

Allergen Control for Food Processors



Presented By:
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Discuss the Fundamentals of Food Allergens

Review the Regulatory Landscape

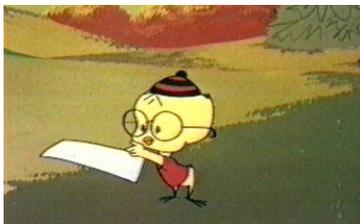
Assist in the Development of an Allergen Control Plan



Presentation Outline

- Background
- Regulatory Considerations
- Allergen Control Plan
- Key Elements of Control
- Complaint Handling
- What now?
- Resources

Allergen Awareness Exercise



Write down the contents of your last meal.

Background



Food Allergy Facts and Statistics

- **Food Allergen** – immunologic response that involves IgE antibodies. Symptoms range and vary.
- **Food Intolerance/Hypersensitivity** – adverse response to food limited to gastrointestinal problems
- There is no cure for food allergies.
- Food allergies are a growing public health concern.

Common Food Hypersensitivities

- Strawberries
- Sulfites
- FD&C Yellow #5
- MSG (monosodium glutamate)
- Lactose
- **Gluten**

Gluten?

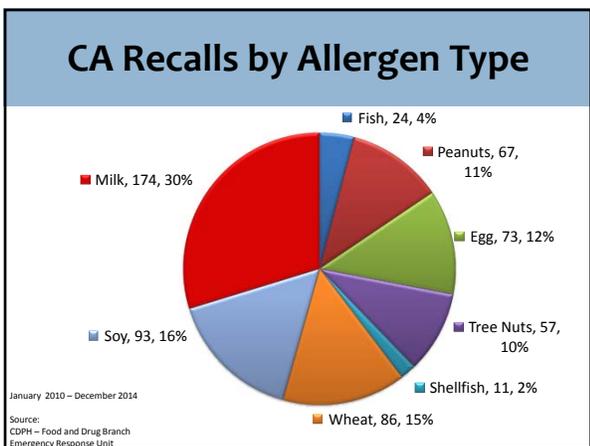


- Proposed Rule 1/2007, Final Rule 8/2013
- Defines term “Gluten Free” and similar terms
- Establishes 20 PPM threshold
- Use of term is voluntary, threshold is not
- More information at: FDA.gov - search “gluten free”

Why Increased Attention to Allergens?

- Increased awareness – consumers and industry
- Improved detection methods (ELISA, PCR, etc)
- Trend toward value-added products
- Negative publicity; financial impact; regulatory actions
- Severe adverse reactions





Impacts?

Increase in Food Recalls

Economic/Financial

Reputation

Public Health

News Reports



Natalie Giorgi, 2013

ht for - in a shell

Young children show big increase in deadly peanut allergy

Schools on alert to ca for killer nut allergi

Warning on nut allergy dangers

GPs advised on fatal peanut allergy

Regulatory Considerations

Which Laws/Regulations Apply?



- FALCPA
- Sherman Food, Drug and Cosmetic Law
- 21 CFR Part 110
- 21 CFR Part 101

Compliance and Enforcement



State and federal law deem food that is not properly labeled to be misbranded.

Misbranded food can lead to:

- Notice of Violation
- Embargo
- Recall
- Fines and Penalty

Allergen Labeling Law: FALCPA



The Federal Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) was signed into law on 8/2/2004.

- Food labels must list the food source names of all ingredients that contain any protein derived from the **eight major food allergens**.
- FALCPA labeling requirements became effective on January 1, 2006.
- Pursuant to California Health and Safety Code section 110100, FALCPA is adopted as California law.

FALCPA Requirements

Food facilities are required to:

1. Comply with practices to reduce or eliminate cross-contact of a food with residues of major food allergens that are not intentional ingredients of the food.
2. Ensure that major food allergens are properly labeled on foods.



What are the Major Food Allergens?

- Milk
- Eggs
- Fish
- Crustacean shellfish (e.g., crab, lobster, shrimp)
- Tree nuts (e.g., almonds, walnuts, pecans, coconuts)
- Peanuts
- Wheat
- Soybeans

FALCPA Exemptions

FALCPA law does not apply to:

- Highly refined oils
- Raw agricultural commodities

FALCPA Exemptions

- Food ingredient exempt under a **petition or notification** process
 - Petition standard: "... does not cause an allergic response that poses a risk to human health."
 - Notification standard: "... does not contain allergenic protein."
 - Scientific evidence must be provided for FDA's review.

Allergen Food Label

The name of the food source of a major food allergen must appear in **one of two ways**:

- In parentheses following the name of the ingredient
e.g., lecithin (soy), flour (wheat), and whey (milk)
- Immediately after or next to the list of ingredients in a "Contains" statement
e.g., "Contains Wheat, Milk, and Soy"

Unrequired Label Statements?

- "May contain..."
- "Produced in facility which also manufactures..."
- "Manufactured on shared equipment..."

Flavors, Coloring and Incidental Additives

A flavoring, coloring or incidental additive that contains a major food allergen is subject to FALCPA labeling requirements.

Allergen Awareness Exercise

Did your last meal include any of the eight major food allergens? If yes, which one(s)?

- Milk
- Eggs
- Fish (e.g., bass flounder, cod, etc.)
- Crustacean Shellfish (e.g., crab, lobster, shrimp)
- Tree nuts (e.g., almonds, walnuts, pecans, coconuts)
- Peanuts
- Wheat
- Soy



FSMA

Hazard Analysis Risk-Based Preventative Controls (HARPC)

HARPC Food Safety Plans

1. Identify “Significant” Hazards
2. Implement Risk-Based Preventive Controls
3. Monitor Effectiveness
4. Develop Corrective Actions
5. Verify Controls Used
6. Recordkeeping
7. Re-analyze at least every THREE years



Interesting Fact



On June 8, 2010, the U.S. Department of Transportation issued a proposal to restrict peanuts on commercial airlines. Later, the agency withdrew the proposal citing federal law that indicates no federal money can be used to provide a peanut-free buffer zone or restrict the distribution of peanuts until 90 days after a peer-reviewed study is submitted to Congress.

Quiz



Which of the following contains a major food allergen as defined by **FALCPA**?

- A. Strawberries
- B. Wheat
- C. Gluten
- D. Casein

Quiz



A “may contain” statement can be used in lieu of **current Good Manufacturing Practices**.

True or False

 **Quiz**

By documenting “**whey**” in the ingredient list of a product which contains whey, the manufacturer has met the requirements outlined in **FALCPA**.

True or False

 **Allergen Control Plan**

What is it?

An **Allergen Control Plan** is a written document that includes effective control measures used to minimize allergen cross-contamination and prevent misbranding via a failure to disclose allergens on the label.



How to Develop an Allergen Control Plan

- Assemble an Allergen Control Team
 - Define and assign staff roles and responsibilities
- Establish policies and procedures for allergen control
 - Seven Key Elements of Control
- Reassess the effectiveness of Allergen Control Plan
 - Audits

Assemble the Team



- Research & Product Development
 - Management
 - Quality Assurance
- Purchasing/Distributing
 - Manufacturing
- Packaging/Labeling
 - Warehousing
- Regulatory Affairs
 - Training Officer

Establish the Plan



```
graph TD; RM[Raw Materials] --> ACC((Allergen Cross-Contact)); ET[Employee Training] --> ACC; LP[Labeling and Packaging] --> ACC; R[Rework] --> ACC; CS[Cleaning and Sanitation] --> ACC; MP[Manufacturing and Processes] --> ACC; FD[Facility Design] --> ACC;
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Evaluate the Effectiveness



Key Elements of Control

7 Key Elements of Control



1. Raw Materials

1. Receiving – establish specifications



- Audit **suppliers and co-packers** to ensure compliance with Allergen Control Plan
- Request **Certificates of Analyses (COA)** or **Certificates of Guarantees (COG)** for incoming ingredients
- Verify ingredients against **Bills of Lading, Purchase Orders, or Specifications**

1. Raw Materials

2. Inspection

- Review the **labels** of incoming ingredients for the Big 8 food allergens.
- Clearly mark or tag incoming allergenic ingredients using **color-codes, labels or symbols** to reduce mix-ups and cross-contact.
- Develop a **plan** to handle damaged containers, accidental spills, or misuse of allergenic ingredients.





1. Raw Materials

3. Storage

- Store allergenic ingredients in clearly identified areas or boxes using color-coded labels.



1. Raw Materials

3. Storage

Segregate allergenic raw ingredients in a manner to minimize cross-contamination using the following practices:

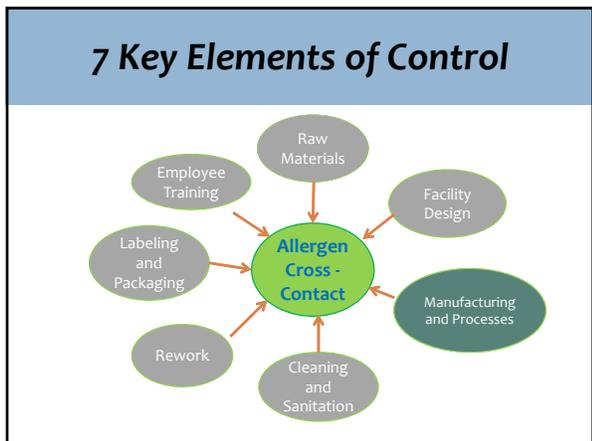
- Use dedicated pallets and bins
- Store allergenic ingredients on lower shelves
- Designate specific storage areas for specific type of allergens (e.g., “wheat only”)
- Ensure containers are tightly sealed to avoid airborne contamination



2. Facility Design



- Traffic flow
- Ventilation/air filtration
- Staging and storage
- Processing lines
- Physical separation or barriers
- Space



3. Manufacturing and Processes

1. Dedicate equipment and food contact surfaces (FCS)

- Segregate the production areas (conveyors, rooms and facilities) for in-process food with major food allergens




Dedicated Equipment and FCS



Use separate lines, equipment or FCS

Dedicated Equipment and FCS

- Use color coding system
 - ▣ Ingredients
 - ▣ Equipment and utensils that contact allergens

- Create barriers to protect in-process food from cross-contamination via adjacent conveyors, carts or other food processing equipment.

3. Manufacturing and Processes

2. Production scheduling

- ▣ Process food containing allergens longer to minimize changeovers
- ▣ Process food containing allergens at the end of the manufacturing run
- ▣ Process food containing allergens separately
- ▣ Schedule cleaning and sanitation between production to prevent cross-contamination of allergens and non-allergens

Which is the IDEAL Production Scheduling?

Run A



Sugar Cookies



Chocolate Chip Cookies



Chocolate Chip + Peanut butter Cookies



Run B



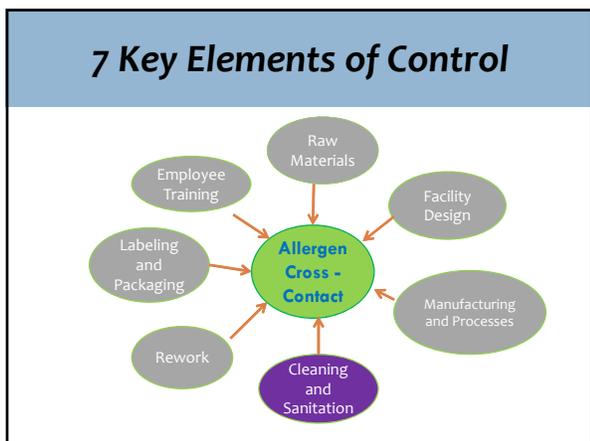
Sugar Cookies



Chocolate Chip + Peanut Butter Cookies



Chocolate Chip Cookies



4. Cleaning and Sanitation

- Ensure equipment design allows for thorough cleaning, sanitizing and inspecting
 - ▣ Avoid dead legs that accumulate food
 - ▣ Clean in Place systems

- Follow Sanitation Standard Operating Procedures (SSOPs)
 - ▣ Clearly written procedures that are easy to follow
 - ▣ Define the scope and schedule for cleaning the equipment, food contact surfaces and the plant
 - ▣ Train employees on the cleaning procedures

4. Cleaning and Sanitation

Use appropriate cleaning methods :

<p>1. Dry cleaning</p> <ul style="list-style-type: none"> ▪ wipe/brush ▪ scrape ▪ vacuum ▪ blow down ▪ compressed air 	<p>2. Wet Cleaning</p> <ul style="list-style-type: none"> ▪ rinse ▪ high pressure water or steam ▪ wash ▪ sanitize
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The Best Approach to Cleaning...

If you can't see it

If you can't reach it



Then, YOU CAN'T CLEAN IT!!!

4. Cleaning and Sanitation

- Verify sanitary practices through frequent visual inspections
 - ▣ Define the scope of verification procedures
- Validate cleaning with analytical methods, via the ELISA test kits
 - ▣ Define the intention and scope of validation
- Document and review cleaning and sanitizing records
 - ▣ Keep detailed records for cleaning, verification and validation
 - ▣ Evaluate the allergen cleaning program annually for effectiveness

7 Key Elements of Control



5. Rework

- **Clearly label rework**
 - ▣ Use color tags, containers, plastic liners or bar coding to document and track reworked product

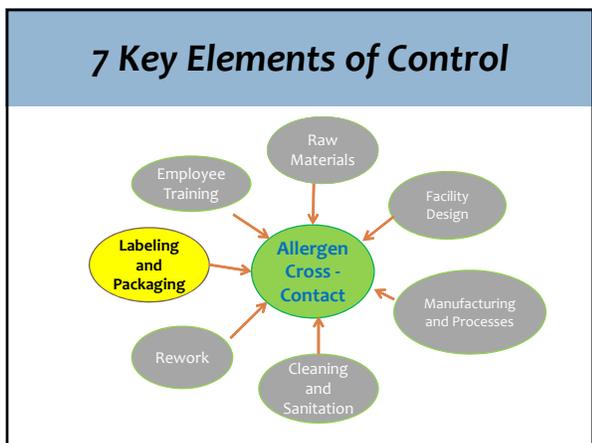
- **Use same ingredients or formulation in the reworked products**
 - ▣ Check specifications for allergens
 - ▣ If rework product calls for reformulation, use the CORRECT labels

5. Rework

- Ensure that shared or re-feed systems are **adequately cleaned**
 - ▣ Equipment, grinders, food contact surfaces and other shared equipment

- Document rework to allow for **proper identification and traceability**
 - ▣ Rework plan and controls
 - ▣ Uses for reworked products
 - ▣ Usage records





Top 3 Reasons for Undeclared Allergens

Labeling 60%	Processor 20%	Supplier 20%
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6. Labeling and Packaging

- 21 CFR Part 101 – Food Labeling
- FALCPA requirements
- Label Control

6. Labeling and Packaging

- Implement a tracking system that includes:
 - Lot coding or Lot numbering
 - BIUB



Words of Caution!!!



Advisory Labeling

- does not replace the firm's responsibility to prevent allergen cross-contact
- should not be used as a "catch all" statement
- should only be used to describe the potential presence of unintentional allergen after a complete risk-assessment

6. Labeling and Packaging

ALLERGY INFORMATION:
Consumers with food allergies or other sensitivities, please review the ingredients carefully.

7 Key Elements of Control



7. Employee Training



Staff in direct contact with food, food contact surfaces and food packaging materials should know how to minimize the intentional and unintentional cross-contamination of food allergens.

7. Employee Training

Curriculum should include:

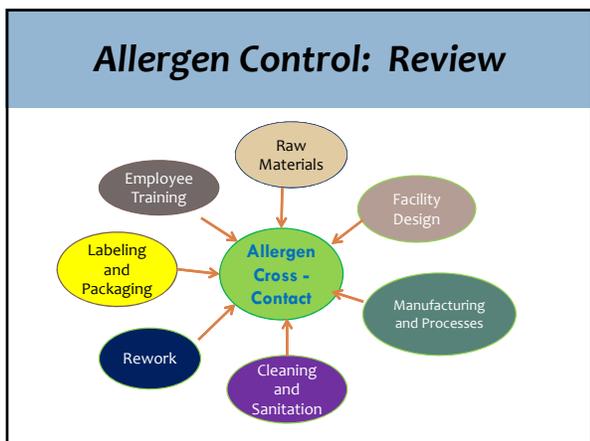
- Top 8 Food Allergens
- Basics of Food Safety (cGMPs, SSOP, HACCP)
- Policies and procedures for allergen control
- Strategies to reduce cross- contamination
 - Color-coding
 - Proximity of equipment
 - Production Scheduling
 - Cleaning/Sanitizing
 - Labeling
 - Rework procedures

7. Employee Training

Training and communication are key to effective allergen control

Management is responsible for the following:

- Ensuring **allergen control** policies and procedures are readily available for employees.
- Ensuring employees are aware of **changes** to allergen control plan.
- Documenting allergen awareness **trainings**.
- Posting of **signage** for use in dedicated areas to minimize the potential for cross-contamination.
- Creating an environment where employees can **report problems** observed.



- ### Group Training Exercise - Scenario
- Scenario – “Yummy Yuckies”
 - Break into 7 small groups (Key Elements)
 - Assign roles to team members (note-taker, facilitator and presenter)
 - Begin discussion (15 minutes)
 - Present and share with the class (3 minutes)

Group Training Exercise - Outcomes

1. Identify one “cause” for the fictitious scenario.
2. Identify one “real world” solution.

How Do We Know There Is A Problem?



Complaint Handling

Allergen Complaints

Customer service response should include training staff on how to handle complaints.

- Step 1: Create a complaint record**
- Step 2: Initiate an investigation**
- Step 3: Evaluate processes and controls**
- Step 4: Develop corrective actions to achieve complaint resolution**

Allergen Complaints

Step 1 – Develop a Complaint Log

- > List complainant's Name and Contact Information.
- > Describe the incident including date and time, nature of complaint, symptoms of illness, etc.
- > Identify product: purchase date and lot code.
- > Sample Log - <http://www.cdph.ca.gov/pubsforms/Documents/fdbRIgde04.pdf>

Anonymous complaints are VERY difficult to substantiate.

PRODUCT COMPLAINT REPORT

Report No: _____

Breeze (No B) _____ Injury Product Spoilage Container Integrity Foreign Object
 Miscellaneous: Odor Taste Color Other _____

Product: _____

Complainant Taken By: _____ Date: _____ Time: _____

Complainant Name: _____
 Company: _____
 Address: _____ Phone: _____
 City: _____ Zip: _____ County of Residence: _____

Product: _____ Brand: _____ Size: _____
 Code/Expiration Date: _____ UPC: _____ Product sold: Short Shelf Life Refrigerated Frozen

Description of Problem (for Breeze see below): _____

Purchase Location: _____ Purchase Date and Time: _____
 Address: _____ City: _____ State: _____ Phone: _____

Product Handling: _____ Storage: _____ Preparation: _____

Name	Age	Symptoms in order of appearance	Time	Medical Treatment Necessary	Diagnosis/Lab Confirmation

Dizziness Vomiting Nausea Headache Diarrhea Fever Burning Rash/Itches
 Medical Provider Name: _____ Address: _____ Phone: _____
 How much (total) consumed? _____ Product Remaining: Yes No Unopened packages _____
 Location of Remaining Product: _____
 How is Product Stored: _____
 Health Department notification: No Yes Department _____

Complaint Intake Form

Allergen Complaints

Sample Tracking Log

Date	Complainant Name and Contact Information	Product Name	Complaint Description	Staff	Investigation Notes	Status	Corrective Action
1/1/2012	John Smith (000) 000-000; not reachable from 8:00 am - 12 noon	ABC Product	Complainant alleges undecleared allergens in ABC product, reporting food made me sick. Complainant reports shortly after eating ABC product, his skin broke out in hives for three days.	QA Manager	Spoke with complainant (or other appropriate staff) appropriate. Complainant reports has allergy to peanuts. Complainant alleges experienced allergic reaction to ABC food product. Met with complainant on 1/4/12 to obtain sample product. Sent to lab for analysis on 1/6/12. Report came back positive for peanut residue on 1/13/12.	Report to manager submitted on 1/14/12. Food Recall issued on 1/14/12	Allergen tracing provided on 1/20/12

Allergen Complaints

Step 2 – Initiate an Investigation

Complaints may reveal problems with the following:

- Failure to List All Ingredients
- Labeling Mistakes or Omissions
- Lapse in Sanitation Controls
- New Supplier Infiltration
- Raw Materials/Ready-to-Eat Food Separation
- Product Identification Numbers/Lot Codes

Allergen Complaints

Step 3 – Evaluate Processes and Controls

Allergens need to be managed from start to finish in the production process to ensure effective controls.

Review current policies and procedures to confirm that products manufactured and/or distributed meet quality control and safety standards.

Allergen Complaints

Step 4 – Develop Corrective Actions to Correct the Problem.

- Fix labeling errors
- Ways to prevent unintentional cross-contamination
 - ▣ retraining staff
 - ▣ more equipment
 - ▣ change of production schedule
 - ▣ other

What Now?

Issue Recall Notice/Press Release



Recall Notice
Press Release

Recall Coordinators

- ▣ **State:** CDPH-FDB – send email to: FDBeru@cdph.ca.gov
- ▣ **Federal:** U.S. FDA - list of regional recall coordinators can be found at: <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm>

Resources

Resources

- **Food and Drug Branch**
 - **Top 8 Food Allergens & Their Common Aliases**
 - **Allergen Scorecard**
 - CDPH.CA.GOV/FDB



Top 8 Food Allergens

The Top 8 Food Allergens and Their Common Aliases

Allergen		Common Aliases	
Almonds	Almond	Almond	Almond
Coconut	Coconut	Coconut	Coconut
Crustacean shellfish	Crustacean shellfish	Crustacean shellfish	Crustacean shellfish
Eggs	Egg	Egg	Egg
Fish	Fish	Fish	Fish
Milk	Milk	Milk	Milk
Peas	Pea	Pea	Pea
Tree nuts	Tree nut	Tree nut	Tree nut
Wheat	Wheat	Wheat	Wheat



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FDA Industry Guidance

FDA industry guidance includes:

- [Food Allergens Labeling](#)
- [Guidance, Compliance & Regulatory Information](#)
- ["Dear Colleague" Letter About the "Food Allergen Partnership"](#)
- [Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food](#)
- [FDA Allergy Warning Letter](#)
- [Food Allergen Awareness: An FDA Priority](#)
- [Food Allergen Labeling and Consumer Protection Act of 2004 \(Public Law 108-282, Title II\)](#)





- ✓ **Discuss the Fundamentals of Food Allergens**
- ✓ **Review the Regulatory Landscape**
- ✓ **Assist in the Development of an Allergen Control Plan**

Questions




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