

grapes is covered under the farm definition unless the grower processes these grapes into wine and bottles or packages the wine itself; and (2) whether the grower would be required to register if the grower grows grapes, sends them to a third party who makes wine from them and bottles or packages the wine, and returns the bottled wine to the grower, who then labels the bottles.

(Response) This comment describes an example of a mixed-type facility. In the first example, the grower of the grapes who does not itself process the grapes into wine, would not be required to register its establishment because it is "farm" and is exempt from registration. If the grower's establishment manufactures/processes the grapes into wine and/or bottles or packages it, the establishment is a facility that must register. In the second example, the grower of the grapes would be exempt as a farm; however, labeling the wine after receiving it back from a third party is considered manufacturing/processing. Thus, both the grape grower's labeling facility and the third party's manufacturing/processing facility must register.

(Comment 55) One commenter asks whether cattle feed yards manufacturing feed that is fed onsite to the cattle are required to register.

(Response) The "farm" definition states that "farm" includes "facilities that manufacture/process food, if all of the food used in such activities is consumed on that farm or another farm under the same ownership." Therefore, a cattle feed yard that manufactures/processes feed that is fed only at that feed yard or another farm or feed yard under the same ownership is a "farm" that is exempt from registration. Conversely, a cattle feed yard that manufactures/processes feed that is fed to cattle at another location that is under different ownership would be required to register as a manufacturing/processing facility.

(Comment 56) One commenter quotes FDA's proposed provision for contract facilities, which states:

[t]he 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.

The commenter states:

[d]espite FDA's clarifications on its definition of farm, it does not specify what happens if these same products are later sold outside the farm or if these products are grown, harvested, held, and sold for consumption of any kind outside the farm, thus going to a second owner and facility to serve other purposes (international commerce).

(Response) This comment is not clear regarding "what happens" if products are "later sold outside the farm" or "are grown, harvested, held, and sold for consumption of any kind outside the farm." The "farm" definition covers a facility that grows crops or raises animals for food. If an establishment sells animal feed obtained from a contract facility to a third person, that establishment would be required to register unless it was exempt as a retail food establishment. If the establishment sells the animal feed to, for example, a distributor or another business, it would not fall within the retail exemption and thus, it would be required to register.

(Comment 57) One commenter states that FDA is proposing to exempt farms from registration even if they conduct packing/holding/processing on their premises, as long as they only handle food grown on that farm or another farm under the same ownership, or if they mix feed from outside sources for exclusive use on that farm. However, the commenter asserts that most farmers that pack or process the crops that they grow may sell or pay for the discarded materials, such as sorted-out produce, hulls, etc., to be used as feed. The commenter asks:

[i]s it FDA's intent to include all incidental by-products from processing that go to feed as feed production, therefore triggering the registration requirement? Would the by-products sold/disposed of as feed need to be listed among the items produced by a facility that is registering for other reasons?

(Response) This comment raises several questions regarding the status of farms that produce animal feed or animal feed components. The farm definition in the interim final rule includes farms packing or holding food, if all of the food used in animal feed production activities is grown or raised on that farm or consumed on that farm. Similarly, a farm that manufactures/processes animal feed is not required to register, if all of the food used in such activities is consumed on that farm or another farm under the same ownership. Thus, if a farm manufactures/processes food grown on the farm and feeds by-products of these crops to the farm's own animals, the farm does not need to register. However, if the facility sells the by-products to another entity, it must register, unless it is otherwise exempt.

Any registered facility that is producing such by-products may identify such products in section 11b of the registration form (Form 3537). Because the categories listed in section 11b of the form are not included in § 170.3, they are optional.

7. Food

(Comment 58) The agency received a number of comments regarding the proposed definition of "food" provided in § 1.227(c)(4). Most of these commenters asserted that the definition was too broad and, for a number of reasons, recommended that certain items covered by the proposed definition be excluded from the rule's coverage. In particular, the commenters requested that food packaging and components of food packaging, other food contact articles (such as food processing equipment and components of such equipment, glassware, dishware, cutlery, kitchen appliances), and so-called indirect additives (including those applied to food contact surfaces) be excluded from the interim final rule's definition of "food."

In support of these proposed exclusions, many commenters cited the language in section 415(a)(1) of the FD&C Act requiring registration of facilities that manufacture, process, pack, or hold "food for consumption in the United States," claiming that such language indicates that Congress intended the registration provision to apply only to facilities that manufacture, process, pack or hold "edible food," "traditionally understood as food," or articles that are "intended for consumption." In addition, one commenter cited the reference in section 415(a)(2) of the FD&C Act to the general categories of food provided in § 170.3, which does not include listings for food packaging or other food-contact materials or their components. Several commenters argued that extending registration to facilities that produce food-contact materials was not consistent with the purpose of the Bioterrorism Act and that there was no historical evidence associating foodborne illness with packaging or other food contact material. Finally, some commenters argued that an overly broad definition of "food" would have the effect of diluting the government's resources and thereby hampering the government's opportunity to achieve the protective goals of the Bioterrorism Act.

Other commenters argued that additional items or facilities should be excluded from the registration requirement; those comments are addressed in section III.D of this document.