A Comprehensive Approach to Reducing the Risk of Allergens in Foods

KURT DEIBEL,1 TOM TRAUTMAN,1 TOM DEBOOM,1 WILLIAM H. SVEUM,2 GEORGE DUNAIF,2 VIRGINIA N. SCOTT,3* and DANE T. BERNARD3

1General Mills, Inc., 9000 Plymouth Ave. N., Minneapolis, Minnesota 55427; 2Campbell Soup Company, Campbell Place, Camden, New Jersey 08103; and 3National Food Processors Association, 1401 New York Ave., N.W., Washington, D.C. 20005, USA

ABSTRACT

The control of food allergens in a food-processing plant presents numerous challenges. An allergen prevention plan must determine potential sources of contaminating allergens and appropriate controls to prevent their introduction into food products. These controls may include scheduling production of allergen-containing products at the end of manufacturing runs, appropriate labeling and use of rework, equipment and system-design considerations, and thorough cleaning of lines after running allergen-containing food products. Proper labeling of food products, effective management of label inventories, control of ingredients from suppliers, and training of employees are key factors in allergen control.

Key words: Food allergens, allergen control

One of the most problematic issues that a food processor must confront is that of food allergy. It is problematic because consumption of certain food proteins can cause serious reactions, including death, in the food-allergic individual. The magnitude of such an outcome demands that the food manufacturer focus on all aspects of ingredient selection, processing, labeling, and food production. Food-manufacturing operations should be carefully analyzed for potential allergen problems. An allergen prevention plan should be implemented for any operation in which potential allergen problems exist in order to effectively manage food-allergy risks.

FOOD ALLERGY

There are many forms of adverse reactions to components of food. What some people call an “allergy” may in reality be an enzyme deficiency, a malabsorption, or other type of food intolerance. A true allergic reaction involves the body’s immune system and is an immune response to a “foreign” protein (4, 11, 14). Small amounts of foreign protein can enter the blood stream in several ways: an insect bite or sting, inhalation of pollen in the hay-fever season, or, in the case of food allergy, ingestion or, very rarely, by inhalation. For reasons that are not well understood, some people become sensitized to a specific foreign protein, which is then called an allergen. Subsequent exposure to the allergen results in an allergic reaction. In such cases, certain immunoglobulins (Ig) in the blood, usually IgE, combine with the allergen at the surface of mast cells and basophils, causing the cells to release compounds that mediate the allergic response; primary among these is histamine (4, 9, 11). The most common manifestations of food allergies involve the gastrointestinal tract (diarrhea, vomiting, abdominal pain, nausea), the skin (hives, rash, dermatitis, angioedema), and the respiratory tract (asthma or laryngeal swelling) (14). In addition to gastrointestinal and skin symptoms, anaphylaxis, the most severe reaction, may result in respiratory (wheezing, labored breathing) and circulatory effects that can lead to shock and death (12, 14, 15, 18). Allergic reactions to foods may have a very rapid onset. For persons with an allergy to a protein found in foods, the only safe course is one of avoidance, i.e., to avoid eating or exposure to the offending food.

COMMON FOOD ALLERGENS

Almost all food allergens are proteins, but only a few of the many proteins in foods are likely to cause allergic sensitization, and even then in only a limited number of susceptible individuals (15). The vast majority of allergic reactions are caused by only a few foods. These are peanuts, tree nuts (almonds, walnuts, hazelnuts, etc.), eggs, milk, soybeans, wheat, fish, and shellfish (4, 10, 11, 15). In fact, it has been reported that these foods account for more than 90 percent of allergic reactions to food (11).
PERSONS AT RISK

While a food allergy can potentially affect anyone, it is estimated that less than 1% of the adult population has a food allergy (3, 11). The incidence is somewhat higher in children (approximately 5%) (3), in whom sensitivity to milk and soy is more common, particularly for those under 3 years of age (2). It is not uncommon for a child to outgrow a milk, soy, or other allergy, but if sensitivity is retained through adolescence into adulthood, it will likely be retained for life (1).

There are no good data on what portion of the allergic population may be subject to the serious, life-threatening set of reactions known as anaphylactic shock. This is partly because of the natural reluctance to test allergic people for such effects and partly because those with a history of more moderate reactions can exhibit anaphylactic shock without warning upon subsequent exposure. Allergic individuals respond quite variably to their offending food. There is a dose-response phenomenon operating in food allergy: the magnitude of the response is proportional to the amount of allergenic food eaten by the food-allergic individual (4, 11). Food-allergic people that also have asthma tend to have more serious reactions (12, 18).

SOURCES OF FOOD ALLERGENS

Allergens may be a component of the food being prepared, but allergens may also become part of a food through unintended routes. Such inadvertent allergens in foods can result from a number of events. Misformulation, improper clean up, and cross-contamination by dust or by pieces of an allergen (e.g., fragments of peanuts) remaining in the processing system are some potential ways in which allergens can enter a product. Some of these routes for allergen addition are explored below.

Understanding the formulation of a product in order to identify any allergic ingredient is a primary responsibility of the manufacturer. A process control check to verify that known allergens are listed on the ingredient label is essential. Additionally, it is important to verify that the food product is placed in the appropriately labeled package and/or that the appropriate label (and correct version of the label) is placed on the product.

The engineering design, equipment installation, and production practices used in food manufacturing should be focused on controlling hazards, including allergens. It is also critical to address the allergen issue as new products or ingredients are introduced into the plant and onto existing manufacturing lines. In many circumstances allergen contamination occurs because of human mistakes. The design of new lines or specific pieces of equipment must minimize the potential for human error. For example, it is necessary to use physical detachments or lockouts of high-risk equipment—the equipment used for allergen-containing products, especially if it is difficult to clean thoroughly—that uses systems such as packaging lines in common with equipment for non-allergen-containing foods.

Cross-contamination is an ongoing concern of the food manufacturer. Product stream contamination could come from mechanical movement of a potentially allergenic product or raw material that could fall from crossover points (a point where one line crosses over the top of another line) if the system is not entirely enclosed, or from equipment common to more than one product that was not properly cleaned, product rework or work-in-process materials that are added back into the wrong product stream, maintenance tools used on a line producing allergen-containing product and then on a different line, recycling or reclaiming systems, waste handling, etc.

The introduction of food allergens can occur at almost any level of the manufacturing process as a result of cross-contamination. Flow diagrams such as the ones recommended for hazard analysis and critical control point (HACCP) plans (6) will help in identifying the points for control of allergens in the process (see Allergen mapping, below).

The optimum situation would be to manufacture allergen-containing products in a separate plant or to have a dedicated physically separated line that manufactures one product type from formulation through packaging. However, this is generally impractical, as most manufacturers cannot have a separate line for each product for economic reasons, such as the cost of equipment and personnel to maintain the line. The typical manufacturing system may have a segment of a production line that is dedicated to the allergen-containing or non-allergen-containing food product. However, even if the line is totally dedicated to an individual product, allergens can enter unintentionally through an ingredient. The allergen-control program must include the sourcing of ingredients to totally document the risk factors associated with an individual product.

ALLERGEN-PREVENTION PLAN

Allergen-prevention team

A cross-functional team similar to the one used for HACCP (7) should be utilized in developing the allergen prevention plan (APP). Typically, the team should consist of representatives from manufacturing, quality and regulatory affairs, research and development, engineering, and food safety. An individual with a knowledge of food allergies may need to be consulted. The plan is facility-, product- and line-specific; therefore, the team should comprise individuals who are close to the day-to-day operation of the plant.

Risk evaluation

The overall risk evaluation should be based on a number of factors. It is important to recognize that an assessment is necessary for each system. Identifying the allergenic material(s) of concern is critical. An understanding of all ingredient processing, handling, and storage, of the product flow through the manufacturing plant, and of the identification of the potential points where cross-contamination can occur is also essential. The allergen-prevention team should review the entire system to determine where the risk of product contamination by an allergen is high and to determine strategies to manage the risk. As system or equipment
Changes and modifications are made the allergen-prevention team must be consulted to re-evaluate the APP.

**Allergen mapping**

Flow diagrams of the process may be used in developing the APP. Since one of the major concerns regarding allergens is cross-contamination of an allergen-free product by an allergen-containing product, a thorough flow chart showing multiple lines may be necessary. Allergen mapping is an approach that begins with preparing a diagram of the equipment that is utilized, highlighting equipment that is used for both allergen and nonallergen products (Figure 1). Figure 1 shows shaded areas that have a higher potential to cause allergen contamination. These highlighted areas are focal points for the allergen-prevention team to concentrate on ways to control or resolve the potential for cross-contamination. Control measures include specific procedures to be included in the sanitation master plan, physical removal of lines with capping off of pipes, lock-out systems, storage and utilization of ingredients, proper documentation of control points, and similar considerations.

Allergen mapping can also be used to assess which processing lines should be used when adding new or reformulated food products to the manufacturing scheme. If a significant portion of the line requires modification or if the down time for proper cleaning after an allergen run is significant, other options might need to be evaluated. Allergen prevention and control is the ultimate goal.

**Ingredients**

It is important not to overlook ingredients when developing the APP. An excellent program could be in place to provide the assurances that there is no cross-contamination of an allergen-free product with an allergen; however, an allergen could unintentionally enter the product stream through an ingredient, not only contaminating the product in which it is intended to be used, but possibly contaminating the entire processing system.

A close working relationship with suppliers is imperative for ensuring that allergens are not inadvertently introduced into the product stream. The ingredient specification should include the statement that the ingredient being purchased is free of foreign material, including allergens that are not listed on the ingredient declaration. Formulated ingredients are of special interest because of the use of multiple components. It is extremely important to confirm that there are no unlabeled allergens in these ingredients. A written specification is still not sufficient to confirm compliance. Close cooperation and communication with suppliers is essential. An on-site audit is recommended to verify that proper practices and procedures are in place to provide assurances of receiving safe and properly labeled raw materials. The supplier should provide a list of materials (or at least of the allergenic type of material) that will be utilized on the processing line on which a manufacturer’s ingredient is being produced. This list should be verified during the audit. Also, the auditor should review the master sanitation schedule and verification steps to assure that the potential for cross-contamination is effectively addressed. It is important to review and verify the supplier’s rework and packaging procedures. The allergen controls in a manufacturing facility with regard to scheduling, traffic patterns, use of rework, labeling, etc., (see below) should be applied at suppliers’ facilities as well. It may be necessary to raise the awareness of suppliers of the importance of food allergies through a training program.

**Engineering and system design**

Systems should be designed wherever possible to minimize allergen-related problems. For example, allergens such as peanuts may be added to a product through a hopper at the end of the product flow, thus minimizing the amount of equipment exposed to the peanut allergen. Systems/equipment should be designed for thorough cleaning and with appropriate access points to verify the system is free of food residues. Such design considerations are particularly important when replacing old equipment or setting up new lines. As noted before, dedicated or isolated lines may need

![FIGURE 1. Allergen mapping: shaded equipment shows potential for cross-contamination.](image)
to be considered for some allergen-containing products. Enclosed systems or systems in which products are well contained can play an important role in allergen control. Line crossovers should be avoided where possible.

**Scheduling**

Scheduling is one of the most practical and easiest approaches to implement and reduce the risk of allergen contamination. Longer run times that minimize changing from one product to another can help minimize potential allergen contamination. When at all possible an allergen-containing product must never be followed by a product that does not contain the allergen. For example, egg noodles should be run after plain noodles, rather than before. By scheduling the allergen-containing product at the end of the manufacturing run, the risk of cross-contamination can be significantly reduced. This precaution does not minimize the importance of proper cleaning and sanitation between product types, but it does simplify the cleaning process and could result in shorter down time for the facility.

**Traffic patterns**

The movement of raw material and ingredients can become a primary source of cross contamination. It is important to cover belts that transport materials to prevent ingredients from falling from one belt to another. While of lesser concern, air drafts or the practice of washing down or blowing off equipment can produce aerosols that could move allergens throughout the facility. Thus, the impact of airflow and in-run cleaning practices on allergen contamination should be considered. It is also important to clearly mark product flow in the plant, especially if three-way valves are utilized. It is advisable to isolate the at-risk products from an equipment standpoint in any way possible.

**Work-in-process and rework**

A food product that is isolated in storage bins, drums, or other containers to be added back into a product stream must be clearly identified. Containers should not be reused unless they are designated for a specific product type or a documented and approved container-cleaning protocol is followed. Rerund and re-feed systems should be dedicated to a particular product whenever possible. Documentation of what the material is, the date of manufacture, etc., is important. There is also a need to document when the material is added back into the product stream, on which line, time of day, for which product, etc. Rework should be audited periodically to ensure that it is properly identified and used. Adequate control of this material is necessary to verify that cross-contamination from rework does not occur.

**Maintenance**

Maintenance tools used in raw and finished product areas need to be considered as potential sources of allergens and managed accordingly. It is important to ensure that tools are not sources of cross-contamination, perhaps by designating, e.g., color-coding, tools for specific areas or by specifying proper cleaning procedures to reduce contamination.

**Packaging and labeling**

Labeling is the primary means a manufacturer has to inform the consumer about potential allergens in a product. Having the correct label on a food product is imperative. An initial evaluation to verify that the draft copy of the package label includes all of the correct ingredients, including allergens, is necessary. Some manufacturers have considered adding an allergen intentionally to a product or to a label (with regulatory approval) because their system design and/or operation cannot assure that it is allergen clean. This practice has been the case with certain candies made on lines where peanut contamination may not be avoidable (13). This is at least a means to protect the consumer until a system can be modified to assure that an effective APP can be implemented.

Verification that the carton or package label matches the finished product formulation is critical. One control system that could be considered to ensure labeling compliance is the addition of bar-code scanners on the production line. This 100% inspection process is useful provided there is documentation that the coder is initially set up properly and that there are audit points to verify that the scanner is functional. If bar-code scanners are not feasible (i.e., for multipacks), color sorters, word scanners, or a similar type of technology can be applied to reduce the risk of mislabeling.

Additional monitoring points that might be necessary include confirming that packaging suppliers are taking every precaution to eliminate mixed bundles of labels or cartons, auditing to confirm that the correct label is selected for the product being run on the line, and auditing to confirm that the label and carton matches the finished product. Particular attention should be paid to labels when an ingredient change or substitution is made.

**Lockout of equipment**

The physical lockout or capping off of equipment for systems that have portions that are designated for allergen-containing or non-allergen-containing products is helpful. This approach provides a physical break in the line, and documentation of the lockout is necessary to confirm that the potential chain of cross-contamination is broken. For example, bulk storage of an allergenic material (i.e., wheat flour) that is metered into a batching operation should be locked out when this ingredient is not in use.

**Allergen-clean system**

Cleanup between product runs is an integral part of the manufacturing operation. Some equipment may need to be disassembled and manually cleaned. Cleanup when changing from an allergen-containing product to a non-allergen-containing product is also extremely important to the safety of the product. Verification that a system is allergen clean should begin with a visual inspection. Ideally the system should be 100% accessible for an operator to visually confirm that the system is free of contaminants. The allergen-prevention team must establish the definition of an allergen-clean system for each processing line. A checklist should be developed to document that the system has been cleaned properly (Figure 2). If the allergen line contains dry
particulates it will be important to determine if there are any areas where particulates may accumulate in the system and then contaminate the next product. It may be possible to engineer these dead spots out of the system. If not, there must be a visual check to confirm that the system is clean. A major problem is that older equipment may not be designed to verify visual cleaning. If at all possible these systems should be designed or modified so that the operator can visually verify that the system is allergen clean. In some cases this may be done by installing sight glasses in the line. Manufacturers should consider dedicating to specific products equipment that is very difficult to clean.

Dust from an allergen-containing product is a potential source of concern. Dust could be on the floor, on the top of enclosed equipment, utensils, employee uniforms, etc. Management of this material, possibly requiring enhanced cleaning, may be necessary in certain situations. Utensils and equipment (scoops, pails, totes, bins, and hoppers) should be dedicated to specific products or thoroughly cleaned between allergen-containing and non-allergen-containing products.

Once appropriate procedures for cleaning are established, steps must be taken to verify the effectiveness of the cleaning procedure. Currently there are no allergen-detection methods validated as appropriate for verifying that a system is allergen-clean. Inhibition radioimmunoassays have been used to detect trace quantities of allergenic proteins in foods (5, 8, 17); however, such assays are based on difficult-to-obtain human antiserum and involve the use of radionuclides (9). Several laboratories are developing commercial ELISA-based procedures for the detection of allergens in foods (9, 16) that could potentially be used as a verification test of the overall cleaning procedure. Thus, current verification practices will typically be limited to visual confirmation.

Training

Employee training programs have proven to be one of the most effective tools for preventing inadvertent contamination with allergens. Videos have been developed to explain the serious nature of food allergies. Some of the most effective videos feature company employees who suffer from food allergies, or whose children have suffered serious reactions from consuming a food with an unlabeled food allergen. Increasing the awareness of the severity of food allergy at all levels of the company, from top executives to production workers and sanitation crews, can result in increased commitment to the APP.

Specific employee training should include a clear definition of an allergen and the consequences of sensitive individuals ingesting allergenic material. Employees should also be trained for control and prevention of allergen contamination, proper documentation of system cleaning, and the control of waste and recycled material. They need to understand the proper mechanism to recognize and report potential cross-contamination with allergens. The plant employee needs to understand the APP and to believe in its importance as a necessary part of the manufacturing operation in providing safe products.

CONCLUSIONS

Allergens can enter the product through various avenues. The presence of food allergens can become a serious problem for sensitive individuals. Food safety is paramount for food manufacturers; preventing food safety hazards includes control of those caused by the presence of inadvertent allergens. The application of an Allergen Prevention Program (APP) to prevent allergens from entering products that are not designed to contain them is a practical way of controlling this safety issue. Identifying points of potential contamination and building a system of prevention is the APP approach to enhancing a food safety process.

ACKNOWLEDGMENTS

The authors are indebted to Dr. J. W. Yunginger for his input to this manuscript. We also thank the National Food Processors Association Microbiology and Food Safety Committee and Food Allergens Task Force for reviewing the manuscript.

REFERENCES