FDA and Seafood Labeling

Tracing Seafood from Vessel to Plate
Environmental Law Institute Seminar
December 13, 2013
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 Mislabeled 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.

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

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

- 102.47 Pacific whiting
- 102.49 Bonito
- 102.50 Crabmeat (king and snow)
- 102.57 Greenland turbot \( (Reinhardtius hippoglossoides) \)

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

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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V. Understanding and Using The Seafood List
VI. Principles for Determining Acceptable Market Names
VII. References
SFL Flow Chart - To Determine if a Name is an Acceptable Market Name

1. Has a name for the species been established by regulation or law? Principle 1
   - Yes: That name is the required market name.
   - No: Has a name been recognized nationally and commonly used by consumers? Principle 3

2. Is the name misleading or confusing? Principle 2
   - Yes: That name is an acceptable market name.
   - No: Is a coined or fanciful name already exist? Principle 6

3. Is there a common name? Principle 4
   - Yes: Is the name misleading or confusing? Principle 2
   - No: Is there an established international name or a name widely recognized and commonly used in the country of origin? Principle 5

4. Is the name misleading or confusing? Principle 2
   - Yes: That name is an acceptable market name.
   - No: Coin a new descriptive name

5. Does a coined or fanciful name already exist? Principle 6
   - Yes: Is the name misleading or confusing? Principle 2
   - No: Coin a new descriptive 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

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

<table>
<thead>
<tr>
<th>Type</th>
<th>Acceptable Market Name(s)</th>
<th>FDA Regulation Reference</th>
<th>Common Name</th>
<th>Scientific Name (Latin binary)</th>
<th>Vernacular Name(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>V</td>
<td>Tuna (*)</td>
<td>21 CFR 161.190</td>
<td>Bullet Tuna</td>
<td>Auxis rochei</td>
<td>Frigate Tuna/Plain Bonito/Bonito/Bul Merv/Black Mackerel</td>
</tr>
<tr>
<td>V</td>
<td>Tuna (*)</td>
<td>21 CFR 161.190</td>
<td>Frigate Tuna</td>
<td>Auxis thazard</td>
<td>Plain Bonito/Jude Melva Ke Oke O/ Auxide Frigate Mackerel</td>
</tr>
<tr>
<td>I</td>
<td>Whelk or Sea Snail</td>
<td></td>
<td>Maculated Ivory Whelk</td>
<td>Babylonia areolata</td>
<td>Babylon Shell/ Spotted Babylon</td>
</tr>
<tr>
<td>V</td>
<td>Goonch or Ayres</td>
<td></td>
<td></td>
<td>Bagarius baganus</td>
<td></td>
</tr>
<tr>
<td>V</td>
<td>Goonch</td>
<td></td>
<td></td>
<td>Bagarius spp.</td>
<td></td>
</tr>
<tr>
<td>V</td>
<td>Goonch</td>
<td></td>
<td></td>
<td>Bagarius yarrelli</td>
<td></td>
</tr>
<tr>
<td>V</td>
<td>Gafftopsail Fish or Gafftopsail Whiskered Fish</td>
<td>FD&amp;C 403(t)</td>
<td>Gafftopsail Catfish (†)</td>
<td>Bagre marinus (DNA)</td>
<td></td>
</tr>
<tr>
<td>V</td>
<td>Perch, Silver</td>
<td></td>
<td>Silver Perch</td>
<td>Bairdiella chrysoura</td>
<td>Mademoiselle/Yellowtail/ Ground Croaker/Sand Perch</td>
</tr>
<tr>
<td>I</td>
<td>Barnacle</td>
<td></td>
<td></td>
<td>Balanus spp.</td>
<td>Spotted Triggerfish/ Leatherjacket/ Turbot/ Cucuy</td>
</tr>
<tr>
<td>V</td>
<td>Triggerfish</td>
<td></td>
<td>Gray Triggerfish</td>
<td>Balistes capriscus (DNA)</td>
<td></td>
</tr>
<tr>
<td>V</td>
<td>Triggerfish</td>
<td></td>
<td>Queen Triggerfish</td>
<td>Balistes vetula (DNA)</td>
<td>Oldwife/Old Wech/Bluestriped Triggerfish/Cocino</td>
</tr>
<tr>
<td>I</td>
<td>Arkshell</td>
<td></td>
<td>Arkshell</td>
<td>Barbata cancellaria</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>Arkshell</td>
<td></td>
<td>Arkshell</td>
<td>Barbata spp.</td>
<td></td>
</tr>
<tr>
<td>V</td>
<td>Red Tailed Tinfoil</td>
<td></td>
<td>Red Tail Tinfoil</td>
<td>Barbonomyus altus (DNA)</td>
<td></td>
</tr>
<tr>
<td>V</td>
<td>Barb</td>
<td></td>
<td>Tinfoil Barb</td>
<td>Barbonomyus schwanefeldii (RFE)</td>
<td></td>
</tr>
<tr>
<td>V</td>
<td>Silverside</td>
<td></td>
<td>South American Silverside</td>
<td>Basilichthys australis</td>
<td></td>
</tr>
</tbody>
</table>