

Record), as well as an option for an "other" type of code; and the appropriate registration number for each option that is checked. The commenters state that this would minimize confusion, especially about which of a facility's multiple registration numbers apply to what types of activities.

(Response) FDA has decided not to implement this suggestion. In the Bioterrorism Act, Congress specified what information must be required in a facility's registration. After careful consideration, FDA has concluded that a few additional elements of information are needed for the efficient enforcement of the act in responding to a bioterrorist threat or other food-related emergency. Because FDA believes the additional information suggested by these comments would not significantly further FDA's efforts in responding to such incidents, we decline to include them as registration elements.

2. Type of Activity Conducted at the Facility

(Comment 133) Several commenters state that the option of including on the registration form the "category" or "type" of food warehoused, produced, or sold by a facility should be required. These commenters state that this information appears to be critical in determining who should be notified in case of a threat or actual terrorist event targeting a particular type of food. One commenter suggests that FDA use a "simpler method" to determine these categories, such as that utilized for classifying an establishment (e.g., 03 for bakeries, 16 for fishery products, 29 for soft drinks, 47 for food warehouses), which should suffice as a means of categorizing establishments. One commenter states that FDA should either make establishment type data mandatory or delete this information entirely. This commenter states that FDA is unlikely to get full compliance voluntarily with the request for establishment type information, when no penalty would be imposed if this optional information were inaccurate when submitted initially or became out of date.

(Response) FDA has required only what is specified in the Bioterrorism Act and information that is necessary for the efficient enforcement of the FD&C Act. Although we believe the information in the optional items can be useful to FDA as well as to facilities in the event of an emergency, we are requiring only those items required by the Bioterrorism Act and those necessary for the efficient enforcement of the FD&C Act.

3. Type of Storage, if the Facility Is Solely a Holding Facility

(Comment 134) FDA received several comments agreeing that a facility that is "solely a warehouse" should only have to check a simplified description of the type of warehousing provided, such as "ambient storage," "refrigerated storage," or "frozen storage," rather than submit a detailed breakdown of the general food product categories stored in the facility, as required in section 11 of the draft form. These commenters state that this simplified option avoids the need to determine and track food product categories for virtually thousands of different food items that may enter or leave a warehouse.

The commenters ask, however, that FDA define what is meant by "solely a warehouse." The commenters state that most, if not all, public and contract food warehouses also provide ancillary services that include labeling, relabeling, packing, and repacking, but the warehouse typically provides these services without in any way changing, contacting, or doing anything at all to the actual food. The commenters state the warehouse never "goes inside" the primary packing, thus avoiding any potential for contamination. The commenters state that these services are incidental to the core function of storing and handling and are performed strictly under the direction and control of the customer.

(Response) As explained previously, to ensure that registrants have completed the section of the form on food product categories, FDA has decided to require that all registrants check at least one box in the mandatory food product categories section of the form (section 11a). Therefore, a facility that is solely a warehouse is required to check either one or several food product categories covered under § 170.3, "the most/all human food product categories," or "none of the above mandatory categories."

Regarding the question of what FDA means by "solely a warehouse," FDA agrees that this term was confusing. We have revised Form 3537 to eliminate that term. We are also providing that all food facilities must complete section 11 which concerns general product categories. We have revised section 10 of the form and § 1.233(i) to refer to facilities that are primarily holders.

4. Food Categories Not Included Under § 170.3

(Comment 135) One commenter argues that FDA's proposed optional food product categories should be mandatory, not optional. This

commenter asserts that FDA should use a simpler method of classification of all food product categories, such as that used for food establishments.

(Response) FDA believes that it is a reasonable choice for the agency to make optional identification of food product categories that are not listed in § 170.3. There is a strong incentive for facilities that handle foods in the optional categories to provide this information, because with such information, FDA will be better able to target its communications in case of a threatened or actual bioterrorist event or other foodborne emergency. Getting prompt and more accurate information will help a facility respond more quickly and efficiently to any incident that may affect that facility. As discussed previously, for ease of use, FDA is using the more common categories found in FDA's product code builder at <http://www.fda.gov/search/databases.html> as the main categories on the registration form, referencing the relevant food product category in § 170.3.

(Comment 136) Several commenters submitted comments regarding the "most/all human food product categories" designation. Most of these commenters agree with FDA's preliminary decision to include "most/all" product categories. One commenter states that a facility that normally carries all food categories and therefore has included "most/all food product categories" in its registration should not be required to amend their registration or be subject to penalties if they have temporarily run out of products in a specific food category, but intend to restock the items. Another commenter argues that FDA should delete the "most/all" food product category. The commenter states that in the event of an emergency, a delay could result since FDA would be unnecessarily contacting facilities that do not manufacture/process, pack, or hold the precise food in question. Also, a facility could process different food products almost daily, but not be required to notify FDA of any changes.

(Response) The interim final rule retains "most/all human food product categories." This category will enable facilities that manufacture/process, pack, or hold many different types of food to check the "most/all" category instead of having to update their registrations frequently. In making this decision, FDA has balanced the greater efficiency of the agency's having specific information regarding food manufactured/processed, packed, or held at each facility against the burden on facilities to submit initially and