

Components of an Effective Allergen Control Plan

A FRAMEWORK FOR FOOD PROCESSORS

An Allergen Control Plan protects consumers — and your company.

When a food safety issue due to mishandling of allergenic ingredients occurs, everyone in the food processing industry suffers. Consumers depend on food companies to provide safe products. Consumers who must be mindful of the foods they eat because of potential allergic reactions are especially dependent on the industry's ability to identify, process, and market foods which are labeled correctly.

Food-allergic consumers must avoid the foods that trigger their allergic reactions. Thus, they rely heavily upon the ingredient statements of packaged food products to identify the products which contain their allergen(s). Labeling of foods for the presence of allergenic foods must identify all foods that intentionally contain the particular food or ingredients derived from that food. However, voluntary labeling for the possible presence of the allergen (e.g. 'may contain x') should be reserved for situations that potentially represent genuine hazards.

In recent years, there has been a proliferation of the use of precautionary allergen statements, which range in wording from "May Contain" and "Processed in a Facility", to "Made on Shared Equipment". This increase has limited consumer food choices. Alarmingly, food-allergic consumers, especially teens, are beginning to ignore precautionary statements, and taking risks regarding the food they choose to eat. This can lead to trouble for both the consumer and the industry.

An Allergen Control Plan is a critical component in your product safety initiatives. You must do everything within your power to ensure allergenic foods and ingredients do not find their way into products for which they are not intended. Your Allergen Control Plan is your company's written document regarding the storage, handling, processing, packaging, and identification of allergenic foods and ingredients.

This is not a one-time effort. Your Allergen Control Plan must be implemented, audited, enforced and updated continually. Every time you make a change in a process or a product, assess your plan and update as needed. Every time you hire a new employee or change the responsibilities of an employee, make certain they understand their role in the Allergen Control Plan through documented training. Every time you begin working with a new supplier, evaluate their Allergen Control plan and change yours as needed. If you change or add locations, a new Allergen Control Plan should be developed specifically for that location.

This document is not intended to be comprehensive by any means. The intent is to provide food processing companies with a framework for an Allergen Control Plan — and an introduction to the issues and considerations which are typically included in such a plan.

Not all recommendations are applicable to all food processing companies. Still, it is important to consider each recommendation and determine the extent to which it may apply to you or your suppliers — and then create the appropriate procedures in the Allergen Control Plan that will help your plant.

An Allergen Control Plan is about protecting the health and confidence of consumers. But it is also about protecting the financial health and reputation of your company.

We hope this document is valuable to you and your team as you create the Allergen Control Plan for your company.

The Fundamentals

RECOMMENDATIONS

The first step in developing your Allergen Control Plan is to identify key leaders in your organization who not only understand how ingredients flow through your facility, but also understand the vital importance of managing and controlling these ingredients at every stage from choosing suppliers to handling, storage, processing, packaging and labeling — every day.

- Form an allergen control team in your company consisting of representatives from all appropriate departments. This may include, but not be limited to:
 - Manufacturing
 - Quality
 - Labeling/Regulatory Compliance
 - Research and Development
 - Engineering
 - Sanitation
 - Food Safety

Note: Smaller companies may not have all of these departments, so select a cross-section of expertise as appropriate to your operation.

- Conduct a risk assessment to determine the choice of specific allergen management procedures.
- Develop an allergen process flow diagram — or “allergen map” — to understand where allergenic ingredients and foods exist in the plant and where they are introduced into the process.
- Develop an Allergen Control Plan specific to each processing facility.
- Review the Allergen Control Plan regularly and update when necessary — especially when new ingredients are added, when processes or protocols are changed, or when new products or equipment are introduced into the plant.

Product Design (Research and Development)

RECOMMENDATIONS

Allergen management begins with new product concepts, research and development product prototypes, new ingredients, and new labels. The following recommendations should help guide your innovation.

- Only add allergens to new products when they make a discernable difference in the taste or functionality of the product.
- Question ingredient suppliers on the functionality and necessity of allergens in their formulation.
- Understand the existing allergens or lack of allergens in the manufacturing facilities when formulating new products.
- Create a process to review allergens in new products with the manufacturing facility prior to ordering ingredients and start up.
- Avoid using allergenic ingredients in such low amounts that they have no or minimal functional effect in the finished product.

Segregation of Allergenic Foods or Ingredients During Receiving, Storage, Handling and Processing

RECOMMENDATIONS

An effective Allergen Control Plan depends on keeping allergenic foods and ingredients separate from all other products and ingredients from the time they enter your facility until they are introduced into the production line and beyond. Every attempt must be made to visibly identify allergens and isolate them — at every step — from other foods, ingredients and equipment.

Receiving

- Review the labels of incoming raw materials for the appropriate allergen information or any changes.
- Tag each case/pallet/bag, etc. as appropriate of raw materials to ensure the allergen is clearly called out as the materials are stored and used in your facility. Companies may want to use color coding, tagging, or other means to identify the allergenic ingredients.
- Handle appropriately any damaged containers of allergens to minimize cross-contact at receipt.

Storage

- Store allergenic ingredients or products separately to prevent cross-contact. Protocols may include:
 - Using clean and closed containers
 - Designating separate storage areas for allergenic and non-allergenic ingredients and/or products. When segregated storage is not possible, use other methods such as not storing allergens over non-allergens, storing like allergens (milk and whey) together, etc.
 - Using and documenting clean up procedures for spills or damaged containers of allergens
 - Using dedicated pallets and bins
 - Using clearly designated staging areas for allergenic foods and ingredients
- Identify allergenic ingredients by a mark or tag (or color code) — and isolate allergens from non-allergenic ingredients/ products in storage.

Supplier Control Programs for Ingredients and Labels

RECOMMENDATIONS

What comes into your facility from suppliers has an equally important impact on the quality and integrity of your food processing protocols — and ultimately your legal exposure as well. Your Allergen Control Plan should also outline expectations, documentation and validation to ensure your suppliers are diligent and equally as dedicated to controlling and managing allergens.

- Require your ingredient suppliers to have a documented Allergen Control Plan.
- Require letters from suppliers that guarantee the ingredients you purchase do not contain undeclared allergens.
- Require your suppliers to notify you of any changes to the allergen status of the ingredients they supply prior to any changes.
- Audit your suppliers on a regular basis to assess the effectiveness of their Allergen Control Plan.
- Require suppliers to have sanitation cleaning procedures in place which are validated on a regular basis and whenever there is a change that may affect the allergen status of the line (i.e. new or changed product, ingredient, equipment, etc.).
- Conduct a supplier survey which includes the following:
 - The Allergen Control Plan of the supplier
 - The range of allergenic products produced by the supplier, especially on shared equipment with your ingredient(s)
 - The supplier's allergen cleaning program and protocols
 - Allergen training records for supplier's employees
- Ensure allergenic ingredients are shipped in clearly marked, sealed containers — and the containers are not damaged or broken.

Prevention of Cross-Contact During Processing

RECOMMENDATIONS

The very act of processing includes a number of opportunities and risks for allergenic ingredients to be introduced into the wrong food product. Human error in formulation is only one risk factor. Intelligent product scheduling and dedicated equipment and processing lines can go a long way toward preventing contamination. It is important to consider factors such as when allergenic ingredients are introduced into the process — and traffic which could inadvertently carry allergens from one point in the facility to another.

Scheduling of processing runs

- Schedule long runs of products containing allergenic ingredients in order to minimize changeovers.
- Segregate production areas for allergenic and non-allergenic products. If this is not possible, schedule manufacturing of non-allergenic foods before processing foods with allergens.
- Schedule sanitation immediately after production of foods containing allergenic ingredients.
- When product design permits, add allergenic ingredients as late in the process as possible.

During manufacture

- Ensure the traffic patterns of raw materials, packaging supplies, and employees are limited during the manufacture of allergen containing products and do not lead to cross-contact.
- If possible, have dedicated processing equipment and lines to prevent allergen cross-contact.
- Whenever possible, make products with similar allergens on the same equipment.
- For production lines with crossover points, prevent allergenic foods from falling onto non-allergenic production lines.
- When processing lines are in close proximity, minimize the allergen risk by adding physical barriers to separate allergenic and non-allergenic production lines.
- Dedicate tools, containers and utensils — and clearly mark them or use a color code to identify allergenic ingredient and/or product. When dedicated utensils and equipment are not possible, the items must be cleaned prior to using in the manufacture of non-allergenic products.
- Minimize the reuse of processing and/or cooking media such as water or oil. If cooking media is reused, test to validate there is no cross-contact for non-allergen products.
- Restrict personnel working on processing lines containing allergenic ingredients from working on non-allergenic production lines. Visually identify which employees are working on a line that contains allergens (different colored uniform, hair net, etc.).
- When products containing allergens are being manufactured, ensure allergens are identified throughout the process including visually tagging or color coding equipment.

Prevention of Cross-Contact During Processing ...continued

Control of rework and work in process

- Use color-coded tags to identify and record:
 - When reworked products with allergenic ingredients are produced
 - Where these products are stored
 - The products into which they are reworked
 - When these products are added back into the line and how much is used
- Use rework containing unique allergenic foods and/or ingredients only in the same formulation (a “like into like” or “exact into exact” practice, for example).

Maintenance and engineering

- Purchase and design equipment using sanitary design principles.
- Maintain equipment to ensure systems are operating as designed.
- Design traffic patterns and airflow in the production facility to prevent allergen cross-contact.
- Ensure equipment is positioned for easy access to clean and inspect.
- Assure maintenance procedures for working on processing lines eliminate cross-contact to non-allergen containing products – both during operations and during preventive maintenance.
- Determine the need to separate allergenic and non-allergenic production lines with physical barriers, separate employees, or other methods to prevent cross-contact.
- For production lines with crossover points (conveyor belts, etc.), prevent allergenic foods from falling onto non-allergenic production lines.
- Assess the risk of migration of allergenic dust to non-allergen product lines during processing .

Product Label Review & Label/Packaging Usage and Control

RECOMMENDATIONS

The only way consumers know of potential allergens in your product is to read the label or packaging. They are placing their trust — and in some cases, their very health and lives — in your hands. Proper packaging labels not only help protect your consumers, but protect your company from costly recalls, regulatory scrutiny, and potential liability.

- Ensure packaged foods regulated under the Federal Food, Drug and Cosmetic Act, comply with the Food Allergen Labeling and Consumer Protection Act of 2004. For these requirements, visit www.cfsan.fda.gov/~dms/algact.html.
- It is important to know companies cannot arbitrarily add “may contain” or other precautionary labeling because in 1996, FDA advised that “because adhering to good manufacturing practice (GMP) is essential for effective reduction of adverse reactions, precautionary labeling should not be used in lieu of adherence to GMP.” (<http://www.cfsan.fda.gov/~lrd/allerg7.html>)
- Ensure packaged foods regulated under the Federal Meat & Poultry Act comply with the Food Allergen Labeling and Consumer Protection Act of 2004. Additionally, USDA requires that meat and poultry plants reassess their HACCP plans and prerequisite programs to address allergens. (<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/05-016N.htm>)
- Ensure label approval processes are in place for new products or changes to current products.
- Review incoming labels prior to receipt for accuracy.
- Ensure product specification and formulation changes are immediately reflected on labels. Consider approaches to highlight newly introduced allergen components.
- Monitor, document, and verify the correct label at all changeovers as they occur.
- Discard all out-of-date labels or packaging in a timely manner.
- Implement proper inventory control procedures for packaging materials.
- Implement proper packaging staging control procedures.
- Train line personnel on techniques for ensuring product labels are switched appropriately at product changeover on the production line.

Validated Allergen Cleaning Program

RECOMMENDATIONS

It doesn't matter what the cause — leftover ingredients in a hard-to-reach corner of your processing line, a half-hearted cleaning effort due to employee fatigue or a looming product deadline — any allergen residue not adequately cleaned and removed from your processing line can find its way into the next product on the line, causing your next product to inadvertently contain an allergen not included on the label — and that can have grave consequences. It's a matter of process design, protocol documentation and thorough validation of cleaning procedures — and your Allergen Control Plan needs to account for it all.

Overall plant design

- Construct processing equipment and overall plant structure with good sanitary features including:
 - Ease of cleaning and sanitizing
 - No “dead spots” that allow accumulation of food or ingredients (no hollow rollers, no holes in welds, equipment that drains, etc.)
 - Accessibility of equipment for visual inspection

Sanitation standard operating procedures

- Protocols should be clearly written and easy to follow and understand.
- Define the scope of the cleaning procedures—range of applications, equipment, products, etc.
- Define who is responsible for the cleaning operations.
- Include detailed cleaning instructions.
 - Documented training should occur on a regular frequency

Cleaning validation procedures

- Protocols should be clearly written and easy to follow and understand.
- Define the intention and scope of validation.
- Describe the sampling procedures and the reason for conducting them.
- Define and describe the analytical procedures to be used.
- Define the final acceptance/validation criteria.
- Ensure **all** associated product is held pending test results.

Cleaning verification procedures

- Protocols should be clearly written and easy to follow and understand.
- Define the intention and scope of verification procedures.
- Describe the sampling procedures and the reason for conducting them.
- Define and describe the analytical procedures to be used.
- Define the final acceptance/verification criteria.

Confirmation and compliance

- Validate the analytical procedures used to verify and validate cleaning efficacy.
- Keep detailed records for cleaning, validation and verification.
- Evaluate the allergen cleaning program periodically for effectiveness and compliance.
- Monitor and verify the Allergen Control Plan frequently with internal and/or external audits.

Staff Training and Education

RECOMMENDATIONS

Ultimately, the effectiveness of your Allergen Control Plan comes down to people: trained employees and managers can be your greatest asset. You want employees who not only understand what to do, when to do it and how to do it — but more importantly, why it needs to be done to protect your company and the consumers who trust your products. Training is essential and needs to be an ongoing commitment, for both new and experienced employees.

- Provide general training on allergen awareness and control for all employees at all levels of the company.
- Provide specific documented training to employees as dictated by their job responsibilities.
- In all training, include information on the reasons protocols are required—as well as the potential consequences should the plan not be followed.

Allergen Precautionary Labeling: Food Manufacturers' Frequently Asked Questions

1. What is the Food Allergen Labeling and Consumer Protection Act (FALCPA)?

FALCPA is a law that went into effect on January 1, 2006. It requires that food labels identify the source of all major allergens in the food's ingredient list in simple language. Unless the food source of a major food allergen is part of the ingredient's common and usual name (e.g. milk, wheat), it must be labeled in one of two ways. It may be added in parenthesis after the ingredient (e.g. whey (milk), flour (wheat)) or can be identified at the end of the ingredient list in a "contains" statement (e.g. contains milk and wheat).

2. What are the major food allergens in the US? Worldwide?

FALCPA identifies eight foods or food groups as the major allergens. They are milk, eggs, fish, crustacean shellfish (e.g. shrimp, crab, lobster), tree nuts (e.g. almonds, walnuts, pecans, etc.), peanuts, wheat and soybeans. On a worldwide basis, the Codex Alimentarius Commission has established a list of common Allergenic Foods. Specific countries have their own distinct lists of common allergenic foods. A compilation of the lists of various countries is available at www.farrp.org.

3. What is cross-contact?

Cross-contact occurs when a residue or trace amount of an allergen unintentionally crosses over into a product that doesn't have that allergen. Such occurrences are sporadic.

4. How does cross-contact occur?

Cross-contact (the inadvertent introduction of an allergen into a product) is generally the result of environmental exposure during food processing or handling. Cross-contact occurs when multiple foods are manufactured on the same processing line, through the misuse of rework, as a result of ineffective cleaning, or from the generation of significant dust containing the allergen.

5. How can cross-contact be prevented?

Cross-contact cannot always be prevented. However, by developing and implementing an Allergen Control Plan, one can either prevent or at least minimize allergen cross-contact as much as possible. The Allergen Control Plan is a written document outlining controls put in place regarding the storage, handling, and processing of allergens and the identification of places where cross-contact is likely to occur. Prevention and monitoring methods are included to prevent cross-contact.

6. How do you develop an effective Allergen Control Plan?

A facility risk assessment should be conducted in order to develop an Allergen Control Plan. This assessment should start with the production of raw materials, storage and handling of raw materials, and every step in the manufacturing process through the packaging and labeling of the finished product. The critical points where allergens may be introduced into the product during manufacturing should be identified and a system established to monitor these points to ensure unintentional cross-contact is prevented.

7. What is precautionary allergen labeling?

Precautionary allergen labeling (sometimes also referred to as allergen advisory labeling) is a voluntary warning to consumers (e.g. may contain milk) added after the ingredient list. Its goal is to indicate a product not intended to contain a specific allergen(s) may sporadically contain that allergen due to unintentional and unavoidable cross-contact in the manufacturing process even after implementing a comprehensive Allergen Control Plan.

8. I don't have designated equipment for allergen-containing products. Should I use precautionary allergen labeling?

Studies show that a high frequency of precautionary labeling may result in an increased likelihood that

Allergen Precautionary Labeling: Food Manufacturers' Frequently Asked Questions ...continued

allergic consumers will ignore these statements, potentially putting them at risk for an allergic reaction. To protect consumers, precautionary allergen labeling should only be used when it is concluded that sporadic cross contamination of a product can not be avoided. This decision should be based on a thorough process assessment and implementation of an effective Allergen Control Plan (including good manufacturing procedures, sanitation and training). If it is concluded that inadvertent cross contamination can not be eliminated, then precautionary allergen labeling is appropriate. Precautionary allergen labeling is never to be used as a substitute for good manufacturing practices and an Allergen Control Plan.

9. What about ingredients derived from commonly allergenic foods?

In most countries (with some exceptions), ingredients derived from commonly allergenic foods must be declared by source on ingredient labels when used in the product formulation. However, the need for exercising an Allergen Control Plan may vary with the ingredient depending upon its actual allergen content. All allergens are proteins. Some ingredients are highly allergenic due to their high protein content (e.g. caseinate, whey protein concentrate, soy protein isolate, wheat gluten and egg lysozyme). But, other ingredients derived from allergenic sources have much lower levels of allergen or protein including soy lecithin, lactose, fish oil, malt extract, and tocopherol (Vitamin E). Extensive allergen clean-up is not necessary if the only allergen sources in a formulation are ingredients with very low allergen content (i.e. not detected with allergen kit). Expert advice may be necessary on specific ingredients. E-mail your questions to FARRP: farrp@unl.edu

10. What about sulfites?

Sulfites do not elicit true allergic reactions. Instead, sulfites cause a form of food intolerance. Sulfite-sensitive consumers tolerate some sulfite in their diets with no ill effects. Thus, extensive allergen cleaning is not necessary for shared equipment used in the manufacture of sulfite-containing products, if sulfite is the only substance of concern in the formulation and if the sulfite carryover is less than 10 ppm.

11. What about tartrazine (FD&C Yellow #5)?

Tartrazine does not elicit a true allergic reaction. Tartrazine may cause a form of food intolerance in some consumers (the clinical evidence is not clear). Tartrazine-sensitive consumers can tolerate some tartrazine in their diets with no ill effects. Thus, extensive allergen cleaning is not necessary for shared equipment used in the manufacture of tartrazine-containing products, if tartrazine is the only substance of concern in the formulation.

12. What about lactose?

Lactose causes a form of food intolerance. Lactose-intolerant individuals can tolerate some lactose in their diets with no ill effects. Thus, extensive allergen cleaning is not necessary for shared equipment used in the manufacture of lactose-containing products, if lactose is the only substance of concern in the formulation.

References

FDA Guidance for industry on FALCPA:

<http://www.cfsan.fda.gov/~dms/alrguid4.html>

FDA information about food allergens:

<http://www.cfsan.fda.gov/~dms/wh-alrgy.html>

FDA guidance for industry on labeling soy lecithin:

<http://www.cfsan.fda.gov/~dms/soyguid.html>

USDA guidance for industry about food allergens:

<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/05-016N.htm>

Food Allergy & Anaphylaxis Network - FAQs on FALCPA:

<http://www.foodallergy.org/advoacy?FALCPAaQ14.html>

Food Allergy & Anaphylaxis Network -

Food Allergy Issues:

<http://www.foodallergy.org/questions.html>

Codex Alimentarius General Standards for Labeling

Prepackaged Foods:

http://www.codexalimentarius.net/download/standards/32/CXS_001e.pdf

Food Allergy Research & Resource Program:

<http://www.farrp.org>

Nutrition and Health Issues – Food Allergies
& Intolerances

(an extensive list of Government websites
related to allergens):

<http://www.nutrition.gov>

US Department of Health & Human Services

(prevention and wellness):

<http://www.healthfinder.gov>

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