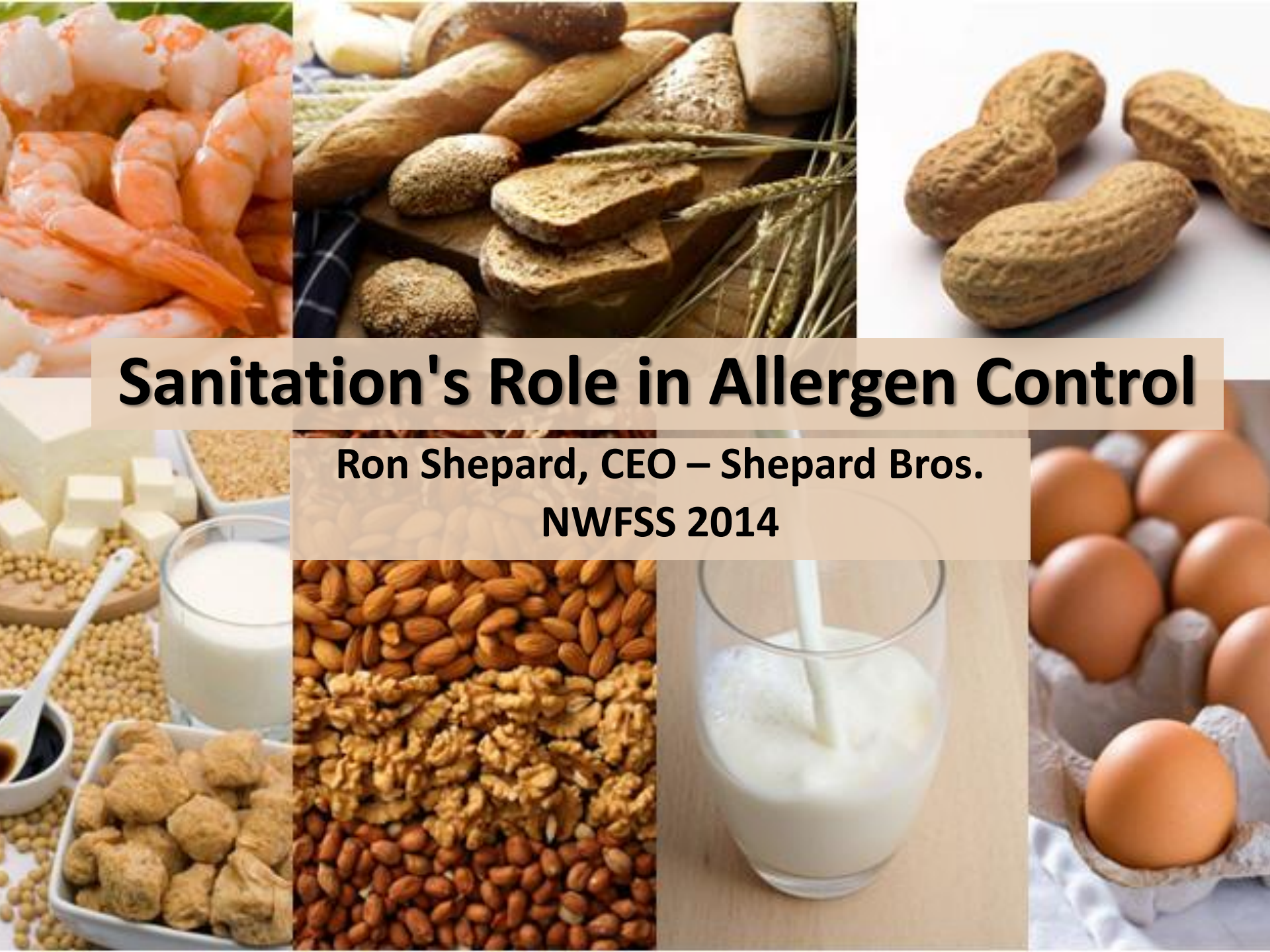

Sanitation's Role in Allergen Control

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NWFSS 2014

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

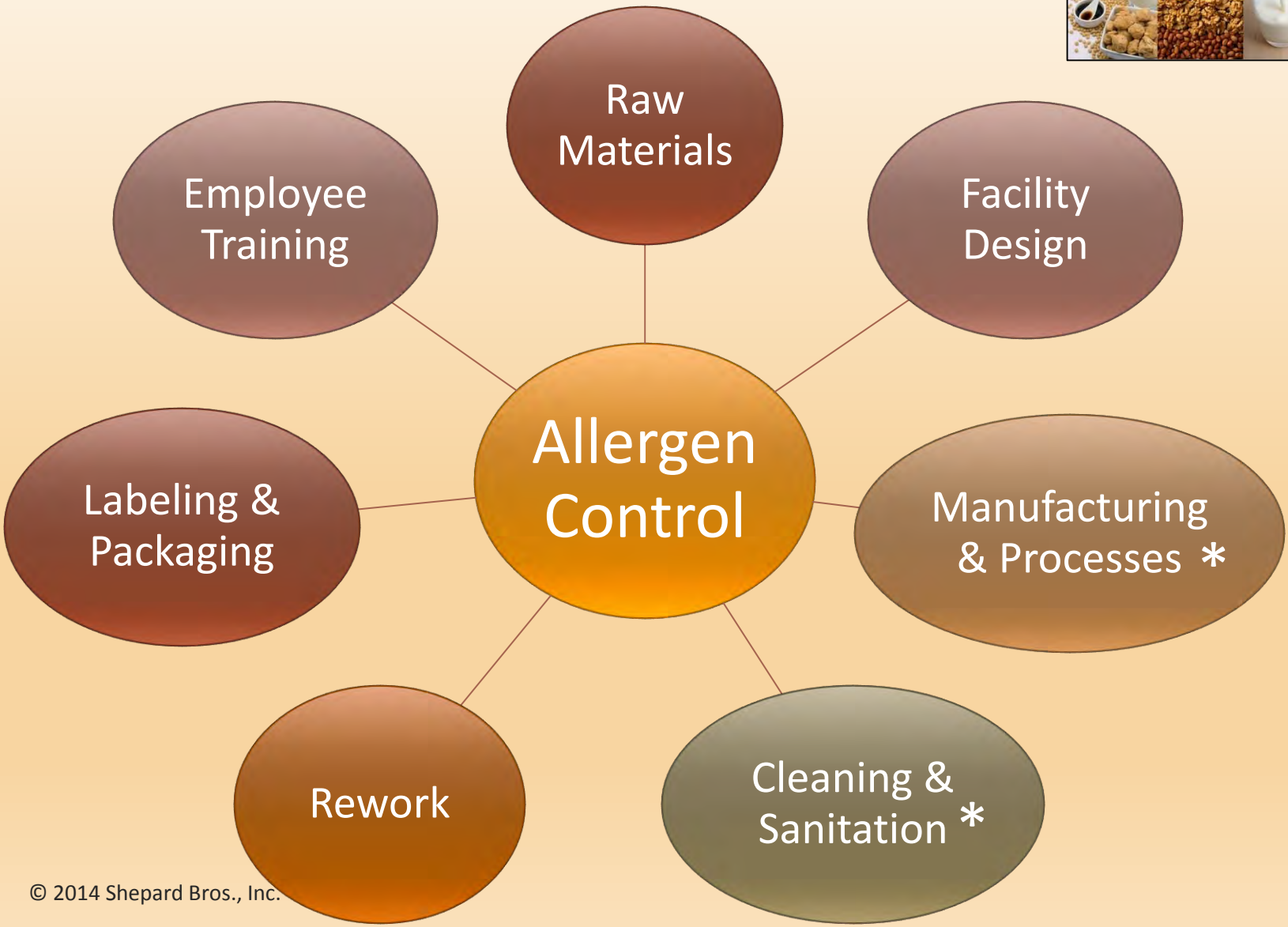
- Eight (8) food allergens account for 90% of all food-allergenic reactions
  - Milk
  - Eggs
  - Peanuts
  - Tree nuts
  - Soy
  - Wheat
  - Fish
  - Shellfish

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

Allergen Control Plan

- 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

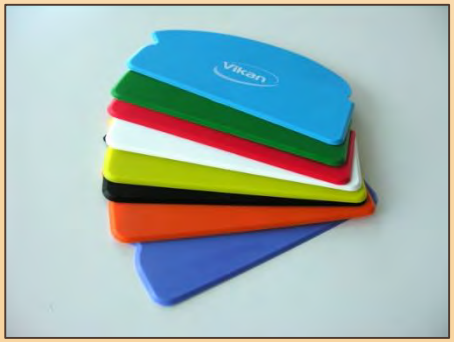


Raw Material Storage Segregation

- 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

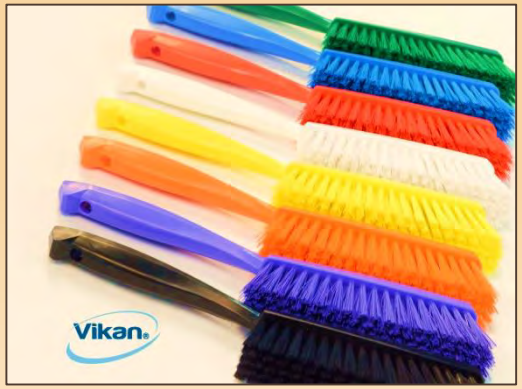
- Color coding – a simple and effective way to identify and segregate allergenic materials throughout the process of food production
- Aids in the prevention of cross-contact
  - Labels for:
    - Raw materials
    - Storage areas
    - Production areas
    - Boxes
    - Pallets
  - Dedicated sanitation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

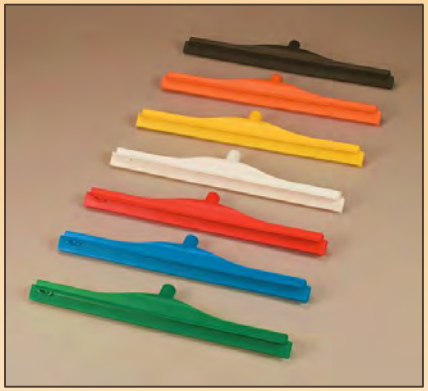


Color-Coding for Identification

- Color coded labels (Al-Aware):

- Sanitation supplies (Vikan):





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

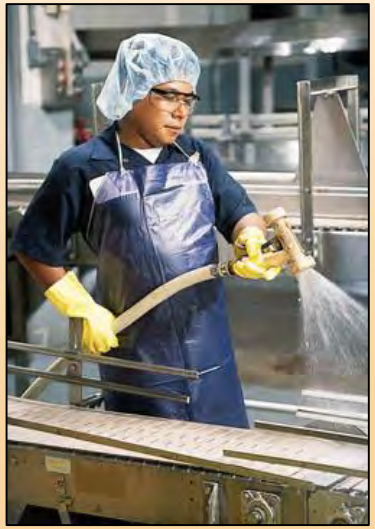
- Cleaning is considered a first line of defense in prevention of allergen cross-contact on shared processing lines
  - Studies have shown inadequately cleaned equipment was deemed responsible for causing people to experience allergic reactions from milk- or peanut-contaminated foods
- Some facilities 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



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

Burnt milk residue

- 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

Dry Cleaning (1)

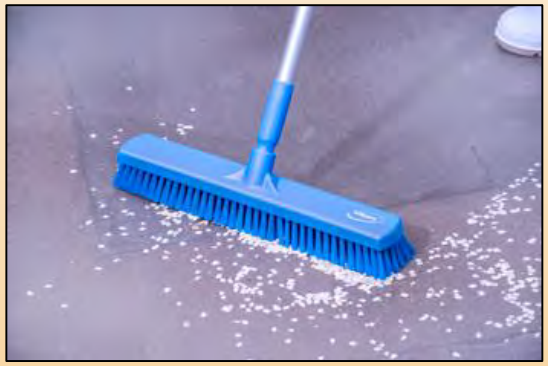
- Dry goods manufacturing (i.e. baked goods, spray-dried foods) may not be designed to accommodate water
  - May even be designed to be free of water to facilitate the manufacture of certain products
- Introducing water to equipment and environments not designed for it may cause significant problems
  - 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 CO_2) 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

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

Summary

- 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