

structures should not be included in the definition of "facility" for purposes of registration. Under section 305(a) of the Bioterrorism Act, the term "facility" includes "any factory, warehouse, or establishment." Congress did not specify any definitions for these terms. According to Webster's II New Riverside University Dictionary (1994), the most relevant definition of "establishment" is "a business firm, club, institution, or residence, including its possessions and employees." Where, as here, the statutory language on its face does not clearly establish Congressional intent, it is appropriate also to consider other language in the section, the language and design of the statute as a whole, and the larger context to determine if the term is ambiguous. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000); *Martini v. Federal Nat'l Mortgage Ass'n*, 178 F.3d 1336, 1345 (D.C. Cir. 1999), citing *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281 (1988).

Traditionally, the Environmental Protection Agency (EPA) has exercised a primary role in the regulation of public water systems (see 44 FR 42775, July 20, 1979). Under the Safe Drinking Water Act (42 U.S.C. 300(f) *et seq.*) (SDWA), EPA regulates public water systems, which are water systems that have at least 15 service connections or serve 25 people per day for 60 days of the year. In addition, Title IV of the Bioterrorism Act creates an extensive scheme for protecting from bioterrorism threats community water systems serving over 3,300 persons. Title IV amends the SDWA to require that such community water systems submit to EPA vulnerability assessments of their facilities and emergency response plans to deal with the possibility of a bioterrorist attack. EPA is authorized to provide funds to community water systems to address critical security enhancements and significant public health threats.

FDA believes that the language and design of the Bioterrorism Act, which in Title IV lays out strategies under EPA's authority for protecting the safety and supply of public drinking water, creates ambiguity about whether Congress intended to require drinking water facilities to register with FDA as food facilities. The traditional EPA role in regulating public water systems, as established by federal legislation and implemented by Federal agencies, also creates ambiguity about Congressional intent to include drinking water facilities within the scope of FDA's food registration scheme.

Based on EPA's primacy in regulating public water systems and on the Bioterrorism Act scheme for water

systems in Title IV, FDA concludes that it is reasonable to interpret the term "facility" to exclude nonbottled drinking water collection and distribution establishments, such as community water systems. Therefore, FDA has revised § 1.227(b)(2) to exclude these nonbottled drinking water establishments from the definition of "facility."

Bottled water, on the other hand, has traditionally been regulated by FDA (see 21 U.S.C. 349, 21 CFR parts 129, 165). Moreover, Title IV of the Bioterrorism Act does not address bottled water issues, but only public drinking water systems. Therefore, FDA believes it is reasonable to include establishments that manufacture/process, pack, or hold bottled water in the definition of "facility."

FDA also has primary responsibility for drinking water that is used in the manufacturing/processing of food that is not bottled water. Thus, once drinking water enters a facility where it is used in food manufacturing/processing, the water is regulated by FDA. Because such facilities are food facilities in the first place, they already are required to register with FDA without regard to the water source.

(Comment 61) Several commenters asked whether facilities that produce water coolers, ozone equipment, carbon dioxide, water storage silos, plastic resins, or chlorine must register with FDA.

(Response) Water coolers, ozone equipment, water storage silos, and plastic resins are food-contact substances (section 409(h)(6) of the FD&C Act) and therefore, facilities that manufacture/process, pack, or hold such items are not required to register because these items are not "food" as defined in this regulation. In contrast, carbon dioxide, if used to make carbonated beverages or to aerate food, is a component of food (section 201(f)(3) of the FD&C Act) that is intended to have a technical effect in the food and therefore, is "food" as defined in this interim final rule. Similarly, chlorine, if used in bottled water, is also a component of food (section 201(f)(3) of the FD&C Act) that is intended to have a technical effect in the food and therefore, is "food" as defined in this interim final rule. Accordingly, facilities that manufacture/process, pack, or hold carbon dioxide or chlorine that will be used in food products must register. Please see the response to comment 62, which addresses multiuse substances.

(Comment 62) Commenters suggest that foreign facilities that process or refine vegetable oils not intended for direct inclusion in food or animal feed

should be exempt from registration. These commenters argue that where bulk ingredients have both food and non-food uses, the standard for registration should be whether the commodity has been sufficiently refined to be directly added to food.

(Response) This interim final rule requires that any domestic facility that manufactures/processes, packs, or holds "food" must be registered unless the facility satisfies one of the exemptions in § 1.226. Foreign facilities are subject to the same registration requirement except that a manufacturer/process or is not required to be registered if a subsequent facility outside the United States performs further manufacturing/processing of more than a *de minimis* nature. 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" (section 409(h)(6)) and "pesticides" (7 U.S.C. 136(u)) are excluded from "food." Under section 201(f), "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. Technical Egg Products*, 171 F.Supp. 326, 328 (N.D. Ga. 1959); *U.S. v. 52 Drums Maple Syrup*, 110 F.2d 914, 915 (2d Cir. 1940). Courts interpreting the "food" definition in the act have held that articles at both ends of the food continuum are "food" for purposes of the FD&C Act. *United States 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 a facility that manufactures/processes, packs, or holds food must be registered (unless subject to one of the exemptions in § 1.226) 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 the owner, operator, or agent in charge of the facility reasonably believes that the substance is reasonably expected to be directed to a food use. In the case of vegetable oil that is not yet food grade, FDA believes that a facility that manufactures/processes, packs, or holds such oil must be registered (assuming the facility does not qualify for an exemption in § 1.226) if the owner, operator, or agent in charge reasonably believes that oil manufactured/processed, packed, or held at the facility