

The FDA product code is a unique numeric code currently used by FDA and customs brokers and self-filers to describe food products, as well as other products regulated by FDA.

(Comments) The majority of comments emphasize the need to use the existing and familiar HTS coding structure for product reporting instead of the FDA product code. Some comments ask FDA to update product codes with current food items, such as botanicals, additives, food contact substances, etc. Some comments state that the importer might not know the exact product they will be receiving until the product is shipped and, therefore, may not know the FDA product code by noon of the day before arrival. One comment recommends clarification of what the FDA product codes are and where they can be found. In addition, another comment was not able to access the FDA product database and urges FDA to correct this situation. Finally, one comment suggests that FDA eliminate this data element.

(Response) The FDA product code is an existing 7-character code that describes a product for FDA purposes by industry type and class, packaging, process, and specific distinctive character. For example, canned tuna is covered by FDA Product Code, 16AEE45. "16A" describes the product as vertebrate fish, the first "E" describes the metal package, the second "E" describes a commercially sterile process, and "45" describes the fish as tuna.

Although the HTS codes are currently utilized by CBP and FDA to identify generally which imports are subject to an FDA admissibility review, these codes are often not sufficient to specifically identify a product for FDA decisionmaking. For example, in many cases, the tariff code does not describe how the product was processed (e.g., commercially sterile or shelf-stable) or how the product is packaged. For example, milk and cream are included in the same codes. These codes differentiate milk and cream for fat content, but do not indicate the process (pasteurization and refrigerated or commercially sterile) or packaging (cardboard carton, plastic bottle, or shelf-stable package). Thus, several products that FDA considers different from each other (because these differences affect the potential safety of the food) may be combined under one tariff number HTS code.

Both the HTS code and the FDA product code are currently required on FDA-regulated products and are submitted through the ABI/ACS interface. Therefore, the FDA product

code is familiar to most of those who will be transmitting prior notice. The FDA product code is currently available via the Internet at <http://www.accessdata.fda.gov/scripts/ora/pcb/pcb.htm> as a "buildable" code.

FDA is requiring submission of this data element for prior notice as an integral part of the identity of the article. Risk-based screening criteria can be very specific. Therefore, the specificity provided by the FDA product code is necessary. In addition, the timing requirements for submitting prior notice have been decreased significantly. Therefore, the issue of adequately identifying the product code at the time of submission has been reduced to the extent possible, given the mandate from Congress to require prior notice.

The FDA PN System Interface has a menu-driven FDA product code builder that enables the submitter to appropriately describe the product. The FDA PN System Interface is also designed to allow a submitter who already knows the product code to enter it directly.

FDA routinely and continually updates the FDA product codes and product code builder electronic files to include more specific food items, such as additives, exotic produce, and some botanicals. FDA intends to issue guidance before the effective date of this rule that will provide the flagged HTS codes and FDA product codes identifying foods for which prior notice is required. This guidance will be posted at <http://www.fda.gov>, see "prior notice."

(Interim final rule) Section 1.281(a)(5)(i) requires the complete FDA product identity code for the article of food covered by a prior notice. The interim final rule allows for submission of product identity information through ABI/ACS. Customs brokers or self-filers, using ABI/ACS, currently may use the FDA product code builder, which is available to the public on the FDA Web site, to identify the appropriate product code. Those submitting prior notice through the FDA PN System Interface will be able to access a FDA product code builder specific to those food covered by the prior notice requirement.

c. *Common, usual or market name* (§ 1.281(a)(5)(ii) Proposed as § 1.288(e)(1)(ii)). FDA proposed to require the submission of the common or usual or market name of the article of food as an element of the identity of the product (§ 1.288(e)(1)(ii)). The customs broker or self-filer currently submits the common or usual or market name to ABI/ACS when entry is made, and it subsequently is transmitted to

OASIS for each entry line, e.g., article of food.

(Comments) One comment is concerned that the appropriate name of fresh produce or fishery products may not be known at the time of shipment.

(Response) This information is necessary to confirm the accuracy of the product code and we have thus retained the requirement to submit it in the interim final rule. The timing requirements for submitting prior notice have been decreased significantly. Therefore, the issue of adequately identifying fresh produce and "catch of the day" at the time of submission has been reduced to the extent possible, given the mandate from Congress to require prior notice.

(Interim final rule) Section 1.281(a)(5)(ii) requires that the submitter supply the common or usual or market name in a prior notice. (See 21 CFR 102.5 for additional information about common or usual names.)

d. *Trade or brand name* (Proposed § 1.288(e)(1)(iii)). FDA proposed to require the submission of the trade or brand name of the article of food, if it is different than the common or usual or market name, as an element of the identity of the product (§ 1.288(e)(1)(iii)).

(Comments) Comments ask for clarification as to why this information is required when the statute does not require it and the information will likely be confusing if provided. Commenters also recommend eliminating this data element. Comments state that some imported products do not have a trade or brand name (e.g., agricultural products, fish, and seafood). In addition, comments note that a single product could have multiple brand names. Several comments note that the importer usually does not know a product's brand or trade name. Comments also recommend that FDA clarify in the final rule that it will not reject an article of food for failure to include trade or brand name when such information does not exist.

(Response) FDA agrees with the comments. FDA has also determined that this information is not critical for risk-based screening, given the other information in a prior notice.

(Interim final rule) FDA has eliminated the requirement to identify the trade or brand name in the interim final rule.

e. *Quantity* (§ 1.281(a)(5)(iii) Proposed as § 1.288(e)(1)(iv)). FDA proposed to require the submission of the quantity of food described from smallest package size to largest container as an element of the identity of the product (§ 1.288(e)(1)(iv)). The number of