

container units and units of measure are to be submitted in decreasing size of packing unit (starting with the largest). The customs broker or self-filer currently submits the quantity of each line entry to ABI/ACS when entry is made, and quantity subsequently is transmitted by CBP to OASIS. FDA requested comments on whether changes in quantity will occur after the deadline for prior notice and, if so, how commonly changes occur and how significant the changes usually are.

(Comments) There were many comments pertaining to quantity. Some commenters object to the requirement, stating that it can be difficult to identify quantity. For example, comments suggest that it can be difficult to identify quantity for processed goods, as quantity may change. Also, the exact quantity is difficult to identify for fresh produce and fresh fishery products due to the fast-paced shipping of perishables and day-to-day harvesting differences. Comments state that it is also difficult to ascertain the exact unit (e.g., weight, volume) for bulk items. Comments also state that quantity information such as package size is not relevant to identify the presence of intentional contamination or a food safety hazard. Some comments object to the level of specificity, stating that the required quantity data is unduly detailed for inspection purposes, seldom needed for risk assessments, and not necessary to meet the statutory requirements. Other comments recommend that FDA allow a 2-hour amendment/update for needed flexibility and accurate reporting or adopt a percentage over/under discrepancy tolerance or approximated total units (e.g., weight, volume). Comments confirm that changes in quantity occur after the proposed deadline for prior notice and that these changes commonly represent significant variations in quantity.

(Response) FDA continues to believe that quantity is a necessary component of product identity. The significant decrease in the filing deadlines addresses concerns raised by many comments. In addition, in further response to the comments on changes in quantity, FDA has revised the requirement to "estimated quantity." This means that the submitter must tell FDA, at the time of submission of Prior Notice, the estimated amount of the article of food that they anticipate will be shipped. This change provides importers with leeway to adjust shipments, while still ensuring FDA has useful information about overall quantity.

FDA believes that package size is necessary and part of product identity.

The base unit of measure is a critical characteristic of product identity and is thus necessary for effective review of the prior notice information. Base unit is critical to processing safety requirements and is particularly important when evaluating the safety of low-acid canned foods. Both base unit and total quantity (which includes knowing the smallest "package size") are necessary for response (examination) and communication with FDA and CBP staff at the border. As noted in FDA's "Food Security Preventive Measures Guidance for Importers" (Ref. 17), they are also critical for food security examinations to determine if the amount ordered is the amount received. For example, if more was received than was ordered, the guidance recommends an investigation to determine the cause of the discrepancy as additional and unwanted articles may have been added to intentionally contaminate the shipment. If less product is received than ordered or than shipped, some of the product may have been intentionally diverted. Both base unit and total quantity are currently data elements that can be submitted via ABI/ACS to OASIS. The tutorial in the FDA product code builder will be revised to recommend the appropriate association of base unit with product code, e.g., FDA Product Code 16AEE45, canned tuna would recommend the base unit as **oz cans.

(Interim final rule) Section 1.281(a)(5)(iii) requires that the prior notice state the estimated quantity of food that will be shipped from largest container to smallest package size. Some examples of quantity descriptions are: 100 cartons of 48/6 oz cans each of tuna; 100 pallets of 2/100 pound (lb) totes each of frozen tuna loins for a total of 20,000 lb; 100 pallets of 2/100 lb cartons each of dehydrated pig ears for a total of 20,000 lb; 100 cartons of 20 lb of fresh watermelons each carton for a total of 2,000 lb, and 2,000 lb of wheat in bulk. A prior notice will not be inadequate if the estimated quantity changes between the confirmation of prior notice and the time of arrival. The interim final rule does not require that a prior notice be cancelled and resubmitted if the estimated quantity changes after confirmation.

f. *Lot or code numbers or other identifier* (Proposed § 1.288(e)(1)(v)). FDA proposed to require the submission of the lot or code numbers or other identifiers that are specific to the article of food, if applicable, as an element of the identity of the product (proposed § 1.288(e)(1)(v)). Currently, when entry information is presented to FDA through ABI/ACS, lot or code numbers

may be transmitted as "affirmations of compliance" and there may be more than one identifier represented in an entry line.

(Comments) Comments state that the addition of lot, code, or other identifier information is burdensome and not valuable for inspection purposes. In addition, often the lot numbers are simply unknown. Comments ask that FDA clarify, if this data element is retained, what "lot or code number or other identifier" means and how it should be entered, such as by bar code, letters, or random number. Comments also ask that FDA consider that there is no lot or code number for bulk or commingled products. Many comments suggest that FDA consider making this data element voluntary or removing it completely.

(Response) FDA agrees in part. The lot or code numbers are the identification numbers or code of a production lot, which can more specifically identify a product for screening and examination purposes and for communication within FDA and with CBP and the grower or manufacturer, etc. For example, recalls involving serious health risks are often associated with a specific production lot, such as counterfeit infant formula or underprocessed canned food. FDA screening targets examinations based on information of public health emergencies or recalls in foreign countries. FDA regulations already require lot/code identifiers for some foods. Currently, low acid canned foods, acidified foods, and infant formula are required to bear lot codes or other identifiers (see 21 CFR 113.60(c) (low-acid canned foods); 21 CFR 114.80(b) (acidified foods); and 21 CFR 106.90 (infant formula low-acid canned foods)). The interim final rule requires lot/code or other identifiers only for these kinds of articles of foods. Many other foods may have lot or code identifiers that are not required by FDA regulation; submission of these identifiers is optional under the interim final rule.

(Comments) Some comments object to the limitation in the proposed rule that each lot number of a food would need its own prior notice and asserted that FDA should permit multiple lot numbers to be identified in one prior notice.

(Response) FDA agrees. Multiple lot numbers may be identified for an article of food. The systems are set up to permit such submissions.

(Interim final rule) Section 1.281(a)(5)(iv) provides that lot or code numbers or other identifiers are required in a prior notice for articles of food that are required to bear such numbers by the FD&C Act or by FDA