

**A** LLERGEN  
**I** NFORMATION  
**M** ANUAL & AUDITOR GUIDELINES



**AIM FOR FOOD SAFETY**



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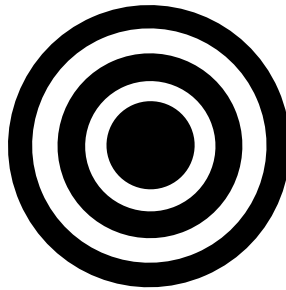
# ALLERGEN INFORMATION

## MANUAL

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# BASIC FOOD ALLERGEN INFORMATION

## INTRODUCTION

A food allergen is defined as “a product or ingredient containing certain proteins that can potentially cause severe (occasionally fatal) reactions in a food allergic person. Allergen proteins are naturally occurring and generally cannot be eliminated by cooking or baking.”

Food allergies cause immune system responses that range from discomfort to life threatening reactions. The body mistakes the protein as a harmful substance and reacts accordingly.

There are currently no medications to cure food allergies. Epinephrine, called adrenaline, is the medication that is commonly used to control the reaction in the case of an allergic response to a food protein. Avoidance of the food is the only means to prevent a reaction.

There are two common tests that are used to determine whether a person has a food allergy: a skin prick test or a RAST (radioallergosorbent test). The skin test involves placing the allergen under the skin to see whether a reaction occurs on the site, while the RAST is a blood test.

## The “Big 8”

There are eight foods containing the proteins that cause 90% of the food allergic reactions according to the Food and Drug Administration (FDA) Guidance Document for Food Investigators<sup>1</sup>. They are milk, eggs, peanuts, tree nuts, fish, shellfish, soybeans (soy or soya), and wheat. The FDA focuses on these foods because they are the primary foods that cause anaphylaxis. Approximately 90% of the remaining reactions are attributed to cottonseed, poppy seed, sunflower seed, sesame seed, legumes, sulfites (not a true food allergen), and celery root. It should be noted there are approximately 220 different food materials that have been identified as causing an allergic response, and the list will likely grow.

Of the allergens, tree nuts include walnuts (English, Persian, Black, Japanese, and California), heartnuts, butternuts, almonds, pecans, hazelnuts/filberts, pistachios, cashews, pine/pinon nuts, macadamia/bush nuts, beech nuts, chinquapin nuts, chestnuts (Chinese, American, European, and Seguin), coconuts, ginko nuts, hickory nuts, lichee nuts, pili nuts, shea nuts, and brazil nuts. Shellfish include crab, crawfish, lobster, and shrimp. Wheat includes common wheat, durum wheat, club wheat, spelt, semolina, Einkorn, emmer, kamut, and triticale. . Lecithin derived from soy would be considered an allergen.

It is important to note that in the past, molluscan shellfish such as clams, mussels or scallops were listed under the “Big 8.” The FDA has now removed these shellfish from the allergen list. In order to comply with FDA requirements on labeling, “the name of the food source from which the major allergen is derived” must be declared. FDA’s seafood list compiling the acceptable market names for imported and domestically available seafood is found at <http://www.cfsan.fda.gov/~frf/seaintro.html>.

There are some very important country and area specific issues. Canada has expanded its list of major allergens (“Big 8,” USA) to include sesame seeds and sulfites; two other examples are buckwheat in Japan and celery root in Europe.

All food allergens are proteins, but not all proteins are allergens. As yet, there is no known minimum limit to the amount of allergenic protein that must be present to elicit an allergenic response. Research is on-going to determine if threshold levels can be identified.

Highly refined oils from peanuts or soy may be consumed by most allergic individuals, and are the only oils that are exempt from labeling according to food allergen labeling regulations. Cold pressed or expelled oils may need to be tested to ensure that they do not contain allergen proteins. It appears that the refining process is what causes this difference. Salad oil is an example of a cold pressed or expelled oil.

Soybean or peanut oil that is not highly RBD (refined, bleached and deodorized) is suspect and scientific data should be provided to show protein carry-over is not an issue.

## **AUDIT OVERVIEW**

The focus of the AIBI Allergen Audit will be on the following criteria: 1) Raw Materials, 2) Chemical Sensitive Ingredients, 3) HACCP Plan/Raw Materials Review, 4) Cross-Contact and Cleaning, 5) Rework, 6) Supplier Approval, 7) Formulation and Reformulation Control, 8) Labeling, and 9) Employee Awareness (Training).

### **Raw Materials**

The focus of the AIBI Allergen Audit will be on the primary eight allergens that cause 90% of the allergenic reactions. Although not part of the “Big 8” allergens, this audit will include sesame seeds (Canada only).

A means for differentiating allergenic raw materials from non-allergenic ingredients should be developed. This can be accomplished in any manner as long as a written and effective program is followed for all raw materials, ingredients, packaging material and processing aids. A means of identifying all allergens in a single ingredient or multi-component ingredients must be provided. Color-coding of the paper used to print the specification, or a prominent statement on the specification are two common ways of identifying the material as an allergen.

Allergen-containing materials must be segregated in raw material storage areas. Labeling of ingredients, dedicated rack storage areas, storage of “like above like,” storage of allergenic ingredients on the bottom rack, or other means of separation should be provided to reduce the possibility of cross-contact in storage.

### **Chemical Sensitive Ingredients**

In the U.S., due to consumer sensitivity to sulfites, this ingredient is included as part of the allergen review. It should also be noted that U.S. labeling laws require that all FD&C colors be included in the ingredient statement. Because of this, Yellow #5 is a part of this program.

Labeling of sulfite content of 10 ppm or greater is part of 21 CFR 101.100(a)(4) and is a mandatory labeling requirement. In order to justify omitting sulfites from the label, calculations or finished product testing verifying sulfite levels of less than 10 ppm must be provided. If sulfites are not used in the plant, either as an ingredient, component of an ingredient, or a processing aid, there will be no added sulfite in the product and it will not be necessary to provide calculations as to sulfite levels or finished product testing.

In Canada, sulfites are considered an allergen and must be declared at 10 ppm or greater. At less than 10 ppm, they are not required to be labeled according to the Canadian allergen labeling guidelines.

### **HACCP Plan/Raw Materials Review**

Allergens, as well as all other raw materials, must be included as part of the Raw Materials Hazard Analysis within a facility’s HACCP Plan. If the facility does not have a HACCP Plan, then raw materials should be reviewed independently for allergen content.

Raw Materials specifications should be reviewed periodically to ensure that there have been no significant changes or reformulations. The plant should have a written review policy for all raw material and packaging material specifications. It is recommended that at least an annual review occur for those

items identified as allergens or potentially containing allergens. Specifications and their review should be dated. Each time a specification is reviewed, the process should be documented.

Single ingredients can be identified from the ingredient declaration, which can be found on the raw material specification or on the ingredient packaging. Due to the possibility that bakery mixes, seasoning and seasoning mixes, and flavors may contain allergens or chemical sensitive ingredients, these should be carefully reviewed.

Processing aids or incidental additives that may contain an allergen or chemical sensitive ingredient should be included in the HACCP Raw Materials Hazard Analysis or as part of an independent allergen raw materials analysis. Currently in Canada, processing aids are not considered part of this program. Soy lecithin must be labeled as a soy allergen if used as a release agent or other processing aid. Labeling requirements are defined in the “Guidance on the Labeling of Certain Uses of Lecithin Derived from Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act,” an guidance for industry released in April 2006. There is no exemption for labeling of soy lecithin as a soy allergen.

Packaging must also be reviewed as part of the allergen program. Some packaging materials may contain release agents that are allergen-based and can transfer to the product packaged inside. An example of an allergen-based release agent would be wheat starch that may be used to keep paperboard from sticking together during processing. The facility should ask the packaging supplier whether any allergen-based release agents, such as wheat starch, are used as part of their manufacturing process. If yes, these release agents should be included as part of the raw materials hazard analysis. If no, a letter stating that no allergen-based release agents are used in the manufacture of the food-contact packaging should be provided from the packaging supplier.

## **Cross-Contact and Cleaning**

The key to managing allergens in processing is to avoid cross-contact. If the same allergenic ingredient or raw material were used in all product formulations, then there would be no risk of cross-contact. This is typically not the case.

Policies and procedures should be in place to address the prevention of cross-contact with allergens. The policies and procedures must include appropriate documentation to support these activities. Some key items that should be considered when developing and implementing these policies and procedures include:

- Allergen changeover cleaning
- Pre-operational inspections
- Allergen changeover inspections
- Color-coding or other designation and segregation of containers and lids, scoops, tools, and sampling devices
- Providing plastic aprons, gloves, or other impermeable clothing barriers to reduce the likelihood that allergens may be transferred by clinging to clothing
- Location of allergen addition
- Dedicated lines
- Run schedules
- Barriers
- Air flow

Dry cleaning may be used where there are no wet, sticky, or gummy residues that could hold allergenic material. Dry cleaning is most effective when the product has already been cooked because it does not cling to process surfaces as easily as uncooked product. Use of compressed air should be controlled to prevent cross-contact. When flushing a system with dry materials such as salt or flour to remove allergens, documentation should be provided to demonstrate the cleaning is effective and to address disposition of the flush material.

Wet cleaning is recommended to eliminate any doughy or sticky allergen-containing residues. When using a Clean In Place (CIP) system, process equipment should be examined for evidence of pitting or rough welds that cannot be adequately cleaned and may trap allergenic residues. CIP components (strainers and spray balls) that can trap material should be carefully examined for residuals that could lead to cross-contact.

Both wet and dry cleaning must be periodically validated through the use of Enzyme Linked Immunosorbent Assay (ELISA), bioluminescence testing, or other testing methodology to provide proof that the method of cleaning is effective for the surface being cleaned. A baseline reading of a clean surface must be used for validation/verification of allergen cleaning when using the bioluminescence technique. Finished product testing may also be used as a validation technique.

The product contact surfaces should be periodically swabbed using ELISA testing, bioluminescence testing, or other verifiable testing method to assure consistent application of the cleaning procedure.

After initial validation of the cleaning procedure, visual examination of product contact surfaces may be used on a day-to-day basis to verify that allergen cleaning has occurred. This visual examination must be documented.

Based on food industry experience, the following are examples of common areas that must be carefully evaluated where allergen cross-contact can occur:

- Equipment used for grinding rework or other materials
- Pans used to bake allergen-containing products. If dedicated pans are not used, pans should be effectively cleaned between uses.
- For lines that cross over each other, a physical barrier must be provided. When barriers are used, the barriers themselves must be cleaned to prevent allergen accumulations and/or overflow. The barrier control devices must be maintained in good condition.
- Scale hoppers, bag houses, pneumatic or other conveying equipment
- Fryer oil
- Plastic trays/containers and scoops used for product transfer, temporary storage, and rework
- Dust collection equipment
- Cleaning utensils or tools (i.e. bag brushes)

## Rework

Rework is another common source of potential cross-contact. Possible sources of rework include, but are not limited to, carry-over, non-conforming product, returns, or downtime related materials. In order to meet these challenges, the plant must have written rework policies and procedures. When rework is added back into the process, it must be documented for traceability purposes.

The most acceptable means of utilizing rework, especially allergen-containing materials, is “like product into like product.” If not using this method, allergen control must be maintained through other acceptable means. If rework is not differentiated as like into like, then all allergens contained within the rework materials must also be listed on the label.

Color-coding or other viable means of identifying allergen-containing rework containers and lids must be provided to prevent cross-contact. Even if single-color containers are used for rework, they must be cleaned and properly labeled between uses. One of the accepted validation test procedures must have been completed to demonstrate that the cleaning procedure is adequate. The validation/verification frequency must meet the plant-defined protocol.

## Supplier Approval

A poor or nonexistent allergen control program at the supplier level could lead to inadvertent contamination of raw materials. Therefore, part of the supplier approval process should include a review of their allergen control program.

Documentation of supplier approval, including allergen control, should be on file and available for review. This can be done through inspection reports, questionnaires, supplier-provided documentation, or a corporate program. This information should be utilized when developing the plant allergen control program. Responsible employees should understand the interpretation of this information.

Whether completed at plant level or through a corporate approval process, an approved supplier list must be available at the facility. The approved supplier list should indicate the supplier name, contact name, telephone number, and raw materials approved for receipt from that supplier.

Protocols should be available in the event of an emergency or if a temporary supplier is required. Approval documentation for the use of a temporary or emergency supplier should be on file and understood by plant personnel. The policy for acceptance of an emergency or temporary supplier may include testing of the raw material for allergen proteins.

## Formulation and Reformulation Control

The lack of formulation or reformulation control is another source of allergen cross-contact. A protocol must be provided that delineates how formulas are developed, controlled, and changed. Items that should be addressed include, but are not limited to, the following:

- Formal development procedure
- Signatures/equivalent required for authorization prior to production
- Document control procedures (issue/revision dates, numbered formulas, allergen color coding, etc.)
- Control of infrequently used or obsolete formulas
- Control of packaging materials (including obsolete or seasonal)
- Evaluation of finished product label
- Assessment of programs/activities affected by change (HACCP, SOPs, work instructions, raw material/finished product specifications, warehouse, packaging, purchasing, sanitation, etc.)
- Notification of changes to affected departments
- Control measures related to trial product manufactured on plant equipment

Reformulation of product may affect the approved supplier list and raw material specifications. New raw material(s) must be evaluated as part of the HACCP Raw Materials Hazard Analysis or a separate allergen raw materials review. If this is a corporate program and the new raw material has been approved as a temporary or emergency supplier, documentation of this should be provided. All ingredients or raw materials used must match those specified in the formulation.

The ingredient statements on all packaging material should be verified for accuracy by the plant or at the corporate level. This is necessary to assure compliance with formulation changes that could affect the product label or ingredient statement. Obsolete packaging material should be segregated, controlled, and accounted for to prevent accidental use. Documentation of control and appropriate disposition of obsolete packaging material should provide evidence that all of the material has been identified and that it matches the inventory originally placed on hold. It is also advisable to contact the packaging material supplier to ensure that they no longer have the obsolete material in stock.

## Labeling

Failure to list any ingredient on the ingredient statement results in a misbranded product that will be subject to regulatory action (i.e. recall). Therefore, it is critical that the ingredient statement include all ingredients used in the manufacture of the product and that allergens be clearly identified.

Plants that produce products that may contain undeclared allergens may use an advisory statement to notify consumers that allergens may be present which are not contained in the ingredient statement. This statement may be in the form of “May contain...,” “Produced in a facility that...,” or “Produced on a line that...” It is not a regulatory requirement that this statement be included on packaged product. Other examples of advisory statements are “peanut-free” or “contains nuts.”

The use of this statement does not preclude the necessity for good allergen control and cleaning procedures. Many companies feel that their allergen policies and cleaning practices allow for minimal risk for cross-contact. However, if a label statement is provided and an FDA allergen inspection occurs, the FDA inspector may ask why the plant feels the need to include this statement. The facility should provide adequate proof in the form of documentation that the inclusion of such a statement is a necessary addition to the labeling statement based on their type of process.

If the facility produces any promotional or sample-size items, labeling on these packages should be reviewed to ensure that allergens are identified for the consumer.

A food labeling change (Food Allergen Labeling and Consumer Protection Act) requiring clearer labeling of food allergens to ensure that ingredients are “understandable to the average consumer,” has been passed and enacted into law in the U.S. effective January 1, 2006. This act requires that spices, flavors, colors, or any other incidental additives that contain or are derived from a major food allergen be labeled by name, and requires that major allergens be declared by common name.

## Employee Awareness (Training)

Employee knowledge and awareness of allergens is an important part of preventing cross-contact. Such allergen awareness should be communicated to employees as part of the HACCP and GMP training programs.

The level of the allergen training should be appropriate to job specific tasks of the employee. For example, personnel who slot ingredients in the warehouse should understand how the allergens are to be labeled and stored. They should be familiar with storage practices to segregate allergen-containing materials from non-allergen containing materials. Part of the skill set needed by a person who scales ingredients or raw materials may include knowledge of the ingredients containing allergens, a color-code identification system, dedicated scoops and containers, etc., that are necessary to eliminate potential cross-contact. Other employees may only need to be aware of the allergens utilized in the facility.

This training must be documented. The documentation may include, but is not limited to, training records, training materials, and testing.

Based on food industry experience, the following are examples of common challenges within the GMPs that must be carefully evaluated to minimize allergen cross-contact:

- Vending machines, cafeterias, and personal food
- Traffic patterns
- Clothing
- Job rotation practices
- Contractors, visitors, non-production personnel, and temporary employees

## Sources of Information

“ABA Allergen Usage Guidelines” obtained from [www.americanbakers.org](http://www.americanbakers.org)

<sup>1</sup>Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients, (Editorial changes only), U.S. Food and Drug Administration, Office of Regulatory Affairs, August 2001

“FDA Allergen Guidance for Investigators Issued”, Northwest Food Processors Association Food Safety Letter, 24 August 2001, 1-2

Pappas, Clifford J., Lecture, AIB, Las Vegas, NV, 11 September 2001

The Food Allergy & Anaphylaxis Network (FAAN), [www.foodallergy.org](http://www.foodallergy.org)

Title II—Food Allergen Labeling and Consumer Protection Act S.741 July 15, 2004 (signed into law August 3, 2004)

Consumer Protection and Food Labeling Act of 2004

21 CFR 101.100(a)(4)

“Guidance on the Labeling of Certain Uses of Lecithin Derived from Soy under section 403(w) of the Federal Food, Drug, and Cosmetic Act, April 2006

“Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4) Final Guidance”, October 2006

Canadian Food Inspection Agency- Food Allergens (Date Modified 6-18-2007)

# ALLERGEN AUDIT GUIDANCE DOCUMENT

## A. Overall Scoring and Rating Criteria

1. Any numbered item in the checklist with all numerical scores blacked out is for informational purposes only. If individual score levels are blacked out, that score level is not available for that item.
2. Scores should be assigned to numbered items, where appropriate, within each category. The score levels are 40 points, 20 points, or 0 points. The score for each item should be assigned utilizing the guidance provided under each item.

Some items may be Not Applicable (N/A) as determined by the auditor or the process. Any item that is N/A should be recorded as such and 40 points assigned.

3. If any of the questions receive zero points, where the relevant 0 points criteria is **bolded**, then an overall “Unsatisfactory” rating will be assigned to the category and audit. For all identified “Unsatisfactory” items, an ‘X’ should be placed in the Unsatisfactory column box for that item.
4. The overall score is determined by totaling the individual category scores. Based on the total score, the overall rating level for the audit is determined by the following:

SUPERIOR	900 - 1000 POINTS
EXCELLENT	800 - 899 POINTS
SATISFACTORY	700 - 799 POINTS
UNSATISFACTORY	<700 POINTS

**Note:** If an unsatisfactory item has been identified, the total score classification will be “Unsatisfactory” regardless of the point total.

## B. General Criteria

1. If an allergen is identified as being used in the plant and that allergen is used in all products, a formalized allergen control procedure will not be necessary for that allergen. For example, if wheat flour were used in all products, then there would be no need to do allergen cleaning at product changeovers to remove wheat flour residue as it is contained in all products. A formalized allergen control policy or procedure will be required for any allergen used in some products, but not all; and any place where there exists a potential for cross-contact.
2. If in Canada, apply the Canadian allergen audit guidelines. If in the USA, use the USA allergen audit guidelines and indicate the standard applied on the rating page of the report.

## C. Individual Item Audit and Scoring Criteria

### Raw Materials

1. List all allergens that may be used or stored in the facility. A list of allergens (US and Canada) is provided below; use the list that is appropriate for the facility. If no allergens are used in the

facility, it should be stated here. Keep in mind that allergens may be derivatives of the major allergens. For tree nuts, fish, etc., list each specific allergen.

Allergen List (US):

- Peanuts
- Tree nuts (walnuts (English, Persian, Black, Japanese, and California), heartnuts, butternuts, almonds, pecans, hazelnuts/filberts, pistachios, cashews, pine/pinon nuts, macadamia/bush nuts, beech nuts, chinquapin nuts, chestnuts (Chinese, American, European, and Seguin), coconuts, ginkgo nuts, hickory nuts, lichee nuts, pili nuts, shea nuts, and brazil nuts)
- Milk (Ex: whey, caseinate, cheese, cheese powder, butter, etc.) derived from cow's milk
- Egg (Ex: yolk, albumin) from chickens
- Fish (Labeled with species)
- Shellfish (crab, crawfish, lobster)
- Soybeans (including lecithin)
- Wheat (common wheat, durum wheat, club wheat, spelt, semolina, Einkorn, emmer, kamut, and triticale)

Allergen List (Canada):

- Peanuts
- Tree nuts (almonds, Brazil nuts, cashews, hazelnuts [filberts], macadamia nuts, pecans, pine nuts [pignolias], pistachios, walnuts)
- Milk (Ex: whey, caseinate, cheese, cheese powder, butter, etc.)
- Eggs (Ex: yolk, albumen)
- Fish, crustaceans (e.g. crab, crayfish, lobster, shrimp) and shellfish (e.g. clams, mussels, oysters, scallops)
- Soya (Ex: soy protein products and lecithin)
- Grains containing gluten (wheat, including spelt, kamut, and triticale)
- Sesame seeds
- Sulfites (10 ppm or more)

2. List the allergens currently present at this facility. If no allergens are currently present, note that here.

## **Chemical Sensitive Ingredients**

3. Indicate if FD&C Yellow #5 and/or sulfites are used in products produced at the facility (US only) in the COMMENTS section.

**Note:** If sulfites are at a level of less than 10 ppm in the finished product, they do not have to be listed on the ingredient label. Plant personnel will need to show the calculations that verify this. A note should be made in the **COMMENTS** section of the report that sulfites were used, they were below the 10 ppm level and that they were not listed on the ingredient label.

**Note:** In Canada, sulfites are captured as allergens in items #1 and #2.

## HACCP Plan/Raw Materials Review

4. Review the HACCP Plan or raw materials analysis for allergens. The Raw Materials Hazard Analysis (HACCP) or raw materials analysis should identify all allergen ingredients. Primary packaging (direct food contact packaging such as cereal box liner, as well as the box containing the liner) may contain release agents containing wheat and must be reviewed as part of the allergen audit. Documentation stating that the release agents do not contain allergen-based materials should be provided. Secondary packaging (corrugated shipping cartons) is not reviewed as part of the allergen audit.

FD&C Yellow #5 (**US only**) and sulfites should also be identified as causing chemical sensitivities.

Processing aids containing allergens, or derived from allergens, must be included in the raw materials analysis.

### **40 points**

- A HACCP Plan or raw materials analysis has been completed and all allergens and chemical sensitive ingredients appear to have been correctly identified, including packaging materials and processing aids containing allergens

### **20 points**

- A HACCP Plan or raw materials analysis has been completed and all allergens and chemical sensitive ingredients appear to have been correctly identified; packaging materials were not addressed

### **0 points**

- **A HACCP Plan or raw materials analysis to identify allergens or chemical sensitive ingredients has not been completed**
- **The analysis is not correct**

5. Select seven (7) ingredients currently being used or stored that contain an allergen or chemical sensitive ingredient. Of the seven (7), four (4) should be multi-component ingredients, if available. In the absence of multi-component ingredients, review single ingredients. Where possible, select one or two chemical sensitive ingredients. List the name of the ingredients reviewed. Verify that the items selected match the HACCP Raw Materials Hazard Analysis or raw materials analysis.

### **40 points**

- All allergens and chemical sensitive ingredients for the selected ingredients have been correctly identified

### **20 points**

- None

### **0 points**

- **One or more allergens or chemical sensitive ingredients in the selected ingredients have not been identified**

6. Verify the plant has a protocol for identifying allergens in their raw materials specification, and a frequency of review has been established. List method of identification and frequency of review.

**Note:** Allergen identification can be done with a statement on the specification, by color-coding of the paper that the specification is printed on, or by some other identifiable means.

**40 points**

- Both components of the protocol are in place.

**20 points**

- The identification component is in place; the frequency of review has not been established.

**0 points**

- There is no protocol, or only the frequency of specification review has been identified.

7. Find the raw materials specifications for the seven (7) ingredients selected in item #5. List the name of the ingredients reviewed. Verify the allergen identification and frequency of review. Are all allergens identified per the protocol? Is the review frequency consistent with the protocol? List the name of the allergenic ingredient and the date of the last review in the COMMENTS section of the report.

**40 points**

- All of the selected specifications have allergens correctly identified. The review has been completed and documented according to established frequency.

**20 points**

- All of the selected specifications have allergens correctly identified. The review frequency has not been met for one or more; however, the specification review has been completed within twice the allowed frequency (i.e. annual frequency established and review was completed within two years of the last review).

**0 points**

- There is no review process, review frequency could not be confirmed through the documentation or the review frequency was longer than twice the established frequency.
- **Any allergens not identified, or misidentified, on one or more specifications**

8. Processing aids may contain or be derived from allergen ingredients. Therefore, the plant must have technical data sheets or specifications for these materials. Review the documentation for each processing aid.

**Note:** In Canada, processing aids are not considered food ingredients and are not required to be listed on the ingredient labels. Processing aids are defined in Canada as a “substance/ingredient which is added to food for a technological effect during processing which are not present in the finished food or are present at insignificant or nonfunctional levels.” **This should be scored as N/A and assigned 40 points in Canada.**

**40 points**

- Processing aids have been properly identified and technical data sheets or specifications are available for each one

**20 points**

- None

**0 points**

- One or more technical data sheets or specifications is missing
- **Processing aids have components that are allergens or have been derived from allergens and have not been identified**

N/A

- No processing aids are used (Assign 40 points)

## Cross-Contact and Cleaning

9. List the step(s) in the process flow where allergen-containing raw materials are added that are not used in **ALL** product formulations. If the plant uses the same allergenic raw materials in all of the product formulations, then there would be no risk of cross-contact. In this case, score all items in this category as N/A and provide an explanation in the **COMMENTS** section that all allergen-containing raw materials are used in all product formulations.
10. Procedures or policies must be in place to prevent cross-contact among allergens and between allergens and non-allergens. The procedures and policies must include the key elements bolded below. Suggested components may include, but are not limited to, those listed in parenthesis for each key element. Components may or may not be applicable to the process reviewed.

- **Allergen Cleaning and Validation** – Allergen Cleaning (changeover matrix, cleaning schedule, individual equipment cleaning procedure [shared equipment], personnel responsible for cleaning); Validation (ELISA testing, bioluminescence, ATP, frequency of validation)
- **Verification** (assigned responsibility, signatures/initials, dates, ATPs, pre- and post-op visual inspections, changeover checklists), appropriate corrective action procedures (re-clean and revalidate/reverify, revised cleaning procedures, training)
- **Segregation Procedures** (color-coding, labeling, dedicated containers, lids, tools, sampling devices, scoops, utensils, including cleaning utensils, washing between use)
- **Equipment and Facility Design** – Equipment (tack welds, dead spaces, pitted surfaces, materials utilized, allergen introduction point, cleanability, initial equipment review); Facility (air flow, traffic patterns, ledges, walls or curtains, and overhead structures)
- **Operational and Maintenance Practices** – Operational (employee practices [gloves, uniforms, hand-washing, personal food], violation of operational protocols, Master Cleaning Schedule issues associated with allergens, vending machines, misuse of floor fans); Maintenance (misaligned catch cloths, damaged barrier control devices, missing filters on dust collection, violation of maintenance protocols)
- **Receiving and Storage Practices** – Receiving (means of identifying allergens by receiver, incoming load inspection for allergen cross-contact, wash tickets); Segregation and Storage (like above like, bottom layer, segregation by partition or location, color-coded or labeled racks, raw material labeling [color-coding, allergen label, bar code])

### 40 points

- Policies and procedures designed to prevent allergen cross-contact include all the key elements

### 20 points

- None

### 0 points

- Any key element is missing

11. Evaluate the documentation of the cleaning procedures and validation of those procedures. Using the last twelve months, select at least four (4), or all, production changeover records from allergen to non-allergen or allergen to a different allergen production run. Evaluate the cleaning documentation for those changeovers according to the written procedures.

Select the validation criteria from the written procedure and review the last two validations. Verify the validations were completed according to the criteria, scheduled frequency, and validated the sanitation procedures.

**40 points**

- All selected line cleaning documents were completed properly
- Type and frequency of validation stated was followed

**20 points**

- All selected line cleaning documents were completed properly; the cleaning procedure has been validated, however, the stated frequency was not followed

**0 points**

- Cleaning procedure had never been validated
- **Changeover cleaning documentation missing or incomplete**

12. Evaluate the verification records for the allergen cleaning procedures. Using the same records as selected in item #11, evaluate that the verification activities have been completed for those changeovers according to the written procedures.

Corrective actions must be documented for all deviations noted during the verification process.

**40 points**

- Verification completed for each record reviewed
- All corrective actions, if any, have been properly documented according to the procedure and the corrective action was appropriate to correct the situation

**20 points**

- None

**0 points**

- No verification program, or gaps are found in verification records
- **Gaps are found in the documentation of corrective action**

13. Evaluate compliance to the segregation procedures defined in the allergen control program.

**40 points**

- Procedures are being followed as written

**20 points**

- None

**0 points**

- **There are no procedures, inadequate procedures, or there is evidence of cross-contact**

14. Evaluate compliance to equipment/facility design criteria defined in the allergen control program.

**40 points**

- No issues observed with equipment/facility design

**20 points**

- Design issues were observed (identify in **COMMENTS**); however, there was no evidence of contamination

**0 points**

- **Design issues were observed and there is evidence of contamination**

15. Evaluate compliance to operational and maintenance practices designed to prevent cross-contact as related to the allergen control program.

**40 points**

- No issues observed with operational or maintenance practices

**20 points**

- Operational or maintenance-related issues were observed (identify in **COMMENTS**); however, there was no evidence of contamination

**0 points**

- **Operational or maintenance-related issues were observed and there is evidence of contamination**

16. Evaluate the receiving, storage, handling, and labeling of allergens in accordance with the allergen control program.

**Note:** Auditor should describe how plant personnel segregate allergen-containing ingredients.

**40 points**

- No issues observed with receiving, storage, handling, or labeling of raw materials

**20 points**

- Receiving, storage, handling, or labeling of raw materials issues were observed (identify in **COMMENTS**); however, there was no evidence of contamination

**0 points**

- **Receiving, storage, handling, or labeling of raw materials issues were observed and there is evidence of contamination**

## Rework

17. Policies and procedures must be in place to address the use of rework containing allergens. The procedures and policies must include the key elements bolded below. Suggested components may include, but are not limited to, those listed in parenthesis for each key element. Components may or may not be applicable to the process reviewed.

**Note:** For this audit, rework is defined as non-conforming product that is reintroduced into the process, or carry-over materials. Carry-over does not include materials, such as trim, that is cycled immediately back into the production process.

- **Traceability** (clean break, formula identification, use identification, source identification, quantity generated and quantity used, documentation)
- **Rework Control** (like into like, finished product labeling, segregation, color-coded or labeled containers, flush material control, point of introduction)

**40 points**

- Policies and procedures designed to prevent allergen cross-contact from rework include both key elements

**20 points**

- None

**0 points**

- A key element is missing

**N/A**

- No rework is used in product (Assign 40 points)

18. Evaluate compliance to the rework procedures defined in the allergen control program. Go to the production records and identify four (4) production runs utilizing allergen-containing rework. Verify the elements identified in the rework control policies and procedures have been followed.

**Note:** If available, one of the production records selected should have used a non-conforming product. This material is typically identified in a hold or non-conforming material log.

**40 points**

- Observation indicates compliance with both elements of the rework policies and procedures

**20 points**

- None

**0 points**

- **Cross-contamination occurred**
- **Traceability could not be verified**

## Supplier Approval

19. A Supplier Approval Program must be in place that includes questions on allergens for all suppliers, including, if used, temporary (R&D or other test market-type items) or emergency suppliers. At a minimum, this program must include the following questions on allergens:

- Are there any allergens in any raw material (including ingredients, primary packaging, and processing aids) supplied to this plant?
- Are these included in the ingredient statements?
- Are other allergens used in the supplier facility?
- Are there defined policies or procedures for preventing cross-contact for **all** allergens, including but not limited to: segregated storage, process/barrier control, allergen change-over cleaning, cleaning verification, rework, and labeling?

A risk-based allergen reassessment schedule must also be part of the Supplier Approval Program.

- **Risk-based** (based on allergens used in supplier facility, reformulations of products, product recalls for similar allergens, customer complaint data, supplier non-conformances, sensitivity of raw material [salt vs. bakery mix], etc.)

**Note:** If this is a corporate program, evidence that this is a component of the supplier approval process must be available at the facility. State in the **COMMENTS** section of the report what evidence was provided to demonstrate that the allergen program was included as part of the supplier approval process. (An example could be a letter or statement of policy from corporate.)

**40 points**

- Facility/Corporate Supplier Approval Program is available and includes all of the allergen control questions and a defined reassessment schedule as stated above

**20 points**

- Not more than one of the questions stated above is missing from the facility/corporate Supplier Approval Program
- Policies and procedures for preventing cross-contact of all allergens are included; however, the individual elements are not specifically addressed (segregated storage, process/barrier control, allergen change-over cleaning, cleaning verification, rework, and labeling)

**0 points**

- The Supplier Approval Program does not address allergen issues or is missing more than one of the questions stated above
- No reassessment schedule defined
- Temporary or emergency suppliers may be used and the allergen issue is not addressed as part of this approval procedure

20. Select a finished product that contains one or more allergens. Obtain the formula or batch sheet for this product. Compare the raw materials (ingredients, processing aids, and primary packaging) with the approved supplier allergen control documentation. Verify the allergen evaluation has been completed for each supplier per facility/corporate Supplier Approval Program.

If emergency or temporary supplier(s) are used, select one supplier and verify compliance per facility/corporate Supplier Approval Program.

**Note:** If a raw material has more than one approved supplier, verify only one supplier.

**Note:** Every raw material in the formula/batch sheet selected must be evaluated.

**40 points**

- All suppliers and raw materials selected for review are in compliance with the facility/corporate program. (All elements as defined in item #19 do not have to be met; however, every question per the facility/corporate program must be completed).

**20 points**

- None

**0 points**

- The evaluation for any raw material or supplier selected for review was missing or incomplete

21. The facility/corporate must review, evaluate, and act upon the supplier allergen control information obtained for all raw materials/suppliers. This would include, but is not limited to:

- Evaluation of the allergen questionnaire/audit findings
- Follow-up to any adverse findings
- Verification of corrective action

Any discrepancies noted must have documented corrective action. The supplier information must be current according to the facility/corporate reassessment cycle for this program.

**Note:** If the Supplier Approval Program is maintained at corporate, evidence that this question (#21) is being addressed must be available at the facility. State in the **COMMENTS** section of the report what evidence was provided to demonstrate that these actions have taken place. (An example could be a letter or statement of policy from corporate.)

**Note:** For this question, use the same raw materials and suppliers identified for review in question #20.

**40 points**

- All information is documented, current, and available

**20 points**

- The reassessment schedule has not been followed per facility/corporate criteria; however, it has been completed within twice the allowed frequency (i.e. annual frequency established and reassessment was completed within two years of the last review).

**0 points**

- Reassessment has been longer than twice the established frequency
- No documented evidence that the frequency has been met
- No reassessment schedule defined as part of the program
- Failure to address any of the deficiencies identified or failure to justify why corrective action was not taken (i.e. issue identified - milk in chocolate; justification - acceptable cleaning process will not assure removal of all milk, therefore, product is labeled as “may contain milk”)

## **Formulation and Reformulation Control**

22. Verify the facility has a development and implementation procedure for formulation and reformulation control that addresses allergen issues. This program must cover all products (including R&D, test market, etc.) produced on manufacturing equipment. It must include, but is not limited to, the following elements:

- Signatures/equivalent required for authorization prior to production
- Document control procedures (i.e. issue/revision dates, numbered formulas, allergen color coding)
- Control of infrequently used or obsolete formulas
- Control of packaging materials (including obsolete or seasonal)
- Evaluation of finished product label
- Assessment of programs/activities affected by change (HACCP, SOPs/work instructions, raw material/finished product specifications, warehouse, packaging, purchasing, sanitation)
- Notification of changes to affected departments

**40 points**

- The program is written and includes all defined elements

**20 points**

- The plant can show evidence that elements 1-4 are being followed; and elements 5-7 are in writing
- If any one of elements 1-4 is missing or no evidence is available

**0 points**

- There is no program
- The program does not include written procedures for elements 5-7
- More than one of elements 1-4 are missing or no evidence is available

23. The finished product formulation utilized in the plant must reflect the elements defined in the finished product formulation/reformulation control program.

Select four different formulas utilizing the following guidelines: one current formulation, one product that has been reformulated within the last twelve months (obtain the prior formula, if possible), a seasonal or R&D product, and an obsolete product. If one or more of these is not available, select allergen-containing formula(s) at random to complete the review.

Evaluate all selected formulas for compliance to the appropriate elements defined in the plant finished product formulation/reformulation control program.

**Note:** If less than four allergen-containing formulas are available, verify all and state in **COMMENTS** section of report.

**40 points**

- All formulas reviewed comply with all elements defined by the plant, as applicable.

**20 points**

- Isolated omissions (no more than one per formula reviewed and/or no more than two of the same element for all formulas reviewed) of a non-critical nature (involving elements #1-2 from question #22)

**0 points**

- Any of elements as defined in items #5-7 from question #22 are missing
- If there is evidence of a systemic pattern of omissions (more than two omissions per formula and/or the same element missing more than twice)
- **Evidence of violation of a critical formulation/reformulation control program procedure (old or obsolete formulas in use on the production floor, obsolete packaging material not on hold or in use)**

## Labeling

24. The plant must have an allergen and chemical sensitivity labeling program, consisting of, at a minimum, the following components:

- Verification that all allergens and chemical sensitive ingredients are on the label
- Processing aids (U.S. only), spices, etc. that are allergens or derived from allergens are included
- FD&C colors (U.S. only)
- Common name labeling for all allergens
- Appropriate use of advisory statement
- Label/package verification procedures
  - receiving (review of ingredient statement and any advisory statement)
  - label/package in-house printing (review of ingredient statement and any advisory statement)
  - material change verification (change-over, start-up, lot number changes, new roll, splice, new carton or pallet). Examples of verification methods include: UPC scanner, visual inspection of the material, or indicators (splice tape, flat stock stripe).
  - primary and secondary packaging match (where secondary packaging contains an ingredient statement or statement of ingredient)

**Note:** In Canada, processing aids are not considered food ingredients and are not required to be listed on the ingredient labels. Processing aids are defined in Canada as a “substance/ingredient which is added to food for a technological effect during processing which are not present in the finished food or are present at insignificant or nonfunctional levels.”

**40 points**

- There is a formalized written program including all applicable elements (including all applicable label/packaging verification procedures sub-elements) noted above

**20 points**

- There is a formalized written program including all applicable elements noted above with the exception of common name labeling and allergen-derived processing aids. An implementation plan is in place to address the Food Allergen Labeling and Consumer Protection amendment.
- There is a formalized written program including all applicable elements; however, some applicable label/packaging verification procedures sub-elements noted above are missing
- Label verification procedure does not include complete, documented review of ingredient statement and any advisory statement at receiving

**0 points**

- There is no formalized written program or procedure, or an applicable element is missing (except for common name labeling and processing aids), including any applicable sub-element of the label/packaging verification procedures

25. Select separate formulas containing one or more of each of the bulleted items listed below and a formula for export (Canada/U.S. – if applicable). If each bulleted item is not available, select a minimum of four different products. Verify that the formulas selected match the batch sheet and finished product packaging material (ingredient statement and label) for that specific item. State the name of all products reviewed in the **COMMENTS** section. After the first audit, different finished products should be selected.

**Note:** If the formulas selected do not contain an FD&C color (U.S. only), sulfite, or a processing aid, state this in the **COMMENTS** section of the report. If less than four products are produced containing the bulleted materials, review all formulas available and state in the **COMMENTS** section.

- Chemical sensitive agents (sulfite and FD&C colors [U.S. only])
- Processing aids (anti-foam, free flow agents, anti-caking, trough lube, etc.)
- Seasonings/flavors derived from allergens (fish flavors, soy sauce)
- Allergens (sulfite and sesame seeds [Canada only])

**Note: If the facility being inspected produces product for export (Canada/U.S.) a formula of export product must be included in this review. This review must be against the regulations of the importing country. If no export product is produced, state this in the COMMENTS section of the report.**

**Note:** In Canada, verify that allergens listed in the multicomponent ingredient are listed on the finished product ingredient legend despite labeling exemptions for multicomponent ingredient as per section B.01.009 of the Food and Drug Act and Regulations. Additionally, do not consider FD&C colors.

**40 points**

- The finished product formula, batch sheet, and ingredient statement/package label all match

**20 points**

- None

**0 points**

- Any ingredient utilized (other than the bulleted items above) is not included in the ingredient statement

- Any ingredient (other than the bulleted items) is included in the ingredient statement but is not included in the formula/batch sheet
- Package ingredient statement lists a bulleted item not in the formula
- **Bulleted items are missing from the package ingredient statement**

26. Select four current allergen-containing labels to verify use of common names (U.S. only) and advisory labeling declaration, if applicable (i.e. peanut-free, contains nuts, may contain, produced on shared equipment, manufactured in a facility that... etc.).

**Note:** If the plant produces allergen-containing products, then an advisory statement may be provided on the package. List the advisory statement(s) from the product(s) examined in the **COMMENTS** section of the report.

**Note:** If the common name of the allergen in question is present anywhere in the ingredient statement it does not have to be re-listed. Examples of common names would be Milk (i.e. for casein, whey), Eggs (i.e. albumin).

**Note:** An advisory statement **is not** a requirement. If none is used, state this in the **COMMENTS** section of the report and evaluate only the common name portion of this question.

**40 points**

- The plant can provide an explanation as to why the advisory statement is being utilized; they do not use the statement as an excuse for inadequate GMP/sanitation practices. State in the **COMMENTS** section their rationale for utilizing the advisory statement.
- Common name(s) shown on all labels reviewed (U.S. only).

**20 points**

- Common name(s) shown on some but not all labels reviewed or documented evidence of program implementation is in place.

**0 points**

- No progress demonstrated for implementation of common name labeling requirements
- **An advisory statement is used in lieu of good GMP/sanitation practices**
- **Common names are missing for any allergens listed on the label (U.S. only)**

27. Verify that packaging/label checks are implemented and documented as defined in the plant packaging/label verification program.

Select one primary packaging material receiving record and/or an in-house printed label for an allergen-containing product and verify the plant has done a documented review in accordance with the plant program requirements. Look for evidence that the ingredient statement and any advisory statement on the package material selected had been reviewed against the applicable standards.

Using the same or a different allergen-containing product, review the production requirements of the packaging/label program against the documented information. Select a current days records, one from a week ago, a month ago, and three months ago (four records total). A record would be a shift or partial shift for the material selected. Verify that plant records reviewed indicate that the correct packaging material was used at start-up, changeover, new roll, roll splice, new carton or pallet as required by the plant program. Where applicable, both primary and secondary package material that contain ingredient or advisory information must be checked.

**Note:** In the event that a mechanical control such as UPC scanner or other device is used, the auditor should challenge the functionality of the device and review the plant's verification records.

**40 points**

- All checks and verifications defined in the plant program are being completed and documented

**20 points**

- Isolated omissions (no more than one per record reviewed and/or no more than two of the same omission for all records reviewed)

**0 points**

- Plant has no documented verification activities
- If there is evidence of a systemic pattern of omissions (more than two omissions per record and/or the same omission more than twice)
- Plant not following written procedures
- **Observed use of wrong packaging material**

## **Employee Awareness (Training)**

28. A documented allergen-awareness training program must be in place. It must include, but is not limited to:

- Scope
  - personnel (company employees, visitors, contractors, and temporary/seasonal employees)
  - job specific (slotting, scaling, sanitation, maintenance, etc.)
  - operational practices (traffic patterns, job rotation practices, personal food, clothing/gloves, cafeteria/vending machines, etc.)
- Training Program
  - communication methods
  - resources (trainers)
  - training materials
  - documentation (attendance records and make-up training, testing or certification of competency)
  - frequency (initial and annual refresher, annual training plan)

**40 points**

- A documented allergen awareness training program is in place and includes all elements

**20 points**

- All elements are included in the allergen awareness training program, but some are not clearly defined or incomplete
- Refresher training has been defined; however, training frequency exceeds twelve months

**0 points**

- There is no documented allergen awareness training program
- Any element omitted from the allergen awareness training program

29. Verify that the plant allergen-awareness training program has been implemented and the results are documented.

Select five individuals: one line employee with allergen responsibility, one sanitation employee, one new employee (less than three months), one maintenance employee, and an allergen auditor.

Look at the allergen awareness training documentation for each individual selected to verify that the training complies with the plant program. In the **COMMENTS** section, state the date of training for each of the individuals selected. If possible and with the permission of plant management, interview the employees and assess their level of allergen awareness. Did the

training appear to be appropriate to the job requirements of each employee and fulfill the allergen awareness training program criteria? If you cannot interview an employee, the record review and plant observations during the audit will replace the interview as evidence.

Evaluate the management of the allergen-awareness training program by reviewing the components of the plant's program.

**Note:** Indicate in the **COMMENTS** section of the report any allergen issue observations previously noted that appeared to be a result of ineffective training.

**40 points**

- All selected individuals have received the required training according to plant procedures and frequency
- Evidence of testing, interviews, or observations indicates allergen awareness is appropriate for the job
- Management activities, including documentation, were completed in accordance with the plant defined procedures

**20 points**

- The training of any employee exceeds the defined frequency, but is not in excess of twice the defined training frequency
- There is a general understanding of allergens; but not complete for job responsibility
- Isolated omissions in training records

**0 points**

- The training of the employees selected is in excess of twice the defined training frequency
- The training is not appropriate to the job; lack of awareness
- Systematic failures in execution and documentation of training activities
- Training materials and/or resources are not available or inadequate

# Rating Analysis

**Date of Audit:**

**Type of Audit:**

**Overall Rating:**

HACCP Plan/Raw Materials Review .....	—
Cross-Contact & Cleaning .....	—
Rework.....	—
Supplier Approval.....	—
Formulation and Reformulation Control.....	—
Labeling .....	—
Employee Awareness (Training) .....	—
<b>Total:</b>	—

# AIB ALLERGEN FOOD SAFETY CHECKLIST

created 1/02  
revised 0

40 = No discrepancies

20 = Program Omissions

0 = Program Failure

N/A = Not applicable

<b>RAW MATERIALS</b>	<b>40</b>	<b>20</b>	<b>0</b>	<b>N/A</b>	<b>UNSAT</b>	<b>Comments</b>
1. List the names of all allergens that may be used or stored in the facility. Use the list of allergens for the US and Canada provided in the Allergen Audit Guidance Document. If in the US, use the US list. In Canada, use the Canadian list. State the allergens in the <b>COMMENTS</b> section of this report. If no allergens are used, state this in the <b>COMMENTS</b> section of the report. <b>(FOR INFORMATION ONLY - NOT SCORED)</b>						
2. List the allergens currently present in the facility. If no allergens are currently present, state that in the <b>COMMENTS</b> section of the report. <b>(INFORMATION ONLY - NOT SCORED).</b>						

<b>CHEMICAL SENSITIVE INGREDIENTS</b>	<b>40</b>	<b>20</b>	<b>0</b>	<b>N/A</b>	<b>UNSAT</b>	<b>Comments</b>
3. State if sulfites and/or FD&C Yellow #5 are used. List the food colorings and/or sulfites used in the product selected. <b>(INFORMATION ONLY - NOT SCORED)</b>  <b>NOTE:</b> Sulfites at levels of less than 10 ppm do not have to be listed on the ingredient label.						

<b>HACCP PLAN/RAW MATERIALS REVIEW</b>	<b>40</b>	<b>20</b>	<b>0</b>	<b>N/A</b>	<b>UNSAT</b>	<b>Comments</b>
4. Food allergens and chemical sensitive ingredients are addressed as part of the HACCP plan <b>OR</b> as a separate ingredient analysis, including primary packaging and processing aids, as applicable.						
5. Allergens/Chemical Sensitive Ingredients are properly identified in the HACCP Plan/Raw Materials Hazard Analysis for 7 selected ingredients. If less than 7 ingredients containing allergens/chemical sensitive ingredients are used, note this in the <b>COMMENTS</b> section. List the 7 ingredients reviewed in the <b>COMMENTS</b> section.						
6. A protocol is defined for identifying allergens in raw materials specifications and a frequency of review has been established. State the method of identification and the frequency of review						

in the **COMMENTS** section.

7. Raw Materials specifications/ identification is provided for the 7 ingredients selected in item #5 and the frequency of review was completed as defined in the program. State the name of the ingredient and date of review in the <b>COMMENTS</b> section of this report.						
8. Processing aids have technical data sheets or specifications that identify allergen content. <b>(US Only)</b> State in the <b>COMMENTS</b> section of the report if processing aids are used and how the information was provided.						
<b>POINTS EARNED:</b>						<b>TOTAL SCORE: (200 POSSIBLE)</b>

<b>CROSS-CONTACT AND CLEANING</b>	<b>40</b>	<b>20</b>	<b>0</b>	<b>N/A</b>	<b>UNSAT</b>	<b>Comments</b>
9. State the step(s) in the process flow where allergens are added that are not used in <b>ALL</b> product formulations. (For example, at the mixer, by a depositor at the oven in-feed, etc.) <b>(INFORMATION ONLY-NOT SCORED)</b>						
10. Policies/procedures are in place to prevent cross contact among allergens and between allergens and non-allergens. The policies/procedures encompass the 6 key bolded elements for this section. Please state in the <b>COMMENTS</b> section those elements that were addressed in addition to any elements that were not included.						
11. Allergen cleaning must be verified. Provide a statement in the <b>COMMENTS</b> section of the findings for the 4 selected allergen changeover records as stated in the guidelines. Also provide a statement in the <b>COMMENTS</b> section for the last 2 validations and if they were completed according to the defined procedure.						
12. Evaluate the verification records for the allergen cleaning procedures. Provide a statement in the <b>COMMENTS</b> section of the report that verification activities, using the same records selected for item #11, were or were not completed in accordance with the written procedure.						
13. Evaluate if the facility is complying with the segregation procedures as identified in the allergen control program. Provide a statement in the <b>COMMENTS</b> section if procedures are or are not being followed.						

14. Evaluate if the facility is in compliance to their defined equipment/facility design criteria as identified in the allergen control program. Provide a statement of findings in the <b>COMMENTS</b> section of this report to indicate compliance to the program criteria.						
15. Evaluate compliance with operational and maintenance practices designed to prevent allergen cross contact. Provide a statement of findings in the <b>COMMENTS</b> section of this report to indicate compliance to the program criteria.						
16. Evaluate compliance with the receiving, handling and storage criteria defined in the allergen control program. Provide a statement of findings in the <b>COMMENTS</b> section of this report to indicate compliance to the program criteria.						
<b>POINTS EARNED:</b>						<b>TOTAL SCORE: (280 POSSIBLE)</b>

<b>REWORK</b>	<b>40</b>	<b>20</b>	<b>0</b>	<b>N/A</b>	<b>UNSAT</b>	<b>Comments</b>
17. Policies and procedures are in place to address the use of rework. Both key elements that are bolded in the guideline have been addressed. Provide a statement in the <b>COMMENTS</b> section of the report stating that a program is or is not in place and contains the 2 key elements as defined in the guideline.						
18. Evaluate compliance to rework procedures defined in the allergen control program. Verify that the elements defined in the rework procedures have been followed for 4 selected production runs utilizing allergen containing rework product. Provide a statement in the <b>COMMENTS</b> section of the report to indicate compliance with the program criteria.						
<b>POINTS EARNED:</b>						<b>TOTAL SCORE: (80 POSSIBLE)</b>

<b>SUPPLIER APPROVAL</b>	<b>40</b>	<b>20</b>	<b>0</b>	<b>N/A</b>	<b>UNSAT</b>	<b>Comments</b>
19. A supplier approval program is in place for the facility and includes allergen questions for <b>ALL</b> suppliers, including R&D, test market items etc. This includes a risk-based assessment as defined in the allergen guidelines. Provide a statement in the <b>COMMENTS</b> section of the report of						

what evidence was provided to demonstrate that allergens and a risk based assessment was included as part of the supplier approval program.						
20. Verify that raw materials and primary packaging materials for one finished product are from an approved supplier. Provide a statement in the <b>COMMENTS</b> section of the report that all raw materials, including primary packaging materials, were from an approved supplier in compliance with the facility/corporate approved supplier program.						
21. Verify that facility/corporate reviews, evaluates and acts upon allergen control information provided for the raw materials and suppliers that were identified in item #20. Provide a statement in the <b>COMMENTS</b> section of the report that the facility/corporate information is documented, current and available and indicated compliance to the program.						
<b>POINTS EARNED:</b>						<b>TOTAL SCORE: (120 POSSIBLE)</b>

<b>FORMULATION AND REFORMULATION CONTROL</b>	<b>40</b>	<b>20</b>	<b>0</b>	<b>N/A</b>	<b>UNSAT</b>	<b>Comments</b>
22. Verify that the facility has a development and implementation procedure for formulation and reformulation that addresses allergen issues. The program must cover ALL products, including R&D, test market; etc products produced on manufacturing equipment and encompasses the criteria as defined in the allergen guideline. Provide a statement in the <b>COMMENTS</b> section of the report that indicates that the program is in place and if all defined elements are included in the procedure.						
23. Raw materials specification changes are part of a written procedure. New specifications are dated, and old copies of the specifications are accounted for.						
<b>POINTS EARNED:</b>						<b>TOTAL SCORE: (80 POSSIBLE)</b>

<b>LABELING</b>	<b>40</b>	<b>20</b>	<b>0</b>	<b>N/A</b>	<b>UNSAT</b>	<b>Comments</b>
24. The facility has an allergen and chemical sensitivity labeling program that addresses the elements and sub elements, as applicable, defined in the allergen guidelines. Provide a statement in the <b>COMMENTS</b> section of the report that a program was or was not in place and if it addressed the applicable elements as stated in the guidelines.						
25. For 4 selected products (if possible) verify that the formulas for those products match the batch sheets and the finished product packaging material for the 4 selected items. If less than 4 products produced contain the materials identified in the allergen guideline, state this in the <b>COMMENTS</b> section. In the <b>COMMENTS</b> section of the report, provide a statement that includes the names of the products reviewed and if the batch sheets, formulas, and finished product packaging materials matched for the 4 products selected.						
26. Verify the use of common names and allergen advisory statements, if applicable, for 4 selected allergen-containing products. If no advisory statement is provided state this in the <b>COMMENTS</b> section. Provide a statement in the <b>COMMENTS</b> section indicating how common names are stated on ingredient label, and how advisory statements, if used, are provided on the product. The statement should also include if the facility is in compliance with the requirements as stated in the allergen guidelines.						
27. Verify that packaging/label checks for at least one primary packaging material are implemented and documented as defined in the plant packaging/label verification program. Provide a statement in the <b>COMMENTS</b> section of the report of what reviews or evidence was provided to demonstrate compliance to this program.						
<b>POINTS EARNED:</b>						<b>TOTAL SCORE: (160 POSSIBLE)</b>

<b>EMPLOYEE AWARENESS (TRAINING)</b>	<b>40</b>	<b>20</b>	<b>0</b>	<b>N/A</b>	<b>UNSAT</b>	<b>Comments</b>
28. The facility has a documented allergen-awareness training program that includes all of the elements defined for scope and training program as defined in the allergen guideline. State in the <b>COMMENTS</b> section of the report what was included in the facility procedure defining the scope and training programs for the facility.						
29. Verify that the plant allergen-awareness training program has been implemented and results have been documented for 5 individuals. Provide a statement in the <b>COMMENTS</b> section of the evidence provided to indicate compliance or non-compliance with the plant-established program.						
<b>POINTS EARNED:</b>						<b>TOTAL SCORE: (80 POSSIBLE)</b>