

Customs entry might be a considerable distance from the actual port of arrival, the date of Customs entry is difficult to predict. Another comment questions the usefulness of the Customs date of entry in determining whether to inspect the products at the port of arrival. A few comments ask for clarification of the Customs entry process.

(Response) FDA agrees. FDA has eliminated the Customs date of entry in the interim final rule. Due to interfacing with ABI/ACS and development of various means of communication with CBP, this information is no longer necessary in the prior notice submission.

(Interim final rule) The interim final rule does not require submission of the anticipated date of Customs entry.

16. Importer, Owner, Ultimate Consignee (§ 1.281(a)(12), (a)(13), and (a)(14) Proposed as § 1.288(n), (o), and (p))

Under section 801(m)(2)(B)(i) of the FD&C Act, an article of food that is imported or offered for import with inadequate notice may not be delivered to the importer, owner, or consignee. Thus, FDA proposed to require their identities so that FDA can take steps to ensure that food refused admission under section 801(m) of the FD&C Act is not delivered to them illegally. FDA proposed that only one importer, owner, and consignee could be identified for each prior notice.

(Comments) Some comments argue that section 307 of the Bioterrorism Act does not require the prior notice to identify the importer, owner, or consignee of the article of food that is the subject of the notice. They recommend that this requirement in the proposed rule be eliminated as beyond the scope of the statute and unnecessary for the purposes of section 307 of the Bioterrorism Act. One comment argues that FDA should not require submission of information about the consignee. However, another comment states that the level of detail required is generally consistent with the information submitted by customs brokers acting as agents for importers of record.

(Response) As requested by some of the comments, FDA considered deleting this information or making identity of importer, owner, and ultimate consignee optional. However, section 801(m) of the FD&C Act explicitly prohibits delivery of an article refused under section 801(m) to the importer, owner, or consignee. Section 801(l) of the FD&C Act likewise prohibits delivery of an article of food that has been imported from an unregistered foreign facility that is required to be registered under

section 415 of the FD&C Act and 21 CFR part 1, subpart H. If we do not know the identity of these persons, we cannot determine if an article of food that has been refused or placed under hold has been illegally diverted and delivered. Accordingly, we have determined that this information is critical to ensure that we can efficiently enforce the prohibitions in section 801(m) and (l). In requiring this information, FDA is relying on both sections 801(m) and (l) and 701(b) of the FD&C Act.

Moreover, information identifying the importer of record and consignee is currently provided as part of the existing entry process (under OMB control number 0910-0046). Under the interim final rule, the CPB and FDA entry submission may be used to satisfy prior notice. We estimate that 80 percent of prior notices will be submitted through the CPB ABI/ACS entry process. We are concerned that deleting this information or making it optional for prior notice purposes could create considerable confusion about whether the information was still required for entry and admissibility purposes. For FDA, these pieces of information are necessary for administering section 801(a) of the FD&C Act and its implementing regulations, which require that FDA provide notice of sampling and notice of intent to refuse admission to the owner or consignee. Indeed, the identities of consignees and importers of record have long been provided to FDA. Prior to the availability of OASIS, FDA was provided with this information about imported foods on the FDA Form 701 (Ref. 18). In addition to the name and address of the importer of record and the consignee, FDA Form 701 included information such as: Entry number and date, bill of lading number, port of lading, country of origin, port of unloading, port of entry, value, container number, vessel name, arrival date, location of lot, date available, contact phone number, broker identification, manufacturer/shipper, quantity, packaging description, and a description of the food including the Food Canning Establishment number. Since the availability of OASIS, all information that has been submitted through the ABI/ACS interface has also included name and address of the importer of record and the ultimate consignee. Those who do not provide entry information electronically through ABI/ACS submit a "paper" entry to CBP and also provide FDA paper notification that includes information on importer and consignee. Some still use the FDA Form 701.

(Comments) One comment asserts that the identity of the consignee is proprietary, implying that it is protected from disclosure to FDA.

(Response) Where consignee information is proprietary, it is likely to be "confidential commercial information" and protected from public disclosure. However, the fact that it is considered "proprietary" is not a bar to requiring it in prior notice and entry submissions.

(Comments) Other comments ask that FDA decrease the burden of providing this information by using the registration number, which FDA could use to obtain the other identity information elements from its databases.

(Response) FDA agrees in part. Although the interim final rule does not require the registration numbers of the importer, owner, or ultimate consignee, the FDA PN System Interface allows for submission of the name of the firm and limited address information (city and country) when a registration number is provided.

(Comments) Other comments seek to decrease the burden by asking FDA to require information regarding the entity submitting the prior notice, which could be the importer, owner, or consignee, but not regarding all three. Another comment concedes that FDA should require the identification of the owner, but that the owner is often the importer or the consignee.

(Response) FDA agrees. The FDA PN System Interface provides the transmitter with the ability to easily repeat information, e.g., the submitter is the same as the importer or the owner is the same as the ultimate consignee. This feature may also be available for submission through ABI/ACS, depending on the specific ABI software used by the customs broker or self-filer. The identity of the owner is only needed if it is not the same as the importer or the ultimate consignee.

(Comments) Several comments state that FDA should be able to communicate its admissibility decisions and decisions about prior notice adequacy with the importer.

(Response) As set out in the interim final rule, in the first instance, the carrier will be notified regarding refusals under section 801(m) of the FD&C Act. Information identifying the importer will allow FDA to follow up with the importer and develop procedures for notifying them as well.

(Comments) A comment asks that FDA define "importer" consistently with CBP. Another comment expresses confusion as to the meaning of the term "owner," asking whether the requirement for the owner's identity in