Allergen Control in the Food Plant

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Presented to: Southern California Institute of Food Technologists

April 18, 2007

Overview

- Allergen hazards
- Regulatory climate
- Industry ‘best practices’ for control
- Evaluating efficacy of controls
- Future challenges

Reference: IFT technical review 2006 (Taylor, S.E. et.al. Analysis and Evaluation of Food Manufacturing Practices Used to Address Allergen Concerns, 2006. Comp. Rev. Food Sci. and Food Safety. (5) 138-157)

Allergen Hazards

- NIH estimates 6-8% of children and 2% of adults have food related allergic reactions
- Greater than 90% of food reactions caused by big 8. (wheat, egg, milk, fish, crustacean shellfish, tree nuts, peanuts, and soy)

Regulatory Climate

- Food Allergen Labeling and Consumer Protection Act (FALCPA) 2004
- Zero tolerance in U.S.
- Detectable quantity of undeclared allergen is violative

Contamination Controls- New Dynamics

Industry 'Best Practices' for Allergen Control

- Vendor/Ingredient controls
- Storage Controls (spills, zoning)
- Line dedication (segregation)
- Production sequencing/scheduling
- Sanitation practices to prevent carry-over from shared equipment
- Processing aid controls
- Labeling
- Rework
- GMP's (food handling,facilities, equipment, etc.)
- Training and allergen awareness systems

Vendor/Ingredient Controls

- Require ingredient statements on all ingredients
- Require specification with allergen presence in ingredient statements
- Ensure ingredient statement accuracy
  - Allergen questionnaire
  - COA
  - Specifications
  - Company evaluations

Ingredient Controls

- Allergen identification labeling on ingredients
- Procedures to prevent cross-contact in transit
- Procedures to prevent cross-contact at receiving
- Separate ingredient storage (zone storage for dry, dusty allergens, spill management)

HACCP controls

- CCP or CP established at key steps
  - Label inspections
  - Residue testing
  - Production sequencing
  - Rework controls
  - Batch controls
  - Line clearance/ changeovers

Line/Equipment Dedication

- Barriers/shields between lines and/or equipment covers
- Equipment/utensil use restricted for one allergen profile only
- Color coding systems for processing and cleaning utensils

Line/Equipment Dedication, Contd.

- Dedicated personnel
- Traffic controls
- Dedicated frocks
- Clearly defined policies and procedures are communicated through training

Line/Equipment Dedication Issues

- **Impractical when many allergen profiles exist**
  - **Prohibitive cost of equipment**
  - **Lack of space (processing, utensil storage)**
  - **Difficult to manage color codes**
    - **Universal allergen color code will not control cross contact between dissimilar allergens**
    - **Numerous color codes (rainbow dilemma)**
    - **Color blind recognition issues**

Allergen Color Coding (Processing utensils, cleaning utensils)

W	Tn
S	F
E	Sh
M	P

Production Sequencing

- Progressive order of production involves addition of allergen types (e.g. W> W, E > W, E, S > W, E, S, M)
- Production of different allergen profiles on different days
- Longer runs to minimize allergen changeovers
- Requires defined allergen profiles for all ingredients and products
- Requires documented production sequence record for verification

Production Sequencing

- Can be complex if flavor carryover issues are additionally of concern

Sanitation Controls

- Written SSOP's
- Equipment disassembly
- Appropriate cleaning
  - Wet (COP, CIP, proper use of detergents)
  - Air (Vacuum)
  - Dry wipe downs
  - Push through (purge and dump)
  - Scraping with non-allergenic materials (e.g. dry ice pellets, salt, rice)
- Validated cleaning methods

Sanitation Control Challenges

- Washouts or sanitizer application not adequate to rid protein soils
- Water exposure to equipment and environment can create other problems
- Cross contamination via splashing and dust generation
- Requires documented inspection for adequacy of cleaning at each allergen changeover

Sanitation Control Challenges

- Requires effective communication between production and QA
- Cleaning utensils can potentially be detrimental if not managed
- Downtime for cleaning may be significant
- Heavy training for staff is necessary

Allergen Soils

- Food scrap/residue
- Dust
- Splashing
- Fog

Dust Controls

- Negative pressure (vacuum) for cleaning
- HEPA filter to prevent contamination
- Ensure pneumatic transfer and other system leaks are controlled
- Dust control systems where necessary for processing
- Particle movement can be surprising

Evaluating Efficacy of Controls

- Routine verification of control measures
- Validation of sanitation control measures

Evaluating Efficacy of Controls- Verification Measures

- Visual inspection of sanitation
- Systems Self Audits
- Label Audits
- Objective sampling and testing
  - Routine monitoring (ingredients, sanitation, rinse water, purge, finished product)
  - Validation

Verifying Control Through Visual Inspection

- Pre-operational sanitation conditions
- Allergen changeovers
  - Soil removal
    - Employees (hands/gloves, aprons/smocks, sleeve guards)
    - Equipment and utensils
  - Dust/splashing controls

Verifying Control Through Visual Inspection

- Allergen changeovers
  - Materials/label removal
    - Line clearance
    - Label clearance
  - Proper sequencing
  - Leftover, WIP, and rework materials properly protected and labeled
  - Staged materials protected
  - Appropriate record keeping of inspection

Verifying Control Through Objective Measures

- Food contact and adjoining surface swabbing
  - Indicators
  - Analysis for target allergens

Implications of Indicator and Targeted Allergen Testing

- Zero tolerance policy causes food in which undeclared allergens are detected to be considered adulterated.
- Push through (purge) and food contact surface swab results can directly implicate product

Strategies for Objective Testing:

- Implement food contact surface regimen with progressive specificity of testing
- Prior validation of push-through (purge)
- Make finished product testing a final verification
- Sanitation breaks to minimize impact

Progressive Specificity of Testing:

- Food contact surface progresses from less specific to more specific
- Visual > Non-Specific soils (ATP or glucose/lactose indicator) > Protein soils (protein indicator)> Targeted allergen protein test

Verifying Control Through Objective Measures- Indicators

- ATP (e.g. Biotrace, Charm, Hygiena)
- Protein detection (e.g. Neogen)

ATP

- Indirect indicator (specificity lacking)
- Immediate result
- Useful for total soils detection
- Luminometer required to read results

Protein Detection Indicators

- Direct indicator (higher specificity for protein than ATP) (no specificity for which allergen)
- Immediate result
- Not useful to indicate microbial or fat residues
- Enzymatic (colorimetric) assay, visual endpoint, no equipment required for reading.

Protein Indicator

- Neogen AccuClean™ swab
- Qualitative
- 5 minutes
- Total protein only, not specific allergen
- Does not indicate microbial presence

Targeted Allergen Testing

- Allergenic Protein ELISA detection
  - Qualitative (sanitation)
  - Quantitative (push through validation, raw ingredient, and finished product testing)

Qualitative ELISA Testing

- Neogen Alert$_{TM}$ commercially available for some proteins
  - Almond
  - Egg
  - Prolamins (wheat gliadin, rye secalin, barley hordein)
  - Milk
  - Peanut
  - Soy flour

Qualitative ELISA Testing

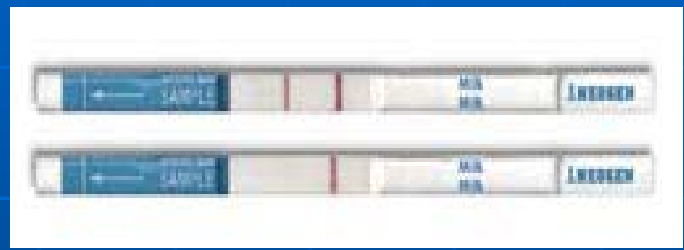
- Hallmark Analytical (Australia) offers crustacea ELISA kits and others

Qualitative Lateral Flow Testing

- Neogen Reveal® commercially available for some proteins
  - Milk
  - Peanut

Qualitative Lateral Flow Test

- Neogen Reveal®
- 5 ppm sensitivity assay, with single cutoff value
- Requires extraction
- 5 minute assay *after* extraction
- Visual endpoint determination
- Test kits have finite shelf life
- No separate kit for swabbing



Qualitative ELISA Testing

- Neogen Alert®
- 5-10 ppm sensitivity assay, with single cutoff value
- Requires extraction
- 30 minute assay *after* extraction
- Visual endpoint determination
- Test kits have finite shelf life
- Need separate kit for swabbing

Quantitative ELISA Testing

- Neogen Veratox$_{TM}$ commercially available for some proteins
  - Almond
  - Egg
  - Prolamins (wheat gliadin, rye secalin, barley hordein)
  - Hazelnut
  - Milk
  - Peanut
  - Soy flour

Quantitative ELISA Testing

- Neogen Veratox®
- 0-50 ppm sensitivity assay, with multiple cutoff value
- Requires extraction
- 30 minute assay *after* extraction
- Optical density endpoint determination (requires 650 nm reader)
- Test kits have finite shelf life

Sanitation Validation Elements

- Define cleaning protocols
- Verify protocols are properly implemented through audits and inspection
- Map equipment for potential failure points (sampling sites)
- Define sampling plan (output product)

Sanitation Validation Elements

- Define objective measurement tool (ATP, protein indicator, allergen)
- Define number of replications (generally at least 3)
- Define acceptance criteria
- Evaluate data to make conclusions.
- Identify the need for push through validation
- Make adjustments to the cleaning procedures
- Re-validate if necessary

Equipment Challenges

- Shared equipment (mixers, fillers, conveyors, scales, tanks, pumps, liquifiers, homogenizers, size reducers, formers, coating/enrobing systems, ovens, spray systems, pasteurizers, sifters, dryers, kettles,storage containers, batter systems, fry oil, etc.)
- Utensils

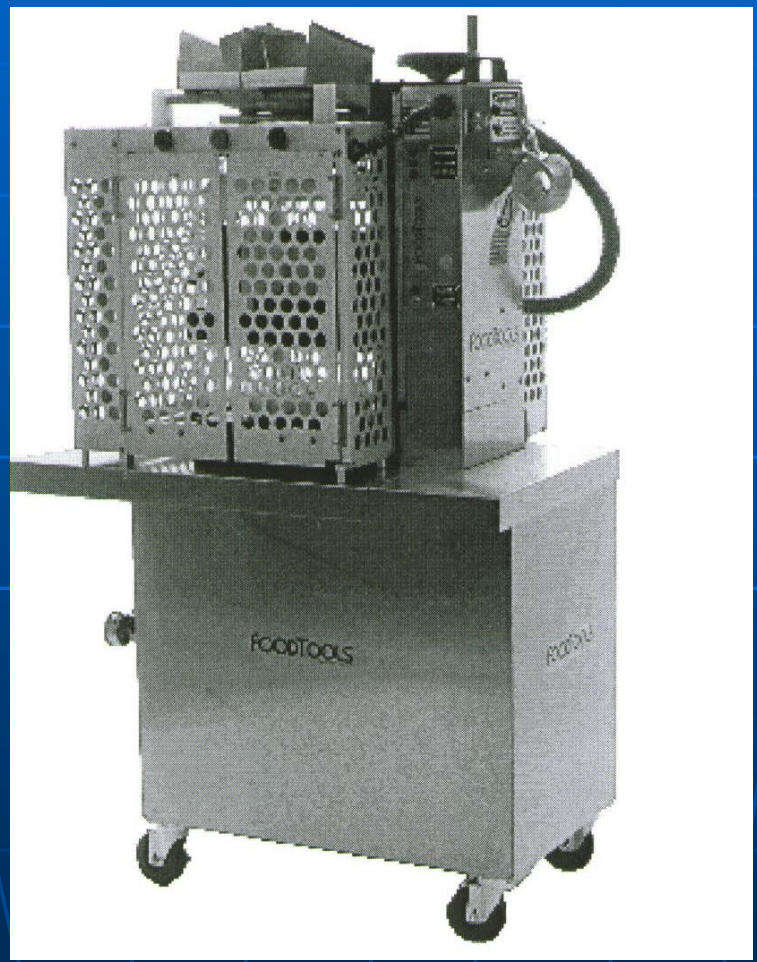
Examples of Potential Sampling Points

- Dead spots
- Accumulation points
- Bearings
- Void spaces at junctions between surfaces
- Ledges
- Mesh belts/screens
- Valves/couplings

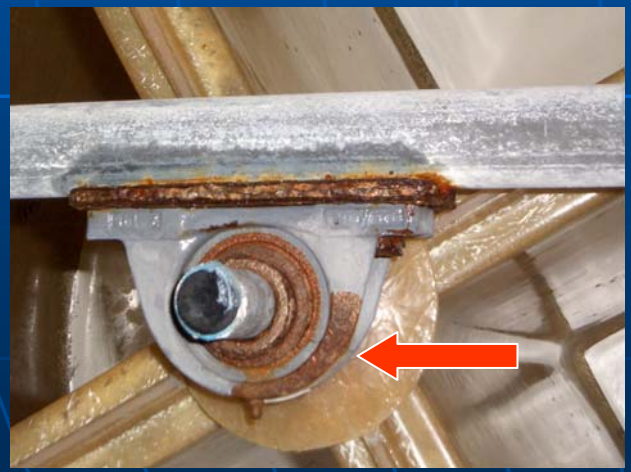
Blender Validation Swab Sites

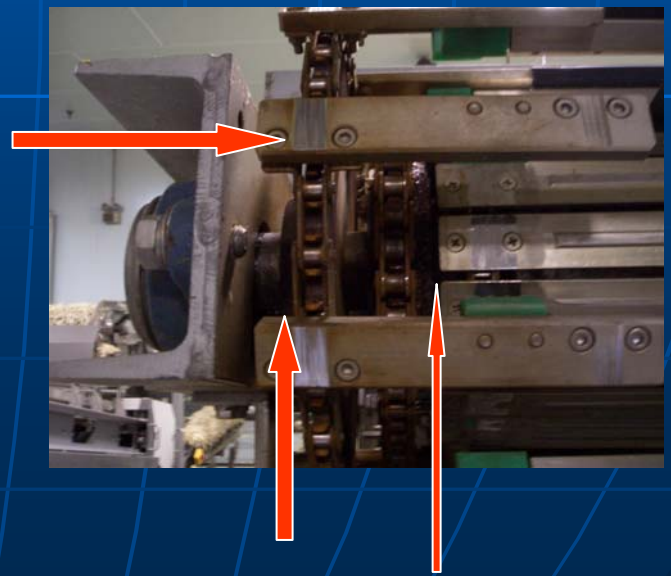
- Bearings on mixing shaft
- Discharge valve gasket
- Discharge valve (inside)
- Connections for scraper paddles
- Hinges on lid
- Sampling should be biased towards sites most likely to contain residue

Cake Slicer

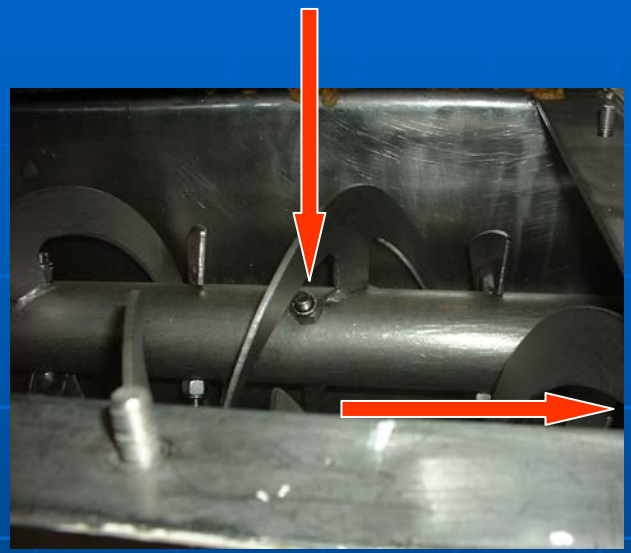


Equipment Challenges





Equipment Design



Push Through (Purge) Validation

- Complete equipment sanitation validation first
- Define allergens of interest
- Define acceptance criteria and method (quantitative)
- Define processing parameters (quantity of push through, run time)
- Define sampling plan
- Assess data and make conclusions

Future Challenges

- Facilities and equipment design
- Space constraints for zoning
- Development of on-line test devices for all allergen categories

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