

# FDA and Seafood Labeling



## Tracing Seafood from Vessel to Plate

Environmental Law Institute Seminar

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# Purpose of Labeling

- To truthfully inform consumer about the product and its contents
- To protect consumers and provide a basis for an informed buying decision
- To prevent fraud, misrepresentation, and unfair competition



# What is FDA's Role

Our role is to ensure that the seafood industry meets its responsibilities to harvest, process and distribute seafood that is safe, wholesome and properly labeled.

# Regulatory Authority

- The Federal Food, Drug, and Cosmetic Act (FD&C)
- The Fair Packaging and Labeling Act (FPLA)
- Public Health Service Act (PHS)

# Food Labels Must Be Accurate



# FDA Monitors Labeling

- Conducts regular inspections
- Follows a regulatory evaluation process
- The agency takes appropriate actions on products that do not comply with labeling laws and regulations.

## §343. Misbranded Food

A food shall be deemed misbranded...

- If the labeling is false or misleading
- Offered for sale under another name
- Imitation of another food

(unless its label bears, in type of uniform size and prominence, the word “imitation” and, immediately thereafter, the name of the food imitated.)



# Some Reasons for Mislabeling Seafood

- **Economic Fraud**
  - Over breading
  - Short weight
  - Color added
  - Species substitution
  
- **Avoid Regulatory Restrictions**
  - Tariffs
  - Endangered species or catch restrictions
  - Avoid controlling a food safety hazard





**Examples of Substituted Seafood**

**Products in Column A have been known to be substituted for those in Column B, which in most cases are products that are more expensive.**

<b>Column A</b>	<b>Column B</b>
<b>Rockfish</b>	<b>Red Snapper</b>
<b>Yellowtail</b>	<b>Mahi Mahi</b>
<b>Mako Shark</b>	<b>Swordfish</b>
<b>Oreo Dory or John Dory</b>	<b>Orange Roughy</b>
<b>Alaska Pollock</b>	<b>Cod</b>
<b>Sea Bass</b>	<b>Halibut</b>
<b>Arrowtooth Flounder</b>	<b>Dover Sole</b>
<b>Black Drum</b>	<b>Red Drum (Red Fish; Southern or Gulf)</b>
<b>White Perch</b>	<b>Lake or Yellow Perch (Great Lakes)</b>
<b>Zander</b>	<b>Lake or Yellow Perch (Great Lakes)</b>
<b>Paddlefish and other Fish Roe</b>	<b>Caviar (Sturgeon species)</b>
<b>Sauger</b>	<b>Walleye</b>
<b>Pacific Salmon</b>	<b>Atlantic Salmon</b>
<b>Pink Salmon</b>	<b>Chum Salmon</b>
<b>Skate Wings</b>	<b>Scallops</b>
<b>Alaskan Pollock</b>	<b>Walleye</b>
<b>Steelhead Trout</b>	<b>Salmon</b>
<b>Imported Crabmeat</b>	<b>Blue Crabmeat</b>
<b>Farm Raised Salmon</b>	<b>Wild Caught Salmon</b>

# Is It Really Caviar?



# Escolar

- Mislabeled (White Tuna, grouper, sole, etc.)
- The first report of illness caused by consumption of this fish was in the early 1990's by a scientist at NIH.

<http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/UCM297627.pdf>



## An Illustration of how Potential Species Related Hazards can be Overlooked or Incorrectly Identified

<b>Actual Species</b>	<b>Potential -Species Related Hazards</b>	<b>Species Inappropriately Labeled As</b>	<b>Species-Related Potential Hazards of Labeled Species (from Table 3-1)</b>
<b>Escolar</b>	<b>Gempylotoxin Histamine</b>	<b>Grouper or Seabass</b>	<b>Parasites Ciguatera Fish Poisoning</b>
<b>Amberjack</b>	<b>Histamine, Ciguatera Fish Poisoning</b>	<b>Whitefish</b>	<b>Environmental, Chemical Contaminants, and Pesticides</b>
<b>Spanish mackerel</b>	<b>Histamine, Ciguatera Fish Poisoning</b>	<b>Kingfish</b>	<b>None</b>
<b>Puffer</b>	<b>Tetrodotoxin and Paralytic Shellfish poisoning</b>	<b>MonkFish</b>	<b>Parasites</b>
<b>Basa</b>	<b>Environmental, Chemical Contaminants, and Pesticides</b>	<b>Grouper</b>	<b>Parasites, Ciguatera Fish Poisoning</b>

# FDA and Seafood Labeling

- FDA's Current Laws, Regulations, and Policies
- The Seafood List

# Specific Law - Catfish

Public Law 107-171, entitled the Farm Security and Rural Investment Act of 2002 (FSRIA), became law. Section 10806 of the FSRIA amends section 403 (the food misbranding provision) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 343) to provide that a food shall be deemed to be misbranded "[i]f it purports to be or is represented as catfish, unless it is fish classified within the family Ictaluridae."

# Standardized Food Regulations

§ 161.130 - Oysters

§ 161.136 - Olympia oysters

§ 161.145 - Canned oysters

§ 161.170 - Canned Pacific salmon

§ 161.173 - Canned wet pack shrimp

§ 161.175 - Frozen raw breaded shrimp

§ 161.176 - Frozen raw lightly breaded shrimp

§ 161.190 - Canned tuna

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=161>



## Specific Common or Usual Name Regulations

[http://www.access.gpo.gov/nara/cfr/waisidx\\_03/21cfr102\\_03.html](http://www.access.gpo.gov/nara/cfr/waisidx_03/21cfr102_03.html)

-102.47 Pacific whiting

-102.49 Bonito

-102.50 Crabmeat (king and snow)

-102.57 Greenland turbot (*Reinhardtius hippoglossoides*)

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=102>

## Import Alerts

- Import Alert 16-04 - Misbranded Seafood Products
- Import Alert 16-128 - Misbranded catfish

<http://www.fda.gov/forindustry/importprogram/importalerts/default.htm>

## Compliance Policy Guides

- 540.150 - Use of Term Caviar - Labeling
- 540.475 - Red Snapper
- 540.700 - Processed and/or Blended Seafood Products
- 540.750 - Common or Usual Names for Seafood Sold in Interstate Commerce

<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119201.htm#SubChapter540>



# THE SEAFOOD LIST

*FDA's Guide to Acceptable Market Names For  
Seafood Sold in Interstate Commerce*

PIKE  
SCALLOP  
LOBSTER  
LING  
MUSSEL  
ABALONE  
SALMON  
OYSTER  
COCKLE  
TROUT  
SHRIMP



[http://www.accessdata.fda.gov/scripts/SEARCH\\_SEAFOOD/index.cfm?other=complete](http://www.accessdata.fda.gov/scripts/SEARCH_SEAFOOD/index.cfm?other=complete)





# Food

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## Guidance & Regulation

Guidance Documents &  
Regulatory Information by Topic

Seafood

## Resources for You

- [The FDA Seafood List - Updates for 2012](#)
- [The FDA Seafood List - Updates for 2011](#)
- [The FDA Seafood List - Updates for 2010](#)
- [Seafood Species Substitution and Economic Fraud](#)

## Guidance for Industry: The Seafood List - FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce

*Contains Nonbinding Recommendations*

*Additional copies are available from:  
Office of Food Safety  
Division of Seafood Safety HFS-325  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740  
(Tel) 240-402-2300  
<http://www.fda.gov/FoodGuidances>*

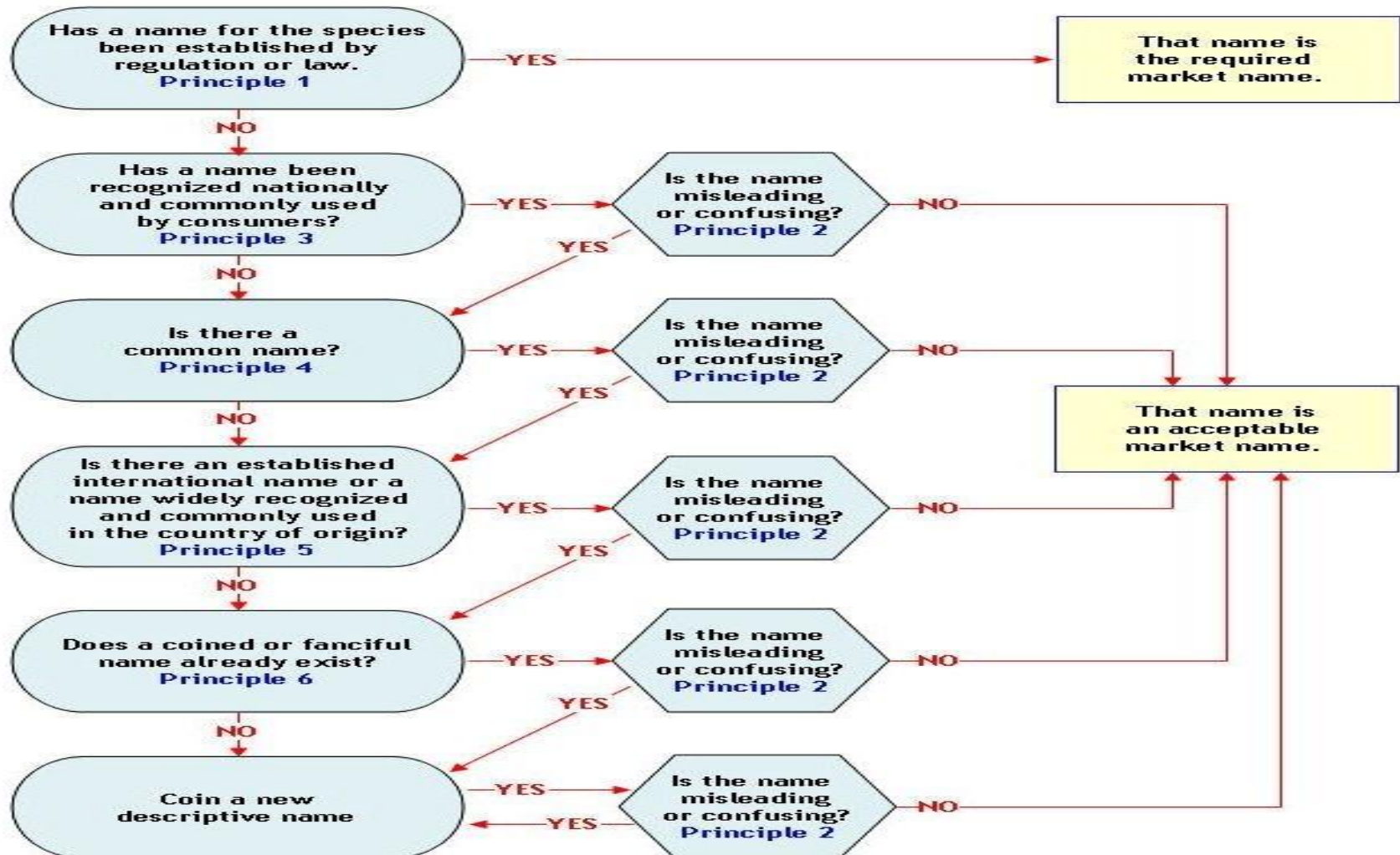
You may submit either electronic or written comments on this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with docket number FDA-1994-D-0221 (formerly 94D-0265).

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Issued: September 1993  
Revised: January 2009  
November 2010  
July 2012**

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## SFL Flow Chart - To Determine if a Name is an Acceptable Market Name



# Criteria for Inclusion in the List

- The seafood species is currently sold in interstate commerce in the United States or has a strong potential for sale.
- The species is currently not listed as endangered.
- The seafood species is not prohibited by law from sale in interstate commerce.



# The Seafood List

[FDA Home](#)
[The Seafood List Guidance](#)
[The Seafood List](#)



Updated November 2013

The *Seafood List* is FDA's Guide to Acceptable Market Names for Seafood sold in Interstate Commerce. The FDA Acceptable Market Name can be used to label seafood products in interstate commerce. When there is no Acceptable Market Name in The Seafood List, or to determine if a different particular name is an Acceptable Market Name use in interstate commerce, consult the [Principles](#) in Section VI of the [Seafood List Guidance](#).

The List is located on FDA's website as a searchable database and contains the following information:

- Type – indicates Vertebrate (V) or Invertebrate (I),
- Scientific Names (Latin binaries),
- Common Names (usually an English language name established by ichthyologists and other fishery experts).
- An acceptable FDA Market Name (or Names),
- An asterisk (\*) next to the FDA Acceptable Market Name indicates that a specific rule or regulation applies to that species. A listed regulation number refers to the applicable section of the regulation cited. A dagger (†) next to the Common Name in The Seafood List identifies names that are prohibited by a law. The specific law is noted to provide additional information.

Detailed information for a specific species is available by clicking on the Scientific Name link. A detail page will appear with the following information, if available.



## Seafood List Output

T Y P E	ACCEPTABLE MARKET NAME(S)	FDA REGULATION REFERENCE	COMMON NAME	SCIENTIFIC NAME <i>Latin binary</i>	VERNACULAR NAME(S)
V	Tuna (*)	21 CFR 161.190	Bullet Tuna	<i>Auxis rochei</i>	Frigate Tuna/ Plain Bonito/ Bonitou/ Melvera/ Bullet Mackerel
V	Tuna (*)	21 CFR 161.190	Frigate Tuna	<i>Auxis thazard</i>	Plain Bonito/ Judeu/ Melva/ Ke Oke O/ Auxide/ Frigate Mackerel
I	Whelk <u>or</u> Sea Snail		Maculated Ivory Whelk	<i>Babylonia areolata</i>	Babylon Shell/ Spotted Babylon
V	Goonch <u>or</u> Ayres			<i>Bagarius bagarius</i>	
V				<i>Bagarius spp.</i>	
V	Goonch			<i>Bagarius yarrelli</i>	
V	Gafftopsail Fish <u>or</u> Gafftopsail Whiskered Fish	FD&C 403(t)	Gafftopsail Catfish (†)	<i>Bagre marinus (DNA)</i>	
V	Perch, Silver		Silver Perch	<i>Bairdiella chrysoura</i>	Mademoiselle/ Yellowtail/ Ground Croaker/ Sand Perch
I	Barnacle			<i>Balanus spp.</i>	
V	Triggerfish		Gray Triggerfish	<i>Balistes caprisus (DNA)</i>	Spotted Triggerfish/ Leatherjacket/ Turbot/ Cucuyo
V	Triggerfish		Queen Triggerfish	<i>Balistes vetula (DNA)</i>	Oldwife/ Old Wech/ Bluestriped Triggerfish/ Cocino
I	Arkshell		Arkshell	<i>Barbatia cancellaria</i>	
I	Arkshell			<i>Barbatia spp.</i>	
V	Red Tailed Tinfoil		Red Tail Tinfoil	<i>Barbonymus altus (DNA)</i>	
V	Barb		Tinfoil Barb	<i>Barbonymus schwanenfeldii (RFE)</i>	
V	Silverside		South American Silverside	<i>Basilichthys australis</i>	