

registration form, FDA “does not ask for specific information for the owner, operator, or agent in charge elsewhere in the form.” The commenter states that it assumes FDA interprets the owner, operator, or agent in charge of the facility “as the facility itself (and not an individual) for which specific information is requested in section 2 of the form” (facility name/address information). The commenter continues that “[o]nce the owner, operator, or agent in charge of the facility has authorized an individual to submit the registration form, that individual becomes synonymous with the ‘owner, operator, or agent in charge.’” The commenter states that if these assumptions are correct, the last box under section 1b should be revised from “Owner, Operator, or Agent in Charge Change” to “Authorized Submitter [Change].”

The commenter also requests that section 12 be revised from its current statement “[t]he owner, operator, or agent in charge of the facility must submit this form. By submitting this form to FDA, the owner, operator, or agent in charge certifies that the above information is true and accurate and that the facility has authorized the submitter to register on its behalf.” The commenter’s suggested revised statement is as follows: “[t]he owner, operator, or agent in charge of the facility must submit this form. By submitting this form to FDA, the owner, operator, or agent in charge of the facility certifies that the above information is true and accurate and that the *submitter has been authorized* to register on its behalf” (suggested changes in *italics*).

(Response) These comments (and others) suggest that certain provisions of the proposed rule and proposed Form 3537 may have been ambiguous or otherwise created confusion about who should complete and submit a registration. As discussed below and elsewhere in this preamble, FDA has clarified several provisions in the interim final rule and has revised Form 3537 as well. The agency believes that these clarifications and revisions generally respond to the foregoing comments. FDA’s more specific responses to these comments are set out below.

Regarding the commenter’s request that FDA define “owner,” “operator,” or “agent in charge,” FDA does not believe that it is necessary to define these terms because the terms are self-explanatory. Accordingly, the interim final rule does not include a definition for owner, for operator, or for agent in charge.

FDA acknowledges that the provision in the proposal regarding the certification statement was unclear due to the language in proposed § 1.232(g) stating that “the person submitting the registration [must be] authorized by the facility to register on its behalf.” This created ambiguity for three reasons. First, the use of “person” created ambiguity as to whether only an individual could submit the registration because “person,” as defined in section 201(e) of the act, includes an individual, partnership, corporation, and association. However, as evidenced by the proposed certification requirement that the name of the person submitting the registration be specified, FDA intended to convey that an individual rather than a “person” must submit the registration. Second, the statement that a person submitting a registration must have been authorized by the facility is inconsistent with the certification statement in the proposed rule, which stated that “the owner, operator, or agent in charge of the facility must submit this form.” Third, the former statement was confusing because a facility itself cannot authorize an individual to register.

The interim final rule resolves these inconsistencies by clarifying who may register a facility. Although the Bioterrorism Act imposes the legal obligation to register on the owner, operator, and agent in charge of a facility, FDA believes that this provision does not prevent the owner, operator, or agent in charge of a facility from authorizing an individual to fill out, sign, and submit the registration. Accordingly, the interim final rule provides that the owner, operator, or agent in charge may authorize an individual to submit the facility’s registration.

In addition, for clarification and for the reasons discussed in the responses to comment 110, in the interim final rule, § 1.232(i) has been added to provide that if the individual submitting the form is an individual authorized to do so by an owner, operator, or agent in charge, the individual must also certify that the individual is authorized to submit the registration form on behalf of the owner, operator, or agent in charge and must identify by name the authorizing individual. This statement must include the individual submitter’s signature (for paper and CD-ROM options) and printed name. If the individual submitter is authorized by someone other than the owner, operator, or agent in charge, the authorizing individual’s name, address, and phone number must be included; the fax

number and e-mail address of the authorizing individual are optional.

FDA does not agree with the commenter’s assumption that if a facility authorizes an individual to submit a registration, the individual then becomes synonymous with the owner, operator, or agent in charge. Although the interim final rule permits an owner, operator, or agent in charge to authorize an individual to submit the registration on its behalf, that individual does not become the owner, operator, or agent in charge for purposes of registration or otherwise alter the legal obligation of the owner, operator, or agent in charge to register. Therefore, we have not revised section 1b as requested by the commenter.

FDA does not fully understand the import of the comment that the agency considers that owner, operator, and agent in charge to be the “facility itself.” In some cases, the owner of the facility may be the same as the facility (e.g., a corporation) while in other instances, the two may be different. The revised Form 3537 reflects these two possibilities in that it requests information about the facility (Section 2, facility name and address) and the owner, operator, or agent in charge (Section 12, owner, operator, or agent in charge address and telephone number.) Form 3537 also recognizes that information in section 12 may overlap with that requested in section 2.

F. Comments on “When Must You Register?” (Proposed § 1.230)

(Comment 97) One commenter states that FDA’s language in proposed § 1.230 (“[t]he owner, operator, or agent in charge of a facility that manufactures/ processes, holds, or packs food for consumption in the United States must be registered no later than December 12, 2003”) is contrary to the Bioterrorism Act, which requires registration by facility, as opposed to by owner, operator, or agent in charge. The commenter also states that language in proposed §§ 1.225 and 1.226 might be interpreted to mean that the owner, operator, or agent in charge is the entity to be registered, not the facility.

(Response) FDA intends to require that the facility be registered, not the owner, operator, or agent in charge of the facility. In response to these comments, FDA has revised the following language: In § 1.225, FDA has added the italicized language to paragraph (a): “You must register *your facility* under this subpart if you are the owner, operator, or agent-in-charge of either a domestic or foreign facility * * *”. The agency also has added the italicized language to paragraph (b): “If