NFI Guide to FDA Labeling Requirements

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NFI members can use this document to assist in applying FDA's laws and regulations for the labeling of seafood products. Labels which comply with FDA's labeling laws and regulations provide consumers and the supply chain with truthful and non-misleading information that allows them to make informed purchasing decisions. In addition, with the implementation of NFI's Seafood Economic Integrity Initiative, NFI members have pledged to adhere to all FDA labeling laws. This document will help NFI members explain pertinent labeling laws and regulations to suppliers and customers.

FDA's Required Label Elements

FDA's regulations require that all food packages display the following information:

- Name of the food
- Net quantity of contents
- Name and location of the food business
- List of ingredients if the food is comprised of more than one ingredient
- Nutrition Fact Label (for packaged products sold at retail)
- Allergen disclosure information for products which contain one or more of the eight major food allergens

More information on each of these elements will be discussed below and/or in the Better Seafood Board Industry Guidance of Best Practices for Addressing Seafood Fraud.

NOTE: Other agencies have labeling requirements in addition to FDA's. Seafood products must meet Customs and USDA Agricultural Marketing Service Country of Origin labeling requirements. Detailed information on these two regulations is provided in Appendix 3 of Better Seafood Board Industry Guidance of Best Practices for Addressing Seafood Fraud. Also USDA FSIS regulates fish of the Siluriformes order (e.g., catfish and pangasius). While that agency's labeling regulations are similar to those of FDA, there are some differences. Information on FSIS labeling requirements is available online.

Individual states may also have certain labeling laws and regulations. For example some states have requirements for "Sell By" or "Best if Used By" dating for perishable foods.

Net Quantity of Contents

FDA has specific requirements for the placement, font size and formatting of the net quantity of content declaration. In brief, the statement is required to:

- be located in lower third of the Principal Display Panel
- stand alone and be free of interference from other graphical elements on the label

- be sized appropriately to the size of package
- accurately reflect the net contents of the product in the package. The net contents do not include the weight of packaging materials or in the case of ice-glazed frozen seafood, the weight of the ice glaze.

Labels of retail packages are required to list the net contents in both the US System and metric system of measurement. Labels of non-retail packages are required to list the net contents in the US System with the option of including metric.

The method to describe the weight is dependent on the size of the package as listed below:

- Packages under 1 pound list in ounces and grams
- Packages between 1 and 4 pounds list in ounces, pounds and grams (or in kilograms when 1 or more kilograms)
- Packages over 4 pounds list in pounds and kilograms

Declaration of Responsibility (Name and Place of Food Manufacturer, Packer or Distributor)

FDA's laws and regulations require that the name and address of the manufacturer, packer or distributor be on each label. For consumer packages this is to include the street address, city, State and zip code. The street address may be omitted if that information is readily available in a public directory. For non-consumer packages the zip code may appear on the label or other labeling such as on an invoice for the product.

If the business listed is not the actual manufacturer than an accurate qualifying statement such as "Manufactured for ___" or "Distributed by ____" must be included.

Ingredient Statements

FDA's labeling laws and regulations require that any food product (including seafood products) that is made with two or more ingredients have an ingredient statement which lists the name of each added ingredient. The ingredient statement must be listed either on the Principle Display Panel or the Information Panel.

The ingredients are required to be listed by common or usual name in descending order of predominance by weight. FDA's regulations do not allow for the use of brand names or "E numbers" to describe ingredients.

Added ingredients that are comprised of other ingredients (e.g., bread crumbs) must be listed to include all the sub-ingredients. This can be accomplished by either incorporating all the sub-ingredients into the ingredient statement in descending order of predominance or by naming the sub-ingredients in parentheses immediately after the ingredient. For example: Bread crumbs (wheat flour, water, salt, baking soda, spices).

Additives must also include the common name and function on the label. For example: Cod, water, sodium tripolyphosphate (to retain moisture).

Water as an ingredient

FDA considers that water added in making a food is an ingredient and must be identified in the list of ingredients and listed in descending order of predominance by weight. The only exception is if all the added water is subsequently removed by cooking or other means during processing. This is addressed in Compliance Policy Guide 555.875 (Water in Food Products (Ingredient or Adulterant)) and FDA's Guidance for Industry: Food Labeling Guide.

Therefore the water that is used to incorporate dry ingredients (e.g., salt, sodium tripolyphosphate, non-phosphate moisture retention agents, batter ingredients) must be listed on the ingredient statement unless the firm can prove that the added water is removed during a subsequent processing step.

Clarification on Incidental Additives and Processing Aids

FDA does not have a "blanket" exception for not including "trace amounts" of an ingredient in the ingredient list. FDA's laws and regulations require that all ingredients in a multi-ingredient food be disclosed on the package. There are exemptions for "incidental additives" and "processing aids" but it is unlikely that any of the components of phosphate or non-phosphate blends designed for moisture retention purposes would meet the regulatory requirements that would allow for an exemption of labeling.

Therefore, it is nearly universally required that manufacturers include on their labels the presence of phosphate or non-phosphate blends

FDA states in the Guidance for Industry: Food Labeling Guide:

> If an ingredient is present at an incidental level and has no functional or technical effect in the finished product, then it need not be declared on the label. An incidental additive is usually present because it is an ingredient of another ingredient.

The key component of the criteria is whether or not the ingredient has a "function or technical effect in the finished product." By nature of being a component of a moisture retention blend, formulated specifically to retain moisture in the finished product, suggests that each individual ingredient in that blend has a technical or functional effect in the food, thus not qualifying for the labeling exemption. A second component of the criteria is whether or not the ingredient is converted into constituents that are normally present in the food but do not significantly increase the amount of the constituent in the food. Some ingredients in moisture retention blends contribute to significantly increase the sodium content of the product. This would disqualify the ingredient in the blend as an incidental additive.

Nutrition Facts Labels

FDA's regulation for Nutrition Facts Label is very complex. The agency recently updated the regulations with full compliance being July 26, 2018 or July 26, 2019 depending on the company size. FDA has recently proposed to extend the full compliance date to January 1, 2020 or January 1, 2021, again depending on company size. More information on the changes to the Nutrition Facts Labels is available on the NFI Member Portal. FDA's nutrition resources are available online.

Some points to remember about Nutrition Facts:

- FDA does not dictate the source of or how the nutrient content values for labeling purposes are calculated. However, companies are responsible for the accuracy of the information that is included on the label.
- Use of available databases such as the USDA National Nutrient Database for Standard Reference, FDA's voluntary point-of-purchase nutrition information for fish sold at retail, historic NOAA Technical Memorandum NMFS F/SEC-11 (Chemical and Nutritional Composition of Finfishes, Whales, Crustaceans, Mollusks, and Their Products) are all useful references for establishing Nutrition Facts Labels. However:
    - NFI members are reminded that treating seafood products with moisture retention ingredients will impact some basic nutritional values such as moisture, sodium and protein.
    - Products that appear to be similar may not necessarily have the same nutrient values because of differences in level of treatment, formulations and added ingredients.
- FDA's regulation allows the following variability:
    - Amounts of vitamins, minerals, protein, total carbohydrates, polyunsaturated or monounsaturated fat or dietary fiber must be at least equal to 80% of the value of the amount declared on the label.
    - Values of calories, total sugars, added sugars, total fat, saturated fat, *trans* fat, cholesterol or sodium must be no greater than 20% higher than the value declared on the label.

Allergen Statement

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) requires that all foods that are not raw agricultural commodities and that contain one or more major food allergens be labeled to clearly identify the name of the allergen(s). The eight major allergens are Eggs, Milk, Soy, Peanuts, Tree nuts, Fish, Crustacean shellfish, and Wheat.

The allergens can be listed in one of two ways:

- In the ingredient statement, in parentheses immediately after the common or usual name of the ingredient that is a major food allergen (e.g., "whey (milk)") when its food

source name is not already included as part of that ingredient's name. For example, "wheat flour" does not need to call out "wheat" a second time.

- In a separate "Contains" statement immediately after or adjacent to the list of ingredients. If the "Contains" statement is used, all of the major food allergens present as ingredients must be listed, even though they may be listed in the ingredient statement.
- The law requires that for fish, tree nuts and crustacean shellfish the ingredient be listed by the specific type of nut or specific species of fish and crustacean shellfish. As examples:
    - For a product containing almonds the statement "Contains Tree Nuts" is incorrect. The correct statement is "Contains Almonds."
    - For a product containing tilapia the statement "Contains Fish" is incorrect. The correct statement is either "Contains Tilapia" or "Contains Tilapia (fish)."
    - For a product containing shrimp the statement "Contains Crustacean Shellfish" is incorrect. The correct statement is either "Contains Shrimp" or "Contains Shrimp (crustacean shellfish)."

The FALCPA requirements apply to all FDA-regulated food products: consumer, non-consumer and bulk packed products.

Additional Requirements

Bilingual labels

FDA's regulations require that if the label includes any information in a language other than English then all required label statements must be in both English and the other language.

Counts stated on packages

Labels should, when describing shrimp sizes by stating a range of the count per pound (e.g., 30-40 shrimp per pound), qualify the statement as "count per pound." If a label merely states the count, state regulators may consider that to be a statement of quantity; and having a range instead of a single number for any statement of quantity is a violation of state labeling laws.

In addition to violating state labeling laws, regulators consider a count "per bag" versus "per pound" to be misleading for consumers who equate the count to size. For example in an 8 ounce bag, 30-40 count per bag equates to a smaller shrimp than 30-40 count per pound.

Use of the term "Natural"

FDA's longstanding policy for the use of the term "natural" is that the product does not contain any added:

- Color of any source

- Artificial flavors
- Synthetic (i.e., man-made) substances

It is important to remember that ingredients may be formulated in different way; 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 mis-use 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.