Allergen Cleaning, Verification & Validation

Dan Schmitz
Director of Operations
Commercial Food Sanitation
Providing durable solutions to food safety and sanitation challenges.

Sanitation Standards | Hygienic Design | Sanitation Expertise | Sanitation Business Optimization
A team of sanitation specialists with an average of 20+ years industry experience
“Bringing a Passion to Food Safety”

CFS Certified Food Industry Professional

Hygienic Design Training  Sanitation Essentials Training
Advanced Food Industry Professionals Training

Hygiene Workshops

- Offerings at Intralox Headquarters in New Orleans, Amsterdam & Shanghai
- More than 30 Trainings Globally in 2018
- For available dates and registration: www.commercialfoodsanitation.com/training-calendar/
SET – Dry Cleaning Workshop
SET – Wet Cleaning Workshop
Agenda

• Allergen Cleaning
• Verification of Allergen Cleaning
• Validation of Allergen Cleaning
FDA/USDA Combined Recalls 2014 - 2017

<table>
<thead>
<tr>
<th>Category</th>
<th>FDA</th>
<th>USDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergen</td>
<td>47%</td>
<td>40%</td>
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<tr>
<td>All Micro</td>
<td>49%</td>
<td>18%</td>
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<tr>
<td>Foreign Objects</td>
<td>4%</td>
<td>8%</td>
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<tr>
<td>Other - Regulatory</td>
<td>34%</td>
<td></td>
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</tbody>
</table>
Elements of an Allergen Control Plan

• Allergen Risk Assessment
• Ingredients / Raw Materials
• Scheduling
• Operations / Processing
• Process Controls
• Maintenance

• Labeling / Packaging
• **Sanitation / Change-over Cleaning**
• Consumer Complaint Systems
• Training
• Verification / Validation
ALLERGEN CLEANING
Allergic Reactions

• One Teaspoon of salt has 25,000 grains
  – 1/2 of a teaspoon has 12,500 grains
  – 1/10 of a teaspoon has 2,500 grains
  – 1/25 of a teaspoon has 1,000 grains
  – 1/50 of a teaspoon has 500 grains
  – 1/1000 of a teaspoon has 25 grains
  – 1/2500 of a teaspoon has 10 grains

• 10 grains is equivalent to 2 milligrams which would cause an allergic reaction.
Cleaning Hurdles

Visually Clean

- Basic expectation
- Not enough
- Not easy to achieve
- Must always do

Microbial Clean

- Needed by all
- Difficult to achieve
- Routine cleaning target

Allergen Clean

- Protein removal is difficult
- Micro Clean does NOT mean Allergen Clean
Allergen Sanitation Process

• Sanitation Execution
  – 7 Steps of Sanitation
    • Dry Cleaning
    • Wet Cleaning
  – Possible extra equipment disassembly
  – Possible product push through / flush

• Pre-Operational Inspection
  – Visually clean expectation
  – Can’t move to next step unless visually clean

• Verification testing
7 STEPS OF EFFECTIVE DRY SANITATION
One step at a time

Good – Enables Effective Sanitation
- Good GMP's
- Continuous employee training
- Dedicated trainers & training tools
- Dedicated tools
- Dedicated tool storage
- Single use cleaning aides
- Synchronized process
- Removal of heavy soils
- Continuous inspection
- Flashlights
- Sanitizing/Disinfecting Wipes
- ATP verification
- Use Vacuums, not air hoses whenever possible

Bad - Can lead to poor Sanitation When not maintained
- Re-usable cleaning tools
- Congested work area
- Poor Cleaning Sequencing
- Adjacent lines

Ugly - Direct Link to Poor Sanitation
- High pressure air
- Inaccessibility
- Aerosols

Step 1
Pre-Sanitation Preparation

Step 2
Disassemble Equipment

Step 3
Dry Clean

Step 4
Detail Clean

Step 5
Self Inspection

Step 6
Post sanitation / Pre-op inspection

Step 7
Sanitize/Disinfect & Assemble
7 STEPS OF EFFECTIVE WET SANITATION
One step at a time

Good – Enables Effective Sanitation
• GMP’s
• Continuous employee training
• Dedicated trainers & training tools
• Dedicated tool storage
• Single use cleaning aids
• Synchronized process
• Manual scrubbing
• Flood sanitizing/disinfecting
• Continuous inspection
• Flashlights
• ATP verification

Step 1
Secure, Disassemble, Dry Clean

Step 2
In sync, top down pre-rinse

Step 3
Apply detergent & scrub

Step 4
Post rinse & self inspect

Step 5
Prepare for formal inspection

Step 6
Post sanitation / Pre-op inspection

Step 7
Sanitize/Disinfect & Assemble

Bad - Can lead to poor Sanitation When not maintained
• High pressure water or air
• Re-usable cleaning tools
• Congested work area
• Bearing
• Door seals
• Switches

Ugly - Direct Link to Poor Sanitation
• Inaccessibility
• Hollow rollers
• Fibrous belting
• Bio films
• Aerosols
• Mops / foam squeegees
• Standing water
• Drain back-ups

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Verification vs Validation

Validation

- Obtaining and evaluating scientific and technical evidence is capable of effectively controlling the identified hazards.

- Does my designed allergen cleaning plan work?

Verification

- The application of methods, procedures, tests operating as intended ....

- Did we execute the allergen cleaning as planned?
VERIFICATION

After you are visually clean
The Role of ATP Monitoring

• Robust hygiene and general sanitation test
  – “Did I clean as well today as yesterday?“
• Acceptable for routine hygiene monitoring
• Not specific or sensitive enough for allergen validation or verification
The Role of Rapid Test Kits

• Become “Standard of Care” in food industry
• Be ready for the results
  – Results become a “smoking gun”
  – Have a corrective action plan in place
• ELISA tests are required in most auditing programs
Limitations of Test Kits

*All antibody based tests.*

- ELISA tests are designed to detect whole, intact proteins
  - Hydrolyzed proteins
    - Example: hydrolyzed vegetable protein, hydrolyzed egg protein
  - Fermentation substrates
    - Examples: xanthan gums, starter cultures, soy sauce
  - Processing aids
    - Examples: lecithin, enzymes

Proteins from these products are generally not detectable on the test kits. However, allergenicity can remain.
Verification Expectations

• Keep on top of sanitation practices
  – KPIs to monitor normal performance
  – Monitor and audit to ensure you stay on plan
  – Training on any differences for allergen cleaning
• Allergen Clean
  – Make the clean up a big deal - Awareness
    • Something special is happening
    • Have heavy oversight to ensure any additional procedures are followed
      (e.g. extra tear down, push throughs, etc…)
  – Intense Pre-op
    • Independent and responsible person(s) – e.g. Quality
  – Verification Testing
    • Testing should cover each piece of equipment – at a minimum
    • Testing coverage will depend on hygienic design – niches
• Document success
  • Pictures of results – tests fade
• Prepare for Corrective Actions
  • Be prepared to fail
ALLERGEN VALIDATION
Allergen Validation: 3 Step Process

1. Pre Assessment
   - Identify all shared equipment and hot spots

2. Physical Verification
   - Pre-operational inspection
   - Must be visually clean before testing

3. Analytical Validation
   - Verify the effectiveness of the test kits
   - Sampling and Testing
Step 1 – Pre Assessment

Identify all shared equipment

Create or Verify Process Flow Chart

Shared Equipment

- Pay Attention to employee practices, staging of ingredients
- Identify tentative swab sites / digital pictures to document sites
- Review written SSOP
- Send product sample to vendor to determine best kit to use
- Run positive control to verify test kit is effective
- Plan allergen validation & production schedule to minimize product hold; Develop contingency plan

Action Register

- Close key gaps necessary for physical verification
Step 2 – Physical Verification

Pre-Operational Inspection

• After closing gaps identified in the first phase “pre assessment”- observe cleaning practices to verify compliance to SSOP (employees practices & tool condition)
• Assess equipment hygienic design
• Assess disassembled equipment for niche areas – take pics, finalize swab sites
• Add niche sites details to Pre-Op Inspection checklist
• Assess sanitation tools (brushes)

Pre-Op
• Verification visibly clean
Step 3 – Analytical Validation

Plan & Execute Validation Samples

• Swab identified / documented sites from physical verification phase
• Adjust schedule to run “LIKE” product containing identical allergen profile following the analytical sampling. If not possible: place product on hold pending analytical results
• If results are positive – perform corrective actions: modify cleaning procedure, retest (multiple tests needed to demonstrate repeatability).

Outcome

• Process Flow chart
• Completed Action Register
• Signed Pre-op
• Acceptable analytical results
• Repeat validation yearly or if changes to product, equipment, or process to ensure the process can be cleaned consistently

Document Results

• Pictured site with analytical result
Summary

• Control of allergens is a significant concern
• Sanitation is a significant part of the allergen control plan
• Huge task to get sanitation to a visually clean standard
• Allergen clean ups need a verification step
  – Visually clean
  – Analytical testing
• Annual validation to show that the plan works
  – 3 step process
  – Repeat tests – Repeatable process
Questions?

THANK YOU
### Causes of Food Allergen Recalls

<table>
<thead>
<tr>
<th>Cause</th>
<th>Number of Recalls</th>
</tr>
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<tbody>
<tr>
<td>Wrong package/label</td>
<td>86</td>
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<tr>
<td>Terminology</td>
<td>59</td>
</tr>
<tr>
<td>Failure to carry forward information from an ingredient to the final label</td>
<td>41</td>
</tr>
<tr>
<td>Cross-contact</td>
<td>28</td>
</tr>
<tr>
<td>Ingredient mislabeled by supplier</td>
<td>21</td>
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