

Guidance for Industry

Questions and Answers Regarding Registration of Food Facilities (Edition 2)

Final Guidance

Comments and suggestions regarding this document may be submitted at any time. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket Number 2003D-0545.

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Revised December 30, 2003**

This is a revision of the first edition of the FDA guidance "Questions and Answers Regarding Registration of Food Facilities," which FDA issued on December 4, 2003.

Guidance for Industry¹

Questions and Answers Regarding the Interim Final Rule on Registration of Food Facilities (Edition 2)

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

On October 10, 2003, FDA issued an interim final regulation to implement the Bioterrorism Act's requirement that domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States must register with FDA by December 12, 2003. (See 68 FR 58894; October 10, 2003.) The interim final rule implements section 305 of the Bioterrorism Act. Section 305 requires domestic and foreign facilities to register with FDA by December 12, 2003, even in the absence of final regulations.

The first edition of this document was issued as Level 2 guidance pursuant to 21 CFR 10.115 and was made available on FDA's website on December 4, 2003. This revision (Edition 2) is being issued as Level 1 guidance and includes answers to new inquiries regarding the implementation of the Registration of Food Facilities Interim Final Rule (21 CFR Part 1, Subpart H). This guidance is immediately effective because FDA has determined that prior public participation is not feasible or appropriate. The revisions made by this edition (Edition 2) are identified below by date.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

¹ This guidance has been prepared by the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

II. Questions and Answers

A. Who Must Register?

Private Residences:

1. Q: If a person has a business in his/her home that involves manufacturing/processing, packing, or holding food, does that person need to register his residence as a food facility?

A: No. A private residence is not a facility as defined in the Interim Final Rule (21 CFR 1.227(b)(2)) and thus, need not be registered.
2. Q: If a person is selling food from his or her private residence through the Internet, does that person need to register his residence as a food facility?

A: No. A private residence is not a facility as defined in the Interim Final Rule (21 CFR 1.227(b)(2)) and thus, need not be registered.
3. Q: Is a private residence in which low acid canned food is produced exempt from the regulations for low acid canned food (21 CFR Part 113)?

A: No. Although such a residence is not required to be registered as a food facility under 21 CFR Part 1, Subpart I, it is not exempt from any other requirements established by any other laws or regulations (21 CFR 1.240).

B. Who is Exempt from Registration?

Farms:

4. Q: Is a facility that manufactures/processes and sells seed to farmers required to be registered if the seed is intended for cultivation? What if the seed is an ingredient that will be included in animal feed?

A: FDA requires registration of any facility that manufactures/processes, packs, or holds food for consumption in the U.S. As noted in a response to a comment in the Interim Final Rule (Comment 62), 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. Therefore, if the owner, operator, or agent in charge of the facility in this question reasonably believes that the seed is reasonably expected to be used as an ingredient for animal feed, the seed is considered "food" and thus, the facility is

required to be registered. However, if the seed is reasonably expected only to be cultivated, the facility is not required to be registered.

5. Q: Is a farm that grows tomatoes and sells them directly to consumers from a roadside stand located on the farm exempt from registration?
- A: Yes. Assuming that the farm on which the tomatoes are grown otherwise satisfies the definition of farm (21 CFR 1.227(b)(3)), it is exempt from registration. If the primary activity of the roadside stand is selling food (including the tomatoes) directly to consumers, it is exempt as a retail food establishment (21 CFR 1.227(b)(11)).
6. Q: If a farm located in a foreign country ships food directly to the U.S., is it required to register?
- A: No. Assuming that the farm otherwise satisfies the definition of farm (21 CFR 1.227(b)(3)), the farm is exempt from registration if it ships food directly to the U.S. However, if prior to export to the U.S., food grown on the farm is shipped to a foreign facility that manufactures/processes, packs, or holds the food, the second facility must register unless the food subsequently undergoes further manufacturing/processing of more than a *de minimis* nature at another foreign facility (21 CFR 1.226(a)). The *de minimis* provision is discussed further in question 21 of this guidance and in the preamble to the Interim Final Rule (responses to comment 17, 21, 25, and 26).
7. Q: Is a mixed-type facility, such as a farm that grows oranges and processes them into orange juice for sale to a distributor, required to register?
- A: Yes. FDA uses the term "mixed-type facility" in the preamble to the Interim Final Rule (response to Comment 46) to refer to an establishment that engages in both activities that are exempt from registration and activities that require the establishment to be registered. In this example, the farm is required to be registered because its processing activities are not covered by the farm definition (21 CFR 1.227(b)(3)).
8. Q: [Added December 30, 2003] Is applying pesticides on a farm considered a "traditional farming activity" within the scope of the farm definition and exemption? Does this include applying a pesticide, for example, on bananas in the field or in the packing station just prior to packing?
- A: Whether the application of a pesticide to a crop is an activity covered by the farm definition depends upon whether the application is prior to or post-harvest. Section 1.227(b)(3) defines a farm as "a facility in one general location devoted to the growing and harvesting of crops, the

raising of animals (including seafood), or both.” FDA considers application of pesticides to a crop prior to harvest as an integral part of growing crops. Such application generally does not involve close manipulation of the food being grown because the application is usually directed at the entire plant. Therefore, an establishment devoted to the growing and harvesting of crops that applies a pesticide to its crops prior to harvest is a "farm" within the meaning of the Interim Final Rule. However, post-harvest application is necessarily directed at the food, not the entire plant, and thus, is considered to be manufacturing/processing under §1.227(b)(6). Therefore, a farm that treats a crop against pests post-harvest must register with FDA unless it satisfies the conditions of § 1.227(b)(3)(ii).

9. Q: [Added December 30, 2003] Is use of chlorinated water to wash lettuce on a farm considered "processing," necessitating registration of a farm?

A: If the farm is using water directly from a public or other water supply that is chlorinated for other purposes, FDA will consider this activity "washing" within the meaning of 21 CFR 1.227(b)(3). Accordingly, an establishment using chlorinated water in this manner is a "farm" and is not required to be registered. In addition, FDA's Good Agricultural Practices guidance document (section 2.2) (<http://www.foodsafety.gov/~dms/prodguid.html>) notes that chlorine is commonly added to water at 50-200 parts per million (ppm) total chlorine, at a pH of 6.0 -7.5, for post harvest treatment of fresh produce, with a contact time of 1-2 minutes. FDA recognizes that chlorination at these levels is the only way many growers and packers can raise the microbiological quality of the water they use to a level that is safe and suitable. Addition of chlorine to water at these levels, therefore, does not constitute "manufacturing/processing" within the meaning of 21 CFR 1.227(b)(3)(ii).

In contrast, if water used as a wash on harvested foods on a farm contains added chlorine above levels of 200 ppm to create a specific wash, FDA considers this activity as "treating" food within the meaning of 21 CFR 1.227(c)(6), which is a manufacturing/processing activity that would require the farm to register, unless it falls under another exemption (e.g., foreign facility exemption).

10. Q: [Added December 30, 2003] Does placing stickers on fruit on a farm amount to "manufacturing/processing" and therefore require registration of the facility in which the application of the stickers occurs?

A: A farm that places stickers on produce grown or consumed on the farm is not required to register as long as the farm otherwise satisfies the definition of farm (21 CFR 1.227(b)(3).) Under §1.227(b)(3)(i), FDA

considers on-farm facilities that pack or hold food as meeting the farm definition, if all food used in such packing or holding is grown, raised, or consumed on that farm or another farm under the same ownership. As stated in the response to comment 41 in the Interim Final Rule, FDA considers certain activities to be “packing,” such as sorting, grading, wrapping, or boxing harvested food for the sole purpose of transporting this food off the farm. FDA also considers placing stickers on produce grown or consumed on a farm part of “packing.”

Retail Facilities:

11. Q: Does a warehouse club that sells to both consumers and businesses need to be registered?

A: A warehouse club is exempt from registration as a retail food establishment (21 CFR 1.227(b)(11)) if it sells food products directly to consumers as its primary function. 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. Businesses are not considered consumers.

12. Q: If a supermarket has a bakery on the premises that bakes bread and sells it to other stores in the same chain, is the supermarket required to be registered?

A: The supermarket is exempt from registration as a retail food establishment (21 CFR 1.227(b)(11)) if its primary function is to sell food products directly to consumers from the supermarket. As noted, an establishment's primary function is to sell food directly to consumers if the annual monetary value of sale of all food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers.

Nonprofit Food Facilities:

13. Q: Are exporters of food for charity exempt from the registration requirements?

A: Yes. A facility, including a non-profit facility, is not required to be registered if all food manufactured/processed, packed, or held at the facility is not for consumption in the U.S. (21 CFR 1.225 and 1.227(b)(7)).

Facilities Regulated Exclusively, Throughout the Entire Facility, by USDA:

14. Q: Are facilities that process deer, elk, and bison required to register with FDA?
- A: Yes. These facilities are required to be registered with FDA because they are not regulated exclusively by the United States Department of Agriculture (USDA) (21 CFR 1.226(g).)

C. Definitions:

Holding:

15. Q: Are local collecting facilities for grains exempt from the registration requirement?
- A: All establishments at which food is manufactured/processed, packed, or held are required to be registered, unless otherwise exempt. FDA understands the term “collecting facilities” to refer to facilities that store or hold food, such as silos or grain elevators. Such a facility must be registered with FDA because food (grain) is held by the facility (21 CFR 1.225; 1.227(b)(5)).
16. Q: If a facility receives packaged produce for shipping and holds it in cold storage, is it required to register?
- A: Yes. The facility in this example is holding food and therefore, must be registered (21 CFR 1.225; 21 CFR 1.227(b)(5)).
17. Q: If finished food products for consumption in the U.S. are held at a third party facility before consolidation for import into the U.S., must this facility be registered?
- A: Yes, if the finished products are held at a third party facility prior to export to the U.S., the facility is required to be registered (21 CFR 1.225; 1.227(b)(5)).
18. Q: [Added December 30, 2003] In a lessor-lessee relationship, such as a food-producing business that rents space from a landlord, who is legally obligated to register the facility?
- A: Either the lessor or the lessee may register the facility as follows. The Bioterrorism Act and the Registration Interim Final Rule place the duty to register a facility on the owner, operator, or agent-in-charge of the facility. Each of these persons has an independent obligation to comply with the registration requirement, and any one of them may satisfy the obligation

for the other two. On the other hand, if a facility is not registered, FDA could proceed with an enforcement action against one or all of the three. A facility is defined as “any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States.” Thus, for a public warehouse, either the owner of the entire warehouse may register the warehouse and satisfy the obligation for all lessees, or an individual lessee, functioning as the operator or agent-in-charge of the portion of the warehouse he/she leases, may register that portion of the facility.

19. Q: [Added December 30, 2003] Post offices and similar facilities owned or operated by express couriers may have packages containing food on their premises as part of the shipment process. Are these types of establishments required to be registered with FDA as food facilities?

A: No. For purposes of the registration Interim Final Rule, post offices and express courier facilities are not required to be registered with FDA as food facilities. The activities of both postal services and express courier services are focused on the transport of goods; their facilities generally serve only as a point of transfer of packages and other freight, including packages containing food. Thus, it is appropriate to view both types of facilities as part of the transportation process. The definition of "facility" in the Interim Final Rule (21 CFR 1.226(b)(2)) does not include transportation vehicles “if they hold food only in the usual course of business as carriers.” Although the registration Interim Final Rule does not define “transportation vehicles,” the proposed rule on the establishment and maintenance of records (68 FR 25188 at 25238; May 9, 2003) defines “transporter” as “a person who has possession, custody, or control of an article of food ... for the sole purpose of transporting the food.” FDA believes that it is appropriate to apply this same rationale to exclude from registration facilities that house food only because they are part of the process of transporting it from one location to another. This analysis is also consistent with the definition of "facility" in 21 CFR 1.227(b)(2). Thus, for the purpose of the registration Interim Final Rule, post offices and express courier facilities operating in a manner comparable to post offices that are part of the transportation network and have possession, custody, or control of food for the sole purpose of transporting it are not required to be registered with FDA.

20. Q: [Added December 30, 2003] Truck terminals and freight forwarders may have food on their premises as part of the shipment process. Are these types of establishments required to be registered with FDA as food facilities?

A: No. Truck terminals and other stationary facilities that serve merely to assist transportation vehicles in the process of transporting food are not required to be registered with FDA. The analysis for post offices and similar facilities is also applicable here. Thus, for the purpose of the registration Interim Final Rule, truck terminals and freight forwarders that are part of the transportation network and have possession, custody, or control of food for the sole purpose of facilitating its transport are not required to be registered with FDA.

FDA acknowledges that this response is not completely consistent with certain prior guidance (Response to Comment 36; 68 Fed. Reg. 58894 at 58904; October 10, 2003). The agency has further considered this issue, as well as related ones, resulting in a revision of the earlier guidance.

Manufacturing/Processing:

21. Q: Is fumigation (such as of bagged cocoa beans) considered *de minimis* processing?

A: No. The Interim Final Rule states that "treating" food is a manufacturing/processing activity (21 CFR 1.227(b)(6); also see the response to Comment 41 in the rule). Therefore, a foreign facility that performs fumigation of food that is for consumption in the U.S., is required to be registered unless another foreign facility conducts further manufacturing/processing of more than a *de minimis* nature before the food is shipped to the U.S. FDA notes that even if fumigation were considered to be a *de minimis* activity, the facility at which the fumigation occurs would be required to be registered. The Bioterrorism Act *de minimis* provision is relevant to whether a particular foreign facility that manufactures/processes, packs, or holds food prior to the "*de minimis* facility" is required to be registered. The response to comment 17 in the preamble of the Interim Final Rule also discusses fumigation of cocoa beans.

22. Q: Is it necessary for a facility housing cotton gins to register if the cotton gins separate cotton from its seeds and hulls and the facility then sells these seeds or hulls to a manufacturer who then further processes the seeds and hulls into feed for sale to livestock operations?

A: FDA notes that the answer to this question depends in part on whether the cotton by-products are "food" as defined in the interim final rule (21 CFR 1.227(b)(4)) and whether the establishment housing the cotton gins is domestic or foreign.

In the preamble to the Interim Final Rule, FDA responded to a comment (Comment 62) regarding facilities that manufacture/process, pack, or hold

multi-use substances. (68 Fed. Reg. 58894 at 58910; October 10, 2003.) The agency believes that discussion is relevant to this question. In the Interim Final Rule, the agency stated that "a product is one that will be used for food if the owner, operator, or agent in charge of the facility reasonably believes that the substance in question is reasonably expected to be directed to a food use." In this example, the facility containing the cotton gins is a food facility because the owner, operator, or agent in charge of the facility knows or should know that the cotton by-products are reasonably likely to be used as components of animal feed.

If the cotton gin establishment is located in the U.S., the establishment is required to be registered because it is manufacturing/processing food (components of animal feed), and the facility does not appear to satisfy any exemption from registration. FDA notes that any subsequent facility that processes the cotton seed and hulls into animal feed is also required to be registered.

However, if the cotton gin establishment and the establishment that processes the cotton seed and hulls into animal feed are both located in a foreign country, the cotton gin establishment would not be required to be registered because a subsequent foreign facility (the feed manufacturer) conducts further manufacturing/processing of the cotton by-products prior to export to the U.S. The foreign feed manufacturing/processing facility must be registered unless, before the feed is exported to the U.S., the feed undergoes further manufacturing/processing of more than a *de minimis* nature at a third foreign facility (21 CFR 1.226(a)).

US Agent:

23. Q: For foreign facilities, may the U.S. agent for the facility also serve as the facility's emergency contact?
- A: Yes. The U.S. agent will be considered the emergency contact for a registered foreign facility unless another name is provided in the facility's registration as the emergency contact (21 CFR 1.227(b)(13); 1.233(e)).
24. Q: Some U.S. law firms are charging fees to serve as a foreign facility's U.S. agent. Some of these firms have the word "FDA" in their name. Must a foreign facility use one of these firms as its U.S. agent?
- A: No. A foreign facility's U.S. agent may be an individual, partnership, corporation, or association; the only requirement for such an agent is that the agent must have a place of business or residence in the U.S. and be physically present in the U.S. For example, a foreign facility may use its U.S. importer as its U.S. agent. FDA does not recommend or endorse any

particular firm, organization, persons, or company to serve as a foreign facility's U.S. agent. FDA is not affiliated with any firm offering its services as a U.S. agent.

25. Q: May a foreign government official residing in the U.S., such as a representative from the foreign country's embassy, act as a foreign facility's U.S. agent for purposes of food facility registration?
- A: In the preamble to the Interim Final Rule (Comment 90), FDA noted that 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 will consider such situations on a case-by-case basis in consultation with the U.S. State Department.
26. Q: I am a foreign facility that does business with several different brokers. May I use more than one of these as my U.S. agent?
- A: No. The Interim Final Rule requires that each foreign facility have only one U.S. agent for food facility registration purposes. However, having a single U.S. agent for FDA registration purposes does not preclude a facility from having multiple brokers for other business purposes. FDA notes that a foreign facility is not required to conduct all of its business in the U.S. through the U.S. agent designated for purposes of registration. 21 CFR 1.227(b)(13)(iii) and the response to comment 86 in the preamble to the Interim Final Rule further discuss this issue.
27. Q: Is the U.S. agent legally liable in the event something goes wrong with food manufactured/processed, packed, or held at the foreign facility for which he serves as U.S. agent?
- A: FDA generally does not intend to hold a foreign facility's U.S. agent responsible for violations of the Bioterrorism Act that are committed by the foreign facility. FDA, however, would consider legal action against a U.S. agent where the agent knowingly submits false information to FDA or the U.S. agent and the foreign facility are 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.

Other Definitions

28. Q: [Added December 30, 2003] How does FDA define “owner,” “operator,” and “agent in charge?”

A: The owner, operator, or agent in charge is a person (21 U.S.C. 321(e)) who has an ownership interest in, or management authority of, a facility or a portion of a facility (e.g., a lessee of a part of a public warehouse).

29. Q: [Added December 30, 2003] How does FDA define “parent company?”

A: The term "parent company" is used in 21 CFR 1.232(b) and is intended to have the meaning it has in the corporate context. If a facility is part of a company that is owned by another corporation, then the corporation would be the parent company. For example, if a facility is owned by Company X, and Company X is a subsidiary of Corporation Y, then the owner of the facility is Company X and the parent company is Corporation Y.