‘Taking the Risk out of Allergen Risk Assessment’.

Practical Tools and Techniques for Successful Allergen Control.

Simon Flanagan
Overview

- Risk assessment – what does this mean?
- HACCP & allergen management
- Factory risk assessments – dos and don'ts
- Considerations in hazard characterisation
- Quantifying risk through validation
- From risk assessment to allergen control plan
## Principles of Risk Analysis

### FSA Orange Guide - FSA 2006

<table>
<thead>
<tr>
<th>Risk Assessment</th>
<th>Risk Management</th>
<th>Risk Communication</th>
<th>Risk Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>what's the risk?</td>
<td>can it be controlled?</td>
<td>how do you warn consumers?</td>
<td>has the risk changed?</td>
</tr>
</tbody>
</table>
Terminology (HSE 2009)

- **Risk assessment** – the semi-quantitative (or, in exceptional circumstances, quantitative) estimation of whether a **hazard** is likely to **occur** in practice; normally expressed as a **risk factor** or score by multiplying the **hazard severity score** by a **likelihood score** (unlikely [score 1], likely [score 2] or very likely [score 3]). All risk scores indicating other than low risk must be investigated and risk control/management procedures followed.

- **Hazard** – a substance etc. which has the potential to be **harmful**. Hazards are very varied... **The severity of the hazard is determined by possible consequences; for risk assessment, the severity of hazards is scored on a simple three point scale: minor injury or effect (score 1), major injury or effect (score 2) or death (score 3).**

- **Risk control/Risk management** – the means by which moderate or high risks identified through risk assessment are eliminated or reduced to acceptable levels.
Can we apply to Allergen Risk Assessment?

- Estimation of risk – subjective
- Likelihood score – subjective
- Severity of hazard
  - Depends on the allergenic ingredient
  - Depends on sensitised individual
  - Spectrum of reaction in sensitised population from mild (1) to death (3)
- Risk management
  - Eliminated (?) or reduced to acceptable level (?)
  - Cannot completely eliminate risk
  - What is an acceptable level (no thresholds)
Pure HACCP based Management Approach

• System widely used for last 10+ years
• Highly conservative – molecule hunting
• Non-standardised approach resulted in:
  – Paralysis – too difficult!!
  – Risk aversion – over labelling
  – Managing all allergenic ingredients similarly
  – Inappropriate levels of testing
  – Inconsistent assessment of supply chain risk
  – Increase in recalls / withdrawals
Current challenges facing Industry and Regulators

- Improvements needed in
  - Label management systems
  - Traceability and allergen visibility
  - Capability - allergen awareness/management

- Guidance needed on
  - Standardised risk assessments -
  - Translation of guidance to different sectors
  - Action levels
  - Distinction between trace level and ingredient level contamination
  - Basis for enforcement activity
  - Analytical methodology
So how do we move forward?

- Standardisation is imperative
- Targeted risk assessments incorporating hazard characterization
- Evolution of 2006 FSA guidelines
- Three-tier allergen mapping
- Assessment of risks arising from the following factors
  - Process
  - Environmental
  - Production
  - People
- Rank risk probability against characterised hazard
- Output forms basis of allergen control plan
## Process

<table>
<thead>
<tr>
<th>Area of Site/Process Step under Consideration</th>
<th>Area of Concern for Potential Allergen Cross Contact</th>
<th>Probability</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingredient Receipt</td>
<td>Contamination from allergenic materials during offloading from delivery vehicle and transfer to storage due to damaged packaging</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ingredient Storage</td>
<td>Contamination from allergenic material due to damage to packaging during storage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ingredient Weighing</td>
<td>Dust generated from powder dispensing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ingredient Weighing</td>
<td>Ingredient will come into direct contact with equipment and utensils.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Environmental factors examples</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warehouse</td>
<td>Contamination of stored products due to air extract into warehouse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maintenance</td>
<td>Contamination from engineers tools - not dedicated to line</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Production

<table>
<thead>
<tr>
<th>Production related activities examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waste Handling</td>
</tr>
<tr>
<td>Uncovered waste receptacle moved</td>
</tr>
<tr>
<td>through production facility</td>
</tr>
<tr>
<td>Labelling control</td>
</tr>
<tr>
<td>Wrong labels used on the line</td>
</tr>
<tr>
<td>People related activities examples</td>
</tr>
<tr>
<td>-----------------------------------</td>
</tr>
<tr>
<td><strong>Hygiene</strong></td>
</tr>
<tr>
<td>Staff moving between different lines without washing hands</td>
</tr>
<tr>
<td><strong>Maintenance</strong></td>
</tr>
<tr>
<td>Maintenance teams tools identified a source of allergen cross contact</td>
</tr>
</tbody>
</table>
Hazard Characterisation

Allergen Biochemistry

• True allergens = always proteins

• Most allergens are incredibly stable molecular structures

• Some resistant to processing
  – Heat treatment
  – Mechanical
  – Fermentation
  – Some rendered ‘more’ allergenic

• Biochemistry (and matrix) influences effectiveness of different cleaning methods
Hazard Assessment – Consider:

- Physicochemical nature of the allergen
- Associated protein level
- Heterogeneous or homogeneous
- Concentration in recipe
- Potential for aerosol / dust generation
- Existing barriers to restrict spread of allergen
- Level of processing allergenic material undergone
- Configuration of equipment and ease of cleaning
Calculation of Hazard Rating

- Use **available** numerical data to estimate severity of hazard
  1. Potency score (derived from threshold studies)
  2. Allergenic protein content (%)
  3. Physical form score – measure of dilution potential through various stages of processing
    - Liquid, powder, viscous paste, particulate, etc.

- **Not exact science** – enables prioritisation of hazards & guides management of risk
Validation of control measures

- Validation - quantifies otherwise subjective (qualitative) assessment
  - Fundamental part of the Hazard Analysis and Critical Control Points (HACCP)
  - ISO 22000 & PAS 220 standards require formal validation of CCPs and PRPs
## Output from Risk Assessment

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<tr>
<th>Area of Site/Process Step under Consideration</th>
<th>Area of Concern for Potential Allergen Cross Contact</th>
<th>Probability</th>
<th>Rationale</th>
<th>Allergen &amp; Hazard rating</th>
<th>Is advisory labelling needed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingredient Storage</td>
<td>Contamination from allergenic material due to damage to packaging during storage</td>
<td>Remote</td>
<td>Handling of this ingredient by people is minimal during storage</td>
<td>Milk – Med Soya Low Almond - High</td>
<td>No – probability of contamination remote. Existing control measures sufficient to minimise risk</td>
</tr>
<tr>
<td>Ingredient Weighing</td>
<td>Dust generated from powder dispensing</td>
<td>Probable</td>
<td>Ingredient is exposed during storage</td>
<td>Milk – Med Wheat - Low</td>
<td>No – risk minimised by modifying procedure and improving local extraction at dispensing unit</td>
</tr>
</tbody>
</table>
## Risk Assessment to Allergen Management

<table>
<thead>
<tr>
<th>Allergen Mapping</th>
<th>✔</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment of Risk, Hazard &amp; Probability</td>
<td>✔</td>
</tr>
<tr>
<td>Assessment of controls</td>
<td>✔</td>
</tr>
<tr>
<td>Validation</td>
<td>✔</td>
</tr>
<tr>
<td>Modify to improve control?</td>
<td>✔</td>
</tr>
<tr>
<td>Cannot improve control?</td>
<td>✔</td>
</tr>
<tr>
<td>Labelling / Communication</td>
<td>✔</td>
</tr>
<tr>
<td>Allergen control plan</td>
<td></td>
</tr>
<tr>
<td>Documentation (SOPs WIs)</td>
<td>✔</td>
</tr>
<tr>
<td>Training programmes</td>
<td>✔</td>
</tr>
</tbody>
</table>
Allergen Management Plan

• Allergens as ingredients
  – Intentional presence – all allergens in recipe appear on the label

• Allergens as contaminants
  – Unintentional presence
  – Process to manage risk (or)
  – Process to communicate risk through advisory labelling

• Intrinsically linked with GMPs
Scope of your Plan

- Raw materials (ingredients)
- Change control
- NPD
- Environment, equipment and process design
- Production scheduling, segregation
- Labelling and packaging
- Rework
- Cleaning
- Training

Ensure that its documented and keep it simple
Allergen Labelling Controls

- Wrong labels account for 75% recalls
- Wrong product in wrong package (cross-packing)
- Ingredients do not match up with ‘contains’ alert box
- ‘May-contains’ statement wrong
Practical Labelling Control for Packaging

- Considerations necessary for effective label control
  - Label copy approval against formulation
  - Verification of incoming labels against approved label copy
  - Processes for issue of correct label to packaging
  - Line clearance on product changeover
  - Line checks on correct label use

- Procedures for managing label changes
  - Introduction of new/reformulated products
  - Introduction of redesigned packaging

- Confirmation of correct legible coding/traceability information
Training and Communication

- Vital for all personnel to be aware of the issues associated with allergens
- Include contractors, visitors etc.
- Education, training and communication is necessary, including ‘refresher’ and ‘update’ information
- Suitable signage may be used to remind personnel of importance of care and compliance with requirements
- Colour-coding - colour blindness
Labelling for unintentional presence

- Precautionary / Advisory / Alibi / May-Contain (traces!!) labelling???

- To quote the FSA
  - “advisory labelling should only be used when, following a thorough risk assessment, there is a demonstrable and significant risk of allergen cross-contamination”

- Not a substitute for poor GMP

- So how do you communicate the risk?
Somewhat risk averse???
Effective Allergen Control

- Training
- Informed Labelling
- Supply chain assessment
- Sampling & Analysis
- Uniformity of Practice (GMP)
- Prerequisite Programmes
- HACCP principals
Summary

- Start your risk assessment with allergen mapping
- Identify risk and characterise associated hazard
- Use validation to test your controls
- Use output to develop allergen control plan
- Allergen management must be bespoke to your site
- Keep it simple or it won’t work & integrate ACP with existing food safety programme
Thank you for your Attention