

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 be 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