A practical approach to managing allergen risk in food ingredients.

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AGENDA

Introduction

Cleaning re-validation approach.

- The Why?
- Implementation Steps
- Key Takeaways and Lessons Learned

Critical Risk Management Process

- C2RI (Risk Bowtie)
- Critical Control Management Procedure (CCMP)
- Adequacy assessment
- Effectiveness test

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- ✓ Local manufacture
- ✓ Local creation & applications
- ✓ 24-hour samples
- ✓ Reverse engineering
- ✓ Marketing
- ✓ Latest trend data

- ✓ PIF's, specs, SDS
- ✓ Halal, Kosher
- ✓ TGA
- ✓ Allergens Management
- ✓ FSSC 22000 certified
- ✓ FFAANZ Member

Cleaning re-validation approach.

The Why?

- Processing facility complexities.
- Nature of contaminants.
- Effectiveness of controls : removal of allergenic material from food contact surfaces.
- Customer confidence
- Product Information Forms (cross contact information).

Definition:

Cleaning validation provides documented proof that the cleaning process can consistently and effectively clean equipment to a specified acceptable level.

- How effective is our current cleaning methodology?
- Are there any sources of cross contact that remain after the cleaning process?
- Method comparison: current vs new
- What information regarding cross contact allergens can we add to the product information form?
- How can we improve our methods if required?
- How do we verify cleaning going forward?

Implementation steps

1
Form team & create master plan.

Dedicated multi-disciplinary team.

Knowledge and expertise required.

Cleaning validation master plan.

2
Group products & equipment.

Allergens in product.

Methods.

Costs of methods & analysis.

Customer lead times.
Categorise products & equipment.

3
Set limits, sampling sites from engineering studies.

Acceptable limits cleanliness.

Equipment design; material construction.
Risk-based approach.
Hang-up points.

4
Select methods & perform recovery studies.

Suitable methods for validation.

Visual inspections.

Collect residue & calc. (VITAL).
Recovery studies.

5
Perform cleaning validation studies.

Take note of production schedule.

Thorough records of results.

Note all observations.

Take pictures.

6
Summary Report & Implement Procedures

Document findings in summary report.

Group review process.

Implement the validated cleaning procedures.

7
Monitoring.

Monitor cleaning processes
Ensure compliance and effectiveness.

Trend results at agreed frequency and review plus adjust if applicable.

2. Process and equipment mapping

- Draw maps of equipment and line if not existing.
- Group processes, products and equipment together.
- Sources of contamination to the line.
- Does product type affect cleaning process.
- How long does the clean take?

3. Review of engineering design of equipment and line

- Material construction of equipment. Hygiene risks from design, harbourage/hang-up points/hard to reach areas.
- Can we use mechanical force to clean?
- Moving parts.
- Cleaning parameters (time, temp and dilutions)

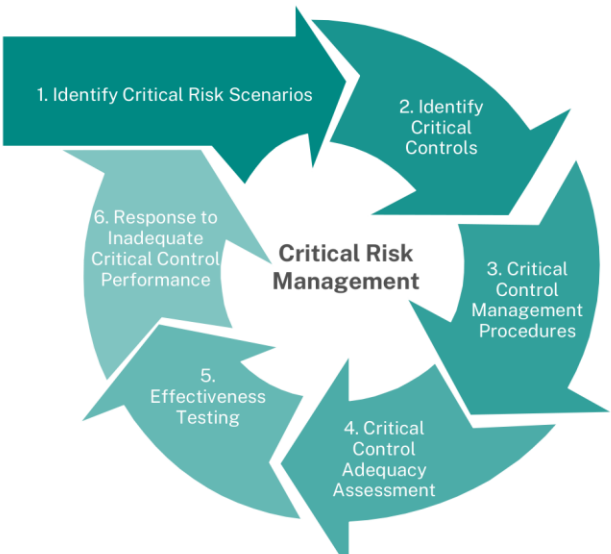
4. Method Selection

- Composition of the food being tested.
- Sensitivity and specificity
- Quantitative vs qualitative methods and when to use.
- Cost of the test method, including equipment, reagents, and labour.
- Validated methods that are specific for your application.

Key take-aways and lessons learnt

- ✓ Visual inspections : quantification using VITAL assessment tool.
- ✓ Product testing.
- ✓ Readily dispersible allergens that become particulate matter and its unique challenges.
- ✓ It's important to consider all services (air, water) for comprehensive allergen detection.
- ✓ Rapid tests and positive controls
- ✓ Each method has its strengths and limitations, and these limitations highlight the importance of selecting the appropriate method.
- ✓ Understanding the effects of different surface materials e.g. rubber surfaces is crucial for selecting appropriate cleaning and testing methods.
- ✓ Allergen cleaning requires a tailored approach; therefore, it's crucial to implement a systematic method to thoroughly identify and mitigate potential risks.
- ✓ Lastly, it's essential to regularly review and enhance the cleaning procedure.

CRITICAL RISK MANAGEMENT PROCESS



Step	Target Outcome
1	Identification of Critical Risk Scenarios
2	Identify existing and potential Critical Controls
3	Develop Critical Control Management Procedures
4	Complete a Critical Control Adequacy Assessment
5	Implement regular Effectiveness Testing
6	Critical Control owners monitor control performance

1. Identification of Critical Risk Scenarios

Allergen contamination was identified as 'critical' risk to the business.

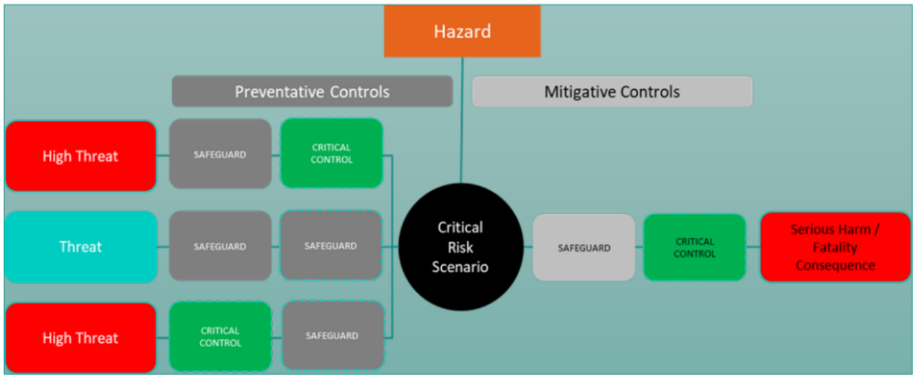
- Critical risks may occur across the supply chain.
- 4 pathways below lead to the allergen contamination

Undeclared allergen in the product	Unidentified and/or potential allergen cross contact in the product	Allergen cross contamination during storage, distribution and transportation	Incorrect documentation on allergen information
• Cross contamination • Supplier miscommunication • Labelling errors • Ingredient substitution • Lack of allergen control program	• Shared equipment • Inadequate cleaning • Improper storage • Human error • Airborne particles • Supplier misinformation	• Improper segregation • Damaged packaging • Mixed Shipment • Inadequate cleaning of transport vehicle • Improper labelling	• Mislabelling • Incomplete records • Human error • Lack of Standardization /Potential miscommunication • Failure to update information regularly

2. Identify Critical Controls

- Control Centred Risk Intelligence - C2RI (Risk Bowtie) was commenced.
- A required **bowtie** was developed and high threats pathways were identified along with control measures.
- Within each high threat, which are the significant contributors to allergen risk, critical controls were identified.
- A critical control management procedure was developed to incorporate all of the critical controls.

C2RI Risk Assessment



- High threat require critical control or control
- Focus is on high threat and its control that can prevent serious consequences
- Reducing the risk to prevent high threat

3. Critical Control Management Procedure

- Defines the requirements for allergen risk management of all food products;
  - products applicable for use in food industries (e.g., food additive, processing aids, cleaning chemicals).
  - Products manufactured, sold, traded, stored and transported by IXOM.
- Defines the controls for managing the risks identified.
  - Assessment and review of raw materials by competent personnel
  - Master list of allergen on site
  - Segregation / separation
  - Cleaning verification and validation
  - GMP checks and training
- Defines what is expected by the business across the supply chain.
- By implementing these controls, we significantly reduce the risk of allergen contamination.

4. Adequacy Assessment

- One off process
- part of the process for implementation of critical controls
- providing a gap analysis of the important aspects of a critical control
- ensures full implementation and readiness for effectiveness testing.
- adequacy assessment checklist is used
- Identified gap is recorded on the checklist

5. Effectiveness testing

- Annual test
- to manage controls and ensure they remain functioning.
- verify critical controls are being managed appropriately and effectively.
- ensures the specific requirements of a CCMP are being carried out in practise.
- allocated to the worker on the site responsible for the management of the critical controls covered by the effectiveness test.
- not considered to be an audit and independence is not required.

In A Nutshell...

Effective allergen risk management is an ongoing process,

and requires vigilance and continuous improvement.

References

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- **Cleaning Validation: The Definitive Guide** (Yeotikar, S., March 28, 2025). Retrieved from Pharma GxP

- **Food Standards Australia New Zealand.** (2024). *P1044 - Plain English Allergen Labelling*. Retrieved from https://www.foodstandards.gov.au/food-standards-code/proposals/P1044PlainEnglishAllergenLabelling

- C2RI reference if there is??? (Check with Darren Baker)


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