

a Territory, the FDA Country of Production is the United States.

6. Food (§ 1.276(b)(5))

The proposed rule defined “food” as having the meaning given in section 201(f) of the FD&C Act. The proposed rule provided examples of food including:

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.

a. Food packaging and other food contact substances.

(Comments) We received several comments on the subject of food contact substances, including packaging. The comments ask that FDA clarify the definition of “food” because the proposed rule included as examples of food not only those items traditionally understood as food, but also items that come into contact with and may migrate into food during processing or packaging. In particular, the comments ask 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 final rule’s definition of “food.”

In support, the comments contend the legislative history of the prior notice provisions establish that Congress did not intend to apply prior notice requirements to these substances even though they can be food within the meaning of section 201(f) of the FD&C Act. In addition, some point to language in section 415 of the FD&C Act (21 U.S.C. 350d) relating to registration and language in section 414(b) of the FD&C Act relating to recordkeeping (21 U.S.C. 350c). Finally, some comments argued that an overly broad definition of “food” would dilute the government’s resources, thereby hampering the government’s opportunity to achieve the protective goals of the Bioterrorism Act.

(Response) We expressly included food packaging and other food contact materials in the proposed definition, with the result that prior notice would have been required for food packaging and other food contact materials and their components (see 68 FR 5428 at

5430). The breadth of the proposed definition of “food” was based on both the statutory definition in section 201(f)(3) of the FD&C Act, which defines articles used as components of food as “food,” as well as the case law interpreting the definition, including *Natick Paperboard v. Weinberger*, 525 F.2d 1103 (1st Cir. 1975) (paperboard containing PCBs intended for food use is adulterated food; *U.S. v. Articles of food * * * 688 Cases * * * of Pottery (Cathy Rose)*, 370 F. Supp. 371 (E.D. Mi. 1974) (ceramic pottery that leaches lead is adulterated food).

The comments on food contact substances raise the question of what Congress intended “food” to mean for purposes of prior notice. In construing the prior notice provision of the Bioterrorism Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented? (“*Chevron* step one”) *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842 (1984). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue (*Young v. Community Nutrition Institute*, 476 U.S. 974, 980 (1986)). If Congress has spoken directly and plainly, the agency must implement Congress’s unambiguously expressed intent (*Chevron*, 467 U.S. at 842–843). If, however, the Bioterrorism Act is silent or ambiguous as to the meaning of “food,” FDA may define “food” in a reasonable fashion (“*Chevron* step two”); *Chevron*, 467 U.S. at 842–843; *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000)).

The agency has determined that, in enacting section 801(m) of the FD&C Act, Congress did not speak directly and precisely to the meaning of “food.” As noted, the FD&C Act has a definition of “food” at section 201(f). It may be a reasonable assumption that, when the term “food” is used in the FD&C Act, section 201(f) applies. However, although there may be “a natural presumption that identical words used in different parts of the same act are intended to have the same meaning [citation omitted], * * * the presumption is not rigid * * *.” (*Atlantic Cleaners & Dyers, Inc. v. U.S.*, 286 U.S. 427, 433 (1932); (accord: *U.S. v. Cleveland Indians Baseball Co.*, 532 U.S. 200, 213 (2000)). Thus, the same word may be given different meanings, even in the same statute, if Congress intended different interpretations or if such different interpretations are reasonable (at step 2) (*Atlantic Cleaners & Dryers, Inc.*, *supra*).

Even before the Bioterrorism Act amendments, the term “food” was not

defined identically throughout the FD&C Act. For example, in construing the parenthetical “(other than food)” in section 201(g)(1)(C) of the FD&C Act, the Seventh Circuit Court noted that Congress meant to exclude only “articles used by people in the ordinary way that most people use food—primarily for taste, aroma, or nutritive value” and not all substances defined as food by section 201(f) (*Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983)). Similarly, section 409(h)(6) of the FD&C Act defines a “food contact substance” as “any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food” (emphasis added). This definition makes sense only if “food” in this context excludes materials that contact food because components of food contact materials are plainly intended to have a technical effect in such materials.²

Thus, in this larger statutory context, FDA has evaluated section 801(m) of the FD&C Act to determine whether the meaning of the word “food” is ambiguous. In conducting this *Chevron* step one analysis, all of the traditional tools of statutory interpretation are available to determine whether the language Congress used is ambiguous (*Pharmaceutical Research & Manufacturers of America v. Thompson*, 251 F.3d 219, 224 (D.C. Cir. 2001)). Beginning with the language of the statute, in section 801(m) of the FD&C Act, “food” is used to describe which subset of FDA-regulated articles are subject to prior notice:

In the case of an article of food that is being imported or offered for import into the United States, the Secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling such article to be inspected at ports of entry into the United States, the submission to the Secretary of a notice * * * (emphasis added).

The Bioterrorism Act is silent as to the meaning of “food.” Congress did not specify whether it intended the definition in section 201(f) of the FD&C Act to apply, one of the other

² FDA’s long-standing interpretation of the FD&C Act’s definition of color additive, section 201(t), is an additional example of where “food” is used more narrowly than as defined in section 201(f). A color additive is defined in section 201(t) of the FD&C Act as a substance that “when applied to a food * * * is capable * * * of imparting color thereto * * *.” The agency’s food additive regulations distinguish between color additives and “colorants,” the latter being used to impart color to a food-contact material (21 CFR 178.3297(a); see also 21 CFR 70.3(f)). Thus, “food” as it appears in the statutory definition of color additive, necessarily excludes food contact materials.