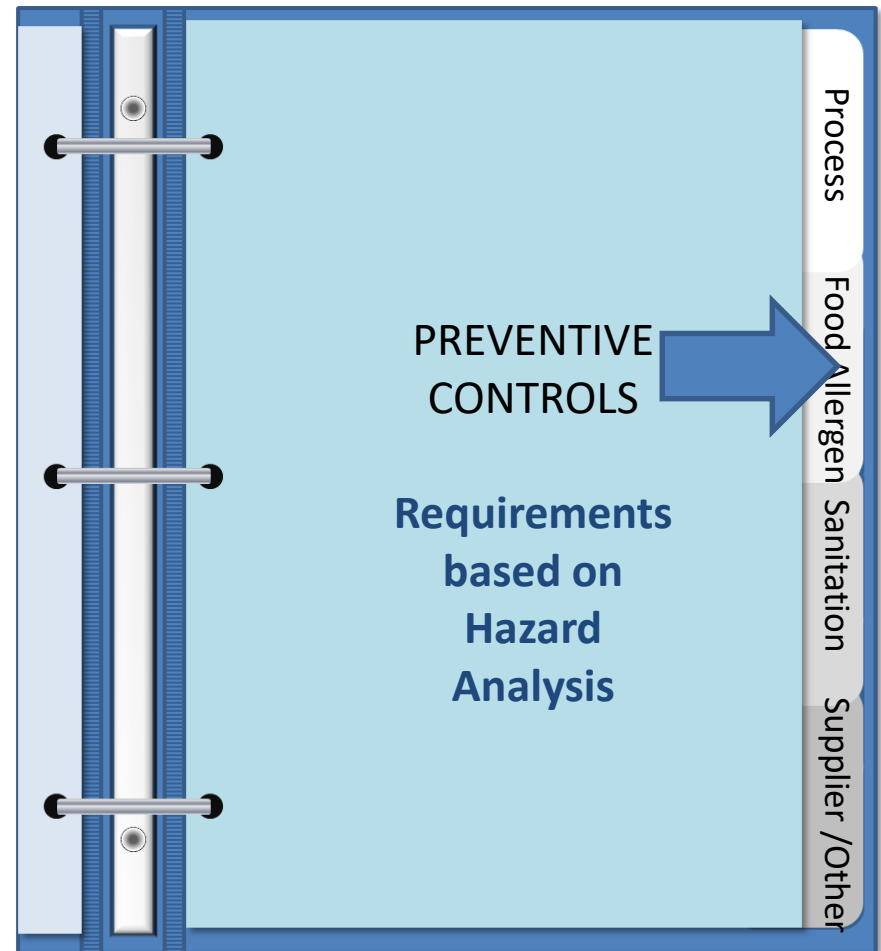


Chapter 10

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

E.G. Food Company Example

PRODUCT: Omelet – Plain, Cheese, and Cheese Biscuit					PAGE X of Y		
PLANT NAME	E.G. Food Company			ISSUE DATE	2/13/2016		
ADDRESS	360 Culinary Circle, Mytown, USA			SUPERSEDES	9/20/2015		
(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
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		X

*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

E.G. Food Company Example

PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit
PLANT NAME: E.G. Food Company
ADDRESS: 360 Culinary Circle, Mytown, USA

PAGE 1 of X
ISSUE DATE mm/dd/yy
SUPERSEDES mm/dd/yy

Product Line Allergen Assessment

Product Name	Production Line	Intentional Allergens							
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Crustacean Shellfish (market name)
Plain Omelet	1	X	X	X					
Cheese Omelet	1	X	X	X					
Cheese Omelet Biscuit	1	X	X	X	X Unique allergen				

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.

E.G. Food Company Example

PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit
PLANT NAME: E.G. Food Company
ADDRESS: 360 Culinary Circle, Mytown, USA

ISSUE DATE
SUPERSEDES

PAGE 1 of X
mm/dd/yy
mm/dd/yy

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.

Product Name	Date	Start Time	End Time	Allergen Clean After run (Yes/No)	Initials for allergen clean
Verification Signature				Date:	

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

PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit
 PLANT NAME: E.G. Food Company
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PAGE 18 of 38

ISSUE DATE
 SUPERSEDES

Ingredient Allergen Assessment

Raw Material Name	Supplier	Allergens in Ingredient Formulation								Allergens in Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shell-fish (market name)	
Whole, liquid pasteurized egg	Your Egg Co.	X								None
Grade A pasteurized milk	A Local Dairy		X							None
Pan release oil, ABC Brand	My distributor			X						None
Salt, XYZ Brand	My distributor									None
Buttermilk biscuit	Flaky Co.		X		X					None
American cheese	Cheesy Co.		X							None

E.G. Food Company Example

PRODUCT: Omelet - Plain
PLANT NAME: E.G. Food Company
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PAGE 1 of X
ISSUE DATE
SUPERSEDES

Allergen Label Verification Upon Receipt and Application to Product

Product	Allergen Statement	Label Number
Plain Omelet	Contains: Egg, milk, and soy	P 082015
Cheese Omelet	Contains: Egg, milk, and soy	C 082015
Cheese Omelet Biscuit	Contains: Wheat, egg, milk, and soy	B 082015

E.G. Food Company Example

PRODUCT: Omelet - Plain

PAGE 1 of X

PLANT NAME: E.G. Food Company

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mm/dd/yy

ADDRESS: 360 Culinary Circle, Mytown, USA

SUPERSEDES

mm/dd/yy

Allergen Control	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving packaging (labeled carton)	Undeclared allergens – egg, milk, soy (wheat in biscuit only)	All finished product labels must declare the allergens present in the formula per listing	Ingredient listing and allergen information matches product	Visual check of carton label to match product formula	Before release to production	Label coordinator	If label is incorrect, reject labels and return to supplier or destroy. Identify root cause and conduct training as needed to prevent recurrence	Review of Label verification, Corrective Action and Verification records within 7 working days	Allergen Label Verification listing; Allergen Label Verification log; Corrective Action records;

E.G. Food Company Example

PRODUCT: Omelet - Plain

PAGE 1 of X

PLANT NAME: E.G. Food Company

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mm/dd/yy

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mm/dd/yy

Allergen Control	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Fill, weigh, label	Undeclared allergens – egg, milk, soy (wheat in biscuit only)	All finished product must have correct labeled carton	Label number matches product	Visual check of carton number to match product	Beginning and end of run and when label stock is changed	Fill line operator	If label is incorrect, segregate product, inspect back to the last good check, relabel product; Identify root cause and conduct training as needed to prevent recurrence	Review of Label Check, Corrective Action and Verification records within 7 working days	Allergen Label Verification listing Allergen Label Check Log; Corrective Action records; Verification records

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 the 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.