CHAPTER 19: Undeclared Major Food Allergens and Certain Food Intolerance Causing Substances and Prohibited Food and Color Additives

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UNDERSTAND THE POTENTIAL HAZARD.

- **Food allergens**

A number of foods contain allergenic proteins, which are natural constituents of the food that can pose a health risk to certain sensitive individuals. The symptoms of food allergies can include a tingling sensation in the mouth, swelling of the tongue and throat, difficulty in breathing, hives, vomiting, abdominal cramps, diarrhea, drop in blood pressure, loss of consciousness, and, in severe cases, death.

The Food Allergen Labeling and Consumer Protection Act of 2004 amended the Federal Food, Drug, and Cosmetic Act (FFD&C Act). The FFD&C Act now requires that all foods that are not raw agricultural commodities and that contain a major food allergen be labeled to clearly identify the name of the food source from which the allergen is derived (21 CFR U.S.C. 343(w)(1)). The Act defines the following eight foods and any ingredients that contain protein derived from these eight foods (with certain exemptions noted in section 201(qq)(2) of the Act) as major food allergens:

- Milk;
- Eggs;
- Fish (e.g., bass, cod, or flounder);
- Crustacean shellfish (e.g., crab, lobster, or shrimp);
- Tree nuts (e.g., almonds, pecans, or walnuts);
- Peanuts;
- Wheat; and
- Soybeans.

The FFD&C Act requires that the name of the food source from which a major food allergen is derived be the same as the name of the major food allergen itself for the following five foods: milk; egg; wheat; peanuts; and soybeans (e.g., milk must be listed as "milk"). The name of the food source that must be listed on the label for tree nuts must be the specific type of tree nut (e.g., almonds, pecans, or walnuts). Likewise, the name of the food source that must be listed on the label for fish or crustacean shellfish must be the specific type of fish (e.g., bass, cod, or flounder) or crustacean shellfish (e.g., crab, lobster, or shrimp) (21 CFR U.S.C. 343(w)(2)). The "market" names of species of fish and crustacean shellfish should be used to identify the food source of these two major food allergens. The market names are found in the document "Guidance for Industry: The Seafood List: FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce" revised 2009 ((*http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/ucm113260.htm*). You may add the term "fish" to the market name on the label if you believe that the market name may not otherwise be recognized to be fish by the consumer (e.g., "gar fish").

To meet the requirements of the FFD&C Act, the food labels of packaged fish and fishery products that are or contain a major food allergen must declare the name of the food source for the allergen, either:

(1) Within the list of ingredients, 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:

(a) is not already included as part of that ingredient's common or usual name (e.g., the food source name "milk" is included in the name of the ingredient "non-fat dried milk"); or

(b) does not appear elsewhere in the ingredient list (e.g., if the food contains both casein and whey and the label lists "whey (milk)," the term "(milk)" need not follow the term "casein"); or

(2) In a separate "Contains" statement immediately after or adjacent to the list of ingredients in a print size no smaller than that used for the ingredient list (e.g., "Contains shrimp and eggs"). If a "Contains" statement is included on the label, it must identify the food source names of all major food allergens present as ingredients whether or not those food source names were previously mentioned within the list of ingredients (21 CFR U.S.C. 343(w)(1)).

This chapter contains guidance on the kinds of preventive controls that may be suitable to ensure proper labeling if your fish or fishery product is made in whole or in part of a food that is a major food allergen. As a practical matter, this guidance covers all finfish and crustacean shellfish and all other fishery products (e.g., molluscan shellfish) that contain one or more of the other major food allergens.

Labeling controls that are designed to ensure that any major food allergen that is present in a food is declared on the label are the most effective means of controlling this hazard. However, such controls are not suitable to prevent the unintentional introduction of allergenic proteins from foods that contain these allergens into foods that are not intended to contain them, through cross-contact (e.g., use of common equipment, improper production scheduling, or improper use of rework material). Unintentional introduction of allergenic proteins should be controlled through rigorous process controls, either as part of a prerequisite program or as part of the Hazard Analysis Critical Control Point (HACCP) program itself. The Fish and Fishery Products regulation, 21 CFR 123 (called the Seafood HACCP Regulation in this guidance document), requires such a regime.

- **Food and color additives**

Certain food and color additives can cause hypersensitivity reactions, or food intolerances, in some consumers. Although in most cases there are no known allergic mechanisms, symptoms may be similar to those caused by food allergens and can include a tingling sensation in the mouth, swelling of the tongue and throat, difficulty in breathing (e.g. asthma), hives, vomiting, abdominal cramps, and diarrhea. Examples of such food and color additives that are used in fish and fishery products include sulfiting agents and FD&C Yellow No. 5 (Yellow No. 5) described below.

- Sulfiting agents are mostly used during on-board handling of shrimp and lobster to prevent the formation of "black spot." They are sometimes used by cooked octopus processors as an antioxidant, to retain the red color of the octopus skin. They are also sometimes used by conch processors to prevent discoloration or are used as stabilizers in some breading meals added to fish. People sensitive to sulfiting agents can experience symptoms that can range from mild severity to life-threatening reactions.
- Yellow No. 5 is sometimes added to smoked fish to impart color. To help protect people who are sensitive to Yellow No. 5, FDA's regulation for Yellow No. 5 states that any food for human use that contains Yellow No. 5 must specifically declare the presence of the color additive by listing it as an ingredient (21 CFR 74.705(d)(2)). If Yellow No. 5 is added to smoked fish but is not declared, the product not only is misbranded

under section 403 of the FFD&C Act, but also is adulterated under section 402(c). (21 U.S.C. 343(m) and 342(c)). People sensitive to Yellow No. 5 can experience symptoms that can range from mild to moderate severity.

Under the FFD&C Act, a use or intended use of a food or additives is deemed unsafe unless the use or intended use either conforms with a regulation prescribing the conditions for safe use or the terms of an exemption for investigational use. A food additive that is a food contact substance also may be used in accordance with an effective notification (21 U.S.C. 348 and 21 U.S.C. 379e). Any food that contains an unsafe food additive or color additive is deemed adulterated under sections 402(a)(2)(C)(i) and 402(c) of the FFD&C Act, respectively (21 U.S.C 342(a)(2)(C)(i) and 342(c)).

The FFD&C Act excludes from the definition of "food additive" substances that are generally recognized among experts qualified by scientific training and experience to evaluate their safety as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of their intended use (21 U.S.C. 321 (s)). A substance (other than a food contact substance) added to food for a use that is not generally recognized as safe (GRAS) under the conditions of its intended use and is not otherwise excluded from the food additive definition in section 201(s) of the FFD&C Act, must be used in accordance with a food additive regulation permitting that specific use (21 CFR 348). Otherwise, the use of that substance in food makes the food adulterated under section 402(a)(2)(C) of the FFD&C Act. Additionally, food may be deemed adulterated if it contains a poisonous or deleterious substance that may render the food injurious to health, but if the substance is not an added substance, the food is not considered adulterated if the quantity of the substance in the food does not ordinarily render the food injurious to health (21 U.S.C. 342(a)(1)). It is important to note that there is no GRAS status for color additives.

In addition to the statutory requirements that ensure the safety of substances added to food, there are labeling requirements that apply to ingredients in food. Under the FFD&C Act, a food is deemed misbranded unless the label bears the common or usual name of each ingredient with the exception of spices, flavorings, and color additives not subject to certification by FDA (21 U.S.C. 343(i)). This list of ingredients on the food label is especially important for people who need to avoid certain ingredients for health reasons.

If a substance is an incidental additive and has no functional or technical effect in the finished product, then it need not be declared on the label. Incidental additives are usually either processing aids present in the finished food or substances that have migrated to the food from packaging or equipment. Sulfiting agents, which are added to food as preservatives, are considered to be incidental only if they have no technical effect in the food and are present at less than 10 parts per million (ppm) (21 CFR 101.100(a)(4)).

Currently, there are six sulfiting agents allowed in processed food. The names by which they are listed on food labels are:

- sulfur dioxide (21 CFR 182.3862);
- sodium sulfite (21 CFR 182.3798);
- sodium bisulfite (21 CFR 182.3739);
- sodium metabisulfite (21 CFR 182.3766);
- potassium bisulfite (21 CFR 182.3616); and
- potassium metabisulfite (21 CFR 182.3637).

The amount of any one or a combination of any of the six sulfiting agents that may be added to a processed food is restricted by Current Good Manufacturing Practices (CGMP) (See 21 CFR part 182, Subpart D). Under CGMP's, the quantity of sulfiting agents added to food should not exceed the amount necessary to achieve the

technical effect. If the total amount of sulfiting agent added to food results in a concentration of 10 ppm or greater, which is the current limit of analytical detection identified in the Code of Federal Regulation § 101.100(a)(4), then the sulfiting agents are not exempt from FFD&C Act food labeling requirements and must be listed as an ingredient on the product label (21 CFR 101.100(a)(4)). Table 19-1, "Rationale for a Finished Product Sulfiting Agent Declaration," provides several examples of raw materials treated with sulfiting agents and the rationale for deciding whether or not the finished product requires a sulfiting agent declaration.

Example:

A processor receives frozen, raw, headless, shell-on shrimp that are labeled with a sulfiting agents declaration. The shrimp were treated with sulfiting agents to prevent the formation of black spot during on-board handling. The processor thaws, peels, and deveins the shrimp, and then adds it to a gumbo in which the processor has determined that the final sulfiting agents concentration is less than 10 ppm. Because the sulfiting agents no longer has a functional effect in the finished food, and because the concentration of the sulfiting agents is less than 10 ppm in the finished product, the processor is not required to have a sulfiting agents declaration on the label of the shrimp gumbo.

Example:

A processor receives frozen, raw, headless, shell-on shrimp that are labeled with a sulfiting agents declaration. The processor uses the shrimp to prepare a shell-on, deveined, easy-peel shrimp, which is packaged and refrozen. Because the sulfiting agents continue to have a functional (ongoing technical) effect in the finished product, the processor is required to have a sulfiting agents declaration on the finished product label, regardless of the concentration of sulfiting agents in the finished product.

Certain other food and color additives are specifically prohibited from use in food because of a determination by FDA that they present a potential risk to the public health (see 21 CFR part 189 and 21 CFR 81.10). Examples of such food and color additives are coumarin, safrole, and FD&C Red No. 4 (Red No. 4).

TABLE 19-1

RATIONALE FOR A FINISHED PRODUCT SULFITING AGENT DECLARATION

Is a Sulfiting Agent Declaration Required?			
EXAMPLES OF SULFITING AGENT USE	EXAMPLES OF FINISHED FOOD	SULFITING AGENT LEVEL IN FINISHED FOOD	
		<10 PPM	≥10 PPM
Raw, shell-on shrimp or lobster treated with sulfiting agents to prevent black spot Sulfiting agents added to cooked octopus as an antioxidant to retain the red skin color of the octopus Sulfiting agents added to conch meat to prevent discoloration	Raw, shell-on shrimp or lobster Cooked octopus Conch meat	YES[1]	YES[1]
Raw, shell-on shrimp or lobster treated with sulfiting agents to prevent black spot Raw, shell-on shrimp or lobster treated with sulfiting agents to prevent black spot	Raw, peeled shrimp or lobster meat Food containing raw, peeled shrimp or lobster meat as an ingredient (e.g., seafood casserole)	NO[2]	YES[2]

1. The sulfiting agents have an ongoing technical or functional effect on/in the finished food and must be declared regardless of the level in the finished food
2. The sulfiting agents have no technical or functional effect in the finished food and do not have to be declared unless the level in the finished food is either ≥ 10 ppm or the sulfiting agents were added to the finished food at any level. To further clarify, if a sulfiting agent or a combination of sulfiting agents is added to finished food such that their collective concentration in/on the finished food is ≥ 10 ppm , then you must declare each by its approved label name (listed above)(21CFR101.100).

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether undeclared major food allergens, certain food intolerance causing substances, and prohibited food and color additives are a significant hazard at a processing step:

1. Is it reasonably likely that an undeclared major food allergen, undeclared food intolerance causing substance (e.g., sulfiting agents or Yellow No. 5), or prohibited food or color additive (e.g., coumarin, safrole, or Red No. 4) will be introduced at each processing step (e.g., does it come in with the raw material or will the process introduce it)?

   Under ordinary circumstances, you should consider whether undeclared major food allergens, certain food intolerance causing substances, and prohibited food and color additives are a significant hazard at the:

   - Receiving step, if your finished product is or contains finfish or crustacean shellfish, because they are major food allergens;
   - Receiving step, if your finished product contains either shrimp or lobster, because there is a potential for sulfiting agents to be present. However, there may be circumstances that would allow you to conclude that the hazard is not reasonably likely to occur. For example, sulfiting agents may not be used in aquacultured shrimp from some regions. You should be guided by information about the historical use of sulfiting agents in your region. Also, in some formulated finished products that contain shrimp or lobster, the sulfiting agent may not have a functional effect and may not be present at 10 ppm or greater. You should conduct a study that tests the range of concentration of sulfiting agents in the raw material and possible variation in formulation to establish that sulfiting agents will not be present at 10 ppm or greater in the finished product;
   - Product formulation step, if your finished product contains one or more of the major food allergens (including non-fishery allergens) listed in the previous section, "Understand the Potential Hazard.";
   - Product formulation step, if you have an ingredient that is or contains one or more of the major food allergens (including non-fishery allergens) or food intolerance causing substances in your facility or use such an ingredient in the formulation of any of your products;
   - Product formulation step, if your finished product is cooked octopus or conch meat, because of the potential presence of sulfiting agents. However, you may not need to identify the hazard as significant if you do not have sulfiting agents in your facility and do not use it in the formulation of any of your products;
   - Product formulation step, if your finished product is a formulated fishery product (i.e., a product in which two or more ingredients are combined) because of the potential presence of Yellow No. 5 or sulfiting agents. However, you may not need to identify the hazard as significant if you do not have Yellow No. 5 in your facility and do not use it in the formulation of any of your products; and
   - Ingredient receiving step, if you receive ingredients in which you have reason to believe prohibited food or color additives (e.g., coumarin, safrole, or Red No. 4) may be present, based, for example, on an historic occurrence of the additive in that ingredient.

2. Can the hazard of undeclared major food allergens, and certain food intolerance causing substances, and prohibited food and color

additives that were introduced at an earlier step be eliminated or reduced to an acceptable level at this processing step?

Undeclared major food allergens, food intolerance causing substances and prohibited food and color additives should also be considered a significant hazard at a processing step if a preventive measure is or can be used to prevent or eliminate the hazard or to reduce the likelihood of its occurrence to an acceptable level. Preventive measures for undeclared major food allergens, food intolerance causing substances and prohibited food and color additives include:

- Reviewing finished product labels to ensure that the presence of certain food intolerance causing substances (e.g., sulfiting agents or Yellow No. 5) is declared;
- Testing incoming shrimp or lobster for residues of sulfiting agents;
- Reviewing a supplier's certification of the lack of sulfiting agent use on incoming lots of shrimp or lobster (with appropriate verification);
- Reviewing the labeling (or accompanying documents, in the case of unlabeled product) on shipments of shrimp or lobster received from another processor for the presence of a sulfiting agent declaration;
- Reviewing finished product labels to ensure that the presence of the major food allergens, listed in the previous section, "Understand the Potential Hazard" is declared;
- Testing incoming lots of ingredients for the presence of prohibited food and color additives that you have reason to believe may be present;
- Reviewing a supplier's certification of the lack of prohibited food and color additive use in incoming lots of ingredients in which you have reason to believe the additive may be present (with appropriate verification).

- **Intended use**

In the case of undeclared major food allergens and certain food intolerance causing substances and prohibited food and color additives, it is not likely that the significance of the hazard will be affected by the intended use of the product.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for undeclared major food allergens, certain food intolerance causing substances and prohibited food and color additives:

1. In the case of shrimp or lobster for which you have identified sulfiting agents as a significant hazard, will the finished product label declare the presence of sulfiting agents?

    a. If the finished product label will declare the presence of sulfiting agents, you should identify the finished product labeling step as the CCP and review the labels at that step. You would not need to identify the shrimp or lobster receiving step as a CCP for this hazard.

    Example:

    A frozen shrimp processor labels all of the finished product with a sulfiting agent declaration. The processor should set the CCP for sulfiting agents at the finished product labeling step, where labels would be reviewed for the presence of the declaration. The processor would not need to have a CCP for this hazard at the shrimp receiving step.

    This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1

- Finished Product Labeling for Control of Food Intolerance Causing Substances from Raw Materials."

b. If the finished product labeling will not declare the presence of sulfiting agents, you should identify the raw material receiving step as the CCP, where you could screen incoming lots for the presence of sulfiting agents. Preventive measures that can be applied here include:

- Testing incoming shrimp or lobster for residues of sulfiting agents at or above 10 ppm.

Example:

A frozen shrimp processor receives shrimp directly from the harvest vessel and does not label the finished product with a sulfiting agent declaration. The processor should set the CCP for sulfiting agents at the raw material receiving step and test incoming lots of shrimp for the presence of sulfiting agents. The processor would not need to have a CCP for this hazard at finished product labeling.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 2 - Raw Material Testing for Control of Food Intolerance Causing Substances and Prohibited Food and Color Additives From Raw Materials."

- Receiving a supplier's certification of the lack of sulfiting agent use on incoming lots of shrimp or lobster (with appropriate verification).

Example:

A frozen shrimp processor receives shrimp directly from the harvest vessel and does not label the finished product with a sulfiting agent declaration. The processor should set the CCP for sulfiting agents at the raw material receiving step and obtain certificates from the harvest vessels that sulfiting agents were not used on the shrimp. The processor should verify the effectiveness of the monitoring procedures by collecting quarterly samples of all incoming shrimp and samples of incoming shrimp from all new suppliers and analyzing for the presence of sulfiting agents. The processor would not need to have a CCP for this hazard at finished product labeling.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 3 - Review of Suppliers' Certificates for Control of Food Intolerance Causing Substances and Prohibited Food and Color Additives from Raw Materials."

- Reviewing the labeling (or accompanying documents, in the case of an unlabeled product) on shipments of shrimp or lobster received from another processor for the presence of a sulfiting agent declaration (with appropriate verification).

Example:

A frozen shrimp processor receives shrimp from another processor and does not label the finished product with a sulfiting agent declaration. The processor should set the CCP for sulfiting agents at the raw material receiving step and reject incoming lots that are identified as having been treated with a sulfiting agent (e.g., identified on the label or, in the case of unlabeled product, on documents accompanying the shipment). The processor should verify the effectiveness of the monitoring

procedures by collecting quarterly samples of all incoming shrimp and samples of incoming shrimp from all new suppliers and analyzing for the presence of sulfiting agents. The processor would not need to have a CCP for this hazard at finished product labeling.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 4 - Review of Suppliers' Labeling for Control of Food Intolerance Causing Substances from Raw Materials."

c. If the finished product label will declare the presence of sulfiting agents only when it is present in the raw material, you should identify the finished product labeling step as the CCP, where you can ensure that the appropriate label is placed on the package based on the results of screening performed at the receiving step for the presence of sulfiting agents. You would not need to identify the shrimp or lobster receiving step as a CCP for this hazard, although you would be exercising controls by performing raw material tests. Preventive measures that can be applied here include:

   - Testing incoming shrimp or lobster for detectable residues of sulfiting agents at or above 10 ppm and review of finished product labels.

   Example:

   A frozen shrimp processor receives shrimp directly from the harvest vessel and labels the finished product with a sulfiting agent declaration only if testing at receiving step identifies a residue of a sulfiting agent. The processor should set the CCP for sulfiting agents at the finished product labeling step and check that the appropriate label is being applied based on the results of the raw material testing. The processor would not need to have a CCP for this hazard at the raw material receiving step, although controls would be exercised there by performing raw material testing at the receiving step.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 5 - Finished Product Labeling Based on Raw Material Testing for Control of Food Intolerance Causing Substances from Raw Materials."

   - Receiving a supplier's certification of the lack of sulfiting agent use on incoming lots of shrimp or lobster (with appropriate verification) and review of finished product labels.

   Example:

   A frozen shrimp processor receives shrimp directly from the harvest vessel and labels the finished product with a sulfiting agent declaration only if a lot of raw material shrimp is received without a certificate attesting to the absence of sulfiting agent use. The processor should set the CCP for sulfiting agents at the finished product labeling step and check that the appropriate label is being applied based on the presence or absence of a certificate. The processor should verify the effectiveness of the monitoring procedures by collecting quarterly samples of incoming shrimp for the presence of sulfiting agents. The processor would not need to have a CCP for this hazard at the raw material receiving step, although controls for the receipt of a certificate attesting to the absence of sulfiting agent use would be applied there.

   This control approach is a control

strategy referred to in this chapter as "Control Strategy Example 6 - Finished Product Labeling Based on Review of Suppliers' Certificates for Control of Food Intolerance Causing Substances from Raw Materials."

- Reviewing the labeling (or accompanying documents, in the case of an unlabeled product) on incoming shipments of shrimp or lobster received from another processor for the presence of a sulfiting agent declaration (with applicable verification), and review of finished product labels.

Example:

A frozen shrimp processor receives shrimp (as raw material) from another processor and labels the finished product with a sulfiting agent declaration only if the incoming lot was identified on the labeling (or, in the case of unlabeled product, on documents accompanying the shipment) as having been treated with a sulfiting agent. The processor should set the CCP for sulfiting agents at the finished product labeling step and check that the appropriate label is being applied based on the raw material label review. The processor should verify the effectiveness of the monitoring procedures by collecting quarterly samples of all incoming shrimp and collect at least one representative sample for each new supplier and analyzing for the presence of sulfiting agents. The processor would not need to have a CCP for this hazard at the raw material receiving step, although controls for reviewing the labeling (or, in the case of unlabeled product, on documents accompanying the shipment) would be applied there.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 7 - Finished Product Labeling Based on Review of Suppliers' Labeling for Control of Food Intolerance Causing Substances from Raw Materials."

2. In the case of (1) cooked octopus or conch meat for which you have identified sulfiting agents as a significant hazard; (2) products for which you have identified Yellow No. 5 as a significant hazard because you use one of this color additive in the product formulation; and (3) products for which you have identified undeclared major food allergens as a significant hazard, you should identify the finished product labeling step as the CCP, where you can ensure that the appropriate label is placed on the package based on the results of a review of the product formula for that product. You would not need to identify the product formulation step as a CCP for this hazard, although you may be exercising control at that point.

Example:

A smoked sablefish processor treats the fish with Yellow No. 5 before smoking. The processor should set the CCP for Yellow No. 5 at the finished product labeling step, where the labels would be examined to ensure that the color additive is declared. The processor would not need to have a CCP for this hazard at the treatment (product formulation) step.

Example:

A cooked octopus processor treats the fish with a sulfiting agent. The processor should set the CCP for sulfiting agents at the finished product labeling step, where the labels would be examined to ensure that the food additive is declared. The processor would not need to have a CCP for this hazard at the treatment (product formulation) step.

Example:

A breaded fish processor uses pollock fillets and a batter mix containing egg and wheat for some formulations but not others listing egg, wheat, and pollock on the label only when those ingredients are included in the formulation. The processor should set the CCP for undeclared major food allergens at the finished product labeling step, where labels would be reviewed for the presence of an ingredient declaration that matches the current product formula.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 8 - Finished Product Labeling Controls for Major Food Allergens and Added Food Intolerance Causing Substances."

3. In the case of products for which you have identified prohibited food and color additives (e.g., coumarin, safrole, or Red No. 4) as a significant hazard because you have reason to believe that it may be present in an ingredient used in the finished product, you should identify the raw material receiving step as the CCP, where you could screen incoming lots for the presence of the additive. Preventive measures that can be applied here include:

   - Testing the incoming ingredient for the additive.

     Example:

     A shrimp salad processor uses an imported ingredient that has historically contained Red No. 4. The processor should test the ingredient at receipt for the additive and set the CCP for prohibited food and color additives at the ingredient receiving step.

     This control approach is the same control strategy previously identified as "Control Strategy Example 2 - Raw Material Testing for Control of Food Intolerance Causing Substances and Prohibited Food and Color Additives from Raw Materials."

   - Receiving a supplier's certification of the lack of prohibited food and color additive use in the ingredient lot (with appropriate verification).

     Example:

     A shrimp salad processor uses an imported ingredient that has historically contained Red 4. The processor should set the CCP for prohibited food and color additives at the ingredient receiving step and obtain certificates from the supplier that Red No. 4 was not used in the formulation of the ingredient lot. The processor should verify the effectiveness of the monitoring procedures by collecting quarterly samples of the imported ingredient for the presence of Red No. 4.

     This control approach is the same control strategy previously identified as "Control Strategy Example 3 - Review of Suppliers' Certificates for Control of Food Intolerance Causing Substances and Prohibited Food and Color Additives from Raw Materials."

DEVELOP A CONTROL STRATEGY.

The following guidance provides eight control strategies for undeclared major food allergens, certain food intolerance causing substances, and prohibited food and color additives. You may select a control strategy that is different from those that are suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

The following are examples of control strategies included in this chapter:

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Finished product labeling for control of food intolerance causing substances from raw materials	✓	✓
Raw material testing for control of food intolerance causing substances and prohibited food and color additives from raw materials	✓	✓
Review of suppliers' certificates for control of food intolerance causing substances and prohibited food and color additives from raw materials	✓	✓
Review of suppliers' labeling for control of food intolerance causing substances from raw materials		✓
Finished product labeling based on raw material testing for control of food intolerance causing substances from raw materials	✓	✓
Finished product labeling based on review of suppliers' certificates for control of food intolerance causing substances from raw materials	✓	✓
Finished product labeling based on review of suppliers' labeling for control of food intolerance causing substances from raw materials		✓
Finished product labeling controls for major food allergens and added food intolerance causing substances	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 - FINISHED PRODUCT LABELING FOR CONTROL OF FOOD INTOLERANCE CAUSING SUBSTANCES FROM RAW MATERIALS**

Set Critical Limits.

- All finished product packages must bear a label that declares the presence of a sulfiting agent.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Labels on finished product packages for presence of sulfiting agent.

» **How Will Monitoring Be Done?**

- Visual examination.

» **How Often Will Monitoring Be Done (Frequency)?**

- Representative number of packages from each lot of a finished product;

» **Who Will Do the Monitoring?**

- Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Segregate and relabel any improperly labeled product.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Modify labeling procedures, as appropriate;

  OR

- Make corrections to the label generation program or equipment;

  OR

- Discontinue use of the label supplier until evidence is obtained that the labeling will contain the appropriate declaration;

AND/OR

- Segregate and return or destroy any label stock or pre-labeled packaging stock that does not contain the proper declaration.

Establish a Recordkeeping System.

- Record of labeling checks of finished product packages.

Establish Verification Procedures.

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 19-2

CONTROL STRATEGY EXAMPLE 1 - FINISHED PRODUCT LABELING FOR CONTROL OF FOOD INTOLERANCE CAUSING SUBSTANCES FROM RAW MATERIALS

This table is an example of a portion of a HACCP Plan using "Control Strategy Example 1 - Finished Product Labeling for Control of Food Intolerance Causing Substances from Raw Materials." This example illustrates how a processor of shell-on shrimp can control sulfiting agents that are used on the harvest vessel. It is provided for illustrative purposes only.

Major food allergens, certain food intolerance causing substances and prohibited food and color additives may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Finished product labeling	Undeclared sulfiting agents	All finished product packages must bear labels that contain sulfiting agent declaration	Labels on the finished product for the presence of sulfiting agent declaration	Visual	One label at the beginning of the production of each lot and one label every hour thereafter	Quality assurance employee	Segregate and relabel improperly labeled product Discontinue use of the label supplier until evidence is obtained that labeling will contain the sulfiting agent declaration	Record of labeling checks of finished product packages	Review monitoring and corrective action records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 2 - RAW MATERIAL TESTING FOR CONTROL OF FOOD INTOLERANCE CAUSING SUBSTANCES AND PROHIBITED FOOD AND COLOR ADDITIVES FROM RAW MATERIALS**

Set Critical Limits.

- Incoming lots of shrimp or lobster must not contain a detectable level of sulfiting agents (Note that <10 ppm sulfiting agents may be present in finished product shell-off shrimp and lobster without a sulfiting agent declaration on the label if the sulfiting agents have no functional (ongoing technical) effect in the finished food. However, if the sulfiting agents have a functional (ongoing technical) effect in finished shell-on or shell-off shrimp or lobster product regardless of level, then they must be declared as ingredients on the product label).

  AND/OR

- An incoming lot of raw materials must not contain a detectable level of prohibited food or color additive.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Each lot at receipt for sulfiting agent residual analysis and/or prohibited food and color additive analysis, as appropriate.

» **How Will Monitoring Be Done?**

- Screening test for sulfiting agents and/or prohibited food and color additives, as appropriate.

» **How Often Will Monitoring Be Done (Frequency)?**

- Representative sample from each incoming lot.

» **Who Will Do the Monitoring?**

- Any person who is qualified by training or experience to perform the screening test procedure.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Reject the lot.

AND

Take the following corrective action to regain control of the operation after a critical limit deviation:

- Discontinue use of the supplier until evidence is obtained that control of sulfiting agents and/or prohibited food and color additives, as appropriate, has improved.

Establish a Recordkeeping System.

- Test results for sulfiting agents and/or prohibited food and color additives, as appropriate.

Establish Verification Procedures.

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 19-3

CONTROL STRATEGY EXAMPLE 2 - RAW MATERIAL TESTING FOR CONTROL OF FOOD INTOLERANCE CAUSING SUBSTANCES AND PROHIBITED FOOD AND COLOR ADDITIVES FROM RAW MATERIALS

This table is a an example of a portion of a HACCP plan using "Control Strategy Example 2 - Raw Material Testing for Control of Food Intolerance Causing Substances and Prohibited Food and Color Additives from Raw Materials." This example illustrates how a processor of shell-on shrimp can control sulfiting agents that are used on the harvest vessel. It is provided for illustrative purposes only.

Major food allergens, certain food intolerance causing substances and prohibited food and color additives may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-3 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Shrimp receiving	Undeclared sulfiting agents	Incoming lots of shrimp must not contain 10 ppm or greater sulfiting agents	Each lot of raw material shrimp for sulfiting agent residual	Malachite green test	Three shrimp selected randomly from each lot of incoming shrimp	Receiving employee	Reject any incoming lot of shrimp that contains a detectable level of sulfiting agent Discontinue use of the supplier until evidence is obtained that control of sulfiting agents has improved	Test results for sulfiting agents	Review monitoring and corrective action records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 3 - REVIEW OF SUPPLIERS' CERTIFICATES FOR CONTROL OF FOOD INTOLERANCE CAUSING SUBSTANCES AND PROHIBITED FOOD AND COLOR ADDITIVES FROM RAW MATERIALS**

Set Critical Limits.

- Incoming lots of shrimp or lobster must be accompanied by a supplier's lot-by-lot certificate that sulfiting agents and/or prohibited food and color additives, as appropriate, were not used.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The supplier's lot-by-lot certificate that no sulfiting agents and/or prohibited food and color additives, as appropriate, were used on the lot.

» **How Will Monitoring Be Done?**

- Visual examination of certificates.

» **How Often Will Monitoring Be Done (Frequency)?**

- Each incoming lot.

» **Who Will Do the Monitoring?**

- Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Reject the lot;

  OR

- Hold the lot until a certificate can be provided;

  OR

- Test the lot for sulfiting agents and/or prohibited food and color additives, as appropriate, and reject the lot if 10 ppm or greater sulfating agents or a detectable levels of prohibited food and color additives are found.

  AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Discontinue use of the supplier until evidence is obtained that certificates will accompany future shipments.

Establish a Recordkeeping System.

- Suppliers' lot-by-lot certificates;

  AND

- Receiving records showing lots received and the presence or absence of suppliers' certificates.

Establish Verification Procedures.

- Collect at least one representative sample per quarter, randomly selected from each supplier, and analyze for sulfiting agents and/or prohibited food and color additives, as appropriate. Additionally, collect at least one representative sample from each new supplier, and analyze for sulfiting agents or prohibited food and color additives, as appropriate;

  AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 19-4

CONTROL STRATEGY EXAMPLE 3 - REVIEW OF SUPPLIERS' CERTIFICATES FOR CONTROL OF FOOD INTOLERANCE CAUSING SUBSTANCES AND PROHIBITED FOOD AND COLOR ADDITIVES FROM RAW MATERIALS

This table is an example of a portion of a HACCP plan using "Control Strategy Example 3 - Review of Suppliers' Certificates for Control of Food Intolerance Causing Substances and Prohibited Food and Color Additives from Raw Materials." This example illustrates how a processor of shell-on shrimp can control sulfiting agents that are used on the harvest vessel. It is provided for illustrative purposes only.

Major food allergens and certain food intolerance causing substances and prohibited food and color additives may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-3 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Shrimp receiving	Undeclared sulfiting agents	All incoming lots of shrimp must be accompanied by a lot-by-lot certificate stating that sulfiting agents were not used	Suppliers' lot-by-lot certificates stating that no sulfiting agents were used on the incoming lot	Visual examination	Every lot received	Receiving employee	Test the lot for sulfiting agents and reject the lot if a detectable level of sulfiting agents is found Discontinue use of the supplier until evidence is obtained that certificates will accompany future shipments	Suppliers' lot-by-lot certificates Receiving records showing lots received and the presence or absence of suppliers' certificates	Collect at least one representative sample per quarter and test for sulfiting agents; in addition, test at least one lot from each new supplier and analyze for sulfiting agents Review monitoring, corrective action, and verification records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 4 - REVIEW OF SUPPLIERS' LABELING FOR CONTROL OF FOOD INTOLERANCE CAUSING SUBSTANCES FROM RAW MATERIALS**

Set Critical Limits.

- The labeling or shipping documents for incoming lots of shrimp or lobster received from another processor must not contain a sulfiting agent declaration.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Suppliers' product labels or shipping documents for the presence of sulfiting agent declaration.

» **How Will Monitoring Be Done?**

- Visual examination of labels.

» **How Often Will Monitoring Be Done (Frequency)?**

- Every incoming lot.

» **Who Will Do the Monitoring?**

- Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Reject the lot;

  OR

- Test the lot for sulfiting agents and reject the lot if 10 ppm or greater of sulfiting agents are found.

AND

Take the following corrective action to regain control of the operation after a critical limit deviation:

- Discontinue use of supplier until evidence is obtained that they will no longer provide a product in which sulfiting agents have been used.

Establish a Recordkeeping System.

- Record of review of labeling or shipping documents for raw materials.

Establish Verification Procedures.

- Collect at least one representative sample per quarter, randomly selected from among your suppliers, and analyze for sulfiting agents. Additionally, collect at least one representative sample for each new supplier, and analyze for sulfiting agents;

  AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 19-5

CONTROL STRATEGY EXAMPLE 4 - REVIEW OF SUPPLIERS' LABELING FOR CONTROL OF FOOD INTOLERANCE CAUSING SUBSTANCES FROM RAW MATERIALS

This table is an example of a portion of a HACCP plan using "Control Strategy Example 4 - Review of Suppliers' Labeling for Control of Food Intolerance Causing Substances from Raw Materials." This example illustrates how a processor of shell-on shrimp can control sulfiting agents that are used on the harvest vessel. It is provided for illustrative purposes only.

Major food allergens and certain food intolerance causing substances and prohibited food and color additives may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Shrimp receiving	Undeclared sulfiting agents	The labeling of incoming lots of shrimp received from another processor must not contain a sulfiting agent declaration	Suppliers' product labels for the presence of sulfiting agent declaration	Visual examination of the labels	Every lot received	Receiving employee	Reject the lot Discontinue use of supplier until evidence is provided that they will not provide sulfiting agent treated shrimp	Record of labeling checks of raw materials	Collect at least one representative sample per quarter and test for sulfiting agents; in addition, test at least one lot from each new supplier and analyze for sulfiting agents Review monitoring, corrective action, and verification records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 5 - FINISHED PRODUCT LABELING BASED ON RAW MATERIAL TESTING FOR CONTROL OF FOOD INTOLERANCE CAUSING SUBSTANCES FROM RAW MATERIALS**

Set Critical Limits.

- All finished product packages processed from raw materials that contain a detectable level of sulfiting agents must bear a label that contains a sulfiting agent declaration. Note that 10 ppm sulfiting agent may be present in finished product shell-off shrimp and lobster without a sulfiting agent declaration on the label. However, any detectable level of sulfiting agent in finished product shell-on shrimp or lobster would require a sulfiting agent declaration on the label, because the sulfiting agents continue to have a functional effect.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Labels on finished product packages for presence of sulfiting agent declaration;

  AND

- A representative sample of each lot of raw material for the presence of sulfiting agents.

» **How Will Monitoring Be Done?**

- For labels on finished packages:
  - Visual examination of labels;

  AND

- For raw material testing:
  - Screening test for sulfiting agents.

» **How Often Will Monitoring Be Done (Frequency)?**

- For finished product labeling:
  - A representative number of packages from each lot of a finished product;

  AND

- For raw material testing:
  - Each lot of raw material shrimp received.

» **Who Will Do the Monitoring?**

- For finished product labeling:
  - Any person who has an understanding of the nature of the controls;

  AND

- For raw material testing:
  - Any person who is qualified by training or experience to perform the screening test.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Segregate and relabel any improperly labeled product.

AND

Take the following corrective action to regain control of the operation after a critical limit deviation:

- Modify labeling procedures, as appropriate.

Establish a Recordkeeping System.

- Record of labeling checks of finished product packages;

  AND

- Record of sulfiting agent test results.

Establish Verification Procedures

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 19-6

CONTROL STRATEGY EXAMPLE 5 - FINISHED PRODUCT LABELING BASED ON RAW MATERIAL TESTING FOR CONTROL OF FOOD INTOLERANCE CAUSING SUBSTANCES FROM RAW MATERIALS

This table is a an example of a portion of a HACCP plan using "Control Strategy Example 5 - Finished Product Labeling Based on Raw Material Testing for Control of Food Intolerance Causing Substances from Raw Materials." This example illustrates how a processor of shell-on shrimp can control sulfiting agents that are used on the harvest vessel. It is provided for illustrative purposes only.

Major food allergens and certain food intolerance causing substances and prohibited food and color additives may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-3 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Finished product labeling	Undeclared sulfiting agents	All finished product packages processed from raw materials that contain 10 ppm or greater sulfiting agents must bear a label that contains a sulfiting agent declaration	Labels on finished product packages for the presence of a sulfiting agent declaration	Visual examination of labels on finished product packages	One label at the beginning of the production of each lot and one label every hour thereafter	Quality control employee	Segregate and relabel any improperly labeled product Modify labeling procedures, as appropriate	Record of labeling checks of finished product packages	Review monitoring and corrective action records within 1 week of preparation
			Analysis of raw material shrimp for sulfiting agent residual	Malachite green test	Three shrimp collected randomly from each lot of raw material shrimp	Quality control employee		Analytical results	

- **CONTROL STRATEGY EXAMPLE 6 - FINISHED PRODUCT LABELING BASED ON REVIEW OF SUPPLIERS' CERTIFICATES FOR CONTROL OF FOOD INTOLERANCE CAUSING SUBSTANCES FROM RAW MATERIALS**

Set Critical Limits.

- All finished product packages must bear a label that contains a sulfiting agent declaration unless they are processed from raw material shrimp or lobster that are accompanied by a supplier's lot-by-lot certificate that states that no sulfiting agents were used.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Labels on finished product packages for the presence of a sulfiting agent declaration;

  AND

- Suppliers' lot-by-lot certificates for raw material shrimp or lobster that no sulfiting agent was used on the lot.

» **How Will Monitoring Be Done?**

- For finished product labeling:
  - Visual examination of the labels;

  AND

- For suppliers' lot-by-lot certificates:
  - Visual examination of the certificates.

» **How Often Will Monitoring Be Done (Frequency)?**

- For finished product labeling:
  - A representative number of packages from each lot of a finished product;

  AND

- For suppliers' lot-by-lot certificates:
  - Each incoming lot.

» **Who Will Do the Monitoring?**

- Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Segregate and relabel any improperly labeled product.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Modify labeling procedures, as appropriate.

Establish a Recordkeeping System.

- Record of labeling checks;

  AND

- Copy of certificates;

  AND

- Receiving record showing lots received and the presence or absence of a certificate.

Establish Verification Procedures.

- Collect at least one representative sample per quarter from lots that are accompanied by a certificate, randomly selected from among your suppliers, and analyze for sulfiting agents. Additionally, collect at least one representative sample for each new supplier and analyze for sulfiting agents;

  AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 19-7

CONTROL STRATEGY EXAMPLE 6 - FINISHED PRODUCT LABELING BASED ON REVIEW OF SUPPLIERS' CERTIFICATES FOR CONTROL OF FOOD INTOLERANCE CAUSING SUBSTANCES FROM RAW MATERIALS

This table is an example of a portion of a HACCP plan using "Control Strategy Example 6 - Finished Product Labeling Based on Review of Suppliers' Certificates for Control of Food Intolerance Causing Substances from Raw Materials." This example illustrates how a processor of shell-on shrimp can control sulfiting agents that are used on the harvest vessel. It is provided for illustrative purposes only.

Major food allergens and certain food intolerance causing substances and prohibited food and color additives may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Finished product labeling	Undeclared sulfiting agents	All finished product packages must bear a label that contains a sulfiting agent declaration unless they are processed from raw material shrimp that are accompanied by a supplier's lot-by-lot certificate that states that no sulfiting agents were used	Labels on finished product packages for the presence of a sulfiting agent declaration	Visual examination of labels on finished product packages	One label at the beginning of the production of each lot and one label every hour thereafter	Labeling supervisor	Segregate and relabel any improperly labeled product Modify labeling procedure, as appropriate	Record of labeling checks	Collect at least one representative sample per quarter from lots that are accompanied by a certificate, selected randomly from among the suppliers and analyze for sulfiting agents; additionally, collect one representative sample from each new supplier and analyze for sulfiting agents Review monitoring, corrective action, and verification records within 1 week of preparation
			Lot-by-lot certificates stating that no sulfiting agent was used on the lot	Visual examination of lot-by-lot certificates	Each incoming lot	Receiving employee		Record of raw material receiving Lot-by-lot certificates	

- **CONTROL STRATEGY EXAMPLE 7 - FINISHED PRODUCT LABELING BASED ON REVIEW OF SUPPLIERS' LABELING FOR CONTROL OF FOOD INTOLERANCE CAUSING SUBSTANCES FROM RAW MATERIALS**

Set Critical Limits.

- All finished product packages must bear a label that contains a sulfiting agent declaration if they are processed from raw material shrimp or lobster that are labeled with a sulfiting agent declaration or accompanied by documents that contain a sulfiting agent declaration.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Labels on finished product packages for the presence of a sulfiting agent declaration;

  AND

- Labeling or shipping documents for each lot of raw material shrimp or lobster received from another processor for the presence of a sulfiting agent declaration.

» **How Will Monitoring Be Done?**

- Visual examination of labels and shipping documents.

» **How Often Will Monitoring Be Done (Frequency)?**

- For finished product labeling:
  - A representative number of packages from each lot of a finished product;

  AND

- For raw material labeling:
  - Each incoming lot.

» **Who Will Do the Monitoring?**

- Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Segregate and relabel any improperly labeled product.

AND

Take the following corrective action to regain control of the operation after a critical limit deviation:

- Modify labeling procedures, as appropriate.

Establish a Recordkeeping System.

- Record of labeling checks of finished product packages;

  AND

- Record of review of raw material labeling or shipping documents.

Establish Verification Procedures.

- Collect at least one representative sample per quarter from lots that are not labeled with a sulfiting agent declaration or not accompanied by documents with a sulfiting agent declaration, randomly selected from among your suppliers, and analyze for sulfiting agents. Additionally, collect at least one representative sample for each new supplier, and analyze for sulfiting agents;

  AND

- Review monitoring, corrective action and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 19-8

CONTROL STRATEGY EXAMPLE 7 - FINISHED PRODUCT LABELING BASED ON REVIEW OF SUPPLIERS' LABELING FOR CONTROL OF FOOD INTOLERANCE CAUSING SUBSTANCES FROM RAW MATERIALS

This table is an example of a portion of a HACCP plan using "Control Strategy Example 7 - Finished Product Labeling Based on Review of Suppliers' Labeling for Control of Food Intolerance Causing Substances from Raw Materials." This example illustrates how a processor of shell-on shrimp can control sulfiting agents that are used on the harvest vessel. It is provided for illustrative purposes only.

Major food allergens and certain food intolerance causing substances and prohibited food and color additives may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Finished product labeling	Undeclared sulfiting agents	All finished product packages must bear a label that contains a sulfiting agent declaration if they are processed from raw material shrimp that are labeled with a sulfiting agent declaration or accompanied by documents that contain a sulfiting agent declaration	Labels on finished product packages for the presence of a sulfiting agent declaration	Visual examination of labels on finished product packages	One label at the beginning of the production of each lot and one label every hour thereafter	Labeling supervisor	Segregate and relabel any improperly labeled product Modify labeling procedure, as appropriate	Record of labeling checks	Collect at least one representative sample per quarter from lots that are not labeled with a sulfiting agent declaration, randomly selected from among your suppliers, and analyze for sulfiting agents; additionally, collect at least one representative sample for each new supplier, and analyze for sulfiting agents Review monitoring, corrective action and verification records within 1 week of preparation
			Labeling for each lot of raw material shrimp received from another processor for the presence of a sulfiting agent declaration	Visual examination of the raw material labeling	Each incoming lot	Receiving employee		Records of raw material labeling checks	

- **CONTROL STRATEGY EXAMPLE 8 - FINISHED PRODUCT LABELING CONTROLS FOR MAJOR FOOD ALLERGENS AND ADDED FOOD INTOLERANCE CAUSING SUBSTANCES**

Set Critical Limits.

- All finished product labeling must accurately list any major food allergens and added sulfiting agents that have an on-going functional effect or Yellow No. 5 that are included in the product formulation.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Labels on finished product packages for comparison with the product formula (recipe), including the market name of any finfish or crustacean shellfish contained in the product.

» **How Will Monitoring Be Done?**

- Visual examination of the finished product labels and product formula.

» **How Often Will Monitoring Be Done (Frequency)?**

- A representative number of packages from each lot of a finished product.

» **Who Will Do the Monitoring?**

- Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Segregate and relabel any improperly labeled product.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Modify label procedures, as appropriate.

Establish a Recordkeeping System.

- Record of labeling checks of finished product packages.

Establish Verification Procedures.

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 19-9

CONTROL STRATEGY EXAMPLE 8 - FINISHED PRODUCT LABELING CONTROLS FOR MAJOR FOOD ALLERGENS AND ADDED FOOD INTOLERANCE CAUSING SUBSTANCES

This table is an example of a portion of a HACCP plan using "Control Strategy Example 8 - Finished Product Labeling Controls for Major Food Allergens and Added Food Intolerance Causing Substances." This example illustrates how a breaded fish processor can control undeclared major food allergens in the production of breaded fish portions containing egg, wheat, and pollock. It is provided for illustrative purposes only.

Major food allergens and certain food intolerance causing substances and prohibited food and color additives may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Finished product labeling	Undeclared major food allergens	Finished product labels must declare the presence of egg, wheat, and pollock	Finished product labels for comparison with product formula	Visual examination of the labels on finished product packages	One label at the beginning of the production of each lot and one label every hour thereafter	Quality assurance staff	Segregate and relabel any incorrectly labeled product Modify labeling procedure, as appropriate	Record of review of finished product labels	Review monitoring and corrective action records within 1 week of preparation

BIBLIOGRAPHY.

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of March 29, 2011, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after March 29, 2011.

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NOTES: