CLEANING STRATEGIES TO REMOVE FOOD ALLERGENS AND TOOLS FOR DETERMINING EFFICACY

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Codex Committee on Food Hygiene (CCFH)
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Food Allergen Recalls

- **Undeclared allergens** – major cause of recalls in U.S.
- **Reportable Food Registry**

![Pie chart showing allergens](chart.png)

- Undeclared allergens increased from 30% of all RFR reports in first year, to 47% of reports in the fifth year
- Recall data from FDA-regulated products is mirrored by data from FSIS/USDA and from Canada (CFIA)
- 5-15% of allergen recalls are associated with consumer reactions

# Causes of Allergen Recalls (FY2007-FY2012)

<table>
<thead>
<tr>
<th>Cause of allergen recalls</th>
<th>Number recalls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omission</td>
<td>191</td>
</tr>
<tr>
<td>Wrong package or label</td>
<td>137</td>
</tr>
<tr>
<td>Terminology</td>
<td>85</td>
</tr>
<tr>
<td>Failure to carry forward information from an ingredient to final label</td>
<td>70</td>
</tr>
<tr>
<td>Ingredient mislabeled from supplier</td>
<td>26</td>
</tr>
<tr>
<td>Cross-contact</td>
<td>52</td>
</tr>
<tr>
<td>Rework</td>
<td>9</td>
</tr>
</tbody>
</table>

From: Gendel and Zhu, J. Food Prot.  2013, 76, 1933-1938
Cross-Contact

How does it occur?

• Dust or aerosols containing allergens
• Cross-over points in processing lines
• Reuse of cooking oil
• Reuse of cleaning solutions
• Ineffective cleaning
General Facts

• Effective cleaning is one of the most important strategies for preventing cross-contact
• Microbiologically clean ≠ allergen clean
• Food proteins can be difficult to remove from food contact surfaces- esp. if the protein has been heated/denatured
• Proteins vary in their “stickiness” to food-contact surfaces
• Wet cleaning can be effective at removing allergenic food soils- **but all procedures must be evaluated**
• Cleaning in a dry environment is a challenge—and it can be difficult to clean to “allergen clean”
• Older food processing equipment- not designed to be cleaned
Factors Affecting Allergen Removal

Allergen-related factors

• Type of food allergen
  o Physical form- paste, particulate, powder, liquid
  o Chemistry- water- vs. lipid-based ingredients
• Concentration of food allergen
  o High vs. low concentration in food

Equipment-related factors

• Equipment design
• Age of equipment
• Type of food-contact surface
  o Composition- stainless steel, plastic, cloth
  o Texture (finish) of surface

Processing-related factors

• Application of heat- hot vs cold soil
• Length of processing run- biofilm/build-up of food material

Cleaning method-related factors

• Type of cleaning method (wet vs dry)
Cleaning Methods

Wet

• Plant area and equipment designed to accommodate water
• Employ detergents and sanitizers
• Can be automated (CIP), semi-automated (COP), or manual
• Purging line with ingredient or next food (water-based)

Dry

• Plant area/equipment not designed to accommodate water (low water activity foods)
• Water use limited
• Compressed air, vacuum and/or dry steam may be used to “clean” surfaces
• Other methods- blasting with CO₂
• Purging line with ingredient (e.g. salt, sugar, corn starch, oil) or next food (dark chocolate)
Factors Affecting Allergen Removal - Wet Cleaning

**Time**

**Action**
- Manual
- Automated

**Soil** (Containing Proteins)

**Chemical**
- Components
- Concentration

**Temperature**

TACT

Clean Surface
Effectiveness of Cleaning Solutions/Detergents for Removing Protein Soils

• Chlorinated Alkaline Detergents (CAD) -- Excellent
• Alkaline/Caustics with $\text{H}_2\text{O}_2$ - Excellent
• Enzymes -- Excellent
• Alkaline/Caustics -- Fair $\Rightarrow$ Very Good
• Detergent Builders/Surfactants -- Fair $\Rightarrow$ Very Good
• Acids -- Poor
• Water --- Poor to fair
Effectiveness of Cleaning Regimens for Removing Milk Residue from a Pilot-Scale HTST Processing Line

Objectives:

• Investigate the efficacy of different cleaning procedures (a water rinse, intermediate cleaning treatments, and a full cleaning cycle).

• Evaluate methods (conventional ATP, sensitive ATP, total protein and ELISA/Lateral flow) for verifying the effectiveness of cleaning procedures.

• Determine the levels of transfer (cross-contact) of milk residue from HTST to simulated apple juice.
Procedure

• Processing nonfat milk (10 g) for 1 h
  o 81°C for 17 sec
  o Re-circulate milk
• Apply cleaning procedure
• Evaluate efficacy of cleaning procedure
  o Swab ports (ELISA, ATP, total protein)
  o Detect milk residue in final rinse water (ELISA, ATP, total protein)
• Process (10 g) “simulated apple juice” (single-pass)
  o Measure presence of milk/protein in simulated juice coming off line as a function of time and after pooled
Levels of milk transferred into simulated apple juice from an HTST processing line after different cleaning regimens (n = 3).

<table>
<thead>
<tr>
<th>Cleaning Regimens</th>
<th>Trial A</th>
<th>Trial B</th>
<th>Trial C</th>
<th>Milk concentration in composite sample of juice (µg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 min water flush</td>
<td>103.8</td>
<td>58.6</td>
<td>150</td>
<td>104 ± 45.7</td>
</tr>
<tr>
<td>15 min full-strength CAD at 81ºC (55-60 gal/h flow rate)</td>
<td>12.83</td>
<td>26.03</td>
<td>46.93</td>
<td>28.6 ± 17.2</td>
</tr>
<tr>
<td>60 min full-strength CAD at 70ºC (55-60 gal/h flow rate)</td>
<td>2.7</td>
<td>5.4</td>
<td>n.d.</td>
<td>2.70 ± 2.70</td>
</tr>
<tr>
<td>60 min ¼-strength CAD at 81ºC (55-60 gal/h flow rate)</td>
<td>0.45</td>
<td>0.6</td>
<td>n.d.</td>
<td>0.35 ± 0.31</td>
</tr>
<tr>
<td>60 min full-strength CAD at 81ºC (55-60 gal/h flow rate)</td>
<td>n.d.</td>
<td>n.d.</td>
<td>n.d.</td>
<td>n.d.</td>
</tr>
</tbody>
</table>
Methods for Cleaning in a Low Water Activity Environment

- Compressed air
- Grit/CO₂ blasting
- Premoistened (alcohol) wipes/cloths
- Vacuum
- “Dry steam”
- Brushing
- Purge/push-through with ingredients or next food
- A combination of dry cleaning methods
Tools for Verifying Cleaning Efficacy

What do we test?

- CIP rinse-water
- Push through materials (salt, sugar, next product)
- First product off line, final product
- Food-contact surfaces (visual inspection; swabs)

Having an adequate sampling plan is important!
Analytical Tools for Detecting Allergens/Allergenic Food Residue

- Visual Inspection
- ATP Swabs
- Total Protein
- DNA-Based/PCR
- Immunochemical
- Mass spectrometry*

*Not a routinely used method
Visual Inspection

• First step in determining if equipment is clean
• Points for inspection
  – Flat surfaces
  – Difficult to clean areas
  – Areas above processing zone

• Advantages
  – Does not require lab equipment/inexpensive
  – Rapid

• Disadvantages
  – Depends on accessibility, lighting, surface, etc.
  – Limited to accessible equipment
  – Does visibly clean = allergen clean?
Examples of “Visibly Dirty” Surfaces
Immunochemical Methods

- Antibody-based detection of allergenic protein, or other (marker) protein in food

- Formats
  - Well & lateral flow devices (LFD)/dipsticks
  - Sandwich and competitive
  - Multiplex LFDs now available
  - xMAP multiplex assay

- Analysis time: typically < 1 h

- Quantitative or qualitative

- Kits available for most of the 8 major allergens

- Used for ingredients, finished products, rinse water, swabs/environmental samples

- Need to ensure that method can detect allergen in food sample
**Advantages**

- Sensitive (ppm range)
- Quantitative or semi-quantitative
- Specific
- Low to moderate cost
- Equipment needs minor
- Skill level- low to medium

**Limitations**

- Cross-reactivity
- Extractability, solubility, and immunoreactivity important
- Matrix effects
- Processing (fermentation/hydrolysis, thermal) effects
- Need to understand what kit detects (e.g. casein vs. total milk vs. BLG)
- Values from different kits do not agree- reference standards needed
Non-Specific Methods: ATP

• Detects ATP from biological sources

• Advantages
  – Rapid (< 30 sec)
  – Less expensive than ELISA
  – Test can be performed on site (‘real time’)

• Disadvantages
  – Limited applicability- wet-cleaned surfaces only; may pick up ATP from water supply
  – Measures presence of ATP, not allergenic food
  – May be difficult to detect some food soils
  – Need to determine background ATP levels at facility
Non-Specific Methods: Total Protein

• Different companies and formats available

• Advantages
  – Rapid (< 5 min)
  – Less expensive than ELISA
  – Measures protein

• Disadvantages
  – Measures all proteins, not specific
### Importance of Choosing Appropriate Analytical Method

**Detection of Soy Milk on Stainless Steel Plates**

<table>
<thead>
<tr>
<th>Soy Product</th>
<th>Method of Detection</th>
<th>Amount of soy product (µg)</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0</td>
<td>50</td>
<td>100</td>
<td>250</td>
<td>500</td>
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<tr>
<td>Soy milk</td>
<td>ELISA 1</td>
<td>0/10</td>
<td>n.d.</td>
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<td>n.d.</td>
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<tr>
<td></td>
<td>ELISA 2</td>
<td>0/10</td>
<td>n.d.</td>
<td>n.d.</td>
<td>n.d.</td>
<td>0/10</td>
</tr>
<tr>
<td></td>
<td>LFD 1</td>
<td>0/10</td>
<td>0/10</td>
<td>0/10</td>
<td>0/10</td>
<td>10/10</td>
</tr>
<tr>
<td></td>
<td>LFD 2</td>
<td>0/10</td>
<td>0/10</td>
<td>0/10</td>
<td>0/10</td>
<td>0/10</td>
</tr>
<tr>
<td></td>
<td>Conventional ATP 1</td>
<td>0/10</td>
<td>0/10</td>
<td>0/10</td>
<td>0/10</td>
<td>0/10</td>
</tr>
<tr>
<td></td>
<td>Conventional ATP 2</td>
<td>0/10</td>
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<td>0/10</td>
<td>0/10</td>
<td>0/10</td>
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<tr>
<td></td>
<td>Sensitive ATP</td>
<td>0/10</td>
<td>1/10</td>
<td>3/10</td>
<td>7/10</td>
<td>9/10</td>
</tr>
<tr>
<td></td>
<td>Total protein 1</td>
<td>0/10</td>
<td>3/10</td>
<td>5/10</td>
<td>8/10</td>
<td>10/10</td>
</tr>
<tr>
<td></td>
<td>Total protein 2</td>
<td>0/10</td>
<td>0/10</td>
<td>0/10</td>
<td>3/10</td>
<td>5/10</td>
</tr>
</tbody>
</table>
Summary

• Effective cleaning is one of the most important strategies for preventing cross-contact.
• Many factors influence the effectiveness of cleaning procedures.
• Wet cleaning methods that use chlorinated alkaline detergents tend to be effective at allergen removal- but methods needs to be evaluated for efficacy.
• Cleaning to “allergen clean” in a dry environment can be challenging.
• Validation of cleaning methods (conditions) is important for ensuring effectiveness for allergen control.
• Many tools are available for detection of allergens or allergenic foods.
  o Choice of method depends on specific use, type of food matrix, and other factors
  o Need to conduct “in-house” validation
Thank you