

REVISED JULY 2022



Retail Allergen Resource Document





Introduction

CASE STUDY:

Food Allergy Causing Anaphylaxis at a Grocery Deli

It was a typical day at the local grocery store. The smell of fresh baked cookies from the bakery welcomed customers as they entered the store. The deli was busy serving customers sliced meats and cheese. Fresh cut produce was being prepared for the after school dinner rush while the meat department was cleaning the beef grinder and other equipment.



Mr. Smith was a regular customer and always enjoyed the service from his local store. This day he approached the deli counter asking for a sandwich to be prepared. Mr. Smith was very intrigued with the new home style salad dressings that were the talk of the town. Fresh turkey, lettuce, tomato and bacon were placed atop the sandwich bread, while the salad dressing made earlier in the day was spread across the top. The customer needless to say was eager to eat this sandwich.

Upon arriving home and unpacking the groceries, Mr. Smith sat down to enjoy the sandwich while catching up on the daily news. Just a few seconds after the first bite, something felt strange. He began coughing, hard. He felt a shortness of breath. After running to the restroom, he saw something very alarming in the mirror. His face was broken out in large, red hives. Mr. Smith immediately dialed 911 and reported a food allergy with concerns he was going into anaphylactic shock. Fortunately, Mr. Smith found his epinephrine pen and prevented anaphylaxis. What Mr. Smith did not realize was the new home style salad dressing contained walnut paste. Walnuts are a tree nut, one of the **9 major food allergens**. The following weeks involved negative publicity of this allergic reaction along with a lawsuit filed against the owner of the grocery store.

Purpose

The retail food industry plays a significant role in assuring a safe food supply for its consumers. At the retail level, activities to control food safety risks can be divided into four key areas: the supplier and source of foods and food ingredients; in-store practices and procedures; education and training of employees and food handlers; and consumer engagement. A comprehensive approach to food safety management must address each of these areas.

This document is intended to address food allergens with store brand products, in-store practices and procedures, employee and customer awareness and engagement. The document represents a collaborative effort. It was developed by food safety professionals from the grocery industry, and was reviewed by individuals from academia as well as state and federal regulatory agencies. This document provides insight, resources and information on food allergen management at retail. This resource document will be updated on a regular basis to maintain its effectiveness and relevancy.



Background

More than 50 million Americans have an allergy of some kind¹. An estimated 4 to 6 percent of children and 4 percent of adults are affected by food allergies, according to the Centers for Disease Control and Prevention (CDC)¹. From 1997 to 2007, the prevalence of reported food allergies increased 18% among children under 18 years of age. The CDC has also reported over 170 different foods that can cause food allergies, but most food allergies are caused by milk, eggs, fish, shellfish, wheat, soy, peanuts, tree nuts and sesame¹. Symptoms from most food-related reactions occur within two hours of ingestion; often starting within minutes. In some rare cases, the reaction may be delayed by four to six hours or even longer¹. Food allergens are food safety risks that impact everyone in the food industry.

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)³ requires packaged foods to comply with federal food allergen labeling requirements, including products packaged and labeled at retail⁵. Under FALCPA⁵, a “major food allergen” is an ingredient that is one of the following nine foods or food groups as the major food allergens. They are milk, eggs, fish (e.g., bass, flounder, cod), Crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, walnuts, pecans), peanuts, wheat, soybeans and sesame. In the case of tree nuts, fish and crustacean shellfish, the specific tree nut or species of fish or shellfish must be listed. FALCPA also covers all ingredients that contain protein derived from milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans or sesame. Retailers have a shared responsibility to work with their co-manufacturers of store brand products to ensure these products meet the food allergen labeling requirements.

The FDA *Food Code*⁴ is a model guidance developed by the U.S. Food and Drug Administration (FDA) and is commonly adopted by state and local regulatory food safety programs. Food allergens were first added to the FDA 2005 *Food Code* to be consistent with FALCPA relative to definitions and demonstration of knowledge by persons in charge. The FDA *Food Code* specifies that restaurant and retail food service managers must be aware of the serious nature of food allergies, including allergic reactions, anaphylaxis, and death; must know the **9 major food allergens**; must understand food allergen ingredient identities and labeling. Moreover, under FDA’s FALCPA Guidance, the agency specifically advises that foods sold from behind a counter and placed in a wrapper, carry-out box, or other “non-durable” container whose sole purpose is to facilitate handling are not “packaged foods” and need not bear nutrition, ingredient, or other labeling⁵.

Retailers should take steps to raise awareness with customers about the use of allergen ingredients within fresh departments as well as any allergen ingredient changes that are made with Consumer Product Goods (CPG) products. Grocery retailers can help customers increase their awareness of food allergens through print brochures, company webpages, social media, and in-store signage. FMI and many of its member companies have worked with the Food Allergy & Anaphylaxis Connection Team (FAACT)⁶ and the Food Allergy Research and Education (FARE)⁷ to help develop solutions to meet the needs of customers who live with the challenges of food allergies.

This Food Allergy Resource Document has been developed to assist the retail food industry gain a better understanding of food allergen risks and good retail practices (GRPs) for management solutions and to be able to effectively communicate these risks with employees and customers.



There are four categories to consider for Retail Allergen Management. Each category will be described in more detail.

1. Customer Notification and Engagement

Providing transparency to the consumer regarding the potential risks related to the exposure to a major allergen is essential for retailers. This section provides guidance and examples on how to communicate to minimize risk to the consumer.

2. Training

Training retail food employees on allergen awareness is essential to successfully implement an allergen management program at retail. This section provides the framework that should be considered when developing the allergen awareness training program.

3. Labeling

Ensuring accurate information is provided to the consumer via the product label is not only critical to informing the consumer of the contents of the item, including allergens, it is also a regulatory requirement. This section reviews the regulatory requirements and provides guidance on implementing systems to verify correct information is provided on the label.

4. Retail Operations

Food preparation at retail provides many challenges as it pertains to managing allergens. This section reviews those challenges and provides guidance on how retailers can minimize the potential for the presence of unintended allergens in food products.

Customer Notification and Engagement

Retailers should establish a transparent allergen management program to assess the presence of each of the **9 major food allergens** in the production area(s) and determine what allergens pose a risk to the consumer. Due to the variety of products, many of which contain allergens, that are handled daily and at times concurrently in each production area, the need to disclose the presence or the potential presence of allergens is essential to protecting consumers.

Consumers with food allergies rely on information that is made available on the product label when making decisions to purchase a particular item. There are a number of opportunities to engage customers about the presence of allergens. Retailers can utilize signage to communicate the possibility of cross contact with an allergen in a department or food preparation area and the potential for allergens that may result in a product prepared in these areas. The following are recommended considerations for in store signage:

- Post signs in each department in a highly visible and conspicuous location where allergens are handled, openly displayed, or offered for sampling. Also, consider posting signs in high traffic areas such as the store entrance or customer service area.





- Consider providing signage in languages appropriate to the demographics of the customers.
- Some jurisdictions may require allergen signage be posted. Consult your local or state regulatory agency to determine whether or not this applies to your operation.

In addition to posting signs in stores, retailers can also explore additional opportunities to engage consumers to increase allergen awareness. These may include the following:

- Increase employee and management allergen knowledge through training so they are better equipped to answer customer questions
- Utilize company website and social media platforms to engage consumers on allergens
- Implement training and provide guidance to corporate consumer call centers on handling questions about allergens
- Utilize corporate or store dietitians to interface with consumers on allergy related messaging and questions

ACTION FOR RETAILERS:

Retailers should establish a transparent allergen management program to assess and communicate the presence of each of the **9 major food allergens** in the production areas to consumers.

Training

Training retail food employees on allergen awareness is important to successfully implement a comprehensive allergen management program in a retail food establishment. Employees should understand their role and responsibility when it comes to food allergies. Management and employees that oversee departments which handle and/or prepare exposed foods containing one or more of the major allergens have the responsibility of assuring food employees working in these departments have received appropriate food allergy training. In order to successfully implement and execute an effective allergen training program, training should be a top down approach with support from senior management to allocate resources and emphasize the importance of the company's allergy management program.

Training for management and retail food employees on the essentials of allergy awareness should focus on:

- Understanding the serious nature of food allergies, including allergic reactions, anaphylaxis, and death
- Identifying the **9 major food allergens**
- Safe product handling; minimizing cross contact during preparation and service
- Labeling requirements for store packaged items and food allergens
- Implementing corrective actions
- Managing ingredients, recipes and ingredient substitutions
- Customer notifications, answering customer questions and generating consumer awareness
- Identifying symptoms of food allergies and response during allergic reactions and emergencies
- Knowing when to notify a manager

ACTION FOR RETAILERS:

Properly train management and retail food employees on the essentials of food allergy awareness.



Labeling

Ensuring accurate information is provided to the consumer via the product label is a regulatory requirement and critical to informing the consumer of the ingredients in an item, including any allergens. Federal regulations dictate specific requirements as it pertains to the labeling of any packaged product sold to consumers; in addition, there may be state labeling requirements that may be applicable to your operation. For more details regarding the regulatory requirements review the following sources.

- FDA Food Code 3-602.11
- FDA Fair Packaging and Labeling Act
- Food Allergen Labeling and Consumer Protection Act (FALCPA) requirements

In general, the product label should include the following information:

1. The common name of the food
2. If product is made from two or more ingredients, a list of ingredients in descending order of predominance by weight, including colors or flavors and preservatives
3. An accurate declaration of the quantity of contents
4. The name and place of business of the manufacturer, packer, or distributor; and
5. The name of the food source for each major food allergen contained in the food unless the food source is already part of the common or usual name of the respective ingredient (e.g., eggs, milk, peanuts, soy)



FALCPA requires labels for food products that contain an ingredient or protein from a major food allergen in one of two ways.

- The first option is to include the name of the food source in parenthesis following the common or usual name of the major food allergen in the list of ingredients in instances when the name of the food source of the major allergen does not appear elsewhere in the ingredient statement.
- The second option is to place the word “Contains” followed by the name of the food source from which the major food allergen is derived, immediately after or adjacent to the list of ingredients, in type size that is no smaller than the type size used for the list of ingredients.

A label management protocol should also be established to verify correct information is contained on the product label for new and existing items. This system should be verified for accuracy on a regular basis as the top reasons for recalls include:

FOOD ALLERGY AWARENESS

Food allergens such as tree nuts, peanuts, seafood, crustacean shellfish, soy, milk, eggs, wheat and sesame are present in various departments in the store.

1. omission of allergen from the label;
2. using the wrong package or label;
3. not identifying the common name of the allergen;
4. failure to carry forward information to the final label; and
5. cross contact between major allergens⁸.



Key components of a label management program should include the following:

- Review and verify ingredient sourcing and recipes match the product specifications
- Letter of guarantee from each supplier of a finished product, component ingredient or raw material which states that they will provide advance notification of any formulation change. The retailer should initiate appropriate follow up with suppliers to assure this happens.
- Ensure standard recipes are followed at store level. No ingredient substitution should be made without prior authorization from management
- Verify the accuracy of the ingredients that are programmed into the scale systems, shelf labels or identification tags that provide ingredient information to consumers
- Verify scale hardware memory capacity allowing accurate ingredient printouts
- Establish a process to verify the product is properly identified and the correct label or sign is placed on the product prior to being placed out for sale

ACTION FOR RETAILERS:
 Establish a system to verify accurate information is provided to the consumer via the product labels.

Retail Operations

Food preparation at retail is unlike manufacturing environments. Often times multiple items containing various major allergens are being prepared at the same time in a confined area. Additionally, the variety of ingredients may change daily, weekly and definitely seasonally while producing significant volumes of food each day. Food safety and public health is extremely important to retailers. Protecting our customers comes naturally so while we try to provide our customers with a wide variety of healthy and safe foods, we also have a responsibility to notify our customers with food allergies about the possible presence of allergens in certain food preparation departments. Open, transparent communication through accurate labeling and signage are essential to maintaining the trust and confidence of customers.

To minimize the potential for cross contact retailers should assess the presence of each of the **9 major food allergens** in each preparation area within their establishment(s). This should include assessing ingredients, raw materials, processing aids and finished products which are processed, produced or handled in an unpackaged manner. This assessment should be done from receiving, through storage, preparation, labeling and display. Part of this assessment should also examine how these items are handled (i.e., repackaging of a ready-to-eat products; production of products from scratch).



Specific programs and processes that should be considered when developing an allergen management program at retail include:

- Spill cleanup program—immediate cleanup of a spill containing one or more major allergens in areas where cross contact is likely to occur.
- Product demonstration program—training and defined procedures to minimize cross contact and communicate allergens to consumers.



- Special order accommodations—making special accommodations for individuals who make specific requests (i.e. cleaning slicers before slicing meat that contains tree nuts from someone who has tree nut allergy). Understand that this alone may not protect a customer with an allergy to a specific allergen.
- Elevating to management—knowing when to elevate a question or situation to the manager in charge.

A thorough evaluation of allergen presence in food production areas and determining the potential risk associated with the handling of those allergens is an important step in understanding each food preparation area. In addition to implementing controls to minimize risk of unintended allergen exposure, the use of a disclosure statement or consumer notification relating to allergens should be implemented.

ACTION FOR RETAILERS:

Retailers should assess the presence of each of the **9 major food allergens** in each preparation area within their establishment and try to control cross contact when possible while understanding that this alone may not prevent allergen proteins from coming into contact with other non-allergen containing products.

Recall Management

Recalls relating to allergens continues to be a major concern for the food industry. Retailers should review their current recall protocols to ensure that appropriate steps can be taken to effectively alert consumers to the potential hazards and provide direction accordingly. Retailers should reference [FMI's Product Recall Guide](#)⁹ for more details on initiating and executing a recall.



ACTION FOR RETAILERS:

Develop a plan to ensure that all consumer complaints are recorded and tracked. Any complaints that involve mislabeling of a food allergen should be forwarded to the supplier or manufacturer.

Customer Complaint Monitoring and Follow Up

A process should be established for consumers to report an incident regarding a product. Retailers should investigate these complaints and consider possible corrections when needed.



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Citations

1. American College of Allergy, Asthma & Immunology, <http://acaai.org/>
2. Branum AM, Lukacs SL. *Food allergy among U.S. children: Trends in prevalence and hospitalizations*. NCHS data brief, no 10. Hyattsville, MD: National Center for Health Statistics. 2008.
3. Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II).
4. *Food Code, 2017 Recommendations of the United States Public Health Service, Food and Drug Administration*, National Technical Information Service Publication IFS17.
5. *Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4)*; Final Guidance. October 2006.
6. Food Allergy & Anaphylaxis Connection Team, <http://www.foodallergyawareness.org/>
7. Food Allergy Research & Education, <http://www.foodallergy.org/>
8. Gendel SM, Zhu J. 2013. Analysis of U.S. Food and Drug Administration food allergen recalls after implementation of the Food Allergen Labeling and Consumer Protection Act. *J. Food Prot* 76(11):1933-1938.
9. *FMI Guidance for Retailers: Product Recalls: February 2020* <https://www.fmi.org/docs/default-source/food-safety/guidance-for-food-retail-product-recall.pdf?sfvrsn=2>



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