

(Response) In drafting the interim final rule, FDA structured the rule to be consistent with the statutory mandates of the Bioterrorism Act and, at the same time, to reduce the costs associated with compliance. As discussed in more detail later in the preamble, FDA carefully considered comments received regarding the burden imposed by the proposed rule, including its impact on international trade. The agency has made a number of changes in the interim final rule that are both consistent with FDA's statutory mandate and that will make it easier and less costly for covered facilities (foreign or domestic) to register. In addition, the interim final rule exempts certain establishments from the registration requirement that, under the rule as proposed, would have been required to register. For example:

- FDA has changed the definition of "food" for purposes of the Bioterrorism Act to exclude food contact substances as defined in section 409(h)(6) of the FD&C Act and pesticides as defined in FIFRA (7 U.S.C. 136(u)).

- FDA has broadened the definition of "farm" to include the activities of harvesting, and the rule considers washing, trimming of outer leaves, and cooling of crops on a farm to be harvesting. Also, in the interim final rule, "farm" includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership.

- FDA is clarifying that having a single U.S. agent for FDA registration purposes does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes.

- The interim final rule allows registrants to submit their registrations by fax or CD-ROM, which FDA will enter into its registration system, along with the mailed submissions, as soon as practicable, in the order received.

- FDA has extended the timeframe in which registrants must update their registrations from 30 to 60 days of any change in the required information.

- FDA has deleted the requirement to update optional information previously submitted.

#### *C. Comments on Who Must Register Under This Subpart? (Proposed § 1.225)*

(Comment 7) Some commenters disputed the statement in the proposed rule that [i]ndividual homes are not subject to the regulation if the food that is manufactured/processed, packed, or held in the home does not enter commerce." (68 FR 5378). These commenters argue that under this

limited exclusion for homes, individuals, such as Girl Scout and Boy Scout volunteer parents, individuals who prepare food in their homes for functions such as church bake sales, and individuals who temporarily store food in their homes as sales samples or small inventories of product for delivery to rural retailers would be required to register because they often hold in their homes food products destined for further movement through commerce. The commenters argue that the Bioterrorism Act does not mention individual residences in the scope of facilities that manufacture, process, pack, or hold food and asserts that Congress did not intend that the registration requirements compel ordinary citizens to register their residences, and that including residences would not give FDA any useful or actionable information. This commenter concludes that FDA should explicitly exempt individual residences under all circumstances.

(Response) FDA has concluded that private individual residences are not "facilities" for purposes of the registration provision of the Bioterrorism Act. Under the Bioterrorism Act, the term "facility" includes "any factory, warehouse, or establishment." Congress did not specify any definition for these terms. Under their common meanings, the terms can include private residences. For example, according to Webster's II New Riverside University Dictionary (1994), the most relevant definition of "establishment" is "a business firm, club, institution, or residence, including its possessions and employees." However, "[i]n determining whether Congress has specifically addressed the question at issue, the court should not confine itself to examining a particular statutory provision in isolation \* \* \*. It is a 'fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'" *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 121 (2000). Other parts of the registration provisions in section 415 of the FD&C Act indicate that Congress only intended businesses to register, and raise a question as to whether Congress intended that private individual residences, even though food is manufactured/processed, packed, or held at such residences, be considered facilities. For instance, a registrant is required to submit "the name and address of each facility at which, and all trade names under which, the registrant conducts business \* \* \*"(21 U.S.C.

350d(a)(2)). Thus it is unclear whether Congress intended all individual private residences at which food is manufactured/processed, packed, or held to be included in the term "facility." Furthermore, the requirement that a facility submit its "name" as well as its "trade names" raises a question as to whether Congress intended "facility" to include private individual residences since it is unlikely that a home would have a name or a trade name. Where the words of the statute are ambiguous, an agency may make a reasonable interpretation of the statute. *Chevron, USA, Inc. v. NRDC, Inc.*, 467 U.S. 837, 842-843 (1984); *Brown & Williamson*, supra, at 132.

Consistent with the language of section 415(a)(2) discussed previously, the agency concludes that interpreting the term "facility" to exclude private individual residences is a reasonable construction for purposes of registration. This interpretation, however, does not necessarily preclude a reasonable construction of other provisions of the FD&C Act to include such residences.

Therefore, in response to these comments, we have revised the interim final rule at 1.227(b) to provide that the definition of facility does not include private residences of individuals. Accordingly, homes that store Girl Scout cookies for distribution, homes in which food is prepared for church bake sales, and homes where individuals temporarily store sales samples or small inventories of products for delivery to rural retailers are not facilities, and therefore, are not subject to registration.

(Comment 8) One commenter requests that FDA clarify whether trans-shippers, who ship products through the United States en route to other countries, are required to register. Another commenter wants FDA to clarify whether it will require registration of foreign facilities that export food to locations outside the mainland United States, such as Hawaii and the Northern Mariana Islands.

(Response) Because the registration requirement only applies to facilities that manufacture/process, pack, or hold food for consumption "in the United States," facilities that manufacture/process, pack, or hold food that is for consumption only in other countries are not required to register. Therefore, manufacturers/processors, packers, or holders of food that is trans-shipped through the United States to other countries for consumption are not required to register. Facilities that export food for consumption in locations that are part of the United States are required to register. Locations are part of the United States if they are