

pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. However, crops that have been cleaned (*e.g.*, dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, waxed, or polished are still in their natural state for purposes of the prior notice interim final rule. Likewise, whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of the prior notice interim final rule.

10. Port of Arrival (§ 1.276(b)(9)) and Port of Entry (§ 1.276(b)(10))

The proposed rule defined “port of entry” as “the water, air, or land port at which the article of food is imported or offered for import into the United States, *i.e.*, the port where food first arrives in the United States.”

(Comments) Many comments suggest harmonizing with, or adopting, the CBP definition for “port of entry.” In the opinion of two comments, the CBP definition is consistent with congressional intent and the FDA departure from the CBP definition is unsupported. Many of these comments state the two definitions would cause confusion in the import community and could delay proper prior notice. Other comments suggest changing the FDA definition of “port of entry” to the “port of arrival.” Another comment suggests defining “port of entry” as the entering point of a country where the merchandise is checked by official authorities. Two comments state that defining “port of entry” as the port of arrival would change business practices by essentially stopping the use of CBP “in-transit” (*i.e.*, IT) entries under bond to inland ports.

(Response) Section 801(m)(2)(A) of the FD&C Act states that FDA’s implementing regulations must require that the notice “be provided by a specified period of time in advance of importation of the article involved * * *.” The stated purpose of section 801(m)(1) is “enabling [articles of food] to be inspected at ports of entry into the United States * * *.” Moreover, the overall purpose of the Bioterrorism Act is “[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.” (Pub. L. 107–188.) The ability to examine or, if necessary, hold a suspect article of food when it first arrives at a port of entry in the United States, rather than later at the port where CBP will process the entry, will most effectively serve this overall purpose. Thus, to ensure that there is clarity that prior notice must be

provided in advance of arrival, we are defining the term “port of arrival” as the water, air, or land port at which the article of food is imported or offered for import into the United States, *i.e.*, the port where the article of food first arrives in the United States.

In addition, we are adopting the CBP definition of “port of entry” to allow flexibility when designating where refused merchandise will be held. The CBP “Port of entry” definition states:

The terms “port” and “port of entry” refer to any place designated by Executive order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms “port” and “port of entry” incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not “port of entry” within the meaning of these regulations) (19 CFR 101.1).

This flexibility will ensure that food that has been refused may move to the port of destination where, for example the consumption or warehouse entry will be filed, unless directed by CBP or FDA. Generally, we do not intend to hold shipments at the border unless our assessment of the situation leads us to believe it is warranted, *e.g.*, the food may present a serious risk to public health or that the prior notice violation is egregious. We intend to implement prior notice, both in terms of determining what warrants a refusal in the first place, and in terms of determining which shipments may move to the port of destination, in a risk-based way.

(Comments) Other comments state rail transportation would be especially affected because inbound trains often are not required to stop at the U.S. border but proceed to inland terminals.

(Response) As explained later, rail shipments that have been refused admission per section 801(m)(1) of the FD&C Act are considered to have the status of general order merchandise. In many cases, it will be operationally difficult to stop an entire train because an article of food on it has been refused admission because of inadequate prior notice. Under CBP regulation, general order merchandise may be stored by the carrier or as the CBP port director may direct (see 19 CFR 123.10(f)). Moreover,

in situations involving shipments by rail, FDA and CBP have the discretion to allow the movement of the cargo from the border crossing to the nearest point where it can be safely and securely held. We intend, whenever possible, to examine articles of food arriving by rail at the appropriate examination site closest to the border. However, if the shipment might pose an immediate danger to public health and safety, an article of food arriving by train may be held at the border pending resolution of the situation.

(Interim final rule) The interim final rule, § 1.276(b)(9) defines “port of arrival” as “the water, air, or land port at which the article of food is imported or offered for import into the United States, *i.e.*, the port where the article of food first arrives in the United States,” (§ 1.276(b)(9)). This port may be different from the port where consumption or warehouse entry or FTZ admission documentation is presented to CBP. The interim final rule (§ 1.285(b)(10)) also defines port of entry as follows:

11. Registration Number (§ 1.276(b)(11))

Although the term appears in several places in the proposed rule, the term “registration number” was not defined.

(Comments) No comments addressed the definition or meaning of “registration number.”

(Response) To clarify that the term refers to registration of food facilities, the interim final rule defines “registration number” as the registration number assigned by FDA under section 415 of the FD&C Act and 21 CFR part 1, subpart H, § 1.276(b)(11). Specific comments addressing when a registration number is required and other aspects of providing registration numbers as information submitted in prior notice are addressed later in this preamble—see “What Information Must be in a Prior Notice?”

12. Shipper (§ 1.276(b)(12))

Section 801(m)(1) of the FD&C Act requires that the “shipper of the article” be provided in a prior notice submission. The proposed rule included the shipper as required information in a prior notice, but did not define the term “shipper.”

(Comments) FDA received no comments concerning the meaning of this term.

(Response) In the proposed rule, we described the “shipper” as “the person who arranges for a shipment to get to its first destination in the United States * * *.” The shipper is usually a foreign firm that is located or maintains an address in the country from which the