

is made, and it subsequently is transmitted to FDA's OASIS for each entry line. This information is necessary to confirm the accuracy of the product code.

iii. *The trade or brand name.* FDA is proposing 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 (proposed § 1.288(e)(1)(iii)). For example, the brand name of canned tuna would be XYZ brand tuna. This information is necessary to ensure that FDA knows the brand identity of the product, which is often a critical piece of information when making inspection decisions. The filer currently submits the trade or brand name to U.S. Customs' ACS when entry is made, and it subsequently is transmitted to FDA's OASIS for each entry line.

iv. *The quantity.* FDA is proposing 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 (proposed § 1.288(e)(1)(iv)). The number of container units and units of measure are to be submitted in decreasing size of packing unit (starting with the largest). Some examples of quantity descriptions are: 100 cartons of 48/6 oz. cans each of tuna; 100 pallets of 2/100 lb. totes each of frozen tuna loins for a total of 20,000 pounds; 100 pallets of 2/100 lbs. cartons each of dehydrated pig ears for a total of 20,000 lbs.; and 100 cartons of 20 lbs. of fresh watermelons each for a total of 2000 lbs. The filer currently submits the quantity of each line entry to U.S. Customs' ACS when entry is made, and it subsequently is transmitted to FDA's OASIS. FDA requests comment 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.

v. *The lot or code numbers or other identifier.* FDA is proposing 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(f)(1)(v)). These numbers are the identification number or code of a production lot and are needed to more specifically identify a product. Currently, there may be more than one identifier represented in an entry line. The prior notice system will be developed to accept more than one lot identifier per article.

f. *The manufacturer.* As provided for in section 801(m)(1), FDA is proposing to require the submission of the identity of the manufacturer of each article of

food (proposed § 1.288(f)). The filer currently submits the identity of the manufacturer to U.S. Customs' ACS when entry is made, and it subsequently is transmitted to FDA's OASIS.

g. *The growers, if known.* As required by section 801(m)(1), FDA is proposing to require the submission of the identity of all growers of each article and the growing location if different from the grower's business address, if known at the time of submission of the prior notice (proposed § 1.288(g)). If the submission is amended, the proposed rule provides that the identity of all growers must be provided if known at the time of the amendment (proposed § 1.290(d)). FDA wants to emphasize that section 801(m)(1) of the act states that grower information must be submitted if it is known. Thus, this information is not optional: if it is known, it must be submitted. If a product is sourced from more than one grower, the prior notice must provide the identification of all growers, if known. The FDA Prior Notice System will be developed to accommodate submission of up to three different growers.

FDA solicits comments on two particular aspects of the statutory requirement that the grower be identified. First, does the act give FDA any flexibility to exempt or otherwise treat differently so-called processed foods produced with products from more than one grower? Second, does the term "grower" include a harvester or collector of wild products, e.g., some fish and botanicals?

h. *The originating country.* As provided for in section 801(m)(1), FDA is proposing to require the submission of the identity of the originating country of the article of food (proposed § 1.288(h)). This term is defined in proposed § 1.277(c)(2).

i. *The shipper.* As provided for in section 801(m)(1), FDA is proposing to require the submission of the identity of the shipper of the article of food (proposed § 1.288(i)). FDA considers the shipper to be the person who arranges for a shipment to get to its first destination in the United States. The shipper typically is responsible for initiating the bill of lading or airbill covering the transportation of the article by the carrier. The shipper is usually a foreign firm that is located or maintains an address in the country from which the article was shipped. The shipper is typically not the carrier.

j. *The country of shipping.* As provided for in section 801(m)(1), FDA is proposing to require the submission of the identity of the country from which the article of food was shipped

(proposed § 1.288(j)). This term is defined in proposed § 1.277(c)(3).

k. *Anticipated arrival information.*

i. *The anticipated port of entry.* As provided for in section 801(m)(1), FDA is proposing to require the submission of the anticipated port of entry at which the article of food will arrive in the United States (proposed § 1.288(k)(1)(i)). "Port of entry" is defined in proposed § 1.277(c)(5).

ii. *The anticipated date of arrival.* FDA is proposing to require the submission of the anticipated date when the article of food will arrive at the port of entry in the United States (proposed § 1.288(k)(1)(ii)). FDA believes that this information is necessary to plan inspections.

iii. *The anticipated time of arrival.*

FDA is proposing to require the submission of the anticipated time when the article of food will arrive at the port of entry in the United States (proposed § 1.288(k)(1)(iii)). FDA believes that this information is necessary to plan inspections.

FDA is proposing to require the prior notice to be updated if any of the anticipated arrival information changes after the submission of the prior notice (proposed § 1.288(k)(2)). Updates are necessary so FDA can change its plan when anticipated arrival information changes. The conditions appropriate for updates are provided in proposed § 1.294.

l. *The port where entry will be made for U.S. Customs purposes.* FDA is proposing to require the submission of the identification of the port where entry will be made for U.S. Customs purposes (proposed § 1.288(l)). Often, this port will be different than the port where the article of food arrived in the United States. FDA believes that this information is necessary to facilitate communication with U.S. Customs and FDA field offices concerning the adequacy of the prior notice. It is also necessary to enable FDA to coordinate resources for inspections, examinations, or sampling.

m. *The anticipated date of U.S. Customs entry.* FDA is proposing to require the submission of the anticipated date of entry for U.S. Customs purposes (subpart 1.288(m)). FDA believes that this information is critical to enable it to allocate resources for inspecting imported food shipments and efficient communication with and between U.S. Customs and FDA field offices.

n. *The importer, owner, and consignee.* Under section 801(m)(2)(B)(i) and proposed § 1.278(e)(2), food that is offered for import with no or inadequate notice may not be delivered to the