

regulations. Submission of the required lot/code identifier will be accommodated by ABI/ACS as an affirmation of compliance or through the FDA PN System Interface. ACS currently allows for submission of more than one affirmation of compliance per article of food. The FDA PN System Interface will accept more than one lot identifier per article of food.

8. Manufacturer (§ 1.281(a)(6) Proposed as § 1.288(f))

As provided for in section 801(m)(1) of the FD&C Act, FDA proposed to require the submission of the identity of the manufacturer of each article of food. The customs broker or self-filer currently submits the identity of the manufacturer to ABI/ACS when entry is made, and it subsequently is transmitted to OASIS.

(Comments) Some comments state that some foods are not processed or manufactured food, *e.g.*, certain wild-caught or agricultural products; therefore, a manufacturer cannot be identified.

(Response) FDA agrees. Identification of a manufacturer only is required for a food that is no longer in its natural state. The FDA PN System Interface will recognize (by FDA product code) these foods. The manufacturer field must be completed for these foods (identified by FDA product code); if it is not completed, the initial validation will reject the submission through ABI/ACS or the FDA PN System Interface. Guidance regarding FDA product codes that require prior notice, which FDA intends to issue before implementation of this rule, will identify which product codes should be associated with a manufacturer.

FDA also recognizes that if an article of food is sent by an individual as a personal gift (*i.e.*, for nonbusiness reasons) to an individual, what will be available to the sender will be the name and address of the firm that appears on the label. Thus, this information may be supplied and a registration number need not be provided.

(Interim final rule) Section 1.281(a)(6) of the interim final rule requires that the identity of the manufacturer of an article of food that is no longer in its natural state be submitted as part of prior notice. However, if the article of food is sent by an individual as a personal gift (*i.e.*, for non-business reasons) to an individual in the United States, the name and address of the firm that appears on the label under 21 CFR 101.5 may be submitted.

9. Grower, If Known (§ 1.281(a)(7) Proposed as § 1.288(g))

As required by section 307 of the Bioterrorism Act, FDA proposed to require the submission of the identity of all growers of each article, if known, and the growing location if different from the grower's business address (proposed § 1.288(g)). If the submission is amended, the proposed rule required that the identity of all growers must be provided if known at the time of the amendment (§ 1.290(d)).

FDA solicited comments on whether the FD&C Act gives FDA any flexibility to exempt or otherwise treat differently so-called processed foods produced with products from more than one grower. FDA also solicited comments on whether the term "grower" includes a harvester or collector of wild products, *e.g.*, some fish and botanicals.

(Comments) A comment states that the agency does not need to identify flexibility to exempt processed foods produced with products from one or more grower, but rather should recognize that there is not a grower of a processed food.

(Response) FDA agrees. Once an article of food, for prior notice purposes, is no longer in its natural state, it has a manufacturer, but not a grower.

(Comments) A commenter states that it is an extremely rare occurrence for any single imported lot of a wild botanical raw material to have been collected by a single collector. Rather, the comment believes that the most common practice of consolidating a single lot of wild-harvested botanical raw material involve the product of many dozen or even hundreds of individual collectors.

(Response) FDA agrees and considers a harvester or collector to be the grower for the purposes of this provision as the definition of grower reflects § 1.276(b)(6)). The interim final rule also allows for the identification of a consolidator, when the submitter does not know the identities of all harvesters or collectors at the time of submission of the prior notice.

(Comments) Comments assert that if the grower is known, then workload for submission of prior notice will increase immensely. The comments recommend submitting a one-time listing of all growers that supply the importing firm with product and the responsible party could update the list as needed or keep a complete grower list with each firm and supply it to FDA when needed.

(Response) The proposed regulation restated the statutory requirement. FDA does not agree that a list would satisfy the statutory requirement, as it would

not tell FDA which grower was associated with the particular article of food as envisioned by the statute.

(Comments) Comments state that it is very difficult to identify a grower for commingled products (fresh produce, fishery products, and grain) and such identification is not a typical industry practice. Comments also ask FDA to define "bulk," and specifically how to address this issue with bulk grain.

(Response) There is only one grower per article of food that is not in its natural state. Thus, tomatoes from two different growers are different articles of food offered for purposes of prior notice. However, FDA has decided that if the identity of all growers is not known for an amount of raw agricultural product consolidated from more than one grower, including grain or aquacultured fishery products, the consolidator firm may be identified in the grower identity data field. FDA emphasizes that the submitter may opt to provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations only when the submitter does not know the identity of any of the growers of the consolidated food. If the submitter knows the identity of any grower for consolidated foods, a separate prior notice must be submitted for each article of food represented by a known grower.

For example, if consolidator X commingles tomatoes from 5 growers into one lot of 90 cartons and the submitter does not know the identities of any of those 5 growers, then the submitter may opt to provide the identity of consolidator X. If consolidator X commingles tomatoes from 3 growers (growers A, B, and C) into one lot of 90 cartons and, although the submitter knows the identities of the growers, none of the tomatoes can be associated with the grower (no grower specific identifier accompanies each carton), then the submitter may opt to provide the identity of consolidator X.

If consolidator X commingles 30 cartons of tomatoes from grower A with 30 cartons of tomatoes from grower B and 30 cartons of tomatoes from grower C and the submitter knows the grower associated with each of those 30 carton lots, then each of those 30 carton lots represents an article of food and a separate prior notice must be submitted for each. However, if consolidator X commingles 30 cartons of tomatoes from grower A with 60 cartons of tomatoes commingled from other growers and the submitter knows the identity of grower A, then that 30 carton lot can be identified by grower and represents an article of food. Two prior notices are