

Compliance Policy Guide

Sec. 540.750 Use of [The Seafood List](#) to Determine Acceptable Seafood Names

Guidance for FDA Staff

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can submit comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft document before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1421.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Regulatory Affairs**

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA) on this topic.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:**

The purpose of this document is to provide guidance for FDA staff regarding use of [The Seafood List](#) to determine whether a seafood name is acceptable.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA's 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.

II. Background:

In 1988, FDA, in cooperation with the National Marine Fisheries Service, published the first comprehensive list of acceptable market names for domestic and imported fish, called *The Fish List*. *The Fish List* helped facilitate consistency and order in the U.S. market place by providing acceptable fish names that would not mislead consumers about the characteristics and value of the fish. Although the first version of *The Fish List* advanced development and use of non-misleading names for finfish, i.e., vertebrates, its usefulness was limited because it did not include invertebrate mollusks and crustaceans. In 1993, *The Fish List* was revised to include the acceptable market names for domestic and imported invertebrate species sold in interstate commerce and was renamed [The Seafood List](#).

[The Seafood List](#) provides information to industry to help them properly label seafood and products containing seafood ingredients (e.g., in the statement of identity (21 CFR 101.3) and in the ingredient list (21 CFR 101.4)). [The Seafood List](#) may be used in

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conjunction with FDA’s “Guidance for Industry: [The Seafood List](#) - FDA’s Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce” (the [Seafood List Guidance](#)). The [Seafood List Guidance](#) provides principles for determining an acceptable market name for a new seafood species introduced into the U.S. market place. The [Seafood List Guidance](#) also defines the categories of names found in [The Seafood List](#) (e.g., acceptable market name, common name, and scientific name).

III. Policy:

Acceptable names for seafood species are listed in the “Acceptable Market Name(s)” and “Common Name” columns of [The Seafood List](#), except when [The Seafood List](#) indicates that the Common Name is prohibited by the Federal Food, Drug, and Cosmetic Act (FD&C Act) or regulation. FDA recognizes these names as suitable for the label statement of identity and ingredient list, as required under the FD&C Act.

When an acceptable name is provided in [The Seafood List](#) and the name used on the seafood product labeling is not an acceptable name provided in [The Seafood List](#), FDA will consider the circumstances of the situation to determine whether the seafood product is misbranded under section 403 of the FD&C Act (21 U.S.C. 343).

When an acceptable name for a seafood species is not provided in [The Seafood List](#), FDA will consider the circumstances of the situation, including consistency with the principles set forth in the [Seafood List Guidance](#), to determine whether the seafood product is misbranded under section 403 of the FD&C Act. In some situations, more than one provision of section 403 of the FD&C Act may apply. For example, when a species of seafood is labeled with the name of another species of seafood (e.g., pollock labeled as cod), FDA may consider the seafood product to be misbranded under section 403(a)(1) of the FD&C Act (21 U.S.C. 343(a)(1)) because the labeling is false or misleading and also misbranded under section 403(b) of the FD&C Act (21 U.S.C. 343(b)) because the seafood is offered for sale under the name of another seafood.

A. FD&C Act and Regulations

In the “Acceptable Market Name(s)” column of [The Seafood List](#), a common or usual name for a seafood species that has been established by the FD&C Act or by regulation is marked with an asterisk (*). An acceptable market name marked with an asterisk must be used to identify the species on the label, including in the statement of identity (21 CFR 101.3(b)(1)) and the ingredient list (21 CFR 101.4). When a different name from the “Acceptable Market Name(s)” column is provided in the “Common Name” column of [The Seafood List](#), the acceptable market name marked with an asterisk (*) must be used. A dagger (†) symbol next to a name in the “Common Name” column indicates that the name is prohibited by the FD&C Act or regulation.

Section 403(t) of the FD&C Act (21 U.S.C. 343(t)) establishes the name “catfish” for fish classified within the family Ictaluridae. The United States Department of Agriculture’s Food Safety and Inspection Service (FSIS), through its mandatory inspection program,

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regulates fish of the order Siluriformes, including catfish, and products derived from these fish (9 CFR chapter III subchapter F). Under the FSIS regulation, the labels and labeling only of fish and fish products within the family Ictaluridae may bear the term “catfish” (9 CFR 541.7(d)(2)).

The regulations in 21 CFR parts 102 and 161 establish common or usual names for some seafood species. A seafood product that does not bear the name established by regulation for a species is misbranded under section 403(i)(1) of the FD&C Act (21 U.S.C. 343(i)(1)). A seafood product that is labeled as a food for which a standard of identity is established by regulation and that fails to meet the standard is misbranded under section 403(g) of the FD&C Act (21 U.S.C. 343(g)).

B. Compliance Policy Guides (CPGs)

[CPG Sec. 540.475 Snapper - Labeling](#) provides guidance on use of the term "red snapper" as an acceptable market name for *Lutjanus campechanus*. FDA may consider a fish other than *Lutjanus campechanus* that is labeled as "red snapper" to be misbranded under section 403(a)(1) of the FD&C Act (21 U.S.C. 343(a)(1)).

[CPG Sec. 540.150 Caviar, Use of Term - Labeling](#) provides guidance on use of the term “caviar.” Although the term “caviar” can be applied to any kind of fish eggs prepared after a special method (salting), the unqualified term “caviar” should be applied only to sturgeon roe. When caviar is made from the roe of fish other than sturgeon, the label should indicate the name of the fish. The roe of other fish may be labeled " _____ Caviar," the blank to be filled in with the common or usual name of the fish from which the roe was taken. FDA may consider the unqualified use of the term “caviar” on the label of a fish egg product that is prepared from the roe of fish other than sturgeon to misbrand the food under section 403(a)(1) of the FD&C Act (21 U.S.C. 343(a)(1)).

IV. Regulatory Action Guidance:

Districts should consider recommending seizure or import refusal, as appropriate, to CFSAN, Office of Compliance, Division of Enforcement (HFS-605) when a seafood product is labeled with a name other than a name that is:

1. A common or usual name established for the seafood species by the FD&C Act or a regulation, or
2. An acceptable name recommended in [The Seafood List](#).

Districts should consult with CFSAN, Office of Compliance, Division of Enforcement (HFS-605) prior to recommending seizure or import refusal, as appropriate, when a name for a seafood species is not established by the FD&C Act or regulation and is not provided as an acceptable name in [The Seafood List](#).

FSIS has regulatory jurisdiction over all fish of the order of Siluriformes, including catfish, and products derived from these fish. Districts that encounter an apparent violation involving Siluriformes fish and fish products should contact their local FSIS

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representative. See [MOU 225-14-0009](#) between FSIS and FDA.

When recommending seizure or import refusal for violations relating to the guidance in this CPG, the Districts should determine whether one or more of the charges in section V. Specimen Charges apply and whether other statutory violations also apply. Section V. Specimen Charges does not provide an exhaustive list of specimen charges for potential violations that may apply to a seafood product.

V. Specimen Charges

Domestic Seizure

Misbranded - offered for sale under the name of another food

The article of food was misbranded when introduced into and while in interstate commerce and is misbranded while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 343(b), in that it is offered for sale under the name of another food.

Misbranded – standard of identity

The article of food was misbranded when introduced into and while in interstate commerce and is misbranded while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 343(g)(1), in that it purports to be a food for which a definition and standard of identity have been prescribed by regulations as provided by 21 U.S.C. 341, and the food does not conform to such definition and standard.

Misbranded – false and misleading

The article of food was misbranded when introduced into and while in interstate commerce and is misbranded while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 343(a)(1), in that its labeling is false and misleading.

Misbranded – common or usual name

The article of food was misbranded when introduced into and while in interstate commerce and is misbranded while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 343(i)(1), in that the label fails to bear the common or usual name of the food.

Import Refusal

Misbranded - offered for sale under the name of another food

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of section 403(b) of the FD&C Act in that it is offered for sale under the name of another food.

Misbranded – standard of identity

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the

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FD&C Act in that it appears to be misbranded within the meaning of section 403(g)(1) of the FD&C Act in that it purports to be a food for which a definition and standard of identity have been prescribed by regulations as provided by section 401 of the FD&C Act and the food does not conform to such definition and standard.

Misbranded – false and misleading

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of section 403(a)(1) of the FD&C Act in that its labeling is false and misleading.

Misbranded – common or usual name

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of section 403(i)(1) of the FD&C Act in that its label fails to bear the common or usual name of the food.*

Material between asterisks is new or revised.

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