

Several commenters favor inclusion of packaging and its components. Some commenters point out that food packaging and components are “food” under section 201(f) of the FD&C Act. Some of these commenters suggest that FDA should require facilities currently manufacturing substances subject to approval under section 409 of the act to register, and FDA should clarify the definition at § 1.227(c)(4), and consider outer packaging food.

(Response) Relying on the act’s definition of “food” in section 201(f), the proposed rule defined “food” as follows:

Food has the meaning given in section 201(f) of the act. Examples of food 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, bakery goods, snack foods, candy, and canned foods (emphasis added).

Thus, food packaging and other food contact materials were expressly included as examples of “food” in the proposed definition, with the result that, under the rule as proposed, facilities that manufacture/process, pack, or hold food packaging, food-contact materials, or their components would have been required to register. (See 68 FR 5378 at 5382). 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,” and the case law interpreting the definition, including *Natick Paperboard v. Weinberger*, 525 F.2d 1103 (1st Circuit 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 in terms of registration of facilities that manufacture, process, pack, or hold “food.” In construing the registration 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 415, 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 different interpretations are reasonable (at “*Chevron* Step two.”). *Atlantic Cleaners & Dyers, Inc.*, *supra*.

Even before the Bioterrorism Act amendments, the term “food” was not given an identical meaning throughout the FD&C Act. For example, in construing the parenthetical “(other than food)” in section 201(g)(1)(C), the seventh circuit 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.¹

¹ FDA’s long-standing interpretation of the FD&C Act’s definition of color additive, section 201(t), is

Thus, in this larger statutory context, FDA has evaluated section 415 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 415(a)(1), “food” is used to describe who must register: “The Secretary shall by regulation require that any facility engaged in manufacturing, processing, packing, or holding *food for consumption in the United States* to be registered with the Secretary (emphasis added).” The Bioterrorism Act is silent as to the meaning of “food.” Furthermore, the prepositional phrase “for consumption in the United States” creates an ambiguity because it could be read to suggest that “food” within the context of the section 415 registration requirement only refers to food that is ordinarily thought of as “consumed.” By modifying the term “food” by the prepositional phrase “for consumption in the United States,” Congress apparently intended to limit the term “food” to something less than the broad definition in section 201(f). Although “consume” has multiple meanings, most relevant in this context is “to eat or drink up; ingest.” *Webster’s II New Riverside University Dictionary* (1994). Emphasizing the word “consumption” could appear to limit “food” to those items commonly eaten primarily for taste, aroma, or nutritive value. *Nutrilab v. Schweiker, supra* at 338.

Where, as here, the statutory language on its face does not clearly establish Congress’s intent, it is appropriate to consider not only the particular statutory language at issue, but also the language and design of the statute as a whole. *Martini v. Federal Nat’l Mortgage Association*, 178 F.3d 1336, 1345 (D.C. Cir. 1999), citing *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281 (1988). Indeed, the analysis should not be confined to the specific provision in isolation because the meaning or ambiguity of a term may

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) 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.