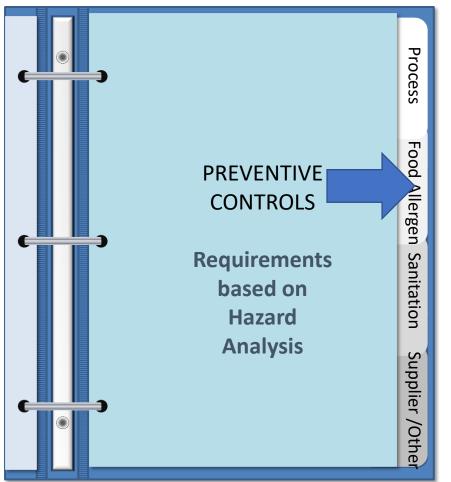
Allergen Control

Food Allergen Preventive Controls Objectives

- Allergen preventive controls link to hazard analysis
- Required food allergen preventive controls
 - Allergen cross-contact prevention
 - Allergen label review
- Allergen preventive controls options



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!

Ingredient Allergen Assessment

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Form Name: Food Allergen Ingredient Analysis

Γ			Food Allergens in Ingredient Formulation								
	Raw Material Name	Supplier	Egg	Milk	Say	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	Allergens in Precautionary Labeling

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

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

Run ordering

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Form Name: Production Line Food Allergen Assessment

			Intentional Allergens						
Product Name	Production Line	223	Mük	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)

Scheduling Implications:

Allergen Cleaning Implications: (Required)

Example Process Order Monitoring Record

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.

				Allergen Clean	Initials for
		Start		After run	allergen
Product Name	Date	Time	End Time	(Yes/No)	clean
Verification Signature		1	1	Date:	

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

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

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!

Allergen Label Verification Receipt

PRODUCT: Ice Creams PLANT NAME: I.B. Frozen Company ADDRESS: 360 Culinary Circle, M	of X DATE EDES						
Allergen Label Verification Upon Receipt and Application to Product							
Product	Allergen Statement	Label Number					
French Vanilla	Contains: Egg, Milk	P 082015					
Peanut Butter Cookie	Contains: Egg, Milk, Peanuts, Wheat	C 082015					
Chocolate	Contains: Milk	B 082015					

"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 Control Program

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

	Records		
	Verification		
	Corrective Action		
atrols		Who	
Form Name: Food Allergen Preventive Controls	Monitoring	Frequency	
Prever	Wo	How	
rgen l		What	
od Alle	Criterion		
ame: Fo	Hazard(s)		
Form N	Allergen Control		

PRODUCT: French Vanilla Ice Cream									PAGE 1 of X
	ME: I.B. Frozei 360 Culinary (ISSUE SUPERS	mm/dd/yy mm/dd/yy					
Allergen				Monito	oring	1	Corrective		
Control	Hazard(s)	Criterion	What	How	Frequency	Who	Action	Verification	Records
Receiving – labels	Chemical – Milk, Egg Allergen	"Contains: Egg, Milk" statement below ingredient statement	Incoming new labels	Checklist for all newly	Receipt of every new shipment of labels	QA trained staff	Reject label shipment	Records reviewed and signed by PCQI or designee within 7 working days.	Label Evaluation Checklist – Receiving

PRODUCT: French Vanilla Ice Cream										
PLANT NAME: I.B. Frozen Company ADDRESS: 360 Culinary Circle, Mytown, USA								ISSUE DATE SUPERSEDES		
Allergen Control	Hazard(s)	Criterion	What	Monito How	oring Frequency	Who	Corrective Action	Verification	Records	
Filler (Pints) weighed and labeled	Chemical – Egg, Milk Allergen	"Contains: Egg, Milk" statement below ingredient statement	Placing of Labels on product package	Check labels versus product	At start of shift and change of lot numbers	Packagin g operator	Place product on hold, re- label product with correct label Determine cause of wrong label and correct. Document corrective action.	Records reviewed and signed by PCQI or designee within 7 working days.	Packaging operator daily log	

Sanitation to prevent cross-contact?

• Will be discussed in sanitation preventive control program