Industry Guidance of Best Practices for Addressing Seafood Fraud

Developed by a Task Force of
Better Seafood Board and
National Fisheries Institute Members

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Industry Guidance of
Best Practices for
Addressing Seafood Fraud

Introduction

The following guidance, developed by a task force of Better Seafood Board and National Fisheries Institute members, is intended to outline best practices for addressing seafood fraud. The task force was composed of seafood industry members who are actively engaged in the buying, selling and processing of seafood products and are knowledgeable about current practices. The guidance provides information to help ensure that sellers are not committing fraud and helps buyers ensure they are receiving the product they want.

The guidance is organized to address four areas of fraud:

- Products are correctly labeled for weights and counts;
- Products are correctly labeled for identity and species are not substituted in any manner;
- Products are correctly labeled for country of origin; and
- Products adhere to all other labeling laws.

Additional background information is included in the five appendices which address each specific area.

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Products are correctly labeled for weights and counts

Introduction: According to federal regulations, seafood is sold by weight, with the exception of whole shellfish which can be sold by weight and/or count, or oysters which may be sold by the gallon. Labels attached to the product must accurately reflect the declared weight or count. Mislabeling for weight, other than what is accurate, is considered a fraudulent activity and lessens the seller's credibility. Examples would include rounding up or adding extra materials, such as water or ice glazing, to increase the weight.

Laws and Regulations: Laws and regulations regarding weights and counts of seafood are contained in the Food, Drug and Cosmetic Act; the Fair Packaging and Labeling Act; 21 CFR, Part 1 Subpart B and Part 101; and additional guidance is contained in the National Institute of Standards and Technology (NIST) Handbook 133. States may have adopted Handbook 133 as their regulations.

Methods to Ensure Correct Weights and Counts during Processing: Measuring devices, such as scales, shall be calibrated regularly to ensure accuracy. Staff should be trained to accurately weigh product before printing and affixing the label. Quality control examples may include:

- *Have a policy statement to always pack the product to at least the declared weight or count.*
- *Have and implement a written net weight control procedure.*
- *Ensure that all relevant staff are trained in the calculation of weights and counts, and the corresponding labeling policy and procedures for weights and counts.*
- *Maintain documentation to demonstrate that in-plant testing has been done and/or net weight calculations are regularly performed to verify products against the label net weight declaration.*
- *Maintain records of operation parameters for glazing process (for frozen products, if applicable).*
- *Follow U.S. Department of Commerce (USDC) or AOAC International (AOAC) method for deglazing and determining net weight for frozen product.*

- *Use AOAC methods for calibration procedures for thermometers and scales.*
- *If purchasing frozen product with the intent to repack, procedures should include calculating the actual glaze percentage, keeping in mind the amount of glaze will be deducted when determining net weight.*

Methods to Verify Supplier is Delivering Correct Weights and Counts: Examples of verification procedures and controls may include:

- *Clearly state in the product purchasing specifications that net weight must be accurate and verified according to the specific testing methodology. For frozen product, specify that the net weight does not include the weight of the glaze.*
- *Establish procedures for addressing short weight shipments with the supplier.*
- *Upon receipt, samples taken from a shipment should be weighed to verify the net weight listed on the label is an accurate statement of the weight of the product (deglazed, if applicable) and documented.*
- *Shipment records and bills of lading should be kept according to regulatory requirements.*

Products are correctly labeled for identity and species and are not substituted in any manner

Introduction: Species of fish can easily be substituted for that listed on the label and not detected by the purchaser due to the similar appearance of the two species. For example, less expensive farm raised tilapia is sometimes substituted for red snapper. This can represent a significant value in economic fraud. In addition, some substitutions may introduce a safety hazard because species-related hazards may be overlooked during a hazard analysis and not controlled with the company's Hazard Analysis and Critical Control Point (HACCP) plan.

Laws and Regulations: Laws and regulations regarding the misrepresentation of seafood species are contained in the Federal Food, Drug, and Cosmetic Act; the Fair Packaging and Labeling Act; and 21 CFR, Parts 101 and 123.

Methods to Ensure Correct Species Identity and Labeling: Buyers should be mindful they are receiving the correct product. Controls will be dependent on the form in which the fish is received (*e.g.*, whole, headed and gutted, fileted). Controls for species verification should be in place and may include:

- *Have a policy statement that all fish will be labeled with an acceptable name in accordance with the guidance and principles expressed in the U.S. Food and Drug Administration (FDA) seafood list.*
- *Have and implement a written procedure for ensuring products are correctly identified.*
- *Have and implement written Product Specifications to communicate and verify the labeling and identity for seafood purchased and packaged from foreign and domestic sources.*
- *Ensure that all relevant staff, including sales, are trained in the company policy for species identification.*
- *If processing species that are commonly substituted, consider periodically submitting samples for DNA species analysis or other species identification testing.*
- *Label all products in storage even those being staged or in storage with identity, which must match if repacking. This should be part of the supply chain monitoring and well documented for traceability. Include product species name and traceability element (ex. product and lot codes).*
- *Request a letter of guarantee from the supplier.*

Methods to Verify Supplier is Delivering Correctly Identified Species: Examples of verification procedures and controls may include:

- *Clearly state the species you want to receive in the purchasing specifications (e.g., specify "Atlantic cod" rather than "Cod" or reference the scientific (Latin) name in the FDA seafood list).*
- *Examine the physical appearance of the fish products upon receipt to verify the product characteristics are as expected (e.g., color, thickness, size of pieces, size of flakes).*
- *Verify the product name upon receipt to ensure it is what was ordered.*
- *Request a letter of guarantee from the supplier.*
- *Conduct random testing for verification when the situation merits and/or for high risk species (e.g., grouper and snapper).*
- *Use the FDA Seafood List as a reference.*

Products are correctly labeled for the country of origin

Introduction: Fresh and frozen raw fish and shellfish sold at retail in the United States are required by U.S. Department of Agriculture (USDA) regulations to have Country of Origin Labeling (COOL). For purposes of COOL, products include fillets, steaks, nuggets, and any other flesh from farm-raised or wild caught fish or shellfish. The label must state the method of production whether that is wild caught or farm raised. U.S. Customs and Border Protection (CBP) also has requirements for country of origin declaration.

Origin labeling can be a complex task with fish and shellfish because the fish may be caught in waters of one country with additional processing added in other countries. CBP determines the country of origin to be the country in which the last substantial transformation occurred. Processed products that have undergone substantial transformation in the USA do not require country of origin statements on the label.

Laws and Regulations: Regulations regarding country of origin labeling are contained in Title 7 CFR Parts 60 and 65, USDA Country of Origin Labeling; 19 CFR, Part 102 and Part 134, U.S. Customs and Border Protection Rules of Origin and Country of Origin Marking; and 16 CFR, Part 323, Federal Trade Commission (FTC) Made in the USA Labeling Standard.

Methods to Ensure Correct Country of Origin Labeling: When packaging with a label or posting signage at point of sale, processors or retailers should have controls and practices in place. Examples may include:

- *Have a policy statement to always label the product according to legal and regulatory COOL requirements.*
- *Have and implement written Product Specifications to verify the country of origin for seafood purchased and packaged from both imported and domestic sources. Check Supplier Agreements, Food Fraud (e.g., transshipment) or Internal Plans and Traceability programs.*
- *Maintain records documenting that all relevant staff and suppliers are trained in the COOL compliance processes and procedures and that those processes and procedures are implemented*
- *Maintain records showing that relevant staff and suppliers are able to recognize when the country of origin changes due to processing (substantial transformation).*
- *Ensure that language used on labels is in compliance with federal regulations. Acceptable terms for method of production are farm-raised, farmed, wild-caught and wild.*

- *If conditions exist that could allow for transshipment to avoid duties or regulatory action, then have the ability to do traceability as part of your internal audit program.*

Methods to Verify Supplier is Properly Indicating Country of Origin Designations: Examples of verification procedures and controls may include:

- *Include country of origin verification in a vendor approval program.*
- *Have the ability to do traceability, including shipping records, from point of origin for both wild caught and farm raised fish and shellfish.*
- *Randomly audit shipping records received from suppliers.*
- *Ensure that language used on labels is in compliance with federal regulations. (For example, ocean caught, line caught, farmed in the wild, fresh water caught and fresh land raised <u>are not</u> acceptable terms for a label.)*
- *Have access to traceability documents such as purchase orders or bills of lading verifying origin.*
- *Compare country of origin and method of production on the label to country of origin and method of production stated on the bills of lading or other purchase documentation.*
- *If repacking or offering for retail sale, maintain internal traceability to ensure correct country of origin labeling.*
- *If conditions exist that could allow for transshipment to avoid duties or regulatory action, then have the ability to do traceability as part of your internal audit program.*

Products adhere to all other labeling laws

Introduction: Fish and shellfish are required to adhere to all other labeling laws, along with those mentioned so far. Examples would include misleading claims that the product contains no additives or preservatives as well as including unsubstantiated health benefits of the fish product or sustainability claims.

Laws and Regulations: Labeling laws are contained in the Federal Food, Drug, and Cosmetic Act; the Fair Packaging and Labeling Act; and the Food Allergen Labeling and Consumer Protection Act (FALCPA). Regulations are contained in 21 CFR Part 1 Subpart B and Part 101, which includes the requirements for making health claims. In addition, be aware of all applicable state and local laws.

Methods to Ensure Label Statements are Truthful and Not Misleading: When developing the language for the label, members should only state information that is known to be truthful and can be substantiated. Examples of practices or controls to have in place may include:

- *All added ingredients, including added water and added protein, must be safe for use in food and listed on the label.*
- *Have proposed labeling claims reviewed by knowledgeable persons (third party, etc.) for accuracy and remove any misleading information.*
- *Expectations for allowed ingredients should be clearly stated in the product specifications.*
- *Random samples of product are tested for any substances for which a claim of the absence or the addition of that substance would be made on the label. (This should be done by both the buyer and seller.) All labeling claims must be in accordance with FDA labeling regulations. See the appendix for reference on labeling guidelines.*

Methods to Verify Supplier is Providing Products with Truthful and Non-misleading Labels: Examples of verification procedures and controls may include:

- *Random samples of product are tested for any substances for which a claim of the absence or the addition of that substance would be made on the label. Require that all added ingredients be listed on the label.*
- *Labels are reviewed any time there is a change in the supplier or source of product. This is covered as part of the initial process under a vendor approval program.*
- *Expectations for allowed ingredients must be clearly stated in the product specifications.*

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Appendix 1 – Net Weight Determination for Seafood

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Background

The net weight of fish and seafood products is a large factor in determining the price and provides insight into the credibility of the seller. As a consequence, determining the correct net weight plays a large role in preventing seafood fraud. The following guidance is offered for determining the correct net weight for seafood.

Accuracy of the Scales

An important first step is maintaining accuracy of the scales. Necessary steps include:

- *Calibrating the scales on a routine basis*
- *Maintaining a log of when scales are checked for accuracy*
- *Conducting, at a minimum, an annual third party or regulatory calibration, e.g., local weights and measures*
- *Checking the calibration weights for accuracy on a regular basis, following state guidelines*

Weighing Procedures

Weighing Procedures include:

- *Training new employees in scale maintenance and instructing them on the importance of preventing water buildup*
- *Keeping scale surfaces free of water and debris while in operation*
- *Using squeegees, as needed, at every scale station to prevent water and particulate build up*

Quality Control

Quality Control steps include:

- *During quality control inspections on incoming products, checking for excess liquid in containers, especially box-in box-out, where a problem could easily be forwarded to the next step in the chain*

- *Controlling the tare on containers in an ongoing manner*
- *Using proper thawing techniques on refreshed products*
- *Ensuring the recorded weight is used to invoice customers*

Sampling Procedures

It will be necessary to take samples to check the quality, weight and other characteristics of seafoods. When organizing lots for sampling, maintain separate lots for each shipment sorted by product type and form. Some basic sampling plans for seafoods are contained in CFR Title 50, Part 260.61.

Other sources of guidance for determining the representative number of samples include:

- National Institute of Science and Technology (NIST) Handbook 133, Chapter 1, Section 1.3, includes how to determine the representative number of samples and Table 2-5 lists the maximum allowable variance (MAV).
- Sampling Plans and Military Standard Sampling Procedures and Tables for Inspection and Attributes.

The methodology for checking the net weight is established by AOAC International (AOAC) and referenced by the U.S. Department of Commerce (USDC)/ National Marine Fisheries Service Seafood Inspection Program. For methodology, please see Chapter 12 of Part 4, Policies, Procedures and Requirements for the Audit of Fisheries Products on a Lot by Lot Basis.

AOAC International Methods

AOAC has established methods for determining net weight and net contents. Four of those methods and one combined method referenced by the NOAA Fisheries Seafood Inspection Program include the following:

AOAC Official Method 963.26
Net Contents of Frozen Food Containers

A. Apparatus

a. *For packages up to 5 lbs*. (2268g)—Use scale of adequate capacity with sensitivity of 0.01 oz. (0.284g).

b. *For packages over 5 lbs*.—Use scale of adequate capacity with sensitivity of 0.025 oz. (0.71g).

B. Procedure

Set scale on firm support and level. Adjust 0 load indicator or rest point and check sensitivity.

a. *Unglazed frozen foods*—Remove package from low temperature storage, remove frost and ice from outside of package, and weigh immediately (W). Open package; remove contents, including any product particles and frost crystals. Air-dry empty package at room temperature and weigh (E). Weight contents = W – E.

b. *Glazed frozen foods*—See 963.18(a).

AOAC 963.18 (a) – Net Contents of Frozen Seafoods – Drained Weight – Glazed Seafoods (Spray – Deglazed Method)

This method is used to determine the net weight of packaged, glazed, Individually Quick Frozen (IQF) shrimp and seafood products that can be deglazed without thawing or partially thawing some or all of the product. This method is not used for block-frozen shrimp, nor for shrimp that are of such small size that glaze cannot be removed practically without thawing, or partially thawing, some of the shrimp. This method also is not used for IQF products that contain clumps or clusters in excess of 15% by weight of the glazed weight. **Results of this method are reported as net weight, regardless of the designation "Drained Weight" in the paragraph heading. The product is not thawed before draining; hence it is not a drained weight.**

Note: Exception to method 963.18 (a): For large packages, cases, or containers of shrimp, a representative subsample is removed from the total contents to facilitate deglazing and for purposes of grading the product to the standard.

AOAC Official Method 963.18
Net Contents of Frozen Seafoods Drained Weight Procedure

Set scale (see 963.26A) on firm support and level. Adjust 0 load indicator or rest point and check sensitivity.

a. *Glazed seafoods*—Remove package from low temperature storage, open immediately, and place contents under gentle spray of cold water. Agitate carefully so product is not broken. Spray until all ice glaze that can be seen or felt is removed. Transfer product to circular No. 8 sieve, 8 in. (20cm) diameter for 0.9 kg (2lb) and 12 in. (30cm) for >0.9kg (2lb). Without shifting product, incline sieve at an angle of 17-20° to facilitate drainage and drain exactly 2 minutes (stopwatch). Immediately transfer product to tared pan (B) and weigh (A). Net Weight product = A – B.

b. *Unglazed seafoods*—See 963.26B.

AOAC 967.13 and 970.60
Drained Weight of Frozen Shrimp and Crabmeat (Immersion-Thaw Method)

These methods are used to determine the net weight of shrimp or other seafood frozen together in a water glazed block (not fish blocks). The individual pieces are not readily separable in the frozen state. These methods are also used for IQF shrimp of such small size that the glaze cannot be removed practically without thawing or partially thawing at least some of the shrimp with the spray method. It is also used for IQF products which contain clumps or clusters in excess of 15% by weight of the glazed weight. Results of these methods are reported as drained weight.

Note: Exception to methods 967.13 and 970.60: Nylon mesh bags are used in lieu of a wire mesh basket.

AOAC Official Method 967.13
Drained Weight of Frozen Shrimp and Crabmeat

A. Apparatus

a. *Container*—Wire mesh basket large enough to hold contents of one package and with openings small enough to retain all pieces. Expanded metal test-tube basket or equivalent, fully lined with standard 16 mesh per linear inch insect screen is satisfactory.

b. *Balance*—Sensitive to 0.25g or 0.01 oz.

c. *Sieves*—U.S. No. 8, 8 in. (20cm) and 12 in. (30cm) diameter.

B. Determination

Place contents of individual package in wire mesh basket and immerse in > 15L (4 gal.) container of fresh water at 26± 3°C (80± 5°F) so that top of basket extends above the water level. Introduce water of same temperature at bottom of container at flow rate of 4-11 L (1-3 gal.)/min. As soon as product thaws, as determined by loss of rigidity, transfer all material to 12 in. (30cm) (for package 450g [1 lb.]) or 8 in. (20cm) (for package < 1 lb.) No. 8 sieve, distributing evenly. Without shifting material on sieve, incline sieve to approximately a 30° from horizontal to facilitate drainage. Two minutes from time placed in sieve (stopwatch), transfer product to previously weighed pan, and weigh. Weight so found minus weight of pan is drained weight of product.

AOAC Official Method 970.60
Drained Weight of Frozen Crabmeat

A. Apparatus

a. *Balance*—Sensitive to 1 g or 0.01 lb.

b. *Thermometer*—Accurate in 0-30°C (30-80°F) range.

B. Determination

Weigh bare block free of all wrappings and record weight. Place block in vessel containing amount of fresh potable water at 27°C (80°F) equal to 8 × declared weight. Leave block in water until all ice is melted. Turn block over several times during thawing. The point at which thawing is complete can be determined by probing block apart.

Pour entire thawed test portion into tared 8 in. (20cm) No. 8 sieve. Incline sieve at an angle 17-20 degrees to facilitate drainage, drain exactly 2 minutes (stopwatch), and weigh. Subtract tare weight of sieve for thawed drained weight of test portion.

Note: Drained weight can be determined whenever requested, however net weight cannot be determined and certified on all lots. When net weight and drained weight can both be determined and the applicant has requested both, the inspector must draw two separate sets of samples, one set for determining the net weight, and one set for determining the drained weight. The applicant must be advised before sampling that two separate sets of samples will be drawn.

The inspector may refuse to perform the spray-deglaze method of determining net weight on shrimp of such small size that the glaze cannot be removed practically without at least partially thawing some of the shrimp. This is a judgment call to be made by the inspector's supervisor, if necessary. If the applicant has requested a net weight determination (not a drained weight determination), and the inspector believes it cannot be performed accurately, the applicant

must be so advised, and permission received to perform a drained weight determination in lieu thereof.

It is important that the certificate state exactly what "weight" was determined, *i.e.*, net weight, drained weight, or both. Further, the inspector must include the AOAC method(s) used (by identifying the section number) on the certification along with the number of the edition of the AOAC manual used.

Exemptions from Net Weight Labeling

Wrapped fish fillets of non-uniform weight and intended to be marked with the correct weight at or before the point of retail sale in an establishment other than that where originally packed shall be exempt from the requirement of section 403(e)(2) of the Act (Federal Food, Drug, and Cosmetic Act) during introduction and movement in interstate commerce and while held for sale prior to weighing and marking, provided that:

- The outside container bears a declaration of the total net weight, and
- The individual packages bear a conspicuous statement "to be weighed at or before time of sale" and a correct statement setting forth the weight of the wrapper.

Provided further, that:

- It is the practice of the retail establishment to weigh and mark the individual packages with a correct net-weight statement prior to or at the point of retail sale. A statement of the weight of the wrapper shall be set forth so as to be readily read and understood, using such term as "wrapper tare __ ounce", with the blank being filled in with the correct average weight of the wrapper use. Protective glazing must be considered when determining the "net weight" and included in the tare.
- The act of delivering the wrapped fish fillets during the retail sale without the correct net-weight statement shall be deemed an act which results in the product being misbranded while held for sale. Nothing in this paragraph shall be construed as requiring net-weight statements for wrapped fish fillets delivered into institutional trade provided that the outside container bears the required information.

Some seafood items, such as shrimp, are sold by net weight but have reference to the count per pound as the declaration of size (*e.g.*, "21 to 30 shrimp per pound"). It is important that this designation represent the ***count per pound*** and not a ***count per bag***.

Including a count per bag on the label is considered by NIST to be a Supplementary Quantity Declaration. Further information is contained in NIST Handbook 130, Section 6.12 which states, "The required quantity declaration may be supplemented by one or more declarations of weight, measure, or count, such declaration appearing other than on a principal display panel. Such supplemental statement of quantity of contents shall not include any term qualifying a

unit of weight, measure, or count that tends to exaggerate the amount of commodity contained in the package (*e.g.*, "giant" quart, "larger" liter, "full" gallon, "when packed," "minimum," or words of similar import)." Including a range (*e.g.*, "21 to 30 shrimp per bag") would be considered to exaggerate the amount of the product in the bag.

Regulation by the States

Each state has comprehensive weights and measures regulations and employs inspectors who monitor and enforce these regulations where seafood is sold. Federal regulations, including those of the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA), pre-empt state authority. Most states adopt the National Conference on Weights and Measures (NCWM) standards that are published in NIST handbooks.

Although there is some uniformity across states in seafood weights enforcement, each state decides:

- *To adopt NCWM standards in NIST Handbooks 130 and 133*
- *The frequency of testing (some states don't test for ice glazing),*
- *Its enforcement actions*

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Appendix 2 - Seafood Names

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Seafood Names – a Bit of Background

With such a wide range of seafood species available, how does one find the answers to correctly name seafood species? In the United States, seafood names that are acceptable for use in interstate commerce for seafood are maintained by the U.S. Food and Drug Administration (FDA) in a searchable database known as The Seafood List. FDA has developed the Seafood List to provide consistent recommendations on acceptable names for seafood sold in the United States.

Before looking at FDA's Seafood List, a bit of background is necessary to understand why naming seafood can be so confusing.

Types of Fish Names

Fishery experts assign two names to all seafood species, the Scientific (Latin) Name and the Common Name. FDA will also assign a third name—the Acceptable Market Name—which is the preferred name to meet FDA's regulations. There are also many regional or vernacular names and the use of these is not allowed for marketing and labeling purposes.

Scientific Name

The Scientific Name is the Latin name that is unique to each individual species. The Scientific Name is assigned by fish scientists (ichthyologists) as they identify new species and their classification within a group. The Scientific Name is comprised of two Latin words – the first word designates the genus categorization and the second identifies the species designation. Many fish that are related can share a genus name, but only a single species can have a specific genus-species combination. The Scientific Name for an individual fish may actually change over time as the science community learns more about different families and re-categorizes species. Scientific Names may often be used by the seafood community, but they are not appropriate to be used alone on a menu or food label without an acceptable market name. However, the Scientific Names may be useful to know when working with your suppliers and customers and may be used on the label as additional labeling information if they do not interfere with required information.

Common Name

The Common Name is a unique, non-scientific name used by fish scientists and some fishermen to describe seafood species. Seafood species that are closely related will have similar names such as "Coho salmon" and "Sockeye salmon" or "Atlantic cod" and "Pacific cod." Common Names will vary within the United States and around the world because they may be in the language of the country or represent a different species or product. As examples: Pacific cod is known as Bacalao del Pacifico in Spain. *Dicentrarchus labrax* is known as Bronzini in the Mediterranean regions but is called European Sea Bass in the US. The fish caught in Alaska known as Black Cod must be labeled Sablefish once it is sold in another state in the United States.

While Common Names may accurately describe species, they are not always used to market the species. Some species are known by the generic family name in a group, because they are similar enough to be identified by the same name. For example, the Common Name for the species *Epinephelus tauvina* is Greasy Rockcod and the Common Name for the species *Epinephelus niveatus* is Snowy Grouper. The FDA Acceptable Market Name for both of these species is "Grouper."

Acceptable Market Name

FDA has identified Acceptable Market Names for labeling species in the Seafood List. These are names that comply with FDA's "common or usual name" regulation and may be simplified versions of the Common Name. In some cases, the Acceptable Market Name is defined by a specific U.S. law or regulation. Quite often, the Acceptable Market Names are recognized by U.S. consumers as referring to a group of similar, related species. Examples of these include "tuna," "trout," "grouper," etc.

What Seafood Name Should I Use?

In the United States, the FDA provides guidance on what to call seafood species. FDA's laws and regulations require that all food (including seafood) be labeled with a suitable statement of identity. FDA has listed in the Seafood List the Common, Scientific (Latin) and Acceptable Market Names. The names that would be acceptable to use on the label and suitable statement of identity would be the Acceptable Market or the Common Name (if there are no regulations or laws that prohibits its use). The Scientific (Latin) Name may also be included on the label if it does not interfere with required labeling information.

FDA has identified principles for establishing the acceptable market name. These include:

- A common or usual name required by regulation or law, is the required market name of the food
- A name that is false or misleading is not an acceptable market name, examples include:
    - The name is not the name required by 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.
- A name that has been recognized nationally in the United States and commonly used by consumers to identify a species may be an acceptable market name
- The common name is generally an acceptable market name
- 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 market name
- A coined name may be an acceptable market name.

Please note that some acceptable market names on the Seafood List are marked with an asterisk (*) (*e.g.*, tuna, bonito, Coho salmon, etc.) meaning these market names for the species are required by regulation. Some common names that are prohibited by law and cannot be used as market names are marked with a dagger (†) symbol.

The principles for Determining Acceptable Market Names for a new species that is not included in the List are found in FDA's Guidance for Industry: The Seafood List and includes a decision tree flowchart for selecting an Acceptable Market Name. This guidance also includes more information about acceptable names for seafood species.

Using FDA's Seafood List

FDA's Seafood List is maintained on FDA's website and is updated twice a year. There are two ways to use the Seafood List:

- by viewing the entire List
- by using the search functions

Viewing the Entire List

The entire Seafood List with over 1800 seafood species is organized alphabetically by the Scientific (Latin) Name. Clicking on the column headings ("Type," "Acceptable Market Name(s)," "Common Name," "Scientific Name") will reorganize the list in alphabetical order based on the chosen heading. The entire list may also be downloaded into an Excel spreadsheet for offline use.

Using the Search Function

The search function of the Seafood List allows for easy searching by scientific (Latin), common, acceptable market and some vernacular names. However, vernacular names are not listed on the primary search page and are included to reference only the acceptable names. Please be aware they are generally not acceptable market names, and their use as such may result in misbranding.

This is a quick way to check to see if a name will be acceptable to use. For example, a search for "Chilean seabass" results in two different fish species that have the Acceptable Market Name of "Chilean seabass". Both the Patagonian Toothfish (*Dissostichus eleginoides*) and Antarctic Toothfish (*Dissostichus mawsoni*) can be called "Chilean seabass" or "toothfish". And there is the option to use the common name, as well, so *Dissostichus eleginoides* can be called Patagonian Toothfish and *Dissostichus mawsoni* can be called Antarctic Toothfish.

Further information on each species can be found by clicking on the highlighted Scientific (Latin) Name. This resulting page lists the Acceptable Market Name(s), the Common Name, and provides links to additional information about the species, such as DNA information, photos of the fish and taxonomic hierarchy. The page will also list other names—Vernacular Names—that may be associated with the species.

Appendix 3 – Country of Origin Labeling

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Background

Country of Origin Labeling (COOL) is required under several laws. The Tariff Act of 1930 mandates country of origin labeling for all imported products, and the 2002 and 2008 Farm Bills and the 2002 Supplemental Appropriations Act mandate COOL labeling for certain agricultural commodities, including seafood. The intent of the laws was to provide consumers with additional information on which they can base their purchasing decisions. Fish and shellfish were added to COOL in 2004.

Other U.S. laws also have an indirect mandate on COOL statements. FDA's Federal Food, Drug, and Cosmetic Act addresses misbranding of food products and the Federal Trade Commission (FTC) Act addresses false or misleading claims that a product is of U.S. origin.

USDA COOL

The Agricultural Marketing Service (AMS) of the U.S. Department of Agriculture (USDA) acts as the regulatory agency for USDA COOL requirements, as mandated by the Farm Bills. The intent of these regulations is to define when a product may be labeled as "Product of the U.S.(A.)" and require COOL labeling for products sold at retail.

"Any person" subject to be licensed as a retailer under the Perishable Agricultural Commodities Act (PACA) of 1930 must label certain commodity products for the country of origin. A "retailer" is defined as a firm with an invoice cost of fresh and frozen fruits and vegetables that exceeds $230,000 annually. Food service establishments, seafood shops and retailers selling less than the requisite amount of fruits and vegetables are exempt.

The following commodities are covered by USDA COOL:

- Fish and shellfish
- Fresh and frozen fruits and vegetables
- Meat muscle cuts and ground meats: lamb, chicken and goat (beef and pork were repealed in late 2015)
- Peanuts, pecans, macadamia nuts
- Ginseng

Provisions for fish and shellfish

The Final Rule definitions for fish and shellfish include:

- Farm-raised fish and shellfish
- Wild fish and shellfish
- Commingled covered commodities
- Pre-labeled
- Processed food items

Farm-raised and wild fish

Farm-raised fish and shellfish are covered and defined by regulation to include:

- Those harvested in controlled environments
    - Including ocean-ranched (*e.g.*, penned) fish
    - Including shellfish harvested from leased beds that have been subjected to production enhancements, such as providing protection from predators, the addition of artificial structures, or providing nutrients
- Fillets, steaks, nuggets, and any other flesh from a farm-raised fish or shellfish

Wild fish and shellfish are covered and defined by regulation to include:

- Naturally born or hatchery-originated fish or shellfish released in the wild, and caught, taken, or harvested from **non-controlled waters or beds** (an example is net-gathered fish)
- Fillets, steaks, nuggets, and any other flesh from wild fish and shellfish

Commingling

When commingling non-processed fish and/or shellfish for retail sale that are sourced from different origins, the declaration of origin shall indicate all of the countries from which the product contained in the package are sourced as well as the method of production (farmed or wild). Processed food items are exempt from the regulations.

Pre-labeled

Pre-labeled is defined by the regulation as a covered commodity that has the commodity's country of origin and the name and place of business (at a minimum, the city, state or other acceptable locale designation) of the manufacturer, packer, or distributor on:

- The covered commodity itself,
- On the package in which it is sold to the customer, or
- On the master shipping container.

Processed food items

Processed food items are exempt from USDA COOL labeling. Processed food items include those with a change of character (except for filleting) or combined with another food component. Substantial transformation (change in character) occurs when a new and different article of commerce emerges from a process with a new name, character, or use different from that possessed by the article prior to processing.

Examples of a change in character include:

- Cooking (*e.g.*, frying, broiling, grilling, boiling, steaming, baking, roasting) Examples are cooked shrimp, canned tuna, canned salmon, canned oysters, crab legs, and seafood medley.
- Curing (*e.g.*, salt curing, sugar curing, drying) an example is pickled herring.
- Smoking (hot or cold) Examples are smoked trout, smoked salmon, salmon jerky, and fish jerky.
- Restructuring (*e.g.*, emulsifying and extruding, compressing into blocks and cutting into portions).

Examples of exempted seafood products as a result of being combined with another food component include stuffed flounder, breaded tilapia, salmon burgers, clams or mussels in tomato sauce, and Cajun catfish. Value added products are those that have one or more additional preparation steps that change the nature of the product, adding value at the time of sale. Examples include seafood medley, coconut shrimp, soups, stews and chowders, sauces, pates, marinated fish filets, crab salad, shrimp cocktail, and breaded shrimp.

Determining Country of Origin Labeling

The origin of the product must be determined whether it is of U.S. origin, foreign origin, or multiple countries of origin.

When the fish or shellfish is imported and not substantially changed in the United States, another country of origin would be stated on the label such as "Product of Country X." The label should state "From Country X, Processed in the U.S." or something similar when the product has been imported AND then has been substantially transformed in the United States. The U.S. country of origin label would apply only for:

- Farm-raised fish and shellfish hatched, raised, harvested, and processed in the United States,
- Wild fish and shellfish harvested in waters of the United States or by a U.S. flagged vessel, and
- Fish and shellfish that have **not** undergone substantial transformation **outside** the United States.

Method of Production

In addition to requiring country of origin, the USDA COOL regulation also requires that the "method of production" be included for fish or shellfish. **Fish and shellfish must list both the country of origin AND method of production on the label.**

The method of production refers to the manner in which the fish are raised in either controlled or non-controlled environments.

Acceptable terms on the label for method of production:

- Farm-raised
- Farmed
- Wild-caught
- Wild

Terms not acceptable on the label for method of production include:

- Ocean caught
- Line caught
- Farmed in the wild
- Fresh water caught
- Fresh land raised

COOL Final Rule References (Final Rule 7 CFR Part 60)

- Farm-raised fish and shellfish – CFR Part 60.106
- Wild fish and shellfish – CFR Part 60.133
- Commingled Covered Commodities – CFR 60.103
- Pre-labeled – CFR Part 60.118
- Processed Food Item – CFR 60.119

U.S. Customs Rules of Origin

Processed food items are generally exempt from USDA AMS COOL regulations but are not exempt from U.S. Customs and Border Protection (CBP) requirements. All products, including processed foods that enter the United States as such, must be marked with the Country of Origin. Processed foods made in the United States may be exempt from COOL requirements, but Customs marking requirements will apply if they are processed in the United States from imported ingredients. If the covered commodity undergoes a substantial transformation after arriving in the United States, then the foreign origins would not need to be marked. If the product is simply repackaged, the country of origin at the time of import would need to be stated on the label.

Example: Alaska flounder shipped to Thailand for filleting becomes a product of Thailand. Russian sockeye salmon filleted in the United States may be labeled without any Customs requirement for foreign origin declaration but would still be subject to USDA AMS COOL labeling requirements, *e.g.*, "Product of Russia, Processed in USA".

U.S. Customs regulations on what constitutes "substantial transformation" can be complex.

CBP also maintains a database of past rulings that can be helpful in determining appropriate country of origin designations for products that are the same as or similar to products for which CBP has already issued a ruling.

The CBP website covers that procedure for obtaining a prospective ruling. Ruling requests can be submitted in writing or electronically.

Some examples of past rulings related to substantial transformation include:

Product	Processing Steps Taken	Ruling by U.S. Customs	Reference
Headed and gutted fish	Thawing, skinning, boning, trimming, freezing and packaging to become quick-frozen fillets	Ruled as substantial transformation because of a change of the appearance and quality	CROSS Ruling: NY 851778
Shrimp	Beheading, peeling, de-veining, freezing, repackaging	Not a substantial transformation	CROSS Ruling: NY N247131
Shrimp	Peeling, de-veining and repackaging foreign-origin shrimp	Not a substantial transformation	CROSS Ruling: HQ 731472
Shrimp	Freezing and packaging headed (without heads) shrimp	Not a substantial transformation	CROSS Ruling: HQ 563123
Crab	Thawing, sorting, blending with domestic product, canning and pasteurization	Not a substantial transformation	CROSS Ruling: HQ 732337
Crab	Crab meat was not largely or wholly removed from the shell	Not a substantial transformation	CROSS Ruling: HQ 109504
Crab	Blending foreign crab meat with U.S. crab meat	Not a substantial transformation	CROSS Ruling: HQ 561208
Crab	Cleaning, cutting the legs from the body, boiling, blast freezing and packaging	Not a substantial transformation	CROSS Ruling: HQ 560322
Calamari (squid)	Imported frozen, raw calamari (squid) tenderized in the United States	Not a substantial transformation	CROSS Ruling: NY N107816

FTC "Product of USA" or "Made in the USA"

The use of "Product of USA" or "Made in the USA" statements are subject to Federal Trade Commission (FTC) rules and guidance. According to the FTC and "Made in USA Labeling" standards, the product must "all or virtually all" be made in the USA, with only a negligible amount of foreign material ingredients.

Claims for "Made in the USA" can be either express or implied. The FTC considers that, "depending on the context, U.S. symbols or geographic references (for example, U.S. flags, outlines of U.S. maps, or references to U.S. locations of headquarters or factories) may convey a claim of U.S. origin either by themselves, or in conjunction with other phrases or images. The Commission is not likely to interpret the mere listing of a company's U.S. address on a package label in a non-prominent way as a claim of U.S. origin."

FTC has additional information to assist with complying with the Made in USA Labeling regulations and standards.

FDA Geographical Label Designations

The U.S. Food and Drug Administration (FDA) allows the use of geographical label designations as long as they are truthful representation of the origins of the food. FDA regulation 21 CFR 101.18, which covers misbranding of food, states, in part:

> ***(c)*** *Among representations in the labeling of a food which render such food misbranded is any representation that expresses or implies a geographical origin of the food or any ingredient of the food, except when such representation is either:*
>
> > ***(1)*** *A truthful representation of geographical origin.*
> >
> > ***(2)*** *A trademark or trade name provided that as applied to the article in question its use is not deceptively misdescriptive. A trademark or trade name composed in whole or in part of geographical words shall not be considered deceptively misdescriptive if it:*
> >
> > > ***(i)*** *Has been so long and exclusively used by a manufacturer or distributor that it is generally understood by the consumer to mean the product of a particular manufacturer or distributor; or*
> > >
> > > ***(ii)*** *Is so arbitrary or fanciful that it is not generally understood by the consumer to suggest geographic origin. (e.g., "Moon Pie")*
> >
> > ***(3)*** *A part of the name required by applicable Federal law or regulation.*

(4) *A name whose market significance is generally understood by the consumer to connote a particular class, kind, type, or style of food rather than to indicate geographical origin. (e.g., "Country Fried Fish")*

Appendix 4 – Label Claims

(Version 10.24.2022)

Introduction

Labels provide needed information for consumers to make informed decisions. U.S. laws, as well as individual state laws, mandate certain information that must be on labels. Additional information may be provided on the product label, but it is important that all label statements and claims be truthful and not misleading.

Labeling requirements are defined by:

- Fair Packaging and Labeling Act
- Food Drug and Cosmetic Act
- FDA regulations
- State laws and regulations

In the United States, the federal Food and Drug Administration (FDA) regulates food labels and labeling.[1] FDA has also taken the position that information about a food conveyed on a website, under defined circumstances, may be regulated as labeling rather than considered as advertising. By listing a seller's website on the label, all statements made on the website are therefore considered to be part of the label.[2]

For example, if a company promotes a food on its website and allows customers to order directly from the website, the website information would likely be considered as labeling. In contrast, information presented on a third-party website and similar to what FDA has generally considered as advertising would not be considered to be labeling.

[1] Note: Siluriformes fish (catfishes) are under the regulatory jurisdiction of U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) and may have different labeling requirements. For example, FSIS safe handling instructions and establishment number and inspection legend will be required on master packaging for food service items and individual packaging for retail sales. The USDA FSIS labeling requirements are defined by the Federal Meat Inspection Act and FSIS regulations.

[2] FDA has stated "in certain circumstances, information about FDA-regulated products that is disseminated over the Internet by, or on behalf of, a regulated company can meet the definition of labeling in section 201(m) of the FDCA" in its response from the Associate Commissioner for Policy to the Washington Legal Foundation regarding a petition denial.

Required Label Elements

- Food label regulations are enforced by FDA and dictate the type of information that must be on the label and where the label can be placed on the package. In addition, some states may enforce labeling laws, which in some cases may require additional components. Before printing labels, make sure you have met all labeling requirements, including Statement of Identity (name of the food)
- Net quantity of contents
- Name and place of business and manufacturer, packer or distributor
- Ingredient statement (except for single ingredient foods)
- Nutrition labeling (for packaged products sold at retail)
- Allergen labeling

There are two ways to label packages and containers. Place all required label statements on the front label panel (the principal display panel or PDP), or place certain specified label statements on the PDP, such as the statement of identity and the net quantity of contents and other labeling on the information panel (the label panel immediately to the right of the PDP)."

Please refer to FDA's online resource, the Food Labeling Guide, for detailed instructions.

The net quantity statement gives the actual weight, volume, or number of pieces of food in the package and must be located on the bottom 30 percent of the PDP. Weights and volumes must be displayed in both U.S. Customary System and metric units--for example, 1 lb. 8 oz. (680 g) or 1 gal (3.79 L).[3]

Product Name and Ingredient Statements

Product names and ingredients listed on the label must fall within guidelines established by FDA.

- FDA's Guidance for Industry: Food Labeling Guide provides guidance on food labeling and naming.
- FDA's Overview of Food Ingredients, Additives & Colors provides guidance on ingredient lists.
- All ingredients, even additives and dips such as phosphates and other moisture retention agent (MRA) ingredients, must be listed in the ingredient statement.

[3] FDA regulations allow for an exemption for net weight labeling of products with non-uniform weight. More information on this exemption is provided in the Appendix for Net Weight Determination for Seafood.

Some examples of fish mislabeling related to required label elements, according to FDA, include:

- *Inaccurate food weight or including the ice glaze as part of the weight*
- *Undeclared preservatives or color—additives*
- *Undeclared moisture retention agents (MRAs)*
- *Undeclared added water*[4]
- *Species substitution*
- *Labeling salad containing surimi as "crab" salad*
- *Short weights*
- *Color enhancements, such as astaxanthin.*

Usually, the principal reason for mislabeling is financial gain, *i.e.,* economic fraud. FDA may consider the product mislabeled if an acceptable market name or common name is not used. Product labeling and invoices should be reviewed regularly for accuracy and matched to each other to monitor and prevent fraud. This is the first line of defense for the buyer to detect economic fraud.

The FDA Seafood List lists acceptable market names for fish sold in interstate commerce and *Appendix 2 - Seafood Names* provides guidance on using the list.

Voluntary Label Statements and Claims

Each statement or claim used must be truthful and not misleading to avoid misbranding the product. Some claims, such as "low fat," have specific regulatory requirements while other claims, such as "raised without antibiotics" or "chemical free," should be evaluated so as to be truthful, not misleading and not disallowed. Examples of potentially misleading voluntary label statements and claims include:

[4] CPG Sec 555.875 Water in Food Products (Ingredient or Adulterant)

Fresh

Care should be taken when using the term "fresh." The term implies the food is unprocessed and

- In a raw state
- Has not been frozen or subjected to any form of thermal processing, and
- Has not been subjected to any other form of preservation, *e.g.*, smoking or pickling.

The terms "fresh frozen" or "frozen fresh" may be used when the food was quickly frozen while still fresh. These terms can be used on retail packaging for frozen seafood as long as they can be substantiated by processing guidelines and documented.

"Previously frozen" refers to product that has been frozen and thawed and then sold in a thawed state. In this case, it must be labeled as "previously frozen." The use of these terms are regulated by 21 CFR (Code of Federal Regulations) 101.95.

Natural

Claims such as "all natural" and "natural ingredients" can be confusing for both marketers and consumers because the terminology has not been officially defined by FDA. However, FDA adheres to the policy that the agency will not object to the use of "natural" if the food does not contain:

- Added color (of any type, whether from a natural or artificial source)
- Artificial flavors, or
- Synthetic substances

FDA's policy does not include the words "minimally processed" but the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) definition includes the phrase "the product and its ingredients are not more than minimally processed." FDA's policy was not intended to address food production methods, such as the use of pesticides, not did it explicitly address food processing or manufacturing methods, such as thermal technologies, pasteurization, or irradiation.

It is important to remember that ingredients may be formulated in different ways; sometimes by a natural process and other times synthesized. It is up to each processor to verify with their ingredient supplier how each ingredient is derived in order to justify the use of the term "Natural". A "naturally sounding" ingredient does not necessarily mean it qualifies as "natural". There has been much scrutiny of the term "natural" in the courts and at FDA. The misuse of the term "natural" on a label could cause the product to be misbranded. FDA is considering through rulemaking whether or not and how to allow the term "natural" on labeling.

Organic

The USDA Agricultural Marketing Service governs the labeling for organic in the United States. A logo is available for products that meet the National Organic Program specifications.

There are currently no standards approved by USDA for labeling seafood as organic. However, USDA is developing regulations for the production and handling of organically grown aquatic animals and their products. In the interim, USDA has allowed fish and other aquatic animal products that have been certified to private organic standards or other countries' organic standards to be labeled as "organic" in the United States (with the exception of California), as long as they do not display the USDA organic logo or reference the USDA organic regulations.

Be aware that the state of California prohibits the sale of seafood labeled as "organic" until national standards for organic seafood have been published. Fish and seafood may also not be advertised or invoiced as "organic" in California until those national standards are in place.

Fat Free or Low Fat

Low fat claims in food are defined by regulation (21 CFR 101.62). "Low fat" is considered to be an expressed Nutrient Content Claim while "healthy, contains 2 g of fat" is considered an implied Nutrient Content Claim. In order to meet fat content claims, the following criteria must be met, according to 21 CFR 101.62:

> The terms "fat free," "free of fat," "no fat," "zero fat," "without fat," "nonfat," "trivial source of fat," "negligible source of fat," or "dietarily insignificant source of fat" may be used on the label or in labeling of products, provided that:
>
> (i) The product contains less than 0.5 gram (g) of fat per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 0.5 g of fat per labeled serving size.
>
> (ii) The product contains no added ingredient that is a fat or is generally understood by consumers to contain fat unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: "Adds a trivial amount of fat," "adds a negligible amount of fat," or "adds a dietarily insignificant amount of fat"; and
>
> (iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to disclose that fat is not usually present in the food (*e.g.*, "broccoli, a fat free food").

Omega-3

A manufacturer may include a statement about a nutrient for which there is no established daily value as long as the claim specifies only the amount of the nutrient per serving and does not implicitly characterize the level of the nutrient in the product. For example, a statement such as "contains X mg of DHA and EPA Omega-3s" is stating a fact and not a nutrient content claim, and therefore allowed. Such claims must be outside the Nutrition Facts Label.[5]

Chemical-Free

The term "chemical free" may be used as long as it is truthful and not misleading. However, this claim is considered misleading when used to imply that a non-phosphate blend used to retain moisture is preferred over the use of a phosphate blend. Non-phosphate blends are added ingredients and therefore required to be listed in the ingredient statement. Labels may cite specific chemicals or additives that are purposely not included, *e.g.*, "no MSG."

No Preservatives

A label may not claim that a food item "contains no preservatives" or is "preservative free" if it does, in fact, contain "any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties," according to 21 CFR 101.22.

When an approved chemical preservative is added to a food, the ingredient list must include both the common or usual name of the preservative and the function of the preservative (*e.g.*, sodium tripolyphosphate (to retain moisture)).

Some preservative food ingredients may perform different functions depending on how they are used. A "No preservative" claim should be carefully considered.

No Antibiotics or Antibiotics Free

The statement "raised without antibiotics" would be appropriate for aquaculture species only. A statement claiming "no antibiotics" or "antibiotics free" would be misleading for a food item for which no antibiotics have been approved (*e.g.*, shrimp) or are not used, as with wild caught species. In this case, for the statement for shrimp to not be misleading, it would need to state

[5] Guidance-for-Industry: Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid and Docosahexaenoic Acid Omega-3 Fatty Acids Small-Entity Compliance Guide. pdf.

that the product was “raised without antibiotics” qualified by a statement such as “FDA has not approved antibiotics for use in raising shrimp.”

Phosphate Free

Phosphates are used in foods as direct additives to retain moisture and protect the flavor. All ingredients must be stated on the label. A phosphate-free claim on a seafood product would be misleading because seafood naturally contains phosphates. A non-misleading claim would be “No added phosphates.” Non-phosphate blends must be included on the label.

Sustainably Raised or Harvested

Sustainability is a subjective term. When making a claim of sustainability, it must be supported by documentation or certification. Some independent groups have developed standards for sustainability certification for seafood.

Claims Made on Labels

FDA has guidance about label claims for conventional foods.

This information covers:

- Health claims, including Nutrition Labeling and Education Act Authorized Health Claims, Health Claims Based on Authoritative Statements and Qualified Health Claims
- Nutrient Content Claims
- Structure Function Claims

Nutrient content claims are covered by FDA regulations in 21 CFR 101.13. Additional guidance may be found in Appendix B: Additional Requirements for Nutrient Content Claims in Guidance for Industry: A Food Labeling Guide.

Made in the USA

The use of “Product of USA” or “Made in the USA” statements are subject to Federal Trade Commission (FTC) rules and guidance. According to the FTC and “Made in the USA” standards, the product must “all or virtually all” be made in the USA, with only a negligible amount of foreign material ingredients.

Claims for “Made in the USA” can be either expressed or implied. The FTC considers, “depending on the context, U.S. symbols or geographic references (for example, U.S. flags,

outlines of U.S. maps, or references to U.S. locations of headquarters or factories) may convey a claim of U.S. origin either by themselves, or in conjunction with other phrases or images.

FTC has additional information to assist with complying with the Made in USA Labeling regulations and standards.

Appendix 5 – Verifying Product Against the Specification

(Version 10.24.2022)

Purpose: Provide guidance to NFI members on establishing seafood product verification programs to answer the question "How do we really know what we are buying?" and provide strategies and guidance on "How do we check?" Intended audience is the entire seafood supply chain.

Scope: This appendix focuses on how to verify that seafood products achieve the four (4) parts NFI's Economic Integrity initiative and pledge. This pledge was developed to help ensure Sellers are not committing fraud and Buyers are receiving the product they ordered but does not go beyond what is required by the FDA, USDA, Customs and Border Protection and, in certain instances, the Federal Trade Commission. The four parts of the pledge are:

- Products are correctly labeled for weights and counts;
- Products are correctly labeled for identity and species are not substituted in any manner;
- Products are correctly labeled for the country of origin; and
- Products adhere to all other labeling laws.

Why Verify?: A well-used phrase in Quality Assurance is "Trust but verify"! Unfortunately, we live in a world where unethical practices occasionally occur, so seafood companies must often earn the customer's trust. Consistency in quality and service as well as good communication increases the customer's level of trust over time, since actions speak louder than words.

Preferred supply chain partners educate their retail and food service buyers on what is being done to ensure the products meet the specification. Seafood supply chains may also include many steps, so being able to trace the raw material back to the source (harvest) provides confidence that sustainability labeling claims are truthful. Verifying the product against the specification and label information protects the company's reputation and protects the brand.

Supplier Approval Program: The first line of defense is to properly vet the supplier by doing some homework prior to purchasing and letting them in the door. You can start by:

- ✓ Looking up the supplier on the FDA Firm/ Supplier Evaluation Dashboard
- ✓ Obtaining the specification to review (unless the Buyer is providing)
- ✓ Reviewing recent third-party audits, including any corrective and preventive actions
- ✓ Reviewing the FDA Seafood HACCP plan for food safety controls

- ✓ Obtaining a HACCP Letter of Guarantee[6] from the Supplier
- ✓ Conducting an in-person plant visit (strongly suggested)[7]
- ✓ Obtaining samples (optional)

A best practice would be to conditionally approve the supplier with an initial high testing frequency before a final recommendation or approval is made.

The Value of the Specification: The specification is the foundation of buying, receiving quality products, and ensuring that the integrity of the product is maintained. A comprehensive specification which spells out exactly what you want to buy or sell puts both parties on the same page. Clear communication between the parties with well-written, comprehensive specifications eliminates gray areas or surprises. Key points include:

- Specifications between buyer and seller shall first meet all regulatory requirements for labeling laws in order to meet local and federal regulatory compliance.
- Specifications should clearly state what ingredients are allowed and that added water must be declared as an ingredient.
- The product specification should clearly state the functionality, processing limits, and finished product attributes when moisture retention agents are used (*e.g.*, sodium tripolyphosphate, phosphate blends, or non-phosphate blends).

Other benefits of written specifications include:

- Captures internal "institutional knowledge" in writing.
- Allows for pictures to illustrate key parts of the specification.
- Has measurable quality and workmanship attributes with defined tolerances.
- Can be part of the contractual documents.

Types of Specifications:

As there are different types of specifications for the same product, a specification may not always include the same information depending on its intended purpose (*e.g.*, who is providing or asking or who is receiving or using it). Examples of the variety of Specifications include:

- Purchasing Specification - key attributes provided by the Buyer to the Supplier
- Processing Specification (often proprietary) - for internal use only

[6] FDA Seafood HACCP (21 CFR Part 123), pertinent FSMA regulations including Good Manufacturing Practices (cGMPs), current FDA Food facility registration or USDA FSIS requirements. The entity itself can issue the HACCP Letter of Guarantee on company letterhead and is not necessary to obtain from a third party.

[7] Knowing your suppliers around the world and visiting them in person can be invaluable. Ongoing frequency of visits can vary based on risk and volume purchased. It is recommended to visit annually for high-risk products (*e.g.*, Scombrotoxin forming species, ready-to-eat, economic integrity) and while visits can be less frequent for lower risk species and products (cod, haddock).

- Customer Facing Specification - set up sheet with key attributes provided by the supplier to the customer, descriptive in nature, and used for setting up the product in the customer's computer system (usually includes Case Cube, Ti/Hi, and Nutritional information)
- Government Specification - USDA AMS Purchasing Programs, USDC Grade A, Child Nutrition label

This guidance is intended to be general in nature and companies should develop procedures to fit different product categories such as fresh or frozen, shrimp, mollusks, finfish, and value-added. A general outline of a process for developing specifications is provided on page 44. A specification template is provided on page 46 as an example of how a company may construct its individual specifications and be used as a foundation upon which to build verification steps. Specific wording may need to be tailored depending on where you are in the supply chain, because "one size doesn't fit all."

Who Verifies?: Specific departments or individuals should be assigned roles and responsibilities for verifying you were sold the correct product(s). Regardless of the size of your company or organizational structure, verification is key to ensuring you receive what was agreed upon. Inspection and analytical testing may be done by:

- Quality Control,
- Quality Assurance,
- Purchasing,
- NOAA Seafood Inspection Services, and/or
- Third-party laboratories.[8]

Frequency: The frequency of inspection and analytical testing may vary based on identified risk(s) for the specific item, supplier history, volume, and/or company budget. Frequency will also vary based on where you are in the supply chain (highest level at processor) and may also depend on the end user use.

A risk assessment must be done first to determine the food safety and economic fraud risk(s) likely to occur. This may include the potential for unauthorized antibiotic use (farmed) and species substitution (economic fraud). This helps a company direct its resources to where they are needed most.[9]

It is recommended to start with an aggressive frequency with new suppliers or products as well as with high-risk products. The inspection frequency can later be reduced based on outcome

[8] You may want to "Test the tester" when it's a third party.
[9] Many companies inspect 100% of the lots received for high-risk species

and supplier history. For example, a common industry practice is to examine the first three to five shipments from a new supplier or for a new product from an existing supplier; the frequency may then be reduced if no issues are found. However, if problems are discovered later at any point and 100 percent inspection is not normally done for all manufactured or received lots, then the frequency can revert to a higher frequency (*i.e.*, tightened inspection frequency). See Verification Frequency Determination Tree on page 45 for guidance on establishing verification plans.

Frequency Examples:

Quality Control	Every half hour during processing
Quality Assurance	Hourly or per designated Statistical Sampling Plan for every production lot
Buyer	Statistical sampling at normal, reduced, tightened rate or none

Sampling Plan: Sampling is always to be done randomly, yet still captures a representative sample from the lot (based on day codes or time stamps). Statistical sampling plans are utilized to determine the number of samples to take and to determine lot acceptance. Common ones used by the seafood industry are 50 CFR Section 260.61 NOAA Seafood Inspection Program (NOAA SIP), Military Standards (MIL-STD-105E), and ANSI/ASQ Z1.4:2008 (which is recognized by FDA).

How do I verify my Product against the Specification: Attributes to inspect will vary by product category or species. Attributes may encompass food safety, labeling, ingredients, and or economic integrity parameters. Regulations also differ slightly between USDA FSIS and FDA, so inspections should be conducted by trained individuals (in house or third party).

Priority attributes to verify to ensure the commitment to "Fair and Lawful Business" pledge made by NFI members is being met:

Attribute	Category	Why	How
Net Weight	Economic Fraud	Ensure product meets stated net weight and additional materials are not included (*e.g.*, weight of packaging and/or water glaze (frozen))	Physically weigh product (deglazed if frozen[10]) on a calibrated scale, must comply with NIST Handbook 133
Count	Economic Fraud	Economic value may vary by size (count/lb.).	Physically count (entire package or 1 lb. subset)
Product Name (species)	Food Safety & Economic Fraud	Substitution may unknowingly cause health risks, and/or be replaced with a lower value species.	Visual inspection - Does the label accurately reflect the product contained within the package? Is it what you ordered? Is it labeled according to the FDA Seafood List? Conduct Visual inspection and/or periodic DNA testing to verify no species substitution occurred.[11]
Country of Origin	Economic Fraud	Country of Origin must meet applicable federal regulations.[12]	Maintain records and know your supply chain. Conduct periodic traceback audits[13].
Adhere to all Other Labeling Laws Label and Product Composition (required fonts and formats, nutrients, and allergen)	Food Safety & Economic Fraud	Must be truthful and not misleading. All added ingredients must be approved and safe for use in food and listed on the label – including added water. Undeclared ingredients[14] and inaccurate nutritional labeling may cause adverse health impacts.	Develop a label review process. Does the label include everything listed in the specification? Are allergens (top 9) correctly labeled? Are the Nutrition Facts Panel and any label Claims accurate (data to support through periodic testing)?

[10] For frozen product, follow USDC or AOAC deglazing procedure. Quick Check Tip: Place case on scale and if weight is equal to or less than declared net weight then the product is out of specification.

[11] Tip: If the species you are buying isn't likely to be substituted than you don't need to test. If the generic species name is used (*e.g.*, snapper or grouper) you may still want to test for the specific species to ensure a substitution was not made with a lower valued species.

[12] US Customs & Border Protection, USDA COOL, Federal Trade Commission Made in or Product of USA.

[13] Due to the complexities of seafood supply chains, companies may also need to do product tracing to determine the actual source and primary processor (often more than one step back in the chain before the end receiver).

[14] If concerns exist due to possible use or abuse of moisture retention agents, there may be an impact on sodium and/or protein content. Undeclared allergens are also the number one reason for food recalls.

Quality attributes that are commonly included:

Attribute	Category	Why	How
Physical Dimensions[15]	Quality	Consistency and if it meets specification	Visual inspection or with rulers or calipers. Check for uniformity of size[16] if applicable.
Appearance	Quality	Workmanship	Visual Assessment Scan for temperature abuse (doubles or clumping), and signs of age (dehydration/freezer burn). Broken or damaged product. Extraneous material (ex. Shell or improperly peeled). Discoloration, Correct color[17] if specified. Fill or Trim level[18] if specified.
Organoleptic/Sensory	Quality	No off odors or flavors, or poor texture to prevent poor consumer experience or adverse health impact to consumer	In raw state and /or cooked. Inspect for ammonia, staleness, sour odors, and tough or mushy texture.

In Conclusion: Your company's reputation is essential to your success as a business. Setting standards and procedures and communicating them to suppliers and customers builds your reputation as a trusted brand in the industry and maintains your commitment to economic integrity.

Specification verification helps maintain compliance by your supplier when communication on their performance (good and bad) is provided. Companies may find a high rate of non-conforming product to start but once the supplier knows you are verifying, the suppliers usually

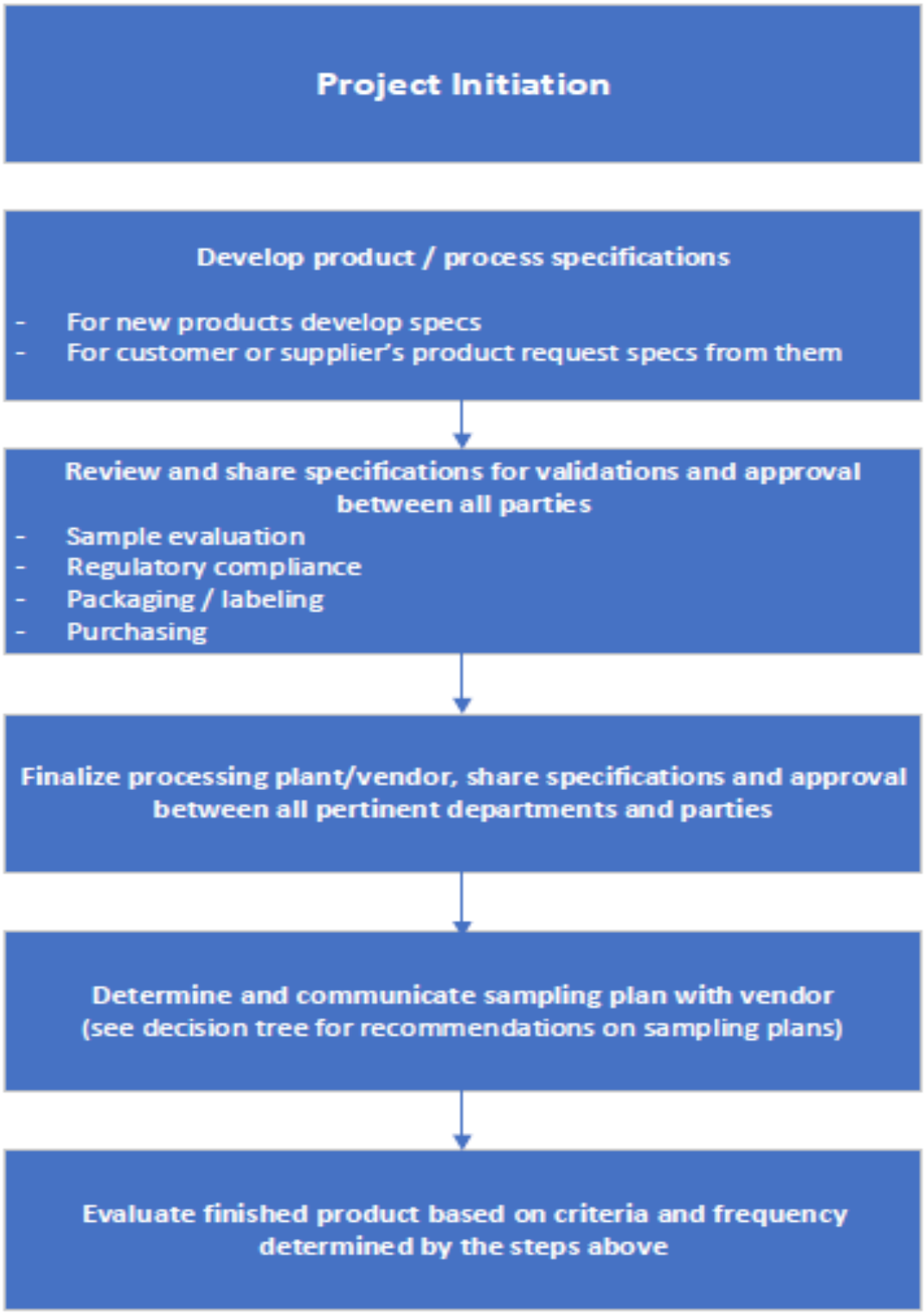
[15] Be aware, the tighter the attribute requirements and tolerances, extra processing diligence will be required by the supplier that may result in higher costs and restricted supply.
[16] See NOAA Seafood Inspection Manual
[17] Industry Color charts exist for salmon and breading color from major suppliers.
[18] Salmon Fillet Trim Guide

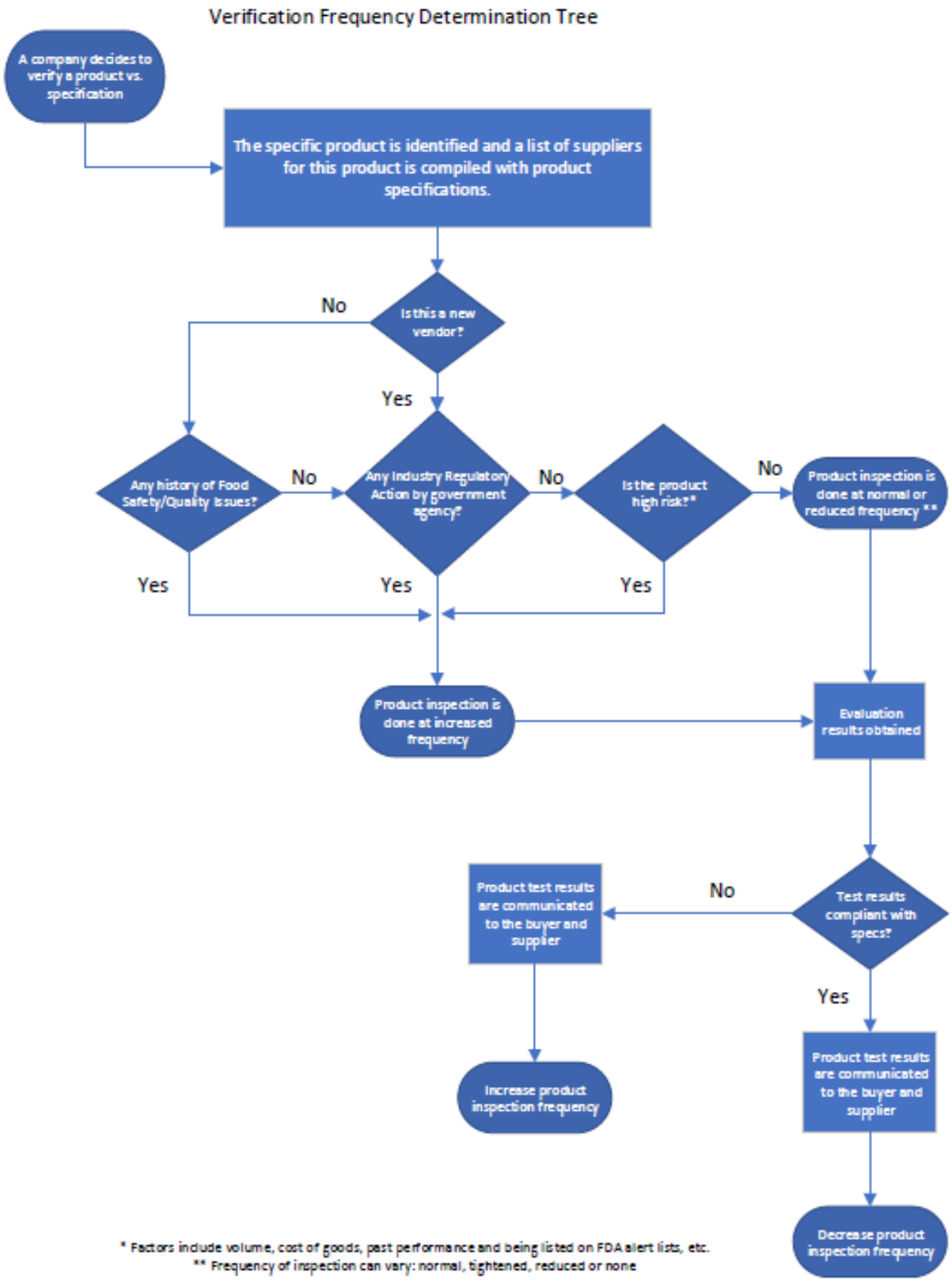
come into compliance quickly and very few rejections occur, so the frequency can be dropped. However, if compliance doesn't improve over time, removing a supplier from your approved supplier list may be a necessary step.

As a way to manage costs, an often-used option is to inspect product overseas before it leaves its country of origin. Recalls and product withdrawals are expensive, so management must understand doing due diligence in country is actually less expensive and provides consumer confidence and brand integrity. Third-party inspection can also be billed back, if this is known up front through the "Terms and Conditions" of the Purchasing Contract. [19]

"An Ounce of Prevention is Worth a Pound of Cure" (Ben Franklin)

[19] Hidden fees within Terms and Conditions may include analytical laboratory testing frequency, and third-party food safety audits requirements.


Project Initiation
Develop product / process specifications
- For new products develop specs
- For customer or supplier's product request specs from them
Review and share specifications for validations and approval between all parties
- Sample evaluation
- Regulatory compliance
- Packaging / labeling
- Purchasing
Finalize processing plant/vendor, share specifications and approval between all pertinent departments and parties
Determine and communicate sampling plan with vendor (see decision tree for recommendations on sampling plans)
Evaluate finished product based on criteria and frequency determined by the steps above


Verification Frequency Determination Tree
A company decides to verify a product vs. specification
The specific product is identified and a list of suppliers for this product is compiled with product specifications.
Is this a new vendor?
No
Yes
Any history of Food Safety/Quality issues?
No
Yes
Any Industry Regulatory Action by government agency?
No
Yes
Is the product high risk?*
No
Yes
Product inspection is done at normal or reduced frequency **
Product inspection is done at increased frequency
Evaluation results obtained
Test results compliant with specs?
No
Yes
Product test results are communicated to the buyer and supplier
Increase product inspection frequency
Product test results are communicated to the buyer and supplier
Decrease product inspection frequency
* Factors include volume, cost of goods, past performance and being listed on FDA alert lists, etc.
** Frequency of inspection can vary: normal, tightened, reduced or none

Better Seafood Board Specification Template

Suggested Product Specification Template for Seafood Buyers

- Product name
- Ingredient statement – includes everything added to the product during processing
- Species name (Latin)
- Country of Origin(s)
- Raw material (as applicable)
- Physical properties (as applicable) – each targeted parameter should be listed with tolerances
  - Weight (for example, 8 ounces +/- .5 ounces with 90% compliance)
  - Thickness
  - Template (length/width)
  - Trim
  - Color
  - Count
- Chemical Properties (as applicable) – each targeted parameter should be listed with tolerances
  - Examples – Sodium, Pesticides, etc.
- Processing
  - This is too long to list because each product has different processing requirements.
- Organoleptic/Sensory (as applicable)
  - Appearance
  - Flavor
  - Odor
  - Texture
- Defects
  - List sample size
  - State AQL level for each defect
  - Total allowable defects
  - The list of defects is difficult to quantify because it is different for each product
- Microbiological (as applicable)
- Packaging
  - Case pack
  - Packaging type
  - Storage temperature
  - Shelf life
  - Code dating
  - Net weight
  - Gross weight
  - Nutritional panel
  - Ti/hi
  - Cube

Specifications often include the product code, cooking instructions (signifies not ready to eat). The Customer specifications may include the Nutrition Facts Panel.

When including dimensions and weight tolerances, be careful because the more specific you are the more expensive the product may become, and that may also limit product availability.

References

Better Seafood Board

Codex Alimentarius standards

FDA Firm or Supplier Evaluation Dashboard

FDA Fish & Fishery Products Hazard Control Guidance

FDA Seafood List

FMI Seafood Specification Templates

GFSI SQF Standards

GFSI BRC Standards

Global Sustainable Seafood Initiative

International Commission on Microbiological Specifications for Foods

Importing Foods Best Practices CFIA

Military Standard Sampling Procedures and Tables for Inspection by Attributes (MIL-STD 105E)

NFI Seafood Specification Templates

NIST Handbook 133

NOAA Seafood Inspection Program Manual

Oregon State University Seafood Information Network

Seafood Source Seafood Handbook

FDA Seafood Species Substitution and-Economic Fraud

USDA FSIS Labeling and Label Approval

Interview your employees to capture unwritten institutional knowledge.

Glossary of Acronyms

AMS	Agricultural Marketing Service
AOAC	AOAC International (formerly known as the Association of Official Analytical Chemists)
CBP	U.S. Customs and Border Protection
CFR	Code of Federal Regulations
COOL	Country of Origin Labeling
CROSS	Customs Rulings Online Search System
DHA	Docosahexaenoic acid (omega-3 fatty acid)
EPA	Eicosapentaenoic acid
FALCPA	Food Allergen Labeling and Consumer Protection Act
FAO	Food and Agriculture Organization of the United Nations
FDA	U.S. Food and Drug Administration
FSIS	Food Safety and Inspection Service
FTC	Federal Trade Commission
HACCP	Hazard Analysis and Critical Control Point
IQF	Individually Quick Frozen
MAV	Maximum Allowed Variance
MSG	Monosodium glutamate
NIST	National Institute of Standards and Technology
NCWM	National Conference on Weights and Measures
PACA	Perishable Agricultural Commodities Act
PDP	Principal Display Panel
USDA	U.S. Department of Agriculture
USDC	U.S. Department of Commerce

Glossary

AQL – Acceptable quality limit.

Attribute – A quality or feature regarded as a characteristic or inherent part of something.

Better Seafood Board (BSB) – Non-profit organization that supports enforcement of existing laws and regulations that prohibit seafood fraud.

Certificate of Analysis (COA) – A document attesting that the specific goods have undergone specified testing and provides the results.

Certificate of Compliance (COC) – A document on company letterhead to state the goods meet the requirements of the United States.

Food Safety – Conditions and practices that preserve the quality of food to prevent contamination and food-borne illnesses.[20]

Global Food Safety Initiative (GFSI) – An International organization that benchmarks and recognizes a number of food safety and quality certification programs. BRC and SQF are examples of GFSI benchmarked programs that a facility can implement and against which can be audited and certified.

Gross Weight – Total weight of the case (including packaging). It is used to comply with regulations for over the road transport.

HACCP Letter of Guarantee – Refers specifically to a written agreement from the company stating compliance with FDA Seafood HACCP requirements and the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended, as well as applicable federal and state regulations.

Inspection – A thorough examination.

Institutional Knowledge – The unwritten knowledge within a company typically shared by word of mouth (if at all).

Maximum Allowed Variance (MAV) – A deviation from the labeled weight, measure, or count of an individual package beyond which the deficiency is considered to be unreasonable.[21]

Moisture Retention Agent (MRA) – Food ingredients used during processing of frozen seafood for the purpose of binding water into the product to minimize moisture loss during thawing.

Net Weight – Weight of the product (without glaze and packaging).

NOAA Seafood Inspection Program (NOAA SIP) – Voluntary seafood inspection program under the United States Department of Commerce, National Oceanic and Atmospheric Administration (NOAA) Office of International Affairs and Seafood Inspection.

[20] https://ask.usda.gov/s/article/What-does-food-safety-mean
[21] NIST Handbook 133, Checking the Net Contents of Packaged Goods

Organoleptic – Related to qualities of a food involving use of the senses (taste, color, odor and feel).

Quality Control – Operationally focused on fulfilling the requirements for quality product.

Quality Assurance – Focused on providing confidence that quality requirements will be fulfilled internally to management and externally to customers and regulators.[22]

Risk Assessment – Identification of the probability of an adverse health effect and severity of reasonably foreseeable hazards, utilizing a systematic and scientific evaluation of known or potential risks.

Specification – A detailed written description of something.

Ti /Hi – The number of boxes stored on a standard pallet (48" x 40"). "Ti" refers to tier (layer) and "Hi" refers to number of layers.

Verification – The process of periodically confirming by examination that the product meets the specification.

[22] https://asq.org/quality-resources/quality-assurance-vs-control