

directly used as food ingredients without further processing or refining.

Another comment notes that gelatin is used for food, pharmaceutical, and technical applications and seeks assistance with establishing a labeling protocol to distinguish between edible gelatin, pharmaceutical gelatin, and technical gelatin. Some comments state FDA should require prior notice only for food intended for consumption and ask FDA to specify the articles that would be considered "food." The comments also state that some imports have both food and nonfood uses and that prior notice should only be required for imports that will be used as a food. In addition, one comment strongly urges FDA to remove indirect food contact colors (*i.e.*, material used to color food contact material) from the requirements of prior notice. The comment indicates that food contact colors are often prepared in bulk and then shipped to companies that can use these pigments in both food and nonfood applications. The process of manufacturing color pigments could be many steps removed from the process of actually using these products in food packaging. Therefore, the decision to use the product in food may not be made until after the pigment has entered commerce.

(Response) For purposes of the interim final rule, "food" has the definition in section 201(f) of the FD&C Act except that "food contact substances" as defined at section 409(h)(6) of the FD&C Act and "pesticides" as defined at 7 U.S.C. 136(u) are excluded from "food." Under section 201(f) of the FD&C Act, "food" means "articles used for food or drink" (section 201(f)(1)) and articles "used for components of any such article" (section 201(f)(3)). The determination of whether a substance is "food" is not a question of intended use (*Nutrilab v. Schweiker*, 713 F.2d 335, 337 (7th Cir. 1983); *U.S. v. 52 Drums Maple Syrup*, 110 F.2d 914, 915 (2d Cir. 1940); *U.S. v. Technical Egg Products*, 171 F.Supp. 326, 328 (N.D. Ga. 1959)). Courts interpreting the "food" definition in the FD&C Act have held that articles at both ends of the food continuum are "food" for purposes of the FD&C Act (*U.S. v. O.F. Bayer & Co.*, 188 F.2d 555 (2d Cir. 1951); *U.S. v. Tuente Livestock*, 888 F. Supp. 1416 (S.D. Ohio, 1995) (live animals for food use are "food" under the FD&C Act); *U.S. v. Technical Egg Products*, *supra*, 171 F.Supp. at 328 (rotten eggs are "food")). Thus, FDA believes that an item may be food even if the food is not yet in the form in which it will be used for food. FDA will consider a product as one that will be used for food if any of the persons

involved in importing or offering the product for import (*e.g.*, submitter, transmitter, manufacturer, grower, shipper, importer, owner, or ultimate consignee) reasonably believes that the substance is reasonably expected to be directed to a food use.

If the substance can be used in some applications that make the substance "food" and some that do not, the same principles apply. With respect to gelatin and other substances that may exist in multiple grades, including food grade, FDA will consider an article one that will be used for food if any of the persons involved in importing or offering the product for import (*e.g.*, submitter, transmitter, manufacturer, grower, shipper, importer, owner, or ultimate consignee) reasonably believes that the substance is reasonably expected to be directed to a food use.

Finally, as set forth previously, the interim final rule excludes food contact substances from the definition of "food." Thus, when substances to color food contact substances or their components are imported, they are not subject to prior notice. However, colors used in such substances are still subject to regulation as food under section 201(f) of the FD&C Act for purposes of other provisions of the FD&C Act.

(Interim final rule) In the interim final rule (§ 1.276(b)(5)), "food" has the meaning given in section 201(f) of the FD&C Act, except for purposes of this rule, it does not include "food contact substances" as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)) or "pesticides" as defined in 7 U.S.C. 136(u). Examples of food include fruits, vegetables, fish (including seafood), dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

#### 7. Grower (§ 1.276(b)(6))

Although the statute and proposed rule used the term grower, the proposed rule did not define the term. However, FDA solicited comments on whether the term "grower" includes a harvester or collector of wild products, *e.g.*, some fish and botanicals.

(Comments) A comment states that although harvesters or collectors of wild botanicals do not grow botanicals and should be differentiated from growers for certain purposes, these can be included in the term "grower"

consistent with the congressional intent in § 307 of the Bioterrorism Act to identify the direct source of the agricultural raw commodity.

(Response and interim final rule) FDA agrees. Accordingly, we have defined "grower" to mean a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both.

#### 8. International Mail (§ 1.276(b)(6))

Although the proposed rule applied to food imported or offered for import by mail, see, *e.g.*, 68 FR 5436, the proposed rule did not define "international mail."

(Comments) There were no comments received concerning any definition of "international mail."

(Response and interim final rule) The interim final rule imposes slightly different requirements relating to prior notice for food arriving by international mail. Thus, FDA determined that a definition of "international mail" would be helpful. The interim final rule defines "international mail" to mean "foreign national mail services." It also expressly excludes express carriers, express consignment operators, or other private delivery services from this definition.

#### 9. No Longer In Its Natural State (§ 1.276(b)(8))

Section 801(m)(1) of the FD&C Act requires that the identity of the manufacturer be submitted as part of a prior notice. However, the proposed rule did not define "manufacturer" or address what constituted the product of a manufacturer versus the product of a grower.

(Comments) Comments raised questions concerning when a manufacturer must be identified for an article of food.

(Response) These comments are discussed under the heading "What Information Must be in a Prior Notice." However, as a result of the comments, we determined that a definition of when food would be "no longer in its natural state" would be helpful to clarify when the identity of a manufacturer versus the identity of a grower must be provided in a prior notice.

(Interim final rule) The interim final rule (§ 1.276(b)(8)), defines the term "no longer in its natural state" to mean that an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Examples of activities that render food no longer in its natural state are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling,