Chapter 10

FOOD ALLERGEN PREVENTIVE CONTROLS FOR HUMAN FOOD
Food Allergen Preventive Controls Objectives

- In this module, you will learn:
  - Allergen preventive controls link to hazard analysis
  - Required food allergen preventive controls
    - Allergen cross-contact prevention
    - Allergen label review
  - Allergen preventive controls options
### Hazard Analysis Form

**PRODUCT:** Omelet – Plain, Cheese, and Cheese Biscuit

<table>
<thead>
<tr>
<th>PLANT NAME</th>
<th>E.G. Food Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADDRESS</td>
<td>360 Culinary Circle, Mytown, USA</td>
</tr>
</tbody>
</table>

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</table>

<table>
<thead>
<tr>
<th>(1) Ingredient/Processing Step</th>
<th>(2) Identify potential food safety hazards introduced, controlled or enhanced at this step</th>
<th>(3) Do any potential food safety hazards require a preventive control?</th>
<th>(4) Justify your decision for column 3</th>
<th>(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?</th>
<th>(6) Is the preventive control applied at this step?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving frozen ingredients – biscuits *</td>
<td>C Allergen – wheat</td>
<td>X</td>
<td></td>
<td>Allergen Control – allergen labeling at other steps</td>
<td>Yes</td>
</tr>
</tbody>
</table>

- **Receiving frozen ingredients – biscuits**
  - C Allergen – wheat
  - X

  Wheat is an allergen that must be labeled to inform consumers. Allergen cross-contact with other products must be controlled because some products do not contain wheat.

  **Allergen Control – allergen labeling** at other steps

  **Sanitation Control** – at a subsequent step to **prevent allergen cross-contact**

*One of several Allergen Controls identified in the Hazard Analysis*
FALCPA* Required Food Allergen Labeling

- Milk
- Egg
- Peanut
- Tree nuts (species specific)
- Fish (species specific)
- Crustacean shellfish (species specific)
- Wheat
- Soy

* Food Allergen Labeling and Consumer Protection Act

Photo Sources: Microsoft Clip Art and KMJ Swanson (soybeans)
Allergen Preventive Controls Requirements

1. Preventing allergen cross-contact
   - Clean shared equipment – potential sanitation controls
   - Properly manage rework
   - Avoid in-process or post-process allergen cross-contact

2. Accurate allergen labeling of finished food
   - Ensure labels are correct – potential supply-chain program
   - Ensure the correct label or package is used

• Human error can be involved – training is essential!
Allergen Cross-contact Prevention Considerations

- Equipment cleaning and sanitary design
- Scheduling
- Manufacturing and engineering controls
- Allergenic ingredient control
- Rework management
- Personnel practices
- Employee training relevant to the above
Equipment Cleaning
A Potential Preventive Control for Allergens

- Thorough cleaning between products with different allergens is required to prevent cross-contact.
- Validation of allergen cleaning procedures is not required but may be useful.
- Optional – Dedicate tools, surfaces and other devices for specific allergens.
Verification of Allergen Cleaning

- Visually clean
  - Minimum requirement
  - No residue, film or sheen

- Optional tests
  - Non-specific tests, e.g., ATP and protein
    - May not be sensitive enough to detect some allergens
  - Allergen test kits
    - Follow manufacturer’s instructions!
  - Complex tests
    - Special situations
Scheduling or Run Sequencing

- Minimize changeovers
- Run dedicated or designated systems as much as possible
- Schedule appropriate sanitation activities
- Control allergen addition
**Product Line Allergen Assessment**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Production Line</th>
<th>Egg</th>
<th>Milk</th>
<th>Soy</th>
<th>Wheat</th>
<th>Tree Nut (market name)</th>
<th>Peanut</th>
<th>Fish (market name)</th>
<th>Crustacean Shellfish (market name)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plain Omelet</td>
<td>1</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cheese Omelet</td>
<td>1</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cheese Omelet Biscuit</td>
<td>1</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Unique allergen</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Scheduling Implications:**
Run the Plain and/or Cheese Omelet in the beginning of the shift and the Cheese Omelet Biscuit at the end of the shift to reduce the potential for allergen cross-contact.

**Allergen Cleaning Implications:**
An allergen clean is required AFTER production of Cheese Omelet Biscuit because it contains a unique allergen – wheat.
Run Order Monitoring Record

**Hazard:** Allergen cross-contact from other products handled at this step; e.g., Cheese Omelet Biscuit.

Run the Plain and/or Cheese Omelet in the beginning of the shift and the Cheese Omelet Biscuit at the end of the shift to reduce the potential for allergen cross-contact. A full allergen clean is required AFTER production of Cheese Omelet Biscuit because it contains a unique allergen – wheat.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Date</th>
<th>Start Time</th>
<th>End Time</th>
<th>Allergen Clean After run (Yes/No)</th>
<th>Initials for allergen clean</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Verification Signature

Date: [ ]

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**E.G. Food Company Example**

PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit

PLANT NAME: E.G. Food Company

ADDRESS: 360 Culinary Circle, Mytown, USA

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PAGE 1 of X  ISSUE DATE mm/dd/yy  SUPERSEDES mm/dd/yy
Manufacturing and Engineering Controls

- Engineer the line to minimize mixing of allergenic products with non-allergenic products
- Use physical barriers to separate processing lines
- Minimize the reuse of water or oil
Maintenance and Engineering

- Sanitary design principles
- Monitor and reduce dust levels
- Minimize use of air compressors
- Maintain tools
Allergenic Ingredient Control

• Develop a master list of allergenic ingredients used in the facility
  ▪ Letters of guarantee from suppliers on the presence or absence of allergenic ingredients
  ▪ Accessibility of master list at receiving dock
  ▪ Use common names of allergens

• Apply careful handling at receiving to avoid allergen cross-contact

• Identify allergens with icons
Receipt of Incoming Goods

• Review labels of incoming raw materials
• Include allergen check as a prerequisite program or in allergen preventive control for deliveries, depending on risk
• Color coding and pallet labeling useful
• Separate each type of tree nut, peanut, fish or crustacean shellfish species
• Consider separate area for each allergen
• Consider dedicated transportation vehicles for different allergens, depending on risk
Storage of Incoming Goods

• Separate allergenic ingredients from non-allergenic ingredients to prevent allergen cross-contact
  ▪ Control traffic patterns also

• Use signage in areas used to store allergens
  ▪ Maintain consistent allergen identifiers – color or image

• Store allergens in sealed, intact containers, as appropriate

• Do not store allergens above non-allergens on racks or pallets

• Store allergens with “like” allergens

• Have documented clean up procedures available
Allergen Cross-contact Prevention During Processing

• Requires segregation of unique allergenic material, e.g.:
  ▪ Weigh powders containing unique allergens in a different area
  ▪ Cover totes containing allergen-containing ingredients during transfer
  ▪ Control ventilation over lines where protein powders are dumped
  ▪ Consider dedicated tools and equipment
  ▪ Proper use of containers that previously held food allergens
Rework and Product on QA Hold

• Store allergen-containing rework or open product on QA hold to avoid cross-contact
• Clearly mark rework or open QA-hold material for the presence of allergens
Personnel Practices

• Manage employee outer clothing to avoid allergen cross-contact
• Consider keeping personnel who handle unique allergens out of non-allergen areas
• Training is essential!
Allergen Labeling Considerations

• Label accuracy
  ▪ Accurate printing of allergen ingredients on the label
  ▪ The right label on the package

• Supply-chain program
  ▪ Ingredients
  ▪ Labels
Product Labeling and Packaging

- Proper package labeling protects:
  - Consumers
    - Only way for them to know the allergen is in the product
  - Companies
    - Product recalls
    - Regulatory inquiry
    - Potential liability

- Preventive controls for food labels and packages are as important as other food allergen management techniques!
Product Labeling Must Be Accurate

- Ensure all allergens are identified in compliance with appropriate law:
  - Food Allergen Labeling and Consumer Protection Act provides requirements for FDA-regulated foods
Considerations for Food Labels and Packages

• Allergen labeling errors are a primary cause of food product recalls
• Consider controls that:
  ▪ Ensure accurate printing
  ▪ Ensure the right label or package is used for the product
  ▪ Manage formula changes to ensure that the correct label is used during transition
Allergen Label Design Control Examples

Examples of procedures:

• Design and copy proofreading
• Written approval of label and package proofs
• Identity coding of printed labels and packages
• Lack of co-mingling when shipping labels and pre-printed packages
“May Contain” Labeling

• “May Contain” or similar labeling is NOT a substitute for appropriate GMPs
• Carefully consider label implications for ingredients with precautionary labels (e.g., “May Contain”)
Allergen Preventive Controls for Labeling

- Preferable continuous review of label or wrap material during a processing run
  - E.g., bar code scanner
- Colored striping on edges of packages stacked flat in packaging machines reduces line operator errors
- Especially important when labels are applied to product held in unlabeled inventory
## Ingredient Allergen Assessment

<table>
<thead>
<tr>
<th>Raw Material Name</th>
<th>Supplier</th>
<th>Egg</th>
<th>Milk</th>
<th>Soy</th>
<th>Wheat</th>
<th>Tree Nut (market name)</th>
<th>Peanut</th>
<th>Fish (market name)</th>
<th>Shell-fish (market name)</th>
<th>Allergens in Precautionary Labeling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole, liquid pasteurized egg</td>
<td>Your Egg Co.</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>None</td>
</tr>
<tr>
<td>Grade A pasteurized milk</td>
<td>A Local Dairy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>None</td>
</tr>
<tr>
<td>Pan release oil, ABC Brand</td>
<td>My distributor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>None</td>
</tr>
<tr>
<td>Salt, XYZ Brand</td>
<td>My distributor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>None</td>
</tr>
<tr>
<td>Buttermilk biscuit</td>
<td>Flaky Co.</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>None</td>
</tr>
<tr>
<td>American cheese</td>
<td>Cheesy Co.</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>None</td>
</tr>
<tr>
<td>Product</td>
<td>Allergen Statement</td>
<td>Label Number</td>
<td></td>
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</tr>
<tr>
<td>Plain Omelet</td>
<td>Contains: Egg, milk, and soy</td>
<td>P 082015</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cheese Omelet</td>
<td>Contains: Egg, milk, and soy</td>
<td>C 082015</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
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<td>Cheese Omelet Biscuit</td>
<td>Contains: Wheat, egg, milk, and soy</td>
<td>B 082015</td>
<td></td>
<td></td>
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<td>Allergen Control</td>
<td>Hazard(s)</td>
<td>Criterion</td>
<td>Monitoring</td>
<td>Corrective Action</td>
<td>Verification</td>
<td>Records</td>
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</tr>
<tr>
<td>Receiving packaging (labeled carton)</td>
<td>Undeclared allergens – egg, milk, soy (wheat in biscuit only)</td>
<td>All finished product labels must declare the allergens present in the formula per listing</td>
<td>Ingredient listing and allergen information matches product formula</td>
<td>Visual check of carton label to match product formula</td>
<td>Before release to production</td>
<td>Label coordinator</td>
<td>If label is incorrect, reject labels and return to supplier or destroy. Identify root cause and conduct training as needed to prevent recurrence</td>
<td>Review of Label verification, Corrective Action and Verification records within 7 working days</td>
<td>Allergen Label Verification listing; Allergen Label Verification log; Corrective Action records;</td>
<td></td>
</tr>
<tr>
<td>Allergen Control</td>
<td>Hazard(s)</td>
<td>Criterion</td>
<td>Monitoring</td>
<td>Corrective Action</td>
<td>Verification</td>
<td>Records</td>
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<td></td>
</tr>
<tr>
<td>Fill, weigh, label</td>
<td>Undeclared allergens – egg, milk, soy (wheat in biscuit only)</td>
<td>All finished product must have correct labeled carton</td>
<td>Label number matches product</td>
<td>Visual check of carton number to match product</td>
<td>Beginning and end of run and when label stock is changed</td>
<td>Fill line operator</td>
<td>Review of Label Check, Corrective Action and Verification records within 7 working days</td>
<td>Allergen Label Verification listing; Allergen Label Check Log; Corrective Action records; Verification records</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PRODUCT:** Omelet - Plain

**PLANT NAME:** E.G. Food Company

**ADDRESS:** 360 Culinary Circle, Mytown, USA
Allergen Control by Suppliers

- Understand allergens handled by suppliers
  - See Chapter 12: Supply-chain Preventive Controls
- Use caution with ingredient substitution
Allergen Training

• Critical to implementation and execution of an Allergen Control Plan
• Applies to a variety of personnel
• Education and knowledge building
• Empower individual role and responsibility
• Reinforce commitment to food safety
• Highlight changes or new development
Allergen Preventive Controls Summary

• Undeclared allergens present a risk:
  ▪ Consumer reactions can be severe
  ▪ Major cause of food recalls

• Allergen preventive controls required to:
  ▪ Prevent allergen cross-contact
  ▪ Accurately label product

• Allergen management best practices exist to:
  ▪ Protect the allergic consumer
  ▪ Reduce a company's risk
  ▪ Make food safer for all to enjoy
EXERCISE

• Use the hazard analysis from the previous exercise.
• Did you identify the need for allergen preventive control?
• Complete allergen forms to manage this hazard. Useful questions to guide discussion:
  ▪ What allergens are present in the facility?
  ▪ Do all products contain the same allergens?
  ▪ If not, what do you do to control these allergens?
  ▪ What considerations did you take into account?
• Potential resources:
  ▪ Allergen section in Chapter 5 – Chemical, Physical and Economically Motivated Food Safety Hazards
• Pick a spokesperson to summarize the process to the rest of the class.