

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