

Food Allergen Labeling and HACCP Control for the Seafood Industry: Undeclared Food Allergens and Their Impact on U.S. Consumers

Abigail Villalba, *Extension Specialist, Virginia Tech Virginia Seafood AREC*
Karla Ruzicka, *USDC/NOAA Seafood Inspection Program Chief, Training & Education*

Introduction

According to the Centers for Disease Control and Prevention, as many as 11 million Americans have food allergies. A food allergy can trigger symptoms ranging from a tingling mouth, swelling of the tongue and throat, hives, and abdominal cramps to anaphylaxis and — in severe cases — death (CDC 2012). Consumers with known allergies must read labels to identify allergenic foods or ingredients on packaged products so they can more easily avoid them.

Without appropriate controls, undeclared allergens in foods are a significant problem. In fact, the U.S. Food and Drug Administration's Reportable Food Registry shows that during 2012, about 38 percent of all food recalls reported were due to undeclared food allergens (FDA 2013b).

So that consumers could identify the presence of allergens in packaged foods, the Food Allergen Labeling and Consumer Protection Act (FALCPA) was passed in 2004. It requires that food manufacturers meet additional allergen labeling provisions (FDA 2004). This law requires that manufacturers use plain language on food labels to clearly identify the ingredients that contain proteins derived from any of the eight major allergenic foods and food groups: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans (fig. 1).

Though many other foods can cause food allergies, mandatory FALCPA labeling requirements are only applied to these eight major food allergens because they account for 90 percent of all food allergies in the U.S. FALCPA labeling requirements apply to all packaged foods sold in the U.S. that are regulated by FDA, including fish and fishery products, and cover both domestically manufactured and imported foods (FDA 2004).



Figure 1. These eight major food allergens account for 90 percent of all documented food allergies in the U.S. (FDA 2004).

Purpose of This Publication

This publication will help seafood processors better understand the seafood Hazard Analysis and Critical Control Points (HACCP) regulation and FALCPA requirements associated with food allergen control and labeling. After reviewing this publication, processors must review the FALCPA provisions in their entirety to ensure they are in compliance with all of the requirements.

Seafood HACCP Regulation and FALCPA Labeling Requirements

Seafood processors are required to meet the allergen control and labeling requirements as outlined in both the seafood HACCP regulation and FALCPA.

The seafood HACCP regulation (21 CFR Part 123) requires that seafood processors determine whether

undeclared allergens are significant. If they are, it requires that processors implement labeling controls as part of their HACCP plan (FDA 1995).

FALCPA requires that food manufacturers, including seafood processors, follow specific labeling requirements to ensure that consumers are alerted to the presence of any of the eight major food allergens or their derivatives in packaged foods (FDA 2004).

It is important to note that two of the major eight food allergens under FALCPA are fish and crustacean shellfish (fig. 2). Under FALCPA, “fish” pertains only to saltwater and freshwater finfish; it does not apply to the other forms of fish, such as alligator, aquatic turtles, etc., as defined by the seafood HACCP regulation. Under FALCPA, “crustacean shellfish” includes, but is not limited to, species such as crab, lobster, and shrimp. It does not include molluscan shellfish such as oysters, clams, mussels, scallops, or other mollusks, such as squid or octopus (FDA 2004). This explains why molluscan shellfish are not subject to FALCPA labeling provisions.



Figure 2. Fish and crustacean shellfish, including crab, shrimp, and lobster, are two of the eight major food allergens.

Preventing Introduction of Undeclared Allergens With Sanitation Controls

A food allergen is a chemical hazard that is not controlled by cooking. Because there are no established minimum safety levels, its mere presence in food may cause a moderate to life-threatening reaction to a person with the food allergy.

Unintentional introduction (cross-contact) of a food allergen can happen during the processing of foods containing different allergens. Therefore, preventing introduction of undeclared food allergens requires the use of adequate sanitation controls such as Good Manufacturing Practices and Sanitation Control Procedures. Using separate lines, scheduling production

sequencing, and conducting proper cleaning between products are some of the ways to prevent cross-contact of allergens (FDA 2001).

More information on how production sequencing and other sanitation controls can help prevent cross-contact of allergens can be found at www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074944.htm.

Meeting FALCPA Allergen Declaration Requirements of Multiple-Ingredient Fishery Products

In the Ingredients List

Foods containing two or more ingredients must contain an ingredients list, per 21 CFR Part 101 labeling requirements. To comply with FALCPA labeling, an ingredients list must include the common or usual name of the major food allergen (milk, egg, wheat, etc.). If the name of the allergen is not commonly known by the consumer, then the name of the allergen must be followed in parentheses by the food allergen source name (USDA 2004). For example, the product “whey” must be written as “whey (milk).”

In a fishery product, the common or usual name included in the ingredient list is the acceptable market name* of the fish or crustacean shellfish contained therein. For example, a processor of smoked king salmon uses the ingredients list to declare the food allergen (fig. 3).

Ingredients: King salmon, sugar, salt and spices

Figure 3. Ingredients list declaring the food allergen by its acceptable market name.

*The FDA maintains a searchable database, the FDA Seafood List, where processors can locate FDA-acceptable market names. The list is located at www.accessdata.fda.gov/scripts/search_seafood/index.cfm?other=complete (FDA 2013a).

Using the terms “fish” or “crustacean shellfish” as stand-alone terms is not acceptable. However, the “Fish and Fishery Products Hazards and Controls Guidance” (FDA Guide) suggests that for lesser-known species of fish such as gar, processors may append the word “fish” to the acceptable market name, i.e., gar fish (fig. 4; FDA 2011).

Ingredients: Gar fish, sugar, salt and spices

Figure 4. Ingredients list declaring the food allergen by its acceptable market name with the word “fish” added as an option.

In a “Contains” Statement

In addition to the ingredient list, a processor can include a “Contains” statement, located immediately after the ingredients list that includes the name of the food source for all major food allergens present. For fish or crustacean shellfish, the acceptable market name must be used.

For example, a processor of smoked king salmon may use a “Contains” statement to declare food allergens (fig. 5).

**Ingredients: King salmon, sugar, salt and spices.
Contains: King salmon**

Figure 5. Ingredients list with optional “Contains” statement declaring food allergen present.

The “Contains” statement must declare **all** of the allergens listed in the ingredients list (fig. 6); it is not permissible to list some of the allergens in the ingredients list and some allergens in the “Contains” statement. A “Contains” statement can help consumers quickly identify if an allergen is present or not and whether they can consume the product.

**Ingredients: Cod, wheat, flour, sugar, salt and spices.
Contains: Cod, wheat**

Figure 6. Ingredients list with optional “Contains” statement declaring **all** allergens present.

Meeting FALCPA Allergen Declaration Requirements for Single-Ingredient Fish and Fishery Products

On the Container

Because single-ingredient food products are not required to have an ingredients list, the name of the food — in this case the acceptable market name — on the container is sufficient to meet the required FALCPA allergen labeling requirement.

For example, a can of blue crab meat meets this requirement by stating on the label of the container blue crab meat, which is the acceptable market name for this product (fig. 7). A wetlock box containing whole tuna and labeled tuna, its acceptable market name, also meets the allergen labeling provision.

Blue Crab Meat

Figure 7. Single-ingredient product label showing the food allergen as part of the name of the product.

In a “Contains” Statement

Additionally, a processor can include a “Contains” statement with the acceptable market name for the fish or crustacean shellfish. For example, a container labeled “blue crab meat” may use a “Contains” statement to declare food allergens.

Controlling Food Allergens Within Your Seafood HACCP Plan

Per the seafood HACCP regulation, processors must perform a hazard analysis to determine whether there are significant hazards and, if so, to control them within a HACCP plan (FDA 1995).

The hazard of undeclared food allergens is significant when (1) a finfish or crustacean shellfish is introduced to a process such as raw materials that are received and further processed, (2) a finfish or crustacean shellfish is added as an ingredient, or (3) a processor packages or repackages the finished product for distribution. Conversely, the hazard of undeclared allergens would not

be significant for a warehouse that receives finished products that are already labeled and does not engage in repackaging or relabeling.

Chapter 19 of the FDA Guide, Undeclared Major Food Allergens and Certain Food Intolerance Causing Substances and Prohibited Food and Color Additives, recommends establishing the step of labeling the finished product as the Critical Control Point (CCP) to control for undeclared allergens (fig. 8; FDA 2011). Monitoring the CCP ensures that known allergens in the product formulation are declared on the label and the correct label is applied to the finished product container or package.

Refer to chapter 19 of the FDA Guide for specific information on how to develop a HACCP plan for undeclared food allergens.

CCP	Hazard	Critical Limit
Finished product labeling	Undeclared allergen(s)	Allergen(s) declared on label of all finished product packages

Figure 8. Critical Control Point and critical limit control strategy for undeclared allergens.

Allergen Advisory Labeling

Though not officially sanctioned, allergen advisory statements or precautionary statements such as “may contain” or “manufactured in a facility that also processes [name of allergen]” are not prohibited, as long as they are not misleading. Their use is strictly voluntary and should not be viewed as a substitute for Good Manufacturing Practices. Keep in mind that if a company chooses to use these “may contain” statements, it would not prevent a recall if undeclared allergens are present but are not listed in the ingredient list.

For more information on how to label food products to meet FALCPA requirements, please refer to “Guidance for Industry: Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Final Guidance” (FDA 2006) at www.fda.gov/downloads/Food/GuidanceRegulation/UCM301394.pdf.

References

- CDC (Centers for Disease Control and Prevention). 2012. “Adolescent and School Health: Food Allergies in Schools.” www.cdc.gov/healthyyouth/foodallergies/.
- FDA (U.S. Food and Drug Administration). 1995. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products. 21 CFR Parts 123 and 1240. Federal Register, Vol. 60, No. 242. www.gpo.gov/fdsys/pkg/FR-1995-12-18/pdf/95-30332.pdf.
- FDA (U.S. Food and Drug Administration). 2001. Allergy Inspection Guide: Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination With Allergenic Ingredients. www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074944.htm.
- FDA (U.S. Food and Drug Administration). 2004. Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II). www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments-RegulatoryInformation/Allergens/ucm106187.htm.
- FDA (U.S. Food and Drug Administration). 2006. Guidance for Industry: Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Final Guidance. www.fda.gov/downloads/Food/GuidanceRegulation/UCM301394.pdf.
- FDA (U.S. Food and Drug Administration). 2011. “Undeclared Major Food Allergens and Certain Food Intolerance Causing Substances and Prohibited Food and Color Additives.” Chapter 19 in Fish and Fishery Products Hazards and Controls Guidance, 355–384. 4th ed. www.fda.gov/downloads/food/guidanceregulation/ucm251970.pdf.
- FDA (U.S. Food and Drug Administration). 2013a. “2013 FDA Seafood Complete List.” FDA Seafood List Search Returns. www.accessdata.fda.gov/scripts/search-seafood/index.cfm?other=complete.
- FDA (U.S. Food and Drug Administration). 2013b. The Reportable Food Registry: Targeting Inspection Resources and Identifying Patterns of Adulteration. Third Annual Report: Sept. 8, 2011–Sept. 7, 2012. FDA Foods and Veterinary Medicine Program. www.fda.gov/downloads/Food/ComplianceEnforcement/RFR/UCM349856.pdf.