CLEANING STRATEGIES TO REMOVE FOOD ALLERGENS AND TOOLS FOR DETERMINING EFFICACY

Lauren S. Jackson, Ph.D.

U.S. Food and Drug Administration
Division of Processing Science & Technology
Institute for Food Safety & Health
6502 S. Archer Rd.
Bedford Park, IL 60501

Codex Committee on Food Hygiene (CCFH)

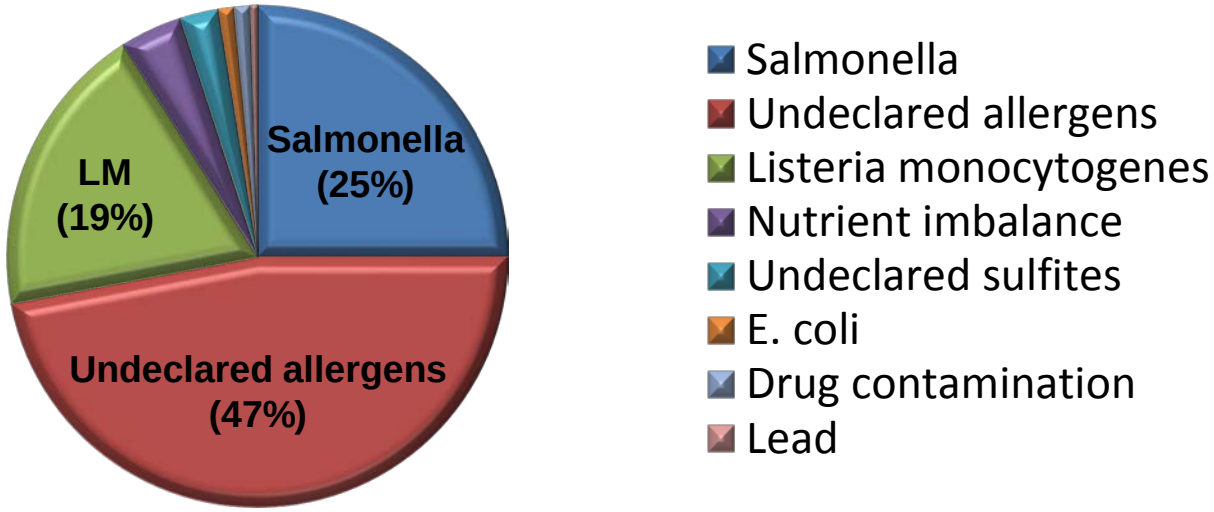
Tuesday, November 14, 2017

FDA CFSAN ILLINOIS INSTITUTE OF TECHNOLOGY IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH

Food Allergen Recalls

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

2013-2014



- Undeclared allergens increased from 30% of all RFR reports in first year, to 47% of reports in the fifth year
- Recall data from FDA-regulated products is mirrored by data from FSIS/USDA and from Canada (CFIA)
- 5-15% of allergen recalls are associated with consumer reactions[1]

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

Causes of Allergen Recalls (FY2007-FY2012)

Cause of allergen recalls	Number recalls
Omission	191
Wrong package or label	137
Terminology	85
Failure to carry forward information from an ingredient to final label	70
Ingredient mislabeled from supplier	26
Cross-contact	52
Rework	9

From: Gendel and Zhu, J. Food Prot. 2013, 76, 1933-1938

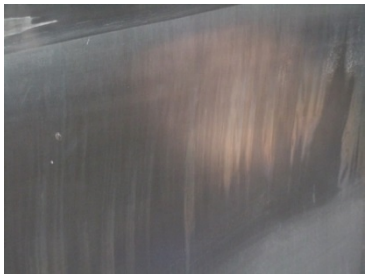
Cross-Contact

How does it occur?

- Dust or aerosols containing allergens
- Cross-over points in processing lines
- Reuse of cooking oil
- Reuse of cleaning solutions
- Ineffective cleaning

General Facts

- Effective cleaning is one of the most important strategies for preventing cross-contact
- Microbiologically clean ≠ allergen clean
- Food proteins can be difficult to remove from food contact surfaces- esp. if the protein has been heated/denatured
- Proteins vary in their “stickiness” to food-contact surfaces
- Wet cleaning can be effective at removing allergenic food soils- **but all procedures must be evaluated**
- Cleaning in a dry environment is a challenge—and it can be difficult to clean to “allergen clean”
- Older food processing equipment- not designed to be cleaned



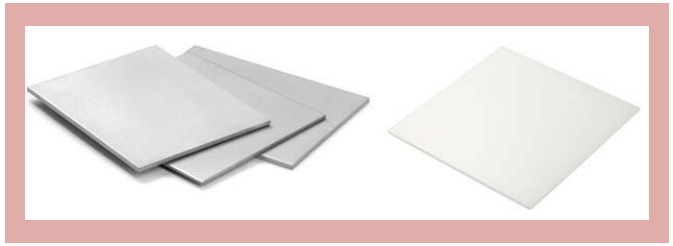
Factors Affecting Allergen Removal

Allergen-related factors

- **Type of food allergen**
  - Physical form- paste, particulate, powder, liquid
  - Chemistry- water- vs. lipid-based ingredients
- **Concentration of food allergen**
  - High vs. low concentration in food

Equipment-related factors

- **Equipment design**
- **Age of equipment**
- **Type of food-contact surface**
  - Composition- stainless steel, plastic, cloth
  - Texture (finish) of surface



Processing-related factors

- **Application of heat- hot vs cold soil**
- **Length of processing run- biofilm/build-up of food material**

Cleaning method-related factors

- **Type of cleaning method (wet vs dry)**

Cleaning Methods

Wet

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

Dry

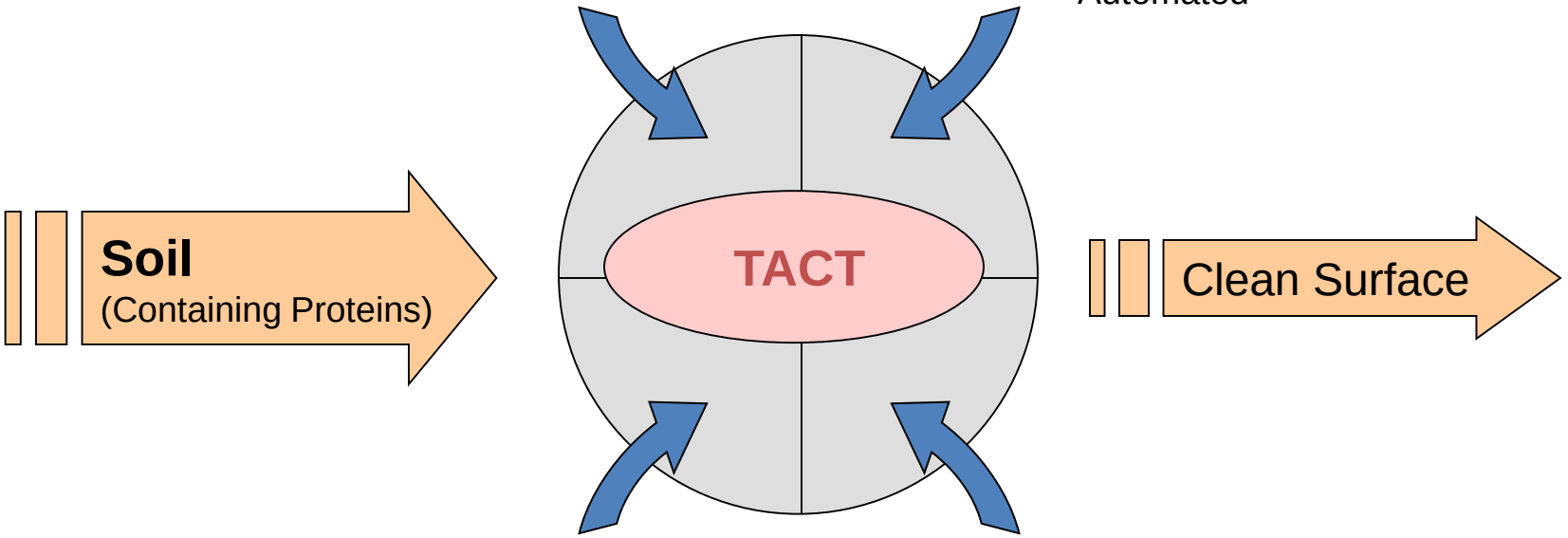
- Plant area/equipment not designed to accommodate water (low water activity foods)
- Water use limited
- Compressed air, vacuum and/or dry steam may be used to “clean” surfaces
- Other methods- blasting with CO_2
- Purging line with ingredient (e.g. salt, sugar, corn starch, oil) or next food (dark chocolate)

Factors Affecting Allergen Removal- Wet Cleaning

Time

Action

- Manual
- Automated



Chemical

- Components
- Concentration

Temperature

Effectiveness of Cleaning Solutions/Detergents for Removing Protein Soils

- **Chlorinated Alkaline Detergents (CAD) -- Excellent**
- Alkaline/Caustics with H_20_2- Excellent
- Enzymes -- Excellent
- Alkaline/Caustics -- Fair ⇒ Very Good
- Detergent Builders/Surfactants -- Fair ⇒ Very Good
- Acids -- Poor
- Water --- Poor to fair

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).
- Evaluate methods (conventional ATP, sensitive ATP, total protein and ELISA/Lateral flow) for verifying the effectiveness of cleaning procedures
- Determine the levels of transfer (cross-contact) of milk residue from HTST to simulated apple juice.

Procedure

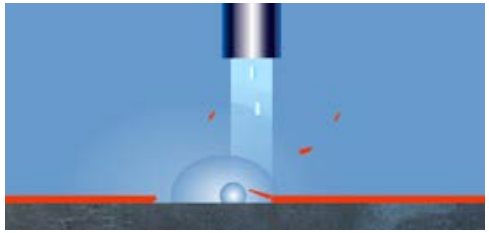
- Processing nonfat milk (10 g) for 1 h
  - 81ºC for 17 sec
  - Re-circulate milk
- Apply cleaning procedure
- Evaluate efficacy of cleaning procedure
  - Swab ports (ELISA, ATP, total protein)
  - Detect milk residue in final rinse water (ELISA, ATP, total protein)
- Process (10 g) “simulated apple juice” (single-pass)
  - Measure presence of milk/protein in simulated juice coming off line as a function of time and after pooled

Levels of milk transferred into simulated apple juice from an HTST processing line after different cleaning regimens (n = 3).

Cleaning Regimens	Trial A	Trial B	Trial C	Milk concentration in composite sample of juice (µg /mL)
15 min water flush	103.8	58.6	150	104 ± 45.7
15 min full-strength CAD at 81ºC (55-60 gal/h flow rate)	12.83	26.03	46.93	28.6 ± 17.2
60 min full-strength CAD at 70ºC (55-60 gal/h flow rate)	2.7	5.4	n.d.	2.70 ± 2.70
60 min ¼-strength CAD at 81ºC (55-60 gal/h flow rate)	0.45	0.6	n.d.	0.35 ± 0.31
60 min full-strength CAD at 81ºC (55-60 gal/h flow rate)	n.d.	n.d.	n.d.	n.d.
Full cleaning cycle	n.d.	n.d.	n.d.	n.d.

Methods for Cleaning in a Low Water Activity Environment

- Compressed air
- Grit/CO_2 blasting
- Premoistened (alcohol) wipes/cloths
- Vacuum
- “Dry steam”
- Brushing
- Purge/push-through with ingredients or next food
- A combination of dry cleaning methods



Tools for Verifying Cleaning Efficacy

What do we test?

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

Having an adequate sampling plan is important!

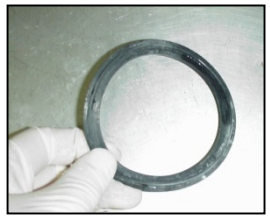
Analytical Tools for Detecting Allergens/Allergenic Food Residue

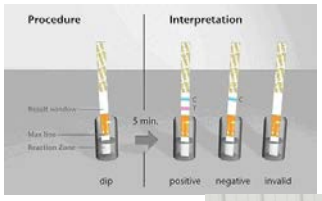
- Visual Inspection
- ATP Swabs
- Total Protein
- DNA-Based/PCR
- Immunochemical
- Mass spectrometry*

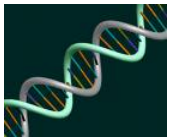
*Not a routinely used method

Least Specific

Most Specific



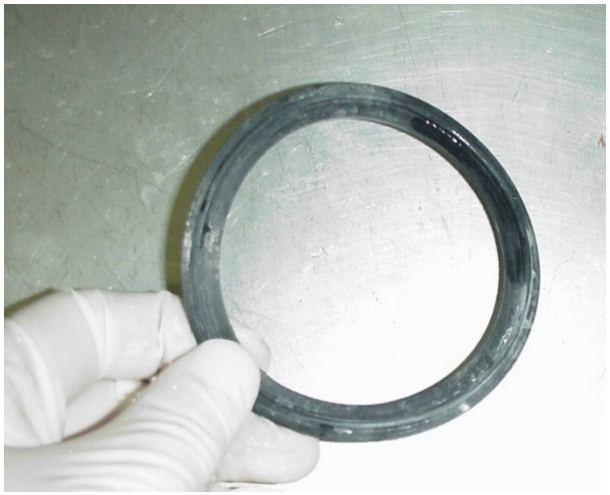




Visual Inspection

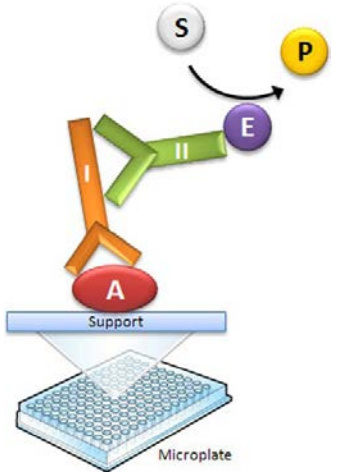
- First step in determining if equipment is clean
- Points for inspection
  - Flat surfaces
  - Difficult to clean areas
  - Areas above processing zone
- **Advantages**
  - Does not require lab equipment/inexpensive
  - Rapid
- **Disadvantages**
  - Depends on accessibility, lighting, surface, etc.
  - Limited to accessible equipment
  - Does visibly clean = allergen clean?

Examples of “Visibly Dirty” Surfaces

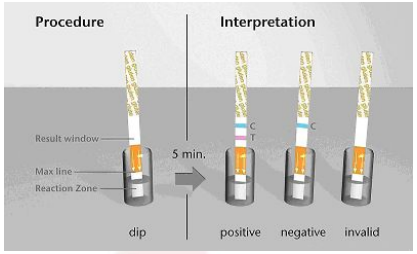


Immunochemical Methods

- Antibody-based detection of allergenic protein, or other (marker) protein in food
- Formats
  - Well & lateral flow devices (LFD)/dipsticks
  - Sandwich and competitive
  - Multiplex LFDs now available
  - xMAP multiplex assay
- Analysis time: typically < 1 h
- Quantitative or qualitative
- Kits available for most of the 8 major allergens
- Used for ingredients, finished products, rinse water, swabs/environmental samples
- **Need to ensure that method can detect allergen in food sample**



Sandwich ELISA



Dipstick/strip tests

Immunochemical Methods

Advantages

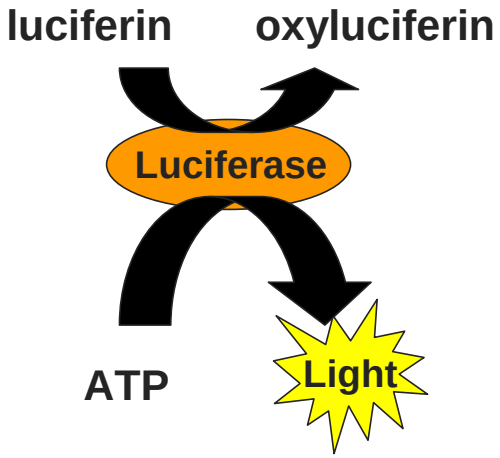
- Sensitive (ppm range)
- Quantitative or semi-quantitative
- Specific
- Low to moderate cost
- Equipment needs minor
- Skill level- low to medium

Limitations

- Cross-reactivity
- Extractability, solubility, and immunoreactivity important
- Matrix effects
- Processing (fermentation/hydrolysis, thermal) effects
- Need to understand what kit detects (e.g. casein vs. total milk vs. BLG)
- Values from different kits do not agree- reference standards needed

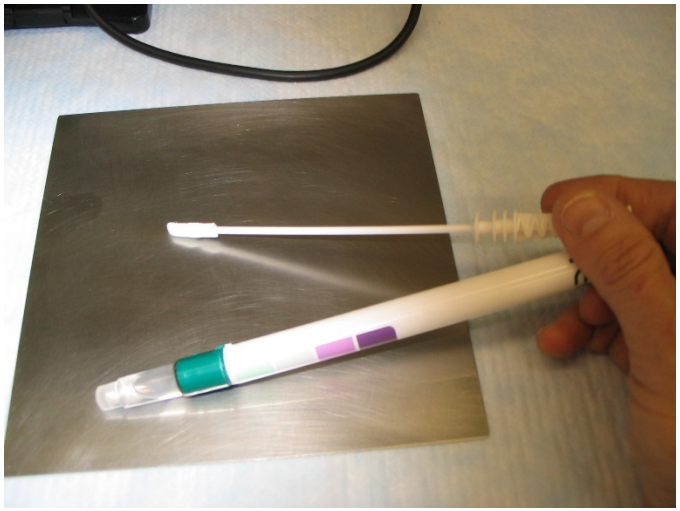
Non-Specific Methods: ATP

- **Detects ATP from biological sources**
- **Advantages**
  - Rapid (< 30 sec)
  - Less expensive than ELISA
  - Test can be performed on site (‘real time’)
- **Disadvantages**
  - Limited applicability- wet-cleaned surfaces only; may pick up ATP from water supply
  - Measures presence of ATP, not allergenic food
  - May be difficult to detect some food soils
  - Need to determine background ATP levels at facility



Non-Specific Methods: Total Protein

- **Different companies and formats available**
- **Advantages**
  - Rapid (< 5 min)
  - Less expensive than ELISA
  - Measures protein
- **Disadvantages**
  - Measures all proteins, not specific



Importance of Choosing Appropriate Analytical Method

Detection of Soy Milk on Stainless Steel Plates

Soy Product	Method of Detection	Amount of soy product (µg)					
		0	50	100	250	500	1000
Soy milk	ELISA 1	0/10	n.d.	n.d.	n.d.	0/10	0/10
	ELISA 2	0/10	n.d.	n.d.	n.d.	0/10	0/10
	LFD 1	0/10	0/10	0/10	0/10	10/10	10/10
	LFD 2	0/10	0/10	0/10	0/10	0/10	0/10
	Conventional ATP 1	0/10	0/10	0/10	0/10	0/10	0/10
	Conventional ATP 2	0/10	0/10	0/10	0/10	0/10	0/10
	Sensitive ATP	0/10	1/10	3/10	7/10	9/10	9/10
	Total protein 1	0/10	3/10	5/10	8/10	10/10	10/10
	Total protein 2	0/10	0/10	0/10	3/10	5/10	10/10

Summary

- Effective cleaning is one of the most important strategies for preventing cross-contact.
- Many factors influence the effectiveness of cleaning procedures.
- Wet cleaning methods that use chlorinated alkaline detergents tend to be effective at allergen removal- but methods needs to be evaluated for efficacy.
- Cleaning to “allergen clean” in a dry environment can be challenging.
- Validation of cleaning methods (conditions) is important for ensuring effectiveness for allergen control.
- Many tools are available for detection of allergens or allergenic foods.
  - Choice of method depends on specific use, type of food matrix, and other factors
  - Need to conduct “in-house” validation

thank you
danke
рахмат
謝謝
ngiyabonga
teşekkür ederim
Баярлалаа
спасибо
faafetai lava
mersi
kia ora
barka
welalin
tack
spas
dank je
misaotra
matondo
paldies
grazzi
mahalo
gracias
tapadh leat
vinaka
спасибi
blagodaram
kiitos
dankie
nanni
nandri
dhanyavad
bedankt
hvala
mauruuru
köszönöm
bayarlalaa
gràcie
enkosi
dziękuję
akun
dankon
aciu
хвала
asante
manana
obrigada
tenki
djiere dieuf
tau
mochchakkeram
murakoze
дякую
mamnun
chokrane
chnorakaloutioun
gratias ago
gràcies
sulpáy
taiku
go raibh maith agat
sobodi
děkuji
obrigado
sagolun
sukriya
kop khun krap
arigatô
takk
dakujem
trugarez
mèsi
didi madloba
ありがとう
tanemirt
grazie
najis tuke
terima kasih
rahmet
diolch
dhanyavadagalu
shukriya
mercé
мерси
kam sah hamnida
rahmat
ευχαριστώ
merci
তোমাকে ধন্যবাদ
감사합니다
xièxie