

possibilities noted above, or another meaning. 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 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 Bioterrorism Act in assessing whether the meaning of "food" in section 801(m) of the FD&C Act is ambiguous. In particular, FDA has considered the language of section 415 of the FD&C Act. 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 is designed to work in concert with prior notice. This is reflected in the Bioterrorism Act's amendment of section 801 of the FD&C Act to provide that food from an unregistered foreign facility be held at the port when imported or offered for import (section 801(l) of the FD&C Act). The information provided by registration will allow FDA to cross-check prior notice submissions against registration data to confirm the identity of manufacturers and others who are required to register. Furthermore, the information provided by prior notice submissions can serve as a cross-check as to whether firms are registered as required and have been providing the necessary updates.

As explained in the preamble to the interim final registration rule published elsewhere in this issue of the **Federal Register**, FDA has concluded that the meaning of the term "food" in section 415 of the FD&C Act is ambiguous. First, the use, in section 415(a)(1) of the FD&C Act, of the phrase "for consumption" after the word "food" 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," Congress apparently intended to limit the term "food" to something less than the broad definition in section 201(f) of the FD&C Act. In addition, in section 415(b)(1) of the FD&C Act, when 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 of the FD&C Act 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 Conf. Rept. 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. Conf. Rept. No. 481, 107th Cong., 2d Sess., 133 (2002)). Similarly, the Conf. Rept. 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 of the FD&C Act creates additional ambiguity as to the meaning of "food."

This ambiguity in the word "food" is further underscored by the legislative history of section 801(m) of the FD&C Act. For example, the Conf. Rept. 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. Conf. Rept. No. 481, 107th Cong., 2d Sess., 136 (2002)). This statement implies that Congress was not relying on the

definition of food in section 201(f) of the FD&C Act. For example, the 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 801(m) of the FD&C Act is ambiguous, FDA has considered how to define the term to achieve a "permissible construction" of the prior notice 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 prior notice provision, to exclude food contact materials from the definition of "food."

Restricting "food" to substances other than food contact materials is consistent with the legislative history of the prior notice provision relating to food packaging and other food contact substances. In addition, it is consistent with the "food for consumption" language in section 415(a)(1) (FD&C Act) of the registration provision. That is, foods that are "consumed" are generally those 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) of the FD&C Act, as well as the legislative history of section 415.

As discussed in the following paragraphs in responses to other comments, FDA has also interpreted "food" for purposes of section 801(m) of the FD&C Act to exclude pesticides as that term is defined under 7 U.S.C. 136(u). Accordingly, FDA has determined that a reasonable interpretation of "food" for purposes of section 801(m) of the FD&C Act is as follows and has revised § 1.276(b)(5) of this interim final rule to provide:

Food has the meaning given in section 201(f) of the act, except for purposes of this subpart, 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.