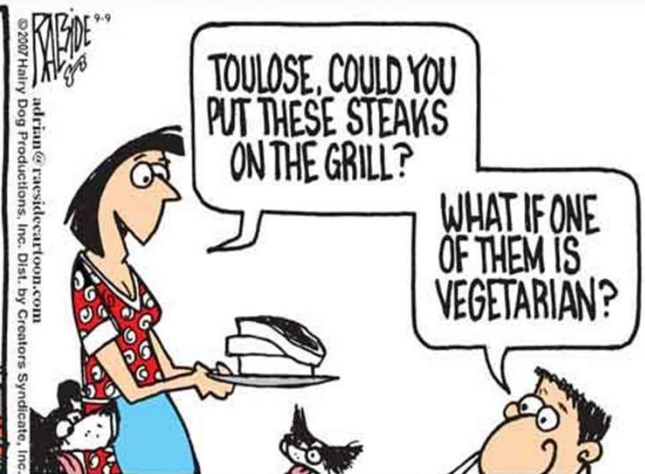


ALLERGENS

**Your Enemy?
WHY ALL THE FUSS?**

CHIRAG BHATT
Director, Regulatory Affairs





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HOW MANY?

- EIGHT
- NINE
- TWELVE
- ASK ME LATER



MAJOR ALLERGENS IN USA



- What is?
- Why all the fuss?
- Solutions
- Allergen Control
- Q&A

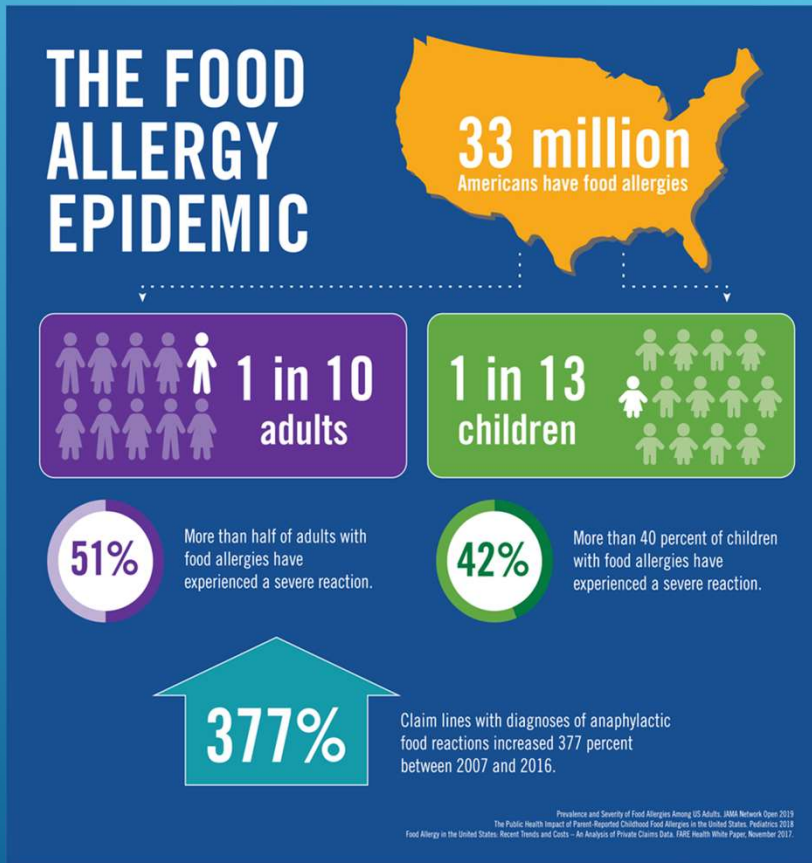


WHAT IS?

- **MEDICAL CONDITION**
- Exposure triggers harmful immune response
- Allergens are **PROTEINS**
- Mild to severe reaction (itchy to breathing)
- Anaphylaxis – serious and sudden
- Wheezing, shortness of breath, dizziness, paleness, tight throat, tongue/lips swelling, hives
- 30,000 ER visits, 2,000 hospitalized, 150 deaths
- 33 million Americans
- Children (<18) 5.6 million
- 40% children – allergic to more than 1
- Shellfish 24%, Dairy + Peanuts 36%



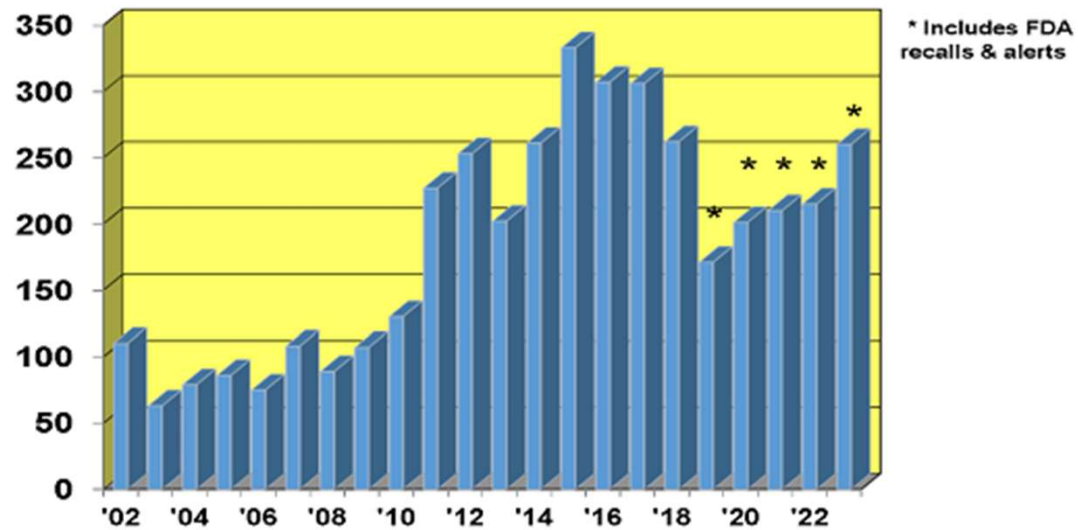
WHAT IS?



- FDA Risk Factor Study (2016 data) indicated that 70% PIC did NOT identify major allergens and related symptoms
- High number of food recalls
- Allergens – Top food safety concern
- 2004: FALCPA act – labeling requirements
- Food allergen awareness - training



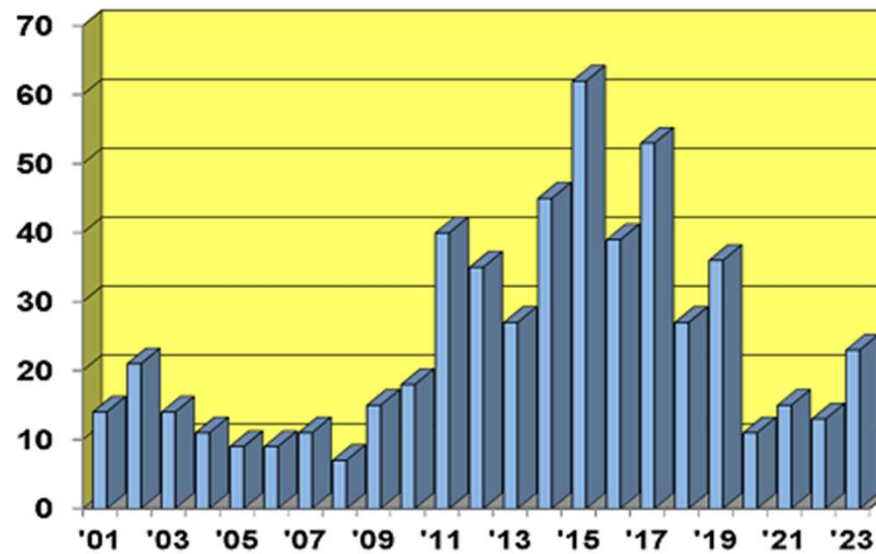
U.S. FDA Food Allergen Recall Incidents 2002-2023



TOP REASON FOR UNDECLARED ALLERGEN RECALLS AND PUBLIC HEALTH ALERTS:

LOSS OF CONTROL DURING PACKAGING AND LABELING

FSIS/ USDA Food Allergen Recalls Calendar Years 2001-2023



food allergy research
& resource program
farrp
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TOP REASON FOR UNDECLARED ALLERGEN RECALLS AND PUBLIC HEALTH ALERTS:
LOSS OF CONTROL DURING PACKAGING AND LABELING



WHAT IS?

THE DANGER OF UNDECLARED ALLERGENS TO CONSUMERS.

- According to the CDC National Center for Health Statistics - 6.2% of American adults had a food allergy in 2021.
- 8% of all children have a food allergy
- Approximately 40% (2 in 5) of children with food allergies in the United States have been treated in the emergency department.

Since people with a food allergy or food sensitivity react to the amount ingested from a mislabeled food, whether undeclared presence in such a food product will provoke a reaction depends on how much food is consumed and the concentration of unintentionally present allergen in food.



WHAT IS?

Prevalence of food allergies:

Highest in women (18–44), and non-Hispanic Black adults

Women (7.8%) were more likely to have a food allergy compared with men (4.6%)

For adults (with food allergy) - decreased with increasing age,

- 6.6% in 18–44
- 6.7% in 45–64
- 5.1% in 65–74
- 4.5% in 75 and over

Black adults (8.5%) were more likely to have a food allergy compared with Hispanic (4.4%), White (6.2%), and Asian (4.5%) adults.

From: National Center for Health Statistics

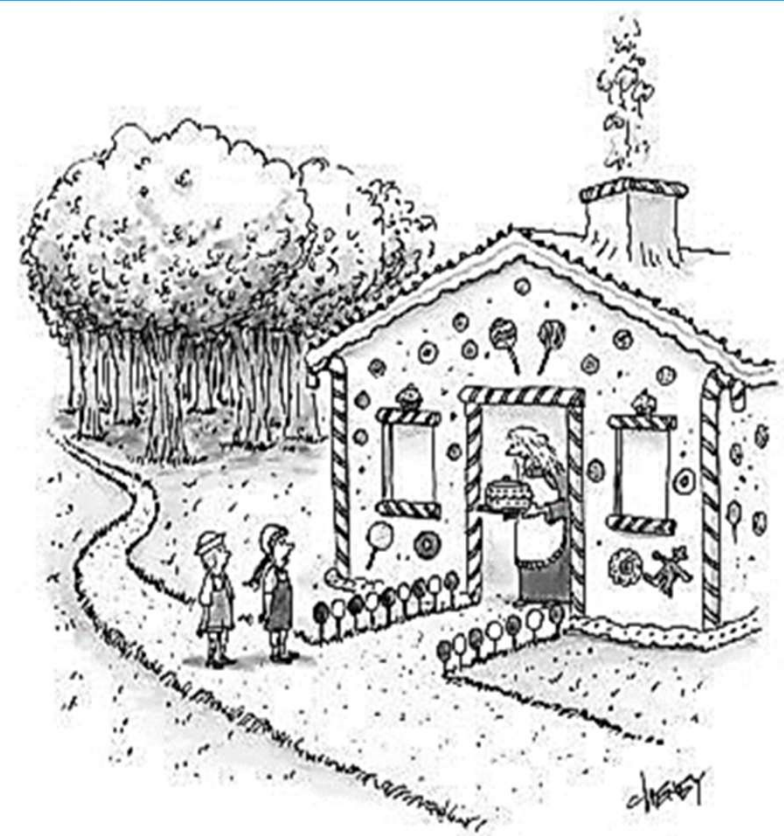


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"Hate is a pretty strong word. Are you sure you're not just lactose intolerant of your mother?"



"Before we come in, was any part of your home produced in a facility that also handles wheat, milk, nuts, eggs, or soy?"

WHAT IS?

- 70% of the total public health alerts and recalls were due to loss of control during the packaging and labeling processes.
- 15% of the mislabeled problems were from inadequate label approval.
- Remaining ones were from allergen cross contact during processing or from supplier failing to disclose specific allergen.

- Wrong packaging, wrong description (butter vs dairy), computer errors, HACCP – not effective or not in place or imported from other country
- 25% of these could have been avoided cGMPs, Preventive Controls, HACCP



ROOT CAUSE



WHY ALL THE FUSS?

A **food safety issue** (mishandling of allergenic ingredients) = industry suffers.

Consumers rely on Industry to identify, process, and market foods which are **labeled correctly**.

Allergic consumers must **avoid the foods** that trigger their allergic reactions.

Labeling of foods for the presence of allergenic foods **must identify all foods** that intentionally contain the particular food or ingredients derived from that food.

Proliferation of the use of **precautionary allergen statements**, which range in wording from “May Contain” and “Processed in a Facility”, to “Made on Shared Equipment”.

Food-allergic consumers (especially teens) **ignore precautionary statements**, and taking risks regarding the food they choose to eat. This can lead to **trouble for both the consumer and the industry**.

What is the solution? **Allergen Control Plan**



ALLERGEN CONTROL - RETAIL

FOUR PILLARS – RETAIL CONTROL

- **UNDERSTAND** – Challenges as it relates to handling allergens. Need to understand what those challenges are and how best to minimize the risk.
- **TRAINING** – Educating employees and managers on allergen awareness is important to effectively implementing an allergen management program.
- **LABELING** – Accurate information is provided to the consumer via the product label is not only critical for informing the consumer, but it is the LAW.
- **NOTIFICATIONS** and **ENGAGEMENT** – Being clear with the consumer regarding the possible risks related to the exposure of a major allergen.



ALLERGEN CONTROL - RETAIL

RECALL MANAGEMENT

- Review recall protocols to ensure the appropriate steps are taken to alert the consumer of potential hazards and to provide direction.

COMPLAINTS

- Establish a system for customers to express any product complaints or concerns. Retailers should analyze and consider these complaints to make any necessary corrections. Follow up to show the customer their concern is taken seriously.

TRAINING

- Train management and all on the fundamentals of food allergy awareness.
- Everyone recognize their role and responsibilities to food allergies.
- Support from senior leadership is essential.
- Identify all 9 major allergens and the symptoms. NOTIFY WHEN NEEDED.



ALLERGEN CONTROL PLAN (FOR ALL)

- An **Allergen Control Plan** is a critical component.
- **Must do everything to ensure allergenic foods and ingredients do not find their way into products for which they are not intended. Allergen Control Plan is company's written document regarding the storage, handling, processing, packaging, and identification of allergenic foods and ingredients.**
- **This is not a one-time effort. Allergen Control Plan must be implemented, audited, enforced and updated continually.**
- **Every time there is a change in a process or a product, Every time a new employee comes in or change the responsibilities of an employee, Every time working with a new supplier, change or add locations, a new Allergen Control Plan should be developed specifically for that location.**



ALLERGEN CONTROL PLAN CONTENT

- Product Design (Research and Development)
- Segregation of Foods or Ingredients - Receiving, Storage, Handling and Processing
- Supplier Control Programs for Ingredients and Labels
- Prevention of Cross-Contact During Processing
- Product Label Review & Label/Packaging Usage and Control
- Validated Allergen Cleaning Program
- Staff Training and Education

Keywords: Menu design and changes, receiving and storage (know the allergens), supplier has a plan, separate storage (when possible), dedicated utensils – equipment – containers, re-use and re-work of items/ingredients, color-coded, designated time/area, effective sanitation, adequate engineering/design, packaging and labeling accuracy and verification, facility design, SOPs, cleaning validation and verification, general and role specific training for everyone (and refreshers).



LABEL

Food Allergen Labeling

The U.S. Food Allergen Consumer and Protection Act (FALCPA) **requires** food manufacturers to list the presence of 8 major allergens.

Here are **3 things** to inform you about allergens in packaged foods:

- 1. Name of the food source in parentheses**
Example: *whey (milk), eggs, vanilla, natural and artificial flavoring*
- 2. "Contains" followed by the name of the allergen**
Example: *Contains wheat, milk, egg and soy*
- 3. Tree nuts and types of fish should be clearly identified**
 - a. Almonds, pecans, walnuts for tree nuts
 - b. Bass, flounder, cod for fish
 - c. Crab, lobster, shrimp for crustacean shellfish



Food label - identify the food source of all major food allergens used to make the food. This requirement is met if the common or usual name of an ingredient already identifies that allergen's food source name (for example: wheat). OR the allergen's food source must be declared at least once on the food label in one of two ways.



1. In parentheses following the name of the ingredient.
e.g. "lecithin (soy)," "flour (wheat)," and "whey (milk)"

2. Immediately after or next to the list of ingredients in a "contains" statement.
e.g. "Contains Wheat, Milk, and Soy."



THANK YOU

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