

processing food are not required to establish and maintain records if another facility further manufactures/processes or packs the food produced at that facility outside the United States.

This exclusion would not apply to facilities if the "further manufacturing/processing" at the subsequent facility is of a de minimis nature, such as adding labeling to a package or adding plastic rings to the outside of beverage bottles to hold them together. In that case, both the facility conducting the de minimis activity and the facility immediately prior to it would be required to register and, therefore, would also be subject to these regulations. FDA seeks comment on the requirement for facilities conducting de minimis activities to keep records. The following are examples of which foreign facilities would be subject to, or excluded from, these regulations based on the activities they perform. As stated previously, the foreign facilities that are subject to these regulations are the same facilities that would be required to register under section 305 of the Bioterrorism Act.

- A foreign facility would be subject to these regulations if it prepares a finished food and places it into packages suitable for sale and distribution in the United States.

- A foreign facility distributing food to food processors outside the United States for further manufacturing/processing before the food is exported for consumption in the United States would not be subject to these regulations, unless the further manufacturing/processing entails adding labeling or other de minimis activity. If the further manufacturing/processing is of a de minimis nature, both the facility conducting the de minimis activity and the facility immediately prior to it would be subject to these regulations.

- The last foreign facility that manufactures/processes an article of food before it is exported to the United States would be subject to these regulations, even if the food subsequently is held or stored at a different facility outside of the United States.

- Facilities located outside the United States that take possession, custody, or control of finished foods for holding, packing, and/or storage prior to export to the United States are subject to these regulations.

Proposed § 1.327(g) provides that persons who manufacture, process, pack, transport, distribute, receive, hold, or import pet food who are not subject to the recordkeeping provisions of the animal proteins prohibited in ruminant feed regulation (21 CFR 589.2000)

would be excluded from the recordkeeping requirements of this proposed rule. However, these entities, like all entities involved in animal food, remain subject to the proposed records access and availability requirements in proposed § 1.361 and § 1.363.

3. What definitions apply to this subpart? (Proposed § 1.328)

Proposed § 1.328 states that the definitions of terms in section 201 of the act (21 U.S.C. 321) apply to such terms when used in this subpart. Section 201 of the act defines various terms that appear throughout the act, including "food" (see section 201(f) of the act). The definitions of such terms apply when we use those terms in these regulations. In addition, proposed § 1.328 defines specific additional terms used in the proposed rule.

Proposed § 1.328 defines "act" as the Federal Food, Drug, and Cosmetic Act.

FDA is proposing in § 1.328 to define "domestic person" consistent with the definition of "State" in section 201(a)(1) of the act. That is, FDA is proposing to define a domestic person as one that is located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

FDA is proposing in § 1.328 to define a "foreign facility" as a facility other than a domestic person that manufactures, processes, packs, or holds food for consumption in the United States.

Proposed § 1.328 defines "farm" as a facility in one general physical location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both. A farm may consist of contiguous parcels of land, ponds located on contiguous parcels of land, or, in the case of netted or penned areas located in large bodies of water, contiguous nets or pens. The term "farm" includes: (a) Facilities that pack or hold food, provided that all food used in such activities is grown or raised on that farm or is consumed on that farm; and (b) 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. "Farm" includes such facilities because they are activities incidental to farming that most farms engage in (e.g., holding and packing of harvested crops). Facilities that engage in manufacturing/processing, packing, or holding of food that is not described in the definition of "farm" are subject to these regulations because such activities are not activities that most farms engage in and are thus not included in the definition of "farm." Some examples of farms include: Apple orchards, hog

farms, dairy farms, feedlots, and aquaculture facilities.

Persons that engage in more than one type of activity may meet the definition of farm as to some of those activities while not meeting the definition of farm as to other activities. Persons that grow crops and raise animals and also manufacture/process food that is sold for consumption off the premises are not farms for purposes of this subpart and are not exempt. For example, a person who grows oranges and manufactures/processes them into orange juice for sale to a distributor would need to keep records under this subpart of both the immediate previous sources and the immediate subsequent recipients of the orange juice. However, establishing and maintaining records of the immediate previous sources would only be required when persons manufacture/process food from ingredients obtained from other sources than that farm.

Similarly, persons who manufacture/process food from ingredients obtained from other sources only meet the definition of farm if all the food used in such activities is consumed on that farm or another farm under the same ownership. If a person combines oranges grown on his farm with oranges obtained from another source, processes them into orange juice on his premises, and consumes all of the orange juice on those premises, he would not need to keep records regarding those oranges. However, if the person sells that orange juice at a roadside stand directly to consumers, that roadside stand would not meet the definition of farm but would fall within the partial retail exclusion provided in proposed § 1.344. Retailers need only keep records identifying the immediate previous source.

Proposed § 1.328 defines "food" as having the meaning given in section 201(f) of the act, which is: "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." FDA also is proposing to include some examples of products that are considered food under section 201(f) of the act. Examples listed in the proposed rule include: Fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals (such as hogs and elk); bakery goods;