

be evident only when considered in a larger context. *FDA v. Brown & Williamson Tobacco Corp.*, *supra* at 132 (2000).

Consistent with this instruction, FDA has considered other parts of the registration provision in assessing whether the meaning of “food” in section 415(a)(1) is ambiguous. In particular, FDA has considered section 415(b)(1). In defining “facility” for purposes of section 415, Congress expressly exempted “farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer \* \* \*.” These exemptions do not make clear whether Congress intended them to cover only food that is ordinarily eaten at some point by consumers primarily for taste, aroma, or nutritive value or whether, for example, a retail food establishment could include retailers of food contact materials, such as retail cookware stores.

The legislative history of section 415 also supports the conclusion that Congress did not speak directly to the meaning of “food” in that Bioterrorism Act provision. Such history is appropriately consulted at *Chevron* step one. *Atherton v. FDIC*, 519 U.S. 213, 228–29 (1997). In particular, the Conference Report to H.R. 3448, which became the Bioterrorism Act, explains what Congress intended by “retail food establishments,” which is used to create an exemption from registration:

The Managers intend that, for the purposes of this section, the term “retail food establishments” includes establishments that store, prepare, package, serve, or otherwise provide articles of food directly to the retail consumer for human consumption, such as grocery stores, convenience stores, cafeterias, lunch rooms, food stands, saloons, taverns, bars, lounges, catering or vending facilities, or other similar establishments that provide food directly to a retail consumer.

H.R. Conf. Rep. No. 481, 107th Cong., 2d Sess., 133 (2002).

Similarly, the Conference Report notes that the term “non-profit food establishments” includes not-for-profit establishments in which food is prepared for, or served directly to the consumer, such as food banks, soup kitchens, homebound food delivery services, or other similar charitable organizations that provide food or meals for human consumption.” (*Id.* at 133–34.) Notably, the examples provided by Congress for both types of exempt food establishments are not those that generally sell or distribute food contact materials. Accordingly, the legislative history of section 415 creates additional ambiguity as to the meaning of “food.”

Finally, a review of section 307 of the Bioterrorism Act (the prior notice of food imports provision) and its legislative history confirms that the meaning of the word “food” when used in the Bioterrorism Act, including section 415, is ambiguous. The Bioterrorism Act’s registration provision is one piece of several enacted by Congress to enhance the safety of the U.S. food supply. Registration works in concert with prior notice (section 307 of the Bioterrorism Act). This is reflected in section 305(c) of the Bioterrorism Act, which requires that food from an unregistered facility be held at the port when offered for import. Thus, this provision and its legislative history are of particular relevance in determining whether “food” is ambiguous in the registration provision. The legislative history of section 307 of the Bioterrorism Act supports the ambiguity of the term “food” in the Bioterrorism Act. For example, the Conference Report states that the prior notice provision is to be construed not to apply to “packaging materials if, at the time of importation, such materials will not be used for or in contact with food \* \* \*.” (See H.R. Conf. Rep. No. 481, 107th Cong., 2d Sess., 136 (2002).) This statement could be read to mean that the term “food” does not include packaging or other materials that contact food.

Having concluded that the meaning of “food” in section 415(a)(1) is ambiguous, FDA has considered how to define the term so as to achieve a “permissible construction” of the registration provision. *Chevron, USA, Inc. v. NRDC, Inc.*, *supra* at 843. In conducting this *Chevron* step two analysis, the agency has considered the same information evaluated at step one of the analysis. *Bell Atlantic Telephone Co. v. FCC*, 131 F. 3d 1044, 1049 (D.C. Cir. 1997); *Chevron U.S.A., Inc. v. FERC*, 193 F. Supp. 2d 54, 68 (D.D.C. 2002). FDA has determined that it is permissible, for purposes of the registration provision, to exclude food contact materials from the definition of “food.”

Excluding food-contact materials (including food packaging) is consistent with the statutory phrase, “food for consumption”, section 415(a)(1), in that foods that are “consumed” are generally those intentionally eaten for their taste, aroma, or nutritive value. In addition, excluding food contact materials from “food” in this regulation is consistent with the exemptions in section 415(b)(1), as well as the legislative history of section 415, in that the establishments exempted by statute and the entities used as examples of retail and nonprofit food establishments are

those that sell, distribute, or otherwise provide what is considered food in the conventional sense and, generally speaking, are not purveyors of food contact articles. Finally, restricting “food” to substances other than food-contact materials is consistent with the legislative history of the prior notice provision of the Bioterrorism Act, a provision linked to the registration provision.

As discussed in responses to comments 64 and 65, FDA has also interpreted “food” for purposes of section 415 to exclude pesticides as defined in FIFRA (7 U.S.C. 136(u)). Accordingly, for the reasons discussed in response to this comment and comments 64 and 65, FDA has determined that a reasonable interpretation of “food” for purposes of section 415 is as follows. Section 1.227(b)(4) of this interim final rule has been revised to provide:

Food has the meaning given in section 201(f) of the act, (i) except for purposes of this subpart, it does not include: (A) food contact substances as defined in section 49(h)(6) of the act (21 U.S.C. 348 (h)(6)); or (B) pesticides as defined in 7 U.S.C. 136(u). (ii) Examples of food include fruits, vegetables, fish, 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.

(Comment 59) One commenter asks FDA to address the foreign facility exemption as it applies to “products that migrate into food from food packaging and other articles that contact food.”

(Response) Because the interim final rule excludes food contact substances from the definition of “food,” establishments that manufacture/process, pack, or hold food contact materials or components of such materials are not required to register, unless these establishments also manufacture/process, pack, or hold “food” as defined in § 1.227(b)(4).

(Comment 60) A commenter asks whether water collection and distribution facilities are required to register as food facilities if the owner or operator of such facility knows that the water is to be used as a food ingredient. The same commenter asks whether community water systems that supply water to bottled water facilities or to bottled water sources must register.

(Response) FDA has determined that nonbottled drinking water collection and distribution organizations and their