

being imported or offered for import into the United States, the Secretary * * * shall by regulation require * * * the submission to the Secretary of a notice * * *." FDA notes that Congress did not explicitly limit this provision to articles of food that are intended for consumption in the United States. However, such limiting language does appear in section 415 of the FD&C Act, which requires certain food facilities to register with the agency. This shows that when Congress crafted the Bioterrorism Act, it knew how to impose the limitation sought by the comments. But neither section 801(m) of the FD&C Act nor its legislative history contains language suggesting this limitation.

The purpose of the Bioterrorism Act is "to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." The prior notice provision furthers this goal by enhancing the agency's ability to inspect imported food upon arrival in the United States. Excluding from prior notice food that is brought into the United States for transshipment or further processing, rather than consumption, would run counter to the purpose of the Bioterrorism Act. Articles entered at the port of arrival under T&E entries with the stated intent to transship and export may be diverted for consumption in the United States and thus remain here rather than leave from another port. Some of this diversion is legitimate; under CBP regulations, importers may change their minds and file a superseding consumption entry. In addition, unscrupulous importers may file a T&E entry instead of a consumption entry to avoid paying duties on foods for consumption in the United States. Unscrupulous importers may also file a T&E entry instead of a consumption entry to try to avoid FDA review of their merchandise: generally, FDA does not receive any notice of these kinds of entries from CBP because these entries are not filed through ABI/ACS.

If we were to interpret "imported or offered for import" to exclude those entries, we could be creating a significant potential gap in section 801(m) of the FD&C Act's coverage. An importer could simply bring in an article of food under a T&E entry without giving prior notice and then, as allowed by CBP regulations, file a consumption or other entry. Thus, this exclusion would create a loophole that could be exploited by those who want to avoid giving prior notice, even for articles of food that are for consumption in the United States. Given the stated

purposes of the Bioterrorism Act and of section 801(m) of the FD&C Act, FDA has concluded that it is reasonable to interpret "imported or offered for import into the United States" to include articles of food entered for transshipment and exportation.

Section 801(a) of the FD&C Act sets out the basic admissibility procedure and standards for foods, drugs, devices, and cosmetics, "which are being imported or offered for import into the United States." As with section 801(m) of the FD&C Act, nothing in section 801(a) limits its requirements just to articles that are intended for consumption in the United States. Indeed, section 801(d)(3) of the FD&C Act exempts from section 801(a)'s admissibility standards certain drugs, devices, food additives, color additives, and dietary supplements if these items are intended at the time of "importation" for further processing or incorporation into a product that will be exported. This exemption is only necessary if the phrase "imported or offered for import" in section 801(a) includes the bringing into the country of some types of goods that are for processing but not consumption in the United States. Thus, in the context of section 801(a) of the FD&C Act, "imported or offered for import into the United States" applies to more than food intended for consumption in the United States. Finally, section 801(d)(1) of the FD&C Act, which limits the circumstances under which U.S.-made drugs can be imported back into the United States, makes it clear that the phrase "imported or offered for import" in section 801(a) applies to items made in the United States, exported, and then "re-imported."

In light of the text of section 801(m) of the FD&C Act, its purpose, and these other provisions in section 801, we believe it is reasonable that this interim final rule applies to food that is brought into the United States for "consumption" (immediate or otherwise) in the United States, for transshipment through the United States and export, or for further processing in the United States and export (often referred to as "import for export"), and to food that is "re-imported." In addition, FDA has concluded in this interim final rule that there are compelling policy reasons for adopting this reasonable definition of "imported," "offered for import," and "importation."

However, when it comes to articles that are imported then exported directly from their port of arrival, we have concluded that it is reasonable to interpret the term "imported or offered

for import" to exclude them from the prior notice requirements.

Food that is brought to a U.S. port but is then directly exported from that port of arrival is entered under a CBP IE entry and subject to the limitations of an IE bond. In essence, this food may not leave the port of arrival until export. These imports are thus subject to almost identical restrictions as food that is refused under section 801(m)(1) of the FD&C Act—foods that are imported under an IE entry may not leave the port of arrival unless exported. Given that controls already exist to ensure that these articles are not released from the port of arrival, FDA believes that it is reasonable to interpret 801(m) as excluding these imports from section 801(m) of the FD&C Act's prior notice requirements.

(Comments) One comment asks that other products covered by USDA programs (such as products included in "CFR(Q37)") be exempt from prior notice in the same manner as foods under the exclusive jurisdiction of USDA.

(Response) The comment did not provide more detail concerning what program is referred to by "CFR(Q37)." As set out in section 801(m)(b)(3)(B) of the FD&C Act, the interim final rule provides that meat food products, poultry products, and egg products that are subject to the exclusive jurisdiction of the USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) are not subject to FDA's prior notice requirements. With regard to other USDA programs, section 315 of the Bioterrorism Act states that no part of Title III should be construed to alter the jurisdiction between USDA and FDA. Notably, under current practice, FDA may have jurisdiction over an imported food under the FD&C Act and USDA may have jurisdiction over an imported food under one or more statutes that it administers, or the two agencies may have joint jurisdiction over an imported food. Under its section 315, the Bioterrorism Act does not change this structure. Accordingly, only imported food that is regulated exclusively by USDA is exempt from prior notice.

In addition, we believe that the statute requires prior notice to be submitted to FDA. As described elsewhere in greater detail, we are working with CBP to modify our existing ABI/ACS and OASIS systems to permit additional data sharing to satisfy prior notice. Although it is theoretically possible for FDA to obtain information from agencies other than CBP, the stringent