

Protecting Your



...from Food Allergens

► Why are Food Allergens a Concern?

- **One hundred to two hundred deaths per year** are due to allergic reactions to food products.
- **Over 5 million people** - approximately 2% of all Americans and 2-8% of all children suffer from a food allergy of some sort.
- Allergens can result in minor symptoms such as hives or trigger a condition known as anaphylaxis, or a severe reaction involving more than one bodily system simultaneously. It can include hives, vomiting, diarrhea, difficulty breathing, swelling of the mouth, tongue, and throat and a rapid drop in blood pressure. Without quick medical attention, a person can die from this condition. There is no treatment for food allergies other than avoiding the food allergen that causes the reaction.

► Why are Allergens a threat to Food and Beverage Processors?

The number one cause of food recalls each year is the presence or suspected presence of allergens in non-allergen products.

These product recalls are generally due to possible cross contamination of allergens as a result of product residue from an allergen-containing food (e.g., product containing peanuts) coming in contact with a non-allergen-containing food (e.g., product that does not contain peanuts.) This can often occur if the same processing line is used to process allergen-containing foods and non-allergen-containing foods.

► What is a Food Allergen?

Food allergens are specific components of foods that can induce adverse allergic reactions, reactions involving the body's immune system, in those people sensitive to the allergen. Food allergens are all proteins. Extremely small amounts, sometimes less than 10 ppm of the food allergen, when ingested by a susceptible person, can cause an allergic reaction to occur. Most food allergens are highly stable molecules that are resistant to food processing conditions (cooking, freezing, pH, and the digestive process).

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To date, 160 foods have been identified as potential causes of allergic reactions; however, eight major foods account for 90% of all severe allergic reactions suffered by humans. They consist of the following:

- Peanuts
- Milk – cow’s milk is the most common allergen among infants, however this is usually outgrown as the infant matures.
- Eggs
- Shellfish
- Tree nuts
- Soybeans
- Wheat
- Fish

► **Cross Contamination**

Allergen cross contamination between foods can occur in several ways including the following.

- **Insufficient cleaning of product contact surfaces and non-product contact surfaces**—insufficient cleaning could put allergen residue on, or into, a product that would not normally contain the allergen, when the same equipment is used to manufacture both types of products.
- **Lack of Understanding** – manufacturers not fully understanding the risk allergens pose to the public.
- **Procedures** – improper material handling and sampling.
- **Rework** – reworking the same ingredients in different batches of product.
- **Ingredients** – not fully understanding all the constituents in the raw ingredients.
- **Packaging** – packaging changes not coordinated with product changes
- **Labeling** – not properly documenting the presence of allergens on the label.
- **Human Error**

To further the concerns of food allergens to food and beverage processors, the FDA recently stated that it would no longer tolerate voluntary labeling as a substitute for good manufacturing practices. It will no longer be acceptable to label products, “may contain suspected food allergens”.

As the topic of food allergens continues to intensify and become further regulated, what strategies are available to food and beverage processors to protect their brand against allergen cross-contamination and potential product recalls?

► **Strategies Available to Food and Beverage Processors**

There are essentially three strategies available to food and beverage processors to protect themselves from the risk of food allergen cross contamination and potential product recalls.

1. Stop the manufacture of allergen-free or allergen-containing products.
Produce one or the other.
2. Dedicate a line or an entire plant exclusively to the production of allergen-free products.
3. Development of an allergen prevention plan and verification of the effectiveness of the current cleaning program. The allergen prevention plan strives to prevent allergens from entering products not designed to contain them.

Options #1 and #2 are largely driven by economic and market factors that will be specific to each organization. Since each organization's internal decision-making process will dictate the feasibility of these options, we will focus our attention on option #3 – development of an allergen prevention plan and verification of the effectiveness of the current cleaning program.

If an organization decides to accept the risk and continue processing both allergen and non-allergen-containing products in the same plant or on the same line, it is important to institute the following procedures in development of an allergen prevention plan.

- **Allergen mapping** – consists of highlighting equipment that is used for both allergen and non-allergen products. The highlighted areas must have adequate controls in place to prevent potential cross-contamination of allergen products. Examples include lock-out systems and proper storage and utilization of ingredients.
- **Ingredients** – all ingredient specifications should include the statement that the ingredient being purchased is free of foreign material, including allergens that are not listed on the ingredient declaration.
- **Engineering and system design** – systems should be designed wherever possible to minimize allergen-related problems. For example, adding an allergen-containing product or ingredient at the end of a process flow minimizes the amount of equipment exposed to the allergen. In addition, processing equipment should allow for thorough cleaning with access points, which can be used to verify the equipment is free of food residues.

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- **Traffic patterns** – the movement of raw materials 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.
- **Work-in-process and rework** – a food product that is isolated in storage bins or other containers to be added back into a product stream must be clearly identified. Use rework only in products containing the same ingredients.
- **Maintenance** – maintenance tools used in raw and finished product areas need to be considered as potential sources of allergens and managed accordingly. This can include using color-coded tools specific to certain areas of the plant or to specific lines.
- **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. Verification that the carton or package labels match the finished product formulation is also critical.
- **Scheduling – development of a non-allergen to allergen manufacturing sequence** – scheduling is one of the most practical and easiest approaches to implement in reducing 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, production of an allergen-containing product must never be followed by production of a product that does not contain the allergen. By scheduling the allergen-containing product at the end of the manufacturing run, the risk of cross-contamination can be significantly reduced.
- **Training** – employee-training programs have proven to be one of the most effective tools for preventing inadvertent contamination with allergens. Specific employee training should include a clear definition of an allergen and the consequences of sensitive individuals ingesting allergenic material.
- **Effective cleaning program** – a full thorough cleanup when changing from an allergen-containing product to a non-allergen containing product is extremely important to the safety of the product. It is also critical to evaluate the effectiveness of a cleaning program in removing allergen products and preventing possible cross contamination. For specific products and procedures, contact your Ecolab representative.

► **Verification**

Once completed, all cleaning programs should be followed with a visual inspection to verify the system is clean and particle free. Unfortunately, there are no allergen detection methods available currently that can validate whether cleaned equipment systems are 100% allergen free.

In addition to thorough cleaning, several other procedures are useful in ensuring sufficient allergen removal:

- Up-to-date monitoring and recording to ensure effective and complete cleaning.
- ATP bioluminescence technology, using ATP monitoring programs, can be helpful in verifying that equipment has been effectively cleaned.

In spite of an effective cleaning program, several caveats are still present and must be considered by the processor.

- Ensuring that 100% of all surfaces are effectively and thoroughly exposed to the cleaning program every time they are cleaned.
- Ensuring that no allergen-containing material is remaining in hard to reach areas, on both food contact and environmental surfaces that could fall into product during production. Even dust in the air from an allergen-containing product coming into contact with a non-allergen containing product could cause potential cross contamination concerns.

► **Conclusions**

Regardless of the procedures utilized, there will always be risk to food and beverage processors if they decide to produce both allergen and non-allergen-containing products in the same plant. There is no method that provides 100% assurance of complete absence of allergens other than not producing an allergen-containing product.

Once the appropriate strategy is chosen it is critical that plant workers are trained and held accountable on the importance of food allergens. Proper and clear labeling of products is also essential. In summary, an allergen prevention plan consisting of awareness, planning, training, labeling, and effective cleaning will help you “Protect Your Brand” by greatly diminishing the threat of allergen cross contamination and potential product recalls. Additional information on food allergens is available by contacting the following organization:

Food Allergy Network
10400 Eaton Place
Suite 107
Fairfax, VA. 22030
Phone: 703-691-3179
Fax: 703-691-2713

For specific products and procedures, contact your Ecolab Representative.

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