



ALLERGEN MANAGEMENT THROUGH HYGIENIC ZONING AND SANITATION

Duane Grassmann
Corporate Hygiene Manager
Nestlé USA & Nestlé Canada

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WHAT IS HYGIENIC ZONING?

Simple or not-so-simple definitions ...

- Simple: “Keeping bad stuff from moving into sensitive areas”
 - Identify the “bad stuff”
 - Define the “sensitive areas” (and “not sensitive areas”)
 - Prevent the “moving”
- Not-so-simple:
 - Protecting the product from hazards originating in the factory environment
 - Dividing the factory into different areas having different levels of risk
 - Creating risk-based controls (barriers and routines) to stop hazard movement between and within zones
- In either case:
 - Controls are monitored, verified and trained upon
 - Hygienic zoning considered in engineering projects and factory changes

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HOW DOES HYGIENIC ZONING HELP WITH ALLERGEN MANAGEMENT?

- Uncontrolled allergens = “bad stuff”
- Allergen management = controlling “allergen cross-contact”
- What is “allergen cross-contact”?
- Hygienic zoning for allergen management considers 3 things:
 - Allergen storage practices
 - Allergen movement through the factory (receiving to shipping)
 - Operations and sanitation practices for allergen control

ALLERGEN STORAGE PRACTICES

- Cross-contact prevention strategies
 - Separate allergens from non-allergens
 - Separate unlike allergens
 - Consider:
 - Spillage and leaks (receiving to shipping)
 - Storage and staging (under, over, beside)
 - Identification schemes
 - Training
 - Monitoring

ALLERGEN MOVEMENT BETWEEN HYGIENIC ZONES

- Warehouse zone ≠ production zone (exposed product)
- Consider cross-contact risks:
 - During transportation through the factory
 - From the forklift or pallet jack
 - Spills or leaks (procedures, training and monitoring)

OPERATIONS AND SANITATION PRACTICES FOR ALLERGENS

- Training and procedures
- Consider:
 - Hands, uniforms, shoes
 - Conditions and practices
 - Dust or aerosols
 - Maintenance and QA activities
 - Wet/dry tracking of spillage on footwear, uniforms, wheels
 - Rework, trash, product waste
 - Tools and equipment
 - Cleaning procedures that consistently and predictably
 - Prevent the spread of allergens
 - Remove allergens to a target level (qualitative/quantitative)
 - Monitoring for compliance



SANITATION AND ALLERGEN MANAGEMENT

- Ask these questions:
 - Why are you cleaning?
 - How clean should you get it?
 - How often should you clean it?
- What is successful allergen cleaning?
 - It depends on whether the next product is the same or a different allergen profile
- Cleaning for allergen removal = undetectable in finished goods
- No test for a specific allergen? Choose a higher concentration surrogate that is equally or more difficult to clean


CHALLENGING THE CLEANING

- Spoiler: Tomorrow ... cleaning validations, monitoring and verifications
- Always validate against the worst-case scenario, e.g.
 - Hardest to reach and clean
 - Hardest to clean product
- Cleaning procedures must be followed as written
- Inspection must be robust and consider allergen types and formats

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NEW PRODUCTS WITH NEW ALLERGENS

- Great new product ideas
 - Clam yogurt
 - Peanut butter pizza
 - Mustard ice cream for Canada
- New allergen introduction!! Consider:
 - Training of factory staff
 - Storage and handling of new allergens
 - Allergen cleaning validations
 - Routine allergen changeovers for the line, etc.
- Complexities = significant costs **often underestimated**
- Allergen addition as far down the process as possible



Q&A