

ownership and the facilities are exclusively used to pack or hold food grown or raised on such farm or another farm under the same ownership. A packing shed that packs food grown or raised on several farms under different ownership is not covered by the farm definition and thus, is required to register.

(Comment 45) Some commenters argue that the farm definition should address whether a farm that engages in agriculture on several different properties under separate ownership will be considered a single farm for purposes of registration.

(Response) The definition of a farm provides that a farm must be in one general physical location and under the same ownership. In the situation described by the comment, different properties under separate ownership, if they otherwise meet the definition of farm, would be exempt from registering.

(Comment 46) Some commenters argue that a farmer who owns more than one field or piece of property and is required to register with FDA should be required to register only once, identifying on the registration form the physical location of all areas under that farmer's cultivation.

(Response) Generally, a farm is exempt from registration unless it is a mixed-type facility. A mixed-type facility performs activities of a facility that is both ordinarily required to register and ordinarily exempt. An example of a farm that is a mixed-type facility is a farm that grows oranges and processes them into orange juice for sale to a distributor at the same physical location. However, if the farmer manufactures/processes the oranges into orange juice in a different physical location, the location where the oranges are grown is exempt as a farm and the facility where manufacturing/processing occurs must register. Because registration is by individual facility, the farmer must, if required to register, register each facility separately and obtain a separate registration number for each facility. The effort to register in this situation will be reduced if the farmer registers electronically, because he can register each facility in succession, "auto-filling" each section of the form that repeats the information contained in the previous registration.

(Comment 47) One commenter asks FDA to clarify that the definition of farm applies to foreign, as well as domestic, farms.

(Response) The commenter is correct; the farm definition applies to both domestic and foreign farms. Therefore, foreign farms that satisfy the farm definition are not required to register,

even if they export food directly to the United States. However, if such a foreign farm harvests food and manufactures/processes it before exporting it to the United States, this would be a mixed-type facility that ordinarily must register. However, the foreign facility exemption may apply to this mixed type facility if further manufacturing/processing that is not of a *de minimis* nature occurs after the food leaves the mixed-type facility and before it is exported to the United States.

(Comment 48) One commenter states that the definition of "farm" is circular in § 1.227(c)(3)(ii). The term "farm" includes: * * * (ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

(Response) In the previous excerpt from the "farm" definition, FDA's intent is to describe a certain activity (manufacturing/processing) in which a farm may engage without losing its exemption as a farm, so long as all food manufactured/processed by the farm is consumed on that farm or another farm under the same ownership.

(Comment 49) Several commenters state that FDA's definition of "farm" should be size-neutral, and apply equally to integrated livestock and poultry facilities as long as the activities at such locations are limited to "growing or raising" farm animals for human food, but do not extend to further processing of food-producing animals into meat, milk, or eggs (which occurs at food processing and packing plants and rendering facilities) for subsequent commercial sale for consumption by humans or animals.

(Response) The proposed rule's definition of "farm" had no size limitation, and neither does the interim final rule's definition. FDA agrees that integrated livestock and poultry operations are "farms," as long as these operations are devoted to raising animals for food, the growing of crops, or both, and otherwise engage in only those activities included in the farm definition. FDA considers milking cows and collecting eggs from chickens to be "harvesting" when applied to animals, because these activities are akin to harvesting crops.

(Comment 50) Several commenters ask FDA to clarify whether packing sheds, warehouses, and low temperature storage facilities located on farms are considered part of the farm.

(Response) The interim final rule clarifies the definition of "farm" and provides that an operation that includes on-farm packing and holding of food

grown, raised, or consumed on the farm or on another farm under the same ownership is still a "farm" under § 1.227(c)(3). The rule also provides that an operation that includes on-farm manufacturing/processing of food, where all food is consumed on that farm or another farm under the same ownership, is still a "farm."

(Comment 51) One commenter requests that FDA clarify that greenhouse facilities devoted to growing fruits and vegetables are considered "farms" for purposes of the farm definition. The commenter states that it appears that greenhouse facilities would easily fit within the proposed definition of farm as "[facilities] in one general physical location devoted to the growing of crops * * *", however, FDA does not explicitly state in the proposed rule or preamble to the proposal that greenhouses would be considered farms.

(Response) FDA agrees with the commenter that a greenhouse devoted to the growing of crops is a "farm" under § 1.227(c)(3).

(Comment 52) One commenter, quoting the proposed definition of farm as including "facilities that manufacture/process food, if all food used in such activities is consumed on that farm or another farm under the same ownership," asks FDA to clarify whether on-farm facilities that manufacture/process food sold to a third party would be required to register with FDA.

(Response) An on-farm operation engaging in manufacturing/processing food that is subsequently sold to an off-farm third party is a facility that is required to register with FDA, unless the facility qualifies under another exemption, such as the retail food establishment exemption.

(Comment 53) One commenter asks FDA to clarify whether a farm is required to register if several companies are involved in the farming operation. For example, some farms may perform their own harvesting or employ another company to provide harvesting services.

(Response) Because registration is by facility, a farm operation is not required to register, provided all of the on-farm activities are covered in the farm definition and the farm is under the same ownership. It therefore makes no difference for purposes of registration if different companies perform different services at a facility. The determinative question is whether the facility is manufacturing/processing, packing, or holding food for consumption in the United States and is not subject to an exemption.

(Comment 54) One commenter asks FDA to clarify: (1) Whether a grower of