CHAPTER 19: UNDECLARED MAJOR FOOD ALLERGENS AND FOOD INTOLERANCE SUBSTANCES

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UNDERSTAND THE POTENTIAL HAZARD

- **Food Allergens**

Food allergies are a significant public health concern. Allergic reactions vary in severity from gastrointestinal disturbances and skin irritation, to anaphylaxis, shock and death. Consumers with allergies must avoid food containing allergenic materials to avoid these reactions. Because of this, consumers rely on food labels to disclose the presence of allergenic ingredients. Successful avoidance requires that food manufacturers develop, implement, and maintain the necessary controls to ensure allergens that are intended to be present in a food are declared on the label and that the presence of unintended allergens is prevented.

Advisory statements such as "may contain [allergen]" or "manufactured on equipment that also processes [allergen]" cannot be used as a substitute for current good manufacturing practices (cGMPs) intended to prevent allergen cross-contact.

Control of allergens will be accomplished through both the implementation of prerequisite programs and through HACCP plan controls that ensure accurate product labeling. Product labeling, label control, and allergen cross-contact controls are important components of a processor's HACCP program. Product development, product formulation, receipt of pre-printed labels, printing of in-house labels, and storage of allergenic ingredients are examples of things to consider during the development of an allergen control strategy.

Domestic and imported food product labels, packaging materials and other finished product containers must accurately reflect U.S. regulations regarding the declaration of major food allergens ingredients.

No minimum threshold has been established for allergenic ingredients, for either intentionally or unintentionally added allergens. However, there are emerging data on levels of major food allergens that may be tolerated by a large majority of individuals in the allergic population and that can be used in manufacturer's risk assessment of allergen cross-contact hazards.

- **Labeling:**

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) has identified a "Major food allergen" (allergen) as one of the following eight foods or food groups:

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

Foods that contain a major food allergen as an ingredient, must (with a few exceptions such as highly refined soybean oil) declare the presence of that allergen in plain English terms using the common or usual name of the major food allergen either as part of the ingredient declaration or in a "contains" statement that is located immediately after or adjacent to the ingredient declaration

on labels. A "contains" statement differs from a "may contain" statement in that the "contains" statement identifies allergenic ingredients added to the commodity based on product formulation; whereby, the "may contain" statement describes the potential presence of an allergenic ingredient which is not part of the product formulation.

The definition of "fish" differs between the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and 21 CFR Part 123 Fish and Fishery Products. For more information regarding FALCPA and the Seafood regulation go their respective websites: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm and https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=123. "Fish", within the context of FALCPA and the identification of allergenic ingredients, refers to finfish such as flounder, tilapia, grouper, and other vertebrate fish with fins. This differs from the definition in 21 CFR Part 123 which includes all aquatic animal life intended for human consumption, excluding mammals and birds. Allergen label declarations must be in compliance with FALCPA as well as other labeling requirements.

FDA considers the "common or usual name" synonymous with the "market" name for the seafood industry. Therefore, the "market" name of fish species and crustacean shellfish should be used to identify the food source for these two major food allergen groups. The "market" names can be found on "The Seafood List". For more information regarding the seafood list, go to its website: https://www.accessdata.fda.gov/scripts/fdcc/?set=seafoodlist. In addition, the term "fish" may be added to the market name on the label if the market name is not otherwise recognized as a fish by the consumer for example, gar fish.

Refer to the following websites for more information regarding allergen labeling requirements:

- https://www.fda.gov/food/ingredientspackaginglabeling/foodallergens/default.htm and
- https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/default.htm.

Raw agricultural commodities (whole raw fish or crustaceans in their natural state), fish other than finfish and crustacean shellfish (i.e., molluscan shellfish), and highly refined oils are exempt from allergen labeling requirements; however, they are still subject to other FDA labeling requirements.

- **Allergen Cross-Contact:**

Processors are required to implement cGMP controls that prevent allergen cross-contact. Allergen cross-contact is defined as the unintentional incorporation of a food allergen into a food. Allergen cross-contact can occur either between foods that contain different food allergens or between foods with and without food allergens. There can be multiple opportunities for cross-contact within a processing facility such as incoming ingredients with unintentional allergens, during processing or storage of ingredients, through inadequate cleaning of equipment and/or utensils [e.g. spoons, spatulas, scoops, employee apparel (aprons and gloves)], lack of process scheduling, and through poor facility design (e.g. air flow movement and filtration). Controls are normally implemented and monitored as part of the cGMP, prerequisite program, and/or sanitation monitoring procedures to prevent cross-contact in these areas.

For facilities that manufacture or process multiple food allergens, FDA recommends the facility take measures to prevent allergen cross-contact and subsequently the hazard of undeclared food allergens with product that do not contain or contain different allergens. Allergen cross-contact controls are needed when ingredients, in-process materials, and finished products are received, handled, transported, and stored.

At this time FDA does not require cross-contact controls between specific finfish species; however, we do require cross-contact controls between crustacean species and finfish species.

Allergen cross-contact controls are intended to provide separation in time and space between the products with different allergenic ingredients. The appropriate allergen control measures are facility and product dependent. Factors to consider include the properties of the allergenic ingredients being used, the manufacturing process, facility structure and design, and the finished product. Areas where controls may be implemented include:

- Review/assessment of incoming or supplier ingredients for allergen cross-contact risk;
- Equipment and process design (look at traffic patterns, air flow, equipment design

to prevent accumulation of food residue, provide shields/catch pans/partitions for equipment);

- Dedication of processing systems (dedicated processing and packaging lines and equipment, dedicated utensils and employees' apparel, color code system for allergens, dedicate and/or restrict movement of employees);
- Product containments and equipment barriers (physically separating the system through the use of walls/closed off rooms);
- Production scheduling (separate by time of manufacture through sequencing whereby the food with the fewest allergen or no allergen is produced first and the food with the most allergens is produced last in combination with effective allergen cleaning and sanitation procedures between changeover of production);
- Management of the movement of materials and personnel (movement of ingredients, equipment, employees, utensils, tools, employees apparel, work-in-progress (WIP), rework, finished products and waste materials during operation needs to be managed to minimize allergen cross-contact); and
- Rework of finished or partially finished products that are reincorporated into the manufacturing process and WIP of partially finished products moving between different productions states/steps. Rework can increase the risk of introducing allergens, either by erroneous addition of allergen-containing rework/WIP into a product that does not contain the specific allergen(s) as ingredients, or by cross-contact of allergen-containing materials with non-allergen-containing materials during holding or storage.
- Control of oil in fryers. Using dedicated fryers would minimize the risk of allergen cross-contact.

Measures should be taken to control allergen cross-contact within the facility; however, the measures do not necessarily have to be incorporated into the HACCP plan itself. The measures can be incorporated into the firm's prerequisite programs or other programs as appropriate.

FDA has been conducting research to determine whether allergenic proteins (shrimp protein) can be transferred through fryer oils. The following conclusions were identified as a result of our first series of tests:

- Shrimp protein was observed being transferred into the fryer oil through the frying process.
- Shrimp protein was transferred to French fries when fried in the same oil used to fry the shrimp; however, limitations were observed to only the first batch of oils and fries tested.

Refer to Appendix 10 of this Guide for further assistance with identification of potential cross-contact areas and establishing controls for allergen cross-contact.

- **Allergen Sanitation Control Procedures:**

Cleaning and sanitation controls are crucial for the prevention of allergen cross-contact within a facility. Establishing written SSOPs or prerequisite programs help to define the controls and ensure cleaning sufficient to prevent cross-contact. Many manufacturing facilities have already established and implemented effective cleaning and sanitation controls for microbial cross contamination; however, procedures targeting microbial hazards may not be adequate for allergen removal. Therefore, it is important to evaluate the sanitation controls to ensure they adequately remove allergen residues from all surfaces.

FDA has identified considerations for establishing and implemented effective cleaning and sanitation controls for allergen removal. Refer to Appendix 9 of this Guide for further assistance with establishing allergen sanitation controls or to assist with verifying and validation of the current controls to ensure they are adequate to prevent allergen cross-contact.

- **Food Intolerance Substances**

Certain food and color additives can cause hypersensitivity reactions, or food intolerances, in some consumers. 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. Food intolerance substances including sulfiting agents and FD&C Yellow No. 5 (Yellow No. 5) are commonly used in fish and fishery products. People sensitive to sulfiting agents can experience symptoms that range from mild to life-threatening reactions. People sensitive to Yellow No. 5 can experience symptoms that can range from mild to moderate severity.

Common uses of Yellow No. 5 include its addition to certain species of smoked fish, such as sable, to impart color. When Yellow No. 5 is used, it must be declared on the label as an ingredient per 21 CFR 74.705. No minimum threshold has been established.

Sulfiting agents are commonly used as a preservative to prevent melanosis or "black spot" on shrimp and spiny lobster shells. In addition, they can be used to retain the red color of the octopus' skin in cooked octopus' processes, to prevent darkening of conch meat, and may be included as an ingredient in breading. FDA requires that processors declare the presence of sulfites when the concentration meets or exceeds 10 ppm. The usage and/or concentration of the sulfiting agent found in the food will determine whether it will be declared on the label as an ingredient (to be discussed later in the chapter.)

Currently, there are six sulfiting agents allowed in processed food. They should be listed on food labels as follows per 21 CFR 101.100(a)(4):

- potassium bisulfite;
- potassium metabisulfite;
- sodium bisulfite;
- sodium metabisulfite;
- sodium sulfite; and
- sulfur dioxide.

Advisory statements such as "may contain sulfites" cannot be used as a substitute for accurate labeling in the ingredient panel through the implementation of HACCP plan controls.

Table 19-1, "When to Declare Sulfiting Agents on Finished Product Label," 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.

TABLE 19-1

Declaring Sulfiting Agents on Finished Product Label

Examples of Sulfiting Agent Use.	Examples of Finished Food.	Label Finished Food when levels are < 10 ppm.	Label Finished Food when Levels are ≥ 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 or cooked shell-on shrimp or lobster. • Cooked octopus. • Conch meat.	YES [1] (Labels required.)	YES [1] (Labels required.)
• 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 or cooked, peeled shrimp or lobster meat. • Food containing raw or cooked, peeled shrimp or lobster meat as an ingredient (e.g., seafood casserole).	NO [2] (Labels not required)	YES [2] (Labels required)

FOOTNOTE:

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. In addition, when 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 each must be declared by its approved label name (listed above).

Example:

A processor receives frozen, raw, headless, shell-on shrimp that are labeled with a sulfiting agent declaration. The shrimp had been 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 agent concentration is less than 10 ppm. Because the sulfiting agent no longer has a functional effect in the finished food, and because the concentration of the sulfiting agent is less than 10 ppm in the finished product, the processor is not required to have a sulfiting agent declaration on the label of the shrimp gumbo.

Example:

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

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT

The following guidance will assist in determining whether undeclared food allergens and food intolerance substances (e.g., sulfiting agents or Yellow No. 5) are a significant hazard at a processing step:

1. **Is it reasonably likely that a major food allergen, and/or food intolerance substance, will be introduced at this processing step (e.g., does it come in with the raw material or will the process introduce it)?**

   Under ordinary circumstances, consider whether food allergens and food intolerance substances are a significant hazard at the:

   - Receiving step:
     - When the raw ingredients contain or are reasonably likely to contain major food allergens and/or food intolerance substances, for example, a historic occurrence of food intolerance substances in that ingredient or containing an allergenic sub-ingredient.
   - Product formulation step:
     - When a raw material is, or contains one or more of the major food allergens (including non-fishery allergens), or a food intolerance substance is used as an ingredient in the formulation of any of the products; AND/OR
     - When sulfiting agent(s) are used or declared in products containing shrimp, lobster or conch meat. A study that tests the range of concentration of sulfiting agents in the raw material and possible variation in formulation should be conducted to establish whether sulfiting agents will not be present at 10 ppm or greater in the finished product;

2. **Can the hazard of undeclared major food allergens, and food intolerance substances that were introduced at an earlier step be eliminated or reduced to an acceptable level at this processing step?**

   Allergens and food intolerance substances may be introduced during processing (e.g., through product formulation). The hazard occurs when the end products are not accurately labeled to declare their presence. The controls are either to ensure an allergen or food intolerance substance is not present or to ensure that its presence is accurately declared on the finished product label. Measures to prevent undeclared major food allergens and food intolerance substances include:

   - Review of raw material labels (e.g., ingredient panel and/or "contains" statement) or accompanying documents in the case of unlabeled products for allergen and/or food intolerance substance declaration;
   - Review of finished product labels to ensure that the presence of allergens and/or food intolerance substances are declared. For example, compare product specifications, raw material labels, and end-product labels for allergen or food intolerance substance declarations;
   - Review of a supplier's certification or accompanying documentation (i.e., certificate of analysis) for lack of sulfiting agent use;
   - Test incoming shrimp, lobster or conch meat for residues of sulfiting agents;
   - Review of the label at the point of application to the finished product to ensure that the appropriate label is placed on the product.

- **Intended use**

In the case of undeclared major food allergens and food intolerance substances the hazard will have no impact on the intended use of the product.

IDENTIFY CRITICAL CONTROL POINTS

Receiving and finished product labeling steps are likely CCPs. A receiving critical control point can be used to monitor the content of pre-printed labels and to identify raw materials containing allergenic or food intolerance ingredients. Monitoring the list of ingredients and "contains" statement declarations also applies to labels generated in-house. The finished product labeling step may be used to monitor the accuracy of the finished product labels

affixed to the packaging. Some operations may only require a single CCP while others may require both critical control points.

The following guidance will assist you in determining whether the receiving or product labeling step is a critical control point (CCP) for undeclared major food allergens and food intolerance substances:

1. In the case of products that are known to contain allergenic or food intolerance ingredients, how will you ensure the finished product labels accurately declare the presence of the hazard?

a. If the finished product is known to contain an allergenic ingredient or a food intolerance substance you should identify the product labeling step as a CCP.

Example:

A smoked sablefish processor treats the fish with Yellow No. 5 before smoking. The sablefish is an allergen and Yellow No. 5 is a food intolerance substance. The finished product labeling step should be identified as the CCP to ensure:

i. The labels declare sablefish and Yellow #5 in the ingredient panel; AND

ii. The correct label is applied to the finished product.

The control approach is referred to in this chapter as: Control Strategy Example 1 – Finished Product Label Examinations.

b. If you receive pre-printed labels and process products that contain identical allergenic or food intolerance substance ingredients, you may identify receipt of preprinted labels step as the CCP.

Example:

A breaded fish processor makes breaded fish fillets and breaded fish fingers using breading and batter that contains the allergens of wheat, eggs, soy, and pollock. The processor may identify receiving of the preprinted packaging materials as their CCP and monitor the packaging ingredients statements for declaration to control the hazards of undeclared allergens (pollock, wheat, eggs, soy).

The control approach is referred to in this chapter as: Control Strategy Example 2 – Receiving Controls for Pre-printed Labels

2. In the case of shrimp, lobster, or conch meat for which sulfiting agents have been identified as a significant hazard, how will you prevent the presence of sulfiting agents?

The receiving step of raw material for the shrimp, lobster, or conch meat should be identified as a CCP when the finished product label does not declare the presence of sulfiting agents. The incoming lots of raw materials should be assessed for the presence of sulfiting agents. Preventive measures that can be applied here include:

a. Testing incoming shrimp, lobster, or conch meat 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 3 - Raw Material Testing.

b. Receiving a supplier's certification identifying whether or not sulfiting agents were used on incoming lots of shrimp, lobster, or conch meat (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 would not need to have a CCP for this hazard at finished product labeling since sulfiting agents are not utilized.

This approach is the control strategy referred to as: Control Strategy Example 4 - Review of Supplier Declarations or Labeling.

DEVELOP A CONTROL STRATEGY

The following guidance provides four (4) control strategies to prevent 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 label examinations	✓	✓
Receiving controls for pre-printed labels	✓	✓
Raw material testing	✓	
Review of supplier declarations or labeling	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 – FINISHED PRODUCT LABEL EXAMINATIONS**

NOTE: Assuring the accuracy of finished product labels may be accomplished through: a single CCP whereby monitoring both the ingredient declaration and application of the label to the appropriate product are conducted in one CCP, usually at the labeling step; **OR** two separate CCPs whereby the label ingredient declarations are monitored at another processing step such as receiving (e.g., Control Strategy Example 2) and the label application to the finished product is monitored at the labeling step. This is an example of implementing a single CCP at the finished product labeling step.

All label declarations must meet FALPCA requirements.

Set Critical Limits.

- All allergen and food intolerance substance ingredients are declared on the labels.

Establish Monitoring Procedures.

➢ What Will Be Monitored?

- The ingredients listing on finished product labels.

➢ How Will Monitoring Be Done?

- Visual comparison of the label against the product specification for accuracy;

  OR

- Visual comparison of the label against a list of allergenic ingredients and/or food intolerance substances incorporated in the finished product.

➢ How Often Will Monitoring Be Done (Frequency)?

- At the start of the production lot;

  AND

- At least every 2 hours.

  OR

- When new containers of labels are opened or rolls of labels are changed.

➢ Who Will Do the Monitoring?

- Any person with an understanding of the nature of the controls such as trained production employees or quality control personnel.

Establish Corrective Action Procedures.

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

- Hold and isolate labeled product since the last acceptable inspection of labels;

AND

- Inspect 100% of affected product and relabel mislabeled products;

AND

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

- Inspect remaining labels staged for use and remove inaccurate labels from processing area;

AND

- Review a representative sample of labels in storage, and hold and isolate inaccurate labels, if appropriate;

AND

- Discontinue use of label supplier;

OR

- Work with label supplier to ensure corrections are made to prevent recurrence;

AND

- 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;

AND

- Verify the product specification against raw materials ingredients' label declarations at least annually and when changes to suppliers or formulation occur;

OR

- Verify the list of allergenic or food intolerance substance ingredients against raw materials ingredients' label declarations at least annually and when changes to suppliers or formulation occur, if appropriate.

TABLE 19-2

Control Strategy Example 1 – FINISHED PRODUCT LABEL EXAMINATIONS

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1." This example illustrates how a smoked fish processor can control undeclared major food allergens and food intolerance substances in the production of hot smoked sablefish. It is provided for illustrative purposes only.

Major food allergens and food intolerance causing substances 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.

Example Only - See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	**Significant Hazard(s)**	**Critical Limit**	**What**	**How**	**Frequency**	**Who**	**Corrective Actions(s)**	**Records**	**Verification**
Finished product labeling	Undeclared major food allergens and food intolerance substances	Finished product labels must declare the presence of sablefish and Yellow No. 5	The ingredients listing on finished product labels	Visual confirmation listing sablefish and Yellow No. 5 on the label	One label at the beginning of the production of each lot and one label every hour thereafter	Quality control staff	Hold and isolate product labeled since last inspection; Inspect affected product labeling and relabel mislabeled products; Inspect remaining labels staged for use and remove inaccurate labels from processing area; Review a representative sample of labels in storage, and hold and isolate inaccurate labels; Work with label supplier to ensure corrections are made to prevent recurrence; and Modify label procedures	Record of review of finished product labels	Review monitoring and corrective action records within 1 week of preparation; Verify product specification against raw materials ingredient's label declaration at least annually and when changes to supplier or formulation occurs

- **CONTROL STRATEGY EXAMPLE 2 – RECEIVING CONTROLS FOR PRE-PRINTED LABELS**

NOTE: Assuring the accuracy of finished product labels may be accomplished through: a single CCP whereby monitoring both the ingredient declaration and application to the appropriate product are conducted in one CCP usually at the labeling step; **OR** two separate CCPs whereby the label ingredients declarations are monitored at another processing step such as receiving and the label application to the finished product (e.g., Control Strategy Example 1) is monitored at the labeling step. This is an example of implementing a single CCP at the receiving step.

All label declarations must meet FALPCA requirements.

Set Critical Limits.

- Pre-printed labels list all food allergen and food intolerance substance ingredients.

Establish Monitoring Procedures.

➢ **What Will Be Monitored?**

- The ingredients listing on pre-printed labeled packaging material.

➢ **How Will Monitoring Be Done?**

- Comparison of pre-printed labels against product specification;

OR

- Comparison of pre-printed labels against list of allergenic ingredients.

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

- A representative number of containers from each lot received.

➢ **Who Will Do the Monitoring?**

- Any person with an understanding of the nature of the controls such as trained production employees or quality control personnel.

Establish Corrective Action Procedures.

Take the following corrective action to pre-printed labels involved in a critical limit deviation:

- Refuse labels.

AND

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

- Discontinue use of supplier;

OR

- Work with supplier to ensure corrections are made to prevent recurrence.

Establish a Recordkeeping System.

- Record of reviewing of pre-printed product labels.

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.

AND

- Verify the product specification against raw materials ingredients' label declarations at least annually and when changes to suppliers or formulation occur, if appropriate;

OR

- Verify the list of allergenic or food intolerance substance ingredients against raw materials ingredients' label declarations at least annually and when changes to suppliers or formulation occur, if appropriate.

TABLE 19-3

Control Strategy Example 2 – RECEIVING CONTROLS FOR PRE-PRINTED LABELS

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2." This example illustrates how a breaded fish processor can control undeclared major food allergens in the production of raw breaded fish fillets and fingers. It is provided for illustrative purposes only.

Major food allergens and food intolerance causing substances 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) Monitoring		(6)	(7)	(8)	(9)	(10)
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**		**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving of pre-printed finished product labels	Undeclared major food allergens	Allergens (pollock, eggs, wheat, soy) accurately declared on labels	The ingredients are listed on pre-printed labels	Visual comparison of label against product specification		A representative number of pre-printed finished product label rolls from each lot received	Quality control staff	Refuse labels; and Work with supplier to ensure corrections are made to prevent recurrence	Record of review of product labels	Review monitoring and corrective action records within 1 week of preparation; Verify the product specification against raw materials ingredients' label declarations at least annually and when changes to suppliers or formulation occur.

- **CONTROL STRATEGY EXAMPLE 3 – RAW MATERIAL TESTING**

Set Critical Limits.

- Less than 10 ppm sulfiting agents detected

NOTE: < 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).

Establish Monitoring Procedures.

➢ **What Will Be Monitored?**

- The presence of sulfiting agents as an ingredient or sub-ingredient.

➢ **How Will Monitoring Be Done?**

- Screening test for sulfiting agents.

➢ **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 agent content has improved.

Establish a Recordkeeping System.

- Test results for sulfiting agents.

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 19-4

Control Strategy Example 3 – RAW MATERIAL TESTING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 3." 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 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)
			Monitoring						
Critical Control Point	Significant Hazard(s)	Critical Limits	What	How	Frequency	Who	Corrective Action(s)	Records	Verification
Shrimp receiving	Undeclared sulfiting agents	Less than 10 ppm sulfites in shrimp	Each lot of raw material shrimp for sulfiting agent residual	Malachite green test	Representative sample from multiple locations in each lot received	Quality control staff	Reject any incoming lot of shrimp that contains ≥ 10ppm of sulfiting agent; and 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; and Annually conduct proficiency testing of QC personnel conducting malachite green testing

- **CONTROL STRATEGY EXAMPLE 4 – REVIEW OF SUPPLIER DECLARATIONS OR LABELING**

Set Critical Limits.

- Supplier's certificate or declaration stating that sulfites have not been used;

  OR

- Product labels do not declare the presence of sulfiting agents.

Establish Monitoring Procedures.

➢ **What Will Be Monitored?**

- Supplier's certificate or declaration;

  OR

- Raw material labels.

➢ **How Will Monitoring Be Done?**

- Review of supplier's certificate or declaration;

  OR

- Visual examination of raw material labels for sulfite declaration.

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

- Each incoming lot.

  OR

- A representative sample of containers/ packages from each incoming lot.

➢ **Who Will Do the Monitoring?**

- Any person who understands 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 or declaration can be provided by supplier;

  OR

- Label finished product with appropriate sulfite declaration.

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' declarations;

AND

- Record of label review or review of supplier declaration.

Establish Verification Procedures.

- Collect at least one representative sample per quarter, randomly selected from each supplier, and analyze for sulfiting agents. Additionally, collect at least one representative sample from 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 Supplier Declarations or Labeling

This table is an example of a portion of a HACCP plan using "Control Strategy Example 4." 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 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, pesticides, and metal fragments).

Example Only: See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	Significant Hazard(s)	Critical Limits	What	How	Frequency	Who	Corrective Action(s)	Records	Verification
Shrimp receiving	Undeclared sulfiting agents	Declaration or certificate stating sulfites were not used on the product	Suppliers' certificate or declaration	Review of certificate or declaration	Every lot received	Receiving employee	Hold lot until certificate or declaration is received; Discontinue use of the supplier until evidence is obtained that certificates will accompany future shipments	Certificates or declarations; Receiving records documenting review of certificates or declarations	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

- **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 July 2018, 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 July 2018.

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NOTES: