

Role of Cleaning and Sanitation at Preventing Allergen Cross-contact



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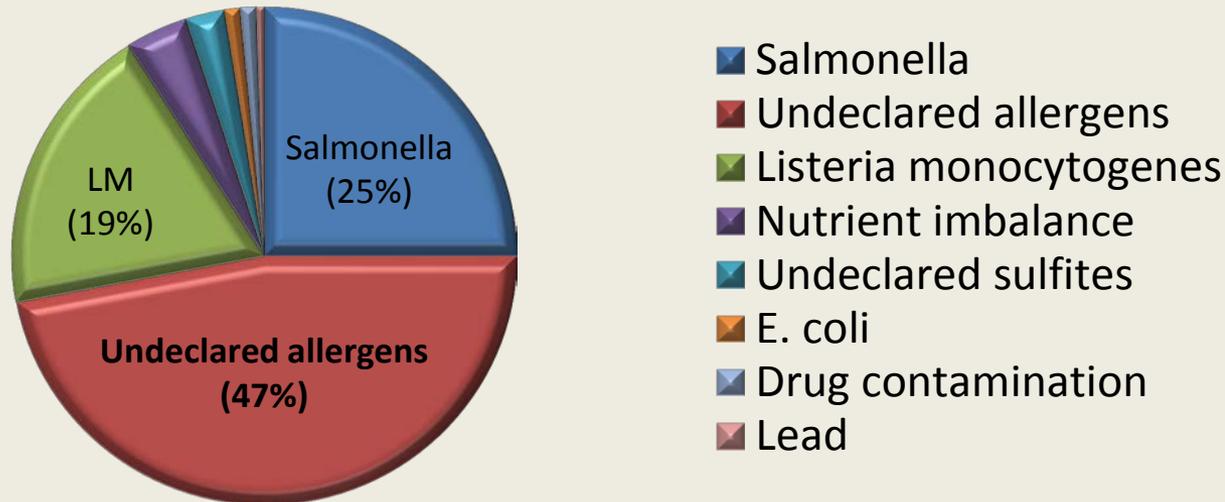


FSIS Public Meeting
Preventing Undeclared Allergens
March 16, 2017
Washington, DC

Introduction

- Undeclared allergens – major cause of recalls in U.S.
- Reportable Food Registry

2013-2014



- 30-40% of total recalls in U.S. are due to undeclared allergens
- Undeclared allergens increased from 30% of all reports in first year, to 47% of reports in the fifth year
- 5-15% of allergen recalls are associated with consumer reactions¹

¹ from: Malyukova, Gendel, Luccioli. JACI 129(2):S234, 2012

Allergen Recalls

Causes of allergen recalls

Cause of allergen recalls	Number recalls
Wrong package or label	153
Terminology	62
Failure to carry forward information from an ingredient to final label	45
Cross-contact	39
Ingredient mislabeled from supplier	38

Most common foods categories involved in food allergen recalls

Food Category	Number recalls	% Class I
Bakery	153	62
Snack	62	62
Candy	45	63
Dairy	39	58
Dressing	38	59

From: Gendel et al. Food Safety April/May 2014

Allergen Cross-Contact

- Unintentional incorporation of a food allergen into a food
- Examples of causes
 - Dusts or aerosols created from allergens
 - Cross-over points in processing lines
 - Improper use of product rework
 - Reuse of cooking/processing media
 - Inadequate cleaning of shared food-contact surfaces
- Possible preventive measures
 - Dedicated facility, line, cooking and processing media
 - Scheduling
 - Manufacturing and engineering controls
 - Properly manage rework
 - **Use of an effective allergen cleaning procedure for shared equipment, utensils, etc.**



Recall Likely Due to Cross-Contact/ Inadequate Cleaning



Smith Dairy Announces Voluntary Recall on SMITH'S Tea with Lemon in Gallon Size Only - Microsoft Internet Explorer

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Address <http://www.fda.gov/Safety/Recalls/ucm167654.htm> Go Links

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Safety

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Home > Safety > Recalls, Market Withdrawals, & Safety Alerts

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Smith Dairy Announces Voluntary Recall on SMITH'S Tea with Lemon in Gallon Size Only

Contact:
Penny Baker
330-634-6526

FOR IMMEDIATE RELEASE -- June 16, 2009 - Smith Dairy Products Company today announced a voluntary recall on SMITH'S Tea with Lemon in gallon size, lot no. 07/07/09. The product is being recalled immediately because it may contain milk which is an undeclared allergen. People who have allergies to milk run the risk of serious or life-threatening allergic reaction if they consume this product.

The specific product in question is:

SMITH'S Tea with Lemon gallon size UPC 70424 00560 Lot No. 07/07/09

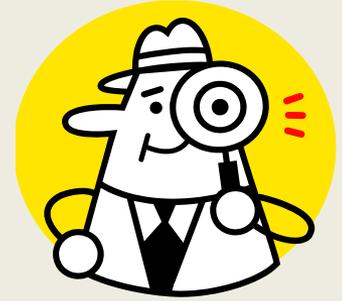
The product was distributed in Ohio. There have been no reported illnesses related to the product.

Local intranet

start 30 E. 4 4 Desktop 8:47 AM

Important Facts

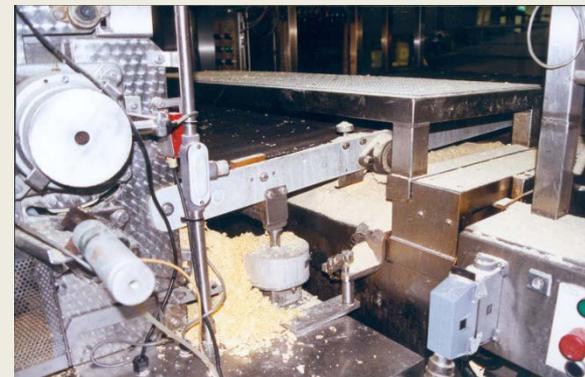
- Microbiologically clean is not equivalent to allergen clean
- Proteins are notoriously “sticky”- difficult to remove from food contact surfaces, especially if the protein has been heated
- Wet cleaning (use of detergents/water) can be effective at removing allergenic food soils- but all procedures should be evaluated for effectiveness
- Cleaning in a dry environment is a challenge—and it can be difficult to clean to “allergen clean”
- All methods for evaluating cleaning efficacy have shortcomings



Factors Affecting Allergen Removal



1. Type of food allergen
 - Physical form: Paste, particulate, powder, liquid
 - Chemistry: Water- vs. lipid-based ingredients
2. Concentration of food allergen
 - High vs. low concentration in food
3. Type of food contact surface
 - Stainless steel, plastic, cloth
 - Texture (finish) of surface
4. How the allergen was applied to the surface
 - Hot vs. cold soil
5. Equipment design
6. Age of equipment
7. Length of processing run
8. Type of cleaning method



Cleaning Methods



Wet

- Plant area designed to accommodate water
- Employ detergents and sanitizers
- Can be automated (CIP), semi-automated (COP), or manual
- Purging line with ingredient or next food*

Dry

- Plant area not designed to accommodate water
- Water use limited
- Compressed air, vacuum and/or dry steam may be used to “clean” surfaces
- Other methods- blasting with CO₂ or food ingredients
- Purging line with ingredient (e.g. salt) or next food*

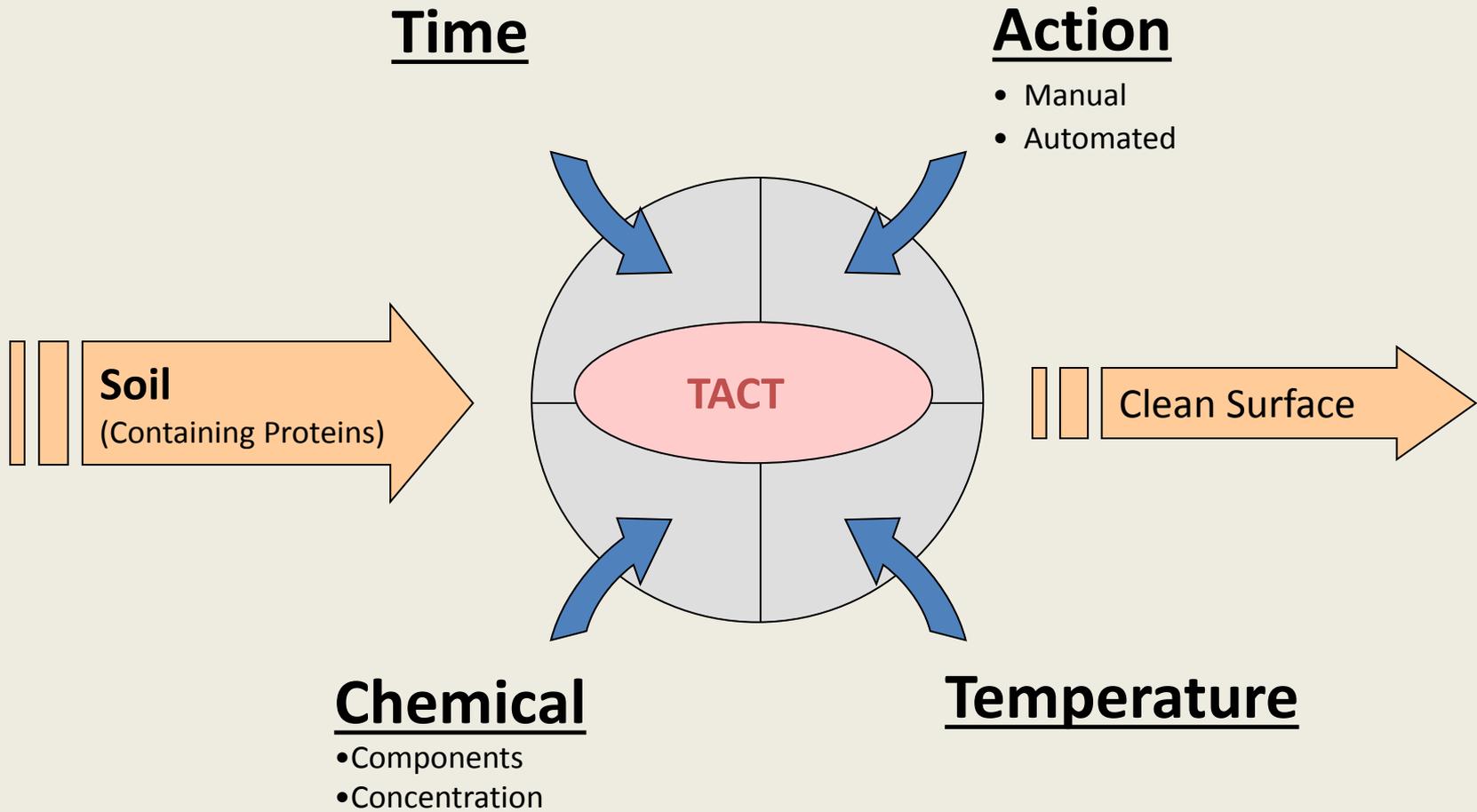
*Make sure that cross-contact issues do not occur

Effectiveness of Cleaning Solutions for Removing Protein Soils



- Chlorinated Alkali Detergents -- **Excellent**
- Alkali/Caustics with H₂O₂- **Excellent**
- Enzymes -- **Excellent**
- Alkali/Caustics -- **Fair ⇒ Very Good**
- Detergent Builders/Surfactants -- **Fair ⇒ Very Good**
- Acids -- **Poor**
- Water --- **Poor to fair**

Factors Affecting Allergen Removal- Wet Cleaning



What Do We Test?

- CIP rinse-water
- Push through materials (salt, sugar)
- First product off line, final product
- Food-contact surfaces (visual inspection; swabs)



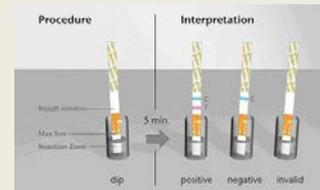
Analytical Tools for Detecting Allergens/Allergenic Food Residue

- Visual Inspection
- ATP Swabs
- Total Protein
- DNA-Based/PCR
- Immunochemical
- **Mass spectrometry***

Least Specific



Most Specific



*Not used routinely for detecting allergens

Effectiveness of Cleaning Regimens for Removing Milk Residue from a Pilot-Scale HTST Processing Line



Objectives:

- Investigate the efficacy of different cleaning procedures (a water rinse, intermediate cleaning treatments, and a full cleaning cycle) on removal of milk proteins from a pilot-plant HTST system
- Evaluate methods (conventional ATP, sensitive ATP, total protein and ELISA/Lateral flow) for verifying the effectiveness of procedures used to clean the HTST
- Determine the levels of transfer (cross-contact) of milk residue from the cleaned HTST processing line to simulated apple juice



Procedures

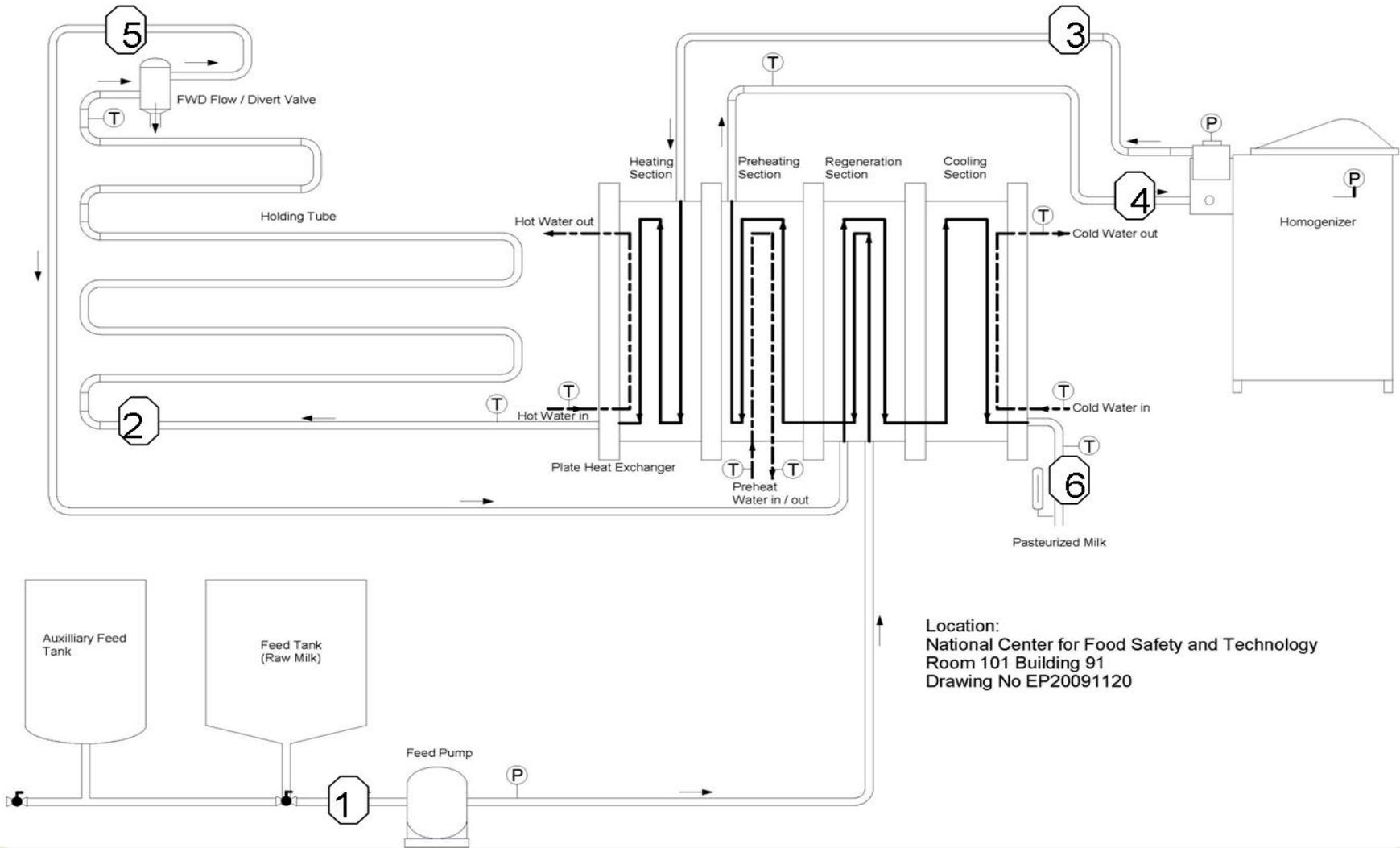
- Processed nonfat milk (38 L)
 - 81°C for 17 sec
 - Re-circulate milk for 1 hour
 - Apply cleaning procedures (water rinse, intermediate cleaning procedures, and a complete cleaning cycle)
- Evaluated efficacy of cleaning procedures
 - Swab ports (ATP, total protein, milk-specific LFD)
- Processed (38 L) “simulated apple juice” (single-pass)
 - Measured presence of milk in the simulated juice coming off line as a function of time and after pooled



Cleaning Procedures

Water rinse		a 15 min water flush at 81°C with a flow rate of 55-60 gal/h
Full-strength CAD		a 15 min water flush + a 60 min wash using full-strength CAD at 81°C with a flow rate of 55-60 gal/h
Intermediate cleaning regimens considered with different parameters	Concentration of CAD	a 15 min water flush + a 60 min with ¼-strength CAD
	Cleaning time	a 15 min water flush + a 15 min full-strength CAD
	Cleaning Temperature	a 15 min water flush + a 60 min CAD at reduced temperature (70°C vs 81°C)
	Cleaning flow rate	a 15 min water flush + a 60 min full-strength CAD at lower flow rate (27.7 gal/h vs 55-60 gal/h)
	Re-use CAD	a 15 min water flush + a 60 min re-use CAD spiked with 1% milk
Full-clean cycle		a 15 min water flush, 60 min full-strength CAD at 81°C, 30 min acid detergent at 70°C, 15 min sodium hypochlorite sanitizer at room temperature at 55-60 gal/h

LOW FLOW HIGH TEMPERATURE SHORT TIME (HTST) SYSTEM



Location:
 National Center for Food Safety and Technology
 Room 101 Building 91
 Drawing No EP20091120

Results: Cleaning studies of HTST processing line with a 15 min water rinse

Swab Results of HTST Processing Line after Water Rinse Cleaning

Sampling port location#	Methods for detecting presence of milk residue			
	Conventional ATP ^A	Sensitive ATP ^B	Total protein ^C	LFD ^D
1	3/3*	3/3	3/3	3/3
2	3/3	3/3	3/3	3/3
3	3/3	3/3	3/3	3/3
4	3/3	3/3	3/3	3/3
5	3/3	3/3	3/3	3/3
6	3/3	3/3	3/3	3/3

* 3/3 trials resulted in detection of milk residue, A:Pocketswab (Charm Sciences), B:Allergiene (Charm Sciences), C:Allertect (3-M), D:Bioavid for milk (R-Biopharm)

Levels of Milk Cross-Contact into Simulated Apple Juice from an HTST Processing Line after Water Rinse ($\mu\text{g}/\text{mL}$)

Sampling time	Trial A	Trial B	Trial C	Milk Concentration (ppm)
2 min	51.1	49.4	376	159 ± 188
4 min	40.3	31.1	180	83.8 ± 83.4
6 min	47.3	29.5	165	80.6 ± 73.8
10 min	45.8	67.9	113	62.7 ± 44.8
12 min	42.8	28.5	101	57.5 ± 38.5
composite sample	103.8	58.7	150	104 ± 45.7

n.d. = not detected



Results: Cleaning of HTST processing line with a lower cleaning temperature (70°C vs 81°C)

Swab Results of HTST Processing Line a 60 min Full-Strength CAD at 70°C

Sampling port location#	Method for detecting presence/absence of milk residue			
	Conventional ATP ^A	Sensitive ATP ^B	Total protein ^C	LFD ^D
1	1/3	3/3	1/3	3/3
2	1/3	3/3	1/3	3/3
3	1/3	3/3	2/3	3/3
4	1/3	3/3	1/3	3/3
5	3/3	3/3	2/3	3/3
6	1/3	3/3	1/3	3/3

Levels of Milk Cross-Contact into Simulated Apple Juice from an HTST Processing Line after a 60 min Full-Strength CAD at 70°C (µg/mL)

Sampling time	TrialA	TrialB	TrialC	Milk Concentration (ppm)
2 min	3.87	38.2	n.d	14.0 ± 21.0
4 min	3.6	2.6	n.d	<LOQ
6 min	3.53	n.d.	n.d	<LOQ
10 min	n.d.	n.d.	n.d.	n.d.
12 min	n.d.	n.d	n.d	n.d.
composite sample	2.7	5.4	n.d	2.70 ± 2.70

n.d. = not detected

Results: Cleaning of HTST processing line with a full cleaning cycle

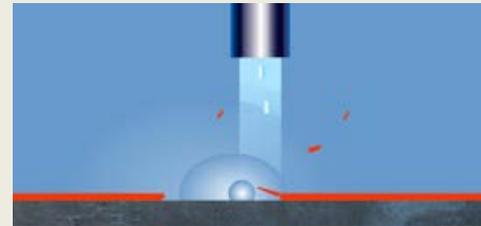
Swab Results of HTST Processing Line after Full-Strength CAD

Sampling port location#	Method for detecting presence of milk residue			
	Conventional ATP ^A	Sensitive ATP ^B	Total protein ^C	LFD ^D
1	0/3	1/3	0/3	0/3
2	0/3	1/3	0/3	0/3
3	0/3	1/3	0/3	0/3
4	0/3	1/3	0/3	0/3
5	0/3	2/3	0/3	0/3
6	0/3	1/3	0/3	0/3

No milk residue was detected in simulated juice processed over the line after a full clean cycle.

Methods for Cleaning in a Low Water Activity Environment

- Compressed air
- Grit/CO₂ blasting
- Premoistened (alcohol) wipes/cloths
- Vacuum
- “Dry steam”
- Brushing
- Purge with other dry ingredients
- A combination of dry cleaning methods



Use of Dry Steam to Clean Transfer Belting

Procedure

- Contaminated surface of urethane-faced belt with peanut butter cookie dough containing peanut butter, egg and milk
- Cleaning variable
 - Cleaning time (0-20 min)
- Swabbed surface of belt and analyzed for ATP, total protein, ELISA (lateral flow); also assessed if surface was “visually clean”



Detection of peanut butter cookie dough containing peanut, milk and egg on urethane-faced belting after cleaning with a commercial belt washing system.

Cleaning Time (min)	Method for Detecting Presence of Food Soil					
	Visual	Conventional ATP	Total Protein	Lateral Flow		
				Peanut	Milk	Egg
0	9/9	9/9	9/9	3/9	6/9	5/9
5	0/9	9/9	5/9	0/9	5/9	3/9
10	0/9	8/9	7/9	0/9	4/9	3/9
15	0/9	6/9	5/9	0/9	4/9	3/9
20	0/9	5/9	3/9	0/9	7/9	3/9

Conclusions

- Cleaning is essential for preventing allergen cross-contact in facilities where equipment is shared
- Allergenic foods/proteins vary in their ability to be cleaned from food-contact surfaces
- Wet and dry cleaning methods are available for removing allergenic food soils; they vary in their effectiveness
- Wet cleaning methods that use detergents which are capable of 1) reducing the interaction between the proteins and the food-contact surface and 2) solubilizing proteins tend to be more effective at allergen removal
- Cleaning to “allergen clean” in a dry environment can be challenging
- It is recommended that all cleaning methods are evaluated for effectiveness
- Development of food-contact surfaces and equipment designs that are more cleanable, particularly in dry food manufacture is needed

Questions ?



FDA

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