

the submitter and transmitter. FDA notes that all messages sent via the FDA PN System Interface will be sent to the transmitter. If prior notice is submitted via ABI/ACS, all messaging goes to the customs broker or self-filer via ABI/ACS.

(Interim final rule) The interim final rule (§ 1.276(b)(14)), defines “you” as the person submitting the prior notice (the “submitter”) or the person transmitting prior notice information on behalf of the submitter (the “transmitter”).

13. Summary of the Interim Final Rule

The interim final rule defines the following terms:

- The act;
- Calendar day;
- Country from which the article originates;
- Country from which the article is shipped;
- FDA Country of Production;
- Food;
- Grower;
- International mail;
- No Longer in Its Natural State;
- Port of arrival;
- Port of entry;
- Registration Number;
- Shipper;
- United States; and
- You.

D. “What Is the Scope of This Subpart?” (Section 1.277 Proposed as § 1.276)

FDA proposed that the prior notice requirements apply to food for humans and other animals that is imported or offered for import into the United States. The proposed rule specified that this included food that is imported or offered for import into U.S. FTZs, for consumption, storage, immediate export from the port of entry, transshipment through the United States to another country, or import for export. The proposed rule said that prior notice did not apply to food carried by an individual in that individual’s personal baggage for that individual’s personal use, meat food products, poultry products, and egg products that are subject to the exclusive jurisdiction of USDA.

(Comments) Some comments state that the prior notice requirements should not apply to food that is brought across the U.S. border but not for consumption in the United States. In particular, the comments focus on food exported from the port of arrival, food imported for transshipment and export from another port, and food imported for further processing and export. The comments argue that Congress did not envision that the prior notice

requirements would cause importers to give notice of food not for consumption within the United States and that notice of such food would not give FDA any useful or actionable information. One comment states that the Bioterrorism Act repeatedly refers to “offered for import into the United States” and concludes, based on this phrase, that prior notice should apply only to food for consumption by the citizens of the United States. One comment points to statutory language that stipulates “for human and animal consumption.” Based on this language, the comment argues that FDA would exceed its statutory authority by requiring prior notice for shipments not intended for consumption within the United States. Another comment states that prior notice should not apply to food of U.S. origin, especially if it was simply transshipped through another country then “re-imported” into the United States.

(Response) These comments on scope raise the question of what Congress intended the phrase “imported or offered for import into the United States” to mean for purposes of section 801(m) of the FD&C Act. 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 “imported or offered for import into the United States,” FDA may interpret the phrase 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 “imported or offered for import into the United States.” For the reasons in the following paragraphs, FDA has determined that, for purposes of section 801(m) of the FD&C Act, the phrase “imported or offered for import into the United States” can reasonably be interpreted to apply to articles that are brought into the United States for consumption in the United States, for transshipment

through the United States and export to another country, for further processing in the United States and export, and articles of U.S. origin that are “re-imported” back into the United States. We have also determined that the phrase “imported or offered for import into the United States” can reasonably be interpreted to exclude articles that are brought to the United States for the purpose of being exported without ever leaving the port of arrival until export.

Neither the Bioterrorism Act nor the FD&C Act defines this phrase. Moreover, courts that have considered the meaning of “import” or similar terms in other statutes have not always arrived at the same conclusions: Sometimes “import” means simply to bring in, but other times “import” means to bring in with the intent to unlade or enter (*Procter & Gamble Manufacturing Co. v. U.S.*, 19 C.C.P.A. 415, 422 (C.C.P.A. 1932) (to import “may mean to bring goods within the jurisdictional limits of the country * * *; or it may mean the time when it is withdrawn from the warehouse and enters the commerce of the country”); compare, e.g., *Canton R. Co. v. Rogan*, 340 U.S. 511, 514–15 (1951) (“to import means to bring into the country”); *Brown v. Maryland*, 25 U.S. 419, 426, 437–38 (1827) (“What, then, are ‘imports’? The lexicon informs us, they are ‘things imported.’ If we appeal to usage for the meaning of the word, we shall receive the same answer. They are the articles themselves which are brought into the country.”) with *United States v. Watches, Watch Parts, Calculators & Misc. Parts*, 692 F. Supp. 1317, 1321 (S.D. Fla. 1988); *United States v. Commodities Export Co.*, 14 C.I.T. 166, 169–70 (Ct. Int’l Trade 1990) (“once goods are within the jurisdictional limits of the United States with the intent to discharge, they are imports under this definition”); *United States v. Boshell*, 14 U.S. Cust. App. 273, 275–77 (Ct. Cust. App. 1922) (“The common ordinary meaning of the word ‘import’ is to bring in. Imported merchandise is merchandise that has been brought within the limits of a port of entry from a foreign country with intention to unlade, and the word ‘importation’ as used in tariff statutes, unless otherwise limited, means merchandise to which that condition or status has attached”).

In considering what is a reasonable interpretation, we considered the language and purpose of section 801(m) of the FD&C Act, as well as the other provisions of the Bioterrorism Act and section 801 of the FD&C Act. Section 801(m)(1) of the FD&C Act states, “In the case of an article of food that is