilities |
|------------|---|----------------------|
| 3111       | Animal food manufacturing                                       | 1,710                |
| 3112       | Grain and oilseed milling                                       | 913                  |
| 3113       | Sugar and confectionery product manufacturing                   | 1,689                |
| 3114       | Fruit and vegetable preserving and specialty food manufacturing | 1,796                |
| 3115       | Dairy product manufacturing                                     | 1,769                |
| 3117       | Seafood product preparation and packaging                       | 854                  |
| 3118       | Bakeries and tortilla manufacturing                             | 10,644               |
| 3119       | Other food manufacturing  | 2,994                |
| 3121       | Beverage manufacturing  | 2,748                |
| 4224       | Grocery and related product wholesale                           | 39,721               |
| 4225       | Farm product raw material wholesale                             | 9,546                |
| 4228       | Beer, wine, distilled alcoholic beverage wholesale              | 4,630                |
| 49312      | Refrigerated warehousing and storage                            | 945                  |
| 49313      | Farm product warehousing and storage                            | 516                  |
| Subtotal   |   | 80,475               |
|            | Substances that contact food                                    | 22,650               |
| Total      |   | 103,125              |

TABLE 2.—COUNT OF FACILITIES IN THE 1999 NONEMPLOYER STATISTICS

| NAICs Code | Type of Industry  | Number of Facilities |
|------------|---|----------------------|
| 3111       | Animal food manufacturing                                       | 642                  |
| 3112       | Grain and oilseed milling                                       | 287                  |
| 3113       | Sugar and confectionery product manufacturing                   | 1,439                |
| 3114       | Fruit and vegetable preserving and specialty food manufacturing | 2,000                |
| 3115       | Dairy product manufacturing                                     | 594                  |
| 3117       | Seafood product preparation and packaging                       | 693                  |
| 3118       | Bakeries and tortilla manufacturing                             | 6,271                |
| 3119       | Other food manufacturing  | 4,725                |
| 3121       | Beverage manufacturing  | 1,608                |
| 4224       | Grocery and related product wholesale                           | 32,050               |
| 4225       | Farm product raw material wholesale                             | 4,795                |
| 4228       | Beer, wine, distilled alcoholic beverage wholesale              | 2,578                |
| 4931       | Warehousing and storage   | 964                  |
| Subtotal   |   | 58,646               |
|            | Substances that contact food                                    | 9,778                |
| Total      |   | 68,424               |

TABLE 3.—FACILITIES THAT MANUFACTURE/PROCESS, PACK, OR HOLD FOOD CONTACT SUBSTANCES IN THE NONEMPLOYER STATISTICS

| NAICs |                              | Total in NAICs | Adjusted by CBP | Percent Used in Food |
|-------|------------------------------|----------------|-----------------|----------------------|
| 322   | Paper manufacturing          | 1,621          | 1,197           | 43                   |
| 3251  | Basic chemical manufacturing | 534            | 385             | 100                  |

TABLE 3.—FACILITIES THAT MANUFACTURE/PROCESS, PACK, OR HOLD FOOD CONTACT SUBSTANCES IN THE NONEMPLOYER STATISTICS—Continued

| NAICs |  | Total in NAICs | Adjusted by CBP | Percent Used in Food |
|-------|--|----------------|-----------------|----------------------|
| 3252  | Resin, synthetic rubber, artificial and synthetic fibers manufacturing | 293            | 293             | 100                  |
| 326   | Plastics and rubber products manufacturing                             | 5,528          | 1,203           | 43                   |
| 3271  | Clay product and refractory manufacturing                              | 4,452          | 448             | 100                  |
| 3272  | Glass and glass product manufacturing                                  | 3,463          | 3,463           | 43                   |
| 331   | Primary metal manufacturing  | 3,447          | 335             | 100                  |
| 332   | Fabricated metal product manufacturing                                 | 33,202         | 393             | 100                  |
| 4226  | Chemical and allied products wholesale                                 | 5,403          | 5,403           | 100                  |
| Total |  |                |                 | 9,778                |

TABLE 4.—FACILITIES THAT MANUFACTURE/PROCESS, PACK, OR HOLD FOOD CONTACT SUBSTANCES IN THE 2000 CBP

| NAICs          |  | Total Number of Facilities | Percent Used in Food |
|----------------|--|----------------------------|----------------------|
| 322            | Paper manufacturing                                      | 4,308                      | 43                   |
| 32513          | Synthetic dye and pigment manufacturing                  | 204                        | 100                  |
| 32518          | Basic inorganic chemical manufacturing                   | 730                        | 100                  |
| 32519          | Basic organic chemical manufacturing                     | 818                        | 100                  |
| 3252           | Resin, synthetic rubber, artificial and synthetic fibers | 863                        | 100                  |
| 326            | Plastics and rubber products manufacturing               | 3,544                      | 43                   |
| 327112         | Vitreous china and other pottery product manufacturing   | 185                        | 100                  |
| 3272           | Glass and glass product manufacturing                    | 2,340                      | 43                   |
| 3313           | Alumina and aluminum production and processing           | 613                        | 43                   |
| 332211         | Cutlery and flatware (except precious) manufacturing     | 166                        | 100                  |
| 332214         | Kitchen utensil, pot and pan manufacturing               | 72                         | 100                  |
| 332431         | Metal can manufacturing                                  | 242                        | 100                  |
| 332439         | Other metal container manufacturing                      | 437                        | 100                  |
| 4226           | Chemical and allied products wholesale                   | 15,293                     | 100                  |
| Adjusted total |  |                            | 22,650               |

TABLE 5.—COUNT OF FACILITIES IN FACTS

| Type of Facility                         | Number of Facilities |
|--|----------------------|
| Manufacturers .....                      | 34,437               |
| Repackers/packer .....                   | 6,204                |
| Warehouses .....                         | 34,760               |
| Shippers .....                           | 1,519                |
| Caterers .....                           | 664                  |
| Commissary .....                         | 705                  |
| Subtotal .....                           | 78,289               |
| Collapsed to account for multiple firms. | 71,871               |

TABLE 6.—NUMBER OF FACILITIES IN INTERSTATE AND INTRASTATE COMMERCE

|  |         |
|--|---------|
| 2000 CBP .....   | 103,125 |
| 1999 Nonemployer statistics .....                        | 68,424  |
| Subtotal of facilities in inter and intrastate commerce. | 171,549 |
| FACTS (interstate commerce) ...                          | -71,871 |
| Facilities only in intrastate commerce.                  | 99,678  |

ii. *Mixed-type facilities.* Although farms and retail facilities are exempted from registration by the Bioterrorism Act, some mixed-type facilities perform activities of a farm or retail facility and

activities of a facility that is required to register. Under this regulatory option, FDA would require mixed-type facilities that manufacture/process food that is not consumed at that facility to register. Examples of manufacturing/processing include canning, freezing, cooking, pasteurization, homogenization, irradiation, milling, grinding, chopping, slicing, cutting, coloring, waxing, shelling of nuts, peeling, labeling, and packaging. Farms that mix feed would be considered mixed-type facilities if they manufacture/process feed at the facility with ingredients obtained from

another source, and the feed is then sold or transferred for final use off-farm.

To estimate the number of mixed-type facilities that grow crops or raise animals and would be subject to the proposed requirements, FDA used the 1997 USDA NASS Census of Agriculture (Ref. 6), and data obtained from various county level Cooperative Extension Service (CES) offices (Ref. 7). The Census of Agriculture provides the total number of farms producing specific commodities. To estimate the number of farms that are mixed-type

facilities, FDA used a sample of counties with information from their respective CES offices. CES offices from Clay County, KS; Monterey, Sonoma, Marin, and San Diego counties in CA; Jackson County, WI; Gillespie and San Saba counties in TX; Carol County, MD; and Berks County, PA provide data on the percentage of farms producing specific commodities to be considered mixed-type facilities (Ref. 7). FDA assumes that farms that produce other commodities, including vegetables

(nonorganic), other fruits, and wheat, plus feed mixing on poultry and other livestock farms are not mixed-type facilities based on CES interviews (Ref. 7). Table 7 of this document lists the numbers and percent of farms that are mixed-type by commodities. Some commodities that are not processed on mixed-type facilities are not included in the table. The total estimate of affected mixed-type facilities is 25,365. FDA requests comments on these assumptions and estimates.

TABLE 7.—COUNT OF MIXED-TYPE FACILITIES THAT ENGAGE IN FARMING AND THAT WOULD BE REQUIRED TO REGISTER UNDER OPTION 2.

| Commodity                             | Facility Number | Percent Mixed Use | Mixed Use Number |
|---------------------------------------|-----------------|-------------------|------------------|
| Pig farms (feed mixing)               | 46,353          | 0.5               | 232              |
| Cattle (feed mixing)                  | 785,672         | 0                 | 0                |
| Poultry (feed mixing)                 | 36,944          | 0                 | 0                |
| Other animal production (feed mixing) | 110,580         | 0                 | 0                |
| Dairy                                 | 86,022          | 0                 | 43               |
| Grain, rice, and beans                | 462,877         | 0                 | 0                |
| Apples                                | 10,872          | 10                | 1,087            |
| Oranges                               | 9,321           | 10                | 932              |
| Peaches                               | 14,459          | 10                | 1,446            |
| Cherries                              | 8,423           | 10                | 842              |
| Pears                                 | 8,062           | 10                | 806              |
| Other fruit                           | 29,413          | 10                | 806              |
| Nuts                                  | 14,500          | 10                | 1,450            |
| Berries                               | 6,807           | 20                | 1,361            |
| Grapes                                | 11,043          | 20                | 2,209            |
| Olives                                | 1,363           | 3                 | 41               |
| Vegetables and melons                 | 31,030          | 0                 | 0                |
| Organic vegetables                    | 6,206           | 50                | 3,103            |
| Honey                                 | 7,688           | 50                | 3,844            |
| Syrup                                 | 4,850           | 100               | 4,850            |
| Herbs                                 | 1,776           | 10                | 178              |
| Total                                 |                 |                   | 25,365           |

Retail facilities that manufacture/process, pack, or hold food, and then transfer the food offsite also would be considered mixed-type facilities under this option. Because FDA lacks data on the number of retail facilities that manufacture/process food for distribution offsite, FDA estimated this

number using the total number of grocery stores and specialty food stores in the 2000 CBP and the 1999 Nonemployer Statistics. FDA assumes that grocery and specialty food stores also may manufacture/process food, but that convenience stores do not manufacture/process food. The 1999

Nonemployer Statistics reports the combined number of grocery and convenience stores and, separately, the number of specialty food stores. To adjust for the grouping of grocery and convenience stores, we assume that the percentage of grocery stores out of the combined number of grocery stores and



convenience stores is the same in the 2000 CBP and the 1999 Nonemployer Statistics and reduce the number of grocery and convenience stores from the 1999 Nonemployer Statistics by the percentage in the 2000 CBP. FDA then assumes that 10 percent of these retail facilities manufacture/process, in addition to direct selling to consumers. This gives a total of 10,410 affected mixed-type retail facilities. Because the number of retail facilities is large, the number of facilities covered is highly sensitive to the percentage assumed to be in mixed-type facilities. FDA requests comments on the number of attached retail facilities under Option 2.

iii. *Foreign manufacturers.* FDA estimates the number of foreign manufacturers that would be affected by the regulation from a count in FDA's OASIS database (Ref. 4). OASIS is an automated FDA system for processing and making admissibility determinations for shipments of foreign-origin FDA-regulated products seeking to enter domestic commerce. There are 125,450 foreign manufacturers in the OASIS database. Table 8 presents the number of foreign manufacturers by the type of food they manufacture/process.

TABLE 8.—NUMBER OF FOREIGN FACILITIES EXPORTING FOOD TO THE UNITED STATES IN FISCAL YEAR 1999

|                              |         |
|------------------------------|---------|
| Foods .....                  | 110,392 |
| Food additives .....         | 2,979   |
| Color additives .....        | 378     |
| Infant formula .....         | 235     |
| Vitamins .....               | 7,986   |
| Animal feeds .....           | 3,330   |
| Medicated animal foods ..... | 150     |
| Total .....                  | 125,450 |

iv. *Foreign holders.* Also covered under this regulatory option are the final food holders in the foreign country prior to export of the product. FDA does not have any information on how many foreign facilities hold foods that are to be exported to the United States. FDA, therefore, assumed that the number of foreign final holders is equal to the number of consignees, brokers, and importers of food products in the United States. The OASIS data has a count of 77,427 U.S. importers, brokers, and consignees, so FDA assumed that there are also 77,427 foreign final holders (Ref. 4). FDA requests comments on this estimate.

v. *Foreign facilities that do de minimis processing or packaging.* Facilities that do de minimis processing or packaging of the food, such as affixing a label, are also required to register. Because their processing is

minimal, these facilities are not included in the OASIS count of foreign manufacturers. To estimate the number of affected foreign facilities, FDA takes the number of packers/repackers in the FACTS database, 6,204, and adjusts it by the ratio of domestic manufacturers in FACTS to the number of foreign manufacturers in OASIS. This adjustment of 3.64, (125,450 foreign facilities divided by 34,437 domestic facilities), gives the total number of de minimis processing foreign facilities as 22,600. FDA requests comments on this estimate.

vi. *New and closing facilities.* In addition to the facilities currently in existence, in future years, new businesses will open and some existing businesses will close. These new businesses would have to register and closing businesses would have to notify FDA to cancel their registration. According to the Small Business Administration (SBA) Office of Advocacy, in 2001, about 10 percent of all businesses were new and 10 percent of businesses closed (Ref. 8). FDA assumes that the rate of new and closing businesses is the same in other countries as in the United States. Thus, in future years 10 percent of the total count of facilities will be new facilities and 10 percent of the total count of food facilities will go out of business and will need to cancel their registration.

b. *Costs—i. Market reaction.* It is expected that most firms will register correctly and on time. If most facilities do not register correctly and on time, then the costs will be higher than estimated. It is also likely that some manufacturers/processors will not register prior to attempting to introduce their products into U.S. interstate commerce, which would increase the amount of time their products are held at the port. In addition, some foreign facilities may determine that registration, in conjunction with prior notice, would make it no longer profitable to continue to manufacture/process and ship food to the United States. That is, if the expected profit from exports is projected to be less than the cost of a U.S. agent, the cost of registration, and the cost of prior notification, they would cease to export to the United States. The marginal costs and benefits that would result from these changes in manufacturer/processor behavior are estimated in the following paragraphs.

ii. *Wage rates.* FDA uses two hourly wage rates from the Bureau of Labor Statistics' National Compensation Survey (Ref. 9). These wage rates then are doubled to include overhead costs, such as office space, health insurance,

and retirement benefits. For an administrative worker, the cost per hour is \$25.10, and for a manager, who would be the owner, operator, or agent in charge, \$56.74. FDA lacks wage data specific to food industry workers in each of the foreign countries that export to the United States and thus used the wage rate for an administrative worker in the United States for the foreign wage rate. We assume that the nature of the worker and the worker's wage would be about the same in foreign countries as in the United States. In open markets where trade takes place, real wage rates tend to be equal for similar work and productivity across countries. However, FDA tests this assumption in the sensitivity analysis and re-calculates the costs if the foreign wage rate is lower than the domestic wage rate.

iii. *First year costs incurred by domestic facilities.* Domestic facilities would incur administrative and form-associated costs to comply with the regulation. The administrative costs would be partially shared between the registration and recordkeeping rules. FDA estimates administrative costs for the recordkeeping regulation and this proposed rule separately, but this probably gives an overestimate of administrative costs. Although recordkeeping has different requirements than registration, it would affect many of the same facilities and FDA expects that the recordkeeping final rule will be published soon after the registration final rule. Individuals from facilities affected by both regulations would most likely search for information for both regulations at the same time and find information in the same places.

There are four steps associated with a domestic facility complying with the regulation. One, the facility becomes aware of the regulation; two, the facility learns what the requirements are; three, an administrative worker fills out the form; and four, the owner, operator, or agent in charge certifies the form.

First, the facility becomes aware of the regulation through normal business activities; reading trade press or industry news; FDA outreach; or conversations with other business operators. Because facility owners, operators, or agents-in-charge must be aware of the requirement to change their activity, FDA assumes that becoming aware of the regulations would occur as part of normal business practice and we thus have included no economic costs for the facility. There may be costs incurred, however, by FDA or trade organizations to undertake the outreach. FDA costs will be considered in a separate section. FDA does not quantify

the costs undertaken by trade organizations, but discusses these costs in the qualitative costs section.

Second, once a representative of the facility becomes aware of the regulations, he or she would need to research the requirements of the regulation. This would require finding a copy of the requirements and reading and understanding them. Representatives of the facility may find a copy of these requirements on the Internet, in the **Federal Register**, in trade association meetings or mailings, or at a library. Several comments stated that many businesses might not have access to the Internet. Administrative costs would be higher for facilities that do not have access to the Internet, and would have to write to FDA or find other sources of information. In the United States, 59.10 percent of the population has accessed the Internet at least once in the three months prior to being surveyed (Ref. 11). An SBA report (Ref. 12) cites two studies that report 40 and 47 percent of small businesses had Internet access in 1998. An updated report from Dun and Bradstreet in 2002 reports 71 percent of small businesses have Internet access (Ref. 13).

Electronic registration will allow facilities an immediate confirmation and registration number. FDA believes that most domestic facilities with Internet access will register electronically. However, some may register on paper forms they receive from trade organizations, newsletters, or other sources. However, FDA believes that this number of paper submissions will be offset by registrants that choose to register electronically who do not have Internet access at their place of business. These registrants may use computers with Internet access belonging to libraries, friends, or in an Internet café. Therefore, FDA assumes that 71 percent of domestic registrants will research and register electronically. FDA estimates it would take facilities with Internet access 1 hour to research the requirements and facilities without Internet access 2 hours. FDA requests comments on this assumption.

Third, once the requirements are understood, the form has to be filled out and sent to FDA, either by mail or electronically. FDA estimates it would take 45 minutes of an administrative worker's time to find the correct information and fill out the form.

Fourth, the owner, operator, or agent in charge must verify the form. This cost would be 15 minutes of the owner, operator, or agent in charge's time.

*iv. Domestic facilities updates, cancellations, and new registrations (annual costs).* Facilities are required to

update their registration when a change occurs in any information previously submitted on the registration form. Several comments suggested the requirement to update registrations might be burdensome because some information such as product lines and facility names change frequently and, therefore, could require frequent changes to registrations. FDA does not have any data on how often changes in product lines or other information included in the registration submission would occur. However, given that 10 percent of facilities go out of business each year, FDA estimates that a higher percentage, 20 percent, of all facilities will have to update their registration each year. FDA requests comments on this assumption. FDA also considers an alternative option (option 5) where product codes are not included on the registration form.

To update a registration, a worker at the facility will have to find a copy of the form, look up the facility's registration number, fill out the form, and the owner, operator, or agent in charge will have to verify the form to update a submission. The cost to the facility of updating would be 45 minutes of an administrative worker's time and 15 minutes of a manager's time to certify the changed registration.

New facilities would incur the same costs to learn about the regulation and fill out the registration form in future years as existing facilities experience in the first year. FDA estimates the number of new facilities entering each year would be equal to 10 percent of the total current number of facilities. Thus, the annual cost for registering new facilities would equal 10 percent of the first year costs to existing facilities.

Facilities that go out of business would need to notify FDA of the cancellation of their registration. Similar to updating registration, a worker at the facility will have to find a copy of the form, look up their registration number, fill out the form, and the owner, operator, or agent in charge will have to verify the form to cancel a registration. The cost to the facility of canceling the registration would be 45 minutes of an administrative worker's time to find and fill out the form and 15 minutes of a manager's time to cancel the registration. FDA estimates that 10 percent of the total, current number of facilities would go out of business each year. Table 9 presents a summary of domestic facilities covered under option 2, and table 10 summarizes the data used to estimate the cost of complying with option 2.

TABLE 9.—NUMBER OF DOMESTIC FACILITIES COVERED UNDER OPTION 2

|  |         |
|--|---------|
| 2000 CBP                                     | 103,125 |
| 1999 Nonemployer statistics                  | 68,424  |
| Mixed-type facilities that engage in farming | 25,365  |
| Retail processors                            | 10,410  |
| Total domestic                               | 207,324 |

TABLE 10.—SUMMARY OF COSTS FOR DOMESTIC FACILITIES UNDER OPTION 2

|  |              |
|--|--------------|
| Administrative worker wage (includes overhead) | 25.1         |
| Manager wage (includes overhead)               | 56.74        |
| Percent with Internet access US                | 71%          |
| Research time with Internet (hours)            | 1            |
| Research time without Internet (hours)         | 2            |
| Research cost with Internet                    | \$3,695,000  |
| Research cost without Internet                 | \$3,018,000  |
| Administrative time for form (hours)           | 0.75         |
| Manager time for form (hours)                  | 0.25         |
| Form costs                                     | \$6,844,000  |
| Percent of businesses going out of business    | 10%          |
| Percent of businesses entering                 | 10%          |
| Percent of businesses with changes             | 20%          |
| Annual facility costs                          | \$3,409,000  |
| Total domestic costs                           | \$13,557,000 |

*v. Foreign facility first year costs.* FDA expects foreign facilities to go through the same four steps to comply with the regulation as domestic facilities: a worker must become aware of the regulation, learn the requirements, and fill out the form; the owner, operator, or agent in charge then must verify the form. There are additional fifth and sixth steps for foreign facilities to find, and then hire a U.S. agent. To estimate the cost of registration for foreign facilities, FDA assumes that they would incur the same per facility costs as

domestic facilities, plus additional costs.

Costs would be higher for many foreign facilities than for domestic facilities at each step due to distance, language difficulties, and lack of Internet access. For some foreign facilities, it may be so difficult to become informed about the regulation, that rather than become informed about the requirements before shipping, some are likely to learn about the requirements at the U.S. port. For these foreign facilities, the cost of learning about the registration requirement would be a possible loss of value to their product due to a delay at the port, storage costs, and transaction costs associated with the delay.

Foreign facilities may learn about the requirements through trade press, importers, U.S. business or trading partners, distributors, or their governments. Foreign facilities, like domestic facilities, then would have to find the requirements of the regulation, obtain the registration form either electronically or in hard copy, and fill out and verify the form. Costs for foreign facilities would vary depending on whether the worker entering the registration information or the owner, operator, or agent in charge of the foreign facility can read and write in English. Comments suggest that many foreign manufacturers are limited in their ability to read and write in English. Estimates of the number of people outside of countries where English is the primary language, who are able to speak English fluently vary widely, ranging from 300 to 750 million (Ref. 14).

To find the number of English speakers outside of the United States, FDA adds the number of English speakers in countries where English is the primary language, excluding the United States, 151 million, the number of English speakers in countries where English is a secondary language, 300 million, and the midpoint, 525 million, of the range of the estimate of the number of speakers of English as a foreign language. FDA then divides this total number of English speakers by the world population minus the U.S. population, 5.9 billion (Ref. 15). Therefore, FDA assumes that 16 percent of foreign manufacturers read and write English well enough to research the registration requirement and fill out the form. FDA requests comments on this assumption. Registrants who do not read and write English would have to hire a translator to aid them in registering and understanding the registration requirements. Alternatively, trade groups, distributors, or the

Government may provide translation services. Regardless of whether the translation is paid for directly by the registrant or a third party, for ease of computation, we assume there is a cost per registration for translation for 84 percent of foreign facilities. FDA assumes it would take facility operators who do not understand English one additional hour to fill out the form, 5 additional hours to find an agent, and 5 additional hours to read and understand the registration requirements. FDA requests comments on these assumptions.

Whether a foreign facility has access to the Internet will determine, in part, the cost of learning about and complying with the registration requirements. Although 71 percent of the small businesses in the United States have Internet access, only 3 percent of the population of China, the country that has the largest number of manufacturers that export to the United States, has access to the Internet (Ref. 11). To get an idea of how many manufacturers that export to the United States have access to the Internet, FDA looked at Internet access for the 26 countries that represent 80 percent of the manufacturers that export to the United States (Ref. 4) and the percent of the population that has access to the Internet worldwide for the remaining 20 percent. A weighted average of these 26 countries by the number of manufacturers suggests that 26 percent of the population that exports to the United States has Internet access. FDA lacks data on the percent of businesses in other countries with Internet access. Because businesses are more likely to have Internet access than individuals, FDA adjusts the percent of the populations of other countries with Internet access upward by the percent difference in Internet access between individuals and small businesses in the United States. Seventy-one percent of small businesses in the United States have Internet access versus 59 percent of the population, or the percent of businesses with Internet access represents a 20 percent increase over the population. Applying this adjustment to Internet access in foreign countries increases the percent of businesses with Internet access from 26 to 31 percent. FDA therefore assumes that 31 percent of foreign manufacturers would register electronically. In option 7, FDA considers how many facilities will be registered electronically if the U.S. agent is able to register on behalf of the foreign facility. Table 11 provides a summary of the 26 countries and the percentage of their population with

Internet access. The remaining 69 percent would either register by mail or would be aided in registering electronically.

Regardless of whether the cost of obtaining Internet access is borne by the facility, or by a third party, for ease of computation, FDA estimates the cost per facility. FDA expects it will be more difficult for foreign facilities that do not have Internet access at their place of business than domestic facilities to access the Internet elsewhere due to the overall lower level of Internet access in foreign countries. FDA assumes it would take facility operators that do not have access to the Internet, one additional hour to fill out the form, 5 additional hours to find an agent, and 5 additional hours to find, read, and understand the registration requirements. FDA requests comments on these assumptions.

TABLE 11.—PERCENT OF THE POPULATION WITH INTERNET ACCESS FOR THE 26 COUNTRIES THAT ARE HOME TO 80 PERCENT OF FOOD EXPORTERS TO THE UNITED STATES

| Country   | Percent of Total Manufacturers | Percent of Population With Internet Access |
|---|--------------------------------|--|
| China (mainland) ..                                 | 9.05                           | 2.92                                       |
| France .....  | 8.61                           | 28.39                                      |
| Italy .....   | 7.96                           | 33.37                                      |
| Canada .....  | 7.78                           | 52.79                                      |
| Japan .....   | 7.69                           | 40.43                                      |
| Mexico .....  | 6.24                           | 3.38                                       |
| United Kingdom ....                                 | 3.80                           | 59.88                                      |
| Germany, Federal Republic of.                       | 3.30                           | 36.37                                      |
| Taiwan, Republic Of China.                          | 2.96                           | 51.85                                      |
| Korea, Republic Of (South).                         | 2.95                           | 46.40                                      |
| India .....   | 2.76                           | 0.67                                       |
| Spain .....   | 2.56                           | 19.69                                      |
| Thailand .....                                      | 2.39                           | 1.96                                       |
| Netherlands .....                                   | 1.40                           | 58.07                                      |
| Australia .....                                     | 1.30                           | 54.38                                      |
| Philippines .....                                   | 1.29                           | 2.46                                       |
| Hong Kong .....                                     | 1.26                           | 59.58                                      |
| Chile .....   | 1.21                           | 20.02                                      |
| Poland .....  | 1.19                           | 16.57                                      |
| Brazil .....  | 1.18                           | 7.74                                       |
| Indonesia .....                                     | 1.06                           | 1.93                                       |
| Belgium .....                                       | 0.89                           | 33.14                                      |
| Switzerland .....                                   | 0.86                           | 46.82                                      |
| Portugal .....                                      | 0.85                           | 34.37                                      |
| Vietnam .....                                       | 0.83                           | 0.49                                       |
| Rest of the world ..                                | 20.00                          | 9.57                                       |
| Weighted average .....                              |                                | 25.50                                      |
| Business adjustment .....                           |                                | 20.34                                      |
| Percent of foreign facilities with Internet access. |                                | 30.69                                      |

vi. *Foreign facility costs to hire a U.S. agent.* The U.S. agent is a person residing or maintaining a place of business in the United States, whom the owner, operator, or agent in charge of a foreign facility designates as its agent. Only one U.S. agent per foreign facility is permitted. The U.S. agent acts as a communications link between the FDA and the facility and FDA would consider providing information to the U.S. agent the same as providing information directly to the foreign facility.

In option 7, facilities can designate their U.S. agent as their agent in charge of the facility for purposes of registration and the agent can register in behalf of the facility. The costs and benefits of permitting the U.S. agent to register on behalf of the facility are considered in option 7.

FDA has little information on how many foreign facilities already have a U.S. agent. Comments stated that many exporters do not currently have a U.S. agent; they would have to hire an agent in response to the regulation. FDA expects, however, that some foreign facilities already have a U.S. representative that can function as a U.S. agent. The U.S. representative may be a business partner, broker, U.S. lawyer, or parent company. FDA assumes that the likelihood that a foreign facility has an existing U.S. agent is related directly to the quantity of product the foreign facility exports to the United States.

To estimate the number of foreign facilities that already have a U.S. agent, FDA assumes that manufacturers/processors that do more business in the United States are more likely to have an existing U.S. agent. To estimate the amount of product a foreign manufacturer/processor exports to the United States, FDA estimates the number of line entries exported to the United States by foreign manufacturers. The term "line entry" refers to a group of products that are subject to the same FDA admissibility decision because they have the same FDA product code, brand name, size or packaging, manufacturer/processor, shipper, consignee, importer's product description, and country of production. One shipment may contain multiple line entries.

FDA used data from OASIS on the average number of line entries and the average number of manufacturers/processors (listed in OASIS under the category "manufacturers") by country and product code to estimate the number of line entries for foreign manufacturers/processors. A shortcoming of these data is that entries

are by product code; thus, manufacturers/processors that are exporting products in more than one product code are in the count of manufacturers/processors for every product code in which they export. A product code designates a category of product, such as cheese and cheese products. The OASIS data consequently have approximately twice as many manufacturers/processors as actually exist. To adjust for this double-counting, FDA assumed the average foreign manufacturer/processor exports in two product categories. To find an approximate number of line entries per manufacturer, FDA divided the total number of manufacturers/processors into the total number of line entries for each country and applied the average number of line entries per manufacturer/processor to all the manufacturers/processors from that country. This method will underestimate the number of very small and very large manufacturers/processors, because it removes the variation in number of line entries exported from countries with a large number of manufacturers/processors exporting to the United States.

To estimate the number of foreign facilities that would have to hire a U.S. agent, FDA assumed that foreign facilities that export more than 100 line entries each year into the United States, or 10 percent of foreign manufacturers/processors, already have a U.S. representative who can function as a U.S. agent. FDA also assumed that the 16 percent of manufacturers/processors that are exporting 10 or fewer line entries to the United States would stop exporting to the United States, rather than incur the expense of registering, hiring a U.S. agent, and providing prior notice under 21 CFR part 1, subpart I. FDA requests comments on these assumptions. Table 12 presents average numbers of line entries and the percent of foreign manufacturers/processors that export that number.

TABLE 12.—AVERAGE NUMBER OF LINE ENTRIES FROM FOREIGN MANUFACTURERS/PROCESSORS

| Average Number of Line Entries | Percent of Total Number of Foreign Manufacturers/Processors | Cumulative Percent of Manufacturers/Processors |
|--------------------------------|---|--|
| ≤10 .....                      | 15.81   | 15.81  |
| 11–20 .....                    | 25.43   | 41.24  |
| 21–40 .....                    | 32.27   | 73.51  |

TABLE 12.—AVERAGE NUMBER OF LINE ENTRIES FROM FOREIGN MANUFACTURERS/PROCESSORS—Continued

| Average Number of Line Entries | Percent of Total Number of Foreign Manufacturers/Processors | Cumulative Percent of Manufacturers/Processors |
|--------------------------------|---|--|
| 41–60 .....                    | 7.30  | 80.81  |
| 61–80 .....                    | 5.88  | 86.69  |
| 81–100 .....                   | 3.64  | 90.33  |
| 101–120 .....                  | 1.78  | 92.11  |
| 121–140 .....                  | 0.72  | 92.83  |
| 141–160 .....                  | 1.59  | 94.42  |
| 161–180 .....                  | 0.48  | 94.90  |
| 181–200 .....                  | 0.83  | 95.73  |
| >200 .....                     | 4.27  | 100.00   |

FDA anticipates that foreign facilities would find U.S. agents through the Internet or business contacts. Finding and hiring an agent would result in labor costs for the facility. FDA requests comments on these assumptions.

FDA bases the estimated cost of hiring a U.S. agent on the fees charged by U.S. agents for foreign drug, biologic, and device manufacturers. The requirements for a U.S. agent for drugs, biologics, and devices (parts 207, 607, and 807, respectively) are very similar to the requirements for a U.S. agent for foods in this proposed regulation, and many of the U.S. agents began working as a response to the drug, biologic, and device foreign facility registration regulations. FDA contacted some active U.S. agents, whose annual cost estimates for their services ranged from \$700 to \$2,000 (Refs. 16 and 17).

vii. *Annual costs for foreign facilities.* Foreign facilities have to retain a U.S. agent. In the first year, the facility would incur costs to hire and retain an agent. In future years, the facility would have to pay an annual fee of approximately one thousand dollars to the agent.

Like domestic facilities, foreign facilities are required to update their registration when a change occurs in any of the information previously submitted. FDA estimates the frequency of registration updates for foreign facilities as 20 percent per year. FDA requests comments on this assumption. The cost to the facility of updating would be 1 hour to find and fill out the form, including translation if necessary, and to certify the changed registration.

New facilities would incur the same costs to learn about the regulation, hire a U.S. agent, and fill out the registration information in future years as existing facilities would incur in the first year.

FDA estimates the number of new facilities entering each year would be equal to 10 percent of the total current number of facilities. Thus, the annual cost for registration of new foreign facilities would equal 10 percent of the first year cost to facilities.

Facilities that go out of business would need to notify FDA of the cancellation of their registration. The cost to the facility of canceling the registration would be the wage rate times 1 hour to cancel the registration. FDA estimates that 10 percent of the total, current number of facilities would go out of business each year. Table 13 presents a summary of the data used to estimate the cost to foreign facilities to comply with option 2.

TABLE 13.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 2

|                                  |         |
|----------------------------------|---------|
| Foreign holders and packagers    | 100,027 |
| Foreign manufacturers/processors | 125,450 |
| Stops exporting                  | 16%     |
| Total facilities                 | 205,405 |

TABLE 14.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 2

|                                  |               |
|----------------------------------|---------------|
| Speaks English                   | 16%           |
| Has Internet access              | 31%           |
| Has U.S. agent                   | 10%           |
| Cost of U.S. agent (annual)      | \$1,000       |
| Hourly wage rate                 | \$25          |
| Time to find agent (hours)       | 5             |
| Additional time language (hours) | 5             |
| Additional time Internet (hours) | 5             |
| First year agent cost            | \$67,340,000  |
| Agent fee (annual cost)          | \$194,868,000 |
| Administrative time (hours)      | 1             |
| Additional time language (hours) | 5             |
| Additional time Internet (hours) | 5             |
| First year administrative costs  | \$44,418,929  |
| Time to fill out form (hours)    | 1             |

TABLE 14.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 2—Continued

|   |               |
|---|---------------|
| Additional time language (hours)            | 1             |
| Additional time Internet (hours)            | 1             |
| Percent of businesses going out of business | 10%           |
| Percent of businesses entering              | 10%           |
| Percent of businesses with changes          | 20%           |
| First year form cost                        | \$12,992,000  |
| Total first year costs                      | \$319,619,000 |
| Total annual costs                          | \$228,370,000 |

viii. *Cost due to port delays.* FDA anticipates that some foreign facilities would not learn of the requirements before shipping their products to the United States. The administrative costs of learning about the registration requirements for these foreign facilities would be the cost of finding out at the port of entry. FDA requests comment on the percentage of foreign facilities that would become aware of the registration requirement at the U.S. port of entry. For these facilities, the cost of complying would be the possible one-time loss of value of their shipment and other costs of delay, in addition to the cost of registering and finding and hiring a U.S. agent. FDA estimates the cost to foreign facilities of becoming informed about the regulatory requirement is the number of foreign facilities multiplied by either the cost of information, re-exporting the shipment, or a delayed shipment at the U.S. port, whichever is lower.

FDA must hold shipments at the U.S. port for as long as it takes the foreign facility to register with FDA. To register, a foreign facility first must be informed of the delay at the port by the importer, consignee, owner, or transporter. This may happen very quickly via a phone call or e-mail message, or take hours if there is a large difference in time zones. Next, the foreign facility must find and hire a U.S. agent, if it does not already have one. If the foreign facility is open during U.S. business hours and has access to the Internet and a fax machine to find an agent and sign a contract, it may find an agent quickly. If the foreign facility is not in a time zone compatible with customary business hours in the United States or does not have easy access to the Internet or fax machine, finding and hiring an agent may take

longer. The cost of the delay to the foreign facility is the cost of storing the shipment and loss of value of the shipment due to the delay. For perishable products, a delay may reduce the value of the shipment significantly, perhaps even to zero. For nonperishable products, there may be transaction costs due to cancellation of a contract and finding a new buyer. FDA expects that to the extent there are significant port delays, they typically will occur with food manufactured/processed, packed or held at facilities that ship infrequently to the United States. Delays also will be longer and more likely for shipments from facilities that are more distant from the United States or have difficulty communicating with the United States. Perishables, due to their short shelf life, are more likely to be shipped from countries that are geographically close to the United States. For these reasons, FDA expects that costs arising from delays for nonperishable products may be as high or higher than costs arising from perishable products. FDA requests comments on the length of delay for shipments held while waiting for the foreign facility to register and on the costs of the delay, such as loss of product value, storage costs, and transaction costs.

ix. *FDA costs.* FDA's costs include creating and maintaining a database, processing paper submissions, and sending annual mailings to registrants. Developing and maintaining a database includes automatically entering registrations into the database that arrive electronically and sending an electronic receipt and facility registration number back to the registrant. FDA estimates that four full time employees (FTEs) would be needed to oversee the database. An employee's wage is estimated to be equal to a GS-12, step one, in the Washington, DC metro area, which is \$55,924 per year (Ref. 10). To get the cost of the labor to FDA, FDA doubles the wage rate to include overhead costs, such as health insurance, office space, and retirement benefits. Additionally, paper submissions would have to be entered manually, at an estimated cost of \$10 per submission. FDA estimates that facilities that do not have access to the Internet would submit paper registrations. FDA also estimates a 10 percent error rate for paper submissions based on estimates of error rates for another FDA database (Ref. 18). Each paper submission with an error will result in an additional cost for mailing and re-processing. FDA intends to send an annual e-mail or mailing to all

registrants reminding them to keep their registrations up-to-date and verifying the mailing addresses of the registrants.

FDA presents costs for the first 5 years in table 15 of this document. Wage rates and paper submission costs are

increased by 3 percent each year to account for inflation. Annual costs are discounted at 7 percent.

TABLE 15.—YEARLY COST ESTIMATE FOR FDA UNDER OPTION 2

| FDA Costs  | 2003         | 2004        | 2005        | 2006        | 2007        |
|--|--------------|-------------|-------------|-------------|-------------|
| Development/modification/enhancement               | \$8,200,000  | \$3,000,000 | \$3,300,000 | \$2,300,000 | \$2,300,000 |
| Maintenance/steady state                           | \$1,560,000  | \$3,500,000 | \$4,300,000 | \$4,300,000 | \$4,300,000 |
| Number of FTEs                                     | 4            | 4           | 4           | 2           | 2           |
| Cost per FTE                                       | \$110,588    | \$110,588   | \$110,588   | \$110,588   | \$110,588   |
| Cost per paper submission                          | \$10         | \$10.00     | \$10.00     | \$10.00     | \$10.00     |
| Number of domestic paper submissions               | 60,124       | 24,050      | 24,050      | 24,050      | 24,050      |
| Number of foreign paper submissions                | 22,677       | 9,071       | 9,071       | 9,071       | 9,071       |
| Total number of domestic registrations in database | 207,324      | 207,324     | 207,324     | 207,324     | 207,324     |
| Total number of foreign registrations in database  | 205,405      | 205,405     | 205,405     | 205,405     | 205,405     |
| Mailings to domestic facilities                    | \$1          | \$1.00      | \$1.00      | \$1.00      | \$1.00      |
| Mailings to foreign facilities                     | \$1          | \$1.00      | \$1.00      | \$1.00      | \$1.00      |
| Error rate for paper submissions                   | 10%          | 10%         | 10%         | 10%         | 10%         |
| Number of errors                                   | 8,280        | 3,312       | 3,312       | 3,312       | 3,312       |
| Cost per error                                     | \$15         | \$15.00     | \$15.00     | \$15.00     | \$15.00     |
| Total costs  | \$11,279,000 | \$7,398,000 | \$8,498,000 | \$7,276,000 | \$7,276,000 |
| Discounted total costs                             | \$11,279,000 | \$6,914,000 | \$7,422,000 | \$5,939,000 | \$5,551,000 |

### 3. Option Three: Require Registration of Domestic and Foreign Facilities That Manufacture/Process, Pack, or Hold Food That Sell Their Products in Interstate Commerce, Including Mixed-Type Facilities

Option three has the same requirements as option two, but does not require domestic facilities that participate only in intrastate commerce to register. FDA tentatively concludes that this option is not legally viable. The Bioterrorism Act does not seem to limit the scope of the statute to facilities that engage only in interstate commerce. Tables 16, 17, 18, 19, and 20 of this document provide a summary of the data for cost estimates under option 3 for domestic facilities, foreign facilities, and FDA, respectively.

Excluding intrastate facilities would lower the number of affected, domestic facilities from 207,324 affected facilities under option two to 107,646. This would lower the first year cost for domestic facilities from \$13.6 to \$7.0 million dollars. The annual cost would be lowered from \$3.4 to \$1.8 million dollars. Total first year costs would be

lowered from \$344.5 to \$337.6 million dollars.

TABLE 16.—NUMBER OF DOMESTIC FACILITIES COVERED UNDER OPTION 3

|                   |         |
|-------------------|---------|
| FACTS data        | 71,871  |
| Mixed-type farms  | 25,365  |
| Retail processors | 10,410  |
| Total domestic    | 107,646 |

TABLE 17.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 3

|  |       |
|--|-------|
| Administrative worker wage (includes overhead) | 25.1  |
| Manager wage (includes overhead)               | 56.74 |
| Percent with Internet access US                | 71%   |
| Research time with Internet (hours)            | 1     |

TABLE 17.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 3—Continued

|   |             |
|---|-------------|
| Research time without Internet (hours)      | 2           |
| Research cost with Internet                 | \$1,918,000 |
| Research cost without Internet              | \$1,567,000 |
| Administrative time for form (hours)        | 0.75        |
| Manager time for form (hours)               | 0.25        |
| Form costs                                  | \$3,553,000 |
| Percent of businesses going out of business | 10%         |
| Percent of businesses entering              | 10%         |
| Percent of businesses with changes          | 20%         |
| Annual facility costs                       | \$1,770,000 |
| Total domestic costs                        | \$7,038,000 |

TABLE 18.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 3

|                                  |         |
|----------------------------------|---------|
| Foreign holders and packagers    | 100,027 |
| Foreign manufacturers/processors | 125,450 |
| Stops exporting                  | 16%     |
| Total facilities                 | 205,405 |

TABLE 19.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 3

|                             |         |
|-----------------------------|---------|
| Speaks English              | 16%     |
| Has Internet access         | 31%     |
| Has U.S. agent              | 10%     |
| Cost of U.S. agent (annual) | \$1,000 |
| Hourly wage rate            | \$25    |

TABLE 19.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 3—Continued

|                                  |               |
|----------------------------------|---------------|
| Time to find agent (hours)       | 5             |
| Additional time language (hours) | 5             |
| Additional time Internet (hours) | 5             |
| First year agent cost            | \$67,340,000  |
| Agent fee (annual cost)          | \$194,868,000 |
| Administrative time (hours)      | 1             |
| Additional time language (hours) | 5             |
| Additional time Internet (hours) | 5             |
| First year administrative costs  | \$44,418,929  |

TABLE 19.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 3—Continued

|   |               |
|---|---------------|
| Time to fill out form (hours)               | 1             |
| Additional time language (hours)            | 1             |
| Additional time Internet (hours)            | 1             |
| Percent of businesses going out of business | 10%           |
| Percent of businesses entering              | 10%           |
| Percent of businesses with changes          | 20%           |
| First year form cost                        | \$12,992,000  |
| Total first year costs                      | \$319,619,000 |
| Total annual costs                          | \$228,370,000 |

TABLE 20.—COSTS INCURRED BY FDA UNDER OPTION 3

| FDA Costs  | 2003         | 2004        | 2005        | 2006        | 2007        |
|--|--------------|-------------|-------------|-------------|-------------|
| Development/modification/enhancement               | \$8,200,000  | \$3,000,000 | \$3,300,000 | \$2,300,000 | \$2,300,000 |
| Maintenance/steady state                           | \$1,560,000  | \$3,500,000 | \$4,300,000 | \$4,300,000 | \$4,300,000 |
| Number of FTEs                                     | 4            | 4           | 4           | 2           | 2           |
| Cost per FTE                                       | \$110,588    | \$110,588   | \$110,588   | \$110,588   | \$110,588   |
| Cost per paper submission                          | \$10         | \$10        | \$10        | \$10        | \$10        |
| Number of domestic paper submissions               | 31,217       | 12,487      | 12,487      | 12,487      | 12,487      |
| Number of foreign paper submissions                | 22,677       | 9,071       | 9,071       | 9,071       | 9,071       |
| Total number of domestic registrations in database | 107,646      | 107,646     | 107,646     | 107,646     | 107,646     |
| Total number of foreign registrations in database  | 205,405      | 205,405     | 205,405     | 205,405     | 205,405     |
| Mailings to domestic facilities                    | \$1          | \$1         | \$1         | \$1         | \$1         |
| Mailings to foreign facilities                     | \$1          | \$1         | \$1         | \$1         | \$1         |
| Error rate for paper submissions                   | 10%          | 10%         | 10%         | 10%         | 10%         |
| Number of errors                                   | 5,389        | 2,156       | 2,156       | 2,156       | 2,156       |
| Cost per error                                     | \$15         | \$15        | \$15        | \$15        | \$15        |
| Total costs  | \$10,907,000 | \$7,243,000 | \$8,343,000 | \$7,122,000 | \$7,122,000 |
| Discounted total costs                             | \$10,907,000 | \$6,769,000 | \$7,287,000 | \$5,814,000 | \$5,433,000 |

4. Option Four: Require Registration of Domestic and Foreign Facilities That Manufacture/Process, Pack, or Hold Food That Sell Their Products in Interstate and Intrastate Commerce, Not Including Mixed-Type Facilities

Option four has the same registration and U.S. agent requirements as option two, but does not require mixed-type facilities to register. Tables 21, 22, 23, 24, and 25 provide a summary of the data for cost estimates under option 4 for domestic facilities, foreign facilities, and FDA, respectively.

FDA does not believe this option is legally viable, since some mixed-type facilities engage in activities (such as manufacturing/processing for commercial distribution) that are clearly within the scope of the registration requirement as enacted by Congress. Nevertheless, we are including a discussion of this option for comparison purposes.

Excluding mixed-type facilities lowers the number of affected domestic facilities, from 207,324 affected facilities under option 2 to 171,549. This would lower the first year cost for domestic facilities from \$13.6 to \$11.2 million dollars. The annual cost for domestic facilities would be lowered from \$3.4 to \$2.8 million. Total first year costs would be lowered from \$344.5 to \$342.0 million dollars.

TABLE 21.—NUMBER OF DOMESTIC FACILITIES COVERED UNDER OPTION 4

|                             |         |
|-----------------------------|---------|
| 2000 CBP                    | 103,125 |
| 1999 Nonemployer statistics | 68,424  |
| Total domestic              | 171,549 |

TABLE 22.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 4

|  |      |
|--|------|
| Administrative worker wage (includes overhead) | 25.1 |
|--|------|

TABLE 22.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 4—Continued

|   |              |
|---|--------------|
| Manager wage (includes overhead)            | 56.74        |
| Percent with Internet access US             | 71%          |
| Research time with Internet (hours)         | 1            |
| Research time without Internet (hours)      | 2            |
| Research cost with Internet                 | \$3,057,000  |
| Research cost without Internet              | \$2,497,000  |
| Administrative time for form (hours)        | 0.75         |
| Manager time for form (hours)               | 0.25         |
| Form costs                                  | \$5,663,000  |
| Percent of businesses going out of business | 10%          |
| Percent of businesses entering              | 10%          |
| Percent of businesses with changes          | 20%          |
| Annual facility costs                       | \$2,821,000  |
| Total domestic costs                        | \$11,217,000 |

TABLE 23.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 4

|                                  |         |
|----------------------------------|---------|
| Foreign holders and packagers    | 100,027 |
| Foreign manufacturers/processors | 125,450 |
| Stops exporting                  | 16%     |
| Total facilities                 | 205,405 |

TABLE 24.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 4

|   |               |
|---|---------------|
| Speaks English                              | 16%           |
| Has Internet access                         | 31%           |
| Has U.S. agent                              | 10%           |
| Cost of U.S. agent (annual)                 | \$1,000       |
| Hourly wage rate                            | \$25          |
| Time to find agent (hours)                  | 5             |
| Additional time language (hours)            | 5             |
| Additional time Internet (hours)            | 5             |
| First year agent cost                       | \$67,340,000  |
| Agent fee (annual cost)                     | \$194,868,000 |
| Administrative time (hours)                 | 1             |
| Additional time language (hours)            | 5             |
| Additional time Internet (hours)            | 5             |
| First year administrative costs             | \$44,418,929  |
| Time to fill out form (hours)               | 1             |
| Additional time language (hours)            | 1             |
| Additional time Internet (hours)            | 1             |
| Percent of businesses going out of business | 10%           |
| Percent of businesses entering              | 10%           |
| Percent of businesses with changes          | 20%           |
| First year form cost                        | \$12,992,000  |
| Total first year costs                      | \$319,619,000 |
| Total annual costs                          | \$228,370,000 |

TABLE 25.—COSTS INCURRED BY FDA UNDER OPTION 4

| FDA Costs                            | 2003        | 2004        | 2005        | 2006        | 2007        |
|--------------------------------------|-------------|-------------|-------------|-------------|-------------|
| Development/modification/enhancement | \$8,200,000 | \$3,000,000 | \$3,300,000 | \$2,300,000 | \$2,300,000 |
| Maintenance/steady state             | \$1,560,000 | \$3,500,000 | \$4,300,000 | \$4,300,000 | \$4,300,000 |
| Number of FTEs                       | 4           | 4           | 4           | 2           | 2           |
| Cost per FTE                         | \$110,588   | \$110,588   | \$110,588   | \$110,588   | \$110,588   |
| Cost per paper submission            | \$10        | \$10        | \$10        | \$10        | \$10        |
| Number of domestic paper submissions | 49,749      | 19,900      | 19,900      | 19,900      | 19,900      |



TABLE 25.—COSTS INCURRED BY FDA UNDER OPTION 4—Continued

| FDA Costs  | 2003         | 2004        | 2005        | 2006        | 2007        |
|--|--------------|-------------|-------------|-------------|-------------|
| Number of foreign paper submissions                | 22,677       | 9,071       | 9,071       | 9,071       | 9,071       |
| Total number of domestic registrations in database | 171,549      | 171,549     | 171,549     | 171,549     | 171,549     |
| Total number of foreign registrations in database  | 205,405      | 205,405     | 205,405     | 205,405     | 205,405     |
| Mailings to domestic facilities                    | \$1          | \$1         | \$1         | \$1         | \$1         |
| Mailings to foreign facilities                     | \$1          | \$1         | \$1         | \$1         | \$1         |
| Error rate for paper submissions                   | 10%          | 10%         | 10%         | 10%         | 10%         |
| Number of errors                                   | 7,243        | 2,897       | 2,897       | 2,897       | 2,897       |
| Cost per error                                     | \$15         | \$15        | \$15        | \$15        | \$15        |
| Total costs  | \$11,145,000 | \$7,342,000 | \$8,442,000 | \$7,221,000 | \$7,221,000 |
| Discounted total costs                             | \$11,145,000 | \$6,862,000 | \$7,374,000 | \$5,894,000 | \$5,509,000 |

5. Option Five: Require Registration of Domestic and Foreign Facilities That Manufacture/Process, Pack, or Hold Food That Sell Their Products in Interstate and Intrastate Commerce for Consumption in the United States, Including Mixed-Type Facilities as Defined in Option 2, but Not Including Product Categories on the Registration Form

Option five covers the same facilities as option two, but requires less information from the registrants. Registrants still would be required to submit the facility's name, address, emergency contact information, name and address of the parent company, trade names, U.S. agent information (if a foreign facility), and the name of the owner, operator, or agent in charge of the facility, but would not be required to submit the general food product categories under § 170.3. Tables 26, 27, 28, 29, and 30 of this document provide a summary of the data for cost estimates under option 5 for domestic facilities, foreign facilities, and FDA, respectively.

Removing the product categories from the registration would decrease the frequency with which facilities have to update their registrations and reduce the amount of time required to register by 15 minutes. FDA requests comment on this estimate. FDA estimates that removing the product categories would reduce the percentage of facilities that have to update their registration from 20 percent each year to 10 percent. First year costs would be lower for foreign and domestic facilities due to facilities needing less time to fill out the form. Total first year domestic costs would be lowered from \$13.6 to \$12.3 million.

Annual costs for domestic firms would be lowered from \$3.4 to \$2.3 million due to less frequent updates. Total first year foreign costs would be lowered from \$319.6 to \$318.3 million and total costs would be raised from \$334.5 to \$341.9 million.

TABLE 26.—NUMBER OF DOMESTIC FACILITIES COVERED UNDER OPTION 5

|  |         |
|--|---------|
| 2000 CBP                                     | 103,125 |
| 1999 Nonemployer statistics                  | 68,424  |
| Mixed-type facilities that engage in farming | 25,365  |
| Retail processors                            | 10,410  |
| Total domestic                               | 207,324 |

TABLE 27.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 5

|  |             |
|--|-------------|
| Administrative worker wage (includes overhead) | 25.1        |
| Manager wage (includes overhead)               | 56.74       |
| Percent with Internet access US                | 71%         |
| Research time with Internet (hours)            | 1           |
| Research time without Internet (hours)         | 2           |
| Research cost with Internet                    | \$3,695,000 |
| Research cost without Internet                 | \$3,018,000 |

TABLE 27.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 5—Continued

|   |              |
|---|--------------|
| Administrative time for form (hours)        | 0.5          |
| Manager time for form (hours)               | 0.25         |
| Form costs                                  | \$5,543,000  |
| Percent of businesses going out of business | 10%          |
| Percent of businesses entering              | 10%          |
| Percent of businesses with changes          | 10%          |
| Annual facility costs                       | \$2,334,000  |
| Total domestic costs                        | \$12,256,000 |

TABLE 28.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 5

|                                  |         |
|----------------------------------|---------|
| Foreign holders and packagers    | 100,027 |
| Foreign manufacturers/processors | 125,450 |
| Stops exporting                  | 16%     |
| Total facilities                 | 205,405 |

TABLE 29.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES

|                     |     |
|---------------------|-----|
| Speaks English      | 16% |
| Has Internet access | 31% |
| Has U.S. agent      | 10% |

TABLE 29.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES—Continued

|                                  |               |
|----------------------------------|---------------|
| Cost of U.S. agent (annual)      | \$1,000       |
| Hourly wage rate                 | \$25          |
| Time to find agent (hours)       | 5             |
| Additional time language (hours) | 5             |
| Additional time Internet (hours) | 5             |
| First year agent cost            | \$67,340,000  |
| Agent fee (annual cost)          | \$194,868,000 |

TABLE 29.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES—Continued

|                                  |              |
|----------------------------------|--------------|
| Administrative time (hours)      | 1            |
| Additional time language (hours) | 5            |
| Additional time Internet (hours) | 5            |
| First year administrative costs  | \$44,418,929 |
| Time to fill out form (hours)    | 0.75         |
| Additional time language (hours) | 1            |

TABLE 29.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES—Continued

|   |               |
|---|---------------|
| Additional time Internet (hours)            | 1             |
| Percent of businesses going out of business | 10%           |
| Percent of businesses entering              | 10%           |
| Percent of businesses with changes          | 10%           |
| First year form cost                        | \$11,708,000  |
| Total first year costs                      | \$318,335,000 |
| Total annual costs                          | \$227,729,000 |

TABLE 30.—COSTS INCURRED BY FDA UNDER OPTION 5

| FDA Costs  | 2003         | 2004        | 2005        | 2006        | 2007        |
|--|--------------|-------------|-------------|-------------|-------------|
| Development/modification/enhancement               | \$8,200,000  | \$3,000,000 | \$3,300,000 | \$2,300,000 | \$2,300,000 |
| Maintenance/steady state                           | \$1,560,000  | \$3,500,000 | \$4,300,000 | \$4,300,000 | \$4,300,000 |
| Number of FTEs                                     | 4            | 4           | 4           | 2           | 2           |
| Cost per FTE                                       | \$110,588    | \$110,588   | \$110,588   | \$110,588   | \$110,588   |
| Cost per paper submission                          | \$10         | \$10        | \$10        | \$10        | \$10        |
| Number of domestic paper submissions               | 60,124       | 18,037      | 18,037      | 18,037      | 18,037      |
| Number of foreign paper submissions                | 22,677       | 6,803       | 6,803       | 6,803       | 6,803       |
| Total number of domestic registrations in database | 207,324      | 207,324     | 207,324     | 207,324     | 207,324     |
| Total number of foreign registrations in database  | 205,405      | 205,405     | 205,405     | 205,405     | 205,405     |
| Mailings to domestic facilities                    | \$1          | \$1         | \$1         | \$1         | \$1         |
| Mailings to foreign facilities                     | \$1          | \$1         | \$1         | \$1         | \$1         |
| Error rate for paper submissions                   | 10%          | 10%         | 10%         | 10%         | 10%         |
| Number of errors                                   | 8,280        | 2,484       | 2,484       | 2,484       | 2,484       |
| Cost per error                                     | \$15         | \$15        | \$15        | \$15        | \$15        |
| Total costs  | \$11,279,000 | \$7,294,000 | \$8,394,000 | \$7,173,000 | \$7,173,000 |
| Discounted total costs                             | \$11,279,000 | \$6,817,000 | \$7,332,000 | \$5,855,000 | \$5,472,000 |

6. Option Six: Require Registration of Domestic and Foreign Facilities That Manufacture/Process, Pack, or Hold Food That Sell Their Products in Interstate and Intrastate Commerce, Including Mixed-Type Facilities.

Mixed-type facilities that engage in farming are covered if they pack or hold food not grown or raised on that facility or manufacture/process food not for consumption on that facility. However, facilities of these types that

manufacture/process food solely for direct sale to consumers from that same facility are exempt.

A mixed-type facility performs activities of a facility that is ordinarily required to register and activities of a facility that is ordinarily exempt, such as a farm or retail facility. Mixed-type facilities that are required to register differ under options 2 and 6. In option 2, mixed-type facilities that manufacture/process food for consumption offsite, where offsite

includes both distribution directly to consumers and distribution to nonconsumers, must register. In option 6, facilities that manufacture/process food and distribute it directly to consumers would not be included in the registration requirement. Option 6 requires registration for mixed-type facilities that pack or hold food that was not grown or raised at that facility; these facilities are not included in the option 2 definition. These changes in coverage raise the total number of affected mixed-

type facilities from 25,365 to 30,497. Facilities that engage in the activities of a retail facility but also manufacture/process food and distribute it to

nonconsumers are considered as manufacturers/processors in the count of facilities in this analysis. FDA requests comment on this

categorization. Table 31 of this document shows the number of affected mixed-type facilities by category of product.

TABLE 31.—NUMBER OF AFFECTED MIXED-TYPE FACILITIES UNDER OPTION 6

| Type                                  | Number of Farms | Percent Mixed Use | Percent Mixed Use |
|---------------------------------------|-----------------|-------------------|-------------------|
| Pig farms (feed mixing)               | 46,353          | 1.5               | 695               |
| Cattle (feed mixing)                  | 785,672         | 1                 | 7,857             |
| Poultry (feed mixing)                 | 36,944          | 1                 | 369               |
| Other animal production (feed mixing) | 110,580         | 1                 | 1,106             |
| Dairy                                 | 86,022          | 1.1               | 903               |
| Grain, rice, and beans                | 462,877         | 1                 | 4,629             |
| Apples                                | 10,872          | 1.5               | 163               |
| Oranges                               | 9,321           | 1.5               | 140               |
| Peaches                               | 14,459          | 1.5               | 217               |
| Cherries                              | 8,423           | 1.5               | 126               |
| Pears                                 | 8,062           | 1.5               | 121               |
| Other fruit                           | 29,413          | 1.5               | 441               |
| Nuts                                  | 14,500          | 2                 | 290               |
| Berries                               | 6,807           | 1.5               | 102               |
| Grapes                                | 11,043          | 10.5              | 1,160             |
| Olives                                | 1,363           | 3.5               | 48                |
| Vegetables and melons                 | 31,030          | 0.5               | 155               |
| Organic vegetables                    | 6,206           | 50                | 3,103             |
| Honey                                 | 7,688           | 50                | 3,844             |
| Syrup                                 | 4,850           | 100               | 4,850             |
| Herbs                                 | 1,776           | 10                | 178               |
| Total                                 |                 |                   | 30,497            |

Tables 32, 33, 34, 35, and 36 of this document provide a summary of the data for cost estimates under option 6 for domestic facilities, foreign facilities, and FDA, respectively. The total number of affected domestic facilities under this option is 202,046. The total first year cost for domestic facilities is reduced from \$13.6 to \$13.2 million, annual cost is reduced from \$3.4 to \$3.2 million. Total first year cost is reduced from \$344.5 to \$344.1 million. The greater total cost for foreign facilities is primarily attributable to the costs associated with hiring and retaining a U.S. agent.

TABLE 32.—NUMBER OF DOMESTIC FACILITIES COVERED UNDER OPTION 6

|  |         |
|--|---------|
| 2000 CBP                                     | 103,125 |
| 1999 Nonemployer statistics                  | 68,424  |
| Mixed-type facilities that engage in farming | 30,497  |
| Total domestic                               | 202,046 |

TABLE 33.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 6

|  |             |
|--|-------------|
| Administrative worker wage (includes overhead) | 25.1        |
| Manager wage (includes overhead)               | 56.74       |
| Percent with Internet access US                | 71          |
| Research time with Internet (hours)            | 1           |
| Research time without Internet (hours)         | 2           |
| Research cost with Internet                    | \$3,601,000 |

TABLE 33.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 6—Continued

|   |              |
|---|--------------|
| Research cost without Internet              | \$2,941,000  |
| Administrative time for form (hours)        | 0.75         |
| Manager time for form (hours)               | 0.25         |
| Form costs                                  | \$6,670,000  |
| Percent of businesses going out of business | 10%          |
| Percent of businesses entering              | 10%          |
| Percent of businesses with changes          | 20%          |
| Annual facility costs                       | \$3,322,000  |
| Total domestic costs                        | \$13,212,000 |

TABLE 34.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 6

|                                  |         |
|----------------------------------|---------|
| Foreign holders and packagers    | 100,027 |
| Foreign manufacturers/processors | 125,450 |

TABLE 34.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 6—Continued

|                  |         |
|------------------|---------|
| Stops exporting  | 16%     |
| Total facilities | 205,405 |

TABLE 35.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 6

|                                  |               |
|----------------------------------|---------------|
| Speaks English                   | 16%           |
| Has Internet access              | 31%           |
| Has U.S. agent                   | 10%           |
| Cost of U.S. agent (annual)      | \$1,000       |
| Hourly wage rate                 | \$25          |
| Time to find agent (hours)       | 5             |
| Additional time language (hours) | 5             |
| Additional time Internet (hours) | 5             |
| First year agent cost            | \$67,340,000  |
| Agent fee (annual cost)          | \$194,868,000 |
| Administrative time (hours)      | 1             |

TABLE 35.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 6—Continued

|   |               |
|---|---------------|
| Additional time language (hours)            | 5             |
| Additional time Internet (hours)            | 5             |
| First year administrative costs             | \$44,418,929  |
| Time to fill out form (hours)               | 1             |
| Additional time language (hours)            | 1             |
| Additional time Internet (hours)            | 1             |
| Percent of businesses going out of business | 10%           |
| Percent of businesses entering              | 10%           |
| Percent of businesses with changes          | 20%           |
| First year form cost                        | \$12,992,000  |
| Total first year costs                      | \$319,619,000 |
| Total annual costs                          | \$228,370,000 |

TABLE 36.—COSTS INCURRED BY FDA UNDER OPTION 6

| FDA Costs  | 2003         | 2004        | 2005        | 2006        | 2007        |
|--|--------------|-------------|-------------|-------------|-------------|
| Development/modification/enhancement               | \$8,200,000  | \$3,000,000 | \$3,300,000 | \$2,300,000 | \$2,300,000 |
| Maintenance/steady state                           | \$1,560,000  | \$3,500,000 | \$4,300,000 | \$4,300,000 | \$4,300,000 |
| Number of FTEs                                     | 4            | 4           | 4           | 2           | 2           |
| Cost per FTE                                       | \$110,588    | \$110,588   | \$110,588   | \$110,588   | \$110,588   |
| Cost per paper submission                          | \$10         | \$10        | \$10        | \$10        | \$10        |
| Number of domestic paper submissions               | 58,593       | 23,437      | 23,437      | 23,437      | 23,437      |
| Number of foreign paper submissions                | 22,677       | 9,071       | 9,071       | 9,071       | 9,071       |
| Total number of domestic registrations in database | 202,046      | 202,046     | 202,046     | 202,046     | 202,046     |
| Total number of foreign registrations in database  | 205,405      | 205,405     | 205,405     | 205,405     | 205,405     |
| Mailings to domestic facilities                    | \$1          | \$1         | \$1         | \$1         | \$1         |
| Mailings to foreign facilities                     | \$1          | \$1         | \$1         | \$1         | \$1         |
| Error rate for paper submissions                   | 10%          | 10%         | 10%         | 10%         | 10%         |
| Number of errors                                   | 5,860        | 2,345       | 2,345       | 2,345       | 2,345       |
| Cost per error                                     | \$15         | \$15        | \$15        | \$15        | \$15        |
| Total costs  | \$11,225,000 | \$7,376,000 | \$8,476,000 | \$7,255,000 | \$7,255,000 |
| Discounted total costs                             | \$11,225,000 | \$6,893,000 | \$7,403,000 | \$5,922,000 | \$5,535,000 |

7. Option Seven: Require Registration of Domestic and Foreign Facilities That Manufacture/Process, Pack, or Hold Food That Sell Their Products in Intrastate and Interstate Commerce, Including Mixed-Type Facilities, as Defined in Option 6. Permits the U.S. Agent to Register on Behalf of the Foreign Facility

Permitting the U.S. agent to register on behalf of the foreign facility would reduce the number of paper registrations significantly. Foreign facilities still would have to go through administrative steps to learn about the regulation and to find and hire a U.S. agent. However, foreign facilities now would have a third option for registering. In addition to electronic and paper registration by a representative at the facility, the foreign facility can authorize its U.S. agent to register the facility. FDA assumes that U.S. agents who register on behalf of foreign facilities will register electronically. Characteristics of foreign facilities, such as access to the Internet, fluency in English, and whether they are informed about the registration requirement before their product reaches the U.S. port, determine whether foreign facilities would be registered by themselves electronically, registered by mail, or registered by their U.S. agent.

FDA assumes that foreign facilities with Internet access would register directly via the Internet. Registration via the Internet would be the fastest, most reliable method for these facilities, and they would receive their confirmation of registration and facility registration number automatically.

Foreign facilities that do not have Internet access or representatives who read or write in English would register through their U.S. agent. The inability to read and write in English increases the cost for foreign facilities that register directly. U.S. agents operating in response to FDA registration requirements for other FDA-regulated products market themselves to certain regions of the world. FDA anticipates these agents would speak the language of the representative of the foreign facility, as well as English, and so could register in English for the facility.

Foreign facilities that do not have Internet access and do not learn of the registration requirements until their product reaches the U.S. border also are likely to register through their U.S. agent. For electronic registrations, the facility is considered registered once FDA enters the registration data into the registration system and the system generates a registration number. For paper registrations, the facility is

considered registered when FDA sends the registration number to the facility. For electronic registrations, confirmation should happen almost instantly. The electronic submission would be automatically entered into the database, undergo consistency checks, and if the information is entered correctly, the confirmation of registration and the facility's registration number would be sent out electronically.

Paper submissions are subject to longer lag times at several points. First, the facility may have to mail or phone in a request for a registration form. Second, the facility may have to wait to receive the form. Third, the registration takes time to travel through the mail from the facility to FDA. Fourth, FDA would require more time to process paper submissions, because the information has to be entered manually into the system. Fifth, FDA has to mail out a copy of the registration as entered, the registration confirmation, and the registration number if the facility's information is complete and legible. Sixth, the registration confirmation has to travel through the mail to the facility. At this time, the facility would know it is registered and have its registration number.

Because time will be important to foreign facilities bringing products into the United States, FDA assumes that they will choose to be registered by their U.S. agent, because the registration process will be much faster. Facilities that do not have Internet access, that have representatives who can read and write in English, and learn about the registration requirements before exporting their product to the United States are most likely to register by a paper submission. These facilities already would have invested the time to learn about the registration requirements and thus are likely to have a hard copy of the form. If time were not a major consideration, a facility is likely to prefer to fill out the registration form onsite. FDA plans to conduct extensive outreach efforts to communicate the registration requirements to affected facilities both domestically and abroad, both at the proposed rule stage and at the final rule stage to minimize the number of facilities that find out about the requirements at the port. FDA does not have the information to estimate how many foreign facilities would not learn about the registration requirements until their goods are at the port. FDA instead estimates the number of foreign paper submissions to FDA as the percent of foreign facilities that do not have Internet access and whose managers are able to read and write in

English. FDA requests comments on this assumption.

Under this option, U.S. agents would have a larger role than under other options. U.S. agents may charge a higher fee if they register for the facility. A higher U.S. agent fee is considered in the sensitivity analysis.

Port delays would be shorter under this option than under alternative options. Foreign facilities still would have delays associated with communication and finding a U.S. agent, but the process would be shortened by allowing the U.S. agent to register on behalf of the foreign facility. This would shorten the time that the product sits in storage and lower the loss of value of the product.

Tables 37, 38, 39, 40, and 41 of this document provide a summary of the data for cost estimates under option 7 for domestic facilities, foreign facilities, and FDA, respectively. The first year costs to foreign facilities would be reduced from \$319.6 to \$311.8 million, annual costs would be reduced from \$228.4 to \$227.6 million. Total costs for the first year would be reduced from \$344.5 to \$336.2 million.

TABLE 37.—NUMBER OF DOMESTIC FACILITIES COVERED UNDER OPTION 7

|  |         |
|--|---------|
| 2000 CBP                                     | 103,125 |
| 1999 Nonemployer statistics                  | 68,424  |
| Mixed-type facilities that engage in farming | 30,497  |
| Total domestic                               | 202,046 |

TABLE 38.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 7

|  |             |
|--|-------------|
| Administrative worker wage (includes overhead) | 25.1        |
| Manager wage (includes overhead)               | 56.74       |
| Percent with Internet access US                | 71%         |
| Research time with Internet (hours)            | 1           |
| Research time without Internet (hours)         | 2           |
| Research cost with Internet                    | \$3,601,000 |
| Research cost without Internet                 | \$2,941,000 |
| Administrative time for form (hours)           | 0.75        |

TABLE 38.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 7—Continued

|   |              |
|---|--------------|
| Manager time for form (hours)               | 0.25         |
| Form costs                                  | \$6,670,000  |
| Percent of businesses going out of business | 10%          |
| Percent of businesses entering              | 10%          |
| Percent of businesses with changes          | 20%          |
| Annual facility costs                       | \$3,322,000  |
| Total domestic costs                        | \$13,212,000 |

TABLE 39.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 7

|                                  |         |
|----------------------------------|---------|
| Foreign holders and packagers    | 100,027 |
| Foreign manufacturers/processors | 125,450 |
| Stops exporting                  | 16%     |
| Total facilities                 | 205,405 |

TABLE 40.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES

|                                  |               |
|----------------------------------|---------------|
| Speaks English                   | 16%           |
| Has Internet access              | 31%           |
| Has U.S. agent                   | 10%           |
| Cost of U.S. agent (annual)      | \$1,000       |
| Hourly wage rate                 | \$25          |
| Time to find agent (hours)       | 5             |
| Additional time language (hours) | 5             |
| Additional time Internet (hours) | 5             |
| First year agent cost            | \$67,340,000  |
| Agent fee (annual cost)          | \$194,868,000 |
| Administrative time (hours)      | 1             |
| Additional time language (hours) | 5             |
| Additional time Internet (hours) | 5             |
| First year administrative costs  | \$44,418,929  |

TABLE 40.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES—Continued

|   |               |
|---|---------------|
| Time to fill out form (hours)               | 1             |
| Additional time language (hours)            | 0             |
| Additional time Internet (hours)            | 0             |
| Percent of businesses going out of business | 10%           |
| Percent of businesses entering              | 10%           |
| Percent of businesses with changes          | 20%           |
| First year form cost                        | \$5,135,000   |
| Total first year costs                      | \$311,762,000 |
| Total annual costs                          | \$227,585,000 |

TABLE 41.—COSTS INCURRED BY FDA UNDER OPTION 7

| FDA Costs  | 2003         | 2004        | 2005        | 2006        | 2007        |
|--|--------------|-------------|-------------|-------------|-------------|
| Development/modification/enhancement               | \$8,200,000  | \$3,000,000 | \$3,300,000 | \$2,300,000 | \$2,300,000 |
| Maintenance/steady state                           | \$1,560,000  | \$3,500,000 | \$4,300,000 | \$4,300,000 | \$4,300,000 |
| Number of FTEs                                     | 4            | 4           | 4           | 2           | 2           |
| Cost per FTE                                       | \$110,588    | \$110,588   | \$110,588   | \$110,588   | \$110,588   |
| Cost per paper submission                          | \$10         | \$10        | \$10        | \$10        | \$10        |
| Number of domestic paper submissions               | 58,593       | 23,437      | 23,437      | 23,437      | 23,437      |
| Number of foreign paper submissions                | 22,677       | 9,071       | 9,071       | 9,071       | 9,071       |
| Total number of domestic registrations in database | 202,046      | 202,046     | 202,046     | 202,046     | 202,046     |
| Total number of foreign registrations in database  | 205,405      | 205,405     | 205,405     | 205,405     | 205,405     |
| Mailings to domestic facilities                    | \$1          | \$1         | \$1         | \$1         | \$1         |
| Mailings to foreign facilities                     | \$1          | \$1         | \$1         | \$1         | \$1         |
| Error rate for paper submissions                   | 10%          | 10%         | 10%         | 10%         | 10%         |
| Number of errors                                   | 5,860        | 2,345       | 2,345       | 2,345       | 2,345       |
| Cost per error                                     | \$15         | \$15        | \$15        | \$15        | \$15        |
| Total costs  | \$11,225,000 | \$7,376,000 | \$8,476,000 | \$7,255,000 | \$7,255,000 |
| Discounted total costs                             | \$11,225,000 | \$6,893,000 | \$7,403,000 | \$5,922,000 | \$5,535,000 |

8. Option Eight: Issue No New Regulation and Allow the Bioterrorism Act's Default Registration Requirements to Take Effect

The Bioterrorism Act requires facilities to register with FDA by December 12, 2003, even if FDA has not issued final regulations by this date. Failure to do so for both foreign and domestic facilities is a prohibited act, and FDA must hold food from unregistered foreign facilities at the port of entry until they are registered. Thus,

facilities have an incentive to register with FDA. Failure to issue a final regulation would result in an unworkable, chaotic system. The Bioterrorism Act also requires facilities that register in the absence of a final rule to re-register with FDA as specified in the final rule once it is issued.

It is not possible to predict the costs or benefits of this option because the statute is not specific enough to predict how it would be implemented. It seems likely that many facilities will attempt to register, given the penalties for failure

to register. However, if FDA receives all paper, non-standardized registrations, it will be extremely difficult for FDA to process the registrations and to use the information provided. It would also be a slow process for FDA to issue registration numbers.

9. Summary of Costs

Table 42 of this document presents a summary of costs for options 2 through 7 for domestic facilities, foreign facilities, and FDA. Costs in future years are discounted at 7 percent.

TABLE 42.—TOTAL COST OF OPTIONS 2 THROUGH 7 FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND FDA.

|                            | Option 2      | Option 3      | Option 4      | Option 5      | Option 6      | Option 7      |
|----------------------------|---------------|---------------|---------------|---------------|---------------|---------------|
| Domestic first year costs  | \$13,557,000  | \$7,038,000   | \$11,217,000  | \$12,256,000  | \$13,212,000  | \$13,212,000  |
| Foreign first year costs   | \$319,619,000 | \$319,619,000 | \$319,619,000 | \$318,335,000 | \$319,619,000 | \$311,762,000 |
| FDA first year costs       | \$11,279,000  | \$10,907,000  | \$11,145,000  | \$11,279,000  | \$11,225,000  | \$11,225,000  |
| Total first year costs     | \$344,455,000 | \$337,564,000 | \$341,981,000 | \$341,870,000 | \$344,056,000 | \$336,199,000 |
| Domestic second year costs | \$3,186,000   | \$1,654,000   | \$2,636,000   | \$2,181,000   | \$3,105,000   | \$3,105,000   |
| Foreign second year costs  | \$213,430,000 | \$213,430,000 | \$213,430,000 | \$212,831,000 | \$213,430,000 | \$212,696,000 |
| FDA second year costs      | \$6,914,000   | \$6,769,000   | \$6,862,000   | \$6,817,000   | \$6,893,000   | \$6,893,000   |
| Total second year costs    | \$223,530,000 | \$221,853,000 | \$222,928,000 | \$221,829,000 | \$223,428,000 | \$222,694,000 |
| Domestic third year costs  | \$2,978,000   | \$1,546,000   | \$2,464,000   | \$2,039,000   | \$2,902,000   | \$2,902,000   |
| Foreign third year costs   | \$199,467,000 | \$199,467,000 | \$199,467,000 | \$198,907,000 | \$199,467,000 | \$198,782,000 |
| FDA third year costs       | \$7,422,000   | \$7,287,000   | \$7,374,000   | \$7,332,000   | \$7,403,000   | \$7,403,000   |
| Total third year costs     | \$209,867,000 | \$208,300,000 | \$209,305,000 | \$208,278,000 | \$209,772,000 | \$209,087,000 |
| Domestic fourth year costs | \$2,783,000   | \$1,445,000   | \$2,303,000   | \$1,905,000   | \$2,712,000   | \$2,712,000   |
| Foreign fourth year costs  | \$186,418,000 | \$186,418,000 | \$186,418,000 | \$185,895,000 | \$186,418,000 | \$185,777,000 |
| FDA fourth year costs      | \$5,939,000   | \$5,814,000   | \$5,894,000   | \$5,855,000   | \$5,922,000   | \$5,922,000   |
| Total fourth year costs    | \$195,140,000 | \$193,677,000 | \$194,615,000 | \$193,655,000 | \$195,052,000 | \$194,411,000 |

a. *Sensitivity to assumptions.* A number of assumptions in the analysis significantly affect the cost estimates. To understand how these assumptions affect the cost estimates, FDA re-estimates the total costs under

alternative assumptions. FDA uses option 7, the proposed option, to compare across assumptions. Table 43 summarizes the results of the sensitivity analysis.

FDA looked at the number of mixed-type facilities. In option 6, FDA estimated that there are approximately 30,497 mixed-type facilities that manufacture/process food for distribution to nonconsumers or pack or

hold food received from off the facility based on data from the Census of Agriculture and information from CES (Ref. 7). Because there are over 2 million farms in the United States, small changes in assumptions about the percentage of farms that are mixed-type facilities would result in a large change in the total number of affected farms. If the total number of farms that are mixed-type facilities were 100,000, the total, first year, domestic costs increase from \$13.2 to \$17.8 million.

Another significant source of uncertainty is the amount of time it would take facility employees to read and understand the requirements and for foreign facilities to find a U.S. agent. To test the time assumptions, FDA estimated the costs assuming all the time estimates for administrative activities were doubled. This increases the cost estimates for domestic facilities from \$13.2 to \$19.8 million and increases the cost estimates for foreign facilities from \$311.8 to \$423.5 million.

Hiring and retaining a U.S. agent is a significant cost for foreign facilities. FDA tested how this affects total cost estimates by doubling the percent of foreign manufacturers that have U.S.

agents from 10 percent to 20 percent. This lowers the first year cost for foreign facilities from \$311.8 to \$297.3 million.

Also subject to a great deal of uncertainty is the number of foreign manufacturers/processors who can read and write in English. Research on the topic shows widely ranging estimates of the number of English speakers in countries where English is not the primary language. Even in countries where English is a primary or secondary language, many inhabitants may not be fluent in English (Ref. 14). However, more than one individual may work in a facility in an appropriate position to fill out the registration form. This increases the probability that an individual with English skills sufficient to fill out the registration form may be available. FDA estimated that 16 percent of foreign facilities had employees that were fluent in English. To test our assumption about the percentage of foreign facilities with employees who are fluent in English, FDA looked at the alternate assumption that 32 percent of foreign facilities would have a worker with the capability to research and fill out the form in English. This change

decreases the total cost to foreign facilities from \$311.8 to \$303.4 million.

FDA assumed that the number of foreign facilities that hold food products before exporting them to the United States is equal to the number of domestic brokers and consignees, because of the lack of data about foreign facilities holding and doing de minimis processing of food. To test this assumption, FDA looked at the costs if the number of foreign holders and de minimis processors is 160,000. Changing this assumption has a large effect on the foreign and total cost, increasing the foreign cost from \$311.8 to \$405.2 million and the total cost from \$336.2 to \$429.7 million.

FDA tested the effect of changing the annual U.S. agent fee. If the average U.S. agent fee is \$1,500, instead of \$1,000, the costs to foreign facilities will be increased from \$311.8 to \$409.2 million.

Finally, FDA tested the assumption that the foreign wage rate is the same as the domestic wage rate and re-estimated the costs for a foreign wage rate of \$15 per hour. The total cost to foreign facilities was reduced from \$311.8 to \$265.0 million under this assumption.

TABLE 43.—SENSITIVITY ANALYSIS (RELATIVE TO OPTION 7)

| First Year Costs                                       | Total Domestic Cost (dollars) | Total Foreign Cost (dollars) | Total FDA Cost (dollars) | Total Cost (dollars) |
|--|-------------------------------|------------------------------|--------------------------|----------------------|
| Under current assumptions <sup>1</sup>                 | 13,212,000                    | 311,762,000                  | 11,225,000               | 336,199,000          |
| Percentage change from baseline                        | 0%                            | 0%                           | 0%                       | 0%                   |
| 100,000 mixed-type facilities that engage in farming   | 17,756,000                    | 311,762,000                  | 11,484,000               | 341,002,000          |
| Percentage change from baseline                        | 34%                           | 0%                           | 2%                       | 1%                   |
| Time costs are doubled                                 | 19,754,000                    | 423,521,000                  | 11,225,000               | 454,500,000          |
| Percentage change from baseline                        | 50%                           | 36%                          | 0%                       | 35%                  |
| 20 percent of foreign manufacturers have U.S. agents   | 13,212,000                    | 297,257,000                  | 11,225,000               | \$321,694,000        |
| Percentage change from baseline                        | 0%                            | -5%                          | 0%                       | -4%                  |
| 32 percent of foreign facilities are fluent in English | 13,212,000                    | 303,395,000                  | 11,474,000               | \$328,081,000        |
| Percentage change from baseline                        | 0%                            | -3%                          | 2%                       | -2%                  |
| 160,000 foreign holders                                | 13,212,000                    | 405,168,000                  | 11,304,000               | 429,684,000          |
| Percentage change from baseline                        | 0%                            | 30%                          | 1%                       | 28%                  |
| U.S. agent fee \$1,500                                 | 13,212,000                    | 409,195,000                  | 11,225,000               | 433,632,000          |
| Percentage change from baseline                        | 0%                            | 31%                          | 0%                       | 29%                  |
| Foreign wage rate \$15                                 | 13,212,000                    | 265,004,000                  | 11,225,000               | 289,441,000          |



TABLE 43.—SENSITIVITY ANALYSIS (RELATIVE TO OPTION 7)—Continued

| First Year Costs                | Total Domestic Cost (dollars) | Total Foreign Cost (dollars) | Total FDA Cost (dollars) | Total Cost (dollars) |
|---------------------------------|-------------------------------|------------------------------|--------------------------|----------------------|
| Percentage change from baseline | 0%                            | -15%                         | 0%                       | -14%                 |

<sup>1</sup> 30,497 mixed-type facilities, time costs under option 7, 10 percent of foreign manufacturers/processors have U.S. agents, 16 percent of foreign facilities are fluent in English, 100,027 foreign holders and packagers, and U.S. agent fee of \$1,000.

b. *Qualitative costs.* For all of the options, except option one, there are a number of costs that FDA was unable to quantify. Loss of products from small exporters who would choose to stop exporting to the United States due to the increased cost of business may represent significant costs. Earlier in the analysis, we estimated that about 16 percent of foreign manufacturers export 10 or fewer line entries per year, and that these manufacturers would cease exporting to the United States. This could result in the elimination of some specialty products that market to very small niche markets in the United States, which would represent a loss to consumers who use these products.

The cost of port delays for facilities that do not learn of the requirements before exporting is another cost FDA was unable to quantify. FDA is unable to estimate how many foreign facilities would not learn about the new requirements before exporting. For this analysis, we estimate the expected cost of learning about registration as the number of hours a worker in a foreign facility needs to learn about the requirements. However, we expect that for some facilities, the cost of learning about the requirements would be much higher than the expected cost. Facilities that do not learn about the registration requirements before reaching the United States port would still have their shipment held at the port. The loss of value may be as low as the cost of storage, or as high as the value of the shipment, if perishable.

Under option 7, FDA expects this cost to be lower. If the U.S. agent registers the foreign facility, this will speed up the registration process and the product

would be released into U.S. commerce faster.

FDA also was unable to quantify the costs incurred by FDA, trade associations, and others for outreach about the registration requirements. FDA will undertake outreach to notify domestic and foreign facilities about registration through public meetings, satellite downlink to five continents, and providing help desk support. FDA also anticipates that trade organizations and others, such as brokers, foreign governments, and U.S. businesses, will undertake to notify facilities of the registration requirements. FDA requests comments on the size and the basis for estimating these costs.

#### 10. Benefits

These provisions would improve FDA's ability to respond to outbreaks from accidental and deliberate contamination from food and deter deliberate contamination. Based on historical evidence, a strike on the food supply has a very low probability, but would be a potentially high cost event. FDA lacks data to estimate the likelihood and resulting costs of a strike occurring. Without knowing the likelihood or cost of an event, we cannot quantitatively measure the reduction in probability of an event occurring or the possible reduction in cost of an event, associated with each regulatory option. Further hindering any quantification of benefits is the interactive effect of the other regulations that are being developed to implement title III of the Bioterrorism Act. Prior notice for imported shipments (section 307 of the Bioterrorism Act) would aid in the enforcement of registration, and in turn, registration would aid in the verification

of prior notice submissions. Registration and recordkeeping also would work cooperatively.

These regulations also improve FDA's ability to prevent and respond to accidental foodborne outbreaks. FDA lacks data on the number of accidental outbreaks that will be prevented or shortened from this proposed rule, as well as from registration working in conjunction with the other regulations being developed to implement title III of the Bioterrorism Act. To understand possible costs of inadvertent foodborne illness and from an intentional strike on the food supply, FDA presents five outbreaks resulting from accidental and deliberate contamination, involving both domestic and imported foods in table 44. Registration will aid FDA in preventing and shortening foodborne outbreaks, but we do not know how frequently an outbreak would occur or the size and severity of the outbreak in the absence of registration. These foodborne outbreaks also do not represent the form a terrorist attack might undertake, but merely illustrate the public health costs of foodborne disasters. It is possible that an intentional attack on the food supply that sought to disrupt the food supply and sicken many U.S. citizens would be much larger. However, the probability of an attack occurring and the exact reduction in risk resulting from registration is unknown. Therefore, FDA is unable to quantify the benefits of registration arising from preventing or lessening the impact of a foodborne outbreak. Instead, we examine four mechanisms through which each regulatory option might act and analyze how each of the options affects these mechanisms.

TABLE 44.—SUMMARY OF FIVE FOODBORNE OUTBREAKS

| Pathogen                      | Location and Year | Vehicle    | Confirmed or Reported Cases | Estimated Number of Cases       | Total Illness Cost (dollars)   |
|-------------------------------|-------------------|------------|-----------------------------|---------------------------------|--------------------------------|
| <i>Salmonella enteritidis</i> | Minnesota 1994    | Ice cream  | 150 cases; 30 hospitalized  | 29,100 in MN; 224,00 nationwide | 3,187,744,000 to 5,629,792,000 |
| <i>Shigella sonnei</i>        | Michigan 1988     | Tofu salad | 3,175 cases                 | Not available                   | 45,183,000 to 79,797,000       |

TABLE 44.—SUMMARY OF FIVE FOODBORNE OUTBREAKS—Continued

| Pathogen  | Location and Year             | Vehicle  | Confirmed or Reported Cases                      | Estimated Number of Cases | Total Illness Cost (dollars) |
|---|-------------------------------|--|--|---------------------------|------------------------------|
| Outbreaks resulting from deliberate contamination |                               |  |  |                           |                              |
| <i>Salmonella Typhimurium</i>                     | Dalles, Oregon 1984           | Salad bars                                     | 751 cases; 45 hospitalized                       | Not available             | 10,687,000 to 18,875,000     |
| <i>Shigella dysenteriae</i> type 2                | Texas 1996                    | Muffins and doughnuts                          | 12 cases; 4 hospitalized                         | All cases identified      | 83,000                       |
| Outbreaks resulting from imported foods           |                               |  |  |                           |                              |
| <i>Cyclospora cayatanensis</i>                    | United States and Canada 1996 | Raspberries (probably imported from Guatemala) | 1465 cases identified, less than 20 hospitalized | Not available             | 3,941,000                    |

a. *Salmonella enteritidis* in ice cream. In 1994, approximately 224,000 people were sickened by ice cream contaminated with *Salmonella enteritidis*. The source of the contamination appeared to be pasteurized pre-mix that had been contaminated during transport in tanker trailers that carried nonpasteurized eggs. There were 150 confirmed cases of salmonellosis associated with the outbreak in Minnesota. However, ice cream produced during the contamination period was distributed to 48 States. To calculate the total number of illnesses associated with the outbreak, researchers calculated an attack rate of 6.6 percent. This attack rate was extrapolated to the population that consumed the ice cream, giving a total number sickened of 224,000 (Ref. 19).

Salmonellosis most commonly causes gastrointestinal symptoms. Almost 91 percent of cases are mild and cause 1 to 3 days of illness with symptoms including diarrhea, abdominal cramps, and fever. Moderate cases, defined as cases that require a trip to a physician, account for 8 percent of the cases. These cases typically have a duration of 2 to 12 days. Severe cases require hospitalization and last 11 to 21 days. In addition to causing gastroenteritis, salmonellosis also can cause reactive arthritis in a small percentage of cases. Reactive arthritis may be short or long term and is characterized by joint pain. Just over 1 percent of cases develop short-term reactive arthritis and 2 percent of cases develop chronic, reactive arthritis.

FDA estimated the costs associated with salmonellosis, including medical treatment costs and pain and suffering.

Table 45 of this document provides a summary of these estimates. Pain and suffering is measured by lost quality adjusted life days (QALDs). QALDs measure the loss of utility associated with an illness. A QALD is measured between zero and one, with one being a day in perfect health. The total loss of a quality adjusted life year (QALY), or the loss of a year of life is valued at \$100,000, based on economic studies of how consumers value risks to life (Ref. 20). Thus, an entire lost QALD would be valued at \$274 and fractions of QALDs are a fraction of the day's value. FDA presents two estimates of values of pain and suffering associated with arthritis, one based on physician estimates (Ref. 21) and another based on a regression analysis approach (Ref. 22). This gives a range of costs for the average case of salmonellosis between \$14,231 and \$25,133.

TABLE 45.—THE COST OF A TYPICAL CASE OF SALMONELLOSIS

| Severity                            | Case Breakdown (percent) | Total QALDs Lost per Illness | Health Loss (dollars) per Case (Discounted) | Medical Costs (dollars) per Case (Discounted) | Weighted Dollar Loss per Case |
|-------------------------------------|--------------------------|------------------------------|---|---|-------------------------------|
| Illness                             |                          |                              |   |   |                               |
| Mild .....                          | 90.7                     | 1.05                         | 660   | 0   | 599                           |
| Moderate .....                      | 8.1                      | 3.68                         | 2,310                                       | 283   | 209                           |
| Severe .....                        | 1.2                      | 9.99                         | 6,266                                       | 9,250   | 188                           |
| Arthritis                           |                          |                              |   |   |                               |
| <i>Regression approach</i> .....    |                          |                              |   |   |                               |
| Short-term .....                    | 1.26                     | 5.41                         | 3,391                                       | 100   | 44                            |
| Long-term .....                     | 2.40                     | 2,613.12                     | 452,554                                     | 7,322   | 11,048                        |
| <i>Direct survey approach</i> ..... |                          |                              |   |   |                               |
| Short-term .....                    | 1.26                     | 10.81                        | 6,778                                       | 100   | 87                            |
| Long-term .....                     | 2.40                     | 5,223.15                     | 904,573                                     | 7,322   | 21,906                        |
| Death .....                         | 0.04                     |                              | 5,000,000                                   |   | 2,143                         |
| Total expected loss per case        |                          |                              |   |   |                               |
| Regression approach .....           |                          |                              |   |   | 14,231                        |
| Direct survey approach .....        |                          |                              |   |   | 25,133                        |

To estimate the economic cost due to illness associated with this outbreak, FDA used the range for the average cost per case. For 224,000 people, this is a total cost of between \$3,187,744,000 and \$5,629,792,000 from this accidental food disaster.

b. *Shigella sonnei* in tofu salad. In 1988, a tofu salad at an outdoor music festival was contaminated with *Shigella sonnei* and sickened an estimated 3,175 people. Over 2,000 volunteer food handlers served communal meals at the festival (Ref. 23). Shigellosis causes similar symptoms and is of similar duration to salmonellosis. It also is associated with short term and chronic reactive arthritis; thus FDA assumed the average case of shigellosis has the same cost as salmonellosis. This gives a total cost of \$45,183,000 to \$79,797,000.

c. *Salmonella typhimurium* in salad bars. During September and October of 1984, two outbreaks of *Salmonella typhimurium* occurred in association with salad bars in restaurants in The Dalles, OR. At least 751 people were affected. Members of the local Rajneeshpuram commune intentionally

caused the outbreak by spraying *Salmonella typhimurium* on the salad bars in local restaurants. Their apparent motivation was to influence a local election by decreasing voter turnout. Intentional contamination was not suspected immediately and no charges were brought until a year after the attacks (Ref. 24).

The 751 people affected primarily were identified through passive surveillance; thus the true number of people actually sickened is undoubtedly much higher. The Dalles is located on Interstate 84 in Oregon and is a frequent stop for travelers who were unlikely to be identified by passive or active surveillance for salmonellosis. However, since we do not have any estimates of the true size of the outbreak, we estimated the costs associated with known cases, recognizing this is an underestimate of the true cost of the outbreak. We use the cost estimates for salmonellosis as ranging from \$14,231 to \$25,133. This gives an estimated cost of known cases for the outbreak of \$10,687,000 to \$18,875,000.

d. *Shigella dysenteriae* type 2 among laboratory workers. Twelve people working in a laboratory who consumed muffins left in the laboratory break room contracted shigellosis. Affected workers had diarrhea, nausea, and abdominal discomfort. Investigators concluded that the outbreak likely was the result of deliberate contamination. All twelve affected workers were treated by, or consulted with, a physician. Nine affected workers went to the emergency room, four of whom were hospitalized (Ref. 25).

To estimate the cost of this outbreak, FDA assumed that the eight cases requiring consultation with a doctor, but not requiring hospitalization, had the same cost as a moderate case of salmonellosis. The four cases requiring hospitalization were estimated to have the same cost as a severe case of gastroenteritis resulting from salmonellosis. This gives a cost of \$83,000 for illnesses associated with the event. Table 46 summarizes the costs associated with this outbreak.

TABLE 46.—SUMMARY OF COSTS FOR CASES OF SHIGELLOSIS

| Severity    | Number of cases | Cost per case (dollars) | Total cost (dollars) |
|-------------|-----------------|-------------------------|----------------------|
| Mild        | 0               | 0                       | 0                    |
| Moderate    | 8               | 2,593                   | 21,000               |
| Severe      | 4               | 15,516                  | 62,000               |
| Grand total |                 |                         | 83,000               |

e. *Cyclospora cayatanensis* in imported raspberries. In 1996, 1,465 cases of cyclosporiasis were linked to consumption of raspberries imported from Guatemala. Nine hundred and seventy eight of these cases were laboratory confirmed. No deaths were confirmed and less than 20 hospitalizations were reported (Ref. 26). Case control studies indicated that raspberries imported from Guatemala were the source of the illnesses. Fifty-five clusters of cases were reported in 20 states, two Canadian provinces, and the District of Columbia (Ref. 27).

Cyclosporiasis typically causes watery diarrhea, loss of appetite, weight loss, and fatigue. Less common symptoms include fever, chills, nausea, and headache. The median duration of illness associated with the outbreak was more than 14 days and the median duration of diarrheal illness was 10 days (Ref. 27). We estimated the cost of a mild case of cyclosporiasis as two and a half times higher than the cost of a mild case of gastroenteritis from salmonellosis due to the longer duration. The reports of cyclosporiasis outbreaks did not include information

on the number of physician visits. We assumed that the percentage of total cases that result in physician visits would be larger than the corresponding percentage for salmonellosis illnesses, due to the longer duration of illnesses. We assumed, therefore, that 40 percent of those infected with cyclosporiasis visited a physician. Less than 20 hospitalizations were reported from the cyclosporiasis outbreak (Ref. 26). No deaths were confirmed. Table 47 summarizes the costs associated with this outbreak.

TABLE 47.—SUMMARY OF COSTS FOR CASES OF CYCLOSPORIASIS

| Severity    | Number of cases | Cost per case (dollars) | Total cost (dollars) |
|-------------|-----------------|-------------------------|----------------------|
| Mild        | 879             | 1,650                   | 1,450,000            |
| Moderate    | 586             | 3,748                   | 2,196,000            |
| Severe      | 19              | 15,516                  | 295,000              |
| Grand total |                 |                         | \$3,941,000          |

f. *Mechanisms.* Requiring registration of manufacturers/processors, packers, and holders of food would aid in deterring and limiting the effects of foodborne outbreaks in four ways: (1) By requiring registration, persons who might intentionally contaminate the food supply would be deterred from entering the food production chain; (2) if FDA is aware of a specific food threat, then it would be able to inform the facilities potentially affected by the threat; (3) FDA would be able to deploy more efficiently its domestic compliance and regulatory resources and better able to identify facilities affected by future FDA actions (including possible regulations); and (4) FDA inspectors, using prior notice and registration, can better identify shipments for inspection.

Registering with FDA creates a paper trail, which would, even if the information in the registration were falsified, provide evidence that could link the registration to the false registrant. By creating this paper trail, persons who might intentionally contaminate the food supply and are considering starting a business in the food supply chain would be deterred by the creation of additional evidence that might be used against them. Persons who might intentionally contaminate the food supply that refuse to register, if foreign, would risk having their product held at the port and, if foreign or domestic, would be subject to criminal sanctions.

With correct contact information and product categories, FDA can quickly contact domestic and foreign facilities that may be targeted by a specific food threat. This quick communication would allow facilities to respond quickly to a threat and possibly limit the effect of a deliberate strike on the food supply, as well as public health emergencies due to accidental contamination.

A complete list of facilities in the food supply chain would aid FDA in scheduling inspections and undertaking compliance activities. Domestically, a complete list of facilities with correct contact information would aid inspectors in contacting facilities, and with product information would aid in identifying facilities for inspections. Because of the turnover in the food industry and the ratio of inspectors to food facilities, FDA never has had a complete list of foreign or domestic facilities that provide food for consumption in the United States. Also, a complete list of facilities would aid FDA in understanding which facilities would be affected by future FDA actions (including possible regulations), which

would result in targeting communication and outreach to these facilities.

In conjunction with the prior notification requirements in 21 CFR part 1, subpart I, FDA can better identify imported food shipments for inspection at the port. The registration would identify the country of the manufacturer, which may not be the same as the country from which the product has been shipped. This information would assist FDA in identifying specific shipments to inspect, if we have information that a particular type of food or shipments from a particular country may be adulterated. Additionally, the database of registrants and products also would aid FDA in verifying that a product is correctly identified by where and by whom it was produced. For example, if the registration information identifies a facility as producing only dairy products and FDA receives a prior notice purportedly from the facility for the shipment indicating that the facility is shipping nuts, FDA can target that shipment for verification based on the discrepancy.

Because we cannot quantify the benefits, we cannot differentiate the benefits of each option in dollar terms. Instead, we look at how effectively each of the mechanisms would operate under each of the options relative to no regulation (option one).

*i. Registration would deter persons who might intentionally contaminate the food supply from entering the food production chain.*

Option 1: No impact.

Option 2: This option is the most comprehensive in the registration requirements and thus would have the largest impact on deterring persons who might intentionally contaminate the food supply.

Option 3: If FDA does not require intrastate facilities to register, then persons who might intentionally contaminate the food supply might be more likely to choose an intrastate facility for carrying out an attack on the food supply. However, intrastate facilities are more likely to be small, and generally do not distribute product widely or in large quantities. These are all characteristics that would make intrastate facilities less attractive to a person who would intentionally contaminate the food supply. Therefore, FDA expects that excluding intrastate facilities would reduce the function of the first mechanism, but not to a great extent.

Option 4: Option four still would cover many of the same facilities as option 2.

However, if mixed-type facilities are not required to register, then these types of facilities may be more vulnerable.

However, many state and local agencies have registration requirements for mixed-type facilities. Some of these facilities would be covered under these State or local agencies. Persons who might intentionally contaminate the food supply might be more likely to choose a mixed-type facility that is not required to register for carrying out an attack on the food supply.

Option 5: This option provides the same coverage of facilities as option 2. It does not require the inclusion of food product categories on the registration form. FDA anticipates that excluding product categories, by reducing the amount of information required by the registrant, would reduce slightly this regulation's ability to deter persons who might intentionally contaminate the food supply.

Option 6: This option provides coverage of the food production chain similar to option two, and so will have a similar effect in deterring persons who might intentionally contaminate the food supply from entering the food production chain.

Option 7: Option 7 would provide the same coverage of the food production chain as option 6, and so would be equally as effective in preventing persons who might intentionally contaminate the food supply from entering the food production chain.

*ii. FDA would be better able to inform facilities if they are affected by a threat.*

Option 1: No impact.

Option 2: This option is the most comprehensive in its coverage and thus would have the largest effect.

Option 3: Excluding intrastate facilities from registering would reduce FDA's ability to inform intrastate facilities of a specific threat. However, intrastate facilities are less likely to be the focus of a threat because of their small size and small distribution range.

Option 4: FDA's ability to inform facilities would be better than without a registration system, but excluding mixed-type facilities from registering would reduce FDA's ability to inform mixed-type facilities of a specific threat.

Option 5: FDA's ability to inform facilities would be better than without a registration system, but not including product categories on the registration form would significantly limit FDA's ability to inform facilities of threats related to specific foods. For example, if FDA receives credible information that persons who might intentionally contaminate the food supply have threatened foreign or domestic cheeses,

inclusion of product categories would allow FDA to communicate quickly with only those facilities impacted by this threat.

Option 6: This option provides coverage of food production chain similar to option 2, and so would have a similar effect in aiding FDA in contacting facilities in response to a threat.

Option 7: Option 7 would provide the same coverage of the food production chain as option 6, and thus would be as effective in aiding FDA in contacting facilities in response to a threat.

*iii. FDA would be more efficient in deploying its enforcement resources and better able to identify facilities affected by future FDA actions (including possible regulations).*

Option 1: No impact.

Option 2: This option is the most comprehensive in its coverage and thus would have the largest beneficial effect of the options.

Option 3: Because FDA exercises less regulatory authority over facilities that operate only in intrastate commerce, and thus seldom inspects these facilities, not requiring facilities that operate only in intrastate commerce to register will have a small effect on FDA's ability to deploy enforcement resources and identify facilities that are affected by future regulations.

Option 4: FDA shares enforcement responsibilities for a number of mixed-type facilities with other Federal, State, and local agencies. Therefore, option 4 would aid FDA in its enforcement activities, though not as fully as option 2. However, FDA would be less able to identify mixed-type facilities that are affected by future regulations for outreach and other activities.

Option 5: Excluding product categories would limit FDA's ability to use the registration database to deploy its enforcement resources. Although FDA still would be aided by the registration requirements under option 5, our efforts would not be as efficient as under option 2. Information from registration makes enforcement more efficient; thus, the more information provided, the greater the increase in efficiency.

Option 6: This option provides similar coverage of the food production chain as option 2 and so will have a similar effect in aiding FDA in deploying enforcement resources and identifying facilities that are affected by future regulations.

Option 7: Option 7 would provide the same coverage of the food production chain as option 6, and thus would be as effective in aiding FDA in deploying resources as option 6.

*iv. Registration, in conjunction with prior notice, would give FDA information that will aid FDA in determining which shipments to inspect.*

Option 1: No impact.

Option 2: This option is the most comprehensive in its coverage and thus would have the largest effect.

Option 3: FDA's ability to target imported foods would be unaffected by excluding intrastate facilities. Option 3 would be as effective as option 2.

Option 4: FDA's ability to target imported foods would be lessened slightly by excluding mixed-type facilities.

Option 5: Not including food product categories would limit FDA's ability to target specific products and country product combinations at the ports. Excluding food categories also would limit FDA's ability to evaluate as thoroughly as possible prior notifications of food imports we receive under 21 CFR part 1, subpart I. For example, if a facility registers as manufacturing/processing only canned goods and we receive a prior notice purportedly from this facility for fresh seafood, FDA would have critical information indicating that the shipment may warrant examination.

Option 6: This option provides similar coverage of the food production chain as option 2, and so would have a similar effect in aiding FDA in determining which shipments to inspect.

Option 7: Option 7 would be as effective as option 2 in aiding FDA in targeting import inspections.

## **V. Initial Regulatory Flexibility Analysis**

### *A. Introduction*

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA is unsure whether or not this proposed rule would have a significant economic impact on a substantial number of small entities, but has analyzed various regulatory options to examine the impact on small entities. The following analysis, together with other relevant sections of this document, serves as the agency's initial regulatory flexibility analysis under the Regulatory Flexibility Act.

### *B. Economic Effect on Small Entities*

Of the 202,046 domestic entities covered by option 7, the proposed option, 99 percent are small according to the definitions of the Small Business Administration. Because such a large percentage of the domestic entities are small, all options considered in the Benefit-Cost Analysis in section IV.A of this document are regulatory relief options. The expected burden for most small entities is low, between \$58 and \$83. However, over 200,000 entities are affected by this rule. If a small percentage of these entities incur costs significantly higher than the expected cost, then a substantial number of small entities may be significantly affected. FDA requests comment on the effect of this proposed rule on small entities.

### *C. Additional Flexibility Considered*

Because of the requirements of the Bioterrorism Act, FDA is precluded from selecting some of the options that typically would be considered to lessen the economic effect of the rule on small entities, including granting an exemption to small entities. FDA tentatively concludes that it would be inconsistent with section 305 of the Bioterrorism Act to allow small entities more time to register, since the Bioterrorism Act established a registration deadline that applies to all covered facilities. Although the recordkeeping provision of the Bioterrorism Act directs FDA to take into account the size of a business when issuing implementing regulations, the registration provision contains no such language. Thus, it appears that Congress intended for all facilities to be subject to the deadline established in the Bioterrorism Act. Nonetheless, the agency recognizes that the registration requirement may cause an economic burden to some small businesses; therefore, we are seeking comment on whether it would be consistent with section 305 of the Bioterrorism Act for the agency to set staggered compliance dates that would give small businesses more time to comply.

However, the Bioterrorism Act does have considerable flexibility for small businesses built into the statute. First, retail facilities and farms are both exempt from registration. Many of these are small entities. Second, the economic impact on small entities is lessened by allowing entities to register either electronically or by mail. Small entities that do not have reasonable access to a computer or the Internet can submit their registration by mail.

## VI. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires cost-benefit and other analyses before any rule making if the rule would include a "Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year." The current inflation-adjusted statutory threshold is \$112.3 million. Because the total cost to the domestic private sector would be \$13 million, FDA has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

## VII. Small Business Regulatory Enforcement Fairness Act Major Rule

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 (Public Law 104-121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: an annual effect on the economy of \$100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this proposed rule, when final, will be a major rule for the purpose of congressional review.

## VIII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). A description of these provisions is given in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information would have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of

the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

### *Title:* Registration of food facilities

*Description:* The Bioterrorism Act contains a provision requiring the Secretary to issue a regulation requiring that domestic and foreign facilities that manufacture/process, pack, or hold food intended for consumption in the United States register with FDA by December 12, 2003. The Bioterrorism Act defines foreign facilities as those that manufacture/process, pack, or hold food for export to the United States without further processing or packaging outside the United States before export. Information FDA proposes to require on the form includes the name and full address of the facility; emergency contact information, including an individual's name, title, office phone, home phone, cell phone (if available) and e-mail address; all trade names the facility uses; general food product categories under § 170.3; and a certification statement that includes the name, title/position, and phone number (e-mail address and fax number if available) of the registrant. Additionally, under the proposed rule, facilities would be encouraged to submit their preferred mailing address; type of activity conducted at the facility; food categories not included under § 170.3, but which are helpful to FDA for responding to an incident; type of storage, if the facility is solely a warehouse/holding facility, and approximate dates of operation if the facility's business is seasonal. Under the proposed rule, facilities would also be required to submit timely updates when any information on their registration form changes, including cancellation of the registration on a separate form.

*Description of Respondents:* Domestic facilities that manufacture/process, pack, or hold food for consumption in the United States are required to register. This includes facilities engaged in both interstate and intrastate commerce and mixed-type facilities as described in option 6. Foreign facilities are required to register if they are manufacture/process, pack, or hold food that is not further processed or packaged outside the United States. The number of respondents is shown in table 48.

TABLE 48.—  
RESPONDENTS

|          |         |
|----------|---------|
| Foreign  | 205,405 |
| Domestic | 202,046 |
| Total    | 407,451 |

### *Burden:*

#### Hour Burden Estimate

FDA estimates that initially it would take an administrative worker with Internet access one hour to read and understand the registration requirements; this time is doubled to two hours of an administrative worker's time for those facilities without Internet access. Foreign facilities' workers would need one hour to read and understand the registration requirements, if they have access to the Internet and can read and write in English. An additional 5 hours would be needed if they do not have Internet access, and an additional 5 hours would be needed if they do not read or understand English. In subsequent years, facilities that enter the industry would have to register, facilities that close would have to notify FDA of their closure, and facilities that have changes in the registration information would have to provide updates to FDA. FDA estimates that annually 10 percent of covered facilities would close, 10 percent would open (Ref. 9) and 20 percent of registered facilities would have changes to their registration information.

Next, FDA estimates that filling out a registration form would take a total of 1 hour: 45 minutes of an administrative worker's time and 15 minutes of a owner, operator, or agent in charge's time to certify the registration before submitting the form to FDA. Foreign facilities' workers would need 1 hour to fill out the form, if they have access to the Internet and can read and write in English. An additional 1 hour would be needed if they do not have Internet access and an additional 1 hour would be needed if they do not read or understand English. Table 49 of this document shows the burden by domestic and foreign facilities, availability of the Internet, and fluency in English. For foreign facilities, FDA only had data on the percentage of facilities with Internet access and percentage fluent in English, but no information on what percentages of facilities are both fluent in English and have Internet access. To calculate the total number of burden hours, FDA assigned the correct percentages of fluent facilities and facilities with Internet access to the total number of

facilities, but for ease of computation excluded a category of facilities that are not fluent in English and have Internet access. FDA requests comments on the number of facilities not fluent in English and without Internet access.

TABLE 49.—ESTIMATED ANNUAL REPORTING BURDEN—FIRST YEAR<sup>1</sup>

| 21 CFR Part           | FDA Form Number | Number of Respondents | Annual Frequency per Respondent | Total Annual Responses | Hours per Response | Total Hours |
|-----------------------|-----------------|-----------------------|---------------------------------|------------------------|--------------------|-------------|
| 1.241(a) <sup>2</sup> | FDA 3537        | 143,453               | 1                               | 143,453                | 2                  | 286,906     |
| 1.241(b) <sup>3</sup> | FDA 3537        | 58,593                | 1                               | 58,593                 | 3                  | 175,779     |
| 1.241(a) <sup>4</sup> | FDA 3537        | 32,864                | 1                               | 32,864                 | 2                  | 65,728      |
| 1.241(b) <sup>5</sup> | FDA 3537        | 30,811                | 1                               | 30,811                 | 7                  | 215,677     |
| 1.241(b) <sup>6</sup> | FDA 3537        | 141,730               | 1                               | 141,730                | 12                 | 1,700,760   |
| Total hours           |                 |                       |                                 |                        |                    | 2,444,850   |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Domestic facilities with Internet access

<sup>3</sup> Domestic facilities without Internet access

<sup>4</sup> Foreign facilities with Internet access and fluent in English

<sup>5</sup> Foreign facilities without Internet access and fluent in English

<sup>6</sup> Foreign facilities without Internet access and not fluent in English

In the following years, new facilities will have to register with FDA. These new facilities will bear the same burden to register that facilities incurred in the first year. Based on estimates by SBA that 10 percent of all businesses are new (Ref. 8), FDA estimates that the number of new facilities each year will be equal to 10 percent of the total number of facilities. Also, facilities that go out of business will have to notify FDA to cancel their registration. FDA estimates

that 10 percent of the total number of facilities will go out of business each year, also based on SBA statistics. Facilities exiting the business will have to send FDA a cancellation of their registration. FDA estimates that it will take these facilities approximately 1 hour to locate the correct form, enter their information, and send it to FDA. Finally, facilities that have a material change of information submitted in their registration will have to notify FDA of

the new information. FDA estimates 20 percent of facilities will have a material change in the information submitted in their registration each year. It will take these facilities approximately 1 hour to locate the correct form, enter their information, and send it to FDA. Table 50 presents an estimate of the burden hours for new facilities, and updates and cancellations for existing facilities in future years.

TABLE 50.—ESTIMATED ANNUAL REPORTING BURDEN—SUBSEQUENT YEARS<sup>1</sup>

| 21 CFR Part 1                    | FDA Form Number | Number of Respondents | Annual Frequency per Respondent | Total Annual Responses | Hours per Response | Total Hours |
|----------------------------------|-----------------|-----------------------|---------------------------------|------------------------|--------------------|-------------|
| New facilities                   |                 |                       |                                 |                        |                    |             |
| 1.241(a) <sup>2</sup>            | FDA 3537        | 14,345                | 1                               | 14,345                 | 2                  | 28,690      |
| 1.241(b) <sup>3</sup>            | FDA 3537        | 5,859                 | 1                               | 5,859                  | 3                  | 17,577      |
| 1.241(a) <sup>4</sup>            | FDA 3537        | 3,286                 | 1                               | 3,286                  | 2                  | 6,572       |
| 1.241(b) <sup>5</sup>            | FDA 3537        | 3,081                 | 1                               | 3,081                  | 7                  | 21,567      |
| 1.241(b) <sup>6</sup>            | FDA 3537        | 14,173                | 1                               | 14,173                 | 12                 | 170,076     |
| Previously registered facilities |                 |                       |                                 |                        |                    |             |
| 1.244(a) <sup>2</sup>            | FDA 3537/3537a  | 43,036                | 1                               | 43,036                 | 1                  | 43,036      |
| 1.244(b) <sup>3</sup>            | FDA 3537/3537a  | 17,578                | 1                               | 17,578                 | 1                  | 17,578      |
| 1.244(a) <sup>4</sup>            | FDA 3537/3537a  | 9,859                 | 1                               | 9,859                  | 1                  | 9,859       |
| 1.244(b) <sup>5</sup>            | FDA 3537/3537a  | 9,243                 | 1                               | 9,243                  | 1                  | 9,243       |

TABLE 50.—ESTIMATED ANNUAL REPORTING BURDEN—SUBSEQUENT YEARS<sup>1</sup>—Continued

| 21 CFR Part 1         | FDA Form Number | Number of Respondents | Annual Frequency per Respondent | Total Annual Responses | Hours per Response | Total Hours |
|-----------------------|-----------------|-----------------------|---------------------------------|------------------------|--------------------|-------------|
| 1.244(b) <sup>6</sup> | FDA 3537/3537a  | 42,519                | 1                               | 42,519                 | 1                  | 42,519      |
| Grand total           |                 |                       |                                 |                        |                    | 366,717     |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Domestic facilities with Internet access

<sup>3</sup> Domestic facilities without Internet access

<sup>4</sup> Foreign facilities with Internet access and fluent in English

<sup>5</sup> Foreign facilities without Internet access and fluent in English

<sup>6</sup> Foreign facilities without Internet access and not fluent in English

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, FDA Desk Officer.

#### IX. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### X. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

#### XI. Comments

Interested persons may submit to the Dockets Management Branch (see ADDRESSES) written or electronic comments regarding this document. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. FDA cannot be responsible for addressing comments submitted to the wrong docket or that do not contain a docket number. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA notes that the comment period for this document is shorter than the 75-day period that the agency customarily provides for proposed rules that are technical or sanitary or phytosanitary (SPS) measures. FDA believes that a 60-day comment period is appropriate in this instance. Executive Order 12889, "Implementation of the North American Free Trade Agreement" (58 FR 69681, December 30, 1993), states that any agency subject to the Administrative Procedure Act must provide a 75-day comment period for any proposed Federal technical regulation or any Federal SPS measure of general application. Executive Order 12889 provides an exception to the 75-day comment period where the United States considers a technical regulation or SPS measures of general application necessary to address an urgent problem related to the protection of human, plant, or animal health or sanitary or phytosanitary protection. FDA has concluded that this proposed rule is subject to the exception in Executive Order 12889.

The Bioterrorism Act states that it is intended "[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." In order to meet these objectives, section 305 of the Bioterrorism Act requires FDA to propose and issue final regulations requiring the registration of food facilities within 18 months of the Bioterrorism Act's enactment, which is by December 12, 2003. Section 305 of the Bioterrorism Act also provides that if FDA does not issue final regulations by this date, facilities still must register with FDA by December 12, 2003, subject

to compliance with the final regulations when the final regulations are made effective. This expedited timeframe reflects the urgency of the U.S. Government's need to prepare to respond to bioterrorism and other food-related emergencies. In addition, section 801 of SBREFA (5 U.S.C. 801), states that a major final rule may not take effect until 60 days after the agency has published the rule and submitted it to Congress for review. A major rule for this purpose is defined in 5 U.S.C. 804 as one that the Administrator of the Office of Information and Regulatory Affairs of OMB has determined has resulted in or is likely to result in: (a) An annual effect on the economy of \$100 million or more; or (b) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

OMB has determined that this proposed rule, when finalized, will be a major rule. Accordingly, FDA must publish the final registration rule no later than October 12, 2003, for it to be effective by the statutory deadline of December 12, 2003. For these reasons, FDA has concluded that the urgency of this matter is sufficient justification for shortening the public comment period for this proposal to 60 days, consistent with Executive Order 12889.

FDA will not consider any comments submitted after the 60-day comment period closes and does not intend to grant any requests for extension of the comment period due to the Bioterrorism Act's requirement to have a final regulation in effect by December 12, 2003, which requires publication on or before October 12, 2003.



## XII. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday. FDA has verified the Web site addresses in this document, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

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27. Herwaldt, B. L., M. L. Ackers, and Cyclospora Working Group, "An Outbreak in 1996 of Cyclosporiasis Associated With Imported Raspberries," *New England Journal of Medicine*, May 29, 1997, 1548-1556.

### List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

### PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 is revised to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 304, 321, 331, 334, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Subpart H is added to part 1 to read as follows (subparts F and G are reserved):

#### Subparts F-G [Reserved]

#### Subpart H—Registration of Food Facilities

##### General Provisions

Sec.

1.225 Who must register under this subpart?

1.226 Who is exempt from this subpart?

1.227 What definitions apply to this subpart?

#### Procedures for Registration of Food Facilities

1.230 When must you register?

1.231 How and where do you register?

1.232 What information is required in the registration?

1.233 What optional items are included in the registration form?

1.234 How and when do you update your registration information?

#### Additional Provisions

1.240 What other registration requirements apply?

1.241 What happens if you fail to register?

1.242 What does assignment of a registration number mean?

1.243 Is food registration information available to the public?

#### General Provisions

##### § 1.225 Who must register under this subpart?

(a) You must register under this subpart if you are the owner, operator, or agent in charge of either a domestic or foreign facility, as defined in this subpart, and your facility is engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States, unless you qualify for one of the exemptions in § 1.226.

(b) An owner, operator, or agent in charge of a domestic facility must register whether or not the food from the facility enters interstate commerce.

(c) An owner, operator, or agent in charge of a foreign facility must register the facility. A foreign facility may designate its U.S. agent as its agent in charge for purposes of registering the facility.

##### § 1.226 Who is exempt from this subpart?

This subpart does not apply to the following facilities:

(a) Foreign facilities, if food from such facilities undergoes further manufacturing/processing (including packaging) by another foreign facility outside the United States. This exemption does not apply to a facility if the further manufacturing/processing (including packaging) conducted by the subsequent facility consists of adding labeling or any similar activity of a de minimis nature;

(b) Farms;

(c) Retail facilities;

(d) Restaurants;

(e) Nonprofit food facilities in which food is prepared for, or served directly to, the consumer;

(f) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing

intended solely to prepare fish for holding on board a harvest vessel. However, those fishing vessels otherwise engaged in processing fish, which for purposes of this section means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding are subject to all of the regulations in this subpart; and

(g) Facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

**§ 1.227 What definitions apply to this subpart?**

(a) *The act* means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply to such terms when used in this subpart.

(c) In addition, for the purposes of this subpart:

(1) *Calendar day* means every day shown on the calendar.

(2) *Facility* means any establishment, structure or structures under one management at one general physical location or, in the case of a mobile facility traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Individual homes are not facilities if the food that is manufactured/processed, packed, or held in the home does not enter commerce. A facility may consist of one or more contiguous structures. A single building may house distinct facilities if they are under separate management.

(i) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(ii) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

(3) *Farm* means a facility in one general physical location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both. The term "farm" includes:

(i) Facilities that pack or hold food, provided that all food used in such activities is grown or raised on that farm or is consumed on that farm; and

(ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on

that farm or another farm under the same ownership.

(4) *Food* has the meaning given in section 201(f) of the act. Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, 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.

(5) *Holding* means storage of food. Holding facilities include, but are not limited to, warehouses, cold storage facilities, storage silos, grain elevators, or liquid storage tanks.

(6) *Manufacturing/processing* means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples include, but are not limited to: Cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.

(7) *Nonprofit food facility* means a charitable entity that prepares, serves, or otherwise provides food to the public. The term includes, but is not limited to, food banks, soup kitchens, and nonprofit food delivery services. To qualify as a nonprofit food facility, the entity must be exempt from paying federal income tax under the U.S. Internal Revenue Code.

(8) *Packing* means placing, putting, or repacking food into different containers without making any change to the form of the food.

(9) *Port of entry* means the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first arrives in the United States. This port may be different than the port where the article of food is entered for U.S. Customs Service purposes.

(10) *Restaurant* means a facility that prepares and sells food directly to consumers for immediate consumption. Restaurants include, but are not limited to, cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens. Facilities that provide food to interstate

conveyances, rather than directly to consumers, are not restaurants.

(11) *Retail facility* means a facility that sells food products directly to consumers only. The term includes, but is not limited to, grocery and convenience stores, vending machine locations, and commissaries. The term includes facilities that not only sell food directly to consumers, but that also manufacture/process food in that facility solely for direct sale to consumers from that same facility.

(12) *U.S. agent* means a person residing or maintaining a place of business in the United States whom a foreign facility designates as its agent. A U.S. agent cannot be in the form of a mailbox, answering machine, or service, or other place where an individual acting as the foreign facility's agent is not physically present. The U.S. agent acts as a communications link between FDA and the facility. FDA will treat representations provided by the U.S. agent as those of the foreign facility, and consider information provided to the U.S. agent as the equivalent of providing the same information or documents to the foreign food facility.

(13) *You or registrant* means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

**Procedures for Registration of Food Facilities**

**§ 1.230 When must you register?**

The owner, operator, or agent in charge of a facility that manufactures/processes, holds, or packs food for consumption in the United States must be registered no later than December 12, 2003. Facilities that begin to manufacture/process, pack, or hold food for consumption in the United States on or after December 12, 2003, must be registered before they begin such activities.

**§ 1.231 How and where do you register?**

(a) Electronic registration: To register electronically, you must register at [a Web site that will be provided in the final rule], which will be available for registration 24 hours a day, 7 days a week. This Web site will be available wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes, as well as a foreign facility's U.S. agent if the facility makes such arrangements. FDA strongly encourages electronic registration for the benefit of both FDA and the registrant. Once you complete your registration, FDA will provide you with an automatic electronic confirmation of

registration and a permanent registration number. You will be considered registered once FDA electronically transmits your confirmation and registration number unless notified otherwise.

(b) Registration by mail: (1) If you do not have reasonable access to the Internet through any of the methods provided under paragraph (a) of this section, you must register by obtaining a copy of the registration from (Office name or mail code), the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or by phone at [toll-free number that will be provided in the final rule].

(2) When you receive the form in the mail, you must fill it out completely and legibly and mail it to the address in paragraph (b) of this section.

(3) If any required information on the form is incomplete or illegible when FDA receives it, FDA will send the form back to you for completion, provided that your mailing address is legible and valid.

(4) FDA will enter completed registration submissions into the system as soon as practicable, in the order received.

(5) FDA will then mail to the mailing address shown on the registration form a copy of the registration as entered, confirmation of registration, and your registration number.

(6) If any information you previously submitted is incorrect as entered into the system, you must update your registration as specified in § 1.234.

(7) You will be considered registered once FDA enters your registration data into the registration system and the system generates a registration number.

(c) No registration fee is required.

(d) You must submit all registration information in the English language.

#### **§ 1.232 What information is required in the registration?**

Each registrant must submit the following information through either of the methods described in § 1.231:

(a) The name, full address, phone number, fax number, and e-mail address of the facility;

(b) The name and address of the parent company, if the facility is a subsidiary of the parent company;

(c) Emergency contact information, including an individual's name, title, office phone, home phone, cell phone (if available), and e-mail address (if available);

(d) All trade names the facility uses;

(e) Product categories as identified in § 170.3 of this chapter;

(f) For a foreign facility, the name, address, phone number, fax number (if

available), and e-mail address (if available) of its U.S. agent; and

(g) A statement certifying that the information submitted is true and accurate, and that the person submitting the registration is authorized by the facility to register on its behalf. The statement requires the name of the person registering the facility. This statement also requires the phone number, e-mail address (if available), and fax number (if available) of the person submitting the registration.

#### **§ 1.233 What optional items are included in the registration form?**

FDA encourages, but does not require, you to submit the following optional items in your registration. These data will enable FDA to communicate more quickly with facilities that may be the target of a terrorist threat or attack, or otherwise affected by, an outbreak of foodborne illness. This information includes:

(a) Preferred mailing address, if different from that of the facility;

(b) Type of activity conducted at the facility (e.g., manufacturing/processing or holding);

(c) Food categories not included under § 170.3 of this chapter, but which are helpful to FDA for responding to an incident (e.g., infant formula, dietary supplements, and food for animal consumption);

(d) Type of storage, if the facility is solely a holding facility;

(e) A food product category of "most/all food product categories", if the facility manufactures/processes, packs, or holds foods in most or all of the categories under § 170.3 of this chapter; and

(f) Approximate dates of operation, if the facility's business is seasonal.

#### **§ 1.234 How and when do you update your registration information?**

(a) The owner, operator, or agent in charge must submit an update to the registration within 30 calendar days of any change to any of the information previously submitted, including, but not limited to, the name of the owner, operator, or agent in charge of a facility.

(b) A facility canceling its registration must do so on the cancellation of registration form.

(c) The cancellation of a facility's registration must include the following information:

(1) The facility's registration number;

(2) Whether the facility is domestic or foreign;

(3) The facility name and address;

(4) The name, address, and e-mail address (if available) of the individual submitting the cancellation; and

(5) A statement in which the individual submitting the cancellation will certify that the information submitted is true and accurate and the submitter is authorized by the facility to cancel its registration.

#### **Additional Provisions**

##### **§ 1.240 What other registration requirements apply?**

In addition to these regulations, you must comply with the registration regulations found in part 108 of this chapter, related to emergency permit control, and any other registration requirements that apply to the facility.

##### **§ 1.241 What happens if you fail to register?**

(a) Failure of a domestic or foreign facility to register in accordance with this regulation is a prohibited act under section 301 of the act (21 U.S.C. 331).

(b) Any person who imports or offers for import an article of food without complying with the requirements of section 801(l) of the act (21 U.S.C. 381(l)) as set out in this subpart, or otherwise violates any requirement under section 801(l) of the act, or any person who causes such an act, commits a prohibited act within the meaning of section 301(dd) of the act.

(c) Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin persons who commit prohibited acts. Under section 303 of the act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute persons who commit prohibited acts. Under section 306 of the act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.

(d) If an article of food is imported or offered for import and a foreign facility that manufactured/processed, packed, or held that food has not registered in accordance with this subpart, the food must be held at the port of entry unless FDA directs its removal to a secure facility in accordance with paragraph (e) of this section.

(e) Under paragraph (d) of this section, if FDA determines that removal to a secure facility is appropriate (e.g., due to a concern with the security of the article of food or due to space limitations in the port of entry), FDA may direct that the article of food be removed to a bonded warehouse, container freight station, centralized examination station, or another appropriate secure facility approved by FDA.

(f) Under paragraph (d) of this section, the owner, purchaser, importer or consignee must arrange for storage of the article of food in an FDA-designated secure facility and must promptly notify FDA of the location. Any movement of the article to the facility must be accomplished under bond.

Transportation and storage expenses shall be borne by the owner, purchaser, importer, or consignee.

(g)(1) Under paragraph (d) of this section, the article of food must be held at the port of entry or in the secure facility until the owner, operator, or agent in charge of the foreign facility has submitted its registration information to FDA, FDA has registered the facility in accordance with § 1.231, and FDA has notified the U.S. Customs Service and the person who submitted the registration that the article of food no longer is subject to a hold under section 801(l) of the act.

(2) Under paragraph (d) of this section, notwithstanding section 801(b)

of the act (21 U.S.C. 381(b)), while any article of food is held at its port of entry or in a secure facility under section 801(l) of the act, it may not be delivered to any of its importers, owners, or consignees.

(h) Under paragraph (d) of this section, a 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) does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

**§ 1.242 What does assignment of a registration number mean?**

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.

**§ 1.243 Is food registration information available to the public?**

(a) Registration forms submitted under this subpart, and any information contained in those forms that would disclose the identity or location of a specific registered person, is not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act).

(b) Paragraph (a) does not apply to any information obtained by other means or that has previously been disclosed to the public as defined in § 20.81 of this chapter.

Dated: January 27, 2003.

**Tommy G. Thompson,**  
*Secretary of Health and Human Services.*

Dated: January 27, 2003.

**Kenneth W. Dam,**  
*Acting Secretary of the Treasury.*

Note: The following appendix will not appear in the Code of Federal Regulations.

**BILLING CODE 4160-01-C**