

Food Allergen Information Sheet

A food allergen is defined as “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 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) is used to determine if a person is allergic to a food. The skin test involves placing the allergen under the skin to see whether a reaction occurs on the site, and the RAST test 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 “FDA Guidance Document for Food Investigators”. The FDA focused on these foods because they are the primary foods that cause anaphylaxis. They are milk, eggs, peanuts, tree nuts, fish, shellfish, soy, and wheat. All food allergens are proteins, but not all proteins are allergens. As yet, there is no known limit to the amount of allergenic protein that must be present to elicit an allergic response. The remaining reactions are attributed to cottonseed, poppy seed, sunflower seed, sesame seed, legumes, sulfites, and celery. There are approximately 170 different food materials that have been identified as causing an allergic response and the list will probably grow. Canada has expanded its list of major allergens (Big 8, USA) to include sesame seeds and sulfites. There are some very important country and area specific issues. Buckwheat in Japan and Celery Root in Europe are two examples.

The focus of the AIBI allergen survey will be on the primary 8 allergens that cause 90% of the allergic reactions, FD&C yellow #5, and sulfites. In Canada, this will include sesame seeds. Although not allergens, the chemical sensitive agents of FD&C yellow #5 and sulfites are included as part of the allergen survey.

Of the allergens, tree nuts would include walnuts, almonds, pecans, hazelnuts/filberts, pistachios, cashews, pine nuts, macadamia nuts and Brazil nuts. Shellfish includes crab, crawfish, lobster, shrimp, mussels, and oysters. Wheat will include Barley, Rye, Oats and Spelt either as the grain or flour or in other form.

Solvent extracted oils from peanuts and soy may be consumed by most allergic individuals. 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.

Chemical sensitivities to sulfites and FD&C yellow #5 are generally as part of the allergen review. Sulfites added at a level of less than 10-ppm do not have to be included on the ingredient label. In order to justify omitting sulfites from the label, calculations verifying sulfite levels of less than 10-ppm must be provided or finished product testing for sulfite levels must be provided as proof that sulfite levels in finished product are less than 10 ppm. If there are no sulfites listed in the ingredient legend and sulfites are not used in the plant as a processing aid, then there will be no sulfite in the product and it will not be necessary to provide calculations as to sulfite levels or finished product testing. Labeling of sulfite content of 10-ppm or greater is part of the CFR and is a mandatory labeling requirement.

HACCP Plan/Ingredient Review

Allergens should be included as part of the ingredient hazard analysis within a facility's HACCP plan. If the facility does not have a HACCP plan then ingredients should be reviewed independently for allergen content. Packaging must also be reviewed as part of the allergen program. Some packaging materials contain release agents that are wheat-based and can transfer to the product packaged inside. An example of a wheat-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 wheat-based release agents, such as wheat starch, are used as part of their manufacturing process. If so, this should be included as part of the ingredient or hazard analysis. If not, a letter stating that no wheat-based release agents are used in the manufacture of the food-contact packaging should be provided. The components of bakery mixes, spice mixes, and natural flavors should be reviewed, as they could contain an allergen, or food sensitivity items such as FD&C yellow #5, or sulfites. Single ingredients can be identified from the ingredient declaration, which can be found on the ingredient specification or on the ingredient packaging.

A means for differentiating allergenic ingredients from non-allergenic ingredients should be developed. The ingredient specification or other means of identifying a single ingredient or component ingredients of a mix as allergens should be provided on the ingredient specification. This can be accomplished in any manner as long as the program is followed. 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. Ingredient specifications should be reviewed periodically to ensure that there have been no significant changes or reformulation. The frequency of review should be established. It is recommended that annual review of ingredient specifications occur for those items identified as allergens or potentially containing allergens as part of the hazard analysis. Specifications should be dated and a policy defining how often that the specification is reviewed should be provided. Each time that an ingredient specification is reviewed, the process should be documented and recorded.

Processing aids or incidental additives that may contain an allergen, sulfites, or FD&C yellow #5 should be included in the ingredient hazard analysis or as part of an allergen ingredient analysis independent of the ingredient hazard analysis for HACCP.

Cross-Contamination and Cleaning

The key to managing allergens in processing is to avoid cross-contamination. For informational purposes, list the area in the process flow where each allergen is added. If the same allergenic ingredient were used in all product formulations, then there would be no risk of cross-contamination. This is generally not the case.

Policies and procedures should be in place to address the prevention and elimination of cross-contamination of allergen-containing ingredients with the non-allergen containing ingredients or products. These policies should include, but are not limited to:

- allergen change-over inspections;
- pre-operational inspections;
- color-coding or other designation and segregation of containers;
- scoops and sampling devices; by dedication, segregation or other means
- providing plastic aprons, gloves or other clothing barriers to reduce the likelihood that allergens may be transferred by clinging to clothing.

Dedication of lines, run schedules, and barriers should be considered to protect product. Equipment used for grinding of rework material should also be evaluated as part of the cleaning verification program, as this is a likely point for cross-contamination.

Visual examination of product contact surfaces must be documented after allergen cleaning has occurred. The product contact surface should be periodically swabbed using bioluminescence testing, Enzyme Linked Immunosorbent Assay (ELISA) testing, or other verifiable testing method to determine whether the cleaning procedure is adequate. Wet cleaning is advised to eliminate any doughy or sticky allergen-containing residues. Dry cleaning may be used where there are no wet, sticky, or gummy residues that could hold on to allergenic residue. Both wet and dry cleaning must be verified through the use of ELISA, bioluminescence testing, or other testing method to provide verification that this method of cleaning is effective for the surface being cleaned. A baseline reading of a clean surface must be used for verification of allergen cleaning using a bioluminescence technique. Dry cleaning is most effective where the product has already been cooked because allergens do not cling to cooked product as easily as they would to precooked product. Clean In Place (CIP) systems used for cleaning should be examined for evidence of pitting or rough welds that cannot be adequately cleaned or may trap allergenic residues.

Separate pans should be used to bake allergen-containing products or pans should be washed between uses. Pans should be examined to determine whether they are being used properly and that effective cleaning is taking place to eliminate allergen-containing residues. If pans are dry cleaned, then visual inspection and periodic verification through ELISA, bioluminescence testing, or other verifiable testing methods must take place per

plant protocol to verify adequate cleaning of the product contact surface. The frequency of testing should be established as part of the allergen policy.

Physical barriers must be provided where lines cross over other lines. 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.

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 protect ingredients in storage.

Rework

The only acceptable means of utilizing allergen-containing rework is like product into like product. Rework, when added back into the process, should be recorded on the batch sheet for traceability. Color-coding or other viable means of separation of allergen-containing rework must be provided to prevent product from potential cross-contamination. If single-color containers are used for rework, they must be properly labeled, cleaned, and swabbed between uses to verify adequate segregation and cleaning of the product contact surface. The swabbing frequency must meet the plant-defined protocol.

Supplier Approval

Part of the supplier approval process for both ingredients and packaging material should include review of the supplier's allergen program. A poor or non-existent program at the supplier level could lead to inadvertent contamination of ingredients used. Protocols should also be provided for use of an emergency or temporary supplier. Approval documentation for the use of a temporary or emergency suppliers should be on file and understood by plant personnel. If no temporary or emergency suppliers are used, then the protocol for acceptance of suppliers should be made available. If the plant approves suppliers, then the protocol for approval of the supplier should be listed and documentation of supplier approval through inspection reports or at the very least questionnaires should be on file and available for review. If this is done outside of the plant, through a corporate approval process, then an approved supplier list should be provided at the facility and verification that ingredient suppliers used are from the approved supplier list should be completed. The approved supplier list should indicate the supplier name, contact name, telephone number, and ingredients approved for receipt from that supplier. The policy for acceptance of an emergency or temporary supplier should include testing of the ingredient for allergen proteins.

Reformulation

If reformulation is a corporate program, then a statement should be provided as part of the allergen policy. A policy must be provided that delineates how formulas are

controlled and the protocol for changing of formulas. Questions that should be asked include, but are not limited to the following:

- Are signatures required for formulation changes?
- Are revision dates provided to indicate the most recent formula revision?
- How do they revoke old formulas and account for them so that an old formula is not accidentally used?

The protocol for the finished product specification should also include any changes in the packaging material and ingredient labeling.

Reformulation of product may also affect the supplier ingredient specifications for the product being used. Again, if this is a corporate program and the new ingredient has been approved either as a temporary or emergency supplier, then documentation of this should be provided. It is also acceptable if ingredient supplier is on the approved supplier list.. The new ingredients must be evaluated as part of the hazard analysis or a separate allergen ingredient review and would also need to be identified as being allergen-containing. Ingredients used must match the ingredients specified in the formulation.

The ingredient legends on new packaging material should be verified for accuracy, by the plant or at the corporate level, and compliance with the formulation changes that have occurred that could affect the product label or ingredient statement determined. As packaging material becomes obsolete as a result of formula changes, then the obsolete packaging material should be segregated, controlled, and accounted for to prevent accidental use. Documentation of control or destruction of obsolete packaging material should provide evidence that all of the material has been identified and that it matches the inventory levels of the material.

Allergen Awareness

Allergen awareness should be communicated to employees either as part of the HACCP training program and in conjunction with GMP training program. Allergen training, that will meet the criteria, may also be included as part of job specific task of the employee and will be documented. For a person who slots ingredients in the warehouse, should understand how the allergens are to be labeled and stored. He or she should be familiar with storage practices to segregate allergen-containing materials to eliminate the risk of cross-contamination through spillage. Part of the skill set needed by a person who scales ingredients should include which of the ingredients contain allergens, what the allergens are, what the color-code identification system is, that scoops must be specific to the container, and that they will need to wear gloves or other barriers to eliminate potential cross-contamination between allergen and non-allergen-containing ingredients. Training records, training materials, testing, and employee interviews should be used to determine if appropriate training has occurred.

Labeling

It is very important that the ingredient legend include all ingredients used in the manufacture of the product and that allergens be clearly listed as part of the ingredient legend. For example, there are many substances that contain milk. A good strategy for labeling of substances that contain milk but may not be easily recognized as containing milk would be: calcium caseinate with a statement, such as milk product, milk protein, or milk derivative in parenthesis. This will identify the ingredient as containing milk protein. It is not required that they put the allergenic substance in parenthesis, but it is a way to clarify that this is a material that would contain the allergen protein listed.

The ingredients used to produce a selected product should be compared to the actual ingredient legend. The ingredients and the ingredient legend must match. Some finished product formulations, such as bakery mixes, contain multi-component ingredients. When products contain sulfite levels of less than 10-ppm, sulfites do not have to be included as part of the ingredient legend. Allergenic ingredients must be included as part of the label and sulfites added at levels above 10-ppm and FD&C yellow #5, if used, must also be included. Multi-component ingredients must be broken out in the ingredient legend. Natural colors and flavors should also be addressed and any allergen-containing materials used in the color or flavor listed. Natural colors and flavors may be listed on the ingredient legend as a natural color or flavor with no ingredient breakdown.

Plants that produce products that contain allergens or use the same line to produce allergen-containing ingredients and non-allergen-containing ingredients will sometimes put a statement on the package, to the effect of “May contain...”, “Produced in a facility that...”, or “Produced on a line that...” as a warning to their consumers that the facility also produces other products that contain allergens that may not be included on the ingredient legend. It is not required that this statement be included on their packaged product. Many companies feel that their allergen policies and cleaning practices allow for minimal risk for cross-contamination. There is no regulatory requirement that this be included on the package. If a label statement is provided and a FDA allergen inspection occurs, the FDA inspector may ask why the plant feels the need to include this statement. If allergen-containing products are run on a line and change-over cleaning and inspection at product change-over occurs in a well executed program then a “May contain...” statement would not be required. The use of this statement does not preclude the necessity for good allergen control and cleaning procedures. Dedicated processing lines or facilities would also negate the need for this kind of labeling. If the facility produces any promotional items or sample-size items, labeling on the packages should be considered to ensure that allergens are identified for the consumer.

Sources of Information

ABA Allergen usage guide obtained from www.americanbakers.org

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

“Guide to Inspections of Firms Producing Foods Susceptible to Contamination with Allergenic Ingredients”, U.S. Food and Drug Administration, Office of Regulatory Affairs, August 2001

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