

of transport; and streamlining the information requirements.

*C. "What Definitions Apply to This Subpart?" (Section 1.276 Proposed as § 1.277)*

1. The Act (§ 1.276(a))

The proposed rule defined "the act" as the Federal Food, Drug, and Cosmetic Act. The proposed rule also applies the definitions of terms in section 201 of the act (21 U.S.C. 321) to such terms as used in the proposed rule.

(Comments) FDA did not receive comments on the definition of "the act."

(Response) We did not change the definition in the interim final rule. We have clarified that the definitions in the FD&C Act do not apply if a term is defined differently in the interim final rule.

(Interim final rule) Section 1.276(a) of the interim final rule defines "the act" as the Federal Food, Drug, and Cosmetic Act. Section 1.276(b) provides the definitions in the FD&C Act apply unless a term is defined differently in the interim final rule.

2. Calendar Day (§ 1.276(b)(1))

The proposed rule defined "calendar day" as "every day shown on the calendar."

(Comments) FDA did not receive comments on the definition of "calendar day."

(Response) We did not change the definition in the interim final rule.

(Interim final rule) "Calendar day" is defined in § 1.276(b)(1) of the interim final rule as "every day shown on the calendar."

3. Country From Which the Article Originates (§ 1.276(b)(2))

Section 801(m)(1) of the FD&C Act requires that "the country from which the article originates" be identified in a prior notice. The proposed rule used the term "originating country" and defined it as "the country from which the article of food originates."

(Comments) Comments were received on the proposed definition of "originating country." These comments are addressed under "FDA Country of Production," which is the term that FDA has chosen in the interim final rule to replace "originating country."

(Response) The term "the country from which the article originates" has been added to the interim final rule to refer back to the statutory language.

(Interim final rule) "Country from which the article originates" is defined as "FDA Country of Production."

4. Country From Which the Article Is Shipped (§ 1.276(b)(3))

The proposed rule defined "country from which the article of food was shipped" as "the country in which the article of food was loaded onto the conveyance that brings it to the United States." A conveyance is the means of transportation, *e.g.*, ship, truck, car, van, plane, railcar, *etc.*, not the shipping container that can be moved from a ship to a truck to a train. FDA requested comment on whether the phrase "country from which the article of food was shipped" should include the countries of intermediate destination.

(Comments) Several comments support identifying countries of intermediate destination, noting that it would be desirable to have this information to support product tracing. One states that even if a food product were merely shipped through another country without further manufacturing/processing, the potential for tampering would still exist. This comment is concerned that, without information on every intermediate country, FDA would lack the ability to trace food for potential contamination back through the distribution chain. Another comment supports providing the countries of intermediate destination. It states that, except in the case of sealed containers, the manufacturer cannot control manipulation that occurs in countries of intermediate destination.

Several comments state that the information required in a prior notice should not include countries of intermediate destination. Other comments note that: An imported article may pass through a number of ports or stops in a variety of countries and never be unloaded; a U.S. importer in most cases has no control of which ports or stops a carrier may make; and exporters cannot guarantee which ports the ship will enter or pass through on its way to a U.S. port. Another comment states the information would not be necessary for sealed containers because alteration or absence of a seal alerts the owner to tampering, but it may be necessary for bulk or unpackaged products. Most of the comments that object conclude that submission of additional countries of intermediate destination would be unreasonable and burdensome and would not improve the safety and security of the food supply.

(Response) Section 801(m)(1) of the FD&C Act uses the singular "country" when it directs submission of the identity of the country from which the article is shipped, not the plural "countries." Thus, FDA has concluded that the text of the statute dictates that

the definition be singular. The interim final rule thus retains the proposed definition of the term "country from which the article was shipped."

(Comments) One comment states that the proposed definition of "country from which the article of food was shipped" is clear and suggests that it be maintained. Several commenters suggest that "country from which the article of food was shipped" should be defined as the country from which the goods were "exported" to the United States as that phrase is used in the CBP regulations defining "country of export."

Other comments suggest that FDA's definition failed to take into account the following considerations: That ocean and air carriers routinely use "feeder" vessels/aircraft to move cargo from the country of origin to a "gateway" for transfer to a larger vessel or aircraft that will transport the cargo to its final destination; and that ocean vessels frequently discharge containers destined for the United States in Canada where they are transferred to a motor carrier for transport to the United States. The comments conclude that the proposal, if implemented, would confuse importers and require them to attempt to obtain the cargo routing from master carriers. They suggest that FDA require instead the reporting of the last country in which a product was stored if that is different from the country in which it was produced (the country of production).

(Response) Section 801(m)(1) of the FD&C Act requires that prior notice submissions identify "the country from which the article is shipped." "Country of export" is not a term formally defined in CBP's regulations.

We acknowledge that food may pass through more than one country before it reaches the United States. However, we do not believe that this practice changes the definition dictated by the statutory language. Several examples may be helpful. In one scenario, a shipper in country A arranges for a food manufactured in country B to be transported to the United States via country C. The food arrives in country C on an ocean vessel and is transferred to a truck that brings it to the U.S. port of arrival. In this first scenario, the country from which the article is shipped is country C.

In a second scenario, a shipper in country A arranges for a food manufactured in country B to be transported to the United States by a ship that is loaded in country B but stops in country C and then continues to the United States where the food is discharged. In this second scenario, the country from which the article is