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GUIDANCE FOR ALLERGEN PROGRAMS

This document is designed to assist facilities that manufacture or handle food products in understanding the proper ways to handle allergens and allergenic materials, and why these materials are of such concern.

What are allergens and why are they a concern?

Allergens are naturally-occurring proteins in numerous types of foods that can cause an adverse reaction in the immune system of people who possess sensitivity to these proteins. The body treats these ingested proteins as foreign and reacts to them in an effort to eliminate them by releasing a class of chemicals called histamines. Occasionally the reactions are severe (choking, swelling tongue, flushed skin, and other visible symptoms). In some instances, these reactions can cause death.

US federal law and worldwide food safety standards have given food manufacturers the responsibility of declaring the presence of certain allergen-possessing foods on their labels. This was done to make consumers more aware of the potential of adverse reactions from food consumed, as well as reducing liability on the part of manufacturers. Because of these declarations, it has become mandatory that the allergen profile as declared on the immediate packaging of the food item is not compromised at any fashion during any point from its raw materials to its final delivery to the consumer.

A number of years ago, Codex Alimentarius and the International HACCP Alliance stated that all food safety plans based on Hazard Analysis Critical Control Point (HACCP) procedures were required to take allergens into account as a potential food safety hazard when creating a HACCP program. Since a HACCP program is now required in all facilities that manufacture or handle food products due to the provisions of the Food Safety Modernization Act of 2011, allergen programs are required in all facilities that handle allergenic materials.

Labeling of immediate packages for allergenic materials were mandated in the US by the Food Allergen Labeling and Consumer Protection Act of 2004, and became a requirement as of January 1st, 2006.

What exactly are considered allergens by law?

There are eight classes of materials that are considered allergens by US federal law, and must be declared on the immediate packaging of any finished product in a separate statement below the ingredients statement. Three others are considered allergens by Canadian federal law and must be declared in the same manner on all products sold in Canada.

The eight types of materials considered allergens by US law are responsible for the vast majority of anaphylactic reactions among US consumers.

Wheat: Certain wheat proteins, commonly known as gluten, triggering anaphylaxis have become a significant concern. This condition is called celiac disease, and has become a common condition with a great deal of media exposure. Gluten is contained in most species of wheat, semolina and durum flour (the two most common types of flour used in pasta), and spelt. Buckwheat is not considered a wheat product in the US and Canada, but it is in other jurisdictions.

Soy: Soy, soybeans, and soy lecithin are considered soy allergens. Soy oil is not an allergen if it is refined, bleached, and deodorized.

Milk/Dairy: Lactose intolerance is a very common condition, and the prevalence of dairy products and materials derived from dairy products makes this a particular material of concern. Milk proteins are not normally de-characterized by processing. Cheese, whey, and other materials derived from dairy products fall under this category.

Egg: This includes materials and products that may only contain egg yolk, egg white, or refined albumen.

Fish: This includes all products derived from finned piscine's. The immediate packaging must declare species of fish according to US regulations.

Shellfish: This includes material such as crabs, shrimp, lobster, and other crustaceans. This category no longer includes mollusks such as clams and scallops.

Tree Nuts: This includes coconuts, almonds, pecans, cashews, macadamia nuts, chestnuts, pistachios, and hazelnuts. FDA has provided this table of materials covered under the FD&C Act as tree nuts:

Common or usual name	Scientific name
Almond	*Prunus dulcis* (Rosaceae)
Beech nut	*Fagus* spp. (Fagaceae)
Brazil nut	*Bertholletia excelsa* (Lecythidaceae)
Butternut	*Juglans cinerea* (Juglandaceae)
Cashew	*Anacardium occidentale*

	(Anacardiaceae)
Chestnut (Chinese, American, European, Seguin)	*Castanea* spp. (Fagaceae)
Chinquapin	*Castanea pumila* (Fagaceae)
Coconut	*Cocos nucifera* L. (Arecaceae (alt. Palmae)
Filbert/hazelnut	*Corylus* spp. (Betulaceae)
Ginko nut	*Ginkgo biloba* L. (Ginkgoaceae)
Hickory nut	*Carya* spp. (Juglandaceae)
Lichee nut	*Litchi chinensis* Sonn. Sapindaceae
Macadamia nut/Bush nut	*Macadamia* spp. (Proteaceae)
Pecan	*Carya illinoensis* (Juglandaceae)
Pine nut/Pinon nut	*Pinus* spp. (Pineaceae)
Pistachio	*Pistacia vera* L. (Anacardiaceae)
Sheanut	*Vitellaria paradoxa* C.F. Gaertn. (Sapotaceae)
Walnut (English, Persian, Black, Japanese, California), Heart nut	*Juglans* spp. (Juglandaceae),

Ground Nuts: This category includes peanuts, one of the most common sources of allergenic reactions. Peanut oil is not an allergen if it is refined, bleached, and deodorized.

In Canada, the following items are legally-defined allergens:

Sulfites: Sulfites at more than 10 parts per million must be declared as an allergen in Canada and as a sensitivity agent in the US.

Sesame: Sesame seeds, sesame derivatives, and sesame oil that are not refined, bleached, and deodorized must be declared as allergens in Canada.

FD&C Yellow #5: This coloring has been shown to trigger anaphylaxis in some people, and Canadian law requires labeling.

There are other materials in other jurisdictions that must be declared on labeling. In Japan, for instance, buckwheat must be declared as an allergen (the EU has been debating the possibility of doing the same). In the EU, celery root is considered an allergen. If a facility is exporting to a particular jurisdiction, it must research the labeling regulations appropriate to that jurisdiction in order to determine if product labeling procedures are compliant with local regulations.

What pre-requisite or food safety programs have to address allergen issues?

Due to the fact that allergenic materials are present in raw materials and in finished product, a number of pre-requisite programs are affected by allergens. Which programs need to account for allergenic materials?

Approved Supplier Program: The facility's Approved Supplier Program needs to include questions regarding allergen profiles of raw materials provided to the facility by the supplier. In order to create a proper allergen profile of raw materials received by the facility, the following should be asked of suppliers:

Are there any allergens in any raw material supplied to this plant?
Are these included in the ingredient statements of the supplied materials?
Are other allergens used in the supplier facility?
Are there defined policies or procedures for preventing cross-adulteration for all allergens at the supplier, including but not limited to segregated storage, process/barrier control, and allergen change-over cleaning, cleaning verification, rework, and labeling?

The supplier must, to the satisfaction of the facility, establish that the risk of cross-adulteration is minimal.

Receiving Program: The receiving program governing the receipt of raw materials must take allergens into account, in terms of handling and inspection of incoming materials.

HACCP Program: According to a revision a number of years ago of the requirements of HACCP as promulgated by Codex Alimentarius, allergens must be considered as part of the Hazard Analysis. This is especially important in the requirement for a Hazard Analysis performed on raw materials received by the facility. If the Approved Supplier Program and Receiving Program properly account for allergens, they can and should be used as measured used to reduce or eliminate hazards in the Hazard Analysis and obviate the need for a Critical Control Point at Receiving for allergenic materials.

Standard Sanitation Operating Procedures: Special provisions must be made for allergen cleaning. This will be discussed in the requirements for an Allergen Program.

Rework Program: Products with different allergen profiles cannot be reworked unless provisions are taken regarding the labeling of the finished product. Allergens need to specifically be accounted for in a rework program and in rework documentation. The principle of "like going into like" that governs rework should especially be kept when it comes to materials with allergens.

Training Program: All employees must be trained in allergen handling, allergen cleaning procedures, and what allergens are. This training should also be done on an annual basis. Documentation regarding training and the training materials used must be available to the auditor.

Labeling Program: Federal regulations govern exactly how a finished product must be labeled in terms of their allergens. If the facility has a documented labeling program, it must explicitly state how allergens are labeled on finished goods.

What needs to be part of an Allergen Program?

An allergen program must be able to provide a basis for controlling the potential for cross-adulteration of products or raw materials. The possibility of allergenic proteins adulterating products or materials that do not possess allergenic proteins or possess a different profile of allergenic proteins that are not labeled on the immediate package must be minimized.

Sometimes, the minimum does not allow absolute insurance that no cross-adulteration will take place, especially with certain types of allergens that pose greater threat to the public. This is why some products have declarations on their packaging such as "Manufactured in a facility that also handles peanuts". Peanut allergens are common and dangerous enough to individuals that a declaration allows for the possibility that accidental adulteration might have taken place. This, however, is an action of last resort. A facility must have a systematic program that reduces the possibility of these instances in the first place.

Even if a facility does not handle allergens, they still need a statement to that effect on file.

What does an Allergen Program have to contain?

A written Standard Operating Procedure (SOP) for the handling and control of allergenic raw materials and finished products

Procedures and methods for handling and control of allergens must be documented and systematized. Full descriptions of how methods are performed must be included as part of this SOP. There are specific points in the process where these methods must be highly detailed; those points will be discussed below.

A list of the major allergens of concern, depending on the jurisdiction and where products are shipped
If in the United States with products only shipped inside the US, the eight allergens listed above must be mentioned in the program. If the facility is in Canada or deals with products shipped to Canada for local resale, the three additional allergens must be mentioned in the program.

Records of the presence of allergenic materials in the facility, plus methods of packaging of allergenic materials
The facility must maintain records of the receipt of material with allergens. These records need to include the type of packaging that allergenic material is received in. Air-tight, moisture-barrier packaging tends to pose far less of a risk of cross-adulteration than packaging that allows air and moisture transfer. An example of the latter is peanuts packaged in burlap sacks.

A method of segregated storage for raw materials containing allergens, with designated storage sites, if possible, for materials in permeable containers
The best method of controlling potential cross-adulteration of allergens is by physically segregating allergen-containing materials from non-allergen-containing materials, and by physically segregating allergen-containing materials from other allergen-containing materials with different allergen profiles. The exact method of segregation is required to be documented in the Allergen Program.

With segregated storage, there should be some sort of key to where and what is stored in segregated storage areas. A map of the storage areas with designations about what can be stored in those areas is an ideal way to do this. However, if a segregated storage space is used for a non-allergenic material (on an emergency basis) or is used for a material with a different allergen profile, there needs to be a designated cleaning method to ensure that all allergenic proteins are eliminated before the emergency storage is commenced.

Provisions that all allergenic raw materials are either stored in original containers or in air-tight, moisture-barrier labeled containers
Removing allergen-containing raw materials from the original containers and placing them into other containers poses a significant risk of cross-adulteration. This should not be done as a normal part of operations. A program should state that allergen-containing raw materials should be kept in original containers. If not stored in original containers, they must be stored in containers that will help prevent cross-adulteration.

Provision that signage be used for allergen-containing storage areas
There must be some sort of commonly-understood method of determining which areas are allergen storage areas, as well as which allergen or allergens is allowed to be stored in a particular area. This can be done through worded signage, color coding, or another

effective method. The method for designation must be part of the Allergen Program, and this must be included as part of the mandatory employee training.

Provision that allergens and non-allergens, or different types of allergens, must not be stored on the same pallet

This may not be done even under emergency conditions. There is simply no way to achieve segregation if materials with different allergen profiles are stored on the same pallet. An explicit mention of this prohibition must be in the Allergen Program.

Written procedures on how to effectively clean storage areas, storage equipment, and pallets when an accidental release of allergens occurs

Should there be an accidental release or spill of an allergen-containing product, the Allergen Program needs to have a method of cleaning specifically designated. This is to include methods and chemicals used, along with a verification method that shows that cleaning operations were effective.

The cleaning procedures need to be effective in removing allergenic materials, and they also need to be effective in preventing potential cross-adulteration that might take place during cleaning. The cleaning methods must be of a nature that will not spread allergenic materials beyond the area of the spill/release.

Written procedures for preventing cross-adulteration during the manufacture of product

All finished products are required to be labeled with their allergen profile. It is the expectation of consumers that only these allergens are or may be present in that finished product and that people with allergies or sensitivities to other food-borne allergens will not be adversely affected by consuming that product. Therefore, it is incumbent upon the manufacturer that no other allergenic materials have a significant chance of affecting that product.

The most effective way to ensure this is through scheduling. If a facility is producing finished goods with allergens and without allergens, the material without allergens should be produced first. If there is an increase in allergen profile between products (for example, one product has wheat and soy allergens and the other wheat, soy, and milk allergens), the material with the lesser number of allergens should be manufactured first.

If there is a difficulty with scheduling, or scheduling cannot be implemented due to various requirements, there must be programs in place to assure that production equipment cannot cross-adulterate product. If allergenic product is produced prior to non-allergenic product or product with a different allergen profile that does not include the allergen(s) of the first product, there must be a thorough clean-up of all equipment between the two products. There also must be a way to verify (say, through inspection) that equipment has been

cleaned prior to the start of making the second product. Again, methods of cleaning and chemicals used must be stated in the program, as well as methods of verification.

Written procedures for validating those sanitation operations are effective in removing allergens

Visual inspection cannot provide complete insurance that equipment has been cleaned thoroughly. There must be a method to periodically insure that sanitation is being performed correctly. This method must be of an objective form rather than subjective like inspection.

There are various types of swabs available that are designed to detect either specific allergenic proteins or proteins in general. The program should state the frequency of swabbing, how many swabs are taken, the general location of where swabs are taken, and the level of tolerance (which should be zero). The Neogen Corporation has a number of available products to assist in validation. If no in-house analysis can be performed, swabs must be taken to a professional laboratory.

The use of swabs designed to detect for adenosine triphosphate (ATP; these units are sold under the name Charm, Lightning, etc.) is not acceptable to validate allergen removal. They are acceptable as validation for general sanitation operations, but they are not designed to detect allergenic proteins.

The method of validation, no matter what is used, must be appropriate for the types of allergens the facility has, must be objective, and must be sufficient to show that testing can demonstrate that removal of allergens in sanitation operations is effective and complete.

Summary

Allergen programs are an area of concern, not just for completing an audit, but for ensuring the financial well-being of a company. An adverse reaction to a product can have a devastating effect on a business. Cross-adulteration of allergens can take place at any point between the initial receipt of raw materials and final shipment to a retail environment, including warehouse storage. With the passage of the Food Safety Modernization Act, it is now a legal requirement for any facility that manufactures or handles food, or creates materials that may contact food, either intentionally or incidentally, to assess the risks that allergens pose to their operations and have a program in place to mitigate those risks.