Guidance for Industry

Questions and Answers Regarding Registration of Food Facilities

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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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.

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.

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 15 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)).

Retail Facilities:

8. 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.

9. 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:

10. 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:

11. 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:

12. 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)).

13. 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)).

14. 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)).

Manufacturing/Processing:

15. 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.

16. 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 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:

17. 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)).

18. 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 <u>not</u> affiliated with any firm offering its services as a U.S. agent.

19. 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.

20. 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.

21. 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.