Environmental Monitoring and Allergen Control - Best Practices

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Eurofins’ Mission is Health and Safety

Our Mission: To contribute to global health and safety by providing our customers with high-quality laboratory and advisory services while creating opportunities for our employees and generating sustainable shareholder value

Food
#1 worldwide

Environment
#1 worldwide

Pharmaceuticals
#1 or 2 worldwide
Eurofins’ Strong International Network of World Class Laboratories
(4) the preventive controls implemented under subsection (c) are effectively and significantly minimizing or preventing the occurrence of identified hazards, *including through the use of environmental and product testing programs* and other appropriate means"
Preventive Control Programs

- Training programs for managers and/or workers
- Written records, e.g., batch records, sanitation records
- Validation of control measures
- Written sanitation SOPs
- Food label review and control program
- Testing of incoming raw materials
- Testing of in-process materials
- Testing of finished products
- Testing of processing environment
Allergen Cross Contamination

• Shared harvesting sacks
• Shared transportation vehicles
• Shared processing equipment
• Allergenic carriers/flow aides
• Mislabeling
Food Allergen Control Program

• Training of processing and supervisory personnel
• Segregation of food allergens during storage & handling
• Validated cleaning procedures for food contact equipment
• Prevention of cross contact during processing through measures such as:
  ▪ Scheduling of production runs – allergen-free products before allergen-containing products
  ▪ Control of rework
  ▪ Use of dedicated production lines and equipment
  ▪ Control of dust and wash water
Food Allergen Control Program

• Product label review and label usage and control
• Ingredient control – know what you are buying and don’t inherit your supplier’s problems, test to make sure you are not bringing allergens into the processing environment
• Facility mapping – know where allergens are likely to occur. Control personnel and equipment traffic.
Environmental Monitoring Program

• Baseline sanitation program to identify and clean potential food allergen harborage sites
• Environmental testing program to assess effectiveness
• Evaluation of results and root cause analysis when positive environmental samples are found
• Corrective actions taken based on root cause analysis
Nobody’s nose knows
Why Test for Allergens?

- Brand protection and liability reduction
- Regulatory expectation
- Validate effectiveness of critical control point interventions such as raw material and ingredient receiving, and labeling
- Validate effectiveness of environmental control programs
- Validate purchase specifications by you or your customers
- Compliance investigations
Cost of Not Testing

- Potential for injuring or killing your customer
- Intrinsic and extrinsic costs associated with recalls
- Facility closure and loss of business
- Damaged brand reputation
- No liability protection – in fact liability increases due to lack of prudence
Environmental Monitoring Program

What are the Goals?

• Find allergens in the environment before they contaminate product – seek and remove
• Assess effectiveness of cleaning, sanitation, and employee hygiene practices

Where to Test?

• Use zone approach
• Direct product contact surfaces
• Non-product contact surfaces
Written Allergen EMP Plan

- Identify sampling sites
  - use facility grid
  - random rotation among grids
  - routine selective sampling of high risk sites
- Frequency of sampling
- Number of samples
- Sampling procedure
- Test method
- Corrective actions
Where to Sample?

- Sample equipment that is used for both allergen-free products and allergen-containing products
- Identify areas that are easily contaminated by employee traffic patterns and behaviors
- Compressed air and dust movement
- Direct product contact surfaces are most important
- Areas where product is exposed to the environment and before package closure are critical
Zone 1

Surfaces where product is exposed to the environment before final package closure

- Tables
- Conveyor belts
- Buckets
- Fillers
- Hoppers
- Utensils
- Employee hands and gloves
Areas in close proximity to zone 1 areas

- Enclosed equipment
- Vacuum cleaners
- Brooms
- Dust collection areas
What Samples?

- Finished product
- Product residue
- Food-contact surfaces
- Non-contact surfaces
- Air
- Water
Testing Frequency

- History and trends
- Features of the plant
- Type of product and volume
- Plant layout
- Product flow
Sampling Frequency

When first starting, sample numerous sites and use large surface areas to gauge degree of contamination and identify potential problem areas.

Increase frequency when:
- Ingredient changes
- Construction events
- Equipment installation
- Whenever unwanted allergens are found
Bulk Tote Bin
Tote Bin Slide Valve
Mills
In Line Magnet
Magnet Grid
Key Points for Sample Collection

- Don’t cross contaminate your sample with dirty hands, dirty attire, or dirty sample collection devices
- Make an effort to find hard-to-clean areas
- Use results to educate employees
Note on Swabs & Sponges

- Use sponges/swabs recommended by kit manufacturers
- Make sure sponge/swabs are free of allergen protein that you are targeting (tryptone/peptone/soy)
Food Allergen Testing at Eurofins

- As an independent, unbiased, ISO 17025 accredited testing laboratory group we perform thousands of food allergen tests per year
- Experienced with a wide range of products
  - raw materials
  - in-process materials
  - finished products
  - processing environment
- Use a variety of conventional and modern methods
- Choice of method is determined by product type and customer expectations
Method Selection

• Don’t make it harder than it has to be

• Sample for the type of allergens expected in the room

• Select appropriate equipment/supplies recognized by industry to perform sampling

• ATP kits are useful to monitor cleanliness but do not directly measure allergens

• ELISA-based methods are specific for specific allergenic protein
  
  ex. Kit for milk protein casein will not detect whey protein β-lactoglobulin
Method Selection

- When allergenic proteins are denatured by heat treatment or fermentation ELISA-based kits may not detect allergens
- DNA-based methods such as PCR can detect residual source material when protein detection is difficult
- PCR can detect source material when ELISA methods are not available
- Very low quantities of heat-processed allergenic proteins can be detected using LC-MS/MS
- Simultaneous multi-protein detection can be achieved by LC-MS/MS
Data Interpretation & Management

- Types of data
- What do the results mean?
- Keep records
- Establish performance targets
- Establish a baseline
- Trend tracking
- Establish an action plan
- Form a response team
Record Keeping

- Date and time of sampling
- Person collecting samples
- Sample locations
- Submission date to laboratory
- Results
- Corrective actions (if necessary)
Establish a Response Team

- QA/QC personnel
- Sanitation supervisor and crew
- Production supervisor and crew
- Maintenance supervisor and crew
Corrective Actions

- Limit access to area
- Break down and inspect equipment
- Thoroughly clean and sanitize all equipment, surfaces, and tools in area
- Increase sample frequency
- Resample equipment and surfaces to determine if contamination is localized or widespread
- Monitor area around hot site to find source
- If preop inspection fails, re-clean, re-sanitize, and resample as needed
- Do not restart operations until all tests are negative
Corrective Actions

- Goal to achieve at least 3 consecutive negatives at contamination site
- Document corrective actions
- Create SOP to prevent reoccurrence
- If problem persists consider removal, replacement, or redesign of contaminated equipment
Routine Preventive Measures

• Control sources of ingredients, water, and air with robust testing programs
• Repair structural damage and eliminate cracks and crevices that can harbor allergens
• Review and monitor GMPs
• Review and monitor SSOPs
• Audit production and maintenance practices
• Reinforce proper employee hygiene practices
Thank you for the opportunity to provide this overview
Eurofins Scientific, Inc.

We look forward to working with you in the future