

manufacturer, and if it is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(g) The name, address, phone number, fax number, and e-mail of all growers, and the growing location if different from business address, if known at time of submission of your prior notice;

(h) The originating country of the article of food;

(i) The name, address, phone number, fax number, and e-mail address of the shipper and, if it is required to register under 21 CFR part 1, subpart H, for a facility associated with the article of food, the registration number assigned to that facility;

(j) The country from which the article of food was shipped;

(k) (1) Anticipated arrival information about the article of food being imported or offered for import, as follows:

(i) The anticipated port of entry and, if the anticipated port of entry has more than one border crossing, the specific anticipated border crossing where the food will be brought into the United States;

(ii) The anticipated date on which the article of food will arrive at the anticipated port of entry; and

(iii) The anticipated time of that arrival;

(2) If any of the anticipated arrival information required under this paragraph changes after you submit your prior notice, you must update your notice in accordance with § 1.294.

(l) The port where entry of the article of food will be made for purposes of the U.S. Customs Service;

(m) The anticipated date of entry for purposes of the U.S. Customs Service; and

(n) The name, address, phone number, fax number, and e-mail address of the importer, and, if the importer is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(o) The name, address, phone number, fax number, and e-mail address of the owner, and if the owner is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(p) The name, address, phone number, fax number, and e-mail address of the consignee, and if the consignee is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility; and

(q) The names, addresses, phone numbers, fax numbers and e-mail addresses of all the carriers which are or will be carrying the article of the food from the country from which the article of food was shipped to the United States, and the carriers' Standard Carrier Abbreviation Codes (SCAC) if appropriate.

§ 1.289 What changes are allowed to a prior notice after it has been submitted to FDA?

After a prior notice has been submitted to FDA, it may only be changed as set out in § 1.290 which relates to product identity amendments or § 1.294 which relates to arrival updates. If other information provided in the prior notice changes, you must cancel the prior notice in the FDA Prior Notice System and submit a new prior notice to FDA.

§ 1.290 Under what circumstances must you submit a product identity amendment to your prior notice after you have submitted it to FDA?

(a) If any of the information required by § 1.288(e)(1) did not exist at the time you submitted your prior notice and the prior notice you submitted was therefore incomplete, you must amend your prior notice with complete product identity information by the deadline specified in § 1.291.

(b) You may only amend your prior notice once.

(c) You may not change the general identity of the article of food that is the subject of the prior notice by amendment. However, if the article is fresh produce or fresh, wild-caught fish, you may amend the last two digits of the product code when you do not know the specific identity of the article at the time of initial prior notice. If your initial prior notice submission identifies the product by the FDA product code for "fresh peppers, refrigerated," when you amend your submission, you must give the product code that identifies with specificity the type of pepper—"fresh green bell peppers, refrigerated." You may also include more than one article in your amendment if the industry and class and process (of the FDA product code) are the same. A prior notice for "refrigerated fresh fish" may be amended as "refrigerated fresh cod" and "refrigerated fresh salmon," but not "refrigerated fresh cod" and "canned shrimp." You may not amend the product identity to refer to another food, e.g., apples, or another process, e.g., canned.

(d) If you did not provide grower identity at the time you submitted your prior notice under this subpart, but you know the identity of the grower when

you submit a product identity amendment to your prior notice, you must include in your amendment: the name, address, phone number, fax number, and e-mail of all growers, and growing location if different from business address.

§ 1.291 What is the deadline for product identity amendments under § 1.290?

Your product identity amendment must be submitted no later than 2 hours prior to the time of arrival.

§ 1.292 How do you submit a product identity amendment to a prior notice?

You must submit product identity amendments in accordance with § 1.287.

§ 1.293 What are the consequences if you do not submit a product identity amendment to your prior notice?

(a) If you informed FDA in your prior notice that you would be submitting a product identity amendment but you do not amend your prior notice completely, the prior notice is inadequate for the purposes of § 1.278(a).

(b) If you informed FDA in your prior notice that you would be submitting a product identity amendment and you submit your amendment after the deadline provided in section 1.291, the prior notice is inadequate for the purpose of § 1.278(a).

§ 1.294 What must you do if the anticipated arrival information (required under § 1.288(k)(1)) submitted in your prior notice changes?

(a) If any of the anticipated arrival information required under § 1.288(k)(1) changes after you submit a prior notice to FDA, you must submit an arrival update updating the information in your prior notice in accordance with § 1.287. Your arrival update must provide the following information:

(1) If the anticipated port of entry changes, provide the updated port of entry;

(2) If the time of arrival is expected to be more than 3 hours later than the anticipated time of arrival, provide the updated time of arrival;

(3) If the time of arrival is expected to be more than 1 hour earlier than the anticipated time of arrival, provide the updated time of arrival.

(b) If you did not provide grower identity at the time you submitted your prior notice under this subpart, but you know the identity of the grower when you update your prior notice, you must include in your update: the name, address, phone number, fax number, and e-mail of all growers, and growing location if different from business address.