



# Allergen Control

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3-A SSI 2008 Annual Meeting

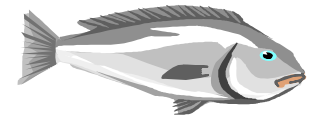
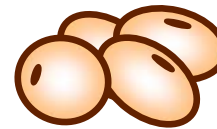
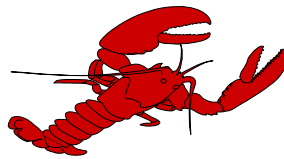
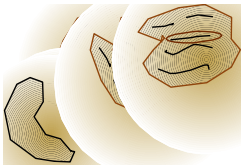
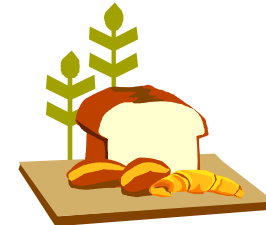
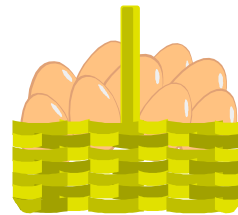
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# Topics

1. Allergen Overview
2. Food Allergen Control Strategies
3. Allergen Removal
4. Case Study on Allergen Removal
5. Allergen Testing
6. U.S. & European Regulations

# Allergen Overview





# Allergen US Factoids

- 11 million food allergic individuals in the US
  - 3.5 - 4% of adults
  - 6 - 8% of infants & young children
- 30,000 anaphylactic reactions in emergency rooms/year
- 150–200 deaths/year
- There is no known cure for food allergies



# Definitions

- Adverse food reaction
  - Any reaction after food ingestion
- Food intolerance
  - Reaction from non-immune cause (e.g., lactose intolerance)
- Food allergy
  - Abnormal IgE- mediated immune response



# Allergic Reaction Symptoms

- Skin Hives, swelling of lips, tongue, face
- Gastro-intestinal Nausea, cramps, diarrhea
- Respiratory Struggle for air
- Circulatory Blood pressure drops, lose consciousness
- Anaphylaxis Multiple organ systems triggered, with death possible in 10 minutes



# Food Allergens

- Naturally-occurring proteins
- Resistant to heat, proteolysis, pH
- Trace amounts can cause reaction
- Thresholds are not well-defined yet
- Sensitivity & severity of reactions vary
- Avoidance is the only protection

# Food Allergens

90%

10%

Peanut

Tree nuts

Milk

Egg

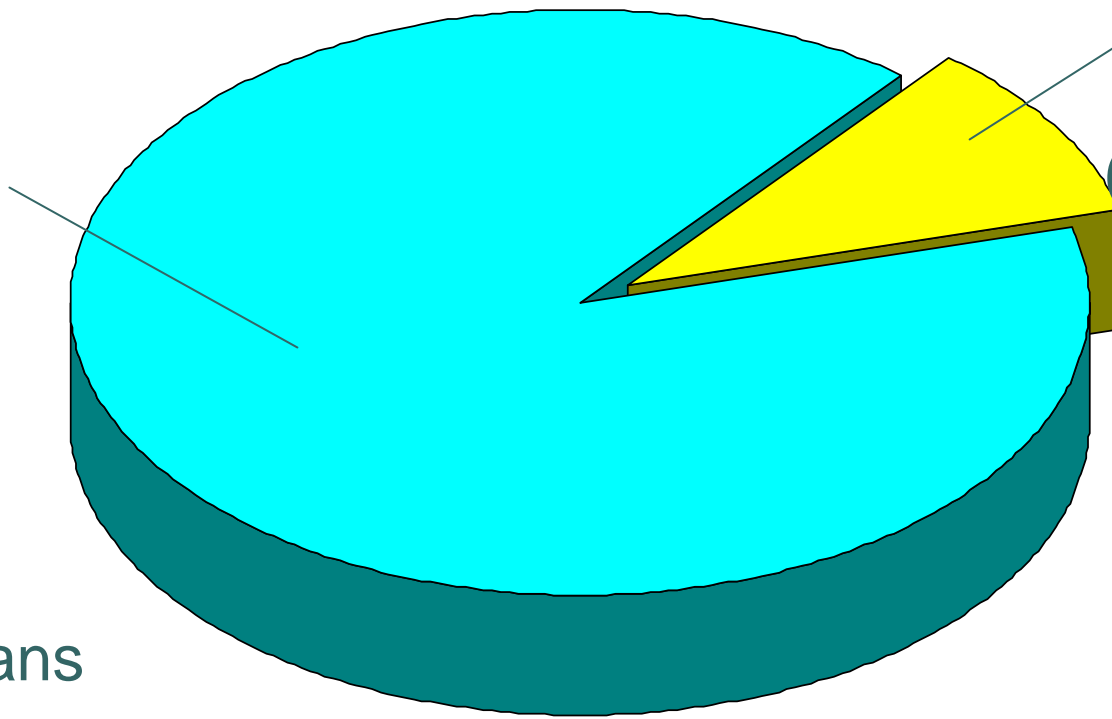
Soybean

Fish

Crustaceans

Wheat<sub>8</sub>

Hundreds  
of others  
(over 160)



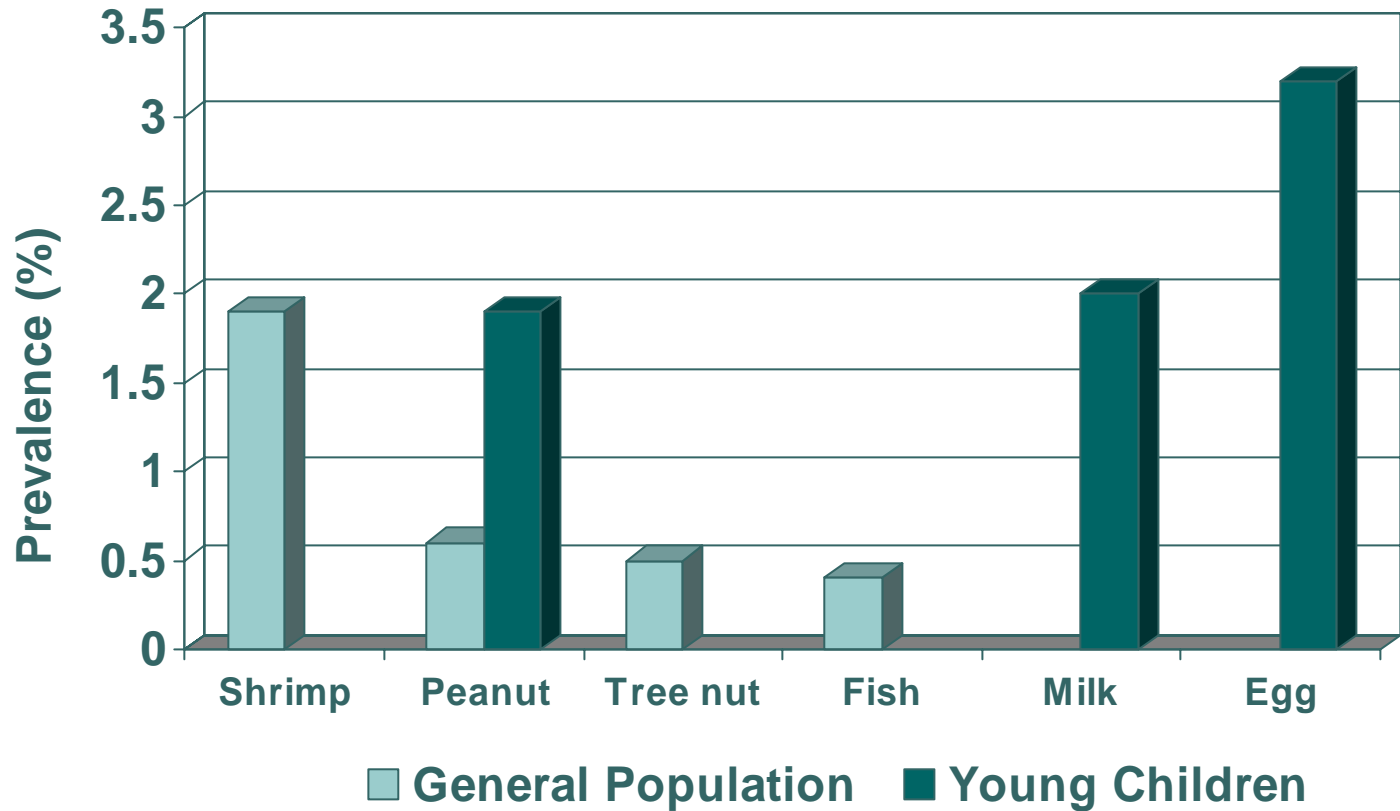


# Food Allergens by Region

- Big 8 (US)
  - Peanut
  - Tree nuts
  - Milk
  - Egg
  - Soybean
  - Fish
  - Crustaceans
  - Wheat
- Canada adds
  - Shellfish
  - Sesame seeds
  - [Suphites]
- European Union adds
  - Celery
  - Sesame seeds
  - Mustard
  - [Sulphites >10 ppm]
  - [Cereals containing gluten]

Note: Items in [brackets] are not true allergens

# Prevalence of food allergies



Source: Taylor & Hefle, 2006. Food Allergies & Intolerances, In Modern Nutrition in Health & Disease.



# Predominant Food Allergens

## Children

- Peanut
- Tree nuts
- Soybean
- Milk
- Eggs
- Wheat

Tend to  
outgrow

## Adults

- Peanuts
- Tree nuts
- Crustacea
  - shrimp, crab, lobster
- Fish



# Food Allergen Control Strategies

Where can risks be managed?



# Food Allergen Control Strategies

1. Only manufacture products with identical allergens
2. Dedicate line or plant
3. Develop “Allergen Prevention Plan”  
“Effective Cleaning”  
“Verification”



# What Goes Wrong?

- Inadequate cleaning of shared equipment
- Use of re-work
- Switching ingredients
- Formulation mistakes
- Wrong labels/packaging
- Labeling terms



# Where Risks Occur

- Product Development
- Raw Materials
- Engineering & System Design
- Production Scheduling
- Labeling & Packaging
- Rework
- Human Error
- Cleaning



# Research & Development

- Minimize use of allergenic ingredients
- Strive for common ingredients on a product line to achieve functionality
- Design to add allergenic ingredients at end of process
- Evaluate cleaning issues during design



# Ingredients

- Raise vendor awareness
- Understand raw ingredient sourcing & ID potential sources of cross-contact
- Obtain fully disclosed label
- Dedicate storage areas for allergenic ingredients
- Beware of raw material shortages and/or substitutions



# Engineering & System Design

- Dedicate production systems and/or parallel modules when not cleanable
- Design access for cleanouts & inspection
- Isolate allergen addition points
- Dedicate recoup / refeed systems
- Eliminate cross over & poor product containment points



# Production Scheduling

- Dedicate production systems
- Long runs & minimize change-overs
- Produce unique allergen products at end of production sequence
- Allow time for thorough cleaning between runs
- Confirm correct packaging available



# Rework

- “Like into Like”
  - Post instructions, maintain records, audit
- Dedicate and label storage containers
  - Color code, plastic liners
- Ensure systems can be cleaned OR dedicate refeed / rework systems
- Promptly report any misuse of rework



# Labeling and Packaging

- Labeling law (January 2006) requires allergen labeling
- Labeling does NOT replace the need for GMP
- Ensure label reflects the current formula
  - Recheck label with formula & ingredient change
- Avoid mixed cartons
  - Scanners at printer & in plant



# Human Error

- Poor cleaning
- Poor procedures
  - Material handling
  - Sampling
  - Rework
- Wrong packaging
- Inaccurate label

Training  
is  
essential!



# Allergen Removal



# The *Allergen Challenge* for Sanitation

- FDA & CFIA have a zero tolerance policy for contamination by food allergens
- If there is an ‘allergen component’ present in food (and it is not declared on the label) the product is considered adulterated and subject to recall.



# The *Allergen Challenge* for Sanitation

- Contamination from equipment is seldom linear
  - contamination will slug through, normally in the first portion of the run
- **Consequently, equipment needs to be 100% allergen free!**

# How do they get there?



**Food allergens are globular proteins having molecular weights between 10,000 - 70, 000 amu.\***

**Process**



**Surface Binding**



- Process:**
- > Heating
  - > Milling
  - > Emulsifying
  - > Blending

- Forces involved:**
- > Dipole-dipole
  - > Hydrogen
  - > Ionic
  - > Van der Waals
  - > Electrostatic forces

**Protein is now bound to the food contact surface**

# Studying Protein Removal in the Laboratory

1. Set soil (this can be the hardest part!)
2. Run the desired test  
(beaker → automated)
3. Quantify soil removal (visual, chemical or instrumental)
4. Screen chemicals and formulations to determine minimum temperature, concentration, action, & time





# Typical Detergents Used in Food Plants for Sanitation

## ○ Built Caustic

- 0.5 - 5% NaOH or KOH
- Hard Water Sequestrants
- Surfactants / Wetting Agents

## ○ Chlorinated Alkali

- 0.1 - 1.0% NaOH or KOH
- 60 - 1,000 PPM NaOCl
- Hard Water Sequestrants
- Surfactants / Wetting Agents

Temperatures: 40 - 200 °F;  
typically 140 °F (60 °C)

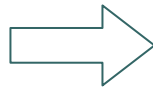
Contact Time: <1 minute to hours

Action: scrubbing, soaking, foaming, or circulation

# Removing Proteins (Allergens) from Food Contact Surfaces



**After Pre-Rinsing, Protein Film Remaining on a Food Contact Surface**



## **Cleaning Process**

- Foaming
- CIP (Clean in Place)

## **Using**

- Alkali
- Oxidizers

## **Peptizing the Protein**

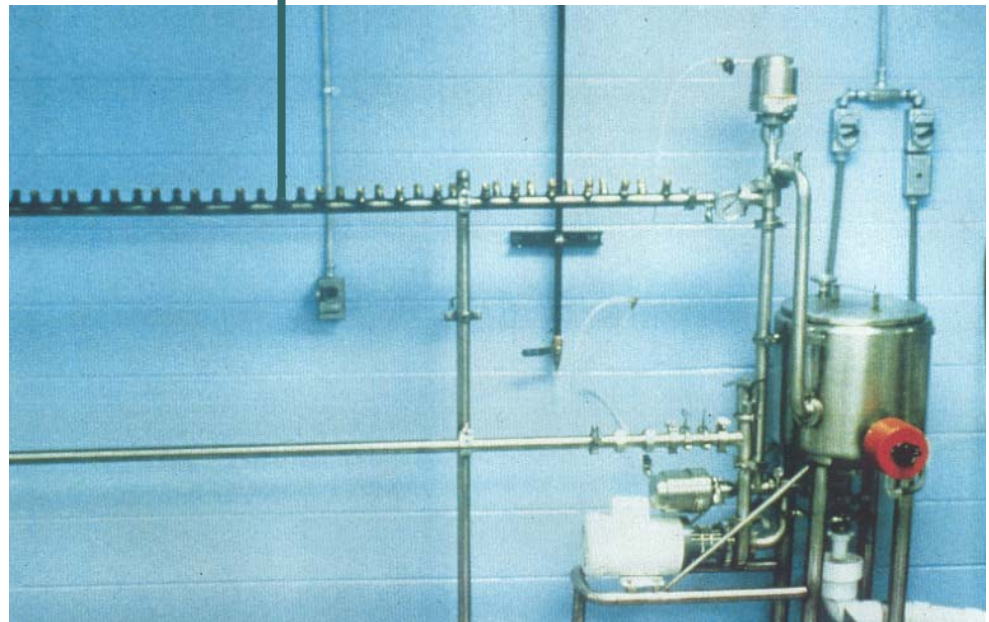
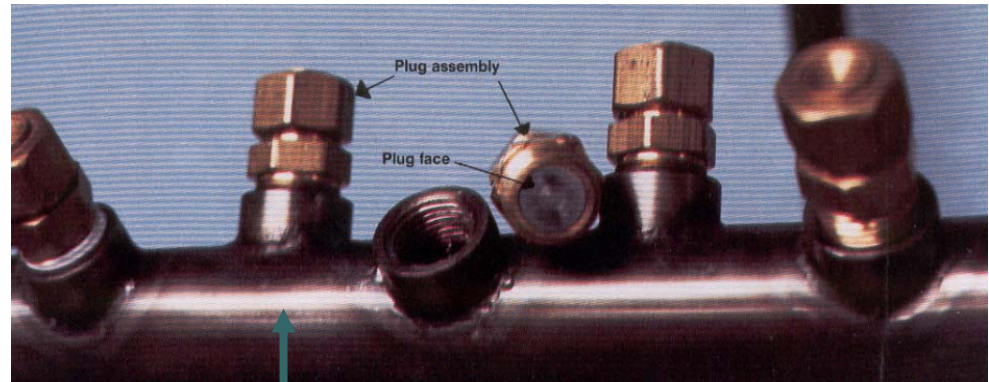
- > breaks bonds
- > solubilize chains



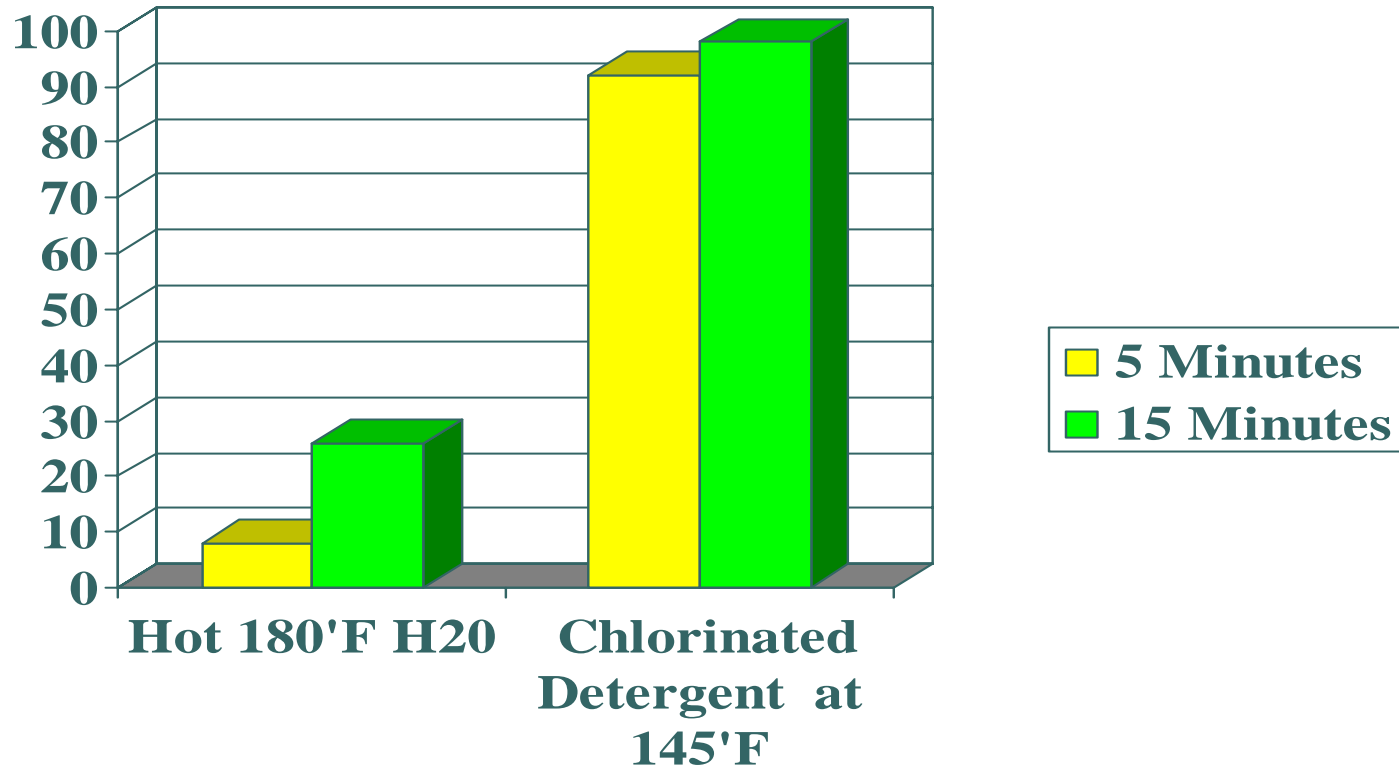
**After Cleaning with a Chlorinated Detergent**

# Studying Protein/Biofilm Removal in the Laboratory -- Dynamic CIP System

- proteinaceous soil (milk) is mixed with bacteria and allowed to soil surface
- proteins now bind to surface
- cleaning tests are run and soil removal quantified

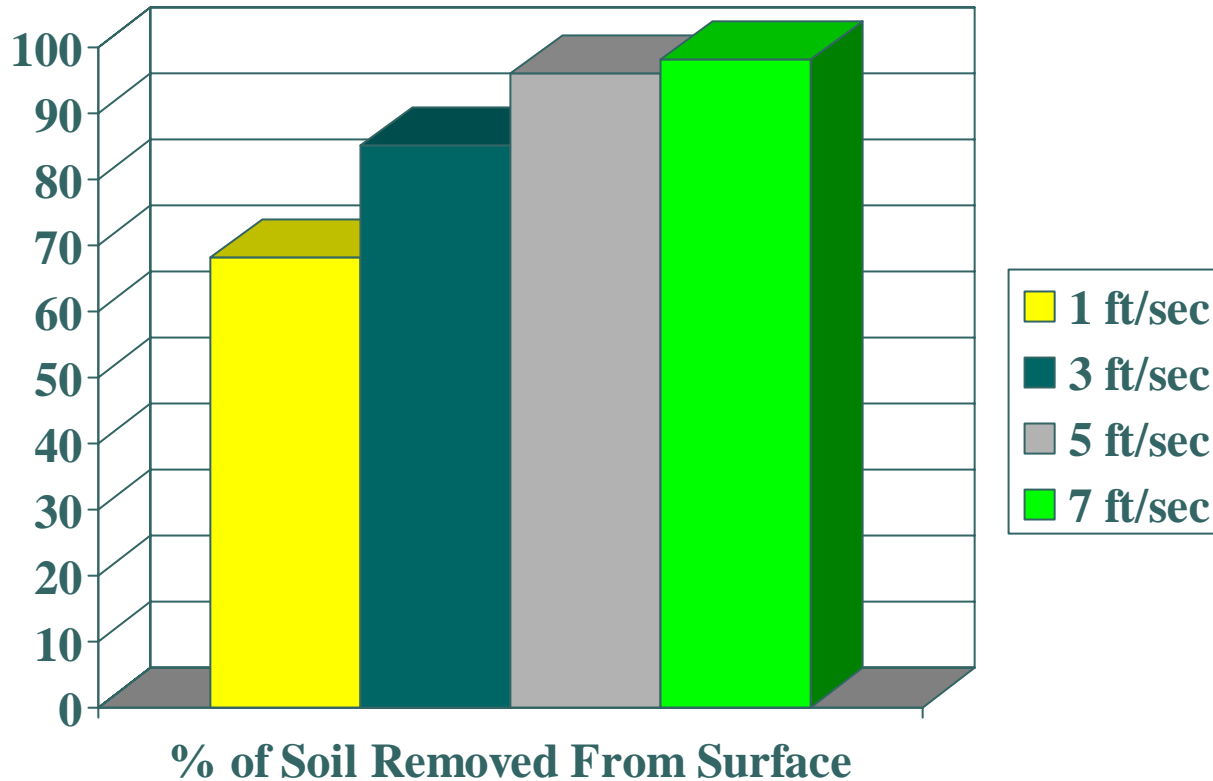


# Effect of Time



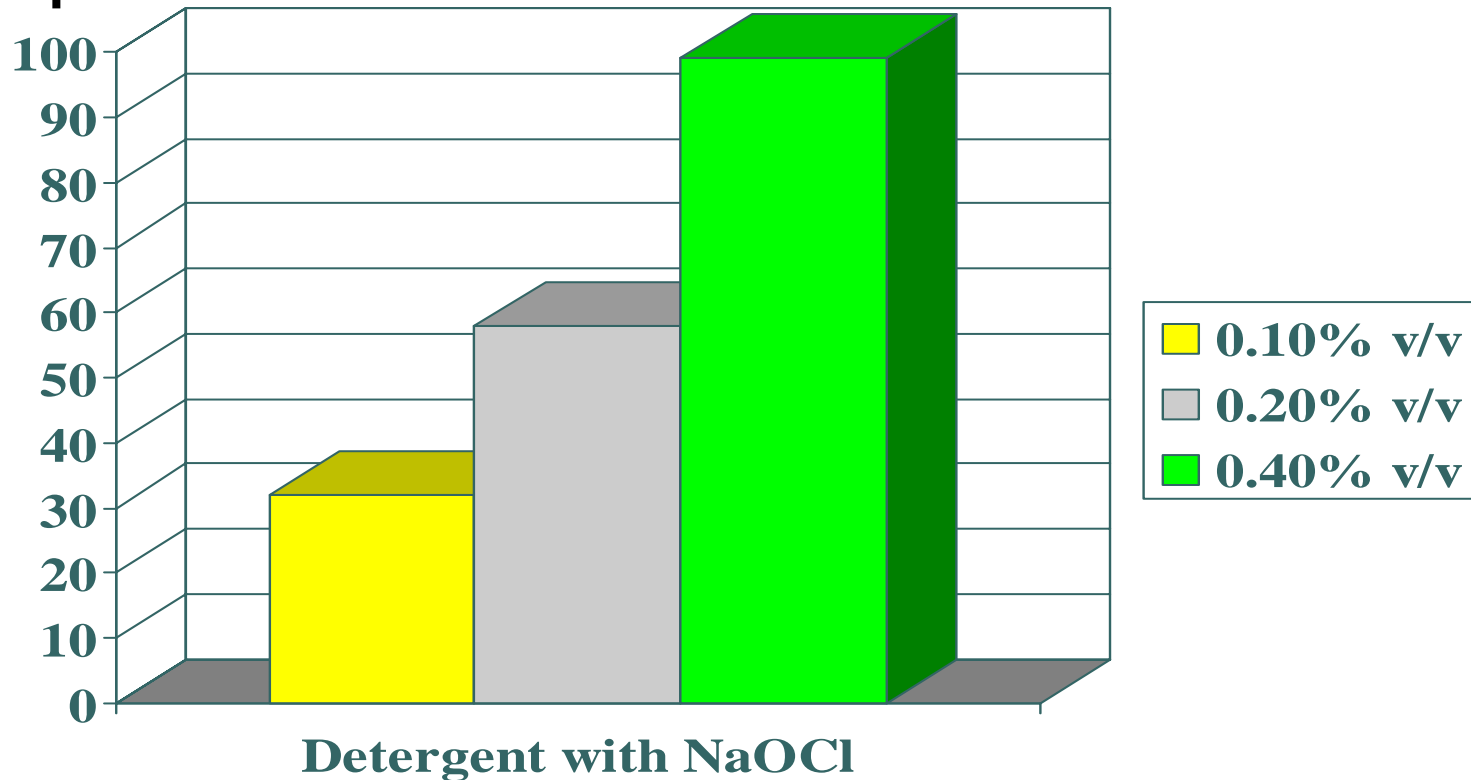
Percentage of soil removed from stainless steel surfaces with circulation cleaning. Flow = 5 ft/sec. Detergent concentration = 0.4%

# Effect of Action (Velocity)



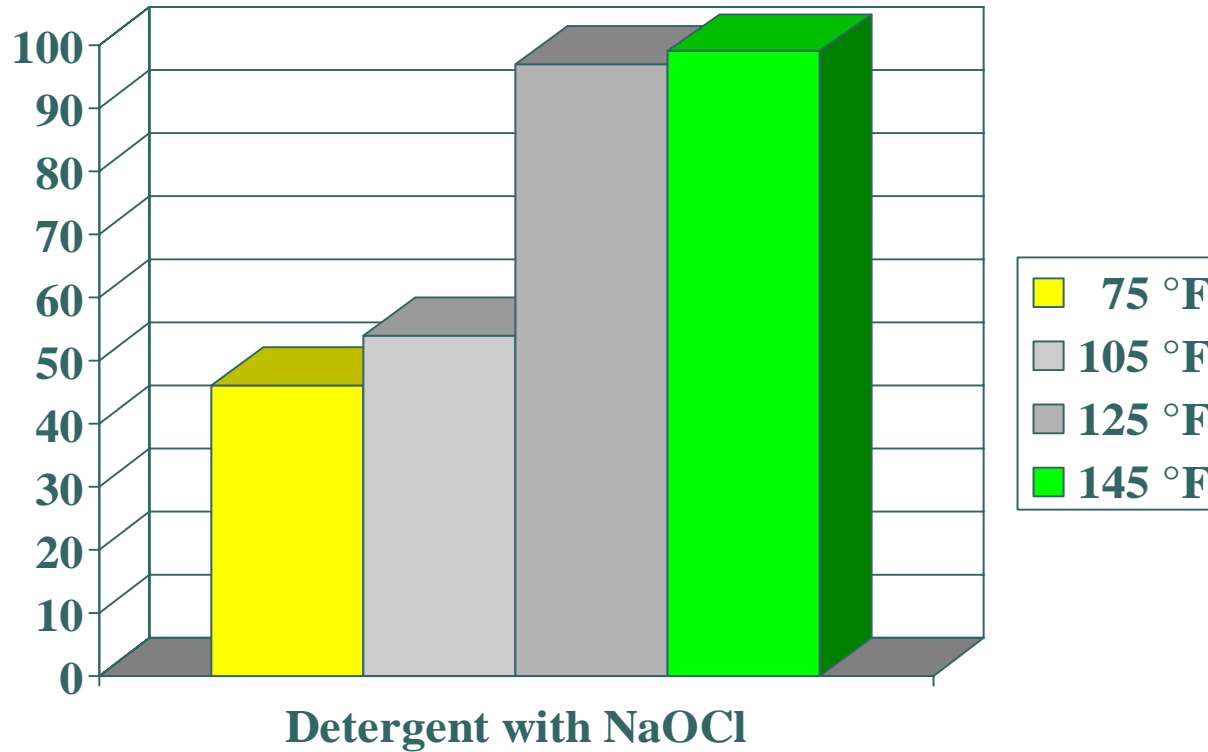
Percentage of soil removed from stainless steel surfaces at various flow rates of a chlorinated detergent after 5 minutes in a circulation cleaning system.

# Effect of Concentration



Percentage of soil removed from stainless steel surfaces with various concentrations of a chlorinated detergent in a circulation cleaning system.

# Effect of Temperature



**Percentage of soil removed from stainless steel surfaces at various temperatures of a chlorinated detergent in a circulation cleaning system. Detergent concentration = 0.4 % v/v.**



# Industrial Detergents that Remove Protein Soils from Food Contact Surfaces

- Chlorinated Alkali (with NaOCl) -- ☀☀☀☀  
**Excellent**
- Alkali/Caustics with H<sub>2</sub>O<sub>2</sub> ☀☀☀☀ **Excellent**
- Enzymes -- ☀☀☀☀ **Excellent** (but ...)
- Built Caustics -- ☀☀☀ **Fair** ⇒ **Very Good**
- Detergent Builders/Surfactants -- ☀☀☀ **Fair**  
⇒ **Very Good**
- Acids -- ☀ **Poor**



# Case Study on Allergen Removal



# Field Study Investigating Allergen Removal

- Location: Large Manufacturing Facility
  - Many Dairy & Other Fluid Products
- Concern: Cross Contamination of Dairy into Other Products
- Purpose:
  - Observe Cleaning & Sanitation Practices
  - Determine Allergen Removal
  - Make Recommendations



# Plant Cleaning Procedures

- 5 Step CIP (Clean in Place) Procedure
  - Chlorinated Alkaline Wash
    - Conc. = 1 oz/gal
    - ~200 PPM  $\text{Cl}_2$
  - Acid Sanitize
- COP (Clean out of Place)
  - Chlorinated Alkaline Powder
    - Conc = 1 oz/gal
    - Rinse & Dry



# Allergen Sanitation Audit

## ○ Inspection

- Equipment Condition
- CIP System
  - Integrity of the steps
  - Performance -- Flow, Velocity & Spray Patterns
  - Hydraulic Balance
- GMPs (Good Manufacturing Practices)

## ○ Testing

- Concentrations of detergents & sanitizers
- Swabbing & checking product contact surfaces for casein residues with ELISA kit

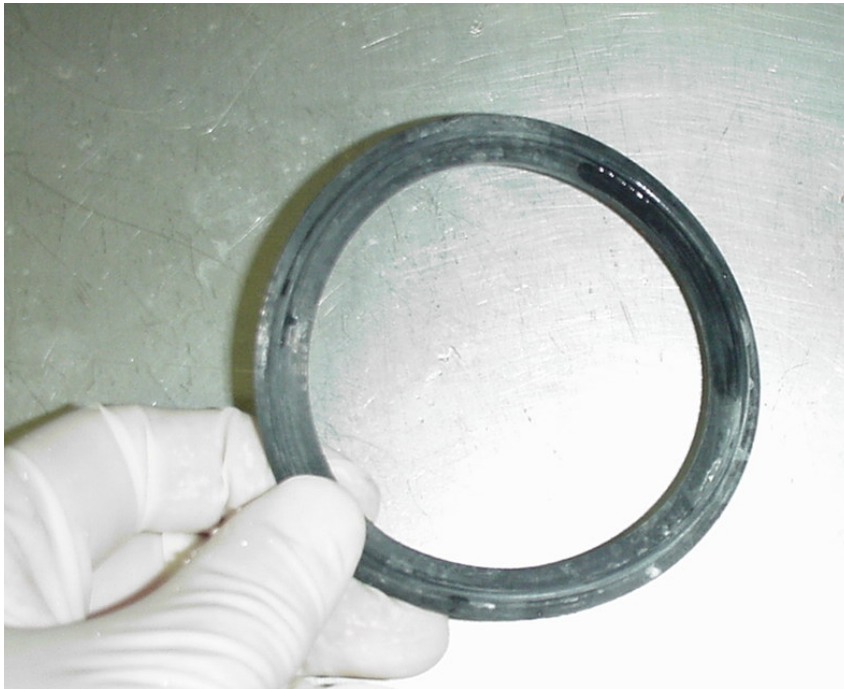
# Summary of Field Results

- Allergen Free Surfaces
  - inside silos
  - flat surfaces
- Allergen Positive Surfaces
  - gaskets
  - inside elbows



# Summary of Field Results

- This gasket tested extremely positive for a milk allergen.



- Broken gaskets need to be replaced





# Recommendations to the Plant for Allergen Control

- Maintain single use CIP system
- Initiate a program of soaking/scrubbing gaskets
- Separate set of gaskets and mandrels for allergenic products
- Develop a gasket replacement program
- Increase degree of brushing for small parts



# Allergen Testing

Can the system be allergen cleaned?

How do you validate?

How do you verify?



# Testing Procedures

- True test – Detecting protein residues or allergens from the allergenic food in the first product after change-over
- Evaluate over time IF product hang up is likely
- Swabbing equipment, filler heads, etc. may ID sources of cross-contact



# Validation

- Process to demonstrate that cleaning procedures are adequate to remove allergens to visibly clean or other standard



# Validation standard

- Visibly clean
  - Inspect all parts of the system
  - Breakdown parts not typically accessed
  - Benchmark what it takes to achieve allergen clean
- ELISA kits
  - Can be helpful in validation if samples are representative



# Commercially Available Tests

Based on Food Allergy Research & Resource Program materials

Company	Allergen	Contact information
ELISA Systems	Peanut, casein, beta-lactoglobulin, egg, gliadin, hazelnut, almond, sesame, crustacean, buckwheat, soy flour*	<a href="http://www.elisasystems.net">www.elisasystems.net</a> Australia; U.S. 877- 599-5583
Neogen	Peanut, total milk (casein and whey), egg, gliadin, hazelnut, almond, soy flour*	<a href="http://www.neogen.com">www.neogen.com</a> Lansing, MI 800-234-5333
r-Biopharm	Peanut, beta-lactoglobulin, egg, gliadin, hazelnut, almond	<a href="http://www.r-biopharm.com">www.r-biopharm.com</a> Marshall, MI 877-789-3033
Tepnel BioSystems	Peanut, casein, whey, gliadin, sesame, egg, soy**	<a href="http://www.tepnel.com">www.tepnel.com</a> UK; U.S. 888-329-0255 x 546

\* detection limit 2.5 ppm

\*\*detection limit 3500 ppm

Units of measurement are different for different kits; please check with manufacturers for specifics



# Verification

- Process to demonstrate that validated procedures are followed
- Generally involves
  - ✓ Visual inspection,
  - ✓ Record review
- Specific allergen testing typically not routine
- Can ATP be used to evaluate cleaning effectiveness for allergen concerns?



# ATP Bioluminescence?

- Food, free & microbiological ATP
- Traditional ATP swabs are not sensitive enough
- Extra sensitive ATP swab AllerGiene may be useful in certain wet cleaning operations
- Measures total ATP and is not specific to allergens
  - May also detect ATP from water supply or biofilms in some situations



# Allergen Regulations

US & Europe



# US Regulations

- effective January 1, 2006
- pertains to labeling of food products
- covers the Big 8 (major food allergens)
  - includes spices, flavorings, coloring and incidental additives
- applies to imported foods



# US Regulations

- label must list allergen in plain English or say “Contains” giving ingredient
- must use common name of food source
- must name specific type, e.g.
  - crustaceans – crab, lobster, shrimp
  - fish – bass, flounder, cod
  - tree nut – almond, pecan, walnut



# US Regulations

Exceptions:

- 1) any highly refined oil derived from a food specified in the Big 8 and any ingredient derived from it
- 2) raw agricultural commodities such as fruits and vegetables



# European Regulations

- effective November 25, 2003
- pertains to labeling of food products
- covers the major food allergens including derivatives
  - includes additives and processing aids



# European Regulations

- label must list allergen or say “Contains” giving ingredient
- must identify specific fruits, vegetables and mushrooms

Nuts include: almond, hazelnut, walnut, cashew, pecan, brazil nut, pistachio nut, macadamia nut