

imported products are correctly identified by where and by when they were produced. For example, if the registration information identifies a facility as producing only dairy products and FDA receives a prior notice purportedly from the facility for the shipment indicating that the facility is shipping nuts, FDA can target that facility for verification based on the discrepancy. FDA believes, however, that information about a facility's food product categories is a key element for both FDA and industry to allow for rapid communications to facilities directly impacted by an actual or potential bioterrorist attack or other food-related emergency. FDA, therefore, is proposing in § 1.232(e) to include on the registration form as a mandatory field the categories from § 170.3. For ease of use, however, the more common categories found in FDA's product code builder at [www.fda.gov/search/databases.html](http://www.fda.gov/search/databases.html) will be listed as the main categories on the form, followed by the food product categories in § 170.3 as references for each FDA product code category. For example, the registration form includes coffee and tea as a product category, which includes the products listed in § 170.3(n)(3) and (n)(7). Categories not in § 170.3 will be listed as optional selections.

FDA believes its proposed approach will both permit the agency to collect vital information regarding usable categories of products produced at the facility, and address industry's concern that the food product categories in § 170.3 are unworkable. FDA is interested in receiving comments on whether use of FDA's product code builder categories as the primary selection, with references immediately after each entry to the food product categories in § 170.3 that apply to each selection, addresses the comments' concerns regarding use of the categories in § 170.3, while complying with the requirements of the Bioterrorism Act.

FDA also is proposing to include several other fields that relate directly to the statutory requirements. The first of these is the name, address, phone number, facsimile number (if available), and e-mail address (if available) of the U.S. agent. Because the U.S. agent will act as a communications link between the facility and FDA, it is vital for FDA to have reliable contact information for the U.S. agent.

FDA also is proposing that a mandatory section of the form include, if applicable, the name and address of parent company, if the facility is owned by a parent corporation. This information is important for FDA in understanding the relationship between

a facility and its parent company regardless of the name under which a facility may be operating.

FDA also is proposing to include as a mandatory section the emergency contact information for a facility, which would include an individual's name, title, office phone, home phone, and cell phone (if available). If FDA receives information regarding a potential or actual threat to the nation's food supply, or other food-related emergency, it must be able to get in touch with an individual at each potentially affected facility who could respond immediately to the threat at any hour. The emergency contact person does not have to be physically located at the facility; however he or she must be accessible and able to respond in an emergency. Thus, for example, a parent corporation can list as the emergency contact the name of an individual at headquarters who has overall responsibility for responding to emergencies at any facility owned by the parent company.

FDA is planning to include at the end of the form a statement in which the person submitting the registration information will certify that the information submitted on the form is true and accurate and the person registering the facility is authorized to do so. If a person submits false information on the registration form, or if a person registers a facility without being authorized to do so, that registration will be considered a materially false, fictitious, or fraudulent statement to the U.S. Government under 18 U.S.C. 1001, which subjects the person to criminal penalties. FDA is including this language on the registration submission to deter individuals from either submitting false information, or registering a facility if they are not authorized by the facility to register it. This applies both to individuals who do not have any relationship with the owner, operator, or agent in charge of a facility, and to those who have a connection to the owner, operator, or agent in charge of a facility, such as the U.S. agent, but who do not have authorization from the facility to register on its behalf.

#### 4. What Optional Items Are Included in the Registration Form? (Proposed § 1.233)

FDA also is proposing in § 1.233 to include several optional fields on the registration form. These items are consistent with the statutory directive, and will enable FDA to communicate more quickly with facilities that may be the target of a bioterrorist attack or other food-related emergency. These proposed fields include:

(a) a preferred mailing address, which would allow a facility's corporate headquarters to serve as the primary contact with FDA instead of the facility;

(b) the type(s) of activity conducted at the facility (e.g., manufacturing/processing, packing, or holding), which would allow FDA to target its communications in emergencies to those facilities potentially impacted based on the information FDA receives (e.g., a threat to a type of food product at manufacturing facilities);

(c) food categories not included in § 170.3 (e.g., dietary supplements, infant formula, and food for animal consumption), which would be helpful to FDA for responding to a terrorist incident or other food safety emergency involving these foods;

(d) the type of storage or manufacturing/processing facility, in the event that the facility is solely a warehouse/holding facility and stores multiple types of food;

(e) a food product category of "most/all food product categories", if the facility manufactures, processes, packs, or holds foods in most or all of the categories under § 170.3; and

(f) the approximate dates of operation, if the facility's business is seasonal.

FDA encourages all facilities to submit this optional information if it applies to the facility's operations.

#### 5. How and When Do You Update Your Registration Information? (Proposed § 1.234)

FDA is proposing in § 1.234 that the owner, operator, or agent in charge must submit a timely update to FDA via the Internet (or by paper copy if no Internet access) within 30 calendar days of any change to any of the information previously submitted, including, but not limited to, the name of the owner, operator, or agent in charge. FDA is proposing 30 calendar days in order to balance the needs of both industry and FDA. In order for FDA to have accurate information for responding to terrorist threats or other food related emergencies, facilities must submit updates within an expedited timeframe. However, FDA also understands that the need to submit updates may coincide with transitions occurring at the facility in which the facility may not be able to provide updates immediately after such transitions occur. FDA believes that requiring updates within 30 calendar days of changes to the information on the initial registration submission is a reasonable balance between FDA's and industry's interests. FDA requests comments on this 30-day timeframe.

With respect to the content of the update, FDA is proposing that the