MARYLAND
Department of Health

Developing an Allergen Control Plan

The new Food Safety Modernization Act (FSMA) stipulates that undeclared food allergens will be considered adulterants. This legal change, among others, is one of the key reasons that food companies need to start preparing for the coming FSMA changes and begin increasing attention to allergen control. This document has been created to help new firms comply with this part of the FSMA.

The Preventive Controls provisions of the FDA Part 117 proposal require a hazard analysis of known or reasonably foreseeable hazards to human food, including food allergens. The manufacturers, processors, packers and holders of human food that must comply with Part 117 are then required to comply with the other preventive controls provisions for the identified food hazards, including food allergens. Setting up and implementing an Allergen Control Plan in your food processing plant is a way to avoid inadvertent allergen cross-contamination and thus avoid potentially damaging recalls and any adverse physiological reactions in the consumer.

An Allergen Control Plan is a systematic method for identifying and controlling allergens, from the incoming ingredients to the final packaged product in any food processing plant. This guide will outline some of the fundamental steps in developing an effective Allergen Control Plan in the food plant.

Controlling the "Big 8" allergens: soy, wheat, eggs, milk, peanuts, tree nuts, fish, and shellfish

As an ancillary program to the manufacturing plant's Hazard Analysis and Critical Control Points (HACCP) Plan, the first step in developing an Allergen Control Plan, is the assessment of allergens as part of your firm's initial Hazard Analysis for each product that will be manufactured in the plant. An allergen within a food product is considered a chemical hazard. Once an allergen is identified by your operation as a raw ingredient or contained within a raw ingredient, control steps must be established to address it within your firm.

An Allergen Control Plan should address the following considerations for a food manufacturing facility:

Supplier Review/Monitoring

Food manufacturers should obtain copies of product or ingredient formulations, specification sheets or certificates of analysis (COA's) from suppliers of raw ingredients. When reviewing specifications, you should look for formulations that list ingredients without the sub-listings. For example: marshmallows may contain eggs, or soy sauce may contain wheat. You should verify that your suppliers have their own Allergen Control Plan.

Plant traffic flow
Review product flow through the production process that will occur operationally in the plant. For example, look for overhead conveyors that cross one another or cross over exposed products. If working from a shared site look to see who had previously used the space before your own processing.

Raw material storage and color-coding systems
Store all allergenic foods or ingredients derived from these foods in an area that is secluded or removed from non-allergenic materials. If this is not possible, require that incoming material pallets are shrink wrapped to contain dust and to prevent other cross-contamination opportunities such as leakage from torn bags.

Allergen identification is also a useful tool for your firm. All raw materials that are allergens should be labeled with a tag that states "ALLERGEN." This can also help avoid substitution mistakes (i.e., wheat flour for soy flour). A color-coded tag may also be an option. It is a good idea to place color-coding charts throughout the plant's production area for easy identification by plant personnel. Store allergenic compounds on the bottom of racks or nearest to the floor to avoid spilling of allergenic ingredients to items below.

Dedicated scoops, utensils and bins used for specific ingredients also assist in keeping allergens segregated.

Production scheduling and cleaning
There are two main methods used to control allergens in the plant. The first method involves producing all allergen-containing as the last product on a production line. If all products manufactured contain the same allergen, a label declaration is enough to contain the allergen. However, if only one product produced contains an allergen, run that last product last. If one product does not contain an allergen, but the rest of the products do, run this product first after a complete wet cleaning procedure or perform a wet cleaning procedure between the allergen-containing product run and non-allergen-containing product run.

Example: A bakery will use wheat as one of its main ingredients. If wheat is included as an ingredient in every item manufactured and is declared on every label, it is not very likely that wheat is an allergen concern for this bakery. However, other products made in the bakery may contain walnuts or soy flour. Any breads or bakery products containing walnuts or soy flour must be produced last to avoid cross contamination.

The second method used for controlling allergen cross-contamination is to implement a wet cleaning procedure prior to or following the run of allergen-containing product on a particular line.

When opting for the wet cleaning method, first assess the food items that are processed on shared equipment. An example is peanut butter cookies, pecan cookies and oatmeal walnut cookies. All of these would probably be mixed in the same mixer and baked on the same sheets. Each product contains a different allergen, necessitating the implementation of scheduling or cleaning procedures. It is important to note that each tree nut is a distinct and individual allergen. Do not schedule all tree-nut containing products together without a wet cleaning procedure in between.

Rework
When using reworked products, always add "like into like." Reworked products should always be labeled with tags that indicate which products contain allergens. The reworked products containing allergenic ingredients must be stored in areas separate from those products that do not contain allergens. Utensils should be color-coded for use with allergen-containing products. If at all possible, rework product back into the same production run.

Evaluation of program effectiveness
Changes in raw materials, suppliers and customer demands result in the need for continuous reevaluation of the effectiveness of the Allergen Control Plan. Incorporating routine auditing practices, both for your suppliers and your own in-plant operations, is a key component in verifying that the plan is working correctly.

Label review policies
Develop a system for maintaining labels that are placed on foods containing allergens in easy to identify areas. Discard old label, as they can cause an error in the future. Conduct a thorough review of the current recipes and match them with the labels used. A good idea to manage your firm's Allergen Control Plan would be to have a binder that lists raw material specification, formulations and the finished product label. When a raw material ingredient statement changes, you would then be able to cross-reference with the finished product labels and understand what products and labels would be affected by the change.

Frequency of Allergen Plan review
Allergen Plans should be reviewed during an annual HACCP validation. Items should include specific allergen policies (scheduling, utensil usage, cleaning, raw ingredient segregation and color coding for example) that are in effect in the plant.

Documentation and reviewing the documentation
The documents created should state what you are going to do within your own plant environment. Essentially say what you are going to do, do what you say and prove it with documentation. If it is not documented, it is not considered done. For example, production schedule and sanitation check-off sheets must be filled out and reviewed by a manager (signed and dated) to complete the records for the allergen policies.

Employee education
Allergen education may be easily incorporated into good manufacturing training periods. As always, you should document the employees that attended as well as the materials conveyed, the date of the training and the trainer for your firm's records.