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U.S.-Origin Statements on Seafood: Guidance for Industry

Draft Guidance

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For questions regarding this draft document, contact the Human Foods Program at HFP-Policy@fda.hhs.gov.

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**U.S. Department of Health and Human Services
Food and Drug Administration
Human Foods Program**

October 2026

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

FDA is responsible for ensuring that the U.S. seafood² supply is safe, sanitary, wholesome, and properly labeled. In general, FDA-regulated food products may bear truthful and not misleading statements, including U.S.-origin statements, in their labeling. These types of statements could include, for instance, “U.S.-Caught” or “U.S. Farm-Raised” as long as the statements are truthful and not misleading and comply with other applicable statutory and regulatory requirements.³

U.S. law prohibits the introduction or delivery for introduction into interstate commerce of any food that is misbranded (section 301(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 331(a))). Section 403(a)(1) of the FD&C Act (21 U.S.C. 343(a)(1)) provides that a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FD&C Act (21 U.S.C. 321(n)) provides that labeling is misleading if, among other things, it fails to reveal facts that are material in light of representations made or suggested on the labeling.

FDA is issuing this guidance for industry to provide examples of U.S.-origin statements in seafood product labeling that we would consider truthful and not misleading.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

¹ This guidance has been prepared by the Office of Nutrition and Food Labeling; the Office of Dairy and Seafood Safety; and the Office of Regulations and International Programs in the Human Foods Program at FDA.

² The Federal Meat Inspection Act (FMIA), at 21 U.S.C. 601(w)(2), defines catfish (i.e., fish of the order Siluriformes) as amenable species. This means the U.S. Department of Agriculture regulates catfish under the FMIA and this guidance does not cover catfish.

³ For example, such requirements include those in the U.S. Department of Agriculture’s country of origin for fish and shellfish regulations (7 CFR Part 60) and the Federal Trade Commission’s “Made in USA” regulations (16 CFR Part 323). The voluntary U.S.-origin statements covered by this guidance are not intended to take the place of the mandatory labeling information required under regulations such as 7 CFR Part 60.

II. Background

A. General Background

Manufacturers and distributors of food in the United States must ensure that the food's labeling is truthful and not misleading. "Labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article (section 201(m) of the FD&C Act (21 U.S.C. 321(m))). When determining whether a food's labeling is false or misleading, and therefore misbranded, under sections 403(a)(1) and 201(n) of the FD&C Act, FDA considers statements in the context of the food's labeling as a whole (e.g., labels, websites).

Manufacturers and distributors might consider using U.S.-origin statements on food labeling to provide consumers with additional information about the foods they consume. The United States Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS) allows "Product of USA" and "Made in the USA" labels on foods under USDA jurisdiction to designate, among other things, single-ingredient products derived from animals born, raised, slaughtered, and processed in the United States (9 CFR 412.3(a)). However, seafood origin is often inherently different than that of the meat, poultry, and egg products USDA regulates. For example, it could be difficult to establish where certain wild-caught fish were spawned, born, or lived (e.g., because of open waters and fish migrations).

U.S. federal fisheries management is authorized under the Magnuson-Stevens Fishery Conservation and Management Act (MSA; 16 U.S.C. 1801 *et seq.*) and implementing statutes for international fishery treaties. Under the MSA, the U.S. government claims sovereign rights and exclusive fishery management authority over all fish within the U.S. exclusive economic zone (EEZ) established in Presidential Proclamation No. 5030 (48 FR 10605, March 10, 1983) and beyond the U.S. EEZ as provided under 16 U.S.C. 1811(b) for anadromous species and Continental Shelf fishery resources. The Presidential Proclamation describes the U.S. EEZ, in part, as a zone contiguous to the territorial sea, including zones contiguous to the territorial sea of the United States, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands (to the extent consistent with applicable agreements), and United States overseas territories and possessions. It extends 200 nautical miles from the baseline from which the breadth of the territorial sea is measured. Consistent with the authorities authorizing U.S. federal fisheries management, the National Oceanic and Atmospheric Administration's National Marine Fisheries Service issues regulations for fishing that may be applicable within the U.S. EEZ and on high seas for vessels under U.S. jurisdiction.

This guidance provides examples of truthful and not misleading U.S.-origin statements for seafood.⁴

⁴ These examples do not imply that any other statements of this type would be false or misleading under sections 403(a)(1) and 201(n) of the FD&C Act.

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B. Scope

This guidance provides examples and explanations regarding:

- Truthful and not misleading U.S.-origin labeling statements for seafood, including both single-ingredient seafood and the seafood components of multi-ingredient foods (e.g., the fish, alone, in breaded fish sticks; the shrimp, alone, in frozen shrimp scampi).⁵
- U.S.-level origin statements. This guidance does not address more specific origin statements, such as those from states, territories, or localities.

III. Discussion

The following are examples⁶ of U.S.-origin labeling statements that, depending on the context of the labeling as a whole, FDA would consider to be truthful and not misleading on seafood products:

1. “U.S.-Caught” in the labeling of wild-caught seafood that was caught in the United States (including the U.S. EEZ) or caught by U.S.-flagged vessels⁷ under U.S. jurisdiction outside of the U.S. EEZ under the authority of the MSA, international fishery treaty implementing statutes, or other U.S. statutes. Other similar example statements include “U.S. Farm-Raised” in the labeling of seafood cultivated in aquaculture facilities within the United States and exported for processing and “Processed in the United States” for seafood caught or farm-raised outside the United States and processed entirely in the United States.
2. “USA Seafood” in the labeling of (a) “U.S.-Caught” seafood (as described above) that is harvested, processed in its entirety, and offered for sale in the United States, or (b) U.S. spawned and farm-raised seafood that is harvested, processed in its entirety, and offered for sale in the United States.
3. “Made with U.S. Seafood” in the labeling of products (such as multi-ingredient products) in which all seafood (vs. other ingredients) is (a) “U.S.-Caught” (as described above), harvested, processed in its entirety, and offered for sale in the United States or (b) U.S. spawned and farm-raised, harvested, processed in its entirety, and offered for sale in the United States. An example of a qualified version of this statement is “Made with U.S.-

⁵ Although the focus of this guidance is seafood, other FDA-regulated food products may bear truthful and not misleading labeling that complies with applicable statutory or regulatory requirements.

⁶ While the examples in this section include a reference to seafood as a general category, similar statements specific to a seafood commodity (e.g., “USA Salmon,” “Shrimp Processed in the United States”) would also be truthful and not misleading.

⁷ According to the U.S. Department of Transportation’s Maritime Administration, “‘U.S. flag’ means a ship is registered in the United States. Ships registered in the United States must meet U.S. Coast Guard requirements for safety. The company operating the ship must also meet citizenship requirements, and abide by the laws of the United States.” See <https://www.maritime.dot.gov/about-us/frequently-asked-questions> (accessed October 8, 2026).

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Caught Seafood” when the seafood is wild-caught in the United States and exported for processing.

Additionally, a graphic may convey a truthful and not misleading U.S.-origin statement. When using a graphic, such as the American flag, in a U.S.-origin labeling context on seafood for which only some product aspects are connected to the United States, FDA recommends including an accompanying statement that describes what product aspects (e.g., catching, processing) are connected to the United States. The following are examples of such a graphic:



Manufacturers and distributors that choose to use U.S.-origin statements on their seafood products should be able to substantiate the statements to show that they are truthful and not misleading (for example, by using recordkeeping that is part of the industry’s usual and customary business practices).