

registration number (if one exists) to minimize the chance that typographical errors in registration numbers will lead to prior notices being considered incorrect and thus inadequate. We are considering designing the Prior Notice System to require at least one "confirmatory" data element (firm name or city or country) in addition to the registration number to allow for validation edits before automatically filling in the remaining data fields.

The phone and fax numbers and e-mail address are required (if they exist) so that FDA can communicate with the firm, if necessary. If the firm does not have a fax number or e-mail address, the prior notice submission should declare this. FDA plans to develop its Prior Notice System to allow submitters to repeat information already entered in the submission where appropriate (e.g., where the submitter is also the importer and consignee of the article).

b. *The U.S. Customs entry type.* FDA is proposing to require the submission of the U.S. Customs entry type associated with the article of food being imported or offered for import (proposed § 1.288(b)). Some examples of types of entries are Consumption entries, Warehouse entries, Temporary Importation Bond entries, Transportation for Exportation Bond entries, Trade Fair entries, mail entries, and baggage entries. Each of these types has a pre-designated U.S. Customs entry type code. That code must be submitted in the prior notice. This information will tell us if the article of food is intended for consumption in the U.S. or is intended for export or other uses. We need this information for proper screening of the information and identification of the appropriate articles for inspection. FDA also believes that submission of this information is critical for matching the prior notice to the corresponding U.S. Customs entry in order to assess the adequacy of the prior notice when shipments arrive and are presented for review.

c. *The U.S. Customs ACS entry line number or other U.S. Customs identification number.* FDA is proposing to require the submission of the U.S. Customs ACS entry line number, consisting of the entry number, the U.S. Customs ACS line number, and the FDA entry line number, which will be associated with the entry of the food for U.S. Customs purposes (proposed § 1.288(c)). For each entry number, there may be one or more U.S. Customs ACS lines and for each U.S. Customs ACS line there may be one or more FDA lines. For example, U.S. Customs entry number 0123456789-0 may identify an entry of peppers; the U.S. Customs ACS

line 123456789-0-001 may identify fresh peppers; and the FDA entry line 0123456789-0-001-001 may identify fresh sweet peppers and FDA entry line 0123456789-0-001-002 may identify fresh hot peppers.

If the article of food is not intended for consumption entry, FDA is proposing to require submission of the U.S. Customs identification number associated with that type of entry. Some examples of other types of entries are Warehouse entries, Temporary Importation Bond entries, Transportation for Exportation Bond entries, and Trade Fair entries.

FDA believes that this information is necessary for proper screening of the information and identification of the appropriate articles for inspection. FDA also believes that submission of this information is critical for matching the prior notice to the corresponding U.S. Customs entry in order to assess the adequacy of the prior notice when shipments arrive and are presented for review. FDA believes that these numbers can be obtained by the proposed deadline for prior notice. We seek comment on this issue.

d. *The location where the food is being held under proposed § 1.278, if applicable.* FDA is proposing to require that, if the article of food has been refused admission due to inadequate prior notice and thus is required to be held at the port of entry or in a secure facility, the submitter of the prior notice must inform FDA both that the article is under hold, and the location where the shipment is being held (proposed § 1.288(d)). Additionally, FDA is proposing to require the date that the article will arrive at that location as well as the identification of a contact at that location. This information is necessary to ensure FDA can locate the food for inspection and to ensure that the hold requirement is being complied with.

e. *The product identity.* Section 801(m)(1) states that a prior notice must contain the identity of the article of food being imported or offered for import. FDA is proposing the following data elements to ensure that each prior notice adequately and completely identifies the food being imported or offered for import.

i. *The complete FDA product code.* FDA is proposing to require the submission of the complete FDA product code as an element of the identity of the product (proposed § 1.288(e)(1)(i)). The FDA product code is a unique code currently used for classification and analysis of merchandise. The FDA product code is currently available via the Internet at www.accessdata.fda.gov/scripts/ora/

pcb/pcb.htm as a "buildable" code which is used to describe the food by industry, industry class, subclass, container/packaging, process, and specific product. We will work with the developers of the FDA prior notice system to ensure that there is a link from that system to the product code builder. We are working with the developers to design the link to the product code builder which will allow the product code selected to be automatically pasted back to the Prior Notice Screen. We will also design the system so that if the submitter already knows the product code, it can be entered directly into the Prior Notice Screen.

The FDA product code for canned tuna fish is 16AEE45, which translates as 16= fishery/seafood products, A= fish, E= subclass metal (cans), E= commercially sterile, 45= tuna. The filer currently submits the FDA product code to U.S. Customs' ACS when entry is made; it subsequently is transmitted to FDA's OASIS for each entry line.

FDA is proposing that if all of the information concerning the product identity exists by noon of the calendar day before the article will arrive at the port of entry, it must be included in the prior notice and the prior notice may not be subsequently amended. (Proposed § 1.288(e)(2)). If any of the product identity information does not exist by the deadline, the information that does exist must be provided to FDA, and the submitter must indicate that it will amend the prior notice. FDA identifies the conditions appropriate for amendments related to product identity in proposed § 1.290. FDA notes that, in determining whether the information exists, the standard set out in the proposed rule is not whether the submitter knows the information when filing the prior notice, but whether the information could be known by the submitter by the noon deadline. In the discussion of proposed § 1.289, we describe under what circumstances we think complete product identity will not exist. FDA solicits comment on this standard and whether it is sufficiently flexible to achieve our goals.

ii. *The Common or usual or market name.* FDA is proposing 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 (proposed § 1.288(e)(1)(ii)). This is a description, in common terms, detailed enough to allow the kind of product to be identified. (See 21 CFR § 102.5 for additional information about common or usual names.) The filer currently submits the common or usual or market name to U.S. Customs' ACS when entry