Chapter 11

DEVELOPING AN ALLERGEN CONTROL PROGRAM

1.0 ALLERGEN OVERVIEW

True food allergies are unfavorable reactions to proteins found in certain foods. Up to six to nine percent of people are sensitive to, or have adverse reactions to, certain foods. Very small amounts of an unfavorable protein can cause reactions.

Although any protein can cause an allergic reaction in sensitive people, the priority allergens identified by Health Canada and the Canadian Food Inspection Agency (CFIA) account for 90% of anaphylactic reactions in Canada. The priority food allergens are:

Eggs	Sesame
Milk	Soy
Mustard	Sulphites
Peanuts	Tree Nuts
Seafood (Fish,Crustaceans and Shellfish)	Wheat

Since sulphites are not proteins, they don't cause a true allergic reaction. Sulphite sensitive people may experience life threatening reactions similar to food allergies and people who have asthma are most at risk to these reactions.

Gluten does not cause an allergic reaction but can cause an adverse reaction for sensitive people therefore its source (such as wheat, rye, barley) must also be declared on the ingredient list and may be controlled through the allergen management program.

Individuals with celiac disease have an intolerance to gluten. Gluten is a type of protein found in wheat, barley, rye and triticale.

The CFIA has excellent information regarding allergens on its website. Please visit:
www.inspection.gc.ca/food/labelling/food-labelling-for-industry/list-of-ingredients-and-allergens/eng/1383612857522/1383612932341

www.inspection.gc.ca/food/information-for-consumers/fact-sheets/food-allergies/eng/1332442914456/1332442980290

If you are a food processor and you wish to explore the growing market for allergy and gluten free foods please visit Alberta Agriculture and Rural Development's Food and Health Unit webpage:
www.agriculture.alberta.ca/foodandhealth

1.1 Allergen Control Program (ACP)

Labels that read 'May Contain [X]' or 'Not suitable for consumption by persons with an allergy to [X]…' are often used to show that products have been produced where cross-contamination is possible. However, overuse of allergen warning labels may limit consumer choice and may reduce the value of the warnings. Also, current best practice for allergen control is to conduct all diligence possible to ensure a safe food product. Therefore, having a strong Allergen Control Program (ACP) is very important.

When setting up an ACP, remember:

- An effective allergen plan needs to be accepted and understood by all food production staff;
- Success depends on management commitment; and
- Unidentified allergens represent a high risk.

The best way to control allergens in the facility is through hazard analysis and hazard management.

The Codex Alimentarius Commission was created in 1963 by the Food and Agriculture Organization and the World Health Organization. Its purpose is to develop food standards and guidelines. The Codex Alimentarius Commission describes seven steps to control allergens, which are very similar to the hazard analysis required for developing a HACCP plan.

The seven steps to control allergens are:

1. Look at the entire production process from start to finish. Identify any hazards that need to be controlled. Identify any steps in the process where controls can be used. This is referred to as Allergen Mapping.
2. Set limits at critical points for what is acceptable and what is not acceptable.
3. Set monitoring procedures for critical points to check whether allergen hazards are being kept within limits (set in step 2).
4. State what corrective actions (e.g. cleaning up spills) are needed when the process is not operating within the set limits.
5. Regularly check that the methods set up are working.
6. Document, document, document so that there is proof showing that the ACP is working well.
7. Improve as necessary, update when changes happen and make sure the ACP continues to work well.

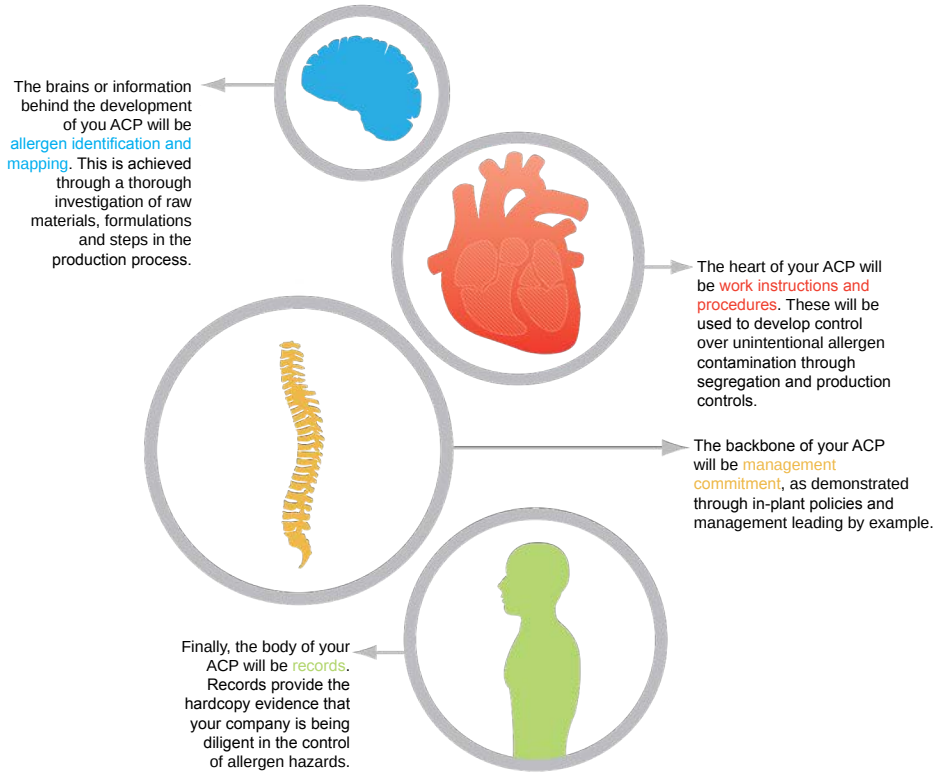
Although these steps may seem to require a lot of work, following this basic procedure will create a very good ACP.

The most common ways for unidentified allergens to enter food products are:

- Cross-contamination of an ingredient with an allergen before or after it is received at the facility;
- Accidentally adding allergens to products that do not usually contain them (mis-formulation); and
- Cross-contamination from a different product containing an unwanted allergen.

Many allergenic food products (e.g. milk powder, sesame seeds, flour, etc.) enter the air supply easily. They can then be deposited onto allergen-free products. This can happen even if the allergenic foods are not produced in the same area or the same production room. Examine whether a common air supply in the facility could cause such problems.

Components of an Allergen Control Program (ACP)



1.2 Management Commitment

Management support is essential. Programs won't thrive without management commitment, however, problems will.

An Allergen Control Program (ACP) needs buy-in or acceptance from all facility employees. The procedures and policies affect all areas of production from maintenance to shipping. However, top management must take a leading and visible role in supporting the ACP.

Strong management commitment will include the following:

- Managers must show that they are acting responsibly and seriously. This impresses on staff that everyone is working under the same standards throughout the facility. It will demonstrate that management sees the ACP as important.
- Make sure communication between personnel and departments are clearly stated and strengthened. This improves the effectiveness of the ACP.
- Develop the program so it takes place with input from production or other departments. For the ACP to be successful, buy-in is needed from all departments. Without needed input and support, the program becomes an ideal rather than a workable means of control.
- Using various resources can strengthen allergen controls. Segregation, labeling and sanitation are examples of areas where better control can be gained by using sufficient resources.
- Make sure employees receive the education, training and experience they need. Employee awareness and training are very important in avoiding allergen contamination of products. Make sure employees understand clearly what allergens might be found in the facility. Make sure they understand what problems an allergen could cause.

2.0 ALLERGEN IDENTIFICATION AND MAPPING

2.1 Assessing Formulas and Raw Materials

The first step to controlling allergens in any environment is allergen identification. To avoid having unintended allergens in products, first identify the sources of allergens in the facility.

- Use a master list of all raw materials used in the facility.
- Identify those raw materials that either contain, or may contain, allergens.
- Consider both primary and secondary ingredients like spices, flavourings and additives.
- Ensure the core components are considered for all ingredients (e.g., bread crumbs must be broken down to its core ingredients).
- Make sure all possible sources are listed.

See Form G.4: Ingredient Allergen Reference.

Depending on the operation, control of all priority allergens may not be required. If certain allergens are present in ALL products they do not require control. For example, a bakery does not control for wheat if it is in all of the products.

2.2 Communicating with Suppliers

It is important to create a complete list of allergens in the facility. To make sure the list is complete, set up a policy and procedure to go over allergens that could come from suppliers.

An excellent tool is the Allergen Check List for Food Suppliers and Manufacturers. This was developed by the Canadian Food Inspection Agency (CFIA) and it lays out a simple way to 'talk' with suppliers.

See Form G.1: Allergen Checklist for Food Suppliers or Manufacturers.

Packaging materials and production aides may also contain allergens and must be assessed. For example, sulphites are used in the production of some food packaging materials such as cellophane. Protective edible coatings and waxes, such as those used by the fresh produce industry, must also be assessed for allergens.

To help manage allergen labeling, keep copies of all raw material specifications and formulations. Also keep copies of finished product labels. All this reference information should be kept so staff can find it easily.

Require all the facility's suppliers of raw materials and packaging to have some form of allergen control program. This reduces the risk of allergens getting into food products unintentionally.

Once a master list of raw materials is created, include this information on the master list of finished products. This complete master list of finished products will then show clearly what allergens are found in each product.

These two lists can then be cross referenced with final products that may share common equipment. The goal is to determine which non-allergen products are processed on equipment also used to process allergen-containing products. Potential points of cross contamination can then be identified and proper control measures shall be designed to avoid unintentional cross-contamination.

See Form G.3: Formula/Product Allergen Reference.

2.3 Controlling Product Development and Purchasing

Controls that are in place at the facility for ingredient substitutions and for product development should also be in place at suppliers' facilities.

Once it is known what allergens are used in the facility, it is important to control allowing any new allergens in. Be especially careful when using new raw materials, recipes or ingredients.

Written allergen policies should include controls for incoming ingredients. They should also include controls for new product development. This will help control the addition of new allergens.

The product development and purchasing staff are very important in controlling incoming allergens. Be sure these staff members know that changes to one production process can risk allergen cross-contamination in other processes and products.

When any ingredient or product changes, a new allergen risk review is needed.

Make sure that product development staff has a master list of current allergens in the facility. This helps staff understand if new products are bringing in new allergenic ingredients.

Also give the master list to ordering staff. This will help when it is necessary to order substitute ingredients. Staff can make sure that replacement materials do not bring new allergens into the product or facility.

Inform those responsible for maintaining the Allergen Control Plan (Quality Assurance, management, etc.) of any changes to raw materials. Also inform them of any changes to product formulation. If new products containing allergens are tested in the facility ensure a validated allergen cleaning procedure is in place as part of the product development process.

2.4 Allergen Mapping

After it is decided what products have allergens, do a walk-through of the facility. This will help the staff determine if there is any shared equipment. It can also help point out and control possible allergen issues. Look for issues related to scheduling, ingredient substitution, cross-contamination, rework and labeling. Ask the following:

- What type of clean-up is used in the plant? Is it thorough enough to remove allergens? Has it been validated to remove the allergen of concern every time?
- Do any conveyors or pipe systems cross over each other, or over exposed product?
- What kind of inventory control is in place?
- What is reworked (if anything)?
- Is there a system for maintaining labels?
- Are allergen issues being dealt with through production scheduling?

Create both a process flow diagram and a plant schematic. These will reveal key areas in the process or facility that might be sources of cross-contamination. A spreadsheet can be used to identify which allergen containing products are produced on equipment that also produces non-allergen containing products. This is a great way to determining where cross-contamination may occur.

See Form G.5: Production Process Allergen Assessment.

3.0 PROCEDURES AND WORK INSTRUCTIONS

3.1 Receiving

Receiving is a facility's entry point for raw materials and non-food items. By placing controls over what is allowed in, the facility can better control incoming allergens.

Incoming material inspection should involve:

- Making sure that all incoming products have clear lot codes on all containers;
- Supervising unloading, including allergen-containing materials;
- Supervising off-hour deliveries to ensure materials are not damaged (which may result in cross-contamination); and
- Rejecting suspicious incoming food, ingredients and other raw materials that are questionable. When in doubt, throw it out.
- Cross reference each incoming ingredient with a list of approved (i.e. reviewed for allergen content) ingredients

If it looks like raw materials that are normally allergen-free have been contaminated, write down observations and do not accept the shipment.

See Forms B8 or B9: Goods Receiving Record Option 1 or 2 found in Chapter 5 Transportation and Storage.

Have the receiver clearly label that these incoming products contain allergens. A predetermined colour coding system should be put in place. A reference guide / key should be posted for employee reference. These can reduce the possibility of allergens getting into products.

3.2 Segregation

Once the source of allergens in the facility is pointed out, identify and segregate or set aside these allergens. Store allergenic materials in areas that are identified and marked clearly.

One method is to set up allergen zones. Do this by painting areas on the floor or racking, or by using colour coded signage Create allergen zones for both finished products and raw materials. This will reduce the possibility of cross-contamination.

Segregation strategies are ways of keeping material apart and controlling the flow of allergens in the facility. Strategies include:

- Having the receiving department identify or mark packages of incoming ingredients that contain allergens. Be sure this is done when ingredients are received.
- Always store allergenic materials on bottom racks so that if spillage occurs there is less opportunity for cross-contaminating allergen-free materials.
- Identify and record all ingredients with unusual or different lot numbers. Be sure this is done when these ingredients are received.
- Track lot numbers throughout production. Link ingredient lot numbers to finished product batches.
- Only allow rework containing allergens to go into products that contain the same allergens (i.e., like into like).

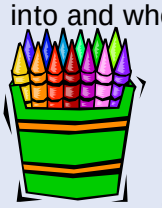
If an allergen is contained within all the facility's products, it is not necessary to identify and segregate the allergen.

Colour coding Equipment and Uniforms

The easiest way to separate allergens in production areas is by setting aside equipment, scoops, utensils and storage areas for dedicated or special purpose use. Colour-coded stickers and equipment will make this segregation clear.

Similar colour coding can be used on maintenance equipment that is dedicated to allergen processing lines.

Another place to use colour coding is on rework material. Colour-coded tags will show when the reworked product was produced. They will show where it is stored, what product it is reworked back into and when it was added and what allergens it contained.



Make sure all employees are trained fully in colour coding. Make sure they're aware of its importance and the meaning of colour codes. Post signs showing what colour can be used with each product. This ensures consistency and reduces training time.

Dedicated Equipment

Cross-contamination with an allergen is the main cause of undeclared or unintentional presence of allergens in food products.

Unplanned entry of allergens into a product from equipment or employees during production is one of the most common causes leading to a product recall.

The best way to avoid this problem is to have production facilities set aside for making or processing specific allergenic products. However, this is not possible in all manufacturing facilities. It is therefore important to have written procedures to dedicate processing equipment and areas. Also create written policies to segregate these products during scheduling and cleaning procedures.

Strategies that can be used during production include:

- Scheduling production of allergenic products just before the end of shifts, then following these up with major clean-ups (validated allergen clean procedures);
- Placing physical barriers (shield covers, catch pans, etc.) to prevent spillage or cross-contact;
- Reducing use of equipment with multiple crossovers and conveyors to decrease potential contamination;
- Using production systems that decrease the equipment exposed to allergens;
- Limiting production of allergenic products to certain areas of the facility; and
- Using care when doing rework.

When doing factory trials of new allergen-containing products, these trials risk cross-contamination with existing products. These new products are just as likely to cause cross-contamination as products already identified and controlled.

Product Scheduling

Most facilities can't set aside equipment and areas only for allergen products. Therefore, it is very important to develop strict segregation of allergenic products. Do this through production scheduling.

Determine if it's possible to manufacture allergen-free products first, and then do allergenic products at the end of the run. Another strategy is to schedule production so that longer runs of allergenic product can be produced at one time. This reduces changeovers and the need for major sanitation shutdowns.

Allergen scheduling tries to ensure that a complete allergen clean is done on all equipment. It should also be done on shared areas that are used for allergenic and non-allergenic products alternately.

3.3 Allergen Clean

Cleaning the production lines in between allergen and non-allergen product runs reduces the risk of allergen cross-contamination. This method is often called an 'Allergen Clean.'

Documented cleaning procedures are necessary to avoid unintentional allergen contamination. As noted, very small amounts of allergens can cause unfavourable reactions in sensitive individuals. Therefore, clean up any spills immediately. Do this for spills that happen during production, storage or transportation of allergen products. This will help to reduce cross-contamination.

During an Allergen Clean, pay special attention to processing aids and the final product lines. For example, oil used for cooking allergenic products cannot be used later for cooking non-allergenic products. As part of an Allergen Clean program, get rid of this oil and clean the vats before producing the next product.

In an allergen clean program consider the following:

- When switching from allergenic to non-allergenic products, change or clean dust socks inside collectors and other absorbent materials.
- Use equipment that is designed for easy cleaning and that provides access to all dead spots, rough surfaces, void areas, etc.
- Use air as little as possible when cleaning allergen areas. Be careful around allergens that can easily become airborne, especially in facilities with a common air supply. Using compressed air for cleaning in these facilities may let allergens into the air supply. This can contaminate non-allergenic products.

- Create check sheets to mark off each cleaning.
- Validate or confirm the cleaning procedures with allergen testing to ensure procedures are working.
- When validating the cleaning program, use tests which are specific to the allergen of concern and sensitive enough to meet the critical limits for the allergen.

Allergens are proteins, not micro-organisms. Therefore, sanitizing will not get rid of allergen risk even if it reduces the levels of cells present. Bacteria-free allergen proteins will still cause a reaction in sensitive people.

When planning an Allergen Clean program, include all splash zones, indirect product contact surfaces and utensils. Ensure that the cleaning of one line or area does not lead to the contamination of another. Generally, use wet cleaning for allergen cleaning. This eliminates any sticky allergen-containing residues.

Current industry best practice for validating the allergen clean program is to use and document some form of allergen residue testing program for product contact equipment.

Depending on risk, finished product testing can be used to enhance the validation and verification of cleaning procedures. However, finished product testing alone is not adequate and should be combined with specific allergen testing on shared equipment.

3.4 Validation and Verification

Validating an Allergen Clean Program

An allergen verification program should be built upon an initial validation study that demonstrates the cleaning procedures being used are effective for the targeted allergens. The validation study will provide proof that the allergen is removed, or reduced to an acceptable limit, by the “allergen clean” procedures.

Testing used for the validation study should be specific to the allergen being removed. For example, ELISA (Enzyme Linked Immuno Assay) test kits are available for most of the common allergens and are commonly used in the food industry. They are available from several manufacturers and are relatively inexpensive and easy to use. These tests are also sensitive and the results are obtained quickly. ELISA tests can have limitations, it is important to research your options carefully.

PCR (Polymerase Chain Reaction) is another method of allergen testing and can also be used to validate your cleaning procedures. PCR tests for the DNA related to specific allergenic materials. These tests are sometimes used on high-risk products. However, PCR is expensive, requires highly trained laboratory staff and specific equipment, and can require up to six hours for results to be ready. For these reasons, most manufacturers do not use this technology.

When there is a mixture of different allergens in the products it is generally accepted to test for the highest risk allergens. Consider concentration of allergens and which are most difficult to remove.

Finished product testing can also be used to validate cleaning procedures and is very important where “allergen free” claims are made. It is recommended to refine and validate the allergen cleaning procedures before conducting finished product testing. When conducting finished product testing put the product on hold in case the allergen is found.

See Form G.2: Allergen Validation Record.

Verifying Allergen Clean Procedures

After the cleaning procedures have been validated, and shown to remove the allergenic materials of concern, verification procedures must be put in place to show that the validated clean procedure is effectively carried out each time.

The first step for verifying your Allergen Clean procedures is by visual examination. Formally inspect the equipment and production areas and document the results. Wait until the equipment and surfaces have dried. Some residues cannot be seen on a wet surface. There should be no visible product on any surface after a complete Allergen Clean.

In addition to the visual examination, direct observation of the validated cleaning procedures during the sanitation process can be used.

Another commonly used practice is to test product contact surfaces with protein swabs. These swabs are highly sensitive and verify that the equipment has been thoroughly cleaned. These swabs test for total protein, not for specific allergens, therefore they are not acceptable for validating the removal of specific allergens.

Another widely used method to verify the Allergen Clean procedures is to test with ATP swabs. ATP (adenosine triphosphate) is a chemical that is associated with living cells. This form of testing is generally used in the food industry to decide the cleanliness of equipment. It helps find 'dirt' quickly.

The major drawback with ATP testing is that it is a non-specific indicator of contamination. In other words, it may be positive when allergens are not present. Also, ATP testing will not tell the amount or the level of allergens present. However, by revealing the cleanliness of the equipment being examined it can serve to verify your cleaning procedures.

When utilizing total protein swabs or the ATP swabs to verify the cleaning procedures, these methods must be calibrated with the validated cleaning procedure. In other words, when conducting your validation by testing with allergen specific ELISA test kits, also test (immediately after the ELISA test) with the total protein swabs or the ATP swabs, and record both results.

3.5 Rework

Inadequate segregation due to poor scheduling and labeling causes loss of control in an Allergen Control Program. Next to this, unregulated rework is the most common reason for manufacturers losing control over their ACP.

Rework is manufactured product that has failed a usability test. It requires additional work, processing or ingredients to avoid being thrown out.

Most often, rework is added in small percentages to newly produced product. Rework that contains allergens should only be used in products containing the same allergens. To ensure this policy is followed, be sure to label and track all rework product throughout the production process.

3.6 Labeling and Packaging

The last step of the ACP is product labeling and packaging. In Canada, new food allergen labelling regulations came into force on August 4, 2012. Some of the highlights include:

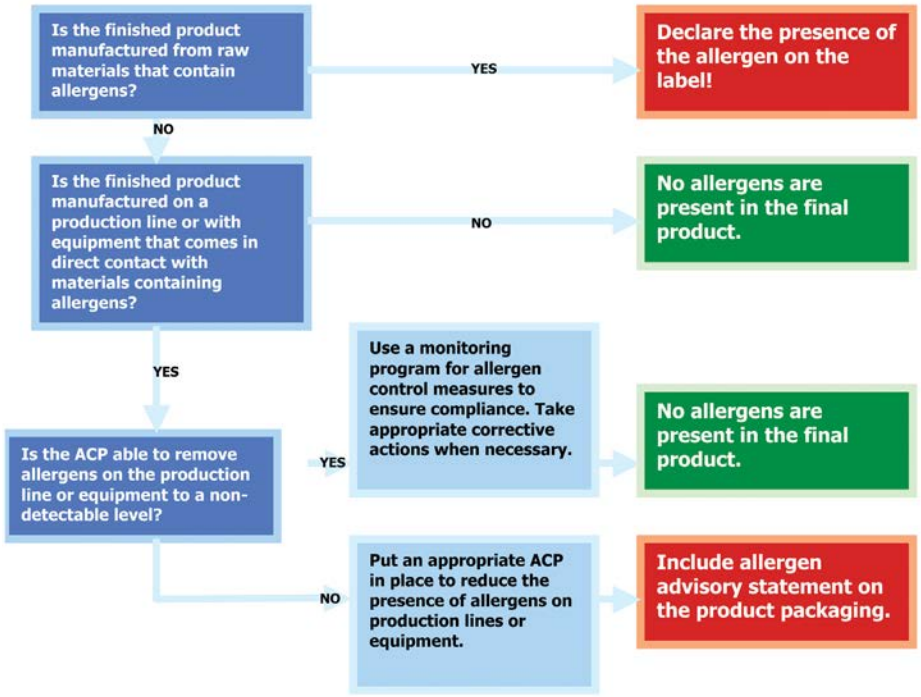
- Food allergens, gluten sources, and sulphites need to be labelled in the list of ingredients or in a statement that begins with “Contains:..”.
- The food allergen or gluten source must be written in commonly used words such as (“milk” or “wheat”).
- Mustard seed has been added to the regulatory definition of food allergen.
- Common name for the plant sources of hydrolyzed protein must be declared. For example, the label may indicate soy, or hydrolyzed vegetable protein (soy), rather than just hydrolyzed vegetable protein.
- For the allergen source: spelt and kamut will be declared as wheat.
- Sulphites above 10 ppm must be treated the same as other allergens. Use of a separate “Contains” statement is optional.
- If a food allergen is present in wine and spirits as a result of the use of fining agents from eggs, fish or milk, the allergen source must be shown on the label of the prepackaged product.
- The source of any allergen or gluten present in the wax coating or their compounds will be required to be shown on the label of prepackaged fruits and vegetables.

It is recommended to refer directly to the Health Canada and Canadian Food Inspection Agency websites, and consult with knowledgeable professionals, when determining the proper labeling of food products. Please visit: www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/index-eng.php

For general information about food labeling visit the CFIA Food Labelling and Advertising webpage at: www.inspection.gc.ca/food/labellingeng/1299879892810/1299879939872

Also, for Guidance on labelling oils derived from food allergens sources: www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/oil-refined-huile-raffinees-eng.php

Allergen Risk Assessment and Labelling



Make sure all products are labeled to identify all allergens. Then use procedures to ensure all labels remain current and correct.

Ways to ensure the accuracy of labels include:

- Install systems, checklists or policies that make sure product is packed in the right secondary packaging.
- When reformulating products, get rid of all packaging material or labels that do not state ingredients correctly.
- Similar products that contain different formulations (e.g. flavours) should have packaging with a different colour or other special identification. This prevents confusion.
- Use verification sheets to prove that labeling is being checked when the product is received, and where it is being used.

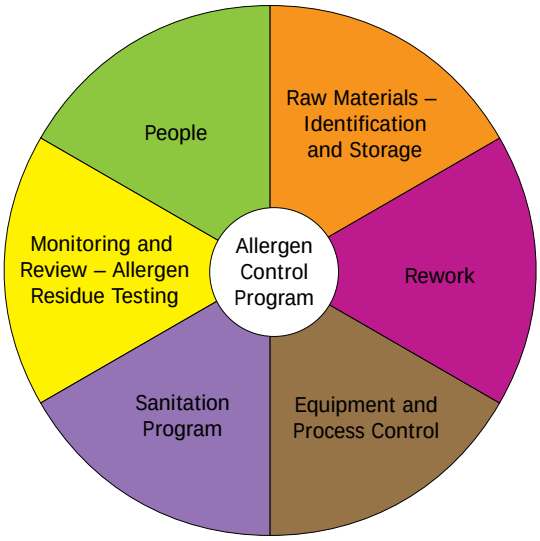
Any new labeling policies should be created with the purchasing and product development teams. Indicate on the label any recipe changes. Also be sure to include the addition of allergenic ingredients. This will help ensure that consumers do not mistakenly consume familiar products that have been redeveloped to contain allergens.

Schedule regular verification or reviews. Make sure that all ingredients are declared correctly on each approved label. Do the same whenever ingredients change or substitutions are made.

4.0 ALLERGEN TRAINING

For all these procedures and policies to work in controlling the facility's allergens, employees must be trained and aware. As the figure below shows, people are a critical part of the ACP.

Functional Allergen Control Program



It only takes one untrained employee for an undeclared ingredient to turn up in products.

All staff who handle and order ingredients, equipment, packaging and finished products must be aware of food allergens. This includes temporary workers, contractors, and management. They must all be aware of the dangers posed for people with allergies.

Train everyone working at the facility on:

- Which allergens are of concern;
- How to avoid cross-contamination;
- How to notify management of allergen concerns during production;
- Policies related to allergen control;
- Handwashing;
- Clothing requirements;
- Waste control;
- Rework control;
- Cleaning procedures;
- Dedicated equipment;
- Storage procedures;
- Labeling procedures;
- Production scheduling;
- Recipes and formulation; and
- Results from sensitive individuals eating allergens.

Most recalls are triggered by products containing allergens. These allergens are not declared clearly on labels.

Communication is very important to allergen control procedures and policies. Make sure that:

- Detailed procedures on allergen controls are readily available;
- Information on prevention of allergen contamination is readily available;
- All information is visible in manufacturing areas;
- All employees know about this information and where to find it; and
- All employees are told about any changes to policies, procedures or formulations (ingredient requirements).

5.0 ALLERGEN FORM TEMPLATES

G.1 Allergen Checklist for Food Suppliers or Manufacturers

G.2 Allergen Validation Record

G.3 Formula/Product Allergen Reference

G.4 Ingredient Allergen Reference

G.5 Production Process Allergen Assessment

6.0 SOURCES OF INFORMATION

1. Anderson, Allen E. *Designing an Allergen Control Plan*. Food Quality Magazine (July/August 2003).

2. Goodwin, Philip R. *Food Allergen Testing*. Food Quality Magazine (April/May 2004).

3. American Bakers Association. *ABA Allergen Usage Guidelines* (2000).

4. AIB International. *Allergen Information Manual and Auditor Guidelines* (2002).

5. Food Standards Agency *Guidance on Allergen Control and Consumer Information* DRAFT (2005).

6. Australian Food and Grocery Council. *Food Industry Guide to Allergen Management and Labelling* (October 2002).

7. Peach, Robert W. et al. *The Memory Jogger 9000/2000 – A pocket guide to implementing ISO 9001* (2000).