To alleviate some of the burden registration may impose on industry, FDA has modified some of the elements of registration, including emergency contact information; the definitions for "farm," "facility," and "retail food establishment," and the timing for submitting updates to FDA when required elements in a registration change. These changes will be discussed in the appropriate sections later in this document.

FDA also believes that its electronic registration system will make registration an efficient and straightforward process. FDA has received positive comments from stakeholders who attended FDA's preliminary demonstrations of the electronic prototype registration system.

(Comment 2) Some commenters request that FDA include a provision in the interim final rule that permits the agency to amend the system quickly to respond to flaws in the rule discovered through practice. Some of these commenters state that this arrangement would be especially helpful for countries that are able to reach a more efficient or effective registration arrangement with FDA that reflects actual reductions in risks through such arrangements.

(Response) FDA always has the option to amend its regulations if the agency believes that improvements would serve the public interest, and interested persons may request such modification by following the procedures in 21 CFR 10.30, regarding citizen petitions. The process for any amendment to an existing FDA regulation must conform to the requirements of the Administrative Procedure Act (APA) (5 U.S.C. 551–559). Notably, section 553 of the APA provides a process for issuing a final rule in an expedited timeframe if certain conditions are met. Importantly, however, FDA can only amend the interim final registration rule consistent with the requirements in the Bioterrorism Act.

(Comment 3) FDA received several comments about the need for outreach efforts regarding the registration requirement. Some commenters encourage FDA to facilitate education regarding the new rule and to provide foreign facilities with information necessary to maintain the flow of trade to the United States. Other commenters encourage FDA to develop clear, definitive statements that outline registration requirements in a simple manner. Some commenters ask about the role of States in the outreach strategy. One commenter recommends that FDA reach out to State agencies and the relevant media to ensure that all affected industries are aware of the registration requirement. Finally, some commenters request that FDA establish consultation services staffed with both English and foreign language speakers to answer questions about the registration system and requirements and to give technical assistance to help foreign facilities meet the requirements of the regulation.

(Response) FDA conducted extensive outreach on the proposed registration rule, including having relevant FDA staff attend 6 international meetings and over 100 domestic meetings to ensure that affected parties were aware of the Bioterrorism Act registration requirement. On January 29, 2003, FDA held a public meeting (via satellite downlink) to discuss the registration and prior notice proposed rules. (See 68 FR 1568, January 13, 2003, or *http://www.accessdata.fda.gov/scripts/oc/ohrms/advdisplay.cfm.*) Nearly 1,000 participants in North and South America and the Caribbean viewed that live broadcast. The meeting was later rebroadcast to Europe, Asia, Africa, and the Pacific (areas in different time zones). FDA has also provided transcripts of the broadcast in English, French, and Spanish (the three official WTO languages) on the agency's Web site. In addition to this outreach to the affected industry, FDA has conducted outreach on the proposed rule to States.

FDA plans similar outreach directed to both domestic and international stakeholders following publication of the interim final rules implementing the registration and prior notice provisions of the Bioterrorism Act. Our outreach will include:

- Dissemination of materials to guide affected domestic and international food facilities through the new processes established to implement the registration and prior notice requirements of the Bioterrorism Act;
- A satellite downlink video broadcast and a series of videoconferences to various regions of the world;
- Materials and events for the media;
- Domestic outreach meetings to States and industry;
- International outreach to U.S. trading partners;
- Online assistance to registrants;
- Presentations by FDA officials and exhibits at professional and trade conferences and meetings to inform industry and State and local government representatives of the new regulations and their requirements; and
- Cooperative arrangements with Customs and Border Protection (CBP) and other Federal agencies to ensure that information on the final regulations and their requirements is disseminated to affected companies and individuals.

More specifics regarding each of these will be included on FDA's Web site at *http://www.fda.gov/oc/bioterrorism/bioact.html.*

FDA will notify the WTO of these regulations. In addition, shortly after publication of this interim final rule, FDA will begin disseminating at the U.S. ports of entry flyers and posters summarizing the new requirements and informing representatives of affected facilities how to register and provide prior notice to FDA.

(Comment 4) One commenter suggests that FDA should utilize State resources to cross-reference with its registration database. This commenter suggests that FDA supply States with copies of registration forms that the State inspectors can give to local facilities during routine inspections, but cautions that FDA should supply the forms so as not to deplete State funds.

(Response) FDA agrees with the commenter's suggestion that FDA should use State resources to cross-reference registrations, and will work with States to do so. FDA believes working in cooperation with our State partners will enhance our collective ability to protect the safety of the U.S. food supply, and our ability to work with facilities in the event of an actual or potential threat against a facility or food product. FDA acknowledges the suggestion that the agency should supply States with copies of the FDA registration form for distribution to potential registrants. However, because FDA is trying to encourage as many registrants as possible to register electronically, FDA intends to make paper forms available only through the methods described in this rule. FDA intends to work with States to disseminate information about the Federal registration requirements.

B. Foreign Trade Issues

(Comment 5) Some commenters questioned the consistency of the proposed regulation with U.S. obligations under the NAFTA and various WTO agreements.

(Response) FDA is aware of the international trade obligations of the United States and has considered these obligations throughout the rulemaking process for this regulation. As noted below, FDA believes that these regulations are consistent with these international trade obligations.

(Comment 6) Some commenters asserted that the proposed regulation is burdensome, costly, discriminatory, and will have a negative impact on foreign trade.

(Response) In drafting the interim final rule, FDA structured the rule to be consistent with the statutory mandates of the Bioterrorism Act and, at the same time, to reduce the costs associated with compliance. As discussed in more detail later in the preamble, FDA carefully considered comments received regarding the burden imposed by the proposed rule, including its impact on international trade. The agency has made a number of changes in the interim final rule that are both consistent with FDA's statutory mandate and that will make it easier and less costly for covered facilities (foreign or domestic) to register. In addition, the interim final rule exempts certain establishments from the registration requirement that, under the rule as proposed, would have been required to register. For example:

- FDA has changed the definition of "food" for purposes of the Bioterrorism Act to exclude food contact substances as defined in section 409(h)(6) of the FD&C Act and pesticides as defined in FIFRA (7 U.S.C. 136(u)).
- FDA has broadened the definition of "farm" to include the activities of harvesting, and the rule considers washing, trimming of outer leaves, and cooling of crops on a farm to be harvesting. Also, in the interim final rule, "farm" includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership.
- FDA is clarifying that having a single U.S. agent for FDA registration purposes does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes.
- The interim final rule allows registrants to submit their registrations by fax or CD–ROM, which FDA will enter into its registration system, along with the mailed submissions, as soon as practicable, in the order received.
- FDA has extended the timeframe in which registrants must update their registrations from 30 to 60 days of any change in the required information.
- FDA has deleted the requirement to update optional information previously submitted.

C. Comments on Who Must Register Under This Subpart? (Proposed § 1.225)

(Comment 7) Some commenters disputed the statement in the proposed rule that [i]ndividual homes are not subject to the regulation if the food that is manufactured/processed, packed, or held in the home does not enter commerce." (68 FR 5378). These commenters argue that under this limited exclusion for homes, individuals, such as Girl Scout and Boy Scout volunteer parents, individuals who prepare food in their homes for functions such as church bake sales, and individuals who temporarily store food in their homes as sales samples or small inventories of product for delivery to rural retailers would be required to register because they often hold in their homes food products destined for further movement through commerce. The commenters argue that the Bioterrorism Act does not mention individual residences in the scope of facilities that manufacture, process, pack, or hold food and asserts that Congress did not intend that the registration requirements compel ordinary citizens to register their residences, and that including residences would not give FDA any useful or actionable information. This commenter concludes that FDA should explicitly exempt individual residences under all circumstances.

(Response) FDA has concluded that private individual residences are not "facilities" for purposes of the registration provision of the Bioterrorism Act. Under the Bioterrorism Act, the term "facility" includes "any factory, warehouse, or establishment." Congress did not specify any definition for these terms. Under their common meanings, the terms can include private residences. For example, according to Webster's II New Riverside University Dictionary (1994), the most relevant definition of "establishment" is "a business firm, club, institution, or residence, including its possessions and employees." However, "[i]n determining whether Congress has specifically addressed the question at issue, the court should not confine itself to examining a particular statutory provision in isolation * * *. It is a 'fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'" *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 121 (2000). Other parts of the registration provisions in section 415 of the FD&C Act indicate that Congress only intended businesses to register, and raise a question as to whether Congress intended that private individual residences, even though food is manufactured/processed, packed, or held at such residences, be considered facilities. For instance, a registrant is required to submit "the name and address of each facility at which, and all trade names under which, the registrant conducts business * * *"(21 U.S.C. 350d(a)(2)). Thus it is unclear whether Congress intended all individual private residences at which food is manufactured/processed, packed, or held to be included in the term "facility." Furthermore, the requirement that a facility submit its "name" as well as its "trade names" raises a question as to whether Congress intended "facility" to include private individual residences since it is unlikely that a home would have a name or a trade name. Where the words of the statute are ambiguous, an agency may make a reasonable interpretation of the statute. *Chevron, USA, Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 842–843 (1984); *Brown & Williamson*, supra, at 132.

Consistent with the language of section 415(a)(2) discussed previously, the agency concludes that interpreting the term "facility" to exclude private individual residences is a reasonable construction for purposes of registration. This interpretation, however, does not necessarily preclude a reasonable construction of other provisions of the FD&C Act to include such residences.

Therefore, in response to these comments, we have revised the interim final rule at 1.227(b) to provide that the definition of facility does not include private residences of individuals. Accordingly, homes that store Girl Scout cookies for distribution, homes in which food is prepared for church bake sales, and homes where individuals temporarily store sales samples or small inventories of products for delivery to rural retailers are not facilities, and therefore, are not subject to registration.

(Comment 8) One commenter requests that FDA clarify whether trans-shippers, who ship products through the United States en route to other countries, are required to register. Another commenter wants FDA to clarify whether it will require registration of foreign facilities that export food to locations outside the mainland United States, such as Hawaii and the Northern Mariana Islands.

(Response) Because the registration requirement only applies to facilities that manufacture/process, pack, or hold food for consumption "in the United States," facilities that manufacture/process, pack, or hold food that is for consumption only in other countries are not required to register. Therefore, manufacturers/processors, packers, or holders of food that is trans-shipped through the United States to other countries for consumption are not required to register. Facilities that export food for consumption in locations that are part of the United States are required to register. Locations are part of the United States if they are

in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico because section 415(b)(2) of the Bioterrorism Act (21 U.S.C. 350d(b)(2)) defines the term "domestic facility" to mean a facility in any of the States or Territories. Facilities that manufacture/process, pack, or hold food for consumption in Hawaii and the Northern Mariana Islands are thus required to register because these locations are respectively a State and a Territory of the United States.

(Comment 9) Several commenters responded to FDA's request for comments on whether it has authority to exempt domestic facilities engaged only in intrastate commerce from the registration requirement and if so, whether the agency should use that authority. The commenters agree with FDA's decision in the proposed rule to require facilities engaged in intrastate commerce to register. One commenter states that intrastate facilities should not be excluded because individuals wanting to contaminate the food supply could choose key States from which to launch an attack. This commenter also points out that foreign facilities are not exempt, even if they only import food into one State. Several commenters argue that requiring these foreign facilities to register, while exempting facilities engaged in intrastate commerce, is discrimination against foreign facilities.

(Response) In the preamble to the proposed rule, FDA tentatively concluded that the Bioterrorism Act requires all domestic facilities to register, whether or not they engage in interstate commerce. Accordingly, proposed § 1.225(b) stated that a domestic facility must register (unless otherwise exempt) "whether or not the food from the facility enters interstate commerce."

FDA sought 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 asked for comment on the number of so-called "intrastate" facilities that would not be covered by one of the exemptions from registration. No one asserted that Congress could not require such facilities to register. Similarly, no one identified intrastate facilities that would not already be covered by one of the exemptions. As noted in the preamble to the proposed rule, FDA believes that most facilities that do not engage directly in interstate commerce would be covered by an exemption in the interim final rule (*e.g.*, residences of private individuals, farms, restaurants, retail food establishments.)

The comments received agreed with FDA's decision in proposed § 1.225 to require all nonexempt facilities to register even if food from the facility does not enter interstate commerce. They agreed with FDA's position that having a central database including all facilities that manufacture/process, pack, or hold food would help achieve the goals of the Bioterrorism Act. Moreover, the commenters gave additional reasons why excluding so-called "intrastate" facilities from the registration requirement could be detrimental or inappropriate. Importantly, no comments presented any reason for excluding facilities from the registration requirement solely on the basis of whether the food from the facility enters interstate commerce.

FDA is mindful that its interpretation of the Bioterrorism Act should not cast doubt on the constitutionality of the statute. (*See Solid Waste Agency of Northern Cook County* v. *U.S.*, 531 U.S. 159 (2001)). The agency has considered the relevant provisions of the Bioterrorism Act, the comments submitted on this issue, FDA's responsibilities in implementing the Bioterrorism Act, and the law interpreting the commerce clause of the Constitution (Article I, section 8). Based on these considerations, FDA is retaining § 1.225(b) as proposed, with the result that all facilities that manufacture/process, pack, or hold food (unless otherwise exempt) must register even if food from the facility does not enter interstate commerce.

Significantly, the plain language of new section 415 of the FD&C Act does not exclude a facility from registration because food from such facility does not enter interstate commerce. Notably, sections 301 and 304 of the FD&C Act (21 U.S.C 334) demonstrate that Congress has included a specific interstate commerce nexus in the provisions of the FD&C Act when that is its intent. Accordingly, it is reasonable to interpret the Bioterrorism Act as not limiting registration only to those facilities with a direct connection to interstate commerce. Congress's power to legislate under the commerce clause is very broad. However, such power is not without limits, *see United States* v. *Lopez*, 514 U.S. 549, 567 (1995); *U.S.* v. *Morrison*, 529 U.S. 598, 618 (2000), and these limits have been construed in light of relevant and enduring precedents.

In particular, in *Lopez, supra*, the Supreme Court acknowledged the continuing vitality of *Wickard* v. *Filburn*, 317 U.S. 111 (1942), noting that "although Filburn's own contribution to the demand for wheat may have been trivial by itself, that was not 'enough to remove him from the scope of federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial.'" (514 U.S. at 556.) This principle applies squarely to the registration provision of the Bioterrorism Act. Accordingly, given the collective impact on commerce of so-called "intrastate" facilities that manufacture/process, pack, or hold food, FDA has concluded that each such facility should be required to register regardless of whether food from that facility enters interstate commerce. Thus, FDA is retaining § 1.225(b) as proposed.

This outcome is consistent with section 709 of the FD&C Act (21 U.S.C 379a), which states that in any action to enforce the act's requirements respecting foods, drugs, devices, and cosmetics, any necessary connection with interstate commerce is presumed. Likewise, this outcome is consistent with Congress's goal in enacting the Bioterrorism Act because the potential harm from bioterrorist attacks or other food emergencies can be great, whether or not the food moves from one state to another. The usefulness of the registration database can also be significant in food emergencies where interstate shipment has not occurred. Finally, as noted, FDA received no comments identifying so-called "intrastate" facilities that would not otherwise be exempt from registration. Thus, this outcome, as a practical matter, should have little if any impact on which facilities must register. Accordingly, FDA concludes that it is appropriate to require facilities that do not fall within an exemption to register regardless of whether the food from the facility enters interstate commerce.

(Comment 10) One commenter states that the proposed rule requires all foreign and domestic facilities with operations that have an effect or impact on food to register unless subject to specific exemptions. The commenter believes that this is vague and not specific for imported shipments, especially fresh produce, and would require all parties having any contact with the produce to register. This commenter also argues that the party registering with FDA for produce shipments should be the exporter.

(Response) The commenter misunderstands the proposed rule. First, the statement that the rule would require registration by all facilities that "have an effect on food" is not accurate. As stated previously, both the Bioterrorism Act and this interim final rule (which is consistent with the proposed rule) provide that a facility must be registered if it is engaged in manufacturing/processing, packing, or holding food for consumption in the United States. Second, both the Bioterrorism Act and the interim final rule (as did the proposal) provide that foreign facilities are exempt from registration if food from these facilities undergoes further manufacturing/processing (including packaging) by another foreign facility outside the United States. Finally, because the registration requirement is facility-based, an exporter is required to register only if it is the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States, and the facility is not subject to any of the listed exemptions. This is consistent with the specific language in the Bioterrorism Act.

(Comment 11) One commenter asks FDA to clarify whether registration applies to "bulk grain handling facilities which exist for the purpose of export and domestic shipments."

(Response) It is not clear from the comment what activities the bulk grain handling facility conducts. If "bulk grain handling" means storing grain in bulk, the facility is required to register with FDA if the grain will be consumed by humans or animals in the United States, because the facility is engaged in "holding" food. Similarly, if "bulk grain handling" is synonymous with the activities of a feedmill, the facility is required to register with FDA because feed mills manufacture/process, pack, and hold feed for animal consumption. The discussion under the definition of "retail food establishment" provides further clarification.

(Comment 12) One commenter has several questions related to who is required to register: Is the registration requirement limited strictly to commercial shipments? How does registration affect United States travelers who bring varying quantities of goods into the United States?

(Response) The registration requirement applies to facilities that manufacture/process, pack, or hold food for consumption in the United States. Thus the requirement is tied to: (1) Facilities, and (2) food that will be consumed in the United States. The Bioterrorism Act, therefore, does not limit the registration requirement to commercial shipments. However, travelers who bring foods into the United States on their person or in their baggage are not facilities under this rule, and thus, they are not required to register. FDA notes that travelers may nevertheless be subject to prior notice if they are carrying or otherwise are accompanied by food that is not for personal use (*i.e.*, for consumption by themselves, family, or friends, and not for sale to anyone.)

(Comment 13) A commenter asks what is the responsibility of foreign governments owning facilities that hold food? Also, what is the responsibility of a country through whom goods of concern may be trans-shipped?

(Response) The registration requirement applies to facilities that manufacture/process, pack, or hold food for consumption in the United States. Thus the requirement is tied to: (1) Facilities, and (2) food that will be consumed in the United States. There is no exemption in the Bioterrorism Act or this interim final rule for facilities that manufacture/process, pack, or hold food that happen to be government-owned. Accordingly, such government-owned facilities are required to register if they meet the other requirements of registration.

A country through which foods may be trans-shipped on their way to the United States has no responsibility regarding registration, as the registration requirement applies to facilities that manufacture/process, pack, or hold food. Under the Bioterrorism Act, the responsibility to register is on the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption by humans or animals in the United States.

(Comment 14) A commenter primarily engaged in exporting products from the United States asks FDA to clarify whether such an exporter is required to register if the foreign country or foreign buyer rejects food being exported from the United States, and the food is returned to the United States.

(Response) Where food exported from the United States is rejected and returned to this country, the owner, operator, or agent of any facility that manufactures/processes, packs, or holds the food is required to register if the food will be consumed in the United States. FDA is assuming in comment 14 that no foreign facility other than the exporting facility manufactures/processes, packs, or holds the food before it is returned to the United States.

(Comment 15) One commenter asks FDA to clarify whether domestic grain handling, and feed manufacturing facilities engaged solely in exporting bulk or processed agricultural commodities to other countries are exempt from the registration requirement.

(Response) A facility is only required to register with FDA if the food manufactured/processed, packed, or held in the facility is for consumption or is actually consumed in the United States by humans or animals.

(Comment 16) One commenter asks "[w]hat happens if [an] exporter cannot get [the foreign] manufacturer to register, and does not have all of the necessary information to do it himself?" The commenter asks whether the exporter "will not be permitted to send the shipment resulting in lost sales to his company."

(Response) The response to comment 17 addresses which foreign facilities are required to register with FDA. If the manufacturer/processor in the above scenario (or a packer or holder) is required to register but fails to do so, the Bioterrorism Act provides that food shall be held at the U.S. port of arrival or in a secure facility until the facility registers (21 U.S.C. 381(l)). However, the provisions of the prior notice interim final rule (which is published elsewhere in this issue of the **Federal Register**) that address product under hold provide for export of such products.

FDA has made some editorial changes in this section for the purpose of clarity.

D. Comments on "Who is Exempt From This Subpart?" (Proposed § 1.226)

In the interim final rule, the title of this section has been changed to "Who does not have to register under this subpart?"

1. Foreign Facilities

(Comment 17) A commenter asks which foreign facilities would be required to register in the case of raw agricultural commodities, such as cocoa beans, which may be dried, (in some cases) fermented, blended with beans from other farms, packed into bags, fumigated, weighed, graded, and stored in one or more warehouses before being exported to the United States.

(Response) The Bioterrorism Act states that a foreign facility must register if food from such a facility is exported to the United States for consumption in this country "without further processing or packaging outside the U.S." Therefore, a foreign facility is only required to register if it manufactures/processes the food without further manufacturing/processing of the food by another foreign facility prior to export to the United States. The foreign facility is required to register even if there is a subsequent facility that further manufactures/processes the food if the activities of the subsequent facility are merely of a *de minimis* nature. A foreign facility must also register if, prior to

export to the United States, it packs or holds food after the last foreign manufacturer/processor of the food. Under these provisions, the last facility that manufactures/processes the cocoa beans, and every facility that subsequently engages in packing or holding the beans, as well as any facility that subsequently engages in *de minimis* manufacturing/processing (such as labeling) of the cocoa beans, is required to register.

(Comment 18) Several commenters argue that registration of foreign facilities should be limited to the last holder of the goods, since it would be difficult for many facilities further up the distribution chain to find a U.S. agent.

(Response) FDA is denying this request due to the registration requirement provided in the Bioterrorism Act for foreign facilities that manufacture/process, pack, or hold food. See the response to comment 17 for these specific requirements.

(Comment 19) A commenter requests clarification on whether registration applies to foreign port facilities such as warehouses or storage and inspection facilities belonging to private companies. Another commenter asks whether brokers, warehousers, or traders who take possession of food before it is exported to the United States need to register.

(Response) As noted, the registration requirement of the Bioterrorism Act is facility-based and has no exemption from registration for port storage and inspection facilities if these facilities are used to hold food. Therefore, foreign port storage and inspection facilities must be registered with FDA if they manufacture/process, pack, or hold food for consumption in the United States. Similarly, a broker, warehouser, or trader who takes possession of food before it is exported to the United States is required to register if the broker, warehouser, or trader is the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

(Comment 20) One commenter states that all foreign processors, holders, and manufacturers throughout the foreign distribution chain should be required to register.

(Response) FDA is denying this request due to the registration requirement provided in the Bioterrorism Act for foreign facilities that manufacture/process, pack, or hold food. See the response to comment 17 for these specific requirements.

(Comment 21) One commenter states that, in its application to foreign facilities, FDA should revise its definition of "holding" to "provid[ing] storage of food products and neither engag[ing] in the manufacturing nor processing of the food products, except for incidental services that do not involve unsealing of the primary food container."

(Response) FDA declines to change "holding" to include "incidental services that do not involve unsealing of the primary food container." This change would blur the distinction between manufacturing/processing and holding because activities that do not involve unsealing of a food container could be considered *de minimis* processing, as opposed to holding. See the response to comment 17 for specific registration requirements for foreign facilities.

(Comment 22) Some commenters involved in the production of food that either has a long shelf life or long production phase ask whether they are required to register with FDA if they do not know the eventual export destination at the time of production. For example, for vintage wine, the eventual destination of the wine (*i.e.*, whether the wine is for consumption in the United States) is generally not known at the time of production. Other commenters state that for similar reasons, registration should not be required of foreign "collection points," which receive products from a large number of suppliers, then distribute or sell them at auctions.

(Response) Under this interim final rule, an owner, operator, or agent in charge must register its facility only if the food manufactured/processed, packed, or held at the facility is for consumption in the United States. In the response to comment 17, FDA has clarified the registration requirements for foreign facilities that manufacture/process, pack, and hold food. That discussion is also relevant to this comment. Although the destination of some food produced abroad is not known at the time of its production, FDA believes that producers and distributors of these products are likely to have an idea of the eventual destination, based on prior sales and promotional activities. Because the Bioterrorism Act generally prohibits food from an unregistered foreign facility from being delivered for distribution in the United States until the facility is registered, FDA recommends that the owners, operators, or agents in charge of facilities producing these types of food register their facilities if they reasonably believe their foods may be consumed in the United States.

(Comment 23) One commenter states that, for commercial confidentiality reasons, foreign traders may not wish to reveal the identity of the packer or producer to the importer, and that the registration requirement would interfere with this confidentiality.

(Response) FDA acknowledges that for some entities, the registration requirements may result in some alterations of their past business practices. However, the Bioterrorism Act imposes certain requirements on the importation of food for consumption in the United States, including registration of foreign and domestic food facilities. It is incumbent on these facilities to make the necessary arrangements to comply with the Bioterrorism Act if they wish to continue to import food into the United States.

(Comment 24) Some commenters request that foreign facilities should be exempt if they export food solely to their own subsidiaries in the United States. These commenters state that these foreign facilities send finished or semifinished goods or raw materials to their subsidiaries in the United States for further processing. The commenters argue that, under these circumstances, the foreign parent company should not have to register; however, under the proposed rule, not only the final processor, but also all of its suppliers, would be required to register.

(Response) FDA is denying this request because the Bioterrorism Act does not authorize an exemption from registration for facilities that export solely to their subsidiaries in the United States. Moreover, it appears that the commenter misunderstands the requirements that apply to foreign facilities. Under both the proposed rule and this interim final rule, suppliers of food need not register if another foreign facility subsequently manufactures/processes the food before it is exported to the United States, unless the subsequent facility is conducting *de minimis* activities, such as labeling. In the latter situation, both facilities would have to register.

(Comment 25) Several commenters request further clarification regarding the "*de minimis*" provision. Some commenters request that FDA exempt foreign facilities engaging in *de minimis* activity. In fact, one commenter mistakenly states that the proposed rule exempts foreign facilities if a facility subsequent to them conducts *de minimis* activity.

(Response) Please see the response to comment 17 regarding the registration requirements as applied to foreign manufacturers/processors. An exemption for foreign facilities engaged in *de minimis* manufacturing/processing would be inconsistent with the Bioterrorism Act language quoted in the response to comment 17.

(Comment 26) One commenter requests that FDA provide either a definition of "*de minimis*" or more examples of what constitutes *de minimis* activity, such as blending, sieving, particle size distribution, drying crops, and repackaging.

(Response) FDA has concluded that *de minimis* manufacturing/processing does not involve direct manipulation of food. Therefore, most of the activities included in the comment (blending, sieving, particle size distribution, and drying crops) are not *de minimis* because they manipulate food. Regarding "re-packaging," it is not clear whether this activity would contact the food itself or merely involve contact with outer materials that do not contact the food. If the re-packaging involves contact with the food itself, it would not be considered *de minimis*.

2. Farms

FDA did not receive any comments on "farm" as an exemption. Please see section III.E.6 of this document for changes FDA made to the definition of "farm." FDA also addresses the comments we received on farms in section III.E.6 of this document.

3. Retail Facilities

FDA did not receive any comments on "retail facilities" as an exemption. In this interim final rule, we have changed the term "retail facility" to "retail food establishment" to be consistent with the statutory term. Please see section III.E.14 of this document for changes FDA made to the definition of "retail food establishment." FDA also addresses the comments we received on retail food establishments in III.E.14 of this document.

4. Restaurants

Please see the definitions section III.E.13 of this document for changes FDA made to the definition of "restaurant." FDA also addresses all but one of the comments we received on the "restaurant" exemption in section III.E.13 of this document.

(Comment 27) FDA did receive one comment specifically addressing the restaurant exemption. This comment states that although the proposed rule provides that restaurants are exempt from registration, it "continues to define when it is necessary for food facilities to register and provides an opportunity for the foreign facilities to designate a U.S. agent for registration. This language alone contradicts the exemption in many circumstances within the restaurant industry. The intention of Congress was to exempt restaurants * * * language must be incorporated to state that foreign facilities should not have the ability to designate a U.S. agent for registration." This commenter also urges FDA to incorporate language in the interim final rule clearly stating that foreign facilities may designate a restaurant as a U.S. agent, while emphasizing that this designation does not remove the restaurant exemption from all restaurants.

(Response) FDA is not certain it understands this comment. This commenter appears to be concerned that the restaurant exemption would conflict with the U.S. agent requirement, if a foreign facility were to choose a domestic restaurant as its U.S. agent. FDA agrees that even if a foreign facility designates a domestic restaurant as its U.S. agent, the restaurant is still exempt from registration itself. In such circumstances, the restaurant can also be authorized by the owner, operator, or agent in charge of the foreign facility to register that facility. Regarding incorporation of language specifying that restaurants can be U.S. agents in the interim final rule, FDA believes that this change is not necessary because the interim final rule states that a U.S. agent is "a person (as defined in section 201(e) of the act (21 U.S.C. 321(e)))." This definition includes a restaurant.

5. Nonprofit Food Facilities

In this interim final rule, FDA has changed the term "nonprofit food facility" to "nonprofit food establishment" to be consistent with the statutory term.

(Comment 28) One commenter asks FDA to confirm that the commenter's affiliates and their agencies are exempt as nonprofit food facilities. This commenter states that all of its food banks, food rescue organizations, and local agencies of its affiliates are required to be incorporated as nonprofit organizations that are exempt from paying income tax as defined by the U.S. Internal Revenue Code Section 501(c)(3) or "the equivalent." The commenter states that its certified affiliate food banks and food rescue organizations provide food to the public through direct distributions and through distributions to local nonprofit section 501(c)(3), or equivalent nonprofit, agencies.

(Response) The interim final rule defines a "nonprofit food establishment" as "a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the U.S." The interim final rule includes central food banks, soup kitchens, and nonprofit food delivery services as examples of nonprofit food establishments. In response to the comment, FDA is clarifying that to be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)). If the commenter's establishments meet all aspects of the definition of nonprofit food establishment in this interim final rule, they would be exempt from registration.

Please see section III.E.10 of this document for changes FDA made to the definition of "nonprofit food establishment."

6. Fishing Vessels

(Comment 29) One commenter states that the fishing vessel exemption will not achieve its intended purpose, due to the Bioterrorism Act's reference to § 123.3(k), which FDA includes in the fishing vessel exemption. The commenter argues that incorporating the reference to § 123.3(k) into the proposed rule invalidates nearly the entire exemption, because harvested fish must be removed from the harvest vessel for any further processing. The exemption, therefore, would only exempt those fishing vessels that transfer harvested fish by brailing or pumping to offshore processing vessels. The exemption would not apply to fishing vessels that enter port and offload fish dockside. As a result of these restrictions on the exemption, the commenter requests that FDA "acknowledge the irony of this exemption" and consider requesting a technical amendment to the Bioterrorism Act to broaden the exemption.

(Response) The Bioterrorism Act (21 U.S.C. 350d(b)(1)) expressly references the Seafood Hazard Analysis Critical Control Point (Seafood HACCP) regulations (§ 123.3(k)) as part of the fishing vessel exemption. Accordingly, to the extent that the exemption for fishing vessels is limited, it is limited by Congress. Importantly, however, FDA notes that "dockside unloading" is included in the definition of "processing" (§ 123.3(k)) to cover waterfront facilities that unload vessels and pack the catch for shipment to buyers, not the vessels from which the catch is unloaded. (See 60 FR 65096, 65114 to 65115, December 18, 1995.) Thus, the comment is not correct that the only vessels that would be exempt are those that transfer fish by brailing or pumping to offshore processing vessels. Generally, vessels covered by the

Seafood HACCP regulations are required to register with FDA.

FDA is using the term "fish" to describe the cargo of fishing vessels in order to be consistent with the use of the term in 21 CFR Part 123. "Fish" is defined in § 123.3(d) as "fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited, to alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption."

(Comment 30) A commenter asks FDA to clarify whether any facilities would be required to register in the following scenario: Company A purchases fish from a Mexican fisherman, loads it onto refrigerated trucks, and transports it to Company B, which is located in the United States.

(Response) Under the interim final rule, fishing vessels are exempt from registration unless processing is done on board the ship. For purposes of this exemption, "processing "is defined in § 123.3(k)(1) as "[h]andling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding." Importantly, however, according to § 123.3(k)(2), harvesting and transport vessels that engage in "[h]arvesting or transporting fish or fishery products, without otherwise engaging in processing," or "[p]ractices such as heading, eviscerating, or freezing, intended solely to prepare a fish for holding on board a harvest vessel," are exempt from registration under 21 CFR 1.126(f). Under the scenario described in the comment, the Mexican fisherman would have to register the vessel if he catches fish and processes it aboard the vessel under § 123.3(k). If the fisherman does not process the fish (other than heading, eviscerating, or freezing the fish to prepare it for holding on board his vessel), the vessel would not need to register. Whether Company A or Company B would be required to register depends upon their activities. If either company engages in manufacturing/processing, packing, or holding the fish, all facilities at which such activities occur must be registered (unless a facility qualifies for one of the exemptions from registration, *e.g.*, a restaurant). A transportation vehicle is not a facility and would not need to register if it holds the fish only in its usual course of business as a carrier (§ 1.226(f).)

7. Facilities Regulated Exclusively, Throughout the Entire Facility, by USDA

(Comment 31) Several commenters ask FDA to clarify which facilities are regulated exclusively by USDA, as USDA versus FDA jurisdiction is not clear to foreign facilities.

(Response) Whether a facility is regulated exclusively by USDA (and thus, is exempt from registration, 21 CFR 1.226(g)) depends upon the products manufactured/processed, packed, or held at the facility. Any facility that manufactures/processes, packs, or holds some foods subject to FDA jurisdiction does not satisfy the exclusivity part of the exemption in § 1.226(g) and thus, must register with FDA.

More specifically, under the Meat Inspection Act (MIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), USDA inspects facilities that slaughter poultry, cattle, sheep, swine, equines, or goats and facilities that process "poultry products" or "meat food products" as defined under the MIA and the PPIA (21 U.S.C. 453(f), 455, 601(j), 603). Any USDA-inspected facility that slaughters only poultry, cattle, sheep, swine, equines, or goats is solely under USDA jurisdiction and is exempt from registration. Facilities that slaughter these animals, but that also slaughter other animals, such as deer or elk, are under both USDA and FDA jurisdiction and must register. Facilities that manufacture/process only "poultry products" or "meat food products," as defined by USDA, are exempt from registration. Facilities that manufacture/process "meat food products," such as pizzas with meat topping, and other products, such as cheese pizzas, are under both FDA and USDA jurisdiction and must therefore register with FDA.

Under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), USDA inspects facilities that process "egg products," which are "any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been * * * considered by consumers as products of the egg food industry * * * " (21 U.S.C. 1033(ff)). A facility is regulated exclusively by USDA if it manufactures/processes only "egg products." If a facility manufactures/processes other food in addition to, or instead of, egg products, the facility is not regulated exclusively, throughout the entire facility, by USDA and it must be registered. Thus, a facility is regulated exclusively, throughout the entire facility, by USDA if it manufactures/processes, packs, or holds only "meat food products," "poultry products," or "egg products" as defined above. If a facility manufactures/processes, packs, or holds other food in addition to meat food products, poultry products, or egg products, the facility is not regulated exclusively, throughout the entire facility, by USDA and thus, would not be exempt from registration.

(Comment 32) One commenter requests FDA to expand this exemption by including all facilities that are subject to USDA jurisdiction, even if they are also subject to FDA jurisdiction. Another commenter asks why, under this exemption, FDA exempts such a considerable part of the production chain from the registration requirements, while also establishing strict requirements for other facilities.

(Response) The Bioterrorism Act requires that, unless exempt, all facilities that manufacture, process, pack, or hold food for consumption in the United States must register (21 U.S.C. 350d(a)). However, section 315 of the Bioterrorism Act states that no part of Title III should be construed to alter the jurisdiction between USDA and FDA. Under current practice, FDA may have jurisdiction over a food facility, USDA's Food Safety and Inspection Service may have jurisdiction over a food facility, or the two agencies may have joint jurisdiction over a food facility. Under section 315, the Bioterrorism Act does not change this structure. Accordingly, only those facilities that manufacture/process, pack, or hold food that is regulated exclusively by USDA is exempt from registration under section 315. In response to the comment asking why FDA exempts such a considerable part of the production chain from registration under this exemption, the authority in the Bioterrorism Act only extends to facilities manufacturing/processing, packing, or holding food under FDA's jurisdiction. Congress did not extend these requirements to facilities under USDA's exclusive jurisdiction. (USDA has other existing authority over facilities under their jurisdiction.) Moreover, even though a facility is exempt from registration with FDA this does not mean that it is exempt from all statutes and regulations that protect the safety and security of food consumed in the United States.

(Comment 33) Several commenters urge FDA to exempt from the registration requirement other facilities in addition to those exclusively regulated by USDA, such as USDA-approved, federally licensed grain storage silos and elevators, low acid canned food, aquatic products, and fruit exporting enterprises. One of these commenters states that under the Warehouse Act, USDA performs regular, unscheduled inspections of these grain storage facilities; therefore, USDA, not FDA, is the most appropriate federal agency to respond to threats affecting these facilities. The other commenter states that fruit exporters have already registered with USDA.

(Response) FDA believes that this interim final rule implements the intent of Congress as expressed in the Bioterrorism Act. The statute does not include exemptions from the registration requirement for the types of facilities listed in the comment, and the comment identifies no other basis for the exemptions proposed.

E. Comments on "What Definitions Apply to This Subpart?" (Proposed § 1.227)

1. The Act

There were no comments on this issue.

2. Calendar Day

There were no comments on this issue.

3. Facility

(Comment 34) Several commenters recommend exempting temporary storage units, public storage facilities, and bulk storage facilities from the definitions of "facility" and "holding," because many of these storage facilities are not staffed, so it would be very difficult for FDA to get in touch with these facilities in the event of a bioterrorist attack or other food-related emergency. In addition, the commenters state that many of these holding facilities only hold goods for several hours; therefore, the contents of the facility are continually changing and would require constant updates.

(Response) The interim final rule maintains the definition of facility as proposed although FDA has clarified that "facility" does not include a transporter that holds food only in the usual course of its business as a carrier, private residences of individuals, and nonbottled drinking water collection and distribution establishments and their structures. The Bioterrorism Act does not exempt facilities based on the period of time during which they hold food. In terms of contacting facilities that are not staffed, the interim final rule requires facilities to provide an emergency contact who is accessible 24 hours/day, 7 days/week. (For foreign facilities, FDA will consider the U.S. agent the emergency contact, unless the facility designates someone else, as provided in § 1.227(b)(13) and § 1.233(e).) This person does not have to be located at the facility, but does need to be accessible to FDA in case of an emergency.

(Comment 35) One commenter cites case law to argue that FDA has authority to provide for an additional *de minimis* exemption because the burdens of regulating very small facilities will yield trivial or no value. The commenters suggest that FDA change the definition of facility to exempt these storage buildings.

(Response) The Bioterrorism Act does not exempt facilities based on their size. Furthermore, many storage facilities, including temporary storage facilities, may be a target of terrorist attack. Therefore, having the registration information for these facilities can facilitate FDA's response to such an attack.

(Comment 36) Several commenters state that the proposed rule is not clear as to whether transport vehicles hauling food are "mobile facilities." These commenters argue that vehicles used to hold food such as rail cars, tanker trucks, river barges, refrigerated/freezer spaces on ships, truck terminals, marine terminals, and freight forwarders should be exempt from registration. One commenter asserted that the intent of the "holding" definition is to "capture those facilities which hold large quantities of food items for extended periods of time, pending some other action such as movement to a subsequent facility for processing," and states that products being held are "deliberately held under physical control, *i.e.*, restrained from movement." In contrast, "transportation of food items means deliberate movement of those items, under specific arrangements as defined in a bill of lading covering the movement, which would delineate the shipper, consignee, date of movement, details of the shipment, liability for freight charges, and many other elements of transportation." The commenter asserts that based on this distinction, transportation providers who are engaged in the movement of goods from a shipper to a consignee, should be exempt from registration.

(Response) FDA has clarified in § 1.227(b)(2) of the interim final rule that a "mobile facility" means a mobile manufacturer/processor, packer, or holder. In addition, the interim final rule provides that a vehicle used to transport food is exempt from registration unless it manufactures/processes, packs, or holds the food beyond the usual course of its business as a carrier. This is consistent with the legislative history of the Bioterrorism Act, which states that "facility" does not include trucks or other motor carriers, by reason of their receipt, carriage, holding, or delivery of food in the usual course of business as carriers (H.R. Conf. Rep. No. 481, 107th Cong., 2d Sess., 134 (2002)). However, stationary facilities that serve to assist transporters, such as truck or marine terminals or freight forwarders, are required to register because they hold food. If a railcar is used as a grain storage bin for a manufacturing plant, it would be akin to a silo, and as such, the railcar would be "holding" food, not transporting it. Thus, the railcar would be a facility that must be registered. As indicated in comment 36, the Bioterrorism Act does not exempt facilities based on how long they hold food.

(Comment 37) One commenter asks whether trucker-dealers, who purchase and take title to grain from producers, and hold the grain in a transportation conveyance until it can be sold to another processor, storage facility, or end user, are mobile facilities.

(Response) Based on the comment, FDA believes that trucker-dealers are mobile facilities, because they are holding grain in a transportation conveyance beyond the usual course of business as carriers.

(Comment 38) Several commenters state that requiring registration of mobile facilities that manufacture/process food is impractical for fishing vessels that process fish. These commenters state that these vessels have a home port designation but no fixed or permanent address; therefore, they would be required to continually update their registrations based on where the vessel was located in the ocean.

(Response) Registration requires a facility to provide sufficient information to enable FDA to contact the facility if FDA receives information about a bioterrorist threat or other food-related emergency, as well as for routine communications. FDA understands that a mobile facility does not have a fixed address. However, the Bioterrorism Act provides that the owner, operator, or agent in charge of a facility must register the facility; therefore, for mobile facilities such as vessels, the owner or operator of the facility usually has a fixed address and may include that fixed address on the registration.

(Comment 39) Several commenters request that FDA change the proposed definition of facility from being in "one physical location" to allow registration to be by firm, instead of by facility.

(Response) The Bioterrorism Act (21 U.S.C. 350d(a)(1)) requires that each domestic and foreign facility be registered. "Facility" is defined as "any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food" (21 U.S.C. 350d(b)(1)). Thus, the plain language of the Bioterrorism Act requires registration to be by individual facility, not by firm. As noted below, FDA will allow a parent company to register all of its facilities; however, each facility must be registered separately and each will receive a separate registration number.

(Comment 40) Some commenters state that FDA should provide a more flexible definition of facility, thereby allowing companies to decide how many buildings to consider a single facility. Some of these commenters question whether two structures under single ownership with different addresses that are physically next to each other, across the street from each other, or around the block from each other, are considered one or two facilities. Other commenters argue that a company may conduct business at more than one address, but may consider all of the locations as part of one operation. For example, an operation could include offsite storage buildings, water pipelines from one area to another, pump-houses, and bulk processing in one location, with finished processing or packaging at another address.

(Response) The Bioterrorism Act (21 U.S.C. 350d(a)(4)) requires that FDA compile and maintain an up-to-date list of registered facilities; this list will serve two purposes. One purpose of the registration database is to provide FDA with information that will permit FDA to respond promptly to a bioterrorist event or other food safety emergency. A second purpose is to provide the agency with a list of facilities for inspection. Because both the agency's emergency response and its inspections are facility specific, it is important for FDA to have particular information about facility location. This need will not be met if a business with multiple locations is registered as a single facility. FDA suggests that one factor for determining whether a business is one or two facilities is through real estate records, because a property line could demonstrate that several buildings are on the same lot, and therefore, are the same facility.

4. Domestic Facility

FDA received no comments on this definition.

5. Foreign Facility

FDA received no comments on this definition.

6. Farm

(Comment 41) Some commenters state that the proposed definition of farm is unduly narrow because it does not exempt farms that engage in activities traditionally performed on farms for nearly all commodities, including farms that cut, trim, wash, grade, mill, wax, size, cool, apply inventory control items (*e.g.*, universal product codes), treat against pests, transport from the fields, transport to storage or processing facilities, mist, treat with water/ice during storage, package, mill, grind, box/wrap for the sole purpose of transport off the farm, and transport from the farm. Some commenters also ask FDA to clarify whether placing produce into netting or bags for retail sale before placing them in cartons is considered "packing."

(Response) In response to these comments and to ensure that FDA is fulfilling Congress's intent to exempt "farms," FDA has revised the definition of farm in the interim final rule (21 CFR 1.227(c)(3)) to state that a farm is a facility in one general location that is devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both, and that washing, trimming outer leaves, and cooling of food are considered part of harvesting. FDA considers several of the activities identified in the comment to be "packing or holding," including sorting, grading, wrapping, or boxing harvested food for the sole purpose of transporting this food off the farm. A farm that performs these activities will not necessarily cease to be a farm and exempt from registration because the definition of farm includes facilities that pack or hold food, provided all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership (21 CFR 1.227(c)(3)(i)). Similarly, FDA considers several of the activities identified in the comment (waxing, milling, grinding, and treating against pests) to be manufacturing/processing. A farm that performs these activities will not necessarily cease to be a farm and exempt from registration because the definition of farm includes facilities that manufacture/process food, provided that all food used in these activities is consumed on that farm or another farm under the same ownership (21 CFR 1.227(c)(3)(ii)). Finally, a farm that transports its products does not cease to be a "farm" within the meaning of 21 CFR 1.227(c)(3) because, as noted earlier in this document, a transport vehicle is not a "facility" for purposes of this rule if it holds food only in the usual course of its business as a carrier and thus, is not required to register.

(Comment 42) Some commenters request that FDA extend the farm definition to public lands used by harvesters or collectors of wild products, including botanicals. The commenters state that these collectors do not manufacture/process or pack foods, and they hold foods similar to many farms.

(Response) FDA does not believe that this comment requires a change in the farm definition. When wild botanicals are grown and harvested on public land, FDA would consider that location to meet the definition of "farm." However, if those harvesting on public land engage in any activity that takes them outside the "farm" definition, they must register the facilities where they conduct these activities.

(Comment 43) Some commenters note that some farming operations are spread out over several locations within several miles or more of each other and all of these locations are under the same ownership and management. Accordingly, these commenters request that FDA change the farm definition to cover several different locations. Another commenter asks whether two facilities separated by fencing, a wooded area, a body of water, or a road are one or two farms. Other commenters request that FDA amend the farm definition to include the term "contiguous," which appears in the preamble to the proposed rule but not the definition itself.

(Response) FDA does not believe that these comments require a modification of the definition of farm. Each of these establishments, whether considered one farm or many farms, is exempt if it meets the definition of farm. Additionally, the interim final rule provides that establishments that pack or hold food fall within the farm definition if all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership. The interim final rule also considers establishments that manufacture/process food as farms if all food used in such activities is consumed on that farm or another farm under the same ownership.

(Comment 44) Some commenters ask FDA to clarify whether packing and other facilities owned by more than one farm on a partnership or cooperative basis fit within the farm definition.

(Response) The farm definition extends to only those packing or holding facilities that are located on a farm or another farm under the same ownership and the facilities are exclusively used to pack or hold food grown or raised on such farm or another farm under the same ownership. A packing shed that packs food grown or raised on several farms under different ownership is not covered by the farm definition and thus, is required to register.

(Comment 45) Some commenters argue that the farm definition should address whether a farm that engages in agriculture on several different properties under separate ownership will be considered a single farm for purposes of registration.

(Response) The definition of a farm provides that a farm must be in one general physical location and under the same ownership. In the situation described by the comment, different properties under separate ownership, if they otherwise meet the definition of farm, would be exempt from registering.

(Comment 46) Some commenters argue that a farmer who owns more than one field or piece of property and is required to register with FDA should be required to register only once, identifying on the registration form the physical location of all areas under that farmer's cultivation.

(Response) Generally, a farm is exempt from registration unless it is a mixed-type facility. A mixed-type facility performs activities of a facility that is both ordinarily required to register and ordinarily exempt. An example of a farm that is a mixed-type facility is a farm that grows oranges and processes them into orange juice for sale to a distributor at the same physical location. However, if the farmer manufactures/processes the oranges into orange juice in a different physical location, the location where the oranges are grown is exempt as a farm and the facility where manufacturing/processing occurs must register. Because registration is by individual facility, the farmer must, if required to register, register each facility separately and obtain a separate registration number for each facility. The effort to register in this situation will be reduced if the farmer registers electronically, because he can register each facility in succession, "auto-filling" each section of the form that repeats the information contained in the previous registration.

(Comment 47) One commenter asks FDA to clarify that the definition of farm applies to foreign, as well as domestic, farms.

(Response) The commenter is correct; the farm definition applies to both domestic and foreign farms. Therefore, foreign farms that satisfy the farm definition are not required to register, even if they export food directly to the United States. However, if such a foreign farm harvests food and manufactures/processes it before exporting it to the United States, this would be a mixed-type facility that ordinarily must register. However, the foreign facility exemption may apply to this mixed type facility if further manufacturing/processing that is not of a *de minimis* nature occurs after the food leaves the mixed-type facility and before it is exported to the United States.

(Comment 48) One commenter states that the definition of "farm" is circular in § 1.227(c)(3)(ii). The term "farm" includes: * * * (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.

(Response) In the previous excerpt from the "farm" definition, FDA's intent is to describe a certain activity (manufacturing/processing) in which a farm may engage without losing its exemption as a farm, so long as all food manufactured/processed by the farm is consumed on that farm or another farm under the same ownership.

(Comment 49) Several commenters state that FDA's definition of "farm" should be size-neutral, and apply equally to integrated livestock and poultry facilities as long as the activities at such locations are limited to "growing or raising" farm animals for human food, but do not extend to further processing of food-producing animals into meat, milk, or eggs (which occurs at food processing and packing plants and rendering facilities) for subsequent commercial sale for consumption by humans or animals.

(Response) The proposed rule's definition of "farm" had no size limitation, and neither does the interim final rule's definition. FDA agrees that integrated livestock and poultry operations are "farms," as long as these operations are devoted to raising animals for food, the growing of crops, or both, and otherwise engage in only those activities included in the farm definition. FDA considers milking cows and collecting eggs from chickens to be "harvesting" when applied to animals, because these activities are akin to harvesting crops.

(Comment 50) Several commenters ask FDA to clarify whether packing sheds, warehouses, and low temperature storage facilities located on farms are considered part of the farm.

(Response) The interim final rule clarifies the definition of "farm" and provides that an operation that includes on-farm packing and holding of food grown, raised, or consumed on the farm or on another farm under the same ownership is still a "farm" under § 1.227(c)(3). The rule also provides that an operation that includes on-farm manufacturing/processing of food, where all food is consumed on that farm or another farm under the same ownership, is still a "farm."

(Comment 51) One commenter requests that FDA clarify that greenhouse facilities devoted to growing fruits and vegetables are considered "farms" for purposes of the farm definition. The commenter states that it appears that greenhouse facilities would easily fit within the proposed definition of farm as "[facilities] in one general physical location devoted to the growing of crops * * *", however, FDA does not explicitly state in the proposed rule or preamble to the proposal that greenhouses would be considered farms.

(Response) FDA agrees with the commenter that a greenhouse devoted to the growing of crops is a "farm" under § 1.227(c)(3).

(Comment 52) One commenter, quoting the proposed definition of farm as including "facilities that manufacture/process food, if all food used in such activities is consumed on that farm or another farm under the same ownership," asks FDA to clarify whether on-farm facilities that manufacture/process food sold to a third party would be required to register with FDA.

(Response) An on-farm operation engaging in manufacturing/processing food that is subsequently sold to an off-farm third party is a facility that is required to register with FDA, unless the facility qualifies under another exemption, such as the retail food establishment exemption.

(Comment 53) One commenter asks FDA to clarify whether a farm is required to register if several companies are involved in the farming operation. For example, some farms may perform their own harvesting or employ another company to provide harvesting services.

(Response) Because registration is by facility, a farm operation is not required to register, provided all of the on-farm activities are covered in the farm definition and the farm is under the same ownership. It therefore makes no difference for purposes of registration if different companies perform different services at a facility. The determinative question is whether the facility is manufacturing/processing, packing, or holding food for consumption in the United States and is not subject to an exemption.

(Comment 54) One commenter asks FDA to clarify: (1) Whether a grower of

grapes is covered under the farm definition unless the grower processes these grapes into wine and bottles or packages the wine itself; and (2) whether the grower would be required to register if the grower grows grapes, sends them to a third party who makes wine from them and bottles or packages the wine, and returns the bottled wine to the grower, who then labels the bottles.

(Response) This comment describes an example of a mixed-type facility. In the first example, the grower of the grapes who does not itself process the grapes into wine, would not be required to register its establishment because it is "farm" and is exempt from registration. If the grower's establishment manufactures/processes the grapes into wine and/or bottles or packages it, the establishment is a facility that must register. In the second example, the grower of the grapes would be exempt as a farm; however, labeling the wine after receiving it back from a third party is considered manufacturing/processing. Thus, both the grape grower's labeling facility and the third party's manufacturing/processing facility must register.

(Comment 55) One commenter asks whether cattle feed yards manufacturing feed that is fed onsite to the cattle are required to register.

(Response) The "farm" definition states that "farm" includes "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." Therefore, a cattle feed yard that manufactures/processes feed that is fed only at that feed yard or another farm or feed yard under the same ownership is a "farm" that is exempt from registration. Conversely, a cattle feed yard that manufactures/processes feed that is fed to cattle at another location that is under different ownership would be required to register as a manufacturing/processing facility.

(Comment 56) One commenter quotes FDA's proposed provision for contract facilities, which states:

> [t]he 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.

The commenter states:

> [d]espite FDA's clarifications on its definition of farm, it does not specify what happens if these same products are later sold outside the farm or if these products are grown, harvested, held, and sold for consumption of any kind outside the farm, thus going to a second owner and facility to serve other purposes (international commerce).

(Response) This comment is not clear regarding "what happens" if products are "later sold outside the farm" or "are grown, harvested, held, and sold for consumption of any kind outside the farm." The "farm" definition covers a facility that grows crops or raises animals for food. If an establishment sells animal feed obtained from a contract facility to a third person, that establishment would be required to register unless it was exempt as a retail food establishment. If the establishment sells the animal feed to, for example, a distributor or another business, it would not fall within the retail exemption and thus, it would be required to register.

(Comment 57) One commenter states that FDA is proposing to exempt farms from registration even if they conduct packing/holding/processing on their premises, as long as they only handle food grown on that farm or another farm under the same ownership, or if they mix feed from outside sources for exclusive use on that farm. However, the commenter asserts that most farmers that pack or process the crops that they grow may sell or pay for the discarded materials, such as sorted-out produce, hulls, etc., to be used as feed. The commenter asks:

> [i]s it FDA's intent to include all incidental by-products from processing that go to feed as feed production, therefore triggering the registration requirement? Would the by-products sold/disposed of as feed need to be listed among the items produced by a facility that is registering for other reasons?

(Response) This comment raises several questions regarding the status of farms that produce animal feed or animal feed components. The farm definition in the interim final rule includes farms packing or holding food, if all of the food used in animal feed production activities is grown or raised on that farm or consumed on that farm. Similarly, a farm that manufactures/processes animal feed is not required to register, if all of the food used in such activities is consumed on that farm or another farm under the same ownership. Thus, if a farm manufactures/processes food grown on the farm and feeds by-products of these crops to the farm's own animals, the farm does not need to register. However, if the facility sells the by-products to another entity, it must register, unless it is otherwise exempt.

Any registered facility that is producing such by-products may identify such products in section 11b of the registration form (Form 3537). Because the categories listed in section 11b of the form are not included in § 170.3, they are optional.

7. Food

(Comment 58) The agency received a number of comments regarding the proposed definition of "food" provided in § 1.227(c)(4). Most of these commenters asserted that the definition was too broad and, for a number of reasons, recommended that certain items covered by the proposed definition be excluded from the rule's coverage. In particular, the commenters requested that food packaging and components of food packaging, other food contact articles (such as food processing equipment and components of such equipment, glassware, dishware, cutlery, kitchen appliances), and so-called indirect additives (including those applied to food contact surfaces) be excluded from the interim final rule's definition of "food."

In support of these proposed exclusions, many commenters cited the language in section 415(a)(1) of the FD&C Act requiring registration of facilities that manufacture, process, pack, or hold "food for consumption in the United States," claiming that such language indicates that Congress intended the registration provision to apply only to facilities that manufacture, process, pack or hold "edible food," "traditionally understood as food," or articles that are "intended for consumption." In addition, one commenter cited the reference in section 415(a)(2) of the FD&C Act to the general categories of food provided in § 170.3, which does not include listings for food packaging or other food-contact materials or their components. Several commenters argued that extending registration to facilities that produce food-contact materials was not consistent with the purpose of the Bioterrorism Act and that there was no historical evidence associating foodborne illness with packaging or other food contact material. Finally, some commenters argued that an overly broad definition of "food" would have the effect of diluting the government's resources and thereby hampering the government's opportunity to achieve the protective goals of the Bioterrorism Act.

Other commenters argued that additional items or facilities should be excluded from the registration requirement; those comments are addressed in section III.D of this document.

Several commenters favor inclusion of packaging and its components. Some commenters point out that food packaging and components are "food" under section 201(f) of the FD&C Act. Some of these commenters suggest that FDA should require facilities currently manufacturing substances subject to approval under section 409 of the act to register, and FDA should clarify the definition at § 1.227(c)(4), and consider outer packaging food.

(Response) Relying on the act's definition of "food" in section 201(f), the proposed rule defined "food" as follows:

> 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 (emphasis added).

Thus, food packaging and other food contact materials were expressly included as examples of "food" in the proposed definition, with the result that, under the rule as proposed, facilities that manufacture/process, pack, or hold food packaging, food-contact materials, or their components would have been required to register. (See 68 FR 5378 at 5382). The breadth of the proposed definition of "food" was based on both the statutory definition in section 201(f)(3) of the FD&G Act, which defines articles used as components of food as "food," and the case law interpreting the definition, including *Natick Paperboard* v. *Weinberger*, 525 F.2d 1103 (1st Circuit 1975) (paperboard containing PCBs intended for food use is adulterated food); *U.S.* v. *Articles of food * * * 688 Cases * * * of Pottery (Cathy Rose)*, 370 F. Supp. 371 (E.D. Mi. 1974) (ceramic pottery that leaches lead is adulterated food).

The comments on food-contact substances raise the question of what Congress intended "food" to mean in terms of registration of facilities that manufacture, process, pack, or hold "food." In construing the registration provision of the Bioterrorism Act , FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented? ("*Chevron* step one"). *Chevron, U.S.A., Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 842 (1984). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue. *Young* v. *Community Nutrition Institute*, 476 U.S. 974, 980 (1986). If Congress has spoken directly and plainly, the agency must implement Congress's unambiguously expressed intent. *Chevron*, 467 U.S. at 842–843. If, however, the Bioterrorism Act is silent or ambiguous as to the meaning of "food," FDA may define "food" in a reasonable fashion ("*Chevron* step two"). *Chevron*, 467 U.S. at 842–843; *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000).

The agency has determined that, in enacting section 415, Congress did not speak directly and precisely to the meaning of "food." As noted, the FD&C Act has a definition of "food" at section 201(f). It may be a reasonable assumption that, when the term "food" is used in the FD&C Act, section 201(f) applies. However, although there may be "a natural presumption that identical words used in different parts of the same act are intended to have the same meaning [citation omitted], * * * the presumption is not rigid * * *" *Atlantic Cleaners & Dyers, Inc.* v. *U.S.*, 286 U.S. 427, 433 (1932). *Accord: U.S.* v. *Cleveland Indians Baseball Co.*, 532 U.S. 200, 213 (2000). Thus, the same word may be given different meanings, even in the same statute, if Congress intended different interpretations or if different interpretations are reasonable (at "Chevron Step two."). *Atlantic Cleaners & Dryers, Inc., supra.*

Even before the Bioterrorism Act amendments, the term "food" was not given an identical meaning throughout the FD&C Act. For example, in construing the parenthetical "(other than food)" in section 201(g)(1)(C), the seventh circuit noted that Congress meant to exclude only "articles used by people in the ordinary way that most people use food-primarily for taste, aroma, or nutritive value" and not all substances defined as food by section 201(f) (*Nutrilab, Inc.* v. *Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983)). Similarly, section 409(h)(6) of the FD&C Act defines a food-contact substance as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding *food* if *such use* is not intended to have any technical effect in *such food* (emphasis added)." This definition makes sense only if "food" in this context excludes materials that contact food because components of food contact materials are plainly intended to have a technical effect in such materials.[1]

Thus, in this larger statutory context, FDA has evaluated section 415 to determine whether the meaning of the word "food" is ambiguous. In conducting this *Chevron* step one analysis, all of the traditional tools of statutory interpretation are available to determine whether the language Congress used is ambiguous. *Pharmaceutical Research & Manufacturers of America* v. *Thompson*, 251 F. 3d 219, 224 (D.C. Cir. 2001). Beginning with the language of the statute, in section 415(a)(1), "food" is used to describe who must register: "The Secretary shall by regulation require that any facility engaged in manufacturing, processing, packing, or holding *food for consumption in the United States* to be registered with the Secretary (emphasis added)." The Bioterrorism Act is silent as to the meaning of "food." Furthermore, the prepositional phrase "for consumption in the United States" creates an ambiguity because it could be read to suggest that "food" within the context of the section 415 registration requirement only refers to food that is ordinarily thought of as "consumed." By modifying the term "food" by the prepositional phrase "for consumption in the United States," Congress apparently intended to limit the term "food" to something less than the broad definition in section 201(f). Although "consume" has multiple meanings, most relevant in this context is "to eat or drink up; ingest." *Webster's II New Riverside University Dictionary* (1994). Emphasizing the word "consumption" could appear to limit "food" to those items commonly eaten primarily for taste, aroma, or nutritive value. *Nutrilab* v. *Schweiker*, *supra* at 338.

Where, as here, the statutory language on its face does not clearly establish Congress's intent, it is appropriate to consider not only the particular statutory language at issue, but also the language and design of the statute as a whole. *Martini* v. *Federal Nat'l Mortgage Association*, 178 F. 3d 1336, 1345 (D.C. Cir. 1999), citing *K Mart Corp.* v. *Cartier, Inc.*, 486 U.S. 281 (1988). Indeed, the analysis should not be confined to the specific provision in isolation because the meaning or ambiguity of a term may

[1] FDA's long-standing interpretation of the FD&C Act's definition of color additive, section 201(t), is an additional example of where "food" is used more narrowly than as defined in section 201(f). A color additive is defined in section 201(t) as a substance that "when applied to a food * * * is capable * * * of imparting color thereto." The agency's food additive regulations distinguish between color additives and "colorants," the latter being used to impart color to a food-contact material (21 CFR 178.3297(a)). (See also 21 CFR 70.3 (f)). Thus, "food" as it appears in the statutory definition of color additive, necessarily excludes food-contact materials.

be evident only when considered in a larger context. *FDA* v. *Brown & Williamson Tobacco Corp., supra* at 132 (2000).

Consistent with this instruction, FDA has considered other parts of the registration provision in assessing whether the meaning of "food" in section 415(a)(1) ambiguous. In particular, FDA has considered section 415(b)(1). In defining "facility" for purposes of section 415, Congress expressly exempted "farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer * * *" These exemptions do not make clear whether Congress intended them to cover only food that is ordinarily eaten at some point by consumers primarily for taste, aroma, or nutritive value or whether, for example, a retail food establishment could include retailers of food contact materials, such as retail cookware stores.

The legislative history of section 415 also supports the conclusion that Congress did not speak directly to the meaning of "food" in that Bioterrorism Act provision. Such history is appropriately consulted at *Chevron* step one. *Atherton* v. *FDIC*, 519 U.S. 213, 228–29 (1997). In particular, the Conference Report to H.R. 3448, which became the Bioterrorism Act, explains what Congress intended by "retail food establishments," which is used to create an exemption from registration:

> The Managers intend that, for the purposes of this section, the term "retail food establishments" includes establishments that store, prepare, package, serve, or otherwise provide articles of food directly to the retail consumer for human consumption, such as grocery stores, convenience stores, cafeterias, lunch rooms, food stands, saloons, taverns, bars, lounges, catering or vending facilities, or other similar establishments that provide food directly to a retail consumer.

H.R. Conf. Rep. No. 481, 107th Cong., 2d Sess., 133 (2002).

Similarly, the Conference Report notes that the term "non-profit food establishments" includes not-for-profit establishments in which food is prepared for, or served directly to the consumer, such as food banks, soup kitchens, homebound food delivery services, or other similar charitable organizations that provide food or meals for human consumption." (*Id.* at 133–34.) Notably, the examples provided by Congress for both types of exempt food establishments are not those that generally sell or distribute food contact materials. Accordingly, the legislative history of section 415 creates additional ambiguity as to the meaning of "food."

Finally, a review of section 307 of the Bioterrorism Act (the prior notice of food imports provision) and its legislative history confirms that the meaning of the word "food" when used in the Bioterrorism Act, including section 415, is ambiguous. The Bioterrorism Act's registration provision is one piece of several enacted by Congress to enhance the safety of the U.S. food supply. Registration works in concert with prior notice (section 307 of the Bioterrorism Act). This is reflected in section 305(c) of the Bioterrorism Act, which requires that food from an unregistered facility be held at the port when offered for import. Thus, this provision and its legislative history are of particular relevance in determining whether "food" is ambiguous in the registration provision. The legislative history of section 307 of the Bioterrorism Act supports the ambiguity of the term "food" in the Bioterrorism Act. For example, the Conference Report states that the prior notice provision is to be construed not to apply to "packaging materials if, at the time of importation, such materials will not be used for or in contact with food * * *" (See H.R. Conf. Rep. No. 481, 107th Cong., 2d Sess., 136 (2002).) This statement could be read to mean that the term "food" does not include packaging or other materials that contact food.

Having concluded that the meaning of "food" in section 415(a)(1) is ambiguous, FDA has considered how to define the term so as to achieve a "permissible construction" of the registration provision. *Chevron, USA, Inc.* v. *NRDC, Inc., supra* at 843. In conducting this *Chevron* step two analysis, the agency has considered the same information evaluated at step one of the analysis. *Bell Atlantic Telephone Co.* v. *FCC*, 131 F. 3d 1044, 1049 (D.C. Cir. 1997); *Chevron U.S.A., Inc.* v. *FERC*, 193 F. Supp. 2d 54, 68 (D.D.C. 2002). FDA has determined that it is permissible, for purposes of the registration provision, to exclude food contact materials from the definition of "food."

Excluding food-contact materials (including food packaging) is consistent with the statutory phrase, "food for consumption", section 415(a)(1), in that foods that are "consumed" are generally those intentionally eaten for their taste, aroma, or nutritive value. In addition, excluding food contact materials from "food" in this regulation is consistent with the exemptions in section 415(b)(1), as well as the legislative history of section 415, in that the establishments exempted by statute and the entities used as examples of retail and nonprofit food establishments are those that sell, distribute, or otherwise provide what is considered food in the conventional sense and, generally speaking, are not purveyors of food contact articles. Finally, restricting "food" to substances other than food-contact materials is consistent with the legislative history of the prior notice provision of the Bioterrorism Act, a provision linked to the registration provision.

As discussed in responses to comments 64 and 65, FDA has also interpreted "food" for purposes of section 415 to exclude pesticides as defined in FIFRA (7 U.S.C. 136(u)). Accordingly, for the reasons discussed in response to this comment and comments 64 and 65, FDA has determined that a reasonable interpretation of "food" for purposes of section 415 is as follows. Section 1.227(b)(4) of this interim final rule has been revised to provide:

> Food has the meaning given in section 201(f) of the act, (i) except for purposes of this subpart, it does not include: (A) food contact substances as defined in section 49(h)(6) of the act (21 U.S.C. 348 (h)(6)); or (B) pesticides as defined in 7 U.S.C 136(u). (ii) Examples of food include fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

(Comment 59) One commenter asks FDA to address the foreign facility exemption as it applies to "products that migrate into food from food packaging and other articles that contact food."

(Response) Because the interim final rule excludes food contact substances from the definition of "food," establishments that manufacture/process, pack, or hold food contact materials or components of such materials are not required to register, unless these establishments also manufacture/process, pack, or hold "food" as defined in § 1.227(b)(4).

(Comment 60) A commenter asks whether water collection and distribution facilities are required to register as food facilities if the owner or operator of such facility knows that the water is to be used as a food ingredient. The same commenter asks whether community water systems that supply water to bottled water facilities or to bottled water sources must register.

(Response) FDA has determined that nonbottled drinking water collection and distribution organizations and their

structures should not be included in the definition of "facility" for purposes of registration. Under section 305(a) of the Bioterrorism Act, the term "facility" includes "any factory, warehouse, or establishment." Congress did not specify any definitions for these terms. According to Webster's II New Riverside University Dictionary (1994), the most relevant definition of "establishment" is "a business firm, club, institution, or residence, including its possessions and employees." Where, as here, the statutory language on its face does not clearly establish Congressional intent, it is appropriate also to consider other language in the section, the language and design of the statute as a whole, and the larger context to determine if the term is ambiguous. *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000); *Martini* v. *Federal Nat'l Mortgage Ass'n*, 178 F.3d 1336, 1345 (D.C. Cir. 1999), citing *K Mart Corp.* v. *Cartier, Inc.*, 486 U.S. 281 (1988).

Traditionally, the Environmental Protection Agency (EPA) has exercised a primary role in the regulation of public water systems (see 44 FR 42775, July 20, 1979). Under the Safe Drinking Water Act (42 U.S.C. 300(f) *et seq.*) (SDWA), EPA regulates public water systems, which are water systems that have at least 15 service connections or serve 25 people per day for 60 days of the year. In addition, Title IV of the Bioterrorism Act creates an extensive scheme for protecting from bioterrorism threats community water systems serving over 3,300 persons. Title IV amends the SDWA to require that such community water systems submit to EPA vulnerability assessments of their facilities and emergency response plans to deal with the possibility of a bioterrorist attack. EPA is authorized to provide funds to community water systems to address critical security enhancements and significant public health threats.

FDA believes that the language and design of the Bioterrorism Act, which in Title IV lays out strategies under EPA's authority for protecting the safety and supply of public drinking water, creates ambiguity about whether Congress intended to require drinking water facilities to register with FDA as food facilities. The traditional EPA role in regulating public water systems, as established by federal legislation and implemented by Federal agencies, also creates ambiguity about Congressional intent to include drinking water facilities within the scope of FDA's food registration scheme.

Based on EPA's primacy in regulating public water systems and on the Bioterrorism Act scheme for water systems in Title IV, FDA concludes that it is reasonable to interpret the term "facility" to exclude nonbottled drinking water collection and distribution establishments, such as community water systems. Therefore, FDA has revised § 1.227(b)(2) to exclude these nonbottled drinking water establishments from the definition of "facility."

Bottled water, on the other hand, has traditionally been regulated by FDA (see 21 U.S.C. 349, 21 CFR parts 129, 165). Moreover, Title IV of the Bioterrorism Act does not address bottled water issues, but only public drinking water systems. Therefore, FDA believes it is reasonable to include establishments that manufacture/process, pack, or hold bottled water in the definition of "facility."

FDA also has primary responsibility for drinking water that is used in the manufacturing/processing of food that is not bottled water. Thus, once drinking water enters a facility where it is used in food manufacturing/processing, the water is regulated by FDA. Because such facilities are food facilities in the first place, they already are required to register with FDA without regard to the water source.

(Comment 61) Several commenters asked whether facilities that produce water coolers, ozone equipment, carbon dioxide, water storage silos, plastic resins, or chlorine must register with FDA.

(Response) Water coolers, ozone equipment, water storage silos, and plastic resins are food-contact substances (section 409(h)(6) of the FD&C Act) and therefore, facilities that manufacture/process, pack, or hold such items are not required to register because these items are not "food" as defined in this regulation. In contrast, carbon dioxide, if used to make carbonated beverages or to aerate food, is a component of food (section 201(f)(3) of the FD&C Act) that is intended to have a technical effect in the food and therefore, is "food" as defined in this interim final rule. Similarly, chlorine, if used in bottled water, is also a component of food (section 201(f)(3) of the FD&C Act) that is intended to have a technical effect in the food and therefore, is "food" as defined in this interim final rule. Accordingly, facilities that manufacture/process, pack, or hold carbon dioxide or chlorine that will be used in food products must register. Please see the response to comment 62, which addresses multiuse substances.

(Comment 62) Commenters suggest that foreign facilities that process or refine vegetable oils not intended for direct inclusion in food or animal feed should be exempt from registration. These commenters argue that where bulk ingredients have both food and non-food uses, the standard for registration should be whether the commodity has been sufficiently refined to be directly added to food.

(Response) This interim final rule requires that any domestic facility that manufactures/processes, packs, or holds "food" must be registered unless the facility satisfies one of the exemptions in § 1.226. Foreign facilities are subject to the same registration requirement except that a manufacturer/process or is not required to be registered if a subsequent facility outside the United States performs further manufacturing/processing of more than a *de minimis* nature. For purposes of the interim final rule, "food" has the definition in section 201(f) of the FD&C Act except that "food contact substances" (section 409(h)(6)) and "pesticides" (7 U.S.C. 136(u)) are excluded from "food." Under section 201(f), "food" means "articles used for food or drink" (section 201(f)(1)) and articles "used for components of any such article" (section 201(f)(3).) The determination of whether a substance is "food" is not a question of intended use. *Nutrilab* v. *Schweiker*, 713 F.2d. 335, 337 (7th Cir. 1983); *U.S.* v. *Technical Egg Products*, 171 F.Supp. 326, 328 (N.D. Ga. 1959); *U.S.* v. *52 Drums Maple Syrup*, 110 F.2d 914, 915 (2d Cir. 1940). Courts interpreting the "food" definition in the act have held that articles at both ends of the food continuum are "food" for purposes of the FD&C Act. *United States* v. *Tuente Livestock*, 888 F. Supp. 1416 (S.D. Ohio, 1995) (live animals for food use are "food" under the FD&C Act); *U.S.* v. *Technical Egg Products, supra*, 171 F.Supp. at 328 (rotten eggs are "food.") Thus, FDA believes that a facility that manufactures/processes, packs, or holds food must be registered (unless subject to one of the exemptions in § 1.226) even if the food is not yet in the form in which it will be used for food. FDA will consider a product as one that will be used for food if the owner, operator, or agent in charge of the facility reasonably believes that the substance is reasonably expected to be directed to a food use. In the case of vegetable oil that is not yet food grade, FDA believes that a facility that manufactures/processes, packs, or holds such oil must be registered (assuming the facility does not qualify for an exemption in § 1.226) if the owner, operator, or agent in charge reasonably believes that oil manufactured/processed, packed, or held at the facility

is reasonably expected to be directed to a food use.

(Comment 63) Several commenters assert that processing aids, such as defoaming agents and biocides, are used in the production of food but are not food in and of themselves and thus facilities that manufacture/process, pack, or hold such substances need not register.

(Response) FDA notes that there are a wide variety of processing aids, including processing aids used in packaging and other food contact materials and processing aids used in "traditional" foods. The commenters do not specify which type or types of processing aids they believe are not "food" such that establishments that manufacture/process, pack, or hold these substances should not be required to register.

Whether a facility that manufactures/processes, packs, or holds a processing aid must be registered depends upon whether such a substance is "food" under this rule. As noted, for purposes of the interim final rule, "food" excludes "food contact substances" (section 409(h)(6)). In addition, "food" excludes "pesticides" (7 U.S.C. 136(u)). Thus, if the processing aid is not a pesticide and is intended to have a technical effect in the food to which it is added, the substance is not exempt from the definition of "food" and the facility must be registered unless otherwise exempt under § 1.226 (*i.e.*, if it is a foreign facility, and food from such facility undergoes further manufacturing/processing (including packaging) by another facility outside the United States). In terms of processing aids, this means that, generally speaking, facilities that manufacture/process, pack, or hold processing aids used in the production of "traditional" food will be required to register. This is a reasonable result in that such processing aids are intentionally and directly added to "traditional" foods.

(Comment 64) Several commenters request an exemption for facilities dealing with agricultural chemicals (fertilizer, pesticides) since these are not food for consumption and they are already registered with EPA. Several other comments asked whether facilities that manufacture/process, pack, or hold anti-microbial pesticides used in or on food must register.

(Response) As discussed in the response to comment 58, the meaning of "food" in section 415 is ambiguous. Therefore, FDA may define "food" in a reasonable manner. FDA believes that excluding "pesticides "(7 U.S.C. 136(u)) from the definition of food is reasonable. Agricultural pesticides, including those used in or on food for human or animal use, are comprehensively regulated by the Federal Government. Under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.*, all pesticides (both food and nonfood use) are registered with EPA. As part of the registration process, establishments in which pesticides are produced must register with EPA (40 CFR 167.3 and 167.20). As part of the importation process, prior notice of all pesticide shipments must be given to EPA (19 CFR 12.112).

Importantly, the Federal regulatory scheme for pesticides was substantially revised in 1996 by the Food Quality Protection Act (FQPA) (Public Law 104–170), and EPA's authority over pesticides was consolidated and also expanded. As a result of FQPA, pesticides and their residues are subject to substantial and comprehensive regulation by EPA. Where another Federal agency has the types of specific and comprehensive authority described above to regulate the safety of certain substances (here, pesticides), FDA believes that it is appropriate to interpret "food" in section 415 of the FD&C Act to not include such substances. Accordingly, FDA has revised the definition of "food" in § 1.227(b)(4) to exclude pesticides as defined by FIFRA (7 U.S.C. 136(u)). Therefore, FDA agrees that facilities that manufacture/process, pack, or hold "pesticides intended for use in or on food" need not register with FDA.

(Comment 65) Several comments asked whether facilities that manufacture/process, pack, or hold antimicrobial pesticides used in or on food must register.

(Response) As noted previously, for the purposes of this rule, the term "food" is defined to exclude any substance defined as a "pesticide" in FIFRA (7 U.S.C. 136(u)). Anti-microbial pesticides meet the FIFRA definition of "pesticide." Thus, facilities that manufacture/process, pack, or hold such substances are not required to register.

(Comment 66) Several commenters question how live food animals relate to the definition of food. One commenter indicates that many small animals are shipped to the United States with the intention to grow them in the United States for food and thus, such animals are not animals for food at the time they are imported. This commenter asks FDA to exempt live food animals from the definition of food.

(Response) As discussed in the response to comment 58, the meaning of "food" in section 415 is ambiguous. Therefore, FDA may define "food" in a reasonable manner. FDA believes that it is reasonable to interpret "food" in section 415 to include live animals. First, such inclusion is consistent with the language in section 415(a), "food for consumption," in that live animals are raw material for, and thus reasonably considered components of, items traditionally consumed for taste, aroma, or nutritive value. Moreover, the products of live food animals are an integral part of the food consumed in the United States, and thus, it is logical to protect the raw materials (*i.e.*, the live animals) and such animal food products by including them under the Bioterrorism Act's safeguards. Second, Congress provided several statutory exemptions from the registration requirement, including "farms," section 415(b)(2), which would reasonably include those raising animals as well as those growing fruits and vegetables. By exempting farms, Congress indicates that, absent an exemption, establishments where fruits, vegetables, and animals are produced would be "food facilities" subject to registration. Third, the inclusion of live animals in the definition of "food" is consistent with the statutory language of the Bioterrorism Act as a whole. In particular, the recordkeeping, administrative detention, and prior notice provisions of the Bioterrorism Act all include an explicit reference to animals in the statutory standard, "serious adverse health consequences or death to humans or animals." (*See, e.g.*, 21 U.S.C. 334(h)(1)(A), 350c(a), and 381(m)(2)(B)(ii).) In each of these provisions, this standard serves as a trigger for FDA action. This standard does not appear in the registration provision, because there is no need for a trigger for FDA action in registration. FDA does not believe that the fact that this standard does not appear in the registration provision evidences the intent on the part of Congress that facilities that manufacture/process, pack, or hold live animals need not register. Accordingly, the interim final rule's definition of "food" includes live food animals.[2] FDA notes, however, that a facility that exports live food animals directly to the United States may be exempt as a "farm" if it satisfies the definition in § 1.227(b)(3).

(Comment 67) Some commenters ask that research and development (R&D) facilities and facilities that manufacture/process, pack, or hold food samples should not be considered "facilities" for purposes of FDA registration. The commenters note that R&D facilities typically hold food and often process it on a small scale, but this food is intended for research purposes and not for commercial sale or public consumption. The commenters explain that sample facilities distribute samples internally to employees and are not commercially distributed.

[2] Defining "food" to include live animals is also consistent with the case law interpreting the term "food" in the broader context of the act. (See *United State* v. *Tuente Livestock*, 888 F. Supp. 1416 (S. D. Ohio, 1995).)

(Response) Under section 305 of the Bioterrorism Act, facilities are required to register if they manufacture/process, pack, or hold food for consumption in the United States. Therefore, R&D facilities and sample facilities that manufacture/process, pack, or hold food that is consumed in the United States, either by the facility's employees or others are required to register. However, if R&D facilities and sample facilities manufacture/process, pack, or hold food and this food is not for consumption or actually consumed in the United States, the facilities are not subject to registration.

(Comment 68) One commenter takes issue with FDA's inclusion of animal feed within the definition of food. This commenter states that in the legislative history of the Bioterrorism Act, Rep. Shimkus (R–IL) repeatedly states that the registration requirement is intended to apply to food for "human" consumption. The commenter also indicates that the Conference Report to the Bioterrorism Act states that the retail exemption applies to facilities that sell to the consumer "for human consumption," stating that FDA took comments on this issue in the proposed rule. The commenter argues that because the recordkeeping, administrative detention, and prior notice parts of the Bioterrorism Act specifically refer to requirements regarding food for animals, as well as for humans, while the registration part of the Bioterrorism Act does not, FDA should limit the food definition to food for human consumption.

(Response) As discussed in the response to comment 58, the meaning of "food" in section 415 is ambiguous. Therefore, FDA may define "food" in a reasonable manner. As noted in the response to comment 66, sections 303, 306, and 307 of the Bioterrorism Act reflect Congressional concern with the health and safety of "animals." In that response, FDA also explains why, logically, the standard in question ("serious adverse heath consequences to human or animals") need not appear in section 305 of the Bioterrorism Act. One important way in which to safeguard animals is to protect their food supply. FDA believes that it is reasonable to include food consumed by animals in the definition of "food" and thus, to require the registration of facilities that manufacture/process, pack, or hold food for consumption by animals. Accordingly, the interim final rule's definition of "food" in § 1.227(b)(4) includes food for consumption by animals.

8. Holding

FDA received many comments regarding whether facilities that hold products on a temporary basis are required to register as holders. Because these comments also questioned whether these units fit within the definition of "facility," FDA has addressed those issues in comment 44 and its response.

(Comment 69) Several commenters request that FDA clarify who is required to register and pay the costs for storage if a manufacturer/processor sends food to a warehouse for holding under the manufacturer/processor's name before export to the United States.

(Response) FDA interprets this question as applying solely to the warehouse, not the manufacturer/processor. Each facility that holds unprocessed food that will be imported into the United States in its unprocessed form for consumption in the United States must be registered with FDA, unless it is exempted by this rule. Additionally, each foreign facility that holds food destined for consumption in the United States subsequent to the last foreign manufacturer/processor must be registered with FDA, unless it is exempted by this rule. Consistent with the plain language of the Bioterrorism Act, the interim final rule places the responsibility of registering a facility on the owner, operator, or agent-in-charge of such facility. Although the interim final rule permits the owner, operator, or agent in charge to authorize an individual to register the facility, the facility's owner, operator, or agent in charge retains the legal responsibility to ensure that the facility is properly registered with FDA. In the situation raised in the comment, whether the warehouse or the manufacturer/processor pays the cost of such storage is a private matter between the manufacturer/processor and the warehouse.

On its own initiative, FDA has made an editorial change in this section for clarity.

9. Manufacturing/Processing

(Comment 70) One commenter requests FDA to clarify whether commercial ripening of fruit fits within the definition of "manufacturing/processing." The commenter states that some cargo containers are equipped with technologies that artificially ripen fruit while in transit. The commenter states that "such technological advancements should not change the interpretation of what defines a facility under the rule," and requests that FDA not consider this activity manufacturing/processing.

(Response) Because this activity involves "treating," "modifying," or "manipulating" food, it constitutes manufacturing/processing as defined by the interim final rule (21 CFR 1.227(b)(6). The fact that these manufacturing/processing activities occur in a transport vehicle does not alter the fact that these activities are manufacturing/processing. Thus, a vehicle engaging in the artificial ripening of food while in transit is required to register.

On its own initiative, FDA has made several editorial changes in this section for clarity.

10. Nonprofit Food Establishment

FDA received no comments on this issue. On its own initiative, FDA has made several changes in this section to be consistent with the legislative history for section 305 of the Bioterrorism Act (21 U.S.C. 415). FDA has also made several editorial changes in this section for clarity.

11. Packing

(Comment 71) One commenter asks FDA to differentiate between "packing" and "packaging." The commenter states that although arguably the terms could be used interchangeably, they are in fact materially different. The commenter states that this distinction is especially important because FDA considers "packaging material" food under § 1.227(c)(4).

(Response) FDA agrees with the commenter and differentiates between these terms in the interim final rule. The interim final rule defines "packaging" (when used as a verb) as "placing food into the container that directly contacts the food and that the consumer receives." (§ 1.227(b)(8)). FDA has redefined "packing" as "placing food into a container other than packaging the food" (§ 1.227(b)(9)). FDA notes that packaging material is no longer included in the definition of "food" as revised in this interim final rule.

(Comment 72) One commenter asks whether putting food into tote bins and bulk containers is considered "packing" for purposes of this rule.

(Response) Putting food into tote bins and bulk containers is "packing" as

defined in the interim final rule (§ 1.227(b)(9)), because it is "placing [food] into a container other than packaging the food."

12. Port of Entry

(Comment 73) Several commenters ask that the definition of "port of entry" be modified so that it is consistent with the U.S. Customs definition, which is "the port at which Customs entry is made for the shipment of imported food for consumption in the United States. This port may be different than the Port of Arrival, which is defined as the first port at which the carrier transporting the merchandise arrives." A commenter states that creating a new definition of "port of entry" is contrary to Congress's intent, which it may be presumed was based on Congress's awareness of Customs' definition of the term.

One commenter states that two Federal Government agencies having two definitions for the same term is potentially troublesome, and "lays the groundwork for confusion and conflict regarding where and when proper declaration is required." Another commenter states that FDA's proposed definition of "port of entry" will create substantial hardship for an importer of the food, who is usually located in close proximity to the inland port and is better equipped to handle compliance or clearance issues locally. The commenter states that, under FDA's proposed definition of "port of entry," imports would be subject to review by two separate FDA Districts, that of the port of arrival and that of the port of entry. This would greatly increase FDA's workload. The commenter also indicates that FDA's proposed definition of "port of entry" would create substantial problems if a foreign facility fails to register, because there is no provision in the statute for FDA to issue a refusal of admission that would enable the importer to export the goods, or any provision for the goods to be designated as general order status. In this case, the importer could not file a consumption entry, after which FDA could issue a refusal of admission under 21 U.S.C. 381(a), because a consumption entry cannot be filed until the goods have arrived at the inland port.

These commenters also argue that FDA's concern that allowing food to be shipped inland before verifying registration could result in loss of government control over the food is inconsistent with the statutory objective. This objective is to prevent food imports from being released from Customs' control until FDA has had an opportunity to screen the shipment and determine if it presents a risk of bioterrorism. The commenter explains that, under Customs' regulations, all food transported in bond to an inland port of entry is subject to Customs' legal control until a consumption entry is filed and a permit for release is issued. Even if cargo is bound for consumption entry in an inland port, the cargo is still subject to detention or inspection by Customs or FDA at the port of arrival. One commenter states that a revised definition of port of entry would also assist express carriers, who are required to hold a shipment in their control until all regulatory agencies have released it.

(Response) As discussed in detail in response to comment 151, this interim final rule does not include a provision regarding consequences for failure to register on imported food. Because the definition of "port of entry" is only relevant to the consequences of failure to register when attempting to import food, we have removed the definition of "port of entry" from this interim final rule. FDA has defined the term "port of entry" in the interim final rule on prior notice of imported food published elsewhere in this **Federal Register**.

13. Restaurants

(Comment 74) One commenter asks FDA to specify that commissaries that are a single source of food for large populations via large chain restaurants should not be exempt from registration as restaurants.

(Response) FDA agrees with the commenter that facilities, such as commissaries or central kitchens that provide food to restaurants that subsequently serve the food to customers, are not restaurants. The proposed definition of restaurant is limited to establishments that prepare and sell food directly to consumers for immediate consumption. Although central commissaries prepare food that is eventually served to consumers, these facilities do not do so directly. Accordingly, FDA is clarifying in the interim final rule that commissaries, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers are not restaurants and thus, are required to register with FDA.

(Comment 75) Several commenters agree with FDA that the restaurant definition (and therefore, the exemption) should include pet shelters, kennels, and veterinary facilities. One of these commenters requests that FDA include these facilities in the interim final rule itself, as opposed to the preamble.

(Response) The preamble to the proposed rule stated that, by analogy, pet shelters, kennels, and veterinary facilities were included in the restaurant exemption. FDA received no comments disagreeing with this approach. For clarity, the interim final rule's definition of restaurant expressly includes pet shelters, kennels, and veterinary facilities.

On its own initiative, FDA has made several editorial changes in this section for clarity.

14. Retail Food Establishment

The interim final rule substitutes the statutory term "retail food establishment" for the term "retail facility," which was used in the proposed rule.

(Comment 76) Some commenters state that the definition of retail facility as "a facility that sells food products directly to consumers only," should be revised to delete "only." This is based on the following arguments: 148 Cong. Rec. H2858 specifies that retail food establishments include those facilities "attendant" to retail operations; because the proposed definition of retail food establishment included commissaries, distribution facilities for grocery stores, which are also attendant facilities, should be included as well; the legislative history makes several references to retail as "sale to consumers as its primary function," warehouse clubs should be included in the definition of retail facility, based on this language at 148 Cong. Rec. H2726: "[Retail] does not include a warehouse that does not provide articles of food directly to a retail consumer as its primary function * * *."

(Response) FDA agrees in part with these comments. Accordingly, we have revised the definition of retail food establishment to eliminate the restriction that such facilities must sell only to consumers to be considered a retail food establishment. This interim final rule defines "retail food establishment" as "an establishment that sells food products directly to consumers as its primary function. A retail establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food that it manufactures/processes, packs, or holds directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term " 'consumers' does not include businesses. A 'retail food establishment' includes grocery stores, convenience stores, and vending machine locations." This change preserves the retail

exemption both for retail food establishments (such as grocery stores) that sell or transfer some products to sources other than a consumer (*e.g.*, to other grocery stores), and for direct selling entrepreneurs, as long as their primary function is to sell directly to consumers.

FDA further agrees that under the revised definition of retail food establishment, certain warehouse clubs may be exempt from registration, if, based on dollar volume of their sales, they sell food directly to consumers as their primary function.

In addition, FDA has determined that an establishment "attendant" to a retail operation, if located separate from the retail food establishment, is not a retail food establishment for purposes of this rule. This is consistent with the Conference Report for the Bioterrorism Act, which states that the term "retail" does not include warehouses that do not sell directly to consumers as their primary function (H.R. Conf. Rep. No. 481, 107th Cong., 2d Sess., 133 (2002)).

Regarding FDA's use of the term "commissaries" in § 1.227(c)(11) of the proposed rule, FDA is clarifying that the term was intended to refer to establishments on military bases that sell food directly to consumers. As noted in the response to comment 74, FDA did not intend to include other types of commissaries, such as central kitchens for restaurants, within the restaurant exemption. To avoid confusion, the interim final rule deletes the word "commissaries" as an example of a "retail food establishment" because this term has multiple meanings. Regardless of what an establishment is called, it is exempt as a retail food establishment if—and only if—it meets the definition.

(Comment 77) Several commenters argue that "direct selling" or "multi-level selling" home-based distributors should be considered retail food establishments because their primary function is selling to consumers. However, because these salespeople also transfer products among themselves, they are not exempt under the proposed rule. The parent company's manufacturing and distribution facilities would be required to register. There are millions of direct selling entrepreneurs and registering them all would flood the registration system and not be meaningful. These salespeople are analogous to retail chain stores that sometimes need to transfer inventory between them.

(Response) As discussed in the response to comment 7, private residences of individuals are not facilities for purposes of this interim final rule and, therefore, are exempt from registration. Accordingly, these home-based distributors are not subject to registration.

(Comment 78) One commenter asks FDA to clarify when operations of a retail food establishment cease to be incidental to the activities of the retail food establishment and cause the retail food establishment to become a mixed-type facility that must register. This commenter asserts that activities such as operating a juice bar, repackaging nuts or dried fruits received in bulk into smaller packages, or unpacking and displaying produce are good examples of incidental activities in a retail food establishment.

(Response) The revised definition of "retail food establishment" clarifies that such establishments may manufacture/process, pack, or hold food so long as the establishment's primary function is to sell from that establishment food that it manufactures/processes, packs, or holds directly to consumers. As noted, a retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. Therefore, if the establishment's primary function is to sell food directly to consumers, repackaging nuts or dried fruit for sale directly to consumers and unpacking and displaying produce for direct sale to consumers are permissible activities. However, if an establishment's primary function is to sell food to distributors, but the establishment also conducts some minor sales directly to consumers, repackaging nuts for sale directly to these consumers does not cause the establishment to fall within the definition of "retail food establishment." Examples of manufacturing/processing that a retail food establishment might perform include making potato salad for sale at the delicatessen counter of a grocery store, filleting fish at a fish market, and cutting cheese from a large block into slices for sale directly to consumers based on the amount they request. Operating a juice bar would be exempt as a "restaurant" because it involves preparing and selling food directly to consumers for immediate consumption.

(Comment 79) Some commenters argue that retail food establishments should include retailers of animal food. They argue that the plain text of the statute does not have a limitation on the scope of the retail food establishment exemption and that because animal food is included in the proposed rule's definition of food, the exemption should also apply to both. These commenters further argue that it would not make sense to hold animal food retailers to a standard higher than that for retailers of human food and note that pet food is offered alongside food for human consumption. Finally, these commenters assert that the failure to exempt pet food retailers would be to eliminate the benefit of the exemption for retail animal food facilities.

(Response) FDA agrees with these comments and advises that the definition of "retail food establishment" includes animal food retailers. FDA believes that this is consistent both with including animal feed as "food," as well as with the language of the Bioterrorism Act. The agency has amended the definition of "retail food establishment," however, to clarify that the term "consumers" does not include businesses. As a result, an establishment that sells animal food to pet owners and other individuals as its primary function is exempt as a retail food establishment. An establishment that sells animal feed to businesses, such as farms, as its primary function must register.

(Comment 80) One commenter asks FDA to clarify whether wholesale establishments are also included in the definition of "retail food establishment."

(Response) Wholesale facilities are not covered by the definition of "retail food establishment" because they do not sell food directly to consumers as their primary function.

(Comment 81) One commenter asks FDA to clarify whether retail co-ops are required to register in light of the proposed rule's statement that "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." The commenter states that "retail co-ops, aside from cooperative ownership, operate no differently than any other retail establishment."

(Response) FDA agrees that a retail food establishment that is cooperatively owned is exempt from registration if it sells food directly to consumers as the co-op's primary function. The establishment's primary function must be to sell food, including that manufactured/processed at the establishment, directly to consumers.

(Comment 82) Several commenters ask whether establishments supplying food to consumers via Internet or mail-order sales are covered under the definition of "retail food establishment."

(Response) Facilities selling food directly to consumers via the Internet or mail-order are covered under the

definition of "retail food establishment" if they meet the other criteria of the "retail food establishment" definition. FDA notes, however, that many of these establishments may also manufacture/process, pack, or hold food that is subsequently sold to consumers. Unless the establishment's primary function is to sell food, including the food it manufactures/processes, directly to consumers, it must register with FDA.

(Comment 83) One commenter asks FDA to clarify whether warehouses that hold food for sales in U.S.-based duty-free stores are required to register. The commenter indicates that products stored in a duty-free enterprise warehouse and sold in an airport duty-free store are purchased solely by travelers departing from the United States, and therefore, are not for consumption in the United States.

(Response) FDA's understanding of duty-free shops is that purchased goods (including food) must be taken out of the United States by the traveler before such goods may be consumed or used. Thus, the agency agrees with the commenter that warehouses holding food for sale in duty-free stores are not required to register as long as the food is not for consumption or actually consumed in the United States.

In addition to the previous comments, FDA has made several editorial changes in this section for clarity.

15. U.S. Agent

(Comment 84) Some commenters claim that FDA's requirements for U.S. agents, and the responsibilities and liabilities of U.S. agents, are not clear. The commenters state that because FDA's proposed requirements are so general, it is difficult for a foreign facility to know what qualifications its U.S. agent should have.

(Response) FDA has retained the criteria for U.S. agent as proposed. As stated in the proposed rule, there are only two qualifications for a U.S. agent: The agent is required to reside or maintain a place of business in the United States and to be physically present in the United States. As far as U.S. agent liability, FDA generally does not intend to hold the U.S. agent responsible for violations of the Bioterrorism Act that are committed by the foreign facility, a position consistent with that articulated in the preamble to the agency's drugs, biologics, and device registration regulations (66 FR 59142, November 27, 2001). FDA, however, would consider legal action against a U.S. agent where the agent knowingly submitted false information to FDA or the agent and the foreign facility were effectively the same entity. Liability issues between the facility and its U.S. agent must be resolved between the private parties (*i.e.*, the facility and its U.S. agent), most likely through the terms of their contractual relationship.

(Comment 85) Some commenters ask FDA to clarify whether it will notify the U.S. agent or a facility's emergency contact in the event of a bioterrorist attack or other food-related emergency that affects a foreign facility.

(Response) Because the role of the U.S. agent is to act as a communications link between the facility and FDA, FDA will communicate with the U.S. agent in both routine and emergency situations. This means that the U.S. agent needs to be accessible to FDA 24 hours a day, 7 days a week, unless the foreign facility opts to designate a different person other than the facility's U.S. agent to serve as the facility's emergency contact by providing the information specified in § 1.233(e) in the facility's registration. If a facility's registration includes an emergency contact person provided under § 1.233(e), FDA will notify this person instead of the U.S. agent during emergencies, but will continue to use the U.S. agent for routine communications with the facility.

(Comment 86) Some commenters argue that FDA's requirement that facilities have a single U.S. agent is contrary to usual business practices. The commenters state that a facility may have several U.S. agents for different business functions, such as separate product lines or different geographic areas.

(Response) FDA believes that it would be unreasonably complex to allow facilities to have several U.S. agents for purposes of FDA registration, as FDA would then have to determine with which agent to communicate for each product line or geographic distribution area. This would likely hinder communication between FDA and the facility and thereby, thwart a chief purpose of the Bioterrorism Act—facilitating a quick and effective response to a terrorist attack or other public health emergency related to the U.S. food supply. Also, section 305 of the Bioterrorism Act is written in the singular—that is, it states that a foreign facility must include the name of its "U.S. agent." Thus, allowing facilities to designate more than one U.S. agent would be inconsistent with the plain language in the Bioterrorism Act.

FDA is clarifying in § 1.227(b)(13)(iii) that having a single U.S. agent for FDA registration purposes does not preclude a facility from having multiple agents (such as foreign suppliers) for other business purposes and that FDA is not requiring that all of a firm's commercial business in the United States be conducted through the U.S. agent designated for purposes of registration.

(Comment 87) Several commenters argue that the U.S. agent requirement is onerous and potentially trade-restrictive. The commenters state that there is no requirement for a third-party go-between for domestic facilities; thus, this requirement is more restrictive on foreign facilities than on U.S. producers.

(Response) FDA believes that it has structured the U.S. agent requirement to be consistent with the statutory mandates of the Bioterrorism Act. The rule sets out only two qualifications for a U.S. agent: The agent is required to reside or maintain a place of business in the United States and to be physically present in the United States. Therefore, many foreign facilities are able to use existing contacts in the United States as their U.S. agents. Moreover, FDA has clarified in the interim final rule that the requirement of a single U.S. agent for FDA registration purposes does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes.

(Comment 88) Some commenters argue against the U.S. agent requirement because they believe the requirement will hinder, not enhance, communication with the foreign facility.

(Response) As discussed in the preamble to the proposed rule, the purpose of the U.S. agent is to serve as a communications link between FDA and an individual facility for a number of purposes, including both emergency situations and day-to-day registration issues. These routine issues may include FDA's need for information about that facility and arranging both routine inspections and inspections or communications with the facility due to a potential bioterrorism threat or other public health emergency.

(Comment 89) Several commenters argue that FDA should allow the U.S. agent to be located outside the United States. They state that many foreign facilities do not have contacts within the United States, so it will be difficult for them to locate a U.S. agent.

(Response) Section 305 of the Bioterrorism Act (which amends the FD&C Act) states that the registration of a foreign facility "shall include with the registration the name of the United States agent for the facility." Thus, requiring a foreign facility's U.S. agent to reside or maintain a place of business in this country is consistent with the plain language of the Bioterrorism Act. This approach is also consistent with FDA's implementation of the statutory requirement for drug, biologics, and device registration (21 U.S.C. 360(i)(1)),

66 FR 59138 (November 27, 2001).) It is reasonable to impute to Congress knowledge of FDA's implementation of this provision, which specifies that the "U.S. agent" be a person in the United States, when Congress incorporated this concept and language into the Bioterrorism Act.

(Comment 90) Several commenters ask whether a foreign government official in the United States, such as a representative from the foreign country's embassy, may act as the U.S. agent for a foreign facility.

(Response) The agency has concerns that acting as a U.S. agent may conflict with the duties of foreign government representatives. Whether it is proper for a foreign government representative to act as a U.S. agent is a fact-specific inquiry, depending on the title and status of the foreign government representative and the functions that the representative assumes as a U.S. agent. FDA believes that the propriety of a foreign government official acting as the U.S. agency of a foreign facility is a determination best made in conjunction with the State Department. If the issue arises after implementation, FDA will discuss the particular situation with the State Department.

(Comment 91) A few commenters suggest that FDA allow registrants to omit U.S. agent information if FDA uses information available from a foreign government agency.

(Response) The Bioterrorism Act requires the owner, operator, or agent in charge of a facility engaged in the manufacturing, processing, packing, or holding food—both domestic and foreign—to register the facility with FDA. The Bioterrorism Act also requires registrants of foreign facilities to provide the name of their U.S. agent. Thus, FDA is not permitted to use information maintained by foreign government agencies or other domestic Federal or State agencies in lieu of having the owner, operator, or agent-in-charge of a facility submit the information to FDA.

(Comment 92) One commenter asks whether a U.S. agent must be one individual or can it be a "person" consistent with the act's definition of "person" as an "individual, partnership, corporation, or association."

(Response) FDA agrees with the commenter and has clarified in the definition of "U.S. agent" that a foreign facility's U.S. agent can be a "person" as defined by the FD&C Act. This interpretation is consistent with the drug, biologics, and device registration regulations in 21 CFR 207.3(a)(11) and (b), 607.3(i) and (j), and 807.3(h) and (r).

(Comment 93) One commenter asks how FDA intends to ensure that a person identifying itself as a U.S. agent does, in fact, meet the requirements for a U.S. agent. The commenter states that some foreign facilities may use a false U.S. agent name, address, or phone number when registering. This commenter suggests that FDA confirm a registration only through a facility's designated U.S. agent, via postal mail.

(Response) FDA believes that there are several checks that will help ensure that registrations are truthful and accurate. The facility's owner, operator, or agent in charge who submits a registration must certify that the registration information is true and accurate. In addition, FDA has revised the interim final rule so that an individual (other than the owner, operator, or agent in charge of the facility) may be authorized to submit the registration on behalf of the owner, operator, or agent. An individual (other than a facility's owner, operator, or agent in charge) who submits the registration form to the FDA must certify that he/she is authorized to submit the registration on the facility's behalf and must identify by name the individual who authorized submission of the registration. The certification statement also states that anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties under 18 U.S.C. 1001. As an additional means to verify the identity of the person submitting the registration, the interim final rule requires that for the paper and CD–ROM registration options, the registration include the signature of the person submitting the registration. FDA believes that the combination of the signed certification statement and federal criminal liability will be a powerful incentive for truthful registrations. Further, because the Bioterrorism Act provides that an owner, operator, or agent in charge is responsible for registering a facility, it would be improper for FDA to confirm that registration only through a facility's U.S. agent if the U.S. agent did not originally submit the registration.

In addition to the changes noted previously, FDA has made several editorial changes to this section on its own initiative.

16. Other Definitions Included in the Interim Final Rule

(Comment 94) One commenter requests that FDA define "trade names" in the interim final rule. This commenter states that the term "trade names" is mentioned in both the Bioterrorism Act and the proposed rule several times, yet is not defined. The commenter requests that "trade names" be defined, "to ensure that the scope of registration reflect[s] the intent and objectives of the statute." The commenter suggests that "trade names" be defined as "the terms relating to the business activity of the facility that denote the names under which the facility conducts business or additional names by which the facility is known." The commenter also requests that FDA clarify that "trade names" "denote terminology associated with the business of the facility, and does not necessarily signify a brand name, which is terminology associated with a product." The commenter provides some examples of trade names, such as: "Facility name: Jones Foods Corporation; Trade Names: doing business as Joe Jones Fruit Processors, doing business as Jones Family Pie Company."

(Response) FDA agrees with the comment, and has added the following definition for "trade names" to the interim final rule (§ 1.227(b)(12)): "*Trade name* means the name or names under which the facility conducts business, or additional names by which the facility is known. A trade name is associated with a facility, and a brand name is associated with a product."

(Comment 95) Several commenters request that FDA clarify who is required to register if a facility has multiple individuals who may qualify as the owner, operator, or agent in charge.

(Response) The Bioterrorism Act and the interim final rule place the responsibility for registering a facility on the owner, operator, and agent in charge of the facility. If a facility has multiple owners, operators, or agents-in-charge, all are collectively responsible for registering the facility and any one of these individuals may register the facility, or as noted in the response to comment 93, authorize an individual to submit the registration for the facility. Although these persons may decide themselves how, as a practical matter, their facility will be registered, the existence of multiple owners, operators, or agents in charge does not affect the legal obligation each has under the rule to register relevant facilities.

(Comment 96) One commenter states that although FDA uses the terms "owner," "operator," or "agent in charge" throughout the proposed rule and the draft registration form, in section 1b (Update of Registration Information) and section 12 (Certification Statement) but these terms are not defined. The commenter also states that although FDA requests changes to the "owner, operator, or agent in charge" in section 1b of the

registration form, FDA "does not ask for specific information for the owner, operator, or agent in charge elsewhere in the form." The commenter states that it assumes FDA interprets the owner, operator, or agent in charge of the facility "as the facility itself (and not an individual) for which specific information is requested in section 2 of the form" (facility name/address information). The commenter continues that "[o]nce the owner, operator, or agent in charge of the facility has authorized an individual to submit the registration form, that individual becomes synonymous with the 'owner, operator, or agent in charge.'" The commenter states that if these assumptions are correct, the last box under section 1b should be revised from "Owner, Operator, or Agent in Charge Change" to "Authorized Submitter [Change]."

The commenter also requests that section 12 be revised from its current statement "[t]he owner, operator, or agent in charge of the facility must submit this form. By submitting this form to FDA, the owner, operator, or agent in charge certifies that the above information is true and accurate and that the facility has authorized the submitter to register on its behalf." The commenter's suggested revised statement is as follows: "[t]he owner, operator, or agent in charge of the facility must submit this form. By submitting this form to FDA, the owner, operator, or agent in charge of the facility certifies that the above information is true and accurate and that the *submitter has been authorized* to register on its behalf" (suggested changes in italic).

(Response) These comments (and others) suggest that certain provisions of the proposed rule and proposed Form 3537 may have been ambiguous or otherwise created confusion about who should complete and submit a registration. As discussed below and elsewhere in this preamble, FDA has clarified several provisions in the interim final rule and has revised Form 3537 as well. The agency believes that these clarifications and revisions generally respond to the foregoing comments. FDA's more specific responses to these comments are set out below.

Regarding the commenter's request that FDA define "owner," "operator," or "agent in charge," FDA does not believe that it is necessary to define these terms because the terms are self-explanatory. Accordingly, the interim final rule does not include a definition for owner, for operator, or for agent in charge.

FDA acknowledges that the provision in the proposal regarding the certification statement was unclear due the language in proposed § 1.232(g) stating that "the person submitting the registration [must be] authorized by the facility to register on its behalf." This created ambiguity for three reasons. First, the use of "person" created ambiguity as to whether only an individual could submit the registration because "person," as defined in section 201(e) of the act, includes an individual, partnership, corporation, and association. However, as evidenced by the proposed certification requirement that the name of the person submitting the registration be specified, FDA intended to convey that an individual rather than a "person" must submit the registration. Second, the statement that a person submitting a registration must have been authorized by the facility is inconsistent with the certification statement in the proposed rule, which stated that "the owner, operator, or agent in charge of the facility must submit this form." Third, the former statement was confusing because a facility itself cannot authorize an individual to register.

The interim final rule resolves these inconsistencies by clarifying who may register a facility. Although the Bioterrorism Act imposes the legal obligation to register on the owner, operator, and agent in charge of a facility, FDA believes that this provision does not prevent the owner, operator, or agent in charge of a facility from authorizing an individual to fill out, sign, and submit the registration. Accordingly, the interim final rule provides that the owner, operator, or agent in charge may authorize an individual to submit the facility's registration.

In addition, for clarification and for the reasons discussed in the responses to comment 110, in the interim final rule, § 1.232(i) has been added to provide that if the individual submitting the form is an individual authorized to do so by an owner, operator, or agent in charge, the individual must also certify that the individual is authorized to submit the registration form on behalf of the owner, operator, or agent in charge and must identify by name the authorizing individual. This statement must include the individual submitter's signature (for paper and CD–ROM options) and printed name. If the individual submitter is authorized by someone other than the owner, operator, or agent in charge, the authorizing individual's name, address, and phone number must be included; the fax number and e-mail address of the authorizing individual are optional.

FDA does not agree with the commenter's assumption that if a facility authorizes an individual to submit a registration, the individual then becomes synonymous with the owner, operator, or agent in charge. Although the interim final rule permits an owner, operator, or agent in charge to authorize an individual to submit the registration on its behalf, that individual does not become the owner, operator, or agent in charge for purposes of registration or otherwise alter the legal obligation of the owner, operator, or agent in charge to register. Therefore, we have not revised section 1b as requested by the commenter.

FDA does not fully understand the import of the comment that the agency considers that owner, operator, and agent in charge to be the "facility itself." In some cases, the owner of the facility may be the same as the facility (*e.g.*, a corporation) while in other instances, the two may be different. The revised Form 3537 reflects these two possibilities in that it requests information about the facility (Section 2, facility name and address) and the owner, operator, or agent in charge (Section 12, owner, operator, or agent in charge address and telephone number.) Form 3537 also recognizes that information in section 12 may overlap with that requested in section 2.

F. Comments on "When Must You Register?" (Proposed § 1.230)

(Comment 97) One commenter states that FDA's language in proposed § 1.230 ("[t]he 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") is contrary to the Bioterrorism Act, which requires registration by facility, as opposed to by owner, operator, or agent in charge. The commenter also states that language in proposed §§ 1.225 and 1.226 might be interpreted to mean that the owner, operator, or agent in charge is the entity to be registered, not the facility.

(Response) FDA intends to require that the facility be registered, not the owner, operator, or agent in charge of the facility. In response to these comments, FDA has revised the following language: In § 1.225, FDA has added the italicized language to paragraph (a): "You must register *your facility* under this subpart if you are the owner, operator, or agent-in-charge of either a domestic or foreign facility * * *". The agency also has added the italicized language to paragraph (b): *"If are* an owner, operator, or agent in charge of a domestic facility * * *, *you* must register *the facility* * * *."

FDA believes no revisions are needed to § 1.226, because it is clear in this section that the exemptions apply to facilities, not the owner, operator, or agent-in-charge of the facilities.

In § 1.230, FDA has made the following change indicated by the italicized language: "[t]he owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States must *register the facility* no later than December 12, 2003."

In § 1.233, in the first paragraph, FDA has made the following change indicated by the italicized language: "FDA encourages, but does not require, you to submit the following items in your *facility's* registration."

(Comment 98) Several commenters submitted comments regarding when to register. Some of these commenters request general information about when they will be able to register with FDA. Others acknowledge the proposed timeframe in which FDA expects to publish the final rule; these commenters question why they cannot register, either electronically or by mail, before publication of the interim final rule. Some commenters ask that FDA publish a final rule and implement its electronic registration system before October 12, 2003. Some commenters suggest that, to alleviate the burden on FDA's electronic system, FDA should either accept staggered registrations based on such identifiers as last name of the facility, or that FDA should only require registration 15 days before a facility's intended date of a food shipment to the United States. One commenter requests that FDA ensure that the final regulation and electronic system are in place by October 12, 2003.

(Response) FDA understands that many commenters may view the proposed 8-week timeframe for facilities to register as too brief. However, this timeframe is limited due in large part to the restrictions imposed by the Bioterrorism Act, which requires FDA to develop both proposed and final regulations detailing the process by which facilities must register by December 12, 2003. Within this timeframe, FDA has also had to develop an electronic system that can implement the requirements of this regulation. FDA has expedited the process for developing and completing the proposed and interim final regulations, as well as the electronic registration system. It is not possible for FDA to complete a final rule in less than 16 months from enactment of the Bioterrorism Act, or before October, 2003. Moreover, because this interim final rule articulates the final requirements for registration, which FDA must incorporate into its electronic registration system, FDA could not allow registration in advance of publication of the interim final rule, either electronically or by mail. FDA also believes the time period for registration is reasonable. Because both the proposed rule and this interim final rule have alerted facilities to the general requirements of registration, facilities have had ample time to prepare for registration pending the issuance of the interim final rule.

(Comment 99) Some commenters argue that FDA should provide a 3 to 6-month grace period after December 12, 2003, in which it will accept late registrations without penalizing the facilities that submit these late registrations. These commenters state that they are concerned that FDA will not be able to accommodate the large number of electronic registrations that must be submitted within this 8-week timeframe, and that this breakdown could cause large monetary losses to industry.

(Response) The Bioterrorism Act provides that the effective date for registration is December 12, 2003. The statute further specifies that, after this date, food imported or offered for import from unregistered facilities must be held at the port until the facility is registered (21 U.S.C. 381(l)). FDA has designed its electronic system to be robust enough to handle the large volume of registrations anticipated during this 8-week period. However, the planned capacity will not be sufficient to process all of the registrations in 1 day; thus, if all registrants wait until the last day to register (*i.e.*, December 12, 2003), the system's capacity could be exceeded. Therefore, FDA encourages facilities to register early.

(Comment 100) Some commenters indicate that the 8-week timeframe does not allow paper registrations as a real alternative to electronic registrations, because FDA states in the proposed rule that registration by mail could take several weeks to several months. This timeframe could render a facility out of compliance with the effective date for registration, because even if a facility were to mail its registration to FDA soon after October 10, FDA might not return the registration number to the facility until after December 12.

(Response) The paper processing facility will be able to electronically process over 1,800 Form 3537 submissions each business day during the regulatory peak processing period of October 16, 2003, through December 12, 2003 (41 business day period). This will result in a total of 73,800 submissions processed in a 41 business day period. All Form 3537 submissions will be processed in the order they are received and will be turned around within a 24-hour period, if the registration form is error free. Submitters should expect to receive their registration number within 5 to 7 days after processing depending on postal mailing delays if the number of submissions does not exceed the processing capacity.

If the registration submissions should exceed the daily 1,800 Form 3537 processing capacity, a backlog will develop. FDA expects that if backlogs occur, they are most likely near the end of the initial 41 business day registration period. If our estimates are correct, FDA would expect a backlog of 2 to 3 weeks. However, if the number of submissions and rejections being resubmitted exceed our estimates, the backlogs will be longer. So including the mailing time, the backlog, and processing times, the delay toward the end of the initial registration period could be 3 to 6 weeks or longer if the number of submissions exceeds our estimates.

If a submission has been rejected due to error the submitter made or failed mandatory validation, the submission will be returned to the submitter via postal mail. Depending on mailing delays, the submitter should expect to receive the rejected submission with a letter explaining the rejection within 5 to 7 days plus the time the submission spent in the processing backlog (0 to 3 weeks). After the submitter corrects their registration and resubmits it to FDA via postal mail, the corrected registration will be processed in the order received along with all other submissions and is subject to all of the delays identified previously.

For the CD–ROM option, submitters are allowed to store a fill-in PDF Form 3537 for each facility onto a CD as a separate file. FDA will process the CD–ROM submission, presumably containing multiple registrations, electronically as part of the paper process. This means the PDFs on the CD–ROM will not be printed out and then keyed in because they are already in the format that the paper process system needs. The PDF files will be fed into the paper process queue in their order of arrival as though they were a normal paper form. Each file on the CD will go through the same validation checks as if it were a normal paper submission. If the registration file on the CD–ROM is processed successfully, the registration will be returned by postal

mail with a registration number. If the registration fails validation checks or contains errors, the registration will be returned with a letter explaining why registration was not successful and will need to be resubmitted in order to complete registration.

The only way for a registrant to ensure a fast response to a registration is to register the facility electronically on the Internet.

(Comment 101) One commenter states that FDA does not mention the registration requirements for facilities that form after December 12, 2003.

(Response) Section 1.230 of the interim final rule states "* * * a facility that begins to manufacture/process, pack, or hold food for consumption in the United States on or after December 12, 2003, must be registered before the facility begins such activities."

FDA has made a small editorial change to this section for clarity.

G. Comments on "How and Where Do You Register?" (Proposed § 1.231)

(Comment 102) Several commenters ask FDA to explain how they should register their facilities with FDA.

(Response) As stated in § 1.231, those wishing to register a facility electronically must access *http://www.fda/furls* and follow the directions on that Web site for registering. This Web site will be available starting on October 16, 2003, at 6:00 p.m. eastern daylight time. Registrants needing technical assistance with the paper or electronic registration forms can call 1–800–216–7331 or 301–575–0156, or can fax their questions to 301–210–0247 or e-mail them to *furls@fda.gov*. Starting on October 16, 2003, these phone numbers will be staffed on business days from 7 a.m. until 11 p.m. eastern standard time.

FDA had anticipated having the electronic and paper systems operational on the date of this interim final rule's publication. However, given the fluid and dynamic nature of developing the electronic system in parallel with finalizing the regulation that determines the requirements for the system and given the short deadline imposed by the statute, much of the development and testing effort of the system had to occur in the last 2 months. Accordingly, for much of these 2 months, work on the system has been taking place 7 days a week. Moreover, hurricane Isabel caused significant delays in the work for the week of Thursday, September 18. Due to these delays, FDA determined that if it postponed the launching of the system until Thursday, October 16, there would be a much higher level of assurance that those persons registering food facilities electronically would be able to do so effectively and efficiently without user frustration or confusion. FDA believes that the slight delay of the system will not affect stakeholders substantially, as potential registrants will need several days to become familiar with the rule and its requirements.

Therefore, beginning on October 16, 2003, the Web site will be available 24 hours a day, 7 days a week, from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. In addition, as noted previously, the owner, operator, or agent of a foreign facility may authorize an individual to register the facility; the owner, operator, or agent in charge may chose to authorize an individual who has access to the Internet. In addition, the Bioterrorism Act requires a foreign facility to designate a U.S. agent. That agent (if an individual) could be authorized by the owner, operator, or agent in charge of a foreign facility to register that facility. If the U.S. agent does not have Internet access onsite, the U.S. agent may register the facility electronically from a local library or other public facility that offers Internet access either free of charge or for a relatively small fee. Thus, all foreign facilities will be able to receive an electronic confirmation of registration and the facility's registration number, as will domestic facilities that register electronically.

FDA strongly encourages electronic registration for the benefit of both FDA and the registrant. FDA will be able to accept electronic registrations from anywhere in the world where the Internet is available 24 hours a day, 7 days a week. Electronic registration also will enable a facility to be registered more quickly than if registering by mail, because obtaining confirmation of registration and the facility's registration number online should be instantaneous once a facility fills in all required fields on the electronic registration form.

As stated in § 1.231(b), a registrant may also register by fax or mail (for example, if none of the means of electronic access mentioned previously are reasonably available). Processing of fax or mail (including CD–ROM) registrations will also begin on October 16, 2003. In registering by mail or fax, a registrant also may fill out one or more forms on behalf of one or more facilities. A registrant registering by mail must call FDA at 1–877–FDA–3882 (1–877–332–3882) to request a copy of the form, or send FDA a written request for the form at U.S. Food and Drug Administration (HFS–681), 5600 Fishers Lane, Rockville, MD 20857. Once the registrant receives the mailed or faxed copy of the form, the form must be filled out completely and legibly, and either mailed back to FDA at the same address, or faxed back to FDA at 301–210–0247. FDA will process the registration forms in the order received. 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. FDA will then mail or fax to the registrant a copy of the registration as entered, confirmation of the registration, and the facility's registration number. When responding to a registration submission, FDA will use the means by which the form was received by the agency (*i.e.*, by mail or by fax). If the copy of the registration form mailed or faxed back to the registrant contains incorrect information, the registrant must update the incorrect information under § 1.234. Registration by CD–ROM, which is also permitted by the interim final rule, is discussed in the response to comment 103.

(Comment 103) Several commenters request that FDA accept batched multiple facility registrations via CD or XML format instead of registering one facility at a time through the online system.

(Response) Due to the stringent timeframe that FDA had to develop proposed and interim final regulations and in which to finalize the electronic registration system, FDA is unable to accept multiple registrations in XML format because it would take substantial additional time and money for FDA to develop the compatibility necessary to accept registrations in this format. However, FDA will accept multiple submissions in CD–ROM format ISO 9660 (CD–R or CD–RW) Data format. These registrations must be submitted on FDA's fill-in Portable Document Format (PDF) rendition of the appropriate form (Form 3537) accompanied by one signed copy of the certification statement on the registration form. Each submission on the CD–ROM must use the same preferred mailing address in the appropriate block on Form 3537. The CD–ROM can contain as many submissions as needed up to its capacity (650–700 megabytes (MB) or about 1,300 submissions per CD–ROM). Importantly,

however, each submission must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company. If FDA receives a CD–ROM that does not comply with these specifications, it will send the CD–ROM back to the registrant unprocessed.

FDA notes that CD–ROM submissions are similar to submissions by mail or fax in terms of how they are processed. FDA will process these CD–ROM submissions along with the mailed and faxed submissions, in the order received. Therefore, registrants wanting to ensure that they receive their registration numbers quickly may wish to register electronically, as described previously. The principal advantage CD–ROMs offer over paper submissions is for firms that own many facilities and do not have reasonable access to the Internet. Using a CD–ROM to submit PDF typed registrations should increase legibility and save on mailing expenses. FDA reiterates, however, that submission by CD–ROM will be slower than submitting registrations electronically.

(Comment 104) Several commenters request that FDA's electronic system provide a way in which a single registrant entering data for many facilities can stop entering data on one day and resume from where they left off on another day.

(Response) FDA's electronic system will save registration data automatically with the completion of the entry of all data for a facility. Thus, it will be possible to stop entering data upon completion of the entry for one facility, and resume entering data for a subsequent facility on another day without loss of any previously entered data that would be applicable to both facilities, such as the name and address of the owner. The information needed for a registration is identified on the electronic registration form. A registrant will know what information is required for the registration before beginning to enter registration data into the system. Once a registrant has all of the required information, the time to register each subsequent facility should decrease, depending on how much of the information can be autofilled from the account information from previous registrations. However, the FDA electronic system does not allow a registrant to save data in the middle of registering a facility. Therefore, FDA suggests that registrants completely finish registering a particular facility before ending an online session.

(Comment 105) Some commenters ask whether the electronic system will allow multiple individuals from the same company to enter registration information simultaneously.

(Response) The FDA electronic registration system is set up to allow a company to establish an enterprise (master) account and multiple subaccounts to allow several persons within a company to enter registrations simultaneously. The enterprise account can be used to enter facility registrations and it also can be used to establish and manage subaccounts. The subaccounts can only enter facility registrations, and unlike the enterprise account, they do not have access to other subaccounts. Generally, the enterprise account has access to all information entered via the subaccounts, unless, when created, the subaccount stipulates that the enterprise account is not to have access to that subaccount.

(Comment 106) Some commenters ask whether the electronic registration system will minimize the reporting burden. These commenters are concerned that the lack of detail FDA has provided regarding the Internet-based electronic registration system has made it difficult for them to evaluate the reporting burden.

(Response) FDA is working expeditiously to ensure that that there will be a minimal reporting burden associated with registration in general, and electronic registration in particular. Registering electronically will be a relatively fast process once the registrant has all of the pertinent information available. Once the facility is registered electronically, its registration number should be provided automatically and instantaneously. FDA has received very positive comments at the several public demonstrations of the prototype of FDA's electronic registration system. Throughout the next couple of months, FDA will continue to conduct outreach activities to both foreign and domestic registrants to explain how the electronic registration system works to expedite registration.

(Comment 107) Some commenters express concern about the security of the electronic system. They state that the registration number alone should not be sufficient to access a facility's registration form in an electronic environment, because registration numbers will be required for prior notice of imports, and thus, are likely to be part of the commercial documentation between parties. These commenters emphasize that FDA must have procedures in place to ensure that only authorized persons can access and change a facility's registration information.

(Response) FDA has taken comprehensive steps to ensure that our electronic registration system is secure. A risk assessment has been done and a formal security plan has been incorporated into the system that addresses both physical and electronic security. The system has undergone an independent security review and assessment as well as complete industry standard certification and accreditation. The system securely communicates with registrants using industry standard, secure socket layer with 128-bit encryption.

A facility's registration number alone is not sufficient to access a registration. To increase security, FDA has provided several layers of controls in the electronic access to registrations, thus preventing unauthorized access. First, an account ID and password must be established. Second, each registration has a unique registration number and PIN (Personal Identification Number), both of which are required to gain access to the registration and are only provided to the registrant. Only the registration number is disclosed as part of the prior notice of an imported food shipment. Thus, to prevent unauthorized access to a facility's registration, it is the responsibility of persons registering to secure their account IDs, passwords, and PINs.

(Comment 108) Some commenters request that the electronic system be available in every world language. Others ask whether shipments will be delayed if issues arise from translation discrepancies between a facility's registration in the English translation of its name and its prior notification with elements in the foreign language.

(Response) In response to the first part of the comment, FDA has determined that registration instructions will be provided in three languages: French, Spanish, and English. As noted, these are the three official languages of the WTO.

In response to the second part of the comment, FDA has determined that all registration information submitted must be in English. However, a person's name, the name of a company, the name of a street, or a trade name may be submitted in a language other than English. All information, including these items, must be submitted using the Latin (Roman) alphabet. These exceptions will ensure that inconsistencies will not arise between a facility's registration and prior notice.

Submissions must be in English (with the exceptions noted) so that FDA can understand the content of the registration, ensure that the registration information is correct, and have a database of facilities that its staff can readily access in the event of a

threatened or actual food-related emergency. To assist registrants who do not speak English, FDA has given a foreign facility the option of authorizing an individual (including its U.S. agent if an individual) to register on its behalf.

(Comment 109) Some commenters question whether there will be a contingency plan if the electronic registration system is not as efficient as expected or if more facilities register than anticipated. Some of these commenters question whether the paper system will be able to handle the 8-week registration period.

(Response) The electronic system is designed to handle anticipated peak loads. The paper-based system is being designed to handle the 8-week registration period; however, depending on the number of paper registrations received, and depending on when FDA receives the registrations within this 8-week period, FDA may be unable to process all paper registrations, confirm the registration, and provide a registration number to each registrant within the 8-week period. For this reason, FDA strongly encourages all facilities to register electronically to ensure they are registered on time.

(Comment 110) Some commenters ask whether trade associations, commodity groups, or parent companies can register on behalf of facilities represented by their organizations.

(Response) As stated in the response to comment 96, we have revised § 1.232(i) and the certification statement on Form 3537 to permit an authorized individual to submit the registration. Thus, a trade association or commodity group cannot submit a registration because these entities are not individuals. However, the owner, operator, or agent in charge can authorize an individual from such a group to submit the registration. We note that the definition of U.S. agent provides that a U.S. agent may be a "person" as defined in section 201(e) of the FD&C Act. Therefore, a foreign facility could designate a trade association or commodity group as the facility's U.S. agent. However, if the U.S. trade association or commodity group agrees to serve as the U.S. agent and the facility authorizes the U.S. agent as the foreign facility's agent in charge for registration, an authorized individual from that association or group must submit the registration. In addition, the interim final rule allows a parent corporation to register on behalf of one or more of its facilities.

(Comment 111) One commenter asks whether FDA can build on the Operational and Administrative System for Import Support (OASIS) that FDA currently has to accept registrations. The commenter states that some prospective registrants already provide information regarding "shipper" and "manufacturer" to FDA via OASIS, and that building a new registration system would cause redundancy for these registrants.

(Response) Although FDA intends to use OASIS for cross-checking registration information, both the required data elements and the universe of facilities required to register are markedly different from those entered into OASIS. Moreover, OASIS does not have the capacity to accept all the registration information from all the facilities required to register with FDA. Thus, FDA has developed a new system for registration that will interface with OASIS.

(Comment 112) One commenter asks whether FDA will accept photocopied versions of the mailed registration form.

(Response) FDA will accept a photocopy of a mailed registration form or the certification statement submitted with a CD–ROM submission, as long as the signature on each individual form is an original signature. We recognize that for multiple facility registrations, photocopying data elements that are common to each facility will reduce the burden on the registrants in completing the forms. While those common data elements may appear as photocopies, the forms must include an original signature.

(Comment 113) One commenter asks how the electronic registration form will allow registrants to proceed through the registration process. For example, if each a registrant must answer each section to proceed to the next section, how will the system address optional information?

(Response) FDA has designed both its electronic and paper registrations to specify which sections are mandatory. The electronic registration system has been designed to highlight or mark a required field that a registrant has left blank so that the submitter must fill it in before proceeding further with the electronic registration process.

(Comment 114) One commenter expresses concern that a registration may get lost in "cyberspace," even though it has been correctly filled out and the facility has received a registration number.

(Response) The system saves all submitted information before issuing a registration number. A submitter would only receive a registration number upon a successful registration; if the registration failed, a facility would not receive a registration number. The Web system is a real time system with tape backups of the data entered. Additionally, the system has battery backups in the unlikely event of a power loss.

In addition to the changes noted previously, on its own initiative FDA has made several editorial changes to this section for clarity.

H. Comments on "What Information Is Required in the Registration?" (Proposed § 1.232)

1. General Comments

(Comment 115) Several commenters believe FDA should make the registration process as simple as possible, limiting required information to name, address, and trade names. These commenters state that the scope, exemptions, definitions, and required information in the proposed rule erode simplicity to the point that exemptions are voided, and would require registrations from a vast array of small facilities.

(Response) The Bioterrorism Act requires that a registration contain each facility's name, address, and all trade names under which the registrant does business (21 U.S.C. 350d(a)(2)). That statute provides no exemption from registration for small-size facilities. FDA believes that the information required for registration is necessary to assist FDA in notifying facilities of a threatened or actual bioterrorist attack or other food-related emergency. Together with the other regulations FDA is developing to implement the Bioterrorism Act, the information in the registration will assist FDA in determining the source and cause of such an event.

Regarding the comment that the scope, definitions, exemptions, and required information are unduly complicated, no comments FDA received in response to the proposed rule argue that the interim final rule should not include any definitions, exemptions, or specify the information to be included in a registration. FDA has made every effort to define clearly which facilities are required to register to ensure that potential registrants will know whether they are subject to the rule. FDA also has provided definitions for each exemption provided in the Bioterrorism Act. Moreover, FDA believes that the registration process itself is as uncomplicated and user-friendly as possible. A facility registering electronically should be able to complete the registration and receive its registration number expeditiously once it has gathered all the requisite information.

(Comment 116) Several commenters state that the information in the registration goes beyond the information required by the Bioterrorism Act, thereby exceeding FDA's statutory authority. One of these commenters states that "there are no references, either in the Bioterrorism Act or the legislative history, to the inclusion of individual names in the registration."

(Response) As noted in section I of this document, in issuing this interim final rule, FDA is relying on the authority in section 305 of the Bioterrorism Act, as well as section 701(a) and (b) of the FD&C Act. Including information regarding both the facility's parent company and the emergency contact will facilitate the efficient enforcement of the act by enhancing FDA's ability to deter and respond quickly to a food-related emergency. Accordingly, the provisions of this interim final rule are consistent with FDA's statutory authority provided by the Bioterrorism Act and the FD&C Act.

The only required elements of the registration that the Bioterrorism Act does not specifically mention are the facility's parent company name, address, and phone number, and emergency contact information. Regarding the emergency contact information, the information will make it possible for FDA to respond quickly to emergencies that occur during nonworking hours by contacting facilities when an emergency occurs.

FDA is also requiring the parent company information for emergency situations. If an emergency occurs with respect to a particular facility or group of facilities, FDA will need to alert the parent company, as well as the affected facilities, because the parent company has ultimate responsibility for the facility. Moreover, in terms of inspections, the relationship between a facility and its parent company is vital for FDA in tracking and investigating incidents.

With regard to that portion of the comment asserting the Bioterrorism Act does not refer to individual names, the interim final rule does not require the submission of an individual's name except for the name of the authorized individual submitting the registration and, if the submitter is authorized by another individual, the name of the authorizing individual. Of course, if the owner, operator, agent in charge, or U.S. agent is an individual, the name of that individual must be submitted. If the emergency contact for a facility is an individual, that name must be submitted as well. However, as stated in responses to comments 124 and 137, the interim final rule does not require an individual to be designated as the U.S. agent or an emergency contact.

(Comment 117) One commenter believes that, contrary to FDA's proposed use of the registration information to determine the source and cause of a bioterrorist event, the proposed requirements are geared to locating and contacting facilities that through some other means have already been associated with the event, thus facilitating further investigation.

(Response) FDA believes that registration both will help the agency contact facilities that already have been the target of an event, and will assist the agency in determining the source and cause of the event. First, registration will provide FDA with a more complete and up-to-date database of facilities to contact if the agency learns of an actual or potential threat to the food supply. The specific registration information, such as food product categories and geographic location, will enable FDA to narrow down the facilities that may be affected by a bioterrorist attack or other food-related emergency, thus saving precious time. Second, registration will assist FDA's implementation of the other regulations and guidance documents that FDA is developing to implement the Bioterrorism Act, namely prior notice, recordkeeping, records access guidance, and detention. Registration, prior notice, and recordkeeping enable FDA either to obtain information it does not currently have, or to obtain that information more quickly than FDA was able to do prior to the enactment of the Bioterrorism Act. This information gives FDA crucial tools to protect the U.S. food supply. For example, registration will enable FDA to fill in incomplete information for certain facilities derived through records about a source of a bioterrorist attack or other food related emergency, thus facilitating a traceback. In this example, registration information would also allow FDA to contact some facilities quickly during a traceback investigation.

(Comment 118) One commenter requests that FDA consider registrations submitted more than once on behalf of a particular facility as valid, since some foreign companies may register multiple times both at the facility and corporate levels.

(Response) Once a facility is registered with FDA, the electronic system will reject any additional registrations that are submitted on behalf of the same facility. To have the system do otherwise does not make sense, because each facility must only register with FDA once and will only be assigned one unique registration number. Accepting multiple registrations would also create confusion in FDA's database of registered facilities, because FDA would not know who to contact in the event of an emergency if there is different emergency contact information in the registrations for the same facility. Once a facility is registered, FDA will send a confirmation to the facility by e-mail, mail, or fax, depending on how the facility registered. Thus, personnel at the facility will be aware that the facility is registered.

(Comment 119) A commenter requests that FDA clarify whether it requires a registrant to specify container/package size in its registration. The commenter states that such a requirement would be very time-consuming and introduce prohibitive costs both financially and in terms of resources. The commenter further states that this potentially could necessitate numerous and frequent updates to registration information.

(Response) Neither the proposed rule nor the interim final rule requires registrants to specify container or package sizes in its registration.

(Comment 120) One trade association believes that FDA should provide "full translation services for non-English speakers and the disabled as required under the Americans with Disabilities Act (ADA)."

(Response) Regarding translation services for non-English speakers, this comment is not clear about whether it is requesting these services for the registration itself, or for outreach activities related to registration. FDA intends to translate all outreach-related slide presentations and downlink transcripts for the interim final rule into French and Spanish, similar to what FDA did for the outreach for the proposed rule. As noted previously, FDA will require the registration to be submitted in English. The owner, operator, or agent in charge of a foreign facility that requires translation services may wish to authorize an English-speaking individual to register on its behalf.

FDA is in full compliance with section 508 of the Rehabilitation Act and provides an "Accessibility Statement" for disabled persons on its Web site. FDA cannot identify from this comment if other "translation services" are being requested for the disabled.

2. Name, Full Address, Phone Number, Fax Number, and E-mail Address

(Comment 121) Several commenters object to FDA's requirement that a registration include the facility's phone number, fax number, and e-mail

address. These commenters state that the e-mail address of the facility is not likely to be that of an individual person, but one for the facility as a whole and is usually staffed by a facility's most junior employee, who would not be the appropriate person for FDA to contact in the case of a bioterrorism incident or other food-related emergency. The commenters also state that FDA will have the phone number and e-mail address of the emergency contact, so it should not be necessary also to require the phone number and e-mail address of the facility as a whole. Regarding the fax number, some commenters argue that they might not have fax machines. Therefore, these commenters request that FDA make the facility fax number and e-mail optional elements of registration.

(Response) FDA agrees with the commenter that a facility's fax number should be optional and that a facility's e-mail address also should be optional unless the facility registers electronically and provides an e-mail address for confirmation. Section two of the proposed registration form states that the registrant is required to provide its fax number and e-mail address "if available." However, to clarify in the rule that this information is optional, FDA has moved these registration elements to the section in the interim final rule entitled "What optional items are included in the registration form?" (§ 1.233). FDA has decided to retain the requirement that a facility's phone number be provided because having that number will facilitate routine communications with the facility. For domestic facilities, the emergency contact information will only be used in the event of an actual or potential emergency; the facility phone number will be used for all other communications (*e.g.*, to schedule an inspection), unless the registration provides other contact information in the "Preferred Mailing Address" section of the form. For foreign facilities, the U.S. agent's information will be used for both routine and emergency contacts, unless the facility chooses to provide a different emergency contact. FDA, however, believes it is important to have a contact phone number for a foreign facility itself, in case FDA cannot contact the U.S. agent.

(Comment 122) Several commenters state that the fields in section 2 of the proposed registration form for facility name and address correspond to addresses in the United States, such as "zip code," and do not take into account address formats used in foreign countries. For example, in many Latin American countries, addresses are not necessarily denoted by a street number and name, but may be identified by a crossing of streets or even by specific reference points that may involve other buildings or landmarks.

(Response) In the electronic registration, FDA intends to provide flexibility to enable a foreign facility to include its street address information in the format used in the foreign country. Regarding "zip codes," in the proposed registration form, FDA's electronic system is designed to request zip code information only for facilities located in the United States, and the postal code for countries that have postal codes. For identification of a country, the electronic system employs a pull-down menu that lists countries' two letter abbreviations as listed in the International Standards Organization 3166. The printed registration will also provide enough space for a registrant to enter the facility's address information in whatever format is used in its own country.

3. Name and Address of the Parent Company

(Comment 123) Several commenters believe that name and address of the parent company should not be required. Another commenter states that it does not object to this requirement.

(Response) The interim final rule retains the requirement that parent company information be provided in a registration if applicable. The parent company information enables FDA to ascertain the relationship between a facility and its parent company, if the facility is a subsidiary of the parent company, because not infrequently, a facility or subsidiary may have a different name than its parent company. FDA is also requiring the parent company information for emergency situations. If an emergency occurs with respect to a particular facility or group of facilities, FDA will need to alert the parent company, as well as the affected facilities, because the parent company has ultimate responsibility for the facility. Moreover, in terms of inspections, the relationship between a facility and its parent company is vital for FDA in tracking and investigating incidents.

4. Emergency Contact Information

(Comment 124) Several commenters believe that FDA should give facilities or their parent companies the option of identifying relevant emergency contact information (phone number, whether cell or land line, e-mail address) without necessarily identifying a specific individual. These commenters state that because the purpose of an emergency contact is for FDA to communicate in an emergency situation with the facility, there is no need for FDA to contact a specific individual. Many facilities already have emergency contact procedures in place for responding to local emergencies; FDA's emergency contact information should provide flexibility for facilities to utilize these existing procedures. Also, requiring an individual to be identified by name may mean a facility would need to provide frequent updates to its registration, because the individual responsible for responding to emergencies may change on a frequent basis. Other commenters request that FDA allow a facility to designate an alternate emergency contact, or that FDA require the emergency contact to be located at the corporate headquarters, instead of at the facility.

Other commenters believe FDA has appropriately defined the scope of information necessary to accomplish the goal of quick response and notification in the case of a bioterrorist attack on the U.S. food supply.

(Response) FDA has considered these comments and in response, has modified the interim final rule so it does not require a facility to provide an individual's name as part of the emergency contact information. However, the facility must ensure that the information it provides will enable FDA to contact a live person representing the facility 24 hours a day, 7 days a week. FDA agrees that emergency contact information should be specific to the facility's already established emergency procedures; therefore, FDA will not necessarily require contact information for a corporate headquarters. However, a facility may designate the emergency contact information for its corporate headquarters, if that is appropriate for operations at that facility.

As noted, for foreign facilities, FDA will consider the facility's U.S. agent as the emergency contact unless specified otherwise in the registration. If a foreign facility designates someone other than its U.S. agent as the emergency contact, FDA will utilize that information to contact the facility instead of the facility's U.S. agent when an emergency occurs.

5. Trade Names

(Comment 125) Several commenters agree that trade names should be required as part of the registration. These commenters request that FDA define "trade names" and provide examples. One commenter states that requiring trade names for food packaging is unworkable because "brand codes" and "grade names" change frequently, and would thus require continual updates.

(Response) The Bioterrorism Act specifically states that trade names should be a required part of the facility's registration, and thus, FDA agrees with the comment that trade names should be a required registration element. FDA also agrees that it should define the term, "trade names," and, as discussed previously, provides a definition of "trade names" in the interim final rule. In response to the comment stating that "brand codes" and "grade names" change frequently, FDA notes that the trade names definition does not include this information, but only information about names the facility itself uses.

6. Product Categories Under § 170.3

(Comment 126) Many commenters assert that registrants should not be required to supply information regarding food product categories associated with a facility. A variety of reasons are offered, including that the categories are outdated and not relevant; the categories are difficult to understand and apply; use of the categories would lead to mistakes regarding a facility's selection of appropriate categories; categories would require a facility to submit constant updates to FDA, as a facility continuously changes the food it produces in response to market demands; use of categories would impose an enormous burden and increased cost; use of categories would limit targeted communications because often one manufacturer's finished product is another's ingredient, which would confuse FDA's efforts to notify affected facilities; facilities would be subject to criminal penalties if product category information is not correct or is outdated; under the Bioterrorism Act, FDA has the discretion to require this information and FDA should not exercise that discretion; use of categories introduces huge uncertainties as to whether the appropriate facilities would be contacted in the event of an emergency, which may lead either to causing unnecessary concern or inadequate notification of affected facilities; some categories overlap each other, yet many foods fall into gaps between categories; and requiring categories would increase the time to complete a registration. One commenter states that FDA should include food product categories, because these categories would help FDA to more closely focus inspection resources.

(Response) The interim final rule maintains the requirement that food product categories be specified in a facility's registration. As required by the Bioterrorism Act, FDA considered in guidance whether such categories should be included and determined that such information will be an important aid to the agency in the event of a foodborne emergency (68 FR 42415). The interim final rule requires each facility to submit the general food product category (as identified under § 170.3) of the food manufactured/processed, packed, or held at such facility. For ease of use, FDA lists the more common categories found in FDA's product code builder at *http://www.fda.gov/search/databases.html* as the main categories on the registration form, referencing the relevant food product category in § 170.3 for each FDA product code category. To relieve some of the burden of frequent updates, FDA has added a "most/all human food product categories" option. Facilities that manufacture/process, pack, or hold food that does not fit into one of the § 170.3 categories are required to check "none of the above mandatory categories." These facilities may also choose to check one or more of the optional boxes that correspond to the category of food manufactured/processed, packed, or held at the facility, as specified in section 11(a) or 11(b) of the registration form.

FDA continues to believe that information regarding food product categories is necessary for a quick, accurate, and focused response to a bioterrorism incident or other food-related emergency. The categories will help FDA to focus its response on the appropriate facilities, saving crucial time. Some threats may be specific to a certain facility type (*e.g.*, a threat against beverage bottling facilities). Under these circumstances, being able to target communications will allow FDA to expedite and focus its response. The fact that in some instances a threat cannot be isolated to a finite set of facilities does not mean that this will be the case in all instances. Being able to focus communications as much as possible based on a particular threat through the use of food product categories will ensure that FDA is able to respond as effectively and efficiently as possible.

(Comment 127) One commenter notes that in the proposed registration form, FDA has stated that warehouses are not required to complete the section on food product categories. The commenter states that this exception for warehouses is not mentioned in the preamble or codified of the proposed regulations, and asks FDA to clarify this exception.

(Response) To ensure that facilities have fully completed the section on food product categories, FDA has changed this section to require all facilities to check at least one box. As noted, as required by the Bioterrorism Act, FDA considered in guidance whether such categories should be included and determined that such information will be an important aid to the agency in the event of a foodborne emergency (68 FR 42415). Thus, this interim final rule requires registrants to identify the food product category under § 170.3 for food manufactured/processed, packed, or held at each facility. FDA has also provided that facilities that manufacture/process, pack, or hold food in many different food product categories (such as many warehouses) do not have to check every food product category, and may instead check the "most/all human food product categories." Importantly, however, the interim final rule requires a warehouse that holds only one or a limited number of different food products to identify those categories listed in § 170.3. Because the proposed rule would not have required a facility to identify a food product category on the registration form if it was manufacturing/processing, packing, or holding food that did not fit into a category under § 170.3, FDA would not have been able to determine whether a registrant's food product categories were not covered under § 170.3, or whether the registrant forgot to complete the section of the registration form on food product categories. Therefore, the interim final rule requires facilities that manufacture/process, pack, or hold food product categories not covered under § 170.3 to check "none of the above mandatory categories." Because the revised version of the Form 3537 requires all facilities to check at least one box in the food product categories section, FDA has deleted the language in the form stating that warehouses are exempt from completing the food product categories section of the form.

7. U.S. Agent

FDA addresses comments related to the U.S. agent requirement in section III.E.15 of this document.

8. Certification Statement

(Comment 128) One commenter notes that the requirements for identifying personal information in the certification statement should relate to the individual making the certification, not the individual submitting the registration. This change would recognize that administrative personnel, not responsible parties of the company, may process the actual facility registration.

(Response) The Bioterrorism Act requires that the "owner, operator, or agent in charge of the facility shall submit a registration" to FDA. Accordingly, the certification statement on the registration form requires the owner, operator, or agent in charge of a facility to submit the registration, or to authorize an individual to submit the facility's registration. Although administrative personnel may prepare the registration, the owner, operator, or agent in charge, or an individual authorized by the owner, operator, or agent in charge to submit a facility's registration must certify that the information included in the registration is true and accurate.

(Comment 129) One commenter states that the certification statement is inadequate to ensure either the veracity of the information provided or the identity and authority of the person submitting it. The commenter states that "[t]he regulation includes no protections that would prevent intentional or unintentional abuse of the system, to the potential detriment of both national security and of legitimate businesses. Without some effective means of verifying at least the identity and authority of the person submitting the registration, the proposed system will be easily subject to misuse and mischief."

(Response) The certification statement requires a person authorized to submit a registration to certify that the registration information is true and accurate, and that owner, operator, or agent in charge of the facility has authorized the submitter to register on its behalf. The certification statement also states that anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties under 18 U.S.C. 1001. As an additional means to verify the identity of the person submitting the registration, the interim final rule requires that for the paper and CD–ROM registration options, the registration include the signature of the person submitting the registration. FDA believes that the combination of the signed certification statement and Federal criminal liability will be a powerful incentive for truthful registrations. In addition, FDA has several methods by which to verify the identity of both facilities and individuals submitting registrations by any of the permissible means; however, for security reasons, FDA declines to elaborate on these methods.

In addition to the changes noted previously, on its own initiative FDA has made several editorial changes to this section for clarity.

I. Comments on "What Optional Items Are Included in the Registration Form?" (Proposed § 1.233)

1. General Comments

(Comment 130) One commenter states that the interim final rule should remain focused on effectively implementing the legislative requirements as is, neither expanding information requirements, nor adding optional information. The submitter states that if the information is not necessary, it should not be collected.

(Response) FDA notes that registrants are not required to submit the elements of optional information specified in the proposed rule and the interim final rule—that is the nature of "optional" information. FDA continues to believe, however, that information described as "optional" will enable FDA to communicate more effectively with facilities that may be the target of an actual or potential terrorist threat or other food-related emergency and that better communication about such emergencies will benefit both FDA and the registered facility. For example, some food products are not covered in the categories specified in § 170.3, such as certain dietary supplements, infant formula, and animal feed, but foods in these categories may nevertheless be the focus of a food-related emergency. Therefore, FDA encourages, but does not require, a registrant to submit in a facility's registration the information identified as optional in the interim final rule.

(Comment 131) Several commenters ask that FDA clarify what sections of the registration form (Form 3537) are mandatory and which are optional. One of these commenters states that FDA should mark optional fields in some form, such as an asterisk, and program the electronic downloadable file to allow the registration to proceed as long as the mandatory fields have been completed. This commenter states that, at a minimum, FDA should insert the word "**REQUIRED:**" or "**OPTIONAL:**" in boldfaced, underscored, and all capital letters following the section titles to clarify further which information is required and which is optional. The commenter also suggests that instructions be provided for filling out the form that include specific citations to those sections where the information is required and where optional. Another commenter suggested that FDA consider a second form for voluntarily-submitted information. Otherwise, the commenter believes that the Food Facility Registration Form will cause confusion as to which information is required by law, versus information that is optional because the optional sections of the form are interspersed with required information sections.

One commenter states that the space on the Registration Form is somewhat limited and proposes that the registration form be expanded to accept appendices for registrants to submit additional information.

(Response) FDA believes its proposed registration form is sufficiently clear as to which sections of the form are required and which are optional. For each section of the registration that is optional, FDA has included the word, "OPTIONAL" in bold. For the food product categories section involving food for human consumption, FDA has included the words, "Optional Selection" in bold after each category that is not required. In the instructions for completing the registration, FDA intends to specify which sections are required and which are optional. FDA notes that the agency considered having a separate form for optional information but rejected it after determining that the order of the sections in the proposed registration form was clearer and flowed more effectively when in a single form, rather than two separate forms.

FDA further advises that the agency's electronic registration system will be sufficiently flexible to permit a registrant to enter all of the information the registrant needs to enter. FDA has revised both the paper and electronic registration forms to provide ample space for including all relevant information. However, for both the printed and electronic versions of the registration, FDA is only accepting information listed on the registration form; registrants should not add information not identified as required or optional in this rule or described on the registration form. Due to the large anticipated volume of registrations, the registration system will not provide for the submission of appendices to the registration form.

(Comment 132) Some commenters suggest that FDA include additional optional sections on the registration form, including sections for type or other facility registration number (*e.g.*, the U.S. Customs Service bonded facility Facilities Information and Resources Management System (FIRMS) code, FDA establishment number, FDA-assigned Food Canning Establishment number, Seafood Hazard Analysis and Critical Control Point importer food number, FDA Affirmation of Compliance code, and the location number of the U.S. domestic party responsible for FDA-regulated goods imported by a foreign Importer of

Record), as well as an option for an "other" type of code; and the appropriate registration number for each option that is checked. The commenters state that this would minimize confusion, especially about which of a facility's multiple registration numbers apply to what types of activities.

(Response) FDA has decided not to implement this suggestion. In the Bioterrorism Act, Congress specified what information must be required in a facility's registration. After careful consideration, FDA has concluded that a few additional elements of information are needed for the efficient enforcement of the act in responding to a bioterrorist threat or other food-related emergency. Because FDA believes the additional information suggested by these comments would not significantly further FDA's efforts in responding to such incidents, we decline to include them as registration elements.

2. Type of Activity Conducted at the Facility

(Comment 133) Several commenters state that the option of including on the registration form the "category" or "type" of food warehoused, produced, or sold by a facility should be required. These commenters state that this information appears to be critical in determining who should be notified in case of a threat or actual terrorist event targeting a particular type of food. One commenter suggests that FDA use a "simpler method" to determine these categories, such as that utilized for classifying an establishment (*e.g.*, 03 for bakeries, 16 for fishery products, 29 for soft drinks, 47 for food warehouses), which should suffice as a means of categorizing establishments. One commenter states that FDA should either make establishment type data mandatory or delete this information entirely. This commenter states that FDA is unlikely to get full compliance voluntarily with the request for establishment type information, when no penalty would be imposed if this optional information were inaccurate when submitted initially or became out of date.

(Response) FDA has required only what is specified in the Bioterrorism Act and information that is necessary for the efficient enforcement of the FD&C Act. Although we believe the information in the optional items can be useful to FDA as well as to facilities in the event of an emergency, we are requiring only those items required by the Bioterrorism Act and those necessary for the efficient enforcement of the FD&C Act.

3. Type of Storage, if the Facility Is Solely a Holding Facility

(Comment 134) FDA received several comments agreeing that a facility that is "solely a warehouse" should only have to check a simplified description of the type of warehousing provided, such as "ambient storage," "refrigerated storage," or "frozen storage," rather than submit a detailed breakdown of the general food product categories stored in the facility, as required in section 11 of the draft form. These commenters state that this simplified option avoids the need to determine and track food product categories for virtually thousands of different food items that may enter or leave a warehouse.

The commenters ask, however, that FDA define what is meant by "solely a warehouse." The commenters state that most, if not all, public and contract food warehouses also provide ancillary services that include labeling, relabeling, packing, and repacking, but the warehouse typically provides these services without in any way changing, contacting, or doing anything at all to the actual food. The commenters state the warehouse never "goes inside" the primary packing, thus avoiding any potential for contamination. The commenters state that these services are incidental to the core function of storing and handling and are performed strictly under the direction and control of the customer.

(Response) As explained previously, to ensure that registrants have completed the section of the form on food product categories, FDA has decided to require that all registrants check at least one box in the mandatory food product categories section of the form (section 11a). Therefore, a facility that is solely a warehouse is required to check either one or several food product categories covered under § 170.3, "the most/all human food product categories," or "none of the above mandatory categories."

Regarding the question of what FDA means by "solely a warehouse," FDA agrees that this term was confusing. We have revised Form 3537 to eliminate that term. We are also providing that all food facilities must complete section 11 which concerns general product categories. We have revised section 10 of the form and § 1.233(i) to refer to facilities that are primarily holders.

4. Food Categories Not Included Under § 170.3

(Comment 135) One commenter argues that FDA's proposed optional food product categories should be mandatory, not optional. This commenter asserts that FDA should use a simpler method of classification of all food product categories, such as that used for food establishments.

(Response) FDA believes that it is a reasonable choice for the agency to make optional identification of food product categories that are not listed in § 170.3. There is a strong incentive for facilities that handle foods in the optional categories to provide this information, because with such information, FDA will be better able to target its communications in case of a threatened or actual bioterrorist event or other foodborne emergency. Getting prompter and more accurate information will help a facility respond more quickly and efficiently to any incident that may affect that facility. As discussed previously, for ease of use, FDA is using the more common categories found in FDA's product code builder at *http://www.fda.gov/search/databases.html* as the main categories on the registration form, referencing the relevant food product category in § 170.3.

(Comment 136) Several commenters submitted comments regarding the "most/all human food product categories" designation. Most of these commenters agree with FDA's preliminary decision to include "most/all" product categories. One commenter states that a facility that normally carries all food categories and therefore has included "most/all food product categories" in its registration should not be required to amend their registration or be subject to penalties if they have temporarily run out of products in a specific food category, but intend to restock the items. Another commenter argues that FDA should delete the "most/all" food product category. The commenter states that in the event of an emergency, a delay could result since FDA would be unnecessarily contacting facilities that do not manufacture/process, pack, or hold the precise food in question. Also, a facility could process different food products almost daily, but not be required to notify FDA of any changes.

(Response) The interim final rule retains "most/all human food product categories." This category will enable facilities that manufacture/process, pack, or hold many different types of food to check the "most/all" category instead of having to update their registrations frequently. In making this decision, FDA has balanced the greater efficiency of the agency's having specific information regarding food manufactured/processed, packed, or held at each facility against the burden on facilities to submit initially and

update this information as circumstances change. While FDA agrees that in some instances this may result in FDA contacting facilities that check the "most/all human food product categories" box when they do not handle a particular food product either at all or at that particular time, on balance, these circumstances are likely to be relatively infrequent compared to those contacts with a facility that does manufacture/process, pack, or hold the food in question.

In addition to the changes noted previously, on its own initiative FDA has made several editorial changes to this section for clarity.

J. Comments on "How and When Do You Update Your Registration Information?" (Proposed § 1.234)

(Comment 137) Several commenters state that the 30-day update requirement is burdensome to industry. Information such as food product categories and emergency contact information is constantly changing and thus, registrants would need to submit updates continuously. Commenters suggest varied timeframes for updates, including 14 days, 60 days, 90 days, 6 months, or every year. In addition, some commenters recommended different update requirements for different information, such as more frequent updates for emergency contact information. Another commenter suggests that FDA require re-registration annually, instead of requiring updates.

(Response) In response to these comments, FDA has decided to change the period for an owner, operator, or agent in charge of a facility to update its registration to 60 days for any change to any of the required registration elements previously submitted. This timeframe strikes a balance between the commenters' concern and FDA's requirement under the Bioterrorism Act to keep our database current. Because registration information will be used both to evaluate prior notice submissions and to notify affected facilities in the event of a food-related emergency, it is advantageous both to FDA and to registrants that the agency's database be current.

In terms of the burden of updating food categories, as noted previously, a facility has the option of specifying the "most/all human food product category" in the food product category section of the registration (if appropriate to the facility). To alleviate at least in part registrants' burden to provide continuous updates, the interim final rule provides that the emergency contact information need only include an emergency contact phone number, instead of a person's name or other individualized information.

(Comment 138) Some commenters ask for clarification regarding what types of changes to a facility's registration require updates. One commenter asks whether FDA requires an update for temporary plant closures due to weather, fumigation activities, or line changeovers. Another commenter asks whether temporary changes in the general food product categories held or processed at the facility would require an update. Another commenter states that numerous changes to production, product lines, packaging, and establishment names should not require an update.

(Response) The interim final rule requires updates for changes that reflect a modification of a facility's operations, as it relates to the required registration elements. Therefore, for facilities engaged in ongoing operations that temporarily close for the reasons identified in the comment, no update to a facility's registration information is required. However, in considering whether to update temporary changes to registration information, foreign facilities should keep in mind that registration information will be matched with prior notice information, and discrepancies in the two databases may cause FDA or CBP to examine a shipment.

(Comment 139) Several commenters ask FDA to clarify whether an update or a cancellation is warranted if a facility changes ownership or goes through a merger or acquisition. One commenter indicates that when a change in ownership occurs, the authority to make changes to a registration would also likely change. Some commenters argue that a registered facility should be able to keep its registration number through change in ownership or management. At some point in the process of ownership or management change, the former registrant should no longer be authorized to make a change, and certainly could not represent the information of the new owner.

(Response) Although the proposed rule and draft Form 3537 provided for information regarding changes in owner, operator, or agent in charge to be submitted as updates to the registration, neither the proposed rule nor the form provided for such information to be submitted in the initial registration. As noted in the response to comment 96, the interim final rule at § 1.232(c) and Form 3537 have been revised and require that the name of the owner, operator, and agent in charge to be provided as part of the initial registration.

FDA believes, however, that a change in the owner of a facility triggers a new registration, because under the Bioterrorism Act, the registration information is confidential, and the former owner should not know the registration number assigned to the new owner. Moreover, the Bioterrorism Act requires the owner, operator or agent-in-charge to register the facility. Therefore, FDA is deleting the reference to "owner," in "Owner, operator, or agent in charge change" in section 1b of the registration form. If a facility comes under new ownership, the former owner must cancel the old registration in accordance with § 1.235, and the new owner must submit a new registration for the facility in accordance with §§ 1.230 and 1.231. FDA realizes, however, that some old owners may not cancel their registrations. Therefore, in new section 1c of the form, FDA is requiring new owners to check the box "Are you a new owner of a previously registered facility?" and asking new owners to provide the previous owner's name and registration number, if known. If the new owner does not provide the old registration number, FDA will keep the old registration in its database until it independently affirms that the facility is under new ownership. If the new owner provides the old registration number, FDA will send a notification to the old owner seeking confirmation, and will cancel the old registration upon receipt of confirmation, or FDA's independent confirmation of a change in ownership, whichever occurs first. If the former owner notifies FDA within this 60-day period that it has not sold the facility, FDA will contact both owners to remedy the discrepancy.

(Comment 140) Some commenters state that FDA should require facilities that go out of business to submit a notice of cancellation of their registration as soon as possible, or no later than 14 days after the business operations cease. These commenters state that updated information on a facility's business status would help ensure that if there is a bioterrorism event, FDA is not wasting resources by attempting to contact facilities that no longer exist or are out of business. The commenters state that requiring cancellation of registration would also help ensure that an organization or group cannot threaten the American food supply by using a former business' registration as a means to import into or distribute within the United States tainted products. One commenter urges FDA to consider ways to purge obsolete registrations from its database because

businesses that cease operations would not necessarily cancel their registrations.

(Response) Because a registration cancellation is essentially an update of registration information, FDA believes the time period for canceling a registration should be 60 days, the same as that for updates. Regarding purging its database of obsolete registrations, FDA will cancel a registration if it independently verifies that the registrant has gone out of business or if someone has registered a facility that does not exist. If FDA cancels a facility's registration that has gone out of business, FDA will mail a confirmation of the cancellation to the facility.

(Comment 141) One commenter believes that the amount of information FDA proposes to require in the cancellation notice is excessive. The commenter requests that FDA require only the facility's registration number, the name and contact information for the person submitting the cancellation, and the certification statement for a cancellation.

(Response) The only elements the cancellation form includes in addition to those listed in the commenter's request is the facility's PIN number, whether the facility is domestic or foreign, and the facility's name and address. FDA believes the information in the cancellation form is necessary for FDA to verify that it is canceling the correct registration, because canceling the wrong facility's registration could have unintended consequences.

(Comment 142) Several commenters request that FDA clarify the penalty for failure to update a registration within the required timeframe. The commenters indicate that absent a coercive element, the value of this tool is subject to failure.

(Response) The Bioterrorism Act requires owners, operators, and agents in charge of facilities to register with FDA and also requires FDA to keep its registration database current. Accordingly, § 1.241 states that failure to submit a timely update to required registration elements is a prohibited act, because obsolete information may hinder FDA's efforts in responding to a threatened or actual bioterrorist act or other food-related emergency. The FD&C Act provides for civil and criminal sanctions for those who commit a prohibited act.

(Comment 143) Several commenters urge FDA to not require facilities to update optional information previously submitted (such as the type of activities conducted at the facility, as well as the optional food categories or type of storage). One commenter requests that FDA state in the interim final rule that the failure to update optional information will not subject the registrant to penalties under the act or FDA's implementing regulations. The commenter states that the requirement to update previously submitted information in optional fields "could have a chilling effect on the willingness of companies to provide the optional information in the first place."

(Response) FDA has considered these comments and has revised § 1.241(a) to delete the reference to optional information. The Bioterrorism Act requires that a registrant notify the Secretary in a timely manner of changes to information submitted in a registration (21 U.S.C. 350d(a)(2)). FDA believes that it is clear that the failure to update required information is a prohibited act (21 U.S.C. 331(dd)). The agency is concerned, however, that extending the prohibited act to failure to update optional information will create a disincentive to registrants to provide the optional information contrary to the interests of the agency and registered facilities. Accordingly, FDA has revised § 1.234(a) to provide that only required information must be updated and § 1.241(a) to provide that failure to update required information is a prohibited act.

Although the interim final rule will not make the failure to update optional information a prohibited act, FDA emphasizes that updates of registration information are very important, because obsolete information may hinder FDA's efforts in responding to a bioterrorist act or other food-related emergency. Accordingly, the agency strongly encourages the owner, operator, or agent in charge of each registered facility that provides FDA with optional information in a registration to promptly update such information when it changes. In addition, FDA encourages the owners, operators, and agents in charge of registered facilities to update their registrations to delete optional information that is obsolete.

(Comment 144) One commenter asks FDA to clarify whether FDA will keep updated information on file as well as the reason for the change. The commenter states that "[i]n order to track activities of all sides, if that is what the intended purpose is, a "tracking and activity mechanism" would have to be in place. This would require, however, that the agency has trained personnel that are able to spot unreasonable irregularities and not go on a "witch hunt."

(Response) FDA intends to keep updated information on file. FDA inspectors will compare a facility's registration information with the information they obtain during the inspection of a registered facility. The failure of an owner, operator, or agent in charge to register a facility is a prohibited act, as is both the failure to update outdated required registration elements within 60 days of the change, and the failure to cancel a registration within 60 days if changes at the facility warrant cancellation.

(Comment 145) One commenter requests that FDA's electronic registration system be designed to permit a facility to use the original information screen as the starting point for updating or canceling the registration.

(Response) FDA advises that when a registrant accesses the electronic system to update the registration for a particular facility, the system is designed to provide the existing registration. Therefore, the registrant will only need to edit the sections of the registration that need to be updated.

(Comment 146) One commenter asks FDA to send an automatic e-mail reminder to registrants on a yearly basis to remind them to update their registrations.

(Response) As resources allow, FDA will to send periodic notices to registrants, reminding them to update, as necessary, information in their registration.

In addition to the changes noted previously, on its own initiative FDA has made several editorial changes to this section for the purpose of clarity. FDA has also added section § 1.235 *"How and when do you cancel your facility's registration information?"* This new section contains information that was previously in section § 1.234, "How and when do you update your registration information?" FDA has added this section for the purpose of clarity.

K. Comments on "What Other Registration Requirements Apply?" (Proposed § 1.240)

(Comment 147) Many commenters state that they have already registered with other U.S. Government agencies, as well as foreign governments and States. The commenters state that requiring these facilities to be registered with FDA as well is a burden. The commenters also argue that FDA should coordinate with other agencies and governments to avoid duplication.

(Response) The interim final rule maintains the registration requirement as proposed, for several reasons. For all facilities that FDA determines are subject to section 305 of the Bioterrorism Act, we believe that the

statute requires the owner, operator, or agent in charge of those facilities to submit a registration to FDA. Obtaining existing registration information from other agencies would not guarantee that FDA has the information for all facilities required by the Bioterrorism Act's registration requirement because there is wide variation in the purposes and information required by other registration or permitting systems. For example, the laws administered by the Alcohol and Tobacco Tax and Trade Bureau (TTB) do not require foreign alcohol beverage producers to obtain permits, unless they are also engaged in the business of importing alcohol beverages into the United States. In addition, the information provided by alcohol beverage permittees to TTB is not entirely identical to the information that must be provided by facilities to FDA in accordance with the provisions of this interim final rule.

Although it is theoretically possible for FDA to obtain information from other agencies, the stringent timeframes for issuing this interim final rule do not provide FDA adequate time to reconcile the different information required or to work with the other agencies to have them amend their existing requirements to capture all the information FDA needs. We would also need to work with other agencies to ensure the confidentiality of nonpublic registration information under relevant information disclosure laws (*e.g.*, §§ 20.85 and 20.88 (21 CFR 20.85 (Federal agencies), 20.88 (State agencies), and 20.89 (foreign governments))). Because the purpose of registration with FDA is to assist FDA in responding to threatened or actual bioterrorist incidents or other food-related emergencies, FDA must have the registration information readily accessible. If FDA has to coordinate with other agencies or governments to obtain from them the information necessary to respond to such an emergency, FDA may be prevented from responding to the emergency in a timely manner.

Regarding facilities that may be registered with FDA under existing regulations (*e.g.*, low acid canned food), like the registrations of other agencies, these FDA registrations also do not contain all of the information required in this interim final rule, because the purposes of the regulations differ. FDA will continue to look for ways to minimize duplicative registrations in the future, but could not do so in the timeframe provided for developing this rule. On its own initiative, FDA has made several editorial changes to this section for the purpose of clarity.

L. Comments on "What Happens if You Fail to Register?" (Proposed § 1.241)

1. Revocation of Registration

(Comment 148) Several commenters submitted comments in response to FDA's request for comments regarding the circumstances under which a firm's registration should be cancelled and/or considered null and void. One commenter states that neither the FD&C Act nor the Bioterrorism Act authorize revocation of registration. One commenter states that because the Bioterrorism Act's Rule of Construction notes that registration is not a licensing or approval process, FDA cannot extend or withdraw approval. This commenter suggests that a registration may only be vacated through the ordinary criminal process to prove fraud if the registration is made fraudulently. Another commenter states that revocation should be reserved for extreme situations of bioterrorism, intentional contamination, and other criminal activity, and should afford a facility an opportunity for an adjudicative hearing, since revocation effectively prohibits a facility from manufacturing/processing, packing, or holding food for consumption in the United States. A foreign commenter suggests that any revocation of registration should occur only after a process that involves foreign authorities within the same locale as the foreign facility, in consultation with the U.S. Embassy. One commenter requests a clear delineation of the circumstances warranting registration suspension, suggesting that it should extend only to the parameters of the Bioterrorism Act. Another commenter suggests that revocation of registration should only be considered for facilities that have ceased trading, or no longer handle food products. A commenter suggests that FDA clarify the distinction between suspension and revocation: Revocation should only be for facilities that have gone out of business or that have submitted false information. FDA should employ the less drastic penalty of suspension for submission of inaccurate, incomplete, or untimely information. The commenter suggests that FDA notify a facility that failure to submit all of the required information within 15 days will result in suspension. Registration could be reinstated when this missing information is provided.

(Response) FDA does not agree that it should have a category of registrations that have been suspended. A facility either is registered by submitting a registration to FDA or it is not registered. Regarding registration cancellation, FDA has determined that the only circumstances under which it will cancel a registration are if the agency independently verifies that a facility has gone out of business or is under a new ownership, or if FDA establishes that the submitted registration is for a facility that does not exist. FDA has clarified this in the interim final rule by adding the following paragraph to § 1.241:

(b) FDA will cancel a registration if the agency independently verifies that the facility is no longer in business or has changed owners and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist. If FDA cancels a facility's registration, FDA will mail a confirmation of the cancellation to the facility at the address provided in the facility's registration.

As mentioned previously, a facility under new ownership is required to submit a new registration.

(Comment 149) One commenter asks that FDA not recall products already distributed into commerce if it determines after confirmation of the registration that the registration contains inadvertent errors.

(Response) Neither the proposed rule nor the interim final rule provide for the recall of food distributed into commerce because FDA subsequently determines that there are inaccuracies in the registration of a facility at which the food was manufactured/processed, packed, or held.

2. Prohibited Act for Domestic or Foreign Facility

(Comment 150) Several commenters request clarification on the penalties that may be imposed for failure to register and who may be subject to these penalties. One commenter states that failure to register may be a simple omission rather than a terrorist act; therefore, FDA should apply criminal actions according to the consequences and characteristics of the act. Another commenter asks FDA to clarify that although failure to register is a prohibited act, importing food from an unregistered facility is not. A commenter asks FDA to clarify that failure to register, although a prohibited act, will not result in debarment. This commenter asks FDA to maintain a public list of debarred individuals and firms, and make this list available on the Internet.

(Response) FDA agrees that § 1.241 was likely confusing and has clarified this provision in the interim final rule. Specifically, the interim final rule consolidates the two provisions relating to the prohibited act of failing to register (21 U.S.C. 331(dd)) and makes clear that the causing of a prohibited act and being responsible for the commission of a prohibited act are both subject to sanction under the act (21 U.S.C. 331). Thus, under the interim final rule, the owner, operator, or agent-in-charge of any facility that manufactures/processes, packs, or holds food for consumption in the United States, who is required to register the facility with FDA but fails to do so, commits a prohibited act under section 301 of the FD&C Act. Similarly, the owner, operator, or agent in charge that fails to update mandatory information or cancel a registration within 60 days (if changes at the facility require an update) commits a prohibited act.

FDA has also clarified that the disposition of a food from an unregistered foreign facility when offered for import into the United States will be governed by subpart I of this part (Prior Notice of Imported Food). FDA is publishing elsewhere in this issue of the **Federal Register** a interim final rule implementing section 307 of the Bioterrorism Act, which requires, among other things, an importer to submit to FDA prior notice of a shipment of food that is offered for import. As discussed in response to comment 162, FDA addresses the consequences for importation of food for failure to register in the interim final rule implementing prior notice published elsewhere in this issue of the **Federal Register**.

With regard to the comment on debarments, § 1.241 merely relates the grounds for debarment specified in section 306(b)(3)(A) of the FD&C Act. The agency's implementation of the details of the debarment provisions of the Bioterrorism Act are outside the scope of this interim final rule.

3. Food Held at the Port

(Comment 151) Many commenters express concerns about the custody and responsibility for products placed under hold. Several commenters ask who is responsible for costs associated with food held at the port. One commenter asks FDA to clarify that any party in the commercial import process, including the shipper, could be responsible for arranging the bonded hold, and that such arrangements are not FDA's responsibility. A commenter requests that FDA be responsible for any costs incurred from mistakes made in enforcement of the rule that results in the holding of imported food. One commenter recommends that a clear chain of custody and fiduciary responsibility must be established for products placed on hold. One commenter requests that FDA and Customs issue guidance on holding food before December 12, 2003.

(Response) In proposed § 1.241, we described the consequences of failure to register when food is imported or offered for import from a foreign facility that is required to register under section 305 of the Bioterrorism Act. At the same time, we included in the proposed rule implementing the prior notice requirements of section 307 of the Bioterrorism Act, a provision requiring the registration number of certain facilities to be provided as part of the required prior notice information. In the prior notice proposal, we also discussed the consequences of failure to provide required information, including required registration information, when importing food. We believe that including consequences of failing to register for foreign facilities in two different regulations may be confusing. Therefore, we have revised § 1.241 to include simply a cross reference to subpart I (Prior Notice of Imported Food), which sets out how food imported or offered for import from facilities not registered as required will be handled. Thus, we have deleted § 1.241(e) through (h). Although we no longer have provisions regarding imported food in this interim final rule, we are addressing the comments we received.

With regard to this comment, before the enactment of the Bioterrorism Act, FDA's role was to make admissibility decisions as to whether food imported or offered for import into the United States should be refused admission under section 801(a) of the FD&C Act. Any storage and transportation costs associated with FDA's refusal process were borne by the relevant private parties according to their contractual agreements. Nothing in the Bioterrorism Act changes who bears the costs related to food that may not be admitted into the United States. Although § 1.241(f) has been removed from this interim final rule, the prior notice interim final rule states that neither FDA nor CBP are liable for transportation, storage, or other expenses. The proposed registration rule and the proposed prior notice rule provided for costs to be borne by the owner, purchaser, importer, or consignee. FDA has reconsidered and believes that it would not be appropriate to specify which parties are responsible for costs as this is a commercial rather than a regulatory matter. Accordingly, the interim final prior notice rule merely provides that FDA or CBP is not liable for the costs.

(Comment 152) Several commenters request that FDA ensure that appropriate and sufficient storage facilities (including climate controlled storage) exist before the Bioterrorism Act is enforced and that FDA release the food immediately once relevant facilities register. One commenter requests that FDA not hold food based on simple problems or errors in registration, such as misspelling. One commenter asks if the "secure location" must be a Customs bonded facility. Another commenter asks FDA to clarify the procedure it will follow to notify a foreign facility when its products have been held at the U.S. port because of failure to register. A commenter asks FDA to permit prompt registration, ideally electronic, when failure to register is discovered at the port of arrival. A commenter argues that if a shipment appears likely to be held, the exporter should have the option of taking it back or sending it to another country. This commenter argues that if FDA delays a shipment too long for administrative reasons, FDA should provide compensation. Another commenter states that the proposed regulations should be amended to specifically provide for release of compliant articles mixed with noncompliant articles. This commenter argues that FDA should not hold compliant articles while it is waiting for registration of the facilities that are associated with the noncompliant articles.

(Response) As stated previously, a facility may register either electronically (the preferred and fastest method) by mail (using paper or CD–ROM), or by fax. A facility that is registered electronically will receive its registration number almost instantaneously. FDA will process registrations received by mail or fax in the order received. It is the responsibility of the owner, operator, or agent in charge of each facility subject to the requirements of this rule to register before December 12, 2003, and before food from the facility is imported or offered for import into the United States. The Bioterrorism Act prohibits food from an unregistered foreign facility from being delivered for distribution in the United States.

As explained in more detail in the preamble to the interim final prior notice rule, the electronic systems for submission of prior notice will not provide confirmation that prior notice has been accepted by FDA for review unless the required registration information is complete and facially correct. Thus, the transmitter of the prior notice may be informed when there is a problem with the registration numbers.

In addition, with regard to whether FDA will notify the foreign facility that its food is being held for failure to register, we intend that FDA or CBP will notify the carrier of the food that the food is being placed under hold. Also, if a shipment includes both compliant and noncompliant articles of food, segregation will be allowed as provided for in the prior notice interim final rule.

If a facility is not registered and discovers this fact at the port, the owner, operator, or agent in charge must register the facility with FDA if they wish the food to be distributed in the United States. FDA strongly encourages electronic registration, as that will be the fastest method. FDA will continue to process registrations submitted via other means in the order received. To do otherwise would be unfair to the other registrants who have submitted their registrations to FDA as required by this interim final rule ahead of the facility whose food is at the port, particularly since many of those facilities also will be importing or offering for import food into the United States.

FDA agrees that appropriate storage and holding conditions must be considered. This means, for example, that if the article of food arrives in frozen condition and has been transported under frozen conditions, the facility used for holding the product must provide adequate frozen conditions.

(Comment 153) One commenter expresses concern that "the entire burden of proof lies with the facility" regarding FDA's determination to not allow food to enter the United States if "registration has [not] been completed." The commenter states that "this may in our view be problematic, especially in the case of registration by regular mail."

(Response) Registered facilities will receive their registration numbers as confirmation of registration with FDA. For a registration submitted electronically, a facility will receive its registration number immediately following completion of the registration process. For registrations submitted by mail, CD–ROM, or fax, FDA considers a facility registered once FDA enters the facility's registration data into the registration system and the system generates a registration number. This means that FDA may consider a facility registered before the facility receives its registration number and confirmation. To ensure that facilities are registered as expeditiously as possible, FDA encourages facilities to register electronically, or if registering by mail, CD–ROM, or fax, to submit the registration as soon as possible after publication of this interim final rule.

(Comment 154) One commenter asks FDA to provide a right for parties adversely affected by a refusal of admission to challenge that determination through judicial review.

(Response) As stated in the response to comment 151, the procedures for imported food are set out in the interim final rule on prior notice of imported food published elsewhere in this issue of the **Federal Register**.

(Comment 155) One commenter asks FDA to include in its protocol that FDA uses for holding food at the port of arrival due to a failure of the facility to register a "clear message to consumers that [the] product is being held because of a registration issue and not because the product poses some food safety or security risk." The commenter states that "poor communication could cause consumer alarm and erode consumer confidence."

(Response) This comment does not affect any of the provisions of this interim final rule. Therefore, FDA will consider this comment as it develops its training procedures. In this interim final rule, we have changed the title of § 1.241 to "What are the consequences of failing to register, update, or cancel your registration?"

M. Comments on "What Does Assignment of a Registration Number Mean?" (Proposed § 1.242)

FDA received no comments on this issue. FDA made a minor editorial change to this section for the purpose of clarity.

N. Comments on "Is Food Registration Information Available to the Public?" (Proposed § 1.243)

(Comment 156) One commenter states that FDA should not share registration information with states or other Federal agencies and, if it does, it must ensure that the other agencies and States protect the confidentiality of the information.

(Response) FDA believes that in certain circumstances, it may need to share information derived from its registration database with States or other Federal agencies consistent with FDA's laws and procedures. Any sharing with another Federal agency would be done under § 20.85 which includes confidentiality provisions. Similarly, any sharing with State officials would be under § 20.88 which also includes confidentiality provisions.

(Comment 157) Several commenters request that third parties, particularly importers, should be able to verify that a particular facility is registered.

(Response) As discussed in response to comment 158, FDA's list of registered facilities and registration documents are not subject to disclosure under the Freedom of Information Act (FOIA). In addition, any information derived from the list of facilities or registration documents that would disclose the identity or location of a specific registered person also is not subject to disclosure under FOIA. However, under the interim final rule on prior notice of imported food published elsewhere in this issue of the **Federal Register**, the prior notice must include the certain registration numbers. Therefore, the submitter of the prior notice must obtain that information from the facility.

(Comment 158) Some commenters suggest that FDA expand the protection from disclosure specified by the Bioterrorism Act to all information derived from registration documents that has not been previously disclosed to the public.

(Response) Section 305 of the Bioterrorism Act states that FDA's list of registered facilities and registration documents FDA receives under the rule are not subject to disclosure under FOIA. Furthermore, section 305 provides that any information derived from the list of facilities or registration documents that would disclose the identity or location of a specific registered person is not to be subject to disclosure under FOIA. If the information derived from registration documents is not exempt from disclosure by FOIA itself, the Bioterrorism Act, or another statute, FDA does not believe that the information is protected from public disclosure.

We realized that the proposed rule may been confusing with regard to the information that is not subject to disclosure. Therefore, we have revised the interim final rule to make it clear. Also, we have made a conforming change to 21 CFR 20.100(c) to add "Registration of food facilities, in § 1.243 of this chapter."

(Comment 159) One commenter asks FDA to require facilities to include their registration numbers on their finished food packaging, to assist in traceback efforts.

(Response) FDA declines at this time to require facilities to display their registration numbers on the food label. FDA believes that it will be able to conduct appropriate traceback efforts using the information presently required on the food label in conjunction with the database of registration information. Moreover, FDA believes it would not be feasible to require manufacturers/processors to place registration numbers on their food labels prior to the December 12, 2003, deadline for registration.

(Comment 160) One commenter requests that FDA provide a facility's registration confirmation in the form of a certificate or card that facilities can display so inspectors can see if the facility is in compliance with the registration requirement.

(Response) FDA will send facilities a confirmation when FDA receives their complete registration. Facilities may use this confirmation to show their registration status.

IV. Analysis of Economic Impacts

A. Final Regulatory Impact Analysis

FDA has examined the economic implications of this interim final 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 interim final rule is a significant regulatory action as defined by Executive Order 12866.

This Final Regulatory Impact Analysis reflects changes made in the regulation from the proposed rule to the interim final rule, as well as changes in estimates in response to comments. It also includes responses to comments on the Preliminary Regulatory Impact Analysis (PRIA) (*see* 68 FR 5387 to 5413). Where there were no changes in the estimates provided in the PRIA, the estimates are summarized here. Interested persons are directed to the text of the PRIA for a fuller explanation of the estimates about which there were no controversy or changes. As noted in section III of this document, FDA received approximately 350 submissions in response to the proposed rule, which raised almost 200 issues. We continue with the discussion of the comments and FDA's responses to those comments using the same presentation as in section III, focusing here on the comments FDA received on the PRIA. Accordingly, the word "Comment" again will appear in parenthesis before the description of the comment, and the word "Response" will appear in parenthesis before FDA's response. As in section III, FDA has numbered each comment to make it easier to identify a particular comment. The number assigned to each comment below continues in sequence from section III and is purely for organizational purposes; it does not signify the comment's value or importance or the order in which it was submitted.

1. Description of Interim Final Rule

This interim final rule requires the registration of facilities that manufacture/process, pack, or hold food intended 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 emergency, this information will help FDA and other authorities determine the source and cause of the event, and communicate with potentially affected facilities.

2. General Comments

(Comment 161) FDA received a number of comments that asserted that the costs or benefits of the proposed rule were incorrectly estimated.

(Response) If the comment asserted costs or benefits were incorrectly estimated without specifying which costs or benefits, there was not sufficient information for FDA to respond to that comment. However, comments that specified which costs or benefits were incorrectly estimated are addressed in later sections of this analysis.

(Comment 162) FDA received a comment that asked what a line entry is.

(Response) A line entry is a term used by FDA's automated system for imports, the OASIS reporting system (Ref. 2). A "line entry" refers to a line on an invoice that reflects a certain article specific to a manufacturer or packaging: *e.g.*, 100 cases containing 48 6-ounce cans of tuna.

3. Number of Facilities Affected

In the PRIA, FDA estimated the number of affected establishments by counting facilities, not firms. A firm may be composed of many facilities under the same ownership. The changes in behavior needed to comply with this regulation may take place at the firm or facility level. However, because facilities must be registered, and for ease of analysis, FDA focused on the facility as the unit of analysis. For a count of domestic facilities, FDA used the 2000 County Business Patterns (Ref. 3), 1999 Nonemployer Statistics (Ref. 4), the FDA Field Accomplishments and Compliance Tracking System (Ref. 5), the Census of Agriculture (Ref. 6), 1997 Economic Census of Transportation and Warehousing (Ref. 7), and information from direct selling marketing trade associations (Refs. 8 and 9). The analysis relies primarily on the Nonemployer Statistics for its count of very small businesses (no paid employees) that may or may not be home-based. The Nonemployer Statistics' primary source is administrative data from Internal Revenue Service records. This may overcount the number of facilities required to register, as some of the facilities may be exempt on the basis of being an individual's private residence. Additional small facilities that are direct marketers are counted using data from direct marketing trade associations. FDA counted the number of facilities in the U.S. outlying islands of Puerto Rico, Guam, Virgin Islands, and Northern Mariana Islands using Economic Censuses available from the U.S. Census Bureau (Refs. 10, 11, 12, and 13). To count the number of foreign manufacturers/processors, FDA used FDA's OASIS database (Ref. 2). As noted, 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. FDA also estimated that 16 percent of the foreign manufacturers/processors would stop exporting to the United States because of the cost of complying with this regulation. Also counted were foreign holders of products to be exported to the United States. FDA did not have data on the number of foreign holders and so assumed that they were equal to the number of consignees, brokers, and importers of food products in the United States. Foreign de minimis processors and packagers were not included in the OASIS count and so were estimated using U.S. data on the number of packer/repackers. Tables 3 through 7 of this document present the counts of domestic and foreign facilities.

(Comment 163) FDA received a number of comments stating that the number of affected facilities had been underestimated.

(Response) Many of these comments did not provide any specific information about the categories of facilities that were undercounted or not included or information about the correct number of facilities. Without this additional information, FDA has no basis for responding to these comments. However, FDA responds in the number of facilities section to comments that

provided additional information about the category or number of undercounted facilities.

(Comment 164) A comment suggests that FDA failed to include very small facilities in its count of affected entities.

(Response) FDA disagrees with this comment. FDA included in its count more than 68,000 very small facilities from the Nonemployer Statistics published by the U.S. Census Bureau. These are all facilities that are run by a single person with no paid employees. Additionally, the majority of the facilities counted from the County Business Patterns published by the U.S. Census Bureau are considered small businesses under the Small Business Administration definition.

(Comment 165) FDA received a comment that the number of foreign holders may be much larger than the number of U.S. consignees and brokers, because a single broker may use multiple warehouses.

(Response) FDA agrees that a single broker may use multiple warehouses, but FDA also believes the converse is true, that a single warehouse may be used by multiple brokers. This comment did not provide an alternative estimate of the number of foreign holders. Therefore, FDA has not altered its estimate of the number of foreign holders.

(Comment 166) FDA received many comments that the count of facilities failed to include transportation company facilities that hold food temporarily, while the product is in transit. Comments mention specific types of facilities, such as rail yards, container yards, LTL truck terminals, FTL truck terminals, Customs bonded Container Freight Stations, air cargo handling agents, and air, ocean, and truck bulk cargo terminals. FDA also received comments that the PRIA fails to include mobile facilities, such as river barges that pick up cargo in one location and travel to an alternate location where the barge may store product in its hull for several months prior to delivering the shipment to the purchaser.

(Response) Transport vehicles are not facilities required to register with FDA, if they hold food only in the usual course of business as carriers. However, facilities that unpack and reload food cargo from road, rail, water, or air transportation or hold food cargo in a facility, or that hold food cargo not only in the usual course of business as a carrier, are required to register. FDA agrees that not all these facilities were counted in the PRIA.

To count these facilities, FDA used the 1997 Economic Census of Transportation and Warehousing (Ref. 7) from the U.S. Census Bureau. Table 1 shows a count of these facilities. This includes the 1,461 warehouses North American Industry Classification System (NAICS 49312 and 49313) counted in the PRIA. These facilities are subtracted from the count of warehouses (NAICS code 493, all warehousing and storage) when final computations of the number of facilities are made. Including the transportation holding facilities in table 1 minus the warehousing facilities already counted in the PRIA increases the total number of facilities required to register by 33,666 facilities.

Table 1.--Transportation Holding Facilities

NAICS Code	Type of Facility	No. of Facilities
4841103	General freight trucking with storage, local, full truckload	542
4841104	General freight trucking with storage, local, less than truckload	373
484121	General freight trucking, long distance	23,111
4881191	Airport operation and terminal services	1,699
4882101	Support activities for rail transportation	816
4883901	Other services incidental to water transportation	640
4842205	Specialized trucking with storage, local	543
4884904	Other services incidental to road transportation	326
488991	Packing and crating (in Support activities for transportation	795
488999	Other support activities	102
493	All warehousing and storage	6,180
		35,127

(Comment 167) FDA received many comments that FDA underestimates the number of facilities covered by the definition of substances and components of substances that contact food. One comment states that FDA does not include the "upstream" manufacturers that make ingredients and components that go into food packaging and that any facility that manufactures/processes, packs, or holds a material that could become a component of packaging or other food contact article would be required to register. The comment further states that there is no logical conclusion to this chain. Also, some comments assert that FDA did not account for warehouses that hold articles that can migrate to food from food packaging or other articles that contact food.

Another comment states that FDA's count of the number of domestic facilities is overly inclusive if FDA's

intention is to include only finished packaging and that the OASIS database used for the count of foreign facilities does not include suppliers of food contact articles.

(Response) Under the interim final rule, manufacturers/processors, packers, and holders of food contact substances as defined in section 409(h)(b) of the FD&C Act are not required to register with FDA. Therefore, it is unnecessary for FDA to respond to the comments asserting the number of these facilities was underestimated. FDA also removes the estimated count of 32,428 facilities in the PRIA from the final analysis.

(Comment 168) One comment states that FDA's count of foreign facilities from OASIS (Ref. 2) did not include manufacturers/processors of articles that contact food and substances that could migrate to food from food packaging.

(Response) FDA agrees with this comment. The count of manufacturer/processors in OASIS (Ref. 2) did include manufacturers of food and food additives, but did not include all manufacturers/processors of substances that could migrate to food from food packaging. However, these facilities are not covered under the interim final rule. Therefore, FDA has not added them to the count of foreign facilities.

(Comment 169) A number of comments states that FDA had underestimated the number of facilities by failing to include individuals that market foods and dietary supplements through direct selling. These individuals often hold food for sale to an intermediary other than the final consumer. Estimates provided by comments were that there are 10 million individuals in the United States and as many as 40,000 direct marketers with a single company. Another comment referred to hundreds of thousands of direct sellers.

(Response) Direct marketers may be required to register if they hold food for distribution to nonconsumers in the United States. However, FDA does not agree that there are 10 million direct marketers in the United States that could potentially be required to register. FDA found estimates of 10 million (Ref. 9) and 12 million (Ref. 8) direct marketers in the United States, but these estimates were of all the direct marketers of both nonfood and food products in the United States. FDA does not have a complete census of the number of marketers of food versus nonfood products. To approximate the percentage of direct marketers selling food, FDA divided the number of direct marketing companies selling food by the number selling all types of products, using data from the directory of companies on the Web site of a large direct selling trade organization (Ref. 8). Of 141 companies in the directory, 7, or 5 percent, market food/beverages. However, most of these direct marketers of food may not be required to register. Direct marketers may be exempt: (1) If their primary function is to sell directly to consumers, or (2) if the establishment is an individual's private residence. FDA assumes that most direct marketers of foods would qualify for one of these exemptions.

To estimate how many direct marketers sell to consumers as their primary function, FDA looked at the type of distributorship. If the marketer has a one or two-person distributorship, FDA assumes that their primary function is to sell to consumers. FDA assumes if a marketer has a multiperson distributorship, they are likely to distribute to other sellers as their primary function. (These are not definitions that FDA will use to determine if selling to consumers is the primary function of a facility; this is merely a method used to provide an estimate for the economic analysis.) According to a large direct selling trade organization (Ref. 8), 2.5 percent of direct salespeople are multidistributorships. These numbers suggest that approximately 12,400 (10 million × .025 × (7/141)) direct marketers of food would be required to register with FDA. This number may be an overestimate because some of these marketers may already have been counted in the CBP (Ref. 3) or Nonemployer Statistics (Ref. 4) or may distribute food from their private individual residence.

(Comment 170) FDA also received comments stating that there were thousands and thousands of wineries in Europe that may not have been included in the estimate of the number of foreign facilities.

(Response) FDA does not agree with this comment. FDA's estimate includes approximately 27,000 European alcohol producers. FDA did not have enough data to separate wineries from other types of alcohol production facilities.

(Comment 171) One comment stated that FDA had failed to count collectors of wild plants. The comment estimates that there are 100,000 individuals that harvest wild plants.

(Response) Only facilities are required to register with FDA; individuals are not required to register. Harvesters of wild plants that manufacture/process, pack, or hold product in facilities outside of an individual's private residence would be required to register the facility with FDA. FDA does not agree that there are 100,000 harvesters that meet these requirements. FDA commissioned a Dietary Supplement Enhanced Establishment Database (DS–EED) in 1999 (Ref. 14). This database gathered data from the American Business Information (now InfoUSA) electronic database, American Herbal Products Association Membership Directory and Resource Guide, Council for Responsible Nutrition Membership Directory, Harris Inc.'s U.S. Manufacturers Database, Hoovers Corporation Infoseek, National Foods Merchandiser '98–99 Retailer Purchasing Guide August 1998, National Products Expo West, Show Directory, March 1998, Official Establishment Inventory, and Thomas Food Industry Register on the Internet. The DS–EED listed 272 ingredient suppliers. The database may have underestimated the number of ingredient suppliers, but only ingredient suppliers that manufacture/process, pack, or hold product in facilities outside an individual's private residence would be required to register the facility with FDA. Some harvesters of wild plants may already be counted in Census databases, and already be included in the count of facilities. Therefore, FDA estimates that there are an additional 272 harvesters/ingredient suppliers for purposes of this analysis.

(Comment 172) Some comments claim that the number of farms that would fall under FDA's definition of a mixed-type facility is much higher than estimated in the PRIA. Under the proposed definition of manufacturing/processing, which included trimming and washing, the comment suggested that most farms wash, cool, or trim outer leaves and so would be required to register.

(Response) Farms are not required to register with FDA. In this interim final rule, FDA defines "farm" as a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting.

Some facilities located on farms may also manufacture/process, pack or hold food, but not meet the definition for farm and therefore, would be considered mixed-type facilities that are required to register. The farm definition also provides that facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership are exempt as farms, as are facilities that manipulate food other than washing, trimming outer leaves, or cooling, provided that all food used in such

activities is consumed on that farm or another farm under the same ownership. Some facilities located on farms may manufacture/process, pack, or hold food but not meet the definition of farm and therefore, would be considered mixed-type facilities that are required to register. Activities that would be considered manufacturing/processing include cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. Farms that mix feed would be considered mixed-type facilities if they manufacture/process feed on the farm with ingredients obtained from another source, and the resulting feed is then sold or transferred for final use offsite.

In the PRIA, FDA considered farms to be mixed-type facilities if they washed, cooled, or trimmed outer leaves. FDA agrees that the PRIA count of mixed-type facilities undercounted these facilities. In the interim final rule, farms that wash, cool, or trim outer leaves are not considered mixed-type facilities, and therefore, the count of mixed-type facilities is unchanged from the count in the PRIA.

To estimate the number of facilities that would be considered mixed-type facilities, FDA used the 1997 USDA National Agricultural Statistics Service Census of Agriculture (Ref. 6), and data obtained from various county level Cooperative Extension Service (CES) offices (Ref. 15). FDA provides an estimate of the number of these mixed-type facilities in table 2. 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, Kansas; Monterey, Sonoma, Marin, and San Diego counties in California; Jackson County, Wisconsin; Gillespie and San Saba counties in Texas; Carroll County, Maryland; and Berks County, Pennsylvania provide data on the percentage of farms producing specific commodities to be considered mixed-type facilities (Ref. 15). FDA assumes that other commodities, including vegetables (non-organic), other fruits, and wheat, plus feed mixing on poultry and other livestock farms are not mixed-type facilities based on CES interviews (Refs. 15 and 1).

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Table 2.--No. of Mixed-Type Facilities

Mixed-Type Facilities			
Type	No. of Facilities	Percent Mixed-Type	No. of Mixed-Type
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 3 through 7 provide detailed counts of facilities as included in the preliminary regulatory impact analysis and as revised under the interim final rule. Tables 3 and 4 provide the number of facilities counted from the CBP and Nonemployer statistics, respectively, these counts were unchanged from the PRIA to the final analysis. Table 5 provides revised counts of domestic facilities from sources other than the CBP and Nonemployer statistics, including several revised counts of facility types based on comments. Table 6 provides a breakdown of the count of foreign manufacturers/processors obtained from OASIS, these estimates did not change from the PRIA to the final analysis. Table 7 provides a summary of the counts of domestic and foreign facilities.