Food Industry Perspective on Managing Food Allergen Risk

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Scott’s presentation reflects his own insights and observations of the Food Industry and do not necessarily reflect specific practices and policies of Conagra Brands.
Conflict of Interest Statement

- Scott Hegenbart is employed by Conagra Brands, Inc., a food company that manufactures and distributes a variety of food products, some of which contain food allergens.
Evolution of Food Allergen Management

- Prior to the mid-1990s: Most food manufacturers had not even heard of food allergens, much less managed them.
- Mid 1990s: Larger companies began voluntarily managing food allergens collaborating through the Food Allergen Research and Resource Program (FARRP).
- 2011: Congress passes Food Safety Modernization Act (FSMA).
Food Allergen Management Necessitated Change

- Product Development
- Supply Chain Management
- Material Receiving, Storage and Handling
- Preventing Cross-Contact During Processing
- Labeling and Packaging Controls
- Sanitation and Changeover
Pre-allergen management

- Use whatever ingredient was right for the product
- Use unique sub-components to enhance performance of ingredients

Allergen-aware practices

- Attempt innovation without changing allergens managed at production facility
- Be mindful to minimize allergens in the formula
Supply Chain Management

Pre-allergen management
- Order ingredients to whatever specification is mutually agreed upon with supplier
- Ingredient declaration alone is sufficient disclosure

Allergen-aware practices
- Specification includes allergen disclosure
- Disclosure is often a separate document that lists food allergens in the product, on the line and in the facility
- Audits assure compliance with expected allergen management practices
Material Receiving, Storage, and Handling

Pre-allergen management

- Ingredients and packaging arrive in facility and are checked to assure the order is properly fulfilled
- Ingredients and packaging materials are stored in the most convenient location

Allergen-aware practices

- Upon arrival, ingredients are:
  - Checked to confirm allergen profile on the bill of lading
  - Actual ingredient statement on packaging is checked
  - Identified with clear marking as to what allergen(s) they contain
  - Stored with appropriate segregation in designated warehouse spaces
- Upon arrival, packaging materials are:
  - Checked to confirm order is correct
  - Checked to affirm allergen information is accurate
  - Stored in designated warehouse space
Preventing Cross-Contact During Processing

Pre-allergen management

- Ingredients for the day are brought to scaling/staging area
- Ingredients weighed into containers and grouped by batch
- Batch sheets used to assure correct proportions for quality

Allergen-aware practices

- Only ingredients for specific products are pulled from warehouse
- A separate scaling area for allergens may be used
- Ingredients still grouped by batch, but labeled more thoroughly including allergen information
- Batch sheets are a cross-check to assure allergens aren’t misused
Labeling and Packaging Controls

Pre-allergen management

- All packaging for the shift is pulled from the warehouse
- Simple verification of item code
- Packaging may stay in place throughout production day
- Partial pallets may be combined for efficient storage

Allergen-aware practices

- Only packaging for immediate use is brought to the line and replenished
- Item code is verified and packaging is cross-checked to confirm it is the right version and has correct allergen information
- Unused packaging returned to storage immediately
- Pallets strictly segregated
Sanitation and Changeover

Pre-allergen management

- When production of a product is complete during a shift, product may be:
  - Rinsed prior to next product
  - Scraped down and pushed through by next product
  - Pushed through by subsequent product
- Sanitation processes largely determined by microbiological risk

Allergen-aware practices

- Production of an allergen containing product will be run for an entire shift
- When production is complete, it triggers a full allergen sanitation and changeover
- Production scheduling and sanitation processes determined by allergen content of products to be made
Facility Cleaning Methods

**Wet cleaning**
- Clearing and disassembly
- Excess material removed (scraping, pre-rinsing)
- Foaming and scrubbing
- Rinsing
- Sanitizing

**Dry cleaning**
- Clearing and disassembly
- Excess material removed (scraping, push-through)
- Detailed soil removal (vacuum, hand brushing, alcohol wipes)
Sea Change of Practice

- Industry knew reaction amounts were very small, but did not have precise idea of how small
- Initially, industry had no simple allergen test methods
- Extreme practices employed to account for uncertainty
- Food allergen thresholds help add clarity, but…
The Perception Problem with Allergen Thresholds

The fear

- Food companies will use thresholds to stop cleaning and segregating
- Cross contact will spiral out of control
- Myself or my loved ones will suffer a potentially fatal allergic reaction

The reality

- Allergen thresholds are very small amounts, regulatory action levels would be smaller
- Cleaning and segregation will remain necessary
- Action levels can help optimize allergen management while supporting clearer communication
- Risk assessment will help guide resource application
Optimizing Wet Cleaning

- Surface swab ELISA testing
- CIP rinse water ELISA testing
- ELISA results below the limit of quantitation usually achievable
- Create cleaning procedures optimized for the appropriate time and chemical use
- Thresholds can help determine appropriate testing application
  - Not all allergens have a test
  - Some food matrices resist testing
  - Certain processes make testing impossible
<table>
<thead>
<tr>
<th>Serving Size (g)</th>
<th>VITAL action level for milk (mg)</th>
<th>% Protein in formula achieving VITAL action level</th>
<th>% Slurry in Product B</th>
<th>% of Product A slurry required to carry over into Product B slurry</th>
</tr>
</thead>
<tbody>
<tr>
<td>86.8</td>
<td>0.1</td>
<td>0.00012%</td>
<td>31.94%</td>
<td>2.7825%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>% Milk protein in Ingredient</th>
<th>% Ingredient in slurry</th>
<th>% Milk protein in slurry</th>
<th>% Slurry in product A</th>
<th>% Milk protein in product A</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.61%</td>
<td>5.80%</td>
<td>0.03538%</td>
<td>36.64%</td>
<td>0.01296%</td>
</tr>
</tbody>
</table>
Case Study: Testing to Optimize Allergen Sanitation

- A facility employs a double CIP process for allergen cleaning after using milk
- Validation study tested CIP rinse water
- Testing showed most milk protein removed during the program’s preliminary rinse
- Changed allergen cleaning procedure to standard, single CIP
Optimizing Dry Cleaning

- Generally cannot swab surfaces
- Can test push-through material
- Can adjust cleaning procedure or amount of push-through to optimize effectiveness and efficiency
- Below the test’s detection limit isn’t always attainable
- Thresholds can help determine how much carryover represents a risk
## Math Minute, Large Batch

<table>
<thead>
<tr>
<th>Carryover achieving VITAL action levels for milk vs. egg</th>
<th>NHANES serving Size (mg)</th>
<th>VITAL action level (mg)</th>
<th>% allergen protein achieving VITAL action level</th>
<th>% product carryover achieving VITAL action level</th>
<th>Batch size (lb)</th>
<th>Weight product carryover achieving VITAL action level (lb)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carryover based on milk</td>
<td>114,000</td>
<td>0.10</td>
<td>0.00009%</td>
<td>0.70128%</td>
<td>13,900</td>
<td>97.48</td>
</tr>
<tr>
<td>Carryover based on egg</td>
<td>114,000</td>
<td>0.03</td>
<td>0.00003%</td>
<td>0.21038%</td>
<td>13,900</td>
<td>29.24</td>
</tr>
</tbody>
</table>
Math Minute, Small Batch

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<td>114,000</td>
<td>0.10</td>
<td>0.00009%</td>
<td>0.70128%</td>
<td>250</td>
<td>1.75</td>
</tr>
<tr>
<td>Carryover based on egg</td>
<td>114,000</td>
<td>0.03</td>
<td>0.00003%</td>
<td>0.21038%</td>
<td>250</td>
<td>0.53</td>
</tr>
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</table>
Clearer Communication

- Only have basic guidance for labeling beyond the “Contains” statement
- Uncertainty of segregation leads to “creative” labeling solutions
- The broad range of statements confuses consumers
- Ultimately, such statements may assure compliance with the law, but defeats the intent of the law by confusing consumers
- And it isn’t just consumers who can be confused…
Case Study: Soy in Breadcrumbs

- Supplier of baked ingredients uses soy in some, but not all breadcrumbs.
- The company has a validated allergen sanitation procedure that requires 90 minutes of downtime.
- The company historically used a “contains soy” statement on all products.
- FDA investigator informed them that a contains statement should coincide with an appropriate ingredient.
- What did the company do?
Implications

- Allergen statements may be tricky
  - Must be truthful
  - Must not be misleading
  - Must not be a substitute for good manufacturing practice
- Post FSMA, suppliers have increased the use of supplemental allergen statements
- Clarity around the true risk can give confidence that GMPs are effective
# Clarity in the Gray Areas

<table>
<thead>
<tr>
<th>Results of testing and risk assessment</th>
<th>Suggested labeling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergen neither added, nor detected</td>
<td>No allergen labeling</td>
</tr>
<tr>
<td>Allergen &gt; LOD periodically &lt; action level</td>
<td>Produced in a facility that also handles X</td>
</tr>
<tr>
<td>Allergen &gt; LOD periodically &gt; action level</td>
<td>May contain X</td>
</tr>
<tr>
<td>Allergen &gt; LOD consistently &gt; action level</td>
<td>Contains X from cross contact</td>
</tr>
<tr>
<td>Allergen added</td>
<td>Contains X</td>
</tr>
</tbody>
</table>
Threshold Thoughts

● Clear, consistent labeling is the best way to help and protect food allergic consumers

● Threshold-based regulatory action levels offer a tool to help create a common language for determining and communicating risk

● Threshold-based action levels will not reduce allergen management efforts, but will change them to adjust focus
  – Using validation to optimize sanitation and make it more efficient
  – Conducting risk assessments to determine appropriate labels
  – Targeted allergen testing to support validation and risk assessment
  – Increase efforts at label verification
### Allergens Lead Recalls

<table>
<thead>
<tr>
<th>Hazard</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Salmonella</em></td>
<td>36.6% (86)</td>
<td>38.2% (86)</td>
<td>28.1% (63)</td>
<td>28.7% (58)</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>14.4% (33)</td>
<td>17.8% (40)</td>
<td>21.4% (48)</td>
<td>17.3% (35)</td>
</tr>
<tr>
<td>Undeclared allergens</td>
<td>30.1% (69)</td>
<td>38.3% (69)</td>
<td>37.9% (85)</td>
<td>43.6% (88)</td>
</tr>
<tr>
<td>Percentage (no. of entries)</td>
<td>82.1% (188)</td>
<td>94.3% (201)</td>
<td>87.4% (196)</td>
<td>89.6% (181)</td>
</tr>
</tbody>
</table>

Causes of Allergen Recalls, 2010-2013

<table>
<thead>
<tr>
<th>Recall Cause</th>
<th>Number</th>
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<tbody>
<tr>
<td>Wrong label or package</td>
<td>82</td>
</tr>
<tr>
<td>Terminology not correct</td>
<td>59</td>
</tr>
<tr>
<td>Ingredient information not carried through</td>
<td>41</td>
</tr>
<tr>
<td>Cross-contact</td>
<td>28</td>
</tr>
<tr>
<td>Ingredient mislabeled</td>
<td>21</td>
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Allergen Preventive Controls

- (2) *Food allergen controls*. Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:
  - (i) Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and
  - (ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.
### Sorting Allergen Recall Causes, 2010-2013

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Looking at Recall Causes Another Way

Recall Causes 2009-2012

- Mispacking/Mislabeling, 79%
- Cross Contact, 12%
- Other, 9%
Based on consumer complaints a company learned that its vegetarian Juicy Burger patties had been packed into its Savory Burger patty packages.

The Juicy Burger patties contain milk protein in the form of a cheese blend.

The Juicy Burger and Savory Burger products only feature slight differences in package design.
Example: Finding the Cause

- Plant appropriately scheduled non-milk patties before milk
- Batch sheets show ingredient scaling and staging was correct
- Plant had thorough controls in place for changing over from milk to non-milk products
- Non-milk packaging was left on machinery when milk-containing product began production
Math Minute

<table>
<thead>
<tr>
<th>% Protein in cheese blend</th>
<th>% Cheese blend in formula</th>
<th>% Protein in formula</th>
<th>Product serving Size (g)</th>
<th>Milk protein per serving (g)</th>
<th>Milk protein per serving (mg)</th>
<th>VITAL action level for milk (mg)</th>
<th>Amount of product achieving VITAL action level (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.50%</td>
<td>2.50%</td>
<td>0.39%</td>
<td>112</td>
<td>0.43400</td>
<td>434.00</td>
<td>0.10</td>
<td>25.81</td>
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# Math Minute

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</thead>
<tbody>
<tr>
<td>112,000</td>
<td>0.10</td>
<td>0.00009%</td>
<td>0.02304%</td>
<td>5,000.00</td>
<td>1.15</td>
</tr>
</tbody>
</table>
Addressing the Greater Risk

- Product Development
- Supply Chain Management
- Material Receiving, Storage and Handling
- Preventing Cross-Contact During Processing
- Labeling and Packaging Controls
- Sanitation and Changeover
Example: Corrective Action

- Institute line-clearance procedure when changing from non-allergen product to allergen
- Add verification step to assure that packaging has been appropriately changed
- Install scanning system
Labeling Controls Begin Earlier

- Product Development
- Supply Chain Management
- Material Receiving, Storage and Handling
- Preventing Cross-Contact During Processing
- Labeling and Packaging Controls
- Sanitation and Changeover
Pre-Printed Packaging Verification

- At the printer
- At the facility before production
- At the facility during production
- Use scanners and vision systems, where appropriate
<table>
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Resources

- Food Allergy Research and Resource Program, “Components of an Effective Allergen Control Plan: A Framework for Food Processors”
- Grocery Manufacturers Association, “Managing Allergens in Food Processing Establishments”
- US Food and Drug Administration, CGMPs and FALCPA Guidance
- VITAL, Allergen Bureau of Australia/New Zealand