Sanitation's Role in Allergen Control

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Outline

- Food Allergy Facts and Statistics
- Seven Elements of Allergen Control
- Manufacturing with Allergens
- Cleaning and Sanitation
- Validation & Verification
- Summary
Allergen Awareness Exercise

- Think about the last meal that you ate
- How many potential food allergens do you think it contained?

- How many of you have a food allergy?
Food Allergy Facts & Stats

- **Food Allergen** – a compound containing a protein(s) capable of causing an immunologic reaction in some people
  - Symptoms range and vary
    - Hives, swelling, respiratory complications, anaphylaxis

- **Food Intolerance/Hypersensitivity** – Adverse response to food that is limited to gastrointestinal problems
  - Gluten

- Children account for most of the estimated 15 million Americans with food allergies
Food Allergy Facts & Stats

- Food allergies in children increased by 50% from 1997 to 2011
  - Cause of increase unknown
  - Affects 1 in every 13 children
  - Economic cost of children's food allergies is approximately $25 billion per year

- There is no cure for food allergies
  - Best approach is avoidance of the food allergen

- Allergens are currently the #1 reason for a food recall in the United States
Top 8 Food Allergens

- Eight (8) food allergens account for 90% of all food-allergenic reactions
  - Milk
  - Eggs
  - Peanuts
  - Tree nuts
  - Soy
  - Wheat
  - Fish
  - Shellfish

- Most food allergies start in childhood
- Peanut, tree nut, fish, and shellfish allergies tend to be lifelong
  - Allergies to cow's milk, eggs, and soy may be outgrown and usually by school age

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A strong allergen control plan is critical to avoid cross-contact of allergens in products

- Conduct a thorough risk assessment
  - Identify the causes of intentional and unintentional allergens in food production
  - Enables development of preventable controls
  - Goal: Minimize possibility of allergen cross-contact

- Establish policies and procedures for allergen control
  - Seven key elements of allergen control

- Reassess effectiveness of Allergen Control Plan through audits
7 Elements of Allergen Control

- Raw Materials
- Facility Design
- Manufacturing & Processes *
- Cleaning & Sanitation *
- Rework
- Labeling & Packaging
- Employee Training

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Raw Material Storage Segregation

- Segregate allergenic raw materials to minimize cross-contamination
  - Use dedicated scoops, pallets and bins
  - Store allergenic materials on lower shelves
  - Designate specific storage areas for specific types of allergens
    - "Wheat only", "Peanut only"
  - Make sure containers are tightly sealed to avoid airborne contamination
Color-Coding for Allergens Identification

- Color coding – a simple and effective way to identify and segregate allergenic materials throughout the process of food production
- Aids in the prevention of cross-contact
  - Labels for:
    - Raw materials
    - Storage areas
    - Production areas
    - Boxes
    - Pallets
  - Dedicated sanitation supplies
    - Brushes, buckets, squeegees, scrapers, etc.
Color-Coding for Identification

- Color coded labels (Al-Aware):
  - Dairy Allergen
  - Egg Allergen
  - Peanut Allergen
  - Shellfish Allergen
  - Fish Allergen
  - Tree Nut Allergen
  - Soy Allergen
  - Wheat Allergen

- Sanitation supplies (Vikan):

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Manufacturing With Allergens

General Guidelines:

- Segregate the production areas for in-process foods containing major food allergens
  - Physical barriers
  - Dedicated employees

- Dedicate equipment and food-contact surfaces when possible

- Manage airflow and traffic flow
  - Design traffic patterns and airflow in production facility to prevent allergen cross-contact
Cleaning & Sanitation

- Cleaning is considered a first line of defense in prevention of allergen cross-contact on shared processing lines
  - Studies have shown inadequately cleaned equipment was deemed responsible for causing people to experience allergic reactions from milk- or peanut-contaminated foods
- Some facilities use equipment and product lines to produce both allergen and non-allergen products
  - The allergen residue (protein) must removed before non-allergen containing products are run
Cleaning & Sanitation

- Standard Sanitation Operating Procedures (SSOPs)
  - Define the scope and schedule for cleaning and sanitizing production areas, including equipment and food contact surfaces
  - Nature of allergenic protein, food matrix, and processing equipment will dictate appropriate cleaning protocols
  - Depending on the product being produced, the method of cleaning may be:
    - Wet cleaning
    - Dry cleaning
Wet Cleaning (1)

- **Four categories:**
  - **Clean in Place (CIP)**
    - Minimal or no disassembly
    - Cleaning fully automated
  - **Clean Out of Place (COP)**
    - Equipment partially disassembled and cleaned in tanks
  - **Foam or Gel Cleaning**
    - Chemical applied to equipment as foam or gel for increased contact time with soil
  - **Manual or Hand Cleaning**
    - Equipment fully disassembled and cleaned by hand

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Wet Cleaning (2)

- **Four interrelated factors affecting cleaning efficacy of overall cleaning process:**
  - Cleaning time
  - Temperature of cleaning solution
  - Composition of the cleaning solution
    - Detergent type
    - Concentration
  - Mechanical force used to apply and agitate the cleaning solution
    - Equipment fully disassembled and cleaned by hand
Wet Cleaning (3)

- Food processors need to evaluate the efficacy of cleaning protocols for each:
  - Type of food soil
  - Food contact surface
  - Piece of equipment
  - Processing line
- Studies have shown no one protocol works for everything
  - Cold milk soils easier to remove than hot milk soils
  - Cleaners more effective at higher temperatures for removing peanut butter residues

Burnt milk residue
Dry Cleaning (1)

- Dry goods manufacturing (i.e. baked goods, spray-dried foods) may not be designed to accommodate water
  - May even be designed to be free of water to facilitate the manufacture of certain products
- Introducing water to equipment and environments not designed for it may cause significant problems
  - May promote uncontrolled microbial growth
  - May cause development of sites that harbor bacteria
    - Pitting, corrosion
  - May cause equipment failure
    - Electronics not water-safe
Dry Cleaning (2)

- Need to balance effective allergen control with effective pathogen control
- Managing allergenic foods in dry foods plants and lines requires rethinking traditional equipment design
  - To increase equipment accessibility and cleanability
- Reportedly more than 50% of companies use dry cleaning practices
  - Most companies use dry cleaning in combination with wet cleaning when water is permissible
Dry Cleaning (3)

- **Main Categories:**
  - Brush/Scrape
  - Sweep
  - Compressed Air
  - Wipe
  - Vacuum
  - Surface blasting
    - Dry ice blasting, sodium bicarb blasting, grit blasting
    - "Push-through" with non-allergenic foods
    - Salt, flour, and starch
Dry Cleaning (4)

- Brushes/Scrapers/Sweepers
  - Should be color coded
  - Dedicated for use on allergenic lines to prevent cross-contact contamination to non-allergenic lines

- Compressed air
  - Often used to dislodge food residue from inaccessible areas of equipment or the environment
  - Introduces significant hygienic challenges to surrounding areas
    - Generates aerosols and airborne dusts
  - Should be used with discretion and as a last resort
Dry Cleaning (5)

- Disposable cloth or paper wipes saturated with water or alcohol
  - Used where water is not compatible with the manufacturing equipment and/or processing environment
  - Localize water and minimize dust generation

- Vacuum
  - High-efficiency particulate air filtration vacuum systems
  - Designed to remove and contain dust and debris during dry cleaning of food plant areas
Dry Cleaning (6)

- Dry ice (solid CO₂) blasting, bicarb blasting, grit blasting
  - Used without water
  - Clean and remove most soils without damaging equipment
  - Usually do not capture the soil removed from the surface
  - Additional steps needed to remove soil from the manufacturing environment

- "Push-through" with non-allergenic foods
  - Salt, flour, and starch
  - "Clean" equipment by purging (pushing through) the allergenic food from surfaces and equipment
  - SQF Code: three product flushes may be required to assure removal of the material of concern

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Allergen Cleaning Program

- Sanitation procedures established for the process must be validated for effectiveness
- Validated procedures are then implemented
- Actual procedures should be verified each time they are carried out
- Procedures should be reviewed any time changes are made
  - New equipment
  - Different cleaning chemicals/tools
  - Product modifications
Validation Testing

- Validation serves to prove the cleaning process is effective in removing/controlling the allergen of concern
  - And once implemented, will produce the same results every time

- Acceptable validation methods involve the use of a test specific to the allergen being removed
  - A quantitative Enzyme-Linked Immunosorbent Assay (ELISA) method often used
  - A qualitative lateral flow device using an ELISA-based method also acceptable
Validation Protocols

Protocols:

- Need to be clearly written and easy to follow and understand
- Define the intention and scope of validation
- Describe the sampling procedures
- Define and describe the analytical procedures to be used
- Define the final acceptance/verification criteria
Planning the Testing

- Plan to run the formula with the highest percentage of allergen to effectively assess the cleaning process
- Don't do testing until you have a plan about what to do with a positive result
  - Communicate and coordinate with senior management to hold or destroy product pending testing results
- "Safe Mode" testing plan
  - Run the same allergenic product before and after sanitation
    - If swab indicates inadequate cleaning, can still ship product
    - Modify the sanitation procedures before next validation test
Verification Testing

- Facility must verify that the validated procedures are used every time
  - Must be documented
- Most common method is direct observation of the validated cleaning procedure during the sanitation process
- Use of highly sensitive swabs that test for proteins is acceptable
  - Only test for total protein, not specific allergens
  - Not acceptable for validation, but verify equipment has been thoroughly cleaned
Verification Testing

- Sensitive ATP swabs also available
  - Presence of ATP does not indicate the presence of protein that is the allergenic material

- The use of total protein swabs or ATP sensitive swabs must be calibrated with the validated cleaning procedure
  - Use them immediately after the validated method is used and record results of both the allergenic specific tests and swab test
With over 50% of food recalls related to allergens, allergen control is an important food safety issue

Proper allergen control requires an Allergen Control Program

Substantial efforts should be made to segregate and separate allergenic- from non-allergenic materials

Sanitation plays a paramount role in the control of allergens in the food processing environment

Validated cleaning procedures that are utilized and verified each time can substantially reduce the incidence of unintentional allergens in food