

The Current State of Enzyme Hygiene Practice to Control Allergy in a Detergent Manufacturer

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ICOH MEETING
 Carson, Mexico
 March 20th 2012

Agenda

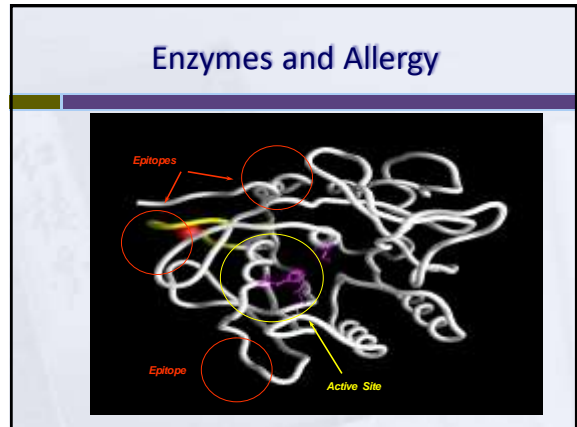
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- > Common Occupational Allergens
- > Enzymes as Allergens.
- > Impairment Scale: Respiratory Allergens
- > Occupational Exposure Limits (OELs)
- > Detergent industry history drove IH Fundamentals.
- > Enzyme Safety Management Strategies (Layers of Protection)
 - > Granular Detergents and Prill Integrity
 - > Controlling Exposure at the Source
 - > Design of Equipment
 - > Maintenance and Assurty of Performance
- > Equipment Interventions, Safety Practices, and a Behavioral Basis for Exposure Prevention
- > Personal Protective Equipment and Hygiene Practices
- > Air Monitoring

Occupational Allergy & Asthma

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High Molecular Weight Agents (>6kDa) - IgE	Workers at Risk
Cereals (Wheat, Rice)	Bakers, Millers, Grain Elevator Operators
Animal Derived Allergens (Dander, Feline Urine Protein)	Animal Handlers
Enzymes	Detergent workers, Pharma Workers, Bakers
Latex	Health Professionals
Shellfish	Seafood Processors
Low Molecular Weight Agents	
Isocyanates	Insulation Installers, Plastics Workers, Automotive/Bridge Painters, Epoxy Workers
Organic and Metallic Anhydrides	Plastics and Epoxy Workers
Dyes	Textile Workers
Persulfates	Beauticians
Metals	Refiners, Solderers
Formaldehyde, Glutaraldehyde	Hospital Workers



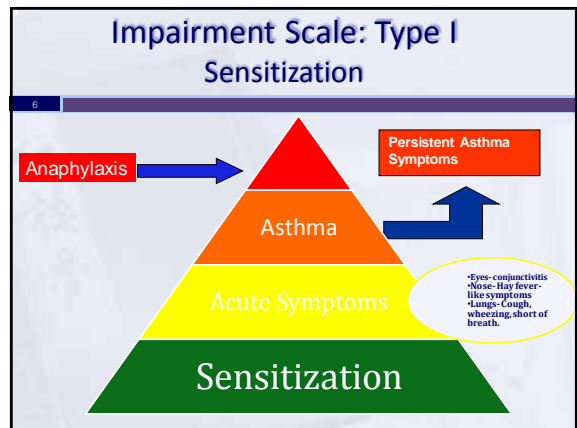
Progression of Type I Allergy

- Sensitization
 - development of IgE antibody
- Elicitation
 - development of symptoms
 - disease state

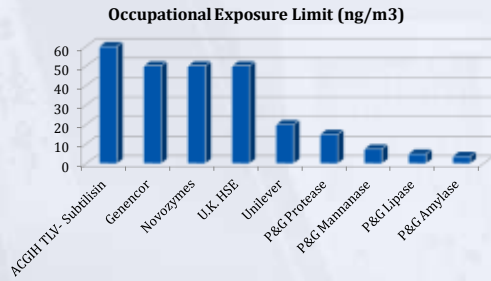
Sensitization is not a disease but it does increase the risk for the disease state.

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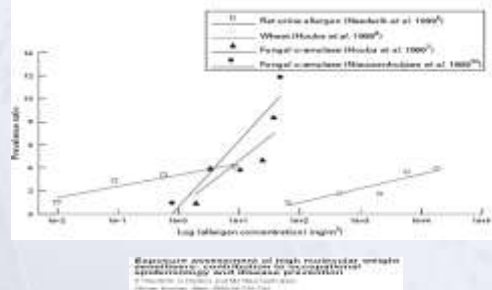
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A sampling of OEL's for Enzymes

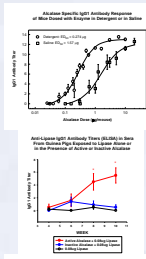


Potency and Establishment of Exposure Levels



Enzymes in a Detergent Matrix and the Impact on OEL's

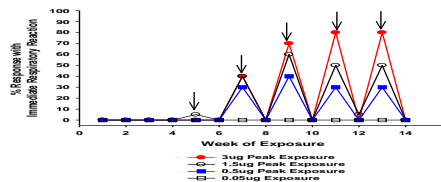
- Surfactants can act as an adjuvant increasing the potency of an enzyme containing detergent.
- Protease enzymes can also act as an adjuvant in a mixture of enzymes.
- P&G Detergent Enzyme Occupational Exposure Guidelines
 - Based on relative potency in GPIT or MINT
 - Difference in potency even within same class have been observed.
 - Protease (protein) - 15 ng/m3**
 - Cellulase (cellulose) - 3.75 - 7.5 ng/m3
 - Lipase (fats and oils) - 5 ng/m3
 - Amylase (carbohydrates) - 3.75 - 5 ng/m3**
- Individuals may be more or less sensitive.



JACI, 1997, 100:480-487

Intermittent or Peak Exposures

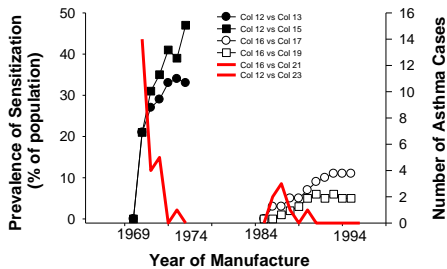
Immediate Respiratory Reaction of Guinea Pigs Following Exposure to 0.05ug Protease Enzyme With or Without "Peak" Exposure to Enzyme at Weeks 5, 7, 9, 11, 13.



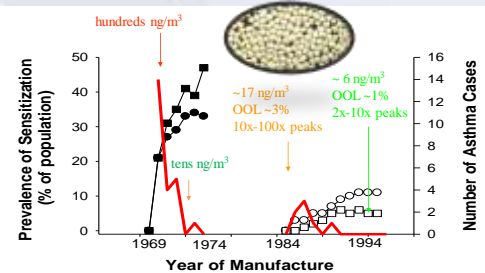
-Low level exposures "prime the immune system"

*Peak exposures can result in conversion (IgE antibody titer) and for the sensitized employee a risk for symptom development.

Detergent Industry Experience



Peak Exposure Considerations in the Workplace



What have we learned from Experience?

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- > There appear to be potency differences in people as well.
- > Peak exposures impact people – we need to control both routine and non-routine (peak) types of exposure
 - > They can sensitize
 - > They can induce symptoms

So what is a Nanogram?

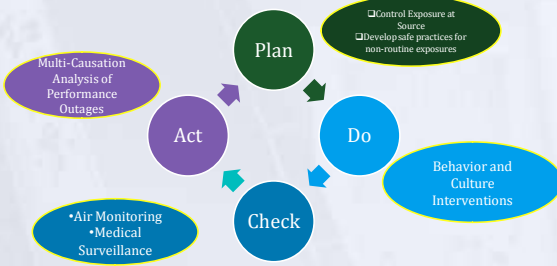
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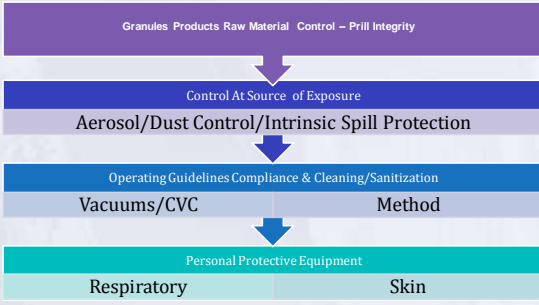
HERE ARE 81 MILLION OF THEM!

Respiratory Allergy Prevention Program

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Layers of Protection and Preventing Exposure



Causes for particle breakup & resulting hygiene issues

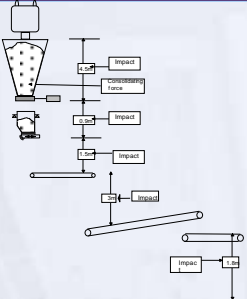
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- > Classification of forces within the manufacturing environment
 - > **Impact forces** - high strain rate forces that act on our granules, e.g. vertical drops
 - > **Shear forces** - high & low strain rate forces that occur whenever powder is flowing, e.g. screw feeders, slide valves, silo emptying
 - > **Consolidation** - low strain rate forces, e.g. in a static silo, over time.

Forces in a typical dry laundry making operation

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- > Impact Forces
 - > Multiple Vertical drops (0.5 to 5 m)
 - > Impact in gates
 - > Vibratory screens
- > Shearing forces
 - > Feeding out of bins
 - > Shear in feeder valves
 - > Shear forces to accelerate granules after conveyor belt drops
- > Consolidating Forces
 - > Occurs in each storage vessel



Prill Integrity

Particle fracture observed after laboratory impact testing @ 9 m/sec

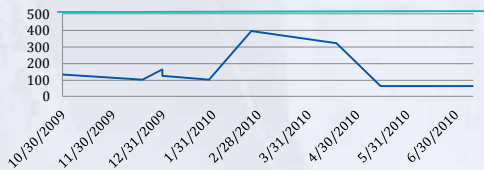


Heubach Analysis

- > What:
 - > Targets for Dust Attrition & Enzyme Attrition
 - > **Screening Method** for potential of breakdown of prill coating and development of enzyme dust fines.
 - > Method assumed to mimic some of forces encounter in processing (not perfect);
 - > Granule to Granule
 - > Granule to Surfaces of Equipment
 - > Granule to move parts
 - > Targets based on a proportion to assigned OEL of the enzyme prill in question.
 - > Principle - The higher the potency of the enzyme the more robust the prill should be.
 - > **Not a substitute for qualification in the plant as systems differ.**

Raw Material Standards

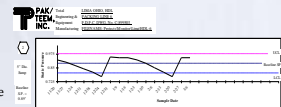
Certificate of Analysis- Heubach Enzyme Dust Results



- Any lot exceeding standard is rejected.
- Any lot exceeding 80% of limit triggers and investigation and study.
- Any new enzyme material performance is evaluated in each plant.

Controlling exposure at its source!

- > Design and Construction
 - > Standard Engineering Design Criteria
 - > Supersack Handling
 - > Liquid Transfers
 - > Bottle Filling
 - > Box Filling
 - > Documentation Requirements
 - > Change Management Requirements
- > Operation and Maintenance
 - > Weekly verification of face velocities and duct S.P.
 - > Preventive and Ongoing Maintenance plan and schedule for each:
 - > Aerosol Control Systems
 - > Central Vacuuming



Exposure Control for Liquids Operations



Exposure Control for Granule Operations

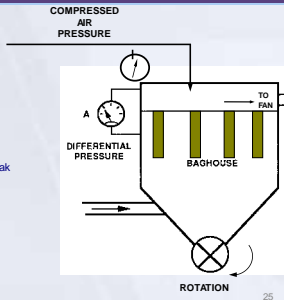


Example of Monitoring and Maintenance Plan

Each Shift or Daily –

Visual Inspection to verify or record:

- No visible stack emissions.
- Filter media differential pressure.
- Pulse cleaning system compressed air pressure.
- Access doors closed and leak free.
- Hopper empty.
- Proper rotation of Rotary Valve / Screw Conveyor.
- Dust fines flow in recycle system



Behavior and Culture Interventions

- Condition Audits to detect and eliminate sources of leaks and exposure.
- Detecting Non-routine sources of intermittent or peak exposure.
- Behavior Observation and Feedback Systems- Are employees following expectations.

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P&G Approach to Operating Guidelines Compliance

- Semi-quantitative assessment of containment and operational excellence.
- Assessment of equipment reliability and maintenance

- No visible dust or aerosol
- No detergent outside of containment
- No gross skin contact
- Treat empty containers as though full

Performance Level Rating – For Operational Guidelines Compliance

New Standard	Old number for OGC	What this means	Example	Action to take
4 - Target	10	The line is in the ideal condition - as if it was just cleaned.	No visible product. No standing water.	None
3 - Acceptable	8,9	Some visible product inside containment (containment = in the aerosol control hoods or spill pans).	Product inside the filter. Some product inside the spill pans.	Clean the area at the end of the shift.
2 - Marginal	6,7	Some visible product outside of containment.	Any product on the floor.	Clean the area at the next available time.
1 - Unacceptable	0 - 5	Visible product outside of containment and continuing to increase.	Leaking product pipe.	Shut down immediately, fix the problem, and clean the area.

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Performance Level Description?



Performance Level Description?



Performance Level Description?



Peak Exposure Assessment- Making Safety Practices Clear

- Using a control banding approach to determining criticality of exposure when tasks requiring intervention in equipment or product are required.
- Consideration are:
 - Potential Exposure level
 - Frequency of exposure
 - Number of people exposed
 - Ability to anticipate the exposure and PPE practices
- Objective- to document assumptions regarding safety practices and countermeasures used.

Critical factor	Rating			
	1	2	3	4
Exposure level (R1)	No leaks or visible detergent outside of containment	Intermittent leak outside breaking zone	Intermittent spillage overhead in breathing zone	Continuous leak/spill
No. Of Events (R2)	< 1/shift	1-4/shift	5-8/shift	≥ 9/shift
Avg. No. Of people (R3)	1	2	3	4
Ability to anticipate (R4)	Scheduled maintenance	Scheduled task	Repetitive task	Immediate response

Behavior Based Safety Tools

Measure critical behaviors – How well does the organization demonstrate critical behaviors:

- BOS - Behavior Observation System
 - Everyone is involved
 - Feedback is given, in addition to measuring behaviors
- SSS - Safety Sampling System
 - Critical measures observed by a select group of skilled observers
 - Better observations, but not intended to give feedback

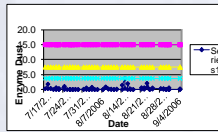
Give and Collect Feedback

- OFS - On-going feedback systems
 - Everyone gives feedback daily, when appropriate with method for tracking the data
- FFS - Focused Feedback System
 - You target identify a specific person to observe and you coach and give them feedback during your observation
 - Provides a great opportunity for leadership to understand what prevents safe behaviors and provide coaching on safe behaviors.

Enzymes: An exposure assessment challenge

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- High Volume Sampling Necessary:
 - Low Occupational Exposure Limits
 - Analytical Limitations
 - Activity
 - ELISA
- Sampling Strategy
 - Randomized collection of fixed areas samples to measure Aerosol Control Capability



Management of Change is very important

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- Applies to;
 - New Enzymes
 - New Formulas
 - Changes to Equipment
- Approach
 - Concern for routine exposure during normal operation.
 - Do existing controls cover exposure during normal operations?
 - What is current equipment availability and reliability?
 - Concern about peak exposure potential.
 - Current plant capability
 - Air Sampling Data
 - Peak Exposure Study
 - OGC
 - BOS
 - Adherence to safe practices.
 - Adherence to PPE
 - Care and Maintenance of ACS/DCS/CVC/PVC

Thanks For Your Attention

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