

(Response) The Bioterrorism Act requires that the “owner, operator, or agent in charge of the facility shall submit a registration” to FDA.

Accordingly, the certification statement on the registration form requires the owner, operator, or agent in charge of a facility to submit the registration, or to authorize an individual to submit the facility’s registration. Although administrative personnel may prepare the registration, the owner, operator, or agent in charge, or an individual authorized by the owner, operator, or agent in charge to submit a facility’s registration must certify that the information included in the registration is true and accurate.

(Comment 129) One commenter states that the certification statement is inadequate to ensure either the veracity of the information provided or the identity and authority of the person submitting it. The commenter states that “[t]he regulation includes no protections that would prevent intentional or unintentional abuse of the system, to the potential detriment of both national security and of legitimate businesses. Without some effective means of verifying at least the identity and authority of the person submitting the registration, the proposed system will be easily subject to misuse and mischief.”

(Response) The certification statement requires a person authorized to submit a registration to certify that the registration information is true and accurate, and that owner, operator, or agent in charge of the facility has authorized the submitter to register on its behalf. The certification statement also states that anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties under 18 U.S.C. 1001. As an additional means to verify the identity of the person submitting the registration, the interim final rule requires that for the paper and CD-ROM registration options, the registration include the signature of the person submitting the registration. FDA believes that the combination of the signed certification statement and Federal criminal liability will be a powerful incentive for truthful registrations. In addition, FDA has several methods by which to verify the identity of both facilities and individuals submitting registrations by any of the permissible means; however, for security reasons, FDA declines to elaborate on these methods.

In addition to the changes noted previously, on its own initiative FDA has made several editorial changes to this section for clarity.

*I. Comments on “What Optional Items Are Included in the Registration Form?” (Proposed § 1.233)*

1. General Comments

(Comment 130) One commenter states that the interim final rule should remain focused on effectively implementing the legislative requirements as is, neither expanding information requirements, nor adding optional information. The submitter states that if the information is not necessary, it should not be collected.

(Response) FDA notes that registrants are not required to submit the elements of optional information specified in the proposed rule and the interim final rule—that is the nature of “optional” information. FDA continues to believe, however, that information described as “optional” will enable FDA to communicate more effectively with facilities that may be the target of an actual or potential terrorist threat or other food-related emergency and that better communication about such emergencies will benefit both FDA and the registered facility. For example, some food products are not covered in the categories specified in § 170.3, such as certain dietary supplements, infant formula, and animal feed, but foods in these categories may nevertheless be the focus of a food-related emergency. Therefore, FDA encourages, but does not require, a registrant to submit in a facility’s registration the information identified as optional in the interim final rule.

(Comment 131) Several commenters ask that FDA clarify what sections of the registration form (Form 3537) are mandatory and which are optional. One of these commenters states that FDA should mark optional fields in some form, such as an asterisk, and program the electronic downloadable file to allow the registration to proceed as long as the mandatory fields have been completed. This commenter states that, at a minimum, FDA should insert the word “**REQUIRED:**” or “**OPTIONAL:**” in boldfaced, underscored, and all capital letters following the section titles to clarify further which information is required and which is optional. The commenter also suggests that instructions be provided for filling out the form that include specific citations to those sections where the information is required and where optional. Another commenter suggested that FDA consider a second form for voluntarily-submitted information. Otherwise, the commenter believes that the Food Facility Registration Form will cause confusion as to which information is required by

law, versus information that is optional because the optional sections of the form are interspersed with required information sections.

One commenter states that the space on the Registration Form is somewhat limited and proposes that the registration form be expanded to accept appendices for registrants to submit additional information.

(Response) FDA believes its proposed registration form is sufficiently clear as to which sections of the form are required and which are optional. For each section of the registration that is optional, FDA has included the word, “OPTIONAL” in bold. For the food product categories section involving food for human consumption, FDA has included the words, “Optional Selection” in bold after each category that is not required. In the instructions for completing the registration, FDA intends to specify which sections are required and which are optional. FDA notes that the agency considered having a separate form for optional information but rejected it after determining that the order of the sections in the proposed registration form was clearer and flowed more effectively when in a single form, rather than two separate forms.

FDA further advises that the agency’s electronic registration system will be sufficiently flexible to permit a registrant to enter all of the information the registrant needs to enter. FDA has revised both the paper and electronic registration forms to provide ample space for including all relevant information. However, for both the printed and electronic versions of the registration, FDA is only accepting information listed on the registration form; registrants should not add information not identified as required or optional in this rule or described on the registration form. Due to the large anticipated volume of registrations, the registration system will not provide for the submission of appendices to the registration form.

(Comment 132) Some commenters suggest that FDA include additional optional sections on the registration form, including sections for type or other facility registration number (e.g., the U.S. Customs Service bonded facility Facilities Information and Resources Management System (FIRMS) code, FDA establishment number, FDA-assigned Food Canning Establishment number, Seafood Hazard Analysis and Critical Control Point importer food number, FDA Affirmation of Compliance code, and the location number of the U.S. domestic party responsible for FDA-regulated goods imported by a foreign Importer of