The Seafood List FDA's Guide to Determine Acceptable Seafood Names: Guidance for Industry

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

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Guidance for Industry¹ *The Seafood List* FDA's Guide to Determine Acceptable Seafood Names

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I. Introduction

This guidance is intended to provide guidance to industry about what FDA considers to be acceptable market and common names for seafood sold in the United States and to help manufacturers in labeling seafood products. This guidance provides more information on the acceptable market name, common name, scientific name, and vernacular name of seafood species sold in the United States. These names are listed in FDA's guide entitled <u>*The Seafood*</u> <u>*List*</u>.

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 guidance documents means that something is suggested or recommended, but not required.

II. Background

Through the years, the Federal Government has worked to provide consistent and scientifically sound recommendations to industry and consumers about acceptable market names for seafood sold in interstate commerce. This advice was consolidated in 1988 when FDA published *The*

¹ This guidance has been prepared by the Office of Food Safety's Division of Seafood Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

Fish List in cooperation with the National Marine Fisheries Service to provide a source of names that would facilitate consistency and order in the U.S. marketplace and reduce confusion among consumers. Although *The Fish List* had significant success in achieving its goal, its usefulness was limited because it did not include invertebrate species. In 1993, *The Fish List* was revised to include the acceptable market names for domestic and imported invertebrate species sold in interstate commerce, and renamed *The Seafood List*. *The Seafood List* provides information to help industry properly label seafood and products containing seafood ingredients as required in the statement of identity (21 CFR 101.3) and in the ingredient list (21 CFR 101.4)).

III. Discussion

The use of an acceptable seafood name is essential in the identification of a seafood product because of the exceptional number and variety of species for seafood products. Very few species have just one nationally recognized, common or usual name that allows consumers to unambiguously identify a species in the marketplace. Typically, even the most popular and widely consumed species have acceptable names in *The Seafood List* that are shared with other species. For example, "salmon," "bass," "tuna," "cod," "halibut," and "snapper" are names generally used to identify particular species. When used as an acceptable name, the group name may properly encompass and adequately identify for consumers any member of the group, but it does not provide enough information for a consumer to identify the specific species, if a consumer desires that level of specificity. The "common name" as used by accredited scientific fishery resources generally provides that level of *specificity* and usually is also an acceptable seafood name.

IV. The Seafood List

When determining how to appropriately label seafood, one should check *The Seafood List*.

V. Understanding and Using The Seafood List

Species that are included on *The Seafood List* are those that FDA has determined are sold in interstate commerce or are likely to be sold in interstate commerce and are not prohibited by law from sale in interstate commerce. An acceptable seafood name may be: (1) a common or usual name established by either a history of common usage in the U.S. or by statute or regulation; (2) a common name as used by accredited scientific fishery resources (e.g., American Fisheries Society Publications, Integrated Taxonomic Information System, FishBase, SeaLifeBase, Food and Agriculture Organization) and recognized within commerce in the U.S., except when the name is prohibited by the Federal Food, Drug, and Cosmetic Act (FD&C Act) or a regulation; or (3) a name specifically coined as the name for a species (e.g., "basa" is the acceptable market name coined for *Pangasius bocourti*). Acceptable names for seafood species are listed in the "Acceptable Market Name" and "Common Name" columns of *The Seafood List*, except when

the "Common Name" column in <u>*The Seafood List*</u> indicates that the listed common name is prohibited by the FD&C Act or regulation. FDA recognizes these names as suitable for the required label statement of identity (21 CFR 101.3(b)(1)) and the required ingredient list (21 CFR 101.4).

The column headings in <u>*The Seafood List*</u> identify four types of names for each species (i.e., acceptable market name, common name, scientific name, and vernacular name(s)). Vernacular name(s) are listed in the far-right column under "Vernacular Name(s)" in <u>*The Seafood List*</u> to assist with cross-referencing to an acceptable name. Vernacular names are generally not acceptable names for a species. A description of the four types of names in <u>*The Seafood List*</u> for each species is provided below:

- Acceptable Market Name: An acceptable market name represents the identity of the species to U.S. consumers and is not confusingly similar to the name of another species nor is otherwise misleading. An acceptable market name may be: (1) a "common or usual name" established by either a history of common usage in the U.S. or by statute or regulation; (2) the "common name"; or (3) more rarely, a name specifically coined as a name for a species (e.g., "basa" is the name coined for *Pangasius bocourti*). The acceptable market names of the species that are required by regulation (e.g., Canned tuna which is required by 21 CFR 161.190) are marked with an asterisk (*) in the "Acceptable Market Name" column of *The Seafood List*. The specific regulation is noted to provide additional information (accessed from the Scientific Name hyperlink). When a different name from the "Acceptable Market Name" column of *The Seafood List*, the acceptable market name marked with an asterisk (*) must be used.
- **Common Name:** The common name is the English version of the name established and commonly used by accredited scientific fishery resources (e.g., American Fisheries Society Publications, Integrated Taxonomic Information System, FishBase, SeaLifeBase, Food and Agriculture Organization, etc.) and recognized within commerce in the U.S. to describe a specific species, and is distinct from the scientific name. In some cases, the acceptable market name and the common name are the same. Almost all species have been assigned a unique common name. The use of the unique common name for species has the advantage of limiting confusion about species identity in the marketplace. For this reason, FDA generally recommends use of the common name as an acceptable name unless a common or usual name has been established by statutory law or regulation. When a common name is listed in parenthesis (e.g., Mongrel Daces), then that common name applies to all species in the entire genera (e.g., Rhinichthys spp.) as indicated in the Scientific Name Column of *The Seafood List*. There are some common names that are prohibited by law and cannot be used as acceptable names. For example, the term "catfish" is not an acceptable name for a non-Ictaluridae member of the Siluriformes (catfish) order (see section 403(t) of the FD&C Act (21 U.S.C. 343(t)). The common name of a species that is prohibited by law is marked with a dagger (†) symbol in *The*

<u>Seafood List</u>, and the specific law is noted on the detail page (accessed from the Scientific Name hyperlink) to provide additional information.

- Scientific Name: The scientific name is the Latin name for the genus and species of a fish, established by fisheries taxonomists. The scientific names are included in <u>The</u> <u>Seafood List</u> to permit exact species identification. However, scientific names are not, by themselves, acceptable market names, although they may be used to supplement an acceptable market name in labeling. We have attempted to list valid scientific names. However, some synonyms are listed because of name changes based on advancing knowledge and views of taxonomic specialists.
- Vernacular Name(s): A vernacular name is a commonly recognized local or regional name for a species. Some species may be recognized by a different vernacular name in another locale or region. Vernacular names generally are not acceptable names and their use as such may result in misbranding. Vernacular names are provided in <u>The Seafood</u> <u>List</u> only to assist with cross-referencing to an acceptable market name. Vernacular names (when they exist in <u>The Seafood List</u>) are displayed in red under the column with the heading "Vernacular Name(s)" on the far right. There is also a bullet in <u>The Seafood List</u> stating that vernacular names generally are not acceptable names.

VI. Principles for Determining Acceptable Names

FDA generally evaluates whether a name is an acceptable name based on the following principles in order:

Principle 1:

A common or usual name required by regulation or law is the required name of the food (see statement of identity requirement in 21 CFR 101.3(b)(1)).

Common or usual names required by regulation or law are:

- Pacific whiting (<u>21 CFR 102.46</u>),
- Bonito (<u>21 CFR 102.47</u>),
- Crabmeat (<u>21 CFR 102.50</u>),
- Greenland turbot (<u>21 CFR 102.57</u>),
- Canned oysters (<u>21 CFR 161.145</u>),
- Canned Pacific salmon (<u>21 CFR 161.170</u>),
- Canned tuna (<u>21 CFR 161.190</u>),
- Catfish (Section 403(t) of the FD&C Act (21 U.S.C. 343(t)), and
- Kanpachi (Section 774, Consolidated Appropriations Act, 2023 (Public Law 117-328)).

In the Acceptable Market Name column of *<u>The Seafood List</u>*, the common or usual names for a seafood species that have been established by regulation are marked with an asterisk (*). The

common names in the Common Name column of <u>*The Seafood List*</u> that are prohibited by law and cannot be used as acceptable market names are marked with a dagger (†) (e.g., Walking Clarias Fish is an acceptable market name for *Clarias batrachus*; however, "Walking Catfish" (†) is not an acceptable name.).

Principle 2:

A name is not false or misleading.

A food is deemed to be misbranded under section 403(a)(1) of the FD&C Act (21 U.S.C. 343(a)(1)) if "...its labeling is false or misleading in any particular..." Some examples of how a name may be false or misleading to a consumer are:

- The name is not the name required by statutory law or regulation.
- The name is the same as the name of another species or is confusingly similar to the name of another species and it is not reasonably encompassed within a group of species so named.
- The name implies a unique geographical origin that is misleading.
- The name is a fanciful or coined name that inaccurately characterizes the quality, value, or other feature of the species.

The use of a false or misleading name may prevent correct species identification and thereby affect the ability of processors and consumers to make accurate assessments of the potential safety hazards associated with seafood. Hazards, such as allergenic proteins, natural marine toxins, and scombrotoxin formation, are associated with some species but not others, presenting potential food safety risks if the food is not accurately labeled. Misbranding may also result in economic fraud, because of the difference in the market value of different but similar species of fish. Geographical designations used as part of a name must truthfully represent the geographical origin of the species (21 CFR 101.18(c)) or otherwise conform to 21 CFR 101.18(c)(4). Geographical designations are sometimes part of a species' common or usual name (e.g., Atlantic salmon). FDA recognizes that these descriptors and those used in some common names can be truthful and meaningful parts of a food's statement of identity. Other uses of a geographical descriptor, for example as part of a coined or fanciful name where the descriptor does not accurately describe the geographical extent of the source of the species, may be misleading and are not recommended. The global spread of aquaculture may further confound the use of place of origin labeling, because a species with natural origins in one region of the world may be aquacultured in another region (e.g., Ictalurus punctatus is native to North America, but is now aquacultured in China (Channel catfish - Cultured Aquatic Species (fao.org)). Thus, references used as part of an acceptable name to source waters or place of geographical origin should be used only to describe a species from an exclusive geographical source or fishery, consistent with 21 CFR 101.18(c).

FDA generally does not recommend the use of the common name of one parent as an acceptable name for a hybrid species (e.g., *Morone saxatilis* ("Striped Bass") X *Morone chrysops* ("White Bass") hybrids should not be marketed solely as "Striped Bass"). If there is no common name

developed by a scientific group for a specific hybrid, then the family group name (e.g., Bass) should be used as an acceptable name or a name can be coined.

Principle 3:

A name that has been recognized nationally in the U.S. and commonly used by consumers to identify a species may be an acceptable name.

Our regulations describe the general principles for establishing an acceptable name, which is based on the common or usual name of a food or a coined term (see 21 CFR 102.5(a)). Some of the most frequently consumed species in *The Seafood List* have acceptable market names that are widely recognized by U.S. consumers as referring to a group of similar, related species. For example, the names "tuna," "salmon," and "grouper" can each be used to refer to a variety of species of finfish. Individual species are at times differentiated by acceptable names that are recognized nationally and commonly used by consumers. Yellowfin tuna, sockeye salmon, and coho salmon are examples of differentiated marketed names. The use of a single unique name for any food is the optimum situation for an orderly market. FDA recognizes, however, that there are instances where more than one acceptable name for a species is recognized in the marketplace. Moreover, these names may have been used interchangeably in the U.S. without causing confusion or misrepresentation of the true character and identity of the species involved. For example, "monkfish" and "goosefish" are acceptable names that may be used interchangeably for various Lophius spp. Conversely, as noted above, several different species in *The Seafood List* may share an acceptable market name without causing apparent market conflict (e.g., the acceptable market name "grouper" may be used for several *Epinephelus* spp.). To the extent possible, acceptable market names should provide a clear distinction between species that have different qualities and value to consumers. For example, "pollock" and "cod" are distinct names for distinct species and consumers generally associate higher quality and value with "cod." FDA also recommends that the acceptable market name allow for the selection by consumers from among species with similar names. Acceptable names that express species qualities can be achieved by using the listed common name, as opposed to the listed acceptable market name, except if a dagger exists for the common name (e.g., the common name "red snapper" for Lutjanus campechanus as opposed to the acceptable market name "snapper" because "red snapper" is more highly valued than other snappers (Lutjanus spp.) (FDA Compliance Policy Guide Sec. 540.475 Snapper - Labeling (CPG 7108.21)).

Principle 4:

The common name is generally an acceptable name, if it is not misleading in the U.S.

The name commonly used to identify the same fish may vary from region to region. A vernacular name (local or regional name) for a species, even though well established in that area, may not be an acceptable name for use in interstate commerce. In the broader marketplace, a vernacular name may be the same as, or confusingly similar to the name used to identify a different species in another region. Conflicts with names used in the marketplace can sometimes be avoided by using species-specific common names that are found in accredited scientific

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resources. Because of their specificity, common names allow consumers to more readily differentiate between similar species. FDA generally regards these common names as acceptable names, provided they are not false or misleading (Principle 2) or prohibited by law. A common name of a species that is prohibited by law is marked with a dagger (†) in *The Seafood List*, and the specific law is noted on the detail page (accessed from the Scientific Name hyperlink) to provide additional information.

Principle 5:

An established international name (e.g., established by the Food and Agriculture Organization of the United Nations (FAO)) or a name that is widely recognized and commonly used in the country of origin may be an acceptable name.

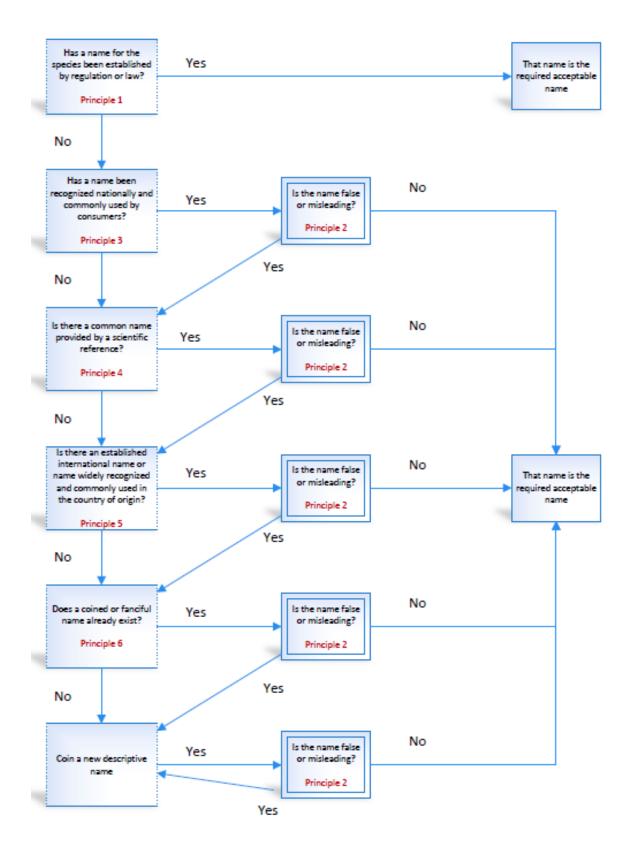
When a species is first introduced into the U.S. market, whether as a new import or a new hybrid, a market name normally is not available. In these instances, an internationally recognized name, such as one recognized by FAO, may be an acceptable name. For example, when a species of crab was first introduced in the U.S. market, Principles 1 and 3 could not be used to develop an acceptable name. The FAO-recognized name "purple stone crab" was identified as a common name, and FDA concluded that this name would be an acceptable name. Alternatively, a name that is widely recognized and commonly used by consumers in the country of origin may be an acceptable name. However, neither an internationally recognized name nor the name most commonly used in other countries will be an acceptable name if it is false or misleading (Principle 2).

Principle 6:

A coined name may be an acceptable name.

When other naming conventions are not available, a coined or fanciful name may be an acceptable name, provided the name is not false or misleading (Principle 2). Coined names are useful when a species has an otherwise unappealing common name (e.g., the coined name "orange roughy" is more appealing than the common name "slime head"), or when the use of a name is prohibited by law. For example, the name "basa catfish" was used for *Pangasius bocourti* before the passage of section 403(t) of the FD&C Act (21 U.S.C. 343(t)). Under section 403(t) of the FD&C Act, a food is deemed misbranded if it purports to be or is represented as catfish, unless it is fish classified within the family Ictaluridae. Thus, the name "basa" was coined for *Pangansius bocourti*. If an acceptable coined or fanciful name does not already exist, one may coin a new descriptive name provided that it is not false or misleading (Principle 2).

Flowchart for Selecting an Acceptable Name



Text Description for the Flowchart above:

The flowchart is in the form of a decision tree. It provides a step-by-step procedure that is used to determine if a name is an acceptable name to use in interstate commerce. Each step in the decision tree provides a response to a question and leads to the next step until a final answer is obtained. The decision tree is derived from the information in the above principles in this guidance document.

VII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at

<u>https://www.regulations.gov</u>. References without asterisks are not on public display at <u>https://www.regulations.gov</u> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

- 1. <u>Fish and Fishery Products Hazards and Controls Guidance</u>, Chapter 3. Food and Drug Administration. (accessed 5/17/2023).*
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Document History

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