



# **GUIDELINE FOR FOOD ALLERGEN AWARENESS IN DAIRY PLANT OPERATIONS**

Publication: DPC080

**JUNE 2021**

Prior Version – June 2005

**APPROVED COPY  
EXCEPTIONS FOR INDIVIDUAL STATES NOTED IN TEXT OR  
FOOTNOTES**

**Additional Guidelines may be ordered from:**

<https://www.dairypc.org>  
[evp@dairypc.org](mailto:evp@dairypc.org)



## Guideline Preparation and Review Process

Guideline development within Dairy Practices Council (DPC) is unique and requires several levels of peer review. The first step in the process of guideline development starts with a Task Force subcommittee comprised of individuals from industry, regulatory and education interested in and knowledgeable about the subject to be addressed. Drafts, referred to as ‘white copies,’ are circulated until all members are satisfied with the text. The final white copy may then be distributed to the entire Task Force, DPC Executive Vice President and whoever the Task Force Director feels would add to the strength of the review. Following final white copy review and correction, the next step in the process requires a yellow cover draft that is circulated to the member Regulatory Agency representatives that are referred to as “Key Sanitarians.” The Key Sanitarians may suggest changes and insert footnotes if their state standards and regulations differ from the text. After final review and editing the guideline is distributed in the distinctive DPC green cover to people worldwide. These guidelines represent the state of the knowledge at the time they are written.

## Disclaimer

The DPC is not responsible for the use or application of the information provided in this Guideline. It is the responsibility of the user to ensure that the information addresses their needs and that any action taken complies with appropriate regulations and standards.

### **DPC is a Registered Trademark of the Dairy Practices Council®**

*Reproduction or use in whole or in part of any text or graphic content without written permission from the DPC is prohibited.*



# TABLE OF CONTENTS

Cover Page .....	i
Guideline Preparation and Review Process .....	ii
Disclaimer .....	ii
TABLE OF CONTENTS.....	1
INTRODUCTION .....	2
DEFINITIONS.....	2
GUIDELINE CONTENT .....	2
What Is A Food Allergy? .....	3
What are Some Common Food Allergen Reactions?.....	3
What Foods Are Frequently Food Allergens?.....	3
A Note About Nuts .....	4
How Common Are Food Allergens? .....	4
Developing A Food Allergen Awareness Program .....	4
Organization and Commitment .....	4
The Food Allergen Awareness Program .....	4
Identify Food Allergens in your Operation .....	5
Identify Failures Which Cause Food Allergen Risks (Means of Failure) .....	6
Failure 1. Incorrect Formula.....	6
Failure 2. Incorrect Rework.....	7
Failure 3. Mislabelled Product .....	7
Failure 4. Sanitation Control .....	8
Failure 5. Cross-Contamination .....	8
Develop a Food Allergen Control Plan .....	9
Background Information to Aid in Putting your Plan Together.....	10
Food Allergen Awareness Training .....	13
Other Training Ideas:.....	13
REFERENCES .....	14
APPENDIX.....	14
CURRENT ACKNOWLEDGEMENTS .....	14
Officers.....	14
Task Force Director.....	14
Lead Author(s) .....	14
Contributor(s) .....	14
HISTORICAL ACKNOWLEDGEMENTS .....	15



# INTRODUCTION

Recalls involving food allergen ingredients are the number one cause of food product recalls in the United States. A program to properly manage the food allergen ingredients in your dairy is essential in preventing life-threatening incidents and recalls. Managing food allergens requires that all employees become “aware” of the procedures and techniques necessary to properly deal with food allergens every day. By following the procedures outlined in this guideline, you will have the tools necessary to begin and maintain a Food Allergen Awareness Program.

Foods that cause allergic reactions or food allergens can cause major problems to dairy processors if they are unaware of what food allergens are and how they must be managed. Processors must be aware that even trace amounts of a food allergen can cause allergic reactions for some consumers.

Food allergen awareness is a universal requirement for dairy processors. Production workers are not the only ones that need to be aware of food allergens. Personnel in other departments, such as raw ingredient receiving, sanitation, warehousing, Research & Development (R&D), purchasing, Quality Assurance (QA), advertising, labeling, and customer service must be aware of food allergens and the effect they have on the way they approach their jobs. Be sure to include personnel that take phone calls from consumers. If a consumer is reporting an allergen incident, it is important that the consumer’s first impression be one of a company that is aware of food allergens.

This guideline will review food allergens and outline key elements of an effective food allergen awareness program that should be included in the standard operating procedures (SOP) in every dairy plant.

# DEFINITIONS

**ARAT** – Allergen Risk Assessment Team

**R&D** – Research and Development

**QA** – Quality Assurance

**SOP** – Standard Operating Procedures

**HACCP** – Hazard Analysis Critical Control Point

**CIP** – Clean in Place

**PM** – Preventive Maintenance

# GUIDELINE CONTENT

Practicing food allergen awareness must be an SOP for dairy plants. Strict adherence to the procedures outlined in this guideline should reduce or eliminate food allergen related recalls and in-house incidents. Keep in mind that most food allergen incidents are the result of mislabeling and virtually all mislabeling problems can be prevented! The bottom line is that food allergen awareness is everyone’s responsibility.



## **What Is A Food Allergy?**

When a person has an immune system response to a normally harmless food and reacts as if the food is a harmful agent, they have experienced a food allergen reaction. Normally, people that know they are allergic to specific foods avoid them. They do not knowingly consume these foods. They develop avoidance strategies such as reading food labels, asking what is in a restaurant prepared meal, and generally avoiding anything that may be suspect.

Consumers of food products rely on ingredient labels to determine when there is an ingredient they must avoid. Consumers are relying on accurate and complete labeling as their defense against an allergic reaction. *All ingredients in a product must be shown on the label!* This topic will be addressed in detail later.

### **What are Some Common Food Allergen Reactions?**

Food allergen reactions can be serious. The following list shows the common reactions a person has after ingesting or being exposed to a food to which they are allergic. This list is shown in progressively worsening order and represents the most common way a reaction occurs in people:

- Hives
- Abdominal Cramps Vomiting
- Diarrhea
- Difficulty Breathing
- Swelling of the Tongue, Throat, Face & Lips
- Asthma
- Rapid Drop in Blood Pressure
- Unconsciousness
- Anaphylactic Shock
- Death

Allergic reactions to foods usually begin within seconds to a few hours after eating the offending food. In very sensitive people, simply touching or smelling the food can produce an allergic reaction.

## **What Foods Are Frequently Food Allergens?**

There are many foods that may be food allergens but more than 90% of the food allergen incidents in the United States are caused by just eight foods which are frequently used as ingredients in other foods. These are listed in order from the most to the least common (the Top 8)<sup>1</sup>:

1. Peanuts
2. Tree Nuts (e.g., almonds, pecans, walnuts)
3. Crustacean Shellfish (e.g., crab, lobster, shrimp)
4. Eggs
5. Milk & Dairy Products
6. Fish (e.g., bass, flounders, cod)

---

<sup>1</sup> Reference: Food Allergen Labeling and Consumer Protection Act of 2004.



7. Soy
8. Wheat

The other 10% of the food allergen incidents in the U.S. are caused by hundreds of other foods. The Top 8 comprise food allergens across all food industries. In this guideline, we will specifically focus on the food allergens that are most common in the dairy industry.

NOTE: Sesame seeds were added as a 9<sup>th</sup> food allergen. This is effective January 1, 2023.

## **A Note About Nuts**

Peanuts and tree nuts (e.g., almonds, walnuts, macadamias, hazelnuts (filberts), cashews and others) are considered among the Top 8 food allergens found in foods in the U.S. Peanuts by far are the number one cause of food allergen incidents. Some people may be allergic to peanuts and not to tree nuts, while other people maybe allergic to tree nuts and not peanuts. In fact, a person who is allergic to one tree nut may not be allergic to other tree nuts. Some people who are allergic to tree nuts are allergic to coconuts, even though coconuts are not considered a nut. This makes it extremely important to use the correct nut as an ingredient in your products and be sure your labeling is accurate.

## **How Common Are Food Allergens?**

The prevalence of possible food allergies in the U.S. population varies. Here are some average statistics:

- Adults – 2% of the adult population have a food allergy.
- Infants and Young Children – 5% of the population of infants and young children have a food allergy.
- Approximately 6 million people have a peanut or tree nut allergy.
- Each year approximately 30,000 people require emergency treatment and 150 people die from food allergen related problems.

## **Developing A Food Allergen Awareness Program**

### **Organization and Commitment**

To deal with food allergens in dairy operations, a Food Allergen Awareness Program must be started. You can begin by organizing a team representing quality, manufacturing, sanitation, engineering, warehousing, distribution, R&D, customer service, purchasing, public relations, and legal. Everyone needs to be involved in food allergen awareness. In small dairy operations, many responsibilities are spread over just a few individuals who then must be the key people in a Food Allergen Awareness Program.

## **The Food Allergen Awareness Program**

One approach is to select key individuals and organize an Allergen Risk Assessment Team (ARAT). *This requires total commitment from the company's owners and management.* Without this commitment, the necessary changes for dealing with food allergen risks will be difficult to



make. A Food Allergen Awareness Program requires total buy-in from top to bottom to make it work.

In order to have a successful Food Allergen Awareness Program, the ARAT must look at **four major areas**:

1. Identify all food allergens in your operation
2. Identify the food allergen risks or means of failure
3. Develop a food allergen control plan
4. Develop a food allergen awareness training program

### Identify Food Allergens in your Operation

A comprehensive survey of *all ingredients* used in the operation must be undertaken to determine which ingredients contain food allergens. This will require reviewing all ingredient labels and ingredient specifications. If there is a question about a particular ingredient, check with the manufacturer to find out if the ingredient is made with anything possibly considered as a food allergen. In fact, all ingredients in your operation should be purchased under an ingredient specification which lists exactly what you intend to purchase.

This specification should be detailed enough to provide the supplier with an accurate list of what you expect to be in the ingredient. Suppliers must have a Food Allergen Awareness Program and have safeguards in place so they are not supplying you with ingredients that may be contaminated with food allergens. For example, if a supplier of pecans also manufactures peanut ingredients, make sure the supplier has safeguards in place to prevent cross contamination of the two nuts.

The key food allergens that may be present in a fluid milk plant include eggs, milk & dairy products, soy, possibly in some plants tree nuts such as almonds and some flavorings and colorings.

The key food allergens that may be present in other dairy plants, including ice cream plants, include peanuts, tree nuts, wheat gluten, milk and dairy ingredients, eggs, soy, flavorings and colorings, and sulfite preservatives.

Here are some examples of each:

**Peanuts:** peanuts, peanut brittle, peanut coatings, and peanut butter

**Tree Nuts:** almonds, walnuts, hazelnuts (filberts), macadamia nuts, cashews, and others.

**Eggs:** egg yolks, egg whites, sugared egg yolks, liquid eggs, dried egg powders, and egg blends.

**Milk & Dairy Products:** milk, cream, skim, milk powders, casein, butter, yogurt, cheese varieties, ice cream and shake mix blends, and other dairy containing ingredients. These are typically found in a dairy plant but can be food allergens when they come in contact with non-dairy products such as sorbets, fruit juices, water, ices and other non-dairy ingredients and products.



**Soy:** lecithin, soy milk & soy milk powders, some baked goods like cookies, some yogurt or cheese cultures, and other soy ingredients.

**Wheat Gluten:** flour used to make cookies, cookie crisps, cookie dough, sandwich wafers, and other wheat-based ingredients.

**Flavorings and Colorings:** various flavors and colors (both natural and artificial). These are not on the Top 8 list but do cause allergic reactions in sensitive individuals. Labeling of these ingredients must be specific.

**Sulfites:** sulfiting agents, sulfite preservatives, and other sulfite compounds. These are not typically considered true food allergens, but some individuals are highly sensitive to these sulfites, so they need to be properly used and labeled.

**A Note about Nut Oils:** Many nut ingredients are fried or baked in a process using nut oils. It is not uncommon to process almonds, cashews, and other nuts with peanut oil. Nut oils are usually highly refined and during the refining process, the protein portion of the nut (the part that may cause allergen reactions) is not usually carried into the oil. High-grade nut oils contain virtually no protein. Some lower grade oils are not highly refined and may contain nut proteins. It is important to check with your nut suppliers to verify they are using the proper oils to process the nuts you buy. By using the same variety of oil as the variety of nut being processed, the problem of protein carryover is eliminated. *If a nut ingredient is processed with different variety nut oil, the oil must be declared as an ingredient.*

### Identify Failures Which Cause Food Allergen Risks (Means of Failure)

Food allergen problems can occur in many ways in a dairy operation. When a system or procedure breaks down, this can cause a means of failure, which allows unintentional food allergen contamination of your products. Most food allergen contamination results in mislabeled product and mislabeling is the number one cause of food allergen product recalls. The following five means of failure present the most common food allergen problems. These are typical in all food manufacturing plants and may be considered for inclusion in your Food Safety Plan or Hazard Analysis Critical Control Point (HACCP) Program.

#### Failure 1. Incorrect Formula

- Wrong formula used: If an operator mistakenly uses the wrong formula when making a product, food allergen ingredients may be included. Or, if the formula is written wrong or entered in the computer incorrectly, this can result in food allergen ingredients being used in product that is incorrectly labeled for the actual ingredients it contains.
- Wrong ingredients used: If an operator by mistake adds the wrong ingredients to a product, this can result in a food allergen being added to a product that is not labeled with the allergen as an ingredient.



## Failure 2. Incorrect Rework<sup>2</sup>

- Rework is mislabeled or the labeling is illegible: This failure may cause the inadvertent use of an allergen containing rework to be used in a product that should not contain the allergen.
- Wrong rework used: If an operator inadvertently uses the wrong rework in a formula, it may cause an allergen to get into the product.
- Non-allergen rework is cross-contaminated with an allergen: In this instance, an allergen-containing rework is inadvertently contaminated or mixed with non-allergen-containing rework. Then, this rework gets used in a formula that does not contain food allergens and contamination results.

## Failure 3. Mislabeled Product

Mislabeled product may involve printing or proof-reading mistakes, packaging supplier mistakes, and changes in formulations without changes in packaging:

- Keyline or proof mistakes: Marketing and technical personnel must carefully proofread new labels prior to printing and use. If not reviewed carefully and checked against the product formula, ingredient and labeling mistakes can easily slip by unnoticed.
- Switched or incorrect packaging: Production personnel can inadvertently bring the wrong packaging out to the production line. Sometimes, packaging is intended to be used in a certain order. This order can be switched, and the incorrect packaging gets used by mistake. This is particularly devastating when the packaging line is producing an allergen-containing product, but a non-allergen labeled container is used by mistake.
- Switched or incorrect ingredients: Production personnel may inadvertently switch ingredients resulting in the use of the wrong ingredients in a batching formula (also see Failure 1.) This is disastrous when the incorrect ingredient is a food allergen.
- Mixed packaging: Packaging suppliers, if they are not careful during their changeovers, can mix two different types of packaging in the same box. This is devastating to a plant that may be producing an allergen-containing product and have a non-allergen containing package mixed in. It is important to specify to your suppliers that mixed packaging can cause major problems to your operation. Packaging suppliers should have a changeover sequence that goes from a non-allergen labeled package to an allergen labeled package, clearly indicating a change in packaging.
- Ingredient declaration not accurate: If the formula contains a food allergen, it must appear on the ingredient declaration. This is extremely important to those consumers who are aware that they have a food allergen and rely on ingredient labeling to avoid those foods. If it is in your product, it must be shown on the ingredient label of every container or package.



<sup>2</sup> Refer to DPC063, *Controlling the Quality and Use of Dairy Product Rework*.

### Failure 4. Sanitation Control<sup>3</sup>

Cleaning and sanitation are extremely important in preventing food allergen problems. It has been shown that even minute amounts (<200ug) of an allergen can cause a reaction in individuals who are very sensitive.

- Improper manual sanitation practices: If processing equipment is left dirty or was improperly cleaned, the residues may contain enough of a food allergen to get carried through to the finished product and cause an allergic reaction. Parts that require manual cleaning should be thoroughly inspected prior to use to be sure that the equipment is clean and ready to run.
- Time/Temperature/Concentration deficiencies: When time, temperature or cleanser concentration deficiencies occur in mechanical cleaning systems [Clean in Place (CIP) systems], there is a likelihood that food allergen residues can remain on product contact surfaces and recontaminate the next product.
- Equipment failures: Stuck valves, incomplete drainage of vessels, and other equipment failures will cause cross contamination of products. A thorough equipment preventive maintenance (PM) program, designed to check seals, gaskets and air valves will prevent most of these problems before they happen. Also, daily pre-operative (pre-op) inspections, which include checking for complete drainage before a tank is used, are recommended.

### Failure 5. Cross-Contamination

- Inadequate cleaning of multi-use equipment: Equipment is used in most operations to produce both non-allergen and allergen-containing products. When a piece of equipment that previously ran products containing food allergens is inadequately cleaned prior to producing a non-allergen product, there is a possibility that cross contamination can occur. This makes pre-operative equipment inspections extremely important.
- Equipment failures: As mentioned above in Failure 4, equipment failures may allow allergen-containing foods to get into non-allergen containing foods. Again, a PM program with frequent inspections of equipment such as valves is necessary.
- Direct connect lines: A physical break in the lines should be considered if two or more products are being pumped at the same time. Example: If a plant is pumping milk and liquid eggs, a physical break is needed in the line to ensure that the milk and/or eggs are not pumped into the wrong product.

The solution to cross-contamination is to have dedicated (single product use) equipment for non-allergen products and separate equipment for allergen-containing products. This has to include all processing and packaging equipment that comes into contact with the food allergen. Ultimately, separate buildings to process allergen vs. non-allergen products would solve the cross-contamination problems, but since most dairy plant equipment is very expensive, the cost of having dedicated equipment or buildings is usually prohibitive.

---

<sup>3</sup> Refer to DPC029, *Cleaning and Sanitizing in Fluid Milk Processing Plants*.



The alternative is to have a Food Allergen Awareness Program with all the prerequisites such as preventive maintenance, and pre-op inspections.

## Develop a Food Allergen Control Plan

All Food Allergen Control Plans should include:

- A listing of all food allergens in your plant: Start with the Top 8 and look for these ingredients in your products. Be sure to check with ingredient suppliers and make sure their ingredient specifications match your ingredient specifications.
- Production Scheduling and Batch Sequence Procedures: If your operation makes both allergen-containing and non-allergen containing products using the same equipment and you do not conduct a full CIP in between products, you will need to sequence the production to make allergen-containing products last. This may require some major changes in the production schedule and may even cause some inefficiency. Allergen awareness training of your production scheduling personnel is imperative and will prevent problems. Written and posted procedures of your production schedule are required. Batch sequencing procedures need to specify that allergens are run last. Again, this may cause some inefficiency in your operation, but it is essential to prevent ingredient allergen issues.
- Changeover Standard Operating Procedures (SOP's): If your operation produces both allergen-containing and non-allergen containing products using common equipment, you will need to schedule the operation to process and package allergen-containing products last to be as safe as possible. Written and posted Changeover SOPs are required.
- Rework SOP's: How rework is handled in your operation needs to be documented into a written procedure. Again, procedures should include handling allergen-containing rework last.<sup>4</sup>
- Sanitation SOP's: You need written and posted procedures on how to clean and sanitize all processing and packaging equipment. When writing these procedures, take into account food allergens and any special requirements necessary to properly clean and rinse your processing and packaging equipment.
- Label/Formula/Product Match Procedures: A procedure must be in place to verify that the product you are producing on a filling line has been produced with the correct formula, that the correct packaging is being used, and that the contents are the right product. This verification should be done on the first sample produced and re-verified whenever new packaging is put on the line. It should be repeated after every changeover to a new product. Consider using bar code readers on the conveyor line to verify correct packaging is being used throughout the day. This Label/Formula/Product Match step should be part of a Prerequisite Program in your Food Safety Plan or HACCP program
- Verification Records: Records to verify that all procedures are being followed should be part of the Allergen Control Plan. These records should be verified daily by supervisors.

---

<sup>4</sup> Refer to DPC063, *Controlling the Quality and Use of Dairy Product Rework*.



## Background Information to Aid in Putting your Plan Together

- **HACCP and Allergens:** Your HACCP program should consider food allergens as chemical hazards in your process. The procedure to match label, formula, and product (refer to Failure 5 above) should be part of a Prerequisite Program to manage food allergens. Also, Allergen Awareness must be recognized along with other HACCP prerequisites such as Good Manufacturing Practices (GMP's), Sanitation, Chemical Control, Specifications, Supplier Control, Training, and Product Trace and Recall.
- **New Products:** All new products must be reviewed for food allergens prior to production. Food allergen control strategies must be set up prior to manufacturing to include new product packaging, production scheduling, classifying rework, special needs on sanitation, cross-contamination possibilities, and other areas to ensure a good manufacturing procedure.
- **Ingredient Storage:** Ingredients containing food allergens must be stored in specific areas and be properly labeled. Warehouse personnel must become “allergen aware” and take precautions not to mix ingredients. To avoid mix-ups, keep all nut varieties and nut-containing ingredients separated, with like kinds stored together.
- **Container/Ingredient Control:** All containers used to store processing ingredients must be clearly labeled. Pails, containers, and utensils that are used to store, prepare, or transfer allergen-containing ingredients must be either single service or plainly marked and used only for one particular ingredient. Color schemes or specific markings should be used to identify different classes of containers and utensils.
- **Design Controls:** The following need to be reviewed to prevent potential food allergen cross-contamination conditions:
  1. Employee traffic and product patterns need to be reviewed for opportunities for cross-contamination. Example: Are employees who just prepared peanut butter ice cream then reassigned to work on the packaging line of another flavor? If so, they will need to “decontaminate” themselves of any peanut residue prior to leaving the original area. This may mean changing clothing, footwear, and other items.
  2. Maintenance and repair procedures need to be reviewed. Example: A mechanic that previously worked on equipment that produced an allergen-containing product now is reassigned to work on a machine where non-allergen product is being produced. Did the mechanic “decontaminate” himself, his tools, and the equipment so there is no chance for cross-contamination? This may require washing tools, changing clothes, and other steps to eliminate cross-contamination.
  3. Air handling (HVAC) and compressed air systems must be checked to prevent food allergen powders or residue from getting into the system and cross-contaminating another area of the operation.
  4. Filtration systems: Mechanical filters and screens of filtration systems in use while producing an allergen-containing product must be thoroughly cleaned of residue before being used for another product.



5. CIP Systems and Mechanical Cleaning: Ideally, dedicated CIP systems and lines should be used to wash allergen-containing equipment to prevent cross-contamination. If dedicated CIP systems are not feasible, then single-use CIP wash tanks, where the tank is completely emptied and cleaned prior to re-use, should be considered. If dedicated or single-use systems are not being used, then wash allergen-containing lines and tanks last to prevent any possible carry-over of allergens into non-allergen product. Procedures need to be developed to remove heavy residues, such as peanut butter, nut paste, egg yolks, and other residues. Product flow must be reviewed to prevent possible cross-contamination conditions. Include possible piping cross-contamination, temporary pipeline hook-ups, valve clusters, gate valves, dead-end piping, and other possible areas of concern. In plants where piping changes frequently take place or where there is remodeling, review the blueprints and check each change on a quarterly basis (or more frequently), checking for cross-connections and dead-ends.
- Labeling: Once a person is confirmed to have a food allergy, the only proven therapy is for them to avoid the offending food. This makes correct food labeling critical. If a food allergen is in your product, be sure it states that on the label.

Guidelines to prevent labeling issues:

1. Develop a system to verify that the correct packaging is being used on the production line. This may include barcode scanning devices that verify the label matches. Caution should be taken to be sure the correct barcode is verified and printed on the package.
2. Ingredient labels must be present on all products containing food allergens. This includes multi-packs, components, small packages, promotional products, and other packaging.
3. Date coding and military time of day must be shown on all products produced on a line that packages food allergen products. If a product trace or recall is required due to contamination with an allergen, military time will allow you to pinpoint the production.
4. Recording lot numbers and/or box numbers of the ingredients and packaging used is necessary when conducting a product trace or recall. Again, these allow you to pinpoint the time when incorrect packaging or ingredients were used.
5. Daily production records, which inform production personnel what products to make, must also include the packaging/labeling requirements for each product.
6. Packaging inventories must be periodically monitored to prevent the use of obsolete, outdated packaging. Many times, labeling and ingredient declarations change due to a change in formula, but the old packaging is not disposed of in a timely manner and can remain in the warehouse and be used incorrectly.
7. Verify that ingredient suppliers have a program in place to ensure that all of their ingredients are properly labeled and declared.



- **Precautionary Labeling:** This is labeling products with statements such as may contain (insert name of allergenic ingredient). FDA states that such precautionary labeling should not be used in lieu of adherence to GMP's. FDA states "Take all necessary steps to eliminate cross-contamination and to ensure the absence of the identified food". However, precautionary labeling may be warranted in situations where allergen-contamination is likely despite adherence to GMP's.
- **Rework:** A policy must be in place which outlines the products that are reworkable, into which products they can be reworked, and the percent allowable.
  1. A policy of like into like is preferred.
  2. Rework must be documented and traceable from its original production into its final use.
  3. Clearly labeled storage containers must be used for rework. Rework containing food allergens must be in dedicated containers with plastic liners. Use a color-coded container policy to identify different allergen ingredients.
  4. Rework that contains nuts or cookies presents special problems for an ice cream operation. Some operations will try to strain the nuts and cookies from the rework prior to incorporating it back into the process. Straining and filtering may take out the large pieces of nuts or cookies, but the nut fines and cookie crumbs remain in the rework. Most of this rework will require pasteurizing prior to use. Nut fines and dissolved cookie pieces are being introduced into the pasteurizer, where pieces may collect in the small spaces between the pasteurizer plates. This creates a cross-contamination incident for products that are run after the rework. Contamination has occurred days and even weeks later. It is *strongly* recommended that ice cream plants do not rework nutted or cookie containing products unless they have dedicated systems for producing those flavors.
- **Sanitation:** Sanitation and cleaning procedures must be established and verified for cleaning between products that use food allergens. This includes cleaning the pasteurizer system, storage tanks, lines, valve groups, flavor vats, nut and fruit feeders, and packaging equipment. Cleaning must be documented.
  1. CIP systems must be monitored and documented for proper time, temperature, and chemical strength.
  2. Cleaning and sanitizing effectiveness must be verified prior to line start-up by documented visual pre-op inspections. Use ATP Bioluminescence Hygiene Monitoring and/or bacterial swabs to verify cleaning effectiveness.<sup>5</sup> Some ATP kits allow sampling of the final rinse water from CIP systems. This may indicate problem lines and circuits that are not cleaning and/or rinsing properly. ATP and bacterial swabs may not detect food allergen residues but will give an indication of gross contamination.
- **Testing:** On shared equipment, after producing an allergen-containing product, it is imperative to know how effective the cleanup was to insure there are no carry-overs of

<sup>5</sup> Refer to DPC060, *Troubleshooting Microbial Defects in Dairy Processing Plants*.



allergen substances into the next product. After an allergen run and subsequent sanitation cycle, testing the final sanitizer rinse for the previous allergen protein may be an option and will give you an indication of cleaning effectiveness. Be sure to verify with the test kit manufacturer that the allergen test you are running is not affected by the presence of the sanitizer in your system. Any modification of standard cleaning procedures (i.e. “quick wash”) must be validated for allergen removal prior to being used as a standard operating procedure. Food Allergen tests are now available for most food allergens.<sup>6</sup> If testing is done, be sure the test is sensitive enough to detect the levels that could cause an allergic reaction. In cases where a test is not available or not being used, it is imperative that a thorough pre-op inspection be performed on the processing equipment that ran a food allergen, prior to running the next, non-allergen product. Consult your state university’s food science department Extension Specialist for more information.<sup>7</sup>

### *Food Allergen Awareness Training*

Allergen awareness, continuous monitoring, and training are key components of an effective Allergen Control Program.

Here are some areas to cover when developing training for your food allergen program:

1. What is an allergic reaction?
2. What are the key food allergens found in your plant?
3. What is the risk to your company?
4. What can employees do to prevent food allergen incidents?
5. Training for personnel that respond to consumer complaints. These people must have specific instructions on what to do, how to respond, and what to say when faced with an allergen related complaint. When a consumer calls a company, their first impression of how aware a company is of food allergens is critical to successfully resolving the complaint.

### *Other Training Ideas:*<sup>8</sup>

- Post awareness posters.
- Discuss with family and friends who have allergens.
- Show photos of cross-contamination or poorly cleaned equipment.
- Discuss high-risk areas.
- Discuss the financial impact on the business.
- Develop internal training materials.
- Show food allergen videos.

---

<sup>6</sup> Refer to references to suppliers of food allergen tests.

<sup>7</sup> The University of Nebraska’s Food Allergy Resource and Research Program (FARRP) is a valuable resource for food allergy information and testing. FARRP can be reached at 402-472-4430 or email at [farrp@unl.edu](mailto:farrp@unl.edu). Website: [www.farrp.org](http://www.farrp.org).

<sup>8</sup> Join the Food Allergy & Anaphylaxis Network (FAAN) (Membership information available by calling 800- 929-4040, email: [faan@foodallergy.org](mailto:faan@foodallergy.org), or website: [www.foodallergy.org](http://www.foodallergy.org).



## REFERENCES

- Biotrace International, Inc. 800-729-7611, customerservice@intlbioproducts.com, [www.biotraceamericas.com](http://www.biotraceamericas.com)
- ELISA Technologies, Inc., 352-337-3929, info@elisa-tek.co, [www.elisa-tek.com](http://www.elisa-tek.com)
- Diffchamb, Inc., 866-343-3242, sales@diffchamb.com, [www.diffchamb.com](http://www.diffchamb.com)
- Giene Technology from Charm Sciences, Inc., 800-343-2170, info@charm.com, [www.charm.com](http://www.charm.com)
- Neogen Corp., 800-234-5333, foodsafety@neogen.com, [www.neogen.com](http://www.neogen.com)
- Tepnel Biosystems, 888-329-0255, inquiries@tepnelbiosystems.com, [www.tepnel.com](http://www.tepnel.com)

## APPENDIX

None.

## CURRENT ACKNOWLEDGEMENTS

*\*This guideline was developed by contributors who are of experienced individuals in a related field(s). The acknowledged persons are included with their professional affiliations and may be contacted via a DPC Officer(s) and/or Task Force Director(s) for questions or concerns.*

### Officers

Name	Position
Chris Hylkema	President
Keith Hay	Vice President
Mary Wilcox	Executive Vice President

### Task Force Director

Jessica Smith, Laboratory & Quality Control Procedures Task Force

### Lead Author(s)

Brooke Pepin, USDA-FMMA

### Contributor(s)

- |                                |                           |                             |
|--------------------------------|---------------------------|-----------------------------|
| • Jessica Smith<br>(USDA-FMMA) | • Heather Torino<br>(AGM) | Carli Peskar<br>(USDA-FMMA) |
|--------------------------------|---------------------------|-----------------------------|



# HISTORICAL ACKNOWLEDGEMENTS

## Version(s)

June 2005

- |  |   |  |
|--|---|--|
| • Patrick Cleary<br><i>(St. Albans Coop.<br/>Creamery, Inc.)</i> | • Jeffrey Bloom<br><i>(Johnson Diversy)</i> | • Rebecca Piston<br><i>(H.P. Hood, Inc.)</i> |
|--|---|--|

August 1999

- |   |   |   |
|---|---|---|
| • Steve Murphy<br><i>(Cornell University)</i>                       | • Jeffrey Bloom<br><i>(Haagen-Dazs)</i>                                       | • Sidney Barnard<br><i>(Penn State, Retired)</i>                      |
| • Craig Boyd<br><i>(MD &amp; VA Milk Producers<br/>Cooperative)</i> | • Shelly Carr<br><i>(Kemp Foods, Inc.)</i>                                    | • Cary Frye<br><i>(IDFA)</i>  |
| • David Hakes<br><i>(Ben &amp; Jerry's Ice Cream)</i>               | • Allison Jewel<br><i>(West Lynn Creamery)</i>                                | • Byron Moyer<br><i>(Vermont Dept. of Ag.<br/>Food &amp; Markets)</i> |
| • Rebecca Piston<br><i>(Garelick Farms of Maine)</i>                | • Harold Rudnick<br><i>(NY State Dept. of Ag. &amp;<br/>Markets, Retired)</i> | • Yolanda Villella<br><i>(Turkey Hill Dairy)</i>                      |

