

# CPG Sec. 560.200 Country of Origin Labeling

## BACKGROUND:

A statement of the country of origin on the labeling of imported foods is not required by the Federal Food, Drug, & Cosmetic Act. This is a requirement of the U.S. Customs \*and Border Protection (CBP)\* as authorized by the Tariff Act of 1930 and CPB regulations (19 USC 1304(a) and 19 CFR Part 134).

Repackers are required by \*CBP\* to mark containers of repackaged imports with the English name of the country of origin. In the event that further reprocessing or material added to the article in another country results in a "substantial transformation" of the product, the other country becomes the country of origin within the meaning of \*CBP's\* labeling requirements, 19 CFR 134.1(b) and 134.11. As a result of \*CBP's\* seizure actions and other regulatory follow-up involving imported shrimp that was peeled, deveined, and repacked in the United States and labeled as a product of the U.S. FDA received congressional, industry, and field inquiries regarding FDA's jurisdiction and policy on country of origin labeling for this product. \*CBP\* considers that peeling, deveining, and repacking is not a "substantial transformation" of the product, sufficient to permit the shrimp to be declared as a product of the U.S., within the meaning of \*CBP's\* laws and regulations.

## POLICY:

Food labeling statements regarding geographical origin must not be false or misleading in any particular. FDA's policy prohibiting false or misleading labeling of food applies equally to imported and domestic products (\*section 403(a)(1)\* and 21 CFR 101.18).

It is possible that a violation of \*CBP's\* requirement concerning country of origin labeling, whether by omission or deviation, could also result in false or misleading labeling that violates the FFD&C Act and FDA regulations.

## Examples:

1. An imported product, such as shrimp, is peeled and deveined or otherwise preserved after importation, but is still identified and sold as "shrimp". If labeled as a "product of the USA," it would be misbranded because the labeling would be false and misleading within the meaning of section 403(a)(1) of the FFD&C Act.
2. An imported product, such as shrimp, is peeled, deveined and incorporated into a shrimp dish, such as "Shrimp Quiche." The product is no longer identifiable as shrimp but as "Quiche." The quiche is a product of the USA. Therefore, labeling it as "product of the

USA" would not be a violation of the FFD&C Act. (Whether or not it violates \*CBP's\* requirements would need to be asked.)

3. An imported product, such as shrimp, is peeled and deveined. It is labeled as "Imported by" or "Distributed by" a firm in the USA. Such labeling would not violate the FFD&C Act, but it would not meet the \*CBP's\* requirement for country of origin labeling. The product would also have to be clearly identified as to country of origin.

FDA's policy regarding false or misleading country of origin labeling is to defer to \*CBP\*. Such labeling is also a violation of the Tariff Act of 1930, which is enforced by \*CBP\*, and \*CBP\* can generally deal with this problem more efficiently than FDA.

#### REGULATORY ACTION GUIDANCE:

Information acquired by FDA personnel regarding false or misleading country of origin labeling should be transmitted by the Program Field Office to the local \*CBP\* office for their consideration, together with offers of FDA cooperation in the matter and a request that the field office be advised of any regulatory follow-up by \*CBP\*.

\*Material between asterisks is new or revised\*

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