

admissions, and for prior notices submitted through the FDA PN System Interface, an entry identifier is critical for matching the prior notice to the corresponding CBP entry if a consumption entry is submitted so FDA and CBP can ensure that prior notice requirements were satisfied. For transmitters submitting prior notice with CBP entry information through the ABI/ACS interface, the CBP entry number assigned by CBP is also the entry identifier. For customs brokers or self-filers submitting prior notice for a food entering the United States as an IT entry, a T&E entry, or FTZ admission, the CPB in-bond number or FTZ admission number assigned by CBP is also the entry identifier.

If prior notice is being submitted through the FDA PN System Interface, the entry identifier will depend on the entry type and the reason for Web submission. If available to the transmitter (e.g., the prior notice is for a CBP entry but the ABI/ACS interface is not available), the CBP entry number must be used. Where appropriate, the in-bond number must be used as the entry identifier. If one of the entry identifiers described above does not exist, the transmitter can request a system-generated entry identifier. The FDA PN System Interface will provide online help to assist the user in determining what information to use as the entry identifier for a specific transaction.

This requirement to provide an entry identifier does not apply to articles of food imported or offered for import by international mail, nor those carried by or accompanying an individual, unless entry is otherwise required by CBP and an associated CBP entry identifier has thus been assigned. In these cases, the FDA PN System Interface will apply a system-generated entry identifier.

FDA agrees with the comments that line numbers are not necessary. Thus, the interim final rule does not require submission of a line number. For transmitters using the FDA PN System Interface, the system will assign each article of food a unique number for processing and, after validation, a PN Confirmation Number will be returned for each article of food. For ABI/ACS submissions, when they are confirmed, the CBP and FDA line numbers will be assigned as they are under current procedures, and the customs broker or self-filer will receive a confirmation number for each line through the OASIS/ACS messaging process.

7. Product Identity (§ 1.281(a)(5) Proposed as § 1.288(e)(1))

Section 801(m)(1) of the Bioterrorism Act states that a prior notice must contain the identity of the article of food being imported or offered for import. To ensure that each prior notice adequately and completely identifies the food being imported or offered for import, § 1.288(e)(1) of the proposed rule required the submission of the following information: FDA product code; common, usual, or market name; brand name; quantity; and lot, code, or other identifying number.

a. *General comments on product identity.* (Comments) Some comments ask that FDA obtain product identity information from existing Customs information. Other comments believe that the information on product identity should be limited to a general description of the product.

(Response) Under section 801(m) of the FD&C Act, FDA must have the information before arrival. Thus, although product identity is provided to CBP when entry is filed, currently that does not generally occur sufficiently before arrival for FDA to review and respond as envisioned by the Bioterrorism Act. Under the interim final rule, with the modifications to ABI/ACS, required product identity information can be provided through ABI/ACS. The transmission to CBP will be enhanced to include the additional product identity information required by prior notice, and will be used satisfy both FDA's prior notice requirements as well as current entry requirements.

FDA does not agree that product identity should be limited to a general description. For prior notice to accomplish its intended purpose and help FDA protect American consumers, a precise description of the product is necessary. For example, FDA needs to know that there are 100 cartons containing 24/12 ounce (oz) bottles of apple juice and 200 cartons containing 48/8 oz bottles of apple juice to make its decision whether to inspect, sample, or hold a shipment. Information about potential contamination may apply only to 8 oz bottles of apple juice. Therefore, it would be a drain on FDA resources, as well as cause delays at the border, to examine and sample all juice or all apple juice imports when only one kind of juice in one kind and size of packaging is affected. Currently, this information is provided to FDA when entry information is submitted via the ABI/ACS interface by a customs broker or self-filer. For those entries submitted via a paper mode, the invoice is included in the submission, as it was

before OASIS and ABI/ACS. The precise description of a food product is commonly included on a commercial invoice, e.g. 200 cartons of 24/6 oz cans of albacore tuna.

(Comments) One comment asks for clarification as to how an "article" of food is defined.

(Response) The description of an "article" of food is not the same as the definition of "food" in § 1.276(b)(5). An "article" refers to a single food that is associated with the same complete FDA Product Code, the same package size, and the same manufacturer or grower. These requirements are found in the information required in the interim final rule in § 1.281(a)(5), (a)(6), or (a)(7) and again in § 1.281(b) and (c).

(Comments) Some comments assert that the proposed rule increases the paperwork burden by requiring separate notices for every article from a different manufacturer or grower. Comments recommend that one way to reduce this burden would be to allow a single prior notice to cover a shipment of multiple articles of food or allow one notice per shipment.

(Response) FDA disagrees. An article of food is a unique item related to a specific manufacturer or grower and a specific process or size. All of these pieces of information are critical for a risk-based assessment of the food. FDA currently receives most of this information from customs brokers or self-filers via ABI/ACS. The ABI/ACS system also provides the capability to submit information for multiple food items as lines in a single entry, when entry level information is consistent for a number of articles in a shipment. For example, shipment level information, such as estimated time of arrival, can be captured once for all articles within a shipment. The ability to minimize data entry by copying specific information from one article, or line, to another depends upon the sophistication of the software being used to create the submission to CBP. The FDA PN System Interface is designed to allow for simplified submission of similar articles of food by allowing the submitter to easily repeat common information (e.g., FDA product code, manufacturer, etc.) while entering different quantities (e.g., amount and package size). Both systems will thus significantly reduce the amount of repetitive entry of information while preserving the identity of each article of food.

b. *Complete FDA product code (§ 1.281(a)(5)(i) Proposed as § 1.288(e)(1)(i)).* FDA proposed to require the submission of the complete FDA product code as an element of the identity of the product (§ 1.288(e)(1)(i)).