

the farm to consumers at a roadside stand.

FDA is proposing to require co-op facilities that manufacture/process, pack, or hold food, and that are not subject to the farm exemption, to register with FDA. Co-ops are organizations formed to perform activities, including manufacturing/processing or packing food, for their members. The product of these activities is distributed to the members or the public. A farm that grows wheat for distribution to co-op members would be exempt from registration, but a processing facility owned by the co-op would be required to register if it is not located on the farm and mills the wheat into flour for consumption by co-op members off the farm.

The definition of farm does not include facilities that contract with multiple farmers to grow crops or raise animals. These facilities may manufacture/process feed and distribute it to the contract farmers for feeding to animals being raised on the farm. FDA is proposing that the facilities that manufacture/process feed for the contract farmers would be required to register. The farms that grow the crops or raise the animals would be exempt from the registration requirement.

e. *Food*. FDA is proposing in § 1.227(c)(4) to define "food" as it is defined in section 201(f) of the act. That definition 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. These examples include, but are not limited to: 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; snack foods; candy; and canned foods. "Substances that migrate into food from food packaging" include immediate food packaging or components of immediate food packaging that are intended for food use. Outer food packaging is not considered a substance that migrates into food."

f. *Holding*. FDA is proposing in § 1.227(c)(5) to define holding as storage of food. The proposed rule gives examples of holding facilities as

including, but not being limited to: Warehouses, cold storage facilities, storage silos, grain elevators, or liquid storage tanks.

g. *Manufacturing/processing*. FDA is proposing in § 1.227(c)(6) to define manufacturing/processing as "making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients." Some examples of manufacturing/processing include, but are not limited to: Cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. FDA is defining manufacturing and processing together because the meanings of the terms overlap. For example, combining two materials into a finished product, such as macaroni and cheese, could be considered manufacturing, processing, or both. Since both manufacturers and processors are required to register with FDA, FDA does not believe it is necessary to distinguish between manufacturing and processing in the proposed rule.

h. *Nonprofit food facility*. FDA is proposing in § 1.227(c)(7) to define a nonprofit food facility as "a charitable entity that prepares, serves, or otherwise provides food to the public." Examples of these facilities include: food banks, soup kitchens, and nonprofit food delivery services. FDA is proposing that in order to qualify as a nonprofit food facility, the entity must be exempt from paying income tax under the U.S. Internal Revenue Code. This requirement serves to ensure that FDA's definition of a nonprofit facility is consistent with that of other agencies of the U.S. Government.

i. *Packing*. FDA is proposing in § 1.227(c)(8) to define packing as "placing, putting, or repacking a food into different containers without making any change to the form of the food." Facilities engaged in packing of food for consumption in the United States must register under the proposed rule, unless exempt.

j. *Port of entry*. For purposes of the proposed rule, FDA is defining "port of entry" as "the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first arrives in the United States." FDA is proposing this definition because the port where the food arrives in the United States may be different than the port where the entry of the article of food is processed for U.S. Customs

purposes, i.e., where the article is "entered." Under U.S. Customs Service statutes, products can be imported into one port, then transported to another port under a custodial bond before a consumption entry is filed. For example, food may be imported into the United States from Canada through Buffalo, NY, but not entered for consumption with U.S. Customs until it reaches St. Louis, MO, several days later. In this example, under FDA's proposed definition, the port of entry is Buffalo, NY.

The registration authority in the Bioterrorism Act is intended to give FDA better tools to deter, prepare for, and respond to bioterrorism. Given this purpose, "port of entry" must be defined as the port of arrival. Allowing food from a facility that has not registered and that is presented for importation into the United States to be shipped around the country and potentially lost to Government control simply is not consistent with the Bioterrorism Act's stated purpose. FDA believes that its ability to protect U.S. consumers from terrorism or other food-related emergencies will be strongest if food can be examined, and if necessary, held at the point where it first arrives in the United States. FDA requests comment on its proposal to define "port of entry" as the port of arrival.

k. *Restaurant*. FDA is proposing in § 1.227(c)(10) to define a restaurant as "a facility that prepares and sells food directly to consumers for immediate consumption." As defined in the rule, some examples of restaurants include, but are not limited to: Cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens. See section III.B.3.c of this document for a discussion of mixed-type facilities, which may include restaurants.

Due to possible ambiguity in the term, "catering facilities", FDA states in the proposed restaurant definition that facilities that provide food to interstate conveyances, such as airplanes, passenger trains, and cruise ships, rather than directly to consumers, are not restaurants. Facilities that provide food to interstate conveyances are not considered restaurants because they do not serve food directly to consumers for immediate consumption. For example, a facility that provides sandwiches to a passenger train for eventual sale to passengers would not be considered a restaurant. However, the snack bar on the train that sells the sandwiches to consumers would be considered a restaurant. FDA has historically