

shipped is country B. In a third scenario, if the food was transferred to a different vessel in country C, the country from which the article is shipped is country C.

(Interim final rule) Section 1.276(b)(3) of the interim final rule defines “country from which the article is shipped” as “the country in which the article of food is loaded onto the conveyance that brings it to the United States.” We changed the term from “country from which the article was shipped” to “country from which the article is shipped” to accurately reflect the language of the statute.

5. FDA Country of Production and Originating Country (§ 1.276(b)(4))

The proposed rule defined “originating country” as “the country from which the article of food originates,” which means the country where the article of food was grown and harvested, or if processed, where the article of food was produced.

(Comments) Many comments regarding the definition of “originating country” suggest that FDA use the “country of origin” definition used by CBP, or the standard rules of origin used by CBP, USDA, and associations such as the WTO.

(Response) Section 801(m)(1) of the FD&C Act requires prior notice submissions to FDA identify “the country from which the article originates.”

We have not changed the definition of “originating country” to align it with “country of origin” as that term is defined by CBP. CBP defines “country of origin” at 19 CFR 134.1(b) as follows: the country of manufacture, production, or growth of any article of foreign origin entering the United States. Further work or material added to an article in another country must effect a substantial transformation in order to render such other country the “country of origin” within the meaning of this part; however, for a good of a NAFTA country, the NAFTA Marking Rules will determine country of origin.

In rulings, CBP has further defined “country of origin” and substantial transformation to identify the country of growth of the main ingredient in a processed food rather than the country of production of “the article [of food]” (emphasis added) in the form it is being imported into the United States. For example, a CBP ruling identified the country of origin as the United States where beans were rehydrated and canned in the Dominican Republic, but grown and dried in the United States (Ref. 1). For purposes of the prior notice provisions of the FD&C Act, the “article of food” is canned beans, not dried

beans. From a food safety standpoint, FDA is most interested in knowing where the article of food was processed and canned. We believe that it best serves the language and the purposes of section 801(m)(1) of the FD&C Act to define the term to focus on the country of production of the specific article of food that is being shipped to the United States. To avoid confusion between FDA’s prior notice requirements and CBP requirements, the interim final rule uses the term “FDA Country of Production” instead of the term “originating country” or “country from which the article originates.” “FDA Country of Production” is already familiar to customs brokers and self-filers using ABI/ACS interface with OASIS.

(Comments) One comment suggests that “EU” (European Union) be acceptable for use as an originating country.

(Response) FDA disagrees. Section 801(m) of the FD&C Act requires identification of “the country from which the article originates” (emphasis added). Accordingly, for purposes of this provision, each sovereign country must be identified when declared as part of the prior notice submission.

(Comments) Several comments suggest that the definition of “country of origin” for fish be the country in which the vessel is flagged or in which the fish was last processed. Another comment asks FDA to use the definition of “country of origin” being used by USDA’s Agricultural Marketing Service for fish and seafood.

(Response) We generally agree. The proposed rule relied in part on USDA’s proposed definition as set out in USDA guidance published in the **Federal Register** on October 11, 2002, and is based on the Farm Security and Rural Investment Act of 2002 (commonly known as the 2002 Farm Bill), as amended. As set out in § 1.276(b)(4) of the interim final rule, if an article of food is wild fish that is still in its natural state and was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. If the article of food is made from wild fish aboard a vessel, the FDA Country of Production is the country in which the vessel is registered.

(Comments) Several comments express concern that the proposed definition, “[o]riginating country means the country from which the article of food originates,” does not take into consideration the producer, processor, vessel or common carrier feeder and

consolidation practices in which components of the shipment may be composites or commingled from more than one country. One comment asks that FDA describe when the country of canning would be the originating country, and when it would not. One comment suggests that decaffeinating or blending coffee be considered processing and that decaffeinated or blended coffee be considered as processed food for the purposes of prior notice.

(Response) Some of these comments appeared to confuse the proposed definition of “country from which the article of food was shipped” with the proposed definition of “originating country,” another reason why we decided to use the term “FDA Country of Production.” As explained above in the discussion of “the country from which the article is shipped,” the two countries will sometimes be different. When determining which country is the FDA Country of Production, the focus should be on the production of the specific article of food. For example, if the article of food is raw, whole, unpeeled carrots, the FDA Country of Production is the country where the carrots were grown and harvested. If the article of food is raw peeled and chopped carrots or canned carrots, the FDA Country of Production is the country where the carrots were peeled and chopped or canned. As a general matter, for canned foods, the FDA Country of Production should be the country where food was canned. Similarly, we consider decaffeinated coffee to be no longer in its natural state and the FDA Country of Production would be the country in which the coffee was decaffeinated.

(Interim final rule) Section 1.276(b)(4) of the interim final rule defines the “FDA Country of Production” for an article of food that is in its natural state, as country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If an article of food is wild fish, including seafood, that was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. For an article of food that is no longer in its natural state, the FDA country of production is defined as the country where the article was made; except that, if an article of food is made from wild fish, including seafood, aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is no longer in its natural state was made in