

# Guidance Document for AIB Allergen Food Safety Checklist

## INSTRUCTIONS FOR USING THE GUIDANCE DOCUMENT

1. Any area where the box for entering the numerical score is blacked out requires information or, if scored, the score level blacked out for that item is not available.
2. Scores should be assigned to each category. Any item that is N/A should be recorded as such and 40 points should be assigned for that item. The score for each item should be assigned utilizing the guidance provided under each score level. The score levels are 40 points, 20 points, or 0 points.
3. An “Unsatisfactory” rating should be assigned for any item scored as zero points in a shaded box.
4. Scoring levels are as follows:

SUPERIOR	900-1000 POINTS
EXCELLENT	800-899 POINTS
SATISFACTORY	700-799 POINTS
UNSATISFACTORY	<700 POINTS
5. If an allergen is identified as being used in the plant and the allergen is used in all products, then 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, where a there exists a potential for contamination.

## CHECKLIST ITEMS

### INGREDIENTS

1. List any of the eight allergens that are used in the facility. In Canada only, sesame seeds and sulfites (< 10 ppm) are considered to be a major allergen and should be included. Tree nuts would include walnuts, hazelnuts/filberts, pistachios, cashews, pine nuts, macadamia nuts, and Brazil nuts. If no allergens are used in the facility, then it should be stated here. Also keep in mind that albumen is an egg product and whey or caseinate are milk products. Shellfish includes crab, crawfish, lobster, fish, clams, mussels and oysters. Wheat includes barley, oats, rye and spelt.
2. List the allergens used in products produced at this facility. If no allergens are used in products, then note that here.

### CHEMICAL SENSITIVITIES

3. Provide a list of the FD&C food colors used in products produced at the facility. If sulfites are used, this should be listed in the COMMENTS section. **Please note: If sulfites are added at a level of less than 10 ppm, then they do not have to be listed on the ingredient label.** Plant personnel will need to show you the calculations that verify this and a statement should be made in the COMMENTS section of the report that sulfites were used at/below the 10 ppm level and that they were not listed on the ingredient label.

### HACCP PLAN/INGREDIENT REVIEW

4. Review the HACCP plan or ingredient review for allergens. The ingredient hazard analysis/ingredient review should identify allergenic ingredients. Packaging must also be reviewed as part of the allergen program. Some packaging materials contain release agents that could have wheat in them. Some verification stating that release agents did not contain wheat should be provided. Yellow #5 and sulfites should also be identified as causing chemical sensitivities.

#### **40 points**

- Allergens and chemical sensitivities have been identified in the HACCP plan/ingredient review

#### **20 points**

- None

#### **0 points**

- An allergenic ingredient is used and has not been identified

- FD&C yellow #5 or sulfites are used but are not identified as causing chemical sensitivities

5. Allergens can be components of bakery mixes or spice mixes that can be used and supplied as ingredients. The component ingredients for any such mixes should be reviewed, in addition to the review of single ingredients as part of the ingredient hazard analysis. The hazard analysis for one multi-component ingredient that contains an allergen should be reviewed. In the absence of a multi-component ingredient, verify the review of a single ingredient. List the name of the product/ingredient reviewed in the report.

**40 points**

- Allergens for a product have been correctly identified

**20 points**

- One non-allergenic ingredient for a product was missed in the hazard analysis

**0 points**

- Allergen in a product has not been identified
- More than one non-allergenic ingredient has been missed in the hazard analysis

6. A statement or some means of identification of the material as being or containing an allergen should be provided in the ingredient specification. This 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**

- The program is in place

**20 points**

- Ingredient is identified as an allergen in the HACCP plan/ingredient review, but not identified as part of the ingredient specification program or by other means as an allergen

**0 points**

- There is no program or means of identifying allergenic ingredients on the ingredient specification or an allergen specification is missing

7. List the frequency of review of the ingredient specifications and state the last date of review. Compare one of the allergen-containing ingredient specifications to an ingredient used in a product produced at the facility. Provide a comment as to the date of the specification and if the specification for the ingredient is appropriate for the material reviewed. List the name of the allergenic ingredient reviewed in the COMMENTS section of the report.

**40 points**

- The review process is in place
- The specification is correct for the ingredient reviewed

**20 points**

- The specification sheet is out of date or has been missed as part of the review process

**0 points**

- The specification sheet does not match the ingredient reviewed

8. If processing aids or incidental additives are used that contain allergenic ingredients, the product must be identified as being allergenic or containing FD&C yellow #5 or sulfiting agents that cause chemical sensitivities.

**40 points**

- Processing aid or incidental additives have been properly identified

**20 points**

- Non-allergenic processing aids or incidental additives are used, but have not been included as part of the hazard analysis

**0 points**

- Processing aids or additives have components that are allergenic and have not been identified as being allergenic
- Processing aids or additives contain sulfites or FD&C yellow #5 that cause chemical sensitivities and have not been identified

N/A

- No processing aids or incidental additives are used (Assign 40 points)
- Ingredient specifications are maintained at corporate and not available for review (Assign 40 points)

## **CROSS-CONTAMINATION AND CLEANING**

9. List where in the process flow the ingredient is added. If it is added in the mixer, then list it there. This is for informational purposes. If the plant uses the same allergenic ingredients in all of the product formulations, then there would be no risk of cross-contamination. In this case, score these items as N/A and provide an explanation in the COMMENTS section that all allergen-containing ingredients are used in all product formulations.

10. Provide a statement of what procedures or policies are in place to prevent cross-contamination between allergen-containing and non-allergen-containing ingredients. Are there segregated areas for scaling? Are separate color-coded containers provided? Is clothing addressed as part of this program? Are cloth belts or other materials that could trap or retain allergenic materials considered as part of the program or procedure?

**40 points**

- Policies and procedures are in place and appear to be followed

**20 points**

- Policies and procedures are in place, but there are gaps in the program with no evidence of observed contamination

**0 points**

- No polices are in place or program is not followed.
- Evidence of cross-contamination of allergen-containing ingredients and non-allergen-containing ingredients

11. Documentation of testing or of visual examinations should be provided. List the method used for verification and how it is documented. Where a CIP system is used for cleaning, the piping should be inspected to ensure that no pitting or rough welds are noted that could provide an area for accumulation of material. Wet cleaning with swab verification would be advised to eliminate doughy or sticky material that could trap allergen-containing residue. Dry cleaning may be effective where there is no grease or sticky residual that may hold onto the allergen-containing material. If dry cleaning is used, it must be periodically verified as being effective through a swab test. Weekly or monthly testing would be the suggested schedule.

**40 points**

- Line cleaning is verified through the use of a protein (ELISA) test, bioluminescence testing, or other test method

**20 points**

- Line cleaning is verified using only visual inspection

**0 points**

- No verification of cleaning after allergen use

N/A

- Allergenic ingredients are used in all product formulations

12. A policy for monitoring of allergens and allergenic products must be provided. This may be in the form of allergen inspections, preoperational inspections, or other defined means of line or product verification. Documentation should include that the correct packaging material is verified prior to start-up and at packaging changes. Corrective actions must be documented for all deviations noted during the monitoring or inspection process.

**40 points**

- The program is in place and appears to be followed

**20 points**

- None

**0 points**

- No monitoring program
- Gaps in the documentation of corrective action

N/A

- The same allergenic ingredients are used in all product formulations

13. Comment on how the segregation of bins is accomplished and whether separate scoops are provided for ingredients

**40 points**

- Separate scoops and labeled bins are provided

**20 points**

- None

**0 points**

- There are no separate bins or scoops for ingredients
- There is a single scoop for scaling of allergen and non-allergenic ingredients
- Bins are mislabeled
- Cross-contamination of bins of ingredients is observed where allergenic ingredients are scaled

14. Make a statement that either separate pans are used for allergen and non-allergen-containing ingredients or there is a pan-washing program between uses. If pans are not cleaned between products, then there must be proof, through bioluminescence, ELISA, or other test method and visual examination, that no allergen-containing residues remain on the pans. Examine several of the pans and observe practices during operations to ascertain whether the program is being followed.

**40 points**

- Separate pans are used for products
- Pan washing is performed between products
- Visual examination and swab testing indicate that no allergen residues are left on the pans without benefit of washing between usage.

**20 points**

- None

**0 points**

- There is no pan segregation program
- There is no cleaning program
- Product residue is observed to be left on pans where cross-contamination could occur

**N/A**

- All of the allergen-containing ingredients are used in all products

15. Physical barriers must be provided where lines cross over other lines. If allergen-containing materials cross over non-allergen-containing materials, segregation and cleaning of the barrier devices to prevent overflow must be done. Processing lines may also be dedicated to allergenic products to provide segregation. Walls may be used for segregation. Pay close attention to shared equipment, such as grinders for rework, that could be shared between allergen-containing and non-allergen-containing equipment. Line-sampling devices should be dedicated or color-coded to prevent cross-contamination. If line-sampling devices are not

dedicated to a process line or if they are not color-coded, then they must be cleaned between every use. Line-sampling devices should be stored separately.

**40 points**

- The program is well defined and appears to be followed

**20 points**

- Catch cloths or catch pans are full, but not overflowing

**0 points**

- There are no effective barriers provided between allergenic and non-allergenic products or ingredients
- Catch cloths or catch pans are overflowing
- There is no separation of material through dedication of processing lines, barriers, line scheduling, cleaning, or segregation of line sampling devices
- Line-sampling devices are not cleaned or color-coded
- Line-sampling devices for an allergenic product is used on a non-allergen containing line or product
- Grinders or other shared equipment is not cleaned between allergen and non-allergen-containing equipment
- Catch pans or catch cloths are in poor repair, with no contamination being observed (example: holes in the catch cloth)

**N/A**

- All of the allergen-containing ingredients are used in all of the products made at the facility

16. Segregation in storage and labeling should be provided for allergenic ingredients. Labeled racking, labeling on ingredients, storage of like product above like product, allergenic ingredients being stored on the bottom of the rack or other means of separation should be provided. Provide a comment about how plant personnel segregate allergen-containing ingredients.

**40 points**

- The program is well defined and followed

**20 points**

- There are gaps in the allergen labeling and segregation program, but no evidence of spillage or cross-contamination is observed

**0 points**

- Spillage or cross-contamination of an allergenic ingredient on an unlike ingredient is observed
- There is no program, or the program is not followed

**REWORK**

17. Policies and procedures must be in place that addresses the use of allergen rework. Like into like would be the only acceptable way of utilizing allergen-containing rework. Look at a batch sheet to see how rework is recorded and note

that in the COMMENTS section of the report. This should be verified by reviewing a batch sheet for product produced where rework is added back as an ingredient. Review a batch sheet and observe practices for a non-allergen-containing product and verify that no rework containing allergens was used in this product.

**40 points**

- Polices and procedures are in place and appear to be followed

**20 points**

- None

**0 points**

- There are no polices or procedures in place for addition and tracking of allergen-containing rework
- Allergen-containing rework is not kept in the correctly identified or color-coded container
- Allergen-containing rework is not recorded on the batch sheet for traceability
- Allergen-containing rework is added to the wrong product

N/A

- No rework is used in product (40 points should be assigned)

18. Are separate color-coded containers being used? If not, are containers washed between use and swabbed or inspected for residue? Provide a statement of what they do.

**40 points**

- A method of separation of allergen and non-allergen-containing material is in place and is followed

**20 points**

- None

**0 points**

- No separation of allergen and non-allergen-containing material
- There are no swabbing records for ingredient containers or scoops

## **SUPPLIER APPROVAL**

19. This information may not be available at the plant level. If this is a corporate program, state that in the report and indicate that the program could not be reviewed. Do ask for an approved supplier list or comment on what program is in place to ensure that only approved suppliers are used at the facility. Do they visit suppliers, or is the approval in a questionnaire format?

**40 points**

- Supplier approval program or list of approved suppliers is in place

**20 points**

- The approved supplier list is not current

**0 points**

- There is no approval program or approved supplier list

20. This information may not be available at the plant level. If this is a corporate program, state this in the report. If an emergency or temporary ingredient supplier is approved, then documentation that this ingredient is approved by corporate must be provided to the plant. The plant should be able to show you the protocol for accepting use of a temporary or emergency supplier even if there are no temporary or emergency suppliers being used during the audit. Does the policy include testing of the ingredient? Do they verify by questionnaire or by visiting the supplier? If a temporary or emergency supplier is being used, verify that temporary approval documentation has been provided. If no emergency or temporary approvals are in use during the audit, then review the plant protocol.

**40 points**

- A plant protocol for approval of a temporary or emergency supplier is in place
- An example of a temporary approval or emergency supplier approval is examined and is verified

**20 points**

- There is no approval on file for a non-allergenic emergency or temporary ingredient being used at the facility (example: salt, baking soda)

**0 points**

- There is no emergency or temporary approval process
- A temporary or emergency ingredient is in use where the ingredient could be allergenic or manufactured in a facility where allergens could be a concern (example: bakery mixes)
- An unapproved material is used that could be an allergen

21. Take one product and compare the ingredient list for the product to the approved supplier list. Ingredients used in the products must be from an approved supplier. If a temporary supplier is used, then documentation of this approval must be provided for the facility to receive full points

**40 points**

- Ingredients used in the product examined are approved

**20 points**

- A non-allergen-containing ingredient is used that does not have temporary or emergency approval and either is not on the approved list or approval documentation is not provided

**0 points**

- No supplier approval process
- A potentially allergenic or allergenic ingredient is used and is not approved

## REFORMULATION

22. If this is a corporate program, then state this in the COMMENTS section. Give a statement as to how the plant deals with reformulation. Are signatures required for formulation? Are formulations controlled? Are formulation sheets numbered and provided with a revision date so that all old sheets can be collected and accounted for? If this changes finished product specifications, are they revoked and replaced? If this is a corporate program, then the plant must follow the corporate protocol. Look at a finished product specification for one product and compare it to the batch sheet for that product to determine whether the program is in place and complied with. List the name of the product reviewed.

**40 points**

- The program is in place and appears to be followed

**20 points**

- None

**0 points**

- There is no program
- The program is not followed

23. If this is a corporate program, then state this in the COMMENTS section. Do state whether the plant follows their own program or if they are following the corporate program as provided to them. Check the ingredient specifications for one product. Match this to product being produced to ensure that the ingredient specifications match the ingredients used in this product.

**40 points**

- Ingredients used in the product reviewed match the specification sheets

**20 points**

- The incorrect specification is used for a non-allergenic ingredient

**0 points**

- The specification for an allergenic ingredient is incorrect
- Specifications are not followed

24. State the plant's policy regarding obsolete packaging material. State how the plant segregates and controls obsolete packaging materials. How do they document destruction of obsolete packaging material?

**40 points**

- A policy and documentation of the disposition obsolete packaging material is provided

**20 points**

- None

**0 points**

- There is no accounting for or disposition records for destruction of obsolete packaging material
- There is no policy for destruction of obsolete packaging material

**EMPLOYEE AWARENESS**

25. State how allergen awareness is communicated to plant employees and supervisors. Training should be conducted on an annual basis. Anyone involved in the handling of allergens should receive training specific to the level of allergen handling in which the employee is involved based on the employee's job requirements.

**40 points**

- A documented training program is in place

**20 points**

- There is a program, but training has not occurred in 12 months

**0 points**

- There is no documented training program

26. Look at the training program for one person who works on a production line. State the last date of training and the level to which the employee was trained. Did the training appear to be appropriate to the job skill level of the employee? If possible, interview the employee and assess the level of allergen awareness of this person. This should be done with the permission of facility management.

**40 points**

- The training program is current for one employee reviewed
- Evidence of testing or an employee interview demonstrates that awareness

**20 points**

- The training of the employee selected is in excess of 12 months

**0 points**

- There is no training program
- The person selected has not received allergen training and is responsible for handling of allergenic materials
- The training is not appropriate to the job

**LABELING**

27. Match the formula and the batch sheet for one product produced at the facility. State the name of the product that was reviewed. In the case that this product contains multi-component ingredients or many multi-component ingredients the entire label will not be verified. In the case of a simple product, then the entire label should be verified. After verification that the formula sheet matches the

batch sheet for one product, take the most complex multi-component ingredient and verify that all ingredients listed in the multi-component ingredient are listed on the finished product ingredient legend. After the first audit, a different multi-component ingredient should be selected if there is more than one used in a product formulation. State the name of the finished product reviewed and the name of the multi-component ingredient verified in the COMMENTS section. The allergens listed in the product formulation should also be verified as being listed on the finished product ingredient legend.

**40 points**

- The batch sheet matches the ingredient legend for the multi-component ingredient selected and the allergens listed in the formulation

**20 points**

- Non-allergen-containing ingredients are missing from the ingredient legend

**0 points**

- FD&C yellow #5 or sulfites are missing from the ingredient legend
- Allergenic ingredients are missing from the ingredient label

28. If the plant runs allergenic products, then a statement may be provided on the ingredient legend. Provide a copy of the allergen statement from the product examined in item #28. Restate the name of this product.

**40 points**

- A statement is provided
- No statement is provided, however, there is changeover cleaning of the line and the line cleaning is verified per plant policy

**20 points**

- No statement is provided on the label. There are gaps in line cleaning or verification as part of the cleaning program between allergen containing and non-allergen containing product runs with no evidence of contamination

**0 points**

- There is no statement on the label and allergens are run on the line. There is no verification of cleaning at change-over from an allergen-containing product to a non-allergen-containing product
- There are gaps in line cleaning verification, and evidence of contamination is observed

**N/A**

- If the product is run on a dedicated line or there is some other reason that this statement would not be needed, provide the reason in the comments section and assign 40 points

29. List the names of the two products that are produced at this facility that were examined for this section. State that the sulfite or the FD&C food colors were listed on the ingredient legend for this product.

**40 points**

- Labels and formulation or batch sheets match
- Sulfites were used as part of an ingredient or as a processing aid with verification that the levels were below 10 ppm

**20 points**

- None

**0 points**

- Sulfiting agent or FD&C yellow #5 was listed as being used on the formula or batch sheet, but was not included on the ingredient label
- Sulfiting agent calculations were incorrect or did not verify that they were used as less than 10 ppm