

(Response) The Bioterrorism Act (21 U.S.C. 350d(a)(1)) requires that each domestic and foreign facility be registered. "Facility" is defined as "any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food" (21 U.S.C. 350d(b)(1)). Thus, the plain language of the Bioterrorism Act requires registration to be by individual facility, not by firm. As noted below, FDA will allow a parent company to register all of its facilities; however, each facility must be registered separately and each will receive a separate registration number.

(Comment 40) Some commenters state that FDA should provide a more flexible definition of facility, thereby allowing companies to decide how many buildings to consider a single facility. Some of these commenters question whether two structures under single ownership with different addresses that are physically next to each other, across the street from each other, or around the block from each other, are considered one or two facilities. Other commenters argue that a company may conduct business at more than one address, but may consider all of the locations as part of one operation. For example, an operation could include offsite storage buildings, water pipelines from one area to another, pump-houses, and bulk processing in one location, with finished processing or packaging at another address.

(Response) The Bioterrorism Act (21 U.S.C. 350d(a)(4)) requires that FDA compile and maintain an up-to-date list of registered facilities; this list will serve two purposes. One purpose of the registration database is to provide FDA with information that will permit FDA to respond promptly to a bioterrorist event or other food safety emergency. A second purpose is to provide the agency with a list of facilities for inspection. Because both the agency's emergency response and its inspections are facility specific, it is important for FDA to have particular information about facility location. This need will not be met if a business with multiple locations is registered as a single facility. FDA suggests that one factor for determining whether a business is one or two facilities is through real estate records, because a property line could demonstrate that several buildings are on the same lot, and therefore, are the same facility.

4. Domestic Facility

FDA received no comments on this definition.

5. Foreign Facility

FDA received no comments on this definition.

6. Farm

(Comment 41) Some commenters state that the proposed definition of farm is unduly narrow because it does not exempt farms that engage in activities traditionally performed on farms for nearly all commodities, including farms that cut, trim, wash, grade, mill, wax, size, cool, apply inventory control items (e.g., universal product codes), treat against pests, transport from the fields, transport to storage or processing facilities, mist, treat with water/ice during storage, package, mill, grind, box/wrap for the sole purpose of transport off the farm, and transport from the farm. Some commenters also ask FDA to clarify whether placing produce into netting or bags for retail sale before placing them in cartons is considered "packing."

(Response) In response to these comments and to ensure that FDA is fulfilling Congress's intent to exempt "farms," FDA has revised the definition of farm in the interim final rule (21 CFR 1.227(c)(3)) to state that a farm is a facility in one general location that is devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both, and that washing, trimming outer leaves, and cooling of food are considered part of harvesting. FDA considers several of the activities identified in the comment to be "packing or holding," including sorting, grading, wrapping, or boxing harvested food for the sole purpose of transporting this food off the farm. A farm that performs these activities will not necessarily cease to be a farm and exempt from registration because the definition of farm includes facilities that pack or hold food, provided all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership (21 CFR 1.227(c)(3)(i)). Similarly, FDA considers several of the activities identified in the comment (waxing, milling, grinding, and treating against pests) to be manufacturing/processing. A farm that performs these activities will not necessarily cease to be a farm and exempt from registration because the definition of farm includes facilities that manufacture/process food, provided that all food used in these activities is consumed on that farm or another farm under the same ownership (21 CFR 1.227(c)(3)(ii)). Finally, a farm that transports its products does not cease to be a "farm" within the meaning of 21 CFR 1.227(c)(3) because, as noted earlier

in this document, a transport vehicle is not a "facility" for purposes of this rule if it holds food only in the usual course of its business as a carrier and thus, is not required to register.

(Comment 42) Some commenters request that FDA extend the farm definition to public lands used by harvesters or collectors of wild products, including botanicals. The commenters state that these collectors do not manufacture/process or pack foods, and they hold foods similar to many farms.

(Response) FDA does not believe that this comment requires a change in the farm definition. When wild botanicals are grown and harvested on public land, FDA would consider that location to meet the definition of "farm." However, if those harvesting on public land engage in any activity that takes them outside the "farm" definition, they must register the facilities where they conduct these activities.

(Comment 43) Some commenters note that some farming operations are spread out over several locations within several miles or more of each other and all of these locations are under the same ownership and management. Accordingly, these commenters request that FDA change the farm definition to cover several different locations. Another commenter asks whether two facilities separated by fencing, a wooded area, a body of water, or a road are one or two farms. Other commenters request that FDA amend the farm definition to include the term "contiguous," which appears in the preamble to the proposed rule but not the definition itself.

(Response) FDA does not believe that these comments require a modification of the definition of farm. Each of these establishments, whether considered one farm or many farms, is exempt if it meets the definition of farm. Additionally, the interim final rule provides that establishments that pack or hold food fall within the farm definition if all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership. The interim final rule also considers establishments that manufacture/process food as farms if all food used in such activities is consumed on that farm or another farm under the same ownership.

(Comment 44) Some commenters ask FDA to clarify whether packing and other facilities owned by more than one farm on a partnership or cooperative basis fit within the farm definition.

(Response) The farm definition extends to only those packing or holding facilities that are located on a farm or another farm under the same