

## **Allergen Management and Cleaning Validation**

Randy Porter  
Director of Sanitation, Hygienic Design and Pest Management  
ConAgra Foods Inc.  
MS: 6-405, 6 ConAgra Drive  
Omaha, NE 68102  
ph: 402.240.6316  
[randy.porter@conagrafoods.com](mailto:randy.porter@conagrafoods.com)

### **Biography of Randy Porter**

Randy Porter is currently the Director of Sanitation, Hygienic Design & Pest Management for ConAgra Foods' World Headquarters in Omaha, NE. He has responsibility for driving sanitation improvement for the consumer foods businesses, which includes providing sanitary design knowledge and oversight for all ConAgra Foods' projects. He has also been actively training key 3<sup>rd</sup> party engineering firms on sanitary design for incorporation in ConAgra projects, as well as, participating on an Industry Sanitation Team to develop Low Moisture Foods/Ingredients Sanitary Design Guidelines. Mr. Porter has 31 years in the food industry, having worked in various operational, engineering, maintenance, quality, food safety and sanitation roles, including five years of international work. He has experience in a variety of different low moisture product/ingredient offerings, including cookies, crackers, breads, cakes, peanut butter and chocolate confectionery.



BCMA Meeting  
10/18/2010

## Active Allergen Management

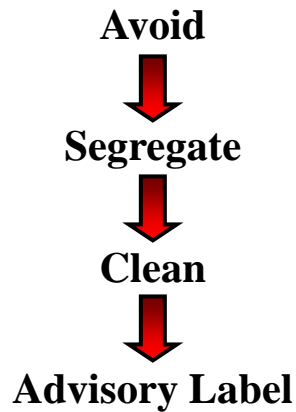
Randy Porter  
Director of Sanitation  
ConAgra Foods

## Agenda



- Allergens / Communication
- Control of Allergens – Food Allergens and HACCP
- Sanitation Plan Validation
- General Sanitation Procedures

## Allergen Management Options



## Allergen Equation Manufacturing and Quality

Sanitary Design Equip & Building + Effective Sanitation Procedures & Execution + Rework, Packaging and label controls + Awareness, (GMPs) and trained inspectors + Cleaning effective and HACCP validated

## Allergen Equation for R&D

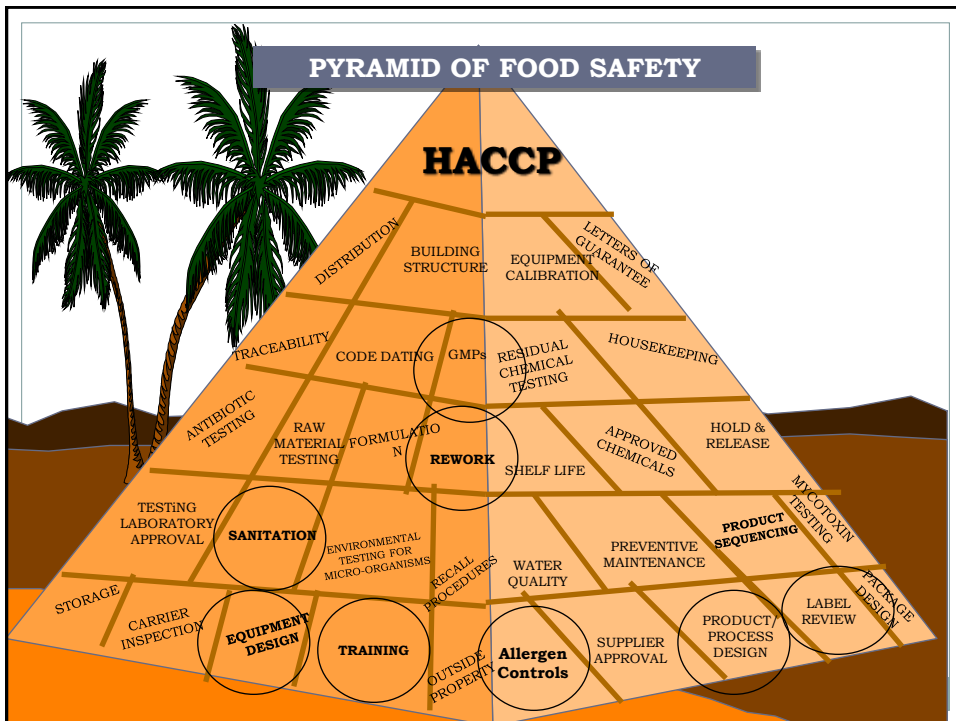
Trained & hands on knowledge of allergens + Effective approach to formulation w/o Allergens + Rework, management, effective communication + Incentives to reduce allergens + Label re-design to reduce complexity and failure

= **Allergen Control**

# Food Allergen Control and HACCP

- Allergens are classified as a chemical hazard.
- The Hazard is Unlabeled Allergens
- Allergens addressed are based upon an established list

MY Co.  
Food Allergen List  
Peanuts  
Tree Nuts  
Fish  
Milk  
Wheat Products  
Soy Products  
Crustacean  
Egg



# Food Allergen Control and HACCP



- HACCP Plan Development
  - Identify of all sources of allergens
  - Establish control mechanisms
  - Establish Critical Control Points (CCPs)
  - Incorporate as part of HACCP program

## Identification of Sources



- All Ingredients
- All rework
- All processing aids (e.g., wheat starch)
- Other products produced on line
- Other materials in facility

# Allergen Assessment

List all allergens in the product. Group the allergens as appropriate into Allergen Category (*Examples: all dairy ingredients may be grouped as one type of ingredient, Milk Protein. Tree nuts and seeds cannot be grouped, each type is a different allergen.*)

Then review this list against ALL of the products run on the specific processing line to determine if the noted allergen is found in ALL products produced on the line. If the allergen is not present in ALL products produced on the line, ("NO" on chart), then there may be a risk of carryover of the allergen into a product where the allergen is not labeled. Further evaluation of this process will need to be done to determine the potential method of control for the allergen.

## PER MANUFACTURING LINE

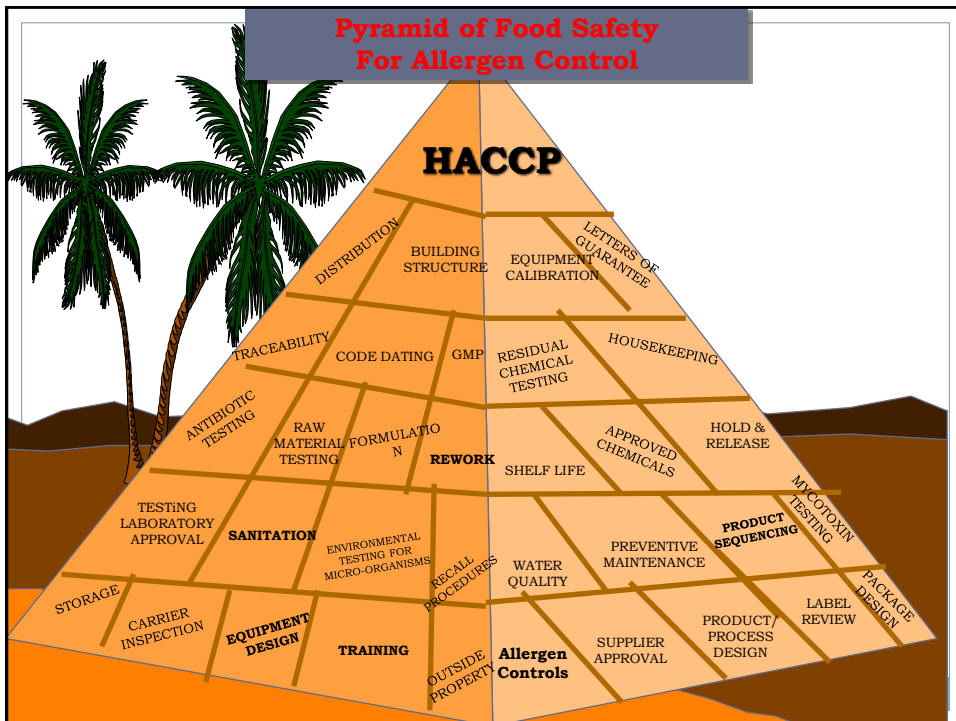
List all products produced on the manufacturing line	Are all identified allergens labeled?		If "No" identify control mechanism(s) ( - CCP) ( - PP)
	YES	NO (list allergens)	

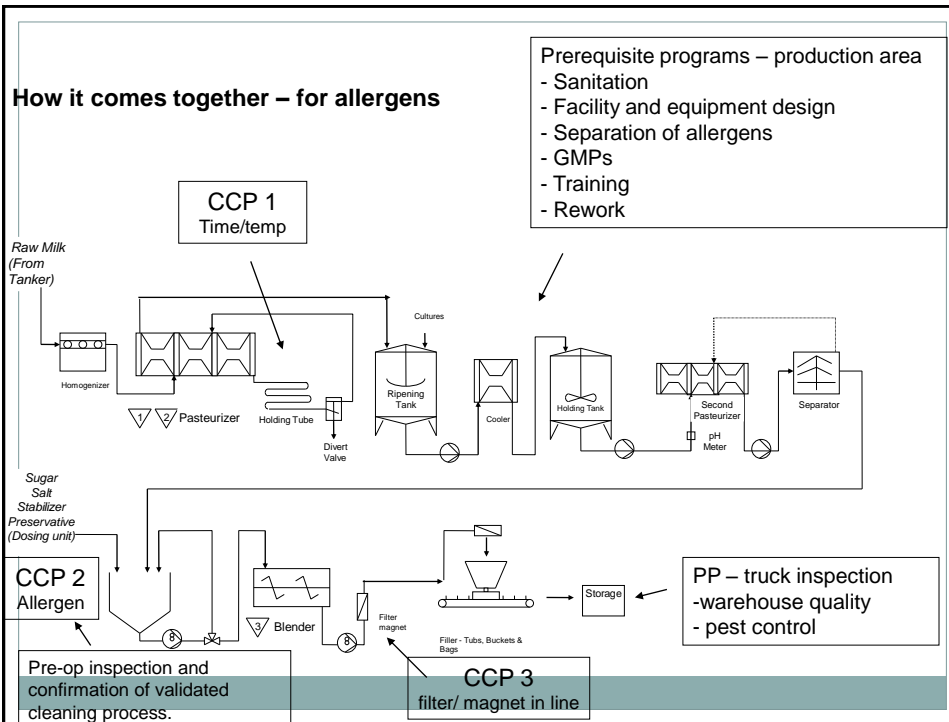
# Determination of Control Mechanisms

- Determination of control mechanism is based upon:
  - Hazard analysis for the product and the process
  - Risk assessment - probability of occurrence

# Allergen Critical Control Points

- Control of Rework - Like into Like ONLY
- Labeling
- Product Changeover



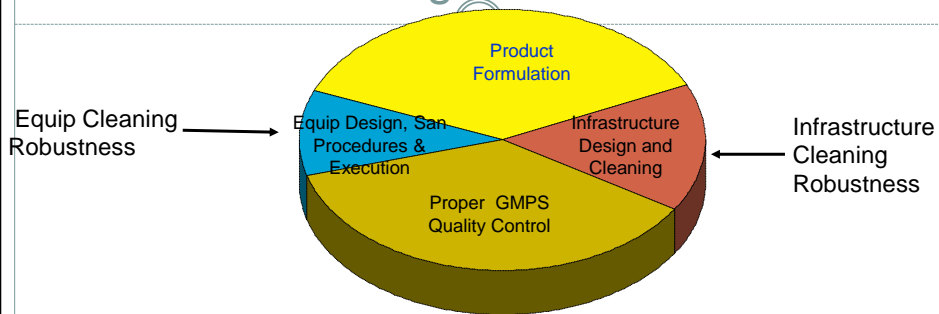


# Sanitation Plan

## To Control Allergens in Your Plant, You Need ...

- Overall Plant Allergen Program
- Dedicated Tools and Equipment.
- Everything properly labeled from when it comes into the door to out the door.
- Strong Label Controls
- Educated and Aware Employees
- Effective Sanitation (validated)
- Validated Changeover Process

## Low Moisture Foods - Allergen Changeovers



- **Formulation** Only functional allergens are permitted.
- **Equip Design** Equipment cleanable and cleaned to a allergen level
- **Infra Design** Cleanable room and environment
- **Quality / GMPs** GMPs established and monitored to control potential cross contamination.

## Goal



- The goal of a sanitation plan for food allergen control is ---

**The removal and verification of allergenic protein from product contact surfaces and areas adjacent to product zones where material could “enter” the product stream**

## Validation Questions



- What is the allergen?
  - Tree nut
  - Dairy (dry, liquid)
  - Peanut
  - Egg
- What is the percentage of allergen in the finished product?
- Is there a test kit available to detect the allergen protein?



## Determine Cleaning Method

- **Wet Cleaning**
  - Removal of soil/residue with water and chemicals
  - Foaming / CIP / COP
- **Dry Cleaning**
  - Removal of soil/residue with physical or mechanical action
  - Vacuum / brushing / blasting
- **Combination**
  - Dry clean followed by wet (damp) wiping
- **Can it be cleaned -- be honest?**

## Allergen Validation Protocol

**Critical Step**

### 1st Step

#### **Physical Validation of an Allergen Change Over / Pre-Op sheets for CCP**

Identifies the protocol to validate that current sanitation procedures according to cleaning or flush are sufficient to prevent allergen carryover on lines where allergens and non-allergens products are produced. It consists of a physical walk through of the line and a tear down of equipment to identify potential catch points (visual pre-op inspection). Identify pre-op ccp inspection points. Modify design flaws.



### 2nd Step

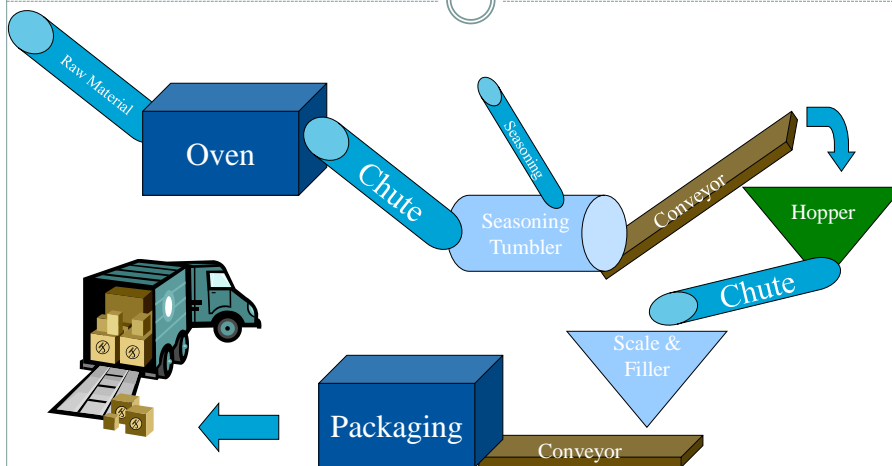
#### **Analytical Validation of Allergens Using Allergen Test Kits**

This method describes analytical validation, if test kits are available. Prior to any analytical validation a physical validation of each line must be completed.

## Types of Validations

- Initial Validation
  - 1<sup>st</sup> time it will be done
- Re-Validation
  - Line has already been validated
  - Occurs when HACCP is re-validation
- New Product
  - New product introduced to existing line
  - Formula change of existing product – **Red Flag**
- New Line / New Equipment
  - Changes in soil load, then need to evaluate.

## Manufacturing Line Example



What equipment is of allergen concern?

**How would you  
clean this  
conveyor?**

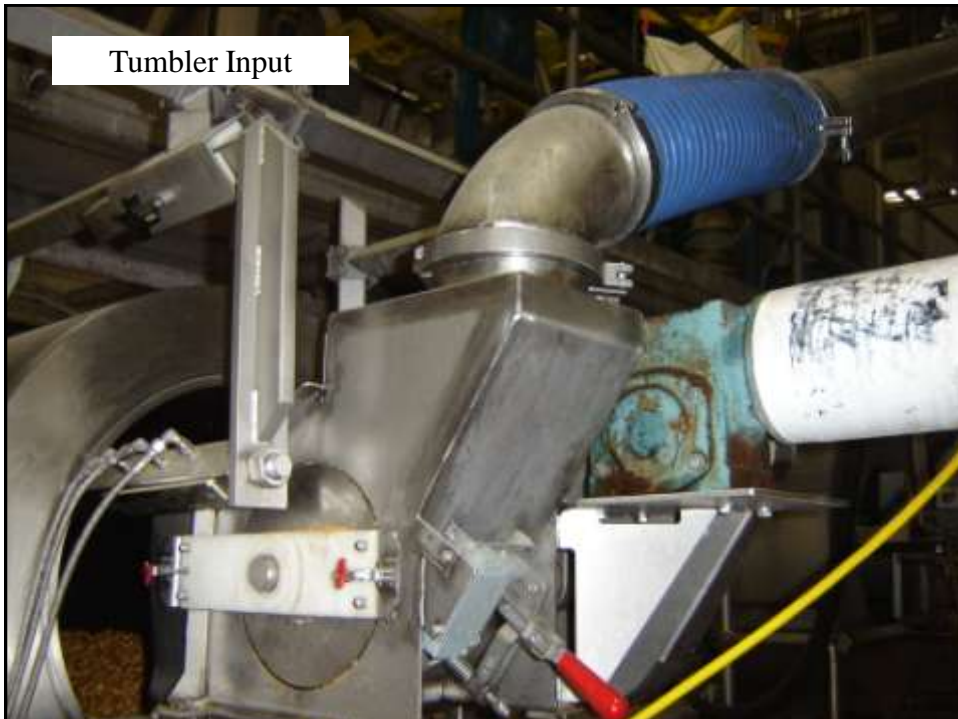


**Allergen  
Clean?**

**How About this Design?**

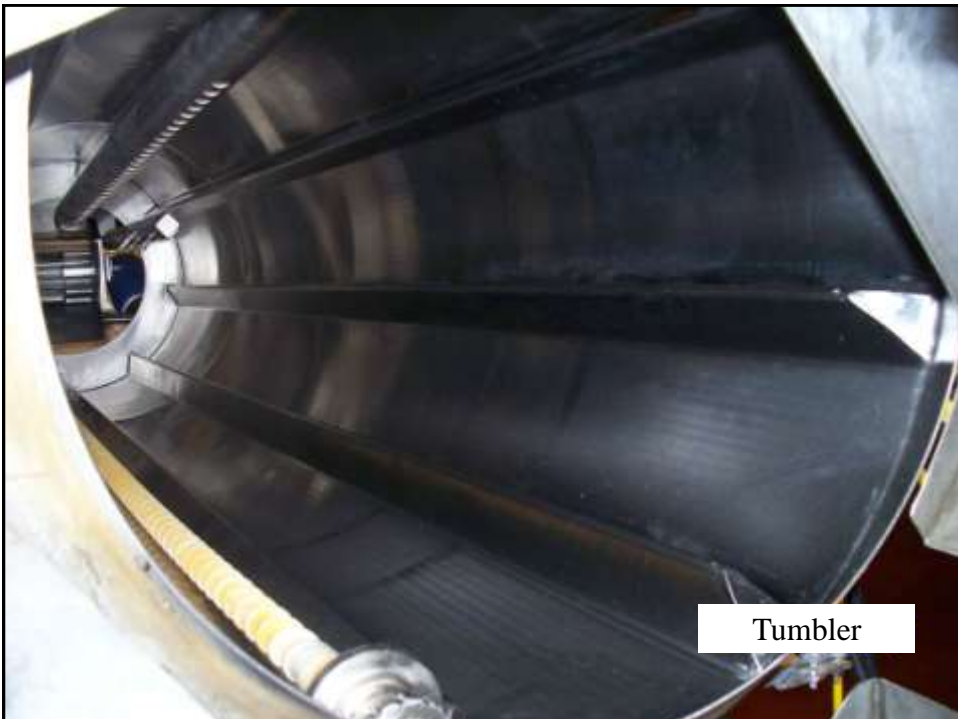


**Tumbler Input**

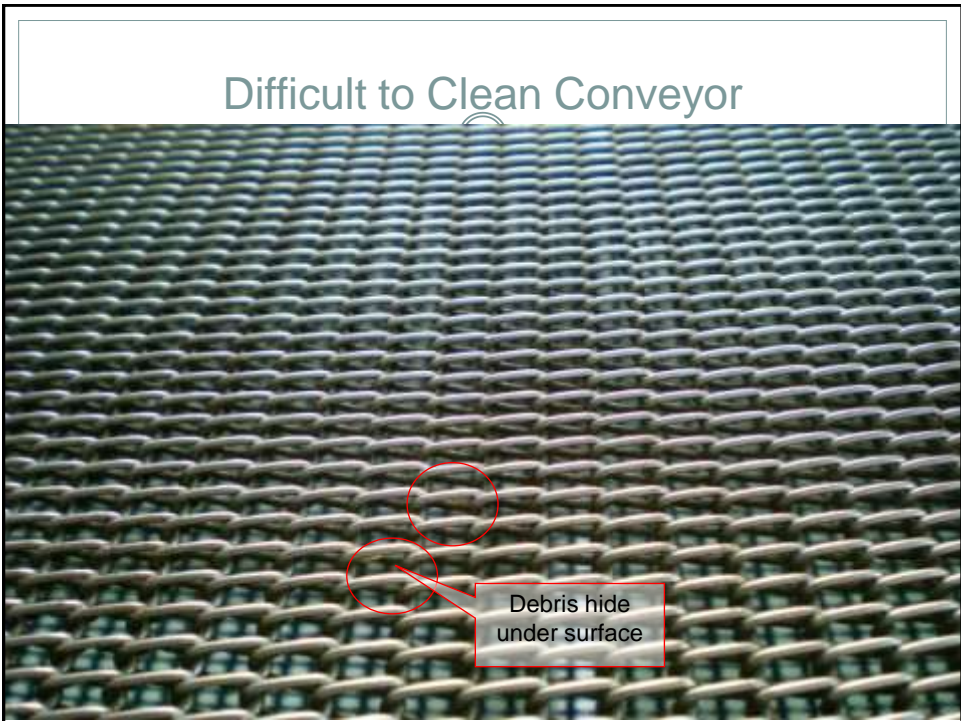




Tumbler Exit



Tumbler



## Develop Sanitation Standard Operating Procedures

- **SSOP Fundamentals**
  - Equipment to be cleaned
  - Cautionary notes (e.g. allergens)
  - Step-by-step instructions
  - Tools / utensils
  - Chemicals and concentration
  - Personal safety requirements
  - Inspection and documentation

## Allergen Cleanup Validation Typical Protocol

- **Verify allergen in previous food**
  - Test for positive control
  - Swabs of equipment prior to cleaning
- **Clean the line/equipment**
  - “Visible clean” is the standard
- **Sampling Strategy**
  - Swabs (8 – 12 depending on process)
  - Intermediate products
  - Final rinse water from CIP systems
  - Finished Product

# Analytical Validation

- **Sampling Protocol**

- Swab, rinsate, product?
- Identify areas: hard to access, hot spots

- **Production Protocol**

- Schedule enough time to reclean
- Like to like

- **Don't Implicate Product**

## Type of testing

Perform physical validation

**Determine type of analytical validation**

If equipment is wet/dry  
Cleaned and all surfaces  
Are accessible.

Swabs

If equipment is wet  
Cleaned but not all  
Surfaces are accessible  
(e.g: CIP and ACS)

Rinsate

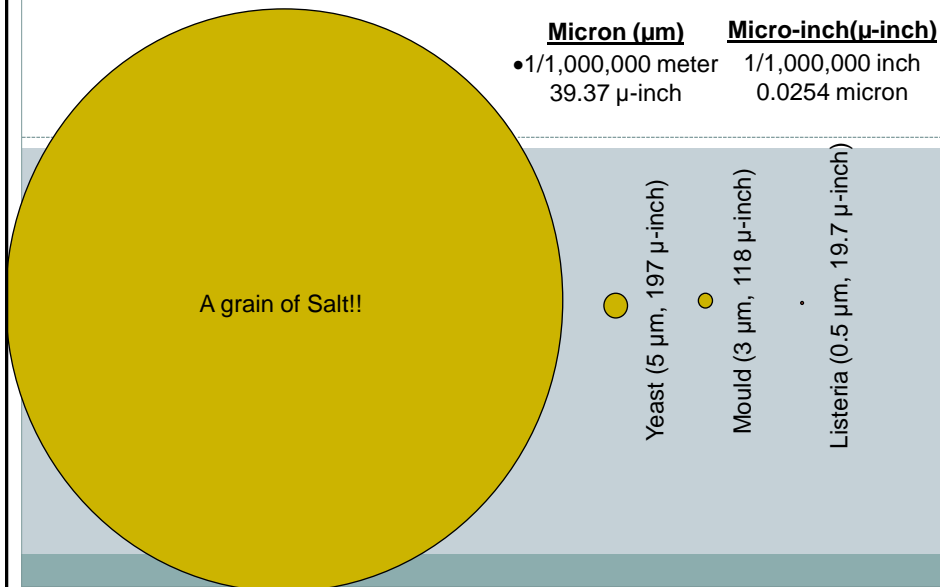
Product testing

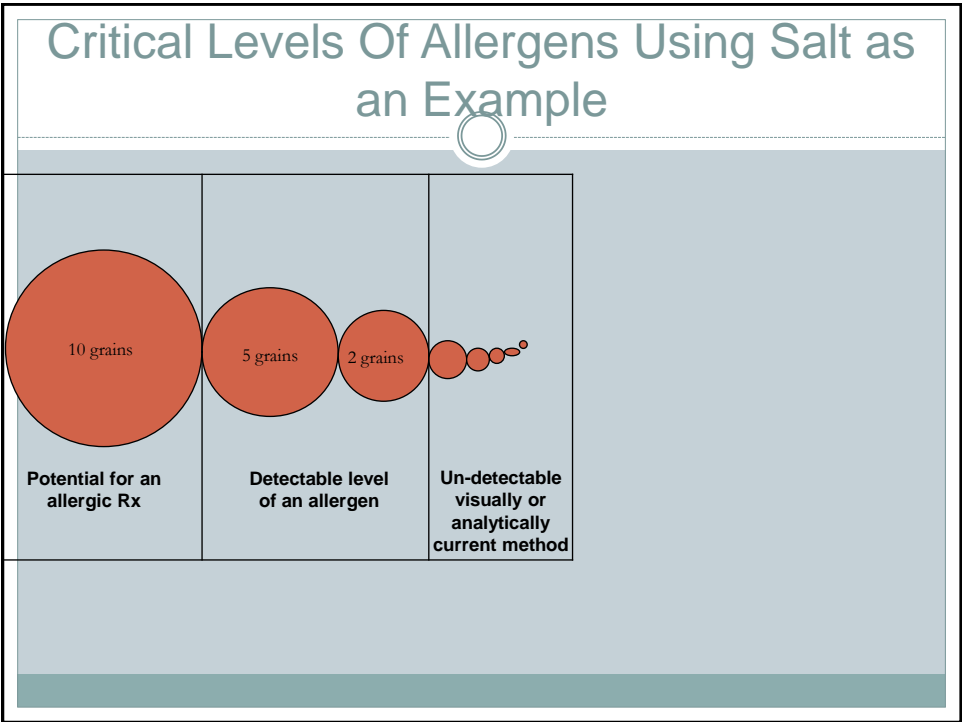


## Salt as an Example

- One Teaspoon of salt has 25,000 grains
- 1/2 of a teaspoon has 12,500 grains
- 1/10 of a teaspoon has 250 grains
- 1/25 of a teaspoon has 1000 grains
- 1/50 of a teaspoon has 500 grains
- 1/1000 of a teaspoon has 25 grains
- 1/2500 of a teaspoon has 10 grains
- 10 grains is equivalent to 2 milligrams and would cause an allergic reaction.



## THE “INVISIBLE” BACTERIA





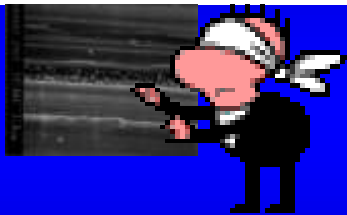
### Sanitation is Critical for Food Allergen Control

- Start with equipment designed to be cleaned!
- If equipment can not be “easily and inexpensively cleaned” does not mean it **CAN'T** be cleaned.
  - Poor equipment design is not an excuse for poor food allergen control programs



## Common Sense Approach to Sanitary Design

IF YOU CAN'T SEE IT AND



YOU CAN'T REACH IT

YOU CAN'T CLEAN IT!

Or sample it.

## Sanitation Plan Validation

- **Validation**

The stage at the end of the development process where sanitation plan is evaluated to ensure that it complies with the requirements. **Determination of the ability of sanitation plan to thoroughly clean the equipment and the environment.**

- **Verification**

Additional proof that something that was believed is true; [syn: confirmation, check, substantiation]  
**Determination of whether CCP is in control for product release.**

## Sanitation Plan Validation



### 1. Visual Inspection

- A complete visual inspection of all product contact surfaces (Zone 1 areas). May require the teardown of equipment

### 2. Zone 1 Swabs for validation of program.

- Positive equipment swab will indicate that there is a residual amount of allergenic protein.
- Validate on “visually clean” equipment

## Sanitation Plan Validation



### 3. Allergen test details

- Use “aseptic like” techniques
- Use rinsate in a wet process.
- Document all details and the sanitation procedure used.
- Detail detail detail.
- Have a plan in the event you get a positive result.

## Sanitation Plan Validation



**If** changeover sanitation is a CCP

**Then** it must be validated...

- Whenever there is a new product added to the production line
- Whenever there is a new process or a change in the process or equipment
- Whenever there is a change in the product
- On a predetermined schedule (e.g. every two years)

## Cross Line Validation

### REPORT FORM FOR HACCP DOCUMENT

Plant \_\_\_\_\_

Line # \_\_\_\_\_ (Allergen producing line)

Line # \_\_\_\_\_ (Line at risk of receiving allergen)

Product on Allergen generating line \_\_\_\_\_

Allergen of concern on generating line \_\_\_\_\_

Time periods exposed \_\_\_\_\_

Results of exposure (dust or no dust) \_\_\_\_\_

Photos on file or attached? Yes or No \_\_\_\_\_

Person completing test \_\_\_\_\_

Signature \_\_\_\_\_

Date of test \_\_\_\_\_

HACCP co-ordinator \_\_\_\_\_

Signature \_\_\_\_\_

## Line Validation Testing

### FORM FOR HACCP VALIDATION DOCUMENT

Plant \_\_\_\_\_ Line # \_\_\_\_\_

Product \_\_\_\_\_ (

Allergens targeted for removal from line \_\_\_\_\_

Test type: Push through \_\_\_\_\_ Contact sample \_\_\_\_\_ Rinse \_\_\_\_\_

Results \_\_\_\_\_

Product disposition \_\_\_\_\_

Line visibly clean? \_\_\_\_\_

Photos on file or attached? Yes or No \_\_\_\_\_

Person completing test \_\_\_\_\_

Signature \_\_\_\_\_

Date of test \_\_\_\_\_

HACCP co-ordinator \_\_\_\_\_

Signature \_\_\_\_\_

## CCP Verification



- Product can not be released until all CCP's have been verified as being in control
- Therefore to verify the CCP on changeover sanitation
  - Verify that the sanitation plan has been followed (time, temperatures, amount of flush material, etc.)
  - Do visual inspection of equipment on pre-identified pieces of equipment

## Cleaning Practices Not Recommended

- By Hand Method
  - Pressurized Air
  - High Pressure water/steam hoses
  - Dry Brushing

Why---

Because these methods blow material around and it is not contained and captured.

## Example Of Pre-Op Inspection Form

Equipment	Acceptable	Rejected	N/A	Defect Description / Action taken
Bran Transfer belting from Sifter screens. Visibly Clean				
Rollers are visibly clean				
Inspect entire shaker conveyor along catwalk, visibly clean				
1 <sup>st</sup> Product belt & rollers, visibly clean				
2 <sup>nd</sup> conveyor & rollers, visibly clean.				

Inspected By: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

Reviewed By: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

Approved for Production: \_\_\_\_\_ Date: \_\_\_\_\_

## *Cleaning is the First But not The Last Control Needed to Avoid Allergen issues!*

- Wrong labels/packages
- Inappropriate use of re-work
- Formulation mistakes
- Switching of ingredients
- Labeling terms
- Inadequate cleaning of shared equipment

## *The 7-Steps of Sanitation The Start of the Process*

- Provides direction for a sanitation process
- Supports an 'Effective' quality sanitation process
- Provides direction for entire room clean
- Identifies 'KEY' value added steps
- Identifies the rights steps in the right order
- Provides in sync process design
- In sync process reduces re-contamination issues

## 7 Steps of Effective Dry Sanitation

1. Pre-Sanitation preparation
2. Secure and dismantle
3. Dry Clean
4. Detail cleaning
5. Post sanitation inspection and reassembly
6. Pre-operational inspection
7. Final inspection and documentation

## Prior to Line / Process Shutdown

- Get ready for sanitation
- Maintain housekeeping
- Necessary tools ready to go: I.e.: chemicals, carts, hoses, foamers, etc.
- Control panels wiped down and covered if applicable
- All unnecessary supplies, etc. removed
- Communication – with partners



## Step 1: Pre-Sanitation Preparation

Remove:

1. All ingredients from the line
2. All packaging from the line
3. Garbage containers from the line

Could some of these steps done externally?

## Step 2: Secure & Dismantle

Per Procedure gather:

- Cleaning Tools
- Supplies
- **Safety** Gear
- Cleaning Chemicals

Could these tasks be completed externally?

### Step 3: Pre-Clean

- Run all product out of the machine.
- Remove chunks of dough, biscuits
- Empty all ingredient reservoirs: such as flour dusting hoppers.
- **Lock & Tag out** the machinery
- Remove the guards
- Loosen belts where applicable

### Step 4: Detail Cleaning

- **Remove soils – work top down**
  - May require **PPE**
  - Vacuum soils
  - Scrape soils
  - Brush off the soils
  - Wet Cleaning (Off Line)
  - Clean guards

## Step 5: Final Cleaning

- Clean the outside of the machinery with dampened wipes
- Removal of all residues
- Clean floors
- Clean framework
- Clean equipment legs



## Step 6: Sanitation Inspections!

- Inspect all areas to ensure that residues and particulates are removed
- **LOTO** - Reassemble guards and any other parts removed for cleaning
- Complete Post Cleaning Inspection Form
- Complete and document any corrective actions

## Step 7: Final Inspection and Documentation

- Start conveyors and run to determine if there were any concealed areas where product had accumulated.
- Clean the belts of any remaining particulate matter.
- Complete final detail cleaning with brush or vacuum cleaner or wipers.
- Inspect and complete CCP inspection.

**Questions?**