

Food Allergen Control Strategies

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Food Allergy

- Continues to be a major public health issue in the U.S. and around the world
 - Overall economic impact of childhood food allergies estimated to exceed \$24.8 billion in the U.S.
- 18% increase in children under 18 years of age
 - Peanut ~1.1% in US (~3 million Americans)
 - US (children) allergy 0.4% to 1.4% (1997-2007)
 - UK peanut sensitization 1.3% to 3.2% (1989-1995)
- Children with food allergy are at higher risk for development of additional allergic/atopic disorders
 - Atopic disorders: atopic dermatitis, asthma, allergic rhinitis and inhalant allergies
 - 30-40% of children with atopic dermatitis will have concomitant FA

R. Gupta et al. (2013). JAMA Pediatr. 167(11):1026-1031

Branum and Lukacs. National Center for Health Statistics. 2008

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The Risks of Uncontrolled Allergens

- Health risk – undeclared allergens can cause consumers to have reactions
- Regulatory risk – undeclared allergens can lead to product recalls, FDA/FSIS audits, etc.
- Business risk - loss of customers, law suits, failed audits (SQF, etc.), cost of product recalls, loss of consumer confidence, loss of retail space for products with your ingredients, allergen control/sanitation, down time, etc.

Regulatory Status

- Labeling laws/regulations in many countries impose a zero threshold for source labeling of ingredients
- Food industry is acutely aware of allergens
 - However there is little or no guidance on action levels/thresholds
 - How much allergenic residue is too much OR how clean is clean enough??
- Public health authorities have not established regulatory action levels for any of the allergenic foods
 - With the exception of Japan (10 µg/g protein limit for labeling)

Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004

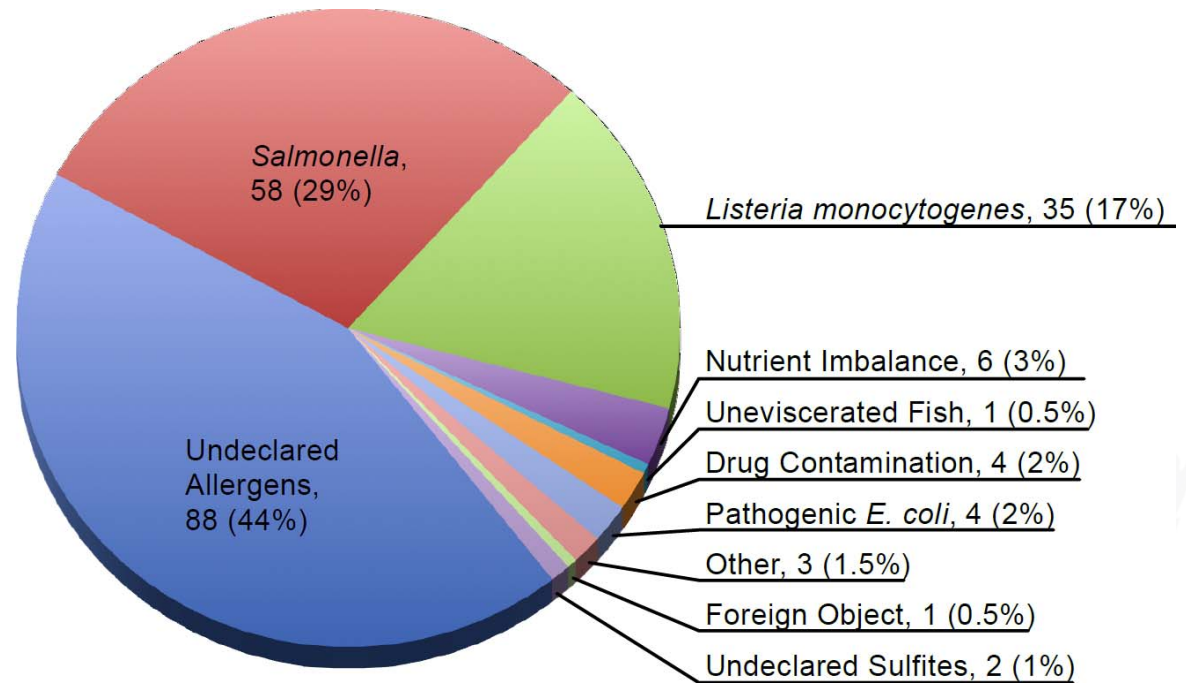
- Law amended the Federal Food, Drug, and Cosmetic Act
 - Requires food manufactures to label food products that contain a major food allergen by common name in the ingredient statement or use a “contains” statement
 - Examples:
 - *Ingredients:* Lecithin (soy), whey (milk)
or
 - Contains: Soy, Milk
- Voluntary use of precautionary allergen labeling (i.e. May Contain, etc.) is allowed

Current Regulations: USDA FSIS

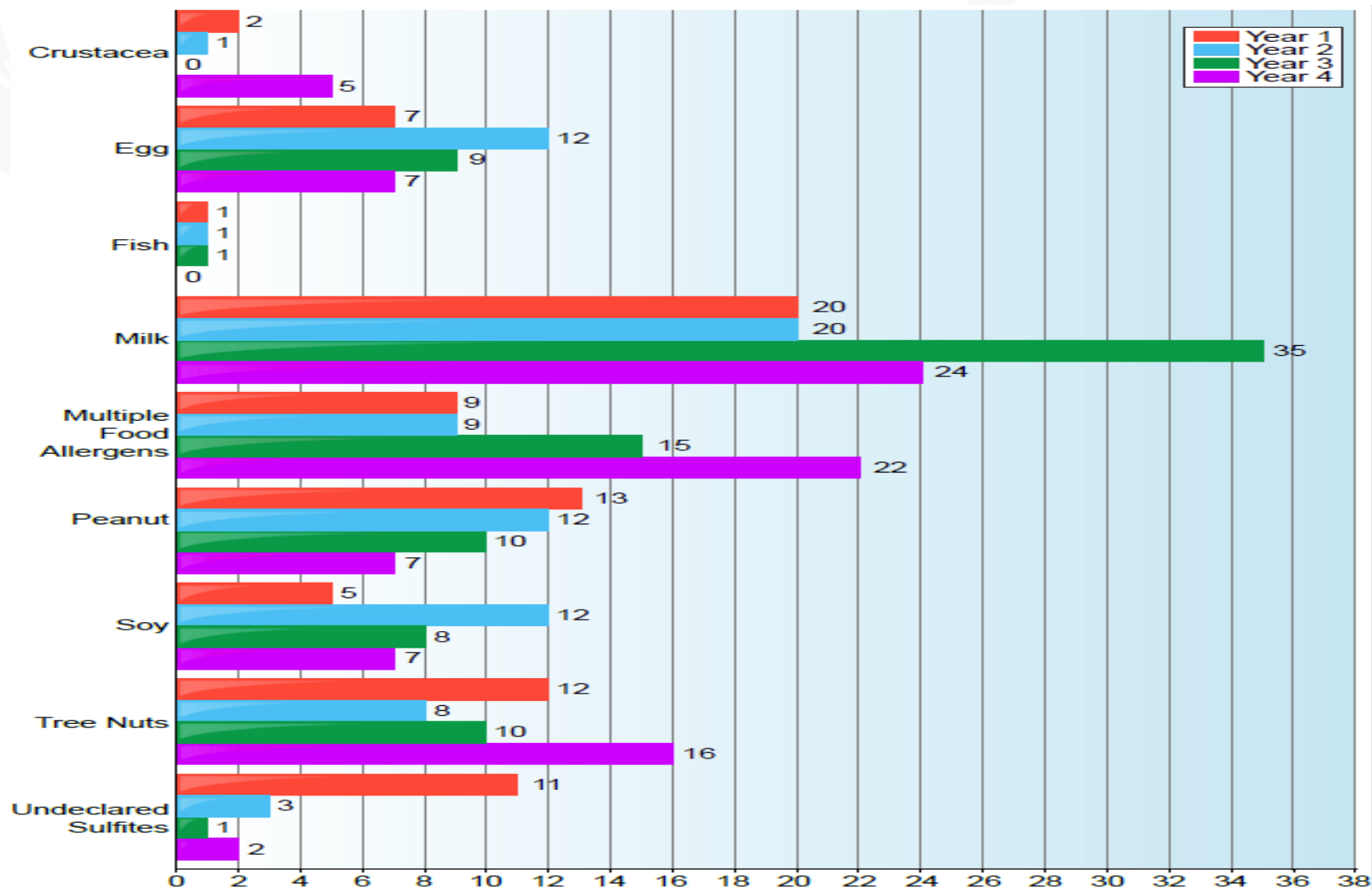
- USDA FSIS also requires labeling of priority allergens
 - Wheat, Crustacean Shellfish, Eggs, Fish, Peanut, Milk, Tree Nuts and Soy
- Labeling policy outlined in FSIS Notice 29-13
 - April 30, 2013
- FSIS Directive 7230.1 (March 10, 2015)
 - Initiated monthly verification task beginning on April 12, 2015 to determine whether establishments accurately control and label the “Big 8” food allergens
 - Verify that all of the ingredients listed in a “May Contain” or “Produced in a facility” statement on incoming food & food ingredients are listed on the final product label, except when:
 - The producer contacts the supplier and confirms in writing that the statement is a cautionary statement, and no such ingredient is in the product; AND
 - Includes a written statement in its hazard analysis documentation to support why the precautionary allergen statement is not carried forward to the finished meat or poultry product

2012-2013 FDA Reportable Food Registry

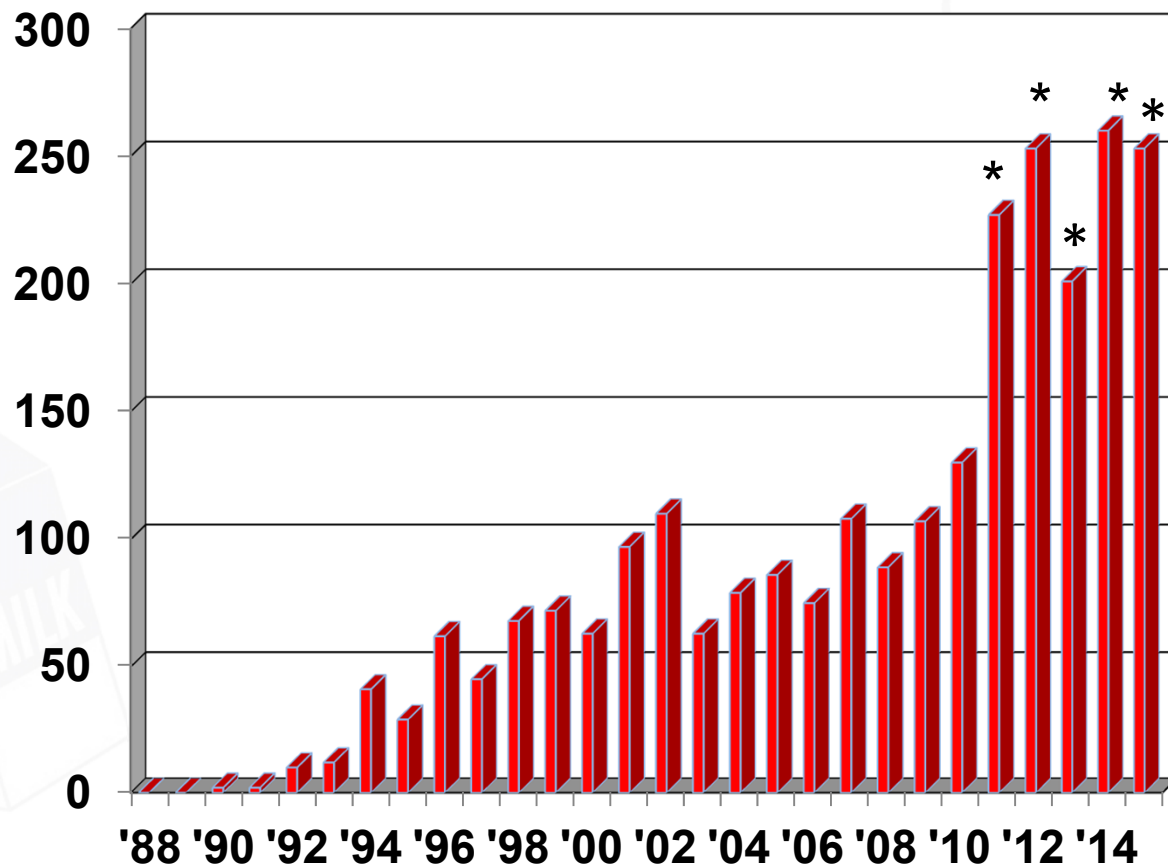
- First time food allergens ranked #1 in RFR entries for the first time
- Bakery (cookies & cakes) and chocolate/confections accounted for 32/88 entries (36%)



2009-2013 FDA RFR

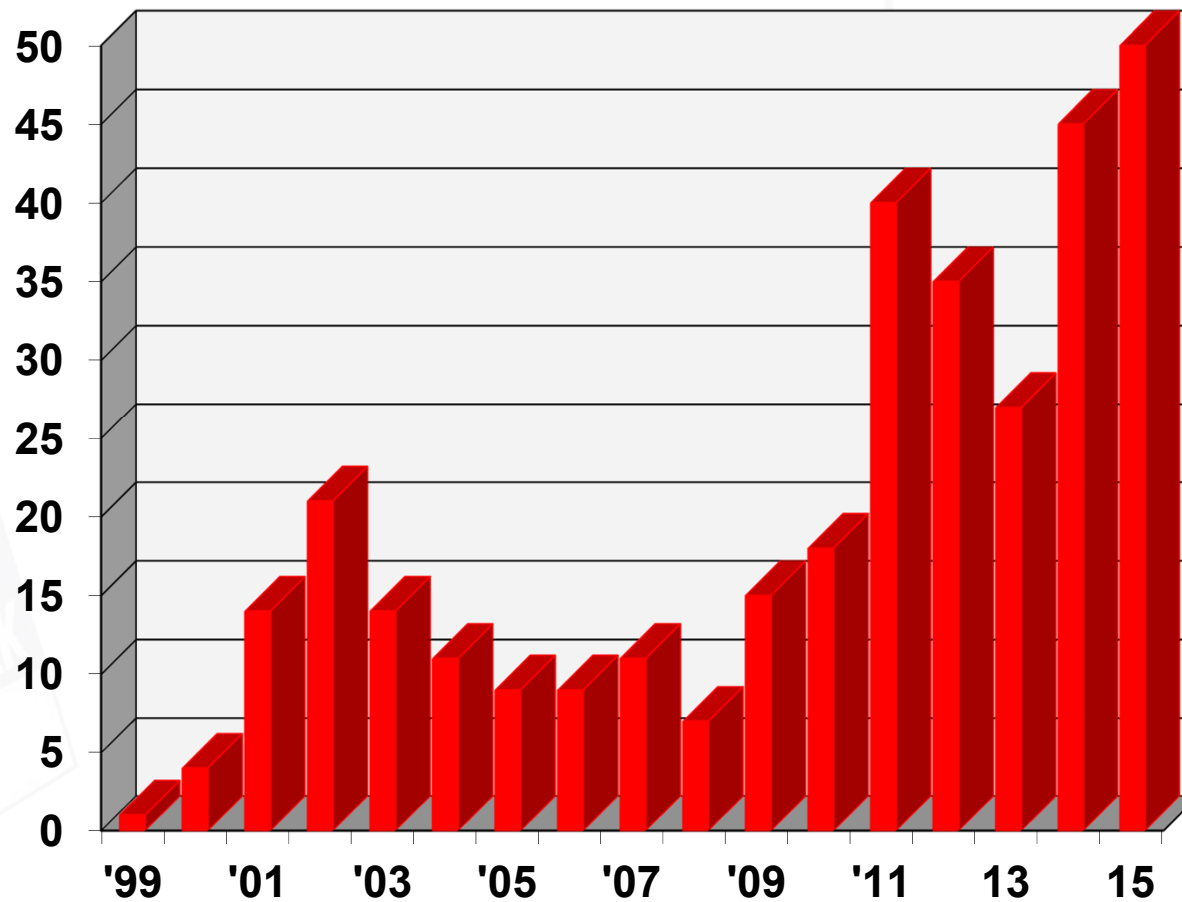


U.S. FDA Food Allergen Recall Incidents 1988-2015



* Includes FDA recalls & alerts

FSIS/ USDA Food Allergen Recalls Calendar Years 1999-2015



Learning from FDA Food Allergen Recalls and Reportable Foods

By Steven M. Gendel, Ph.D., Jianmei Zhu, Ph.D., Nichole Nolan, M.P.H. and Kathy Gombas

COVER STORY | April/May 2014

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

Table 1: Foods Most Often Involved in Allergen Recalls

Allergen	Number of Recalls*
Milk	174
Wheat	130
Soy	118

**Some of the recalls involved multiple allergens*

Table 2: Food Allergens Most Often Involved in Recalls

Cause	Number of Recalls
Wrong package or label	82
Terminology	59
Failure to carry forward information from an ingredient to final label	41
Cross-contact	28
Ingredient mislabeled from supplier	21

Table 3: Causes of Food Allergen Recalls



Allergen Control Strategies

Where Allergen Risks Occur



Key Food Industry Lessons

- Major company recalls
 - Rework
 - Inadequate cleaning of shared equipment
 - Line cross-overs
 - Packaging errors
 - Ingredient suppliers
 - Custom processors

Supplier Qualification/Purchasing

- Address allergens as part of a comprehensive risk-based approval process
 - Require allergen disclosure - are allergens used in the product, on shared equipment, in the same facility?
 - Does the supplier have a documented allergen control plan and validated cleaning/sanitation procedures?
- Require advanced notification of changes that affect allergen status of ingredients sold to your company
- Ensure purchasing group only uses approved suppliers!!
 - Have approved secondary suppliers in case of problems with existing sources

Product Development Strategies: Allergen Gating Process

- Develop an approach to review potential new products at the concept stage to identify potential allergenic components
- Use the allergenic components if they are truly necessary
 - Only use allergenic ingredients if they make a discernable difference to taste or functionality
- Create a process to assure that the processing facility is notified before start-up
 - Do not add allergens to existing products or facilities without allergens without understanding the implications for the system

Receiving

- Review and inspect incoming shipments of raw materials for allergen information
- Develop a company-wide system for tagging all raw materials for easy identification in your facilities (Ex. color coding, symbols/icons, etc.)
- Assure that each incoming container is appropriately tagged and placed in the appropriate storage area

Allergen! ¡Alergénico!

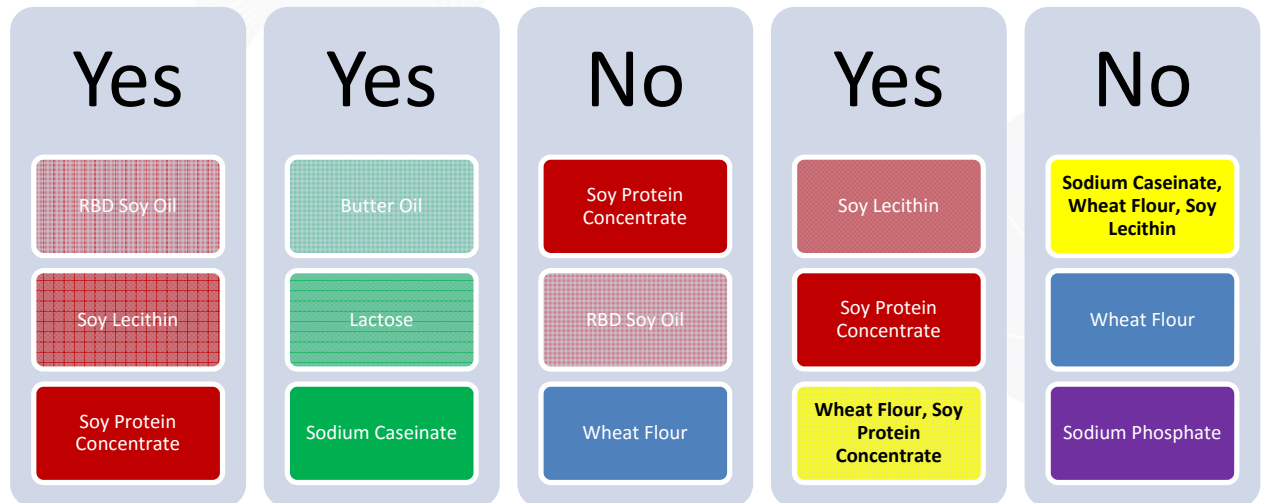
___ Egg/Huevo	___ Peanut/Mani/ Cacahuete
___ Milk/Leche	___ Tree Nut/ Nuez de árbol (list/liste:)
___ Soy/Soya	___
___ Wheat/Trigo	___ Fish/Pescado



Storage – Raw Material

- Segregate allergenic raw materials/products separately to avoid cross contact where possible
 - Avoid storing allergenic ingredients above non-allergens or different allergens where possible
- When storing ingredients from same source together (e.g. all milk) consider the allergen load (butter oil – low; lactose – low to moderate; casein –high)

Same Over Same
Less Over More



Storage – Raw Material

- Mark or tag allergenic ingredients to allow their easy identification in storage and to help assure the items are returned from the staging area to the appropriate storage shelf/area

Allergen! ¡Alergénico!

___ Egg/Huevo	___ Peanut/Mani/ Cacahuate
___ Milk/Leche	___ Tree Nut/ Nuez de árbol (list/liste:)
___ Soy/Soya	___
___ Wheat/Trigo	___ Fish/Pescado



IAFP (<http://www.foodprotection.org/resources/food-allergen-icons/>)

Production Strategies

- Use clearly designated staging areas for allergenic ingredients/products
 - Use segregated/color coded utensils to avoid allergen cross contact
- Clearly label opened, partially used ingredient bags and return these items to the appropriate storage area



<http://remcoproducts.com/>

Production Strategies

- Schedule long runs of allergenic products wherever possible (minimize changeovers)
 - Schedule manufacturing of allergenic products just prior to end of shifts with major clean-up
 - Introduce allergenic components into the products as late in the process as possible
- Clearly label in-process totes/containers, rework storage containers with the allergen content
 - Best use of rework – “exact-into-exact”

Labeling & Packaging Strategies

- Most common cause of recalls
 - Incorrect label information
 - Incorrect label applied to product
- Be careful about gang printing or mixed bundles of packages/labels
 - Use color coding or icons for outer-wraps on bundled packaging for easy identification
 - Visually check for correct label information before start-up
 - Vision systems or bar code readers can be effectively used for formulation and label verification
- Control labels so obsolete stock is destroyed immediately

Cleaning & Sanitation Strategies

- Wet and dry cleaning approaches present different challenges
- Wet cleaning:
 - CIP and COP commonly used
 - Caustic/Alkali detergents used for remove protein (allergen)
 - Consider appropriate time, temperature, detergent concentration, and physical action
 - Hand cleaning may be the most effective approach on valves, mixers, etc.

Cleaning & Sanitation Strategies

- Dry cleaning:
 - Vacuuming
 - Scrapping
 - Wiping
 - Sweeping
 - Pigs for piping
 - Dry ice (watch for contamination of adjacent lines!)
 - Steam cleaning (careful not to introduce too much water!)
 - Pressurized air (watch for contamination of adjacent lines!)
- Push-through or flushing material (sugar, maltodextrin, salt, vegetable oil, etc.) can be an effective way to scour equipment

Cleaning & Sanitation Strategies

- Consider allergen content/potency of ingredient
- Uniform formulation vs. particulate
- Allergen composition – stickiness
- Push-through: an effective practice, but careful with particulates

Cleaning & Sanitation Strategies

- Equipment design
 - Access and ability to thoroughly clean; no static or hidden areas
- Develop and implement clear SSOPs
 - Personnel must be trained, dedicated, alert, and thorough
 - SSOPs must be clear and easily understood
 - Explain not only ‘How’ but ‘Why Is It Important’

Cleaning & Sanitation Strategies

- Establish target allergen residue levels for effective allergen cleaning
 - recommend non-detectable (<2.5 ppm) or 5 ppm
- Verify that allergen cleaning is done consistently each time
 - Visual inspection
 - document it – keep compliance records
- Periodically audit and confirm that allergen cleaning is done in accord with established procedures

Cleaning & Sanitation Strategies

- Visually clean is the standard in the food industry
 - If residue is present on the equipment surface, a positive ELISA is likely
 - No need to test – clean again
- Visual inspection can be quite effective
 - Analytical validation and verification of allergen removal can be used to support visual inspection
 - Swabbing equipment surfaces (contact surfaces and hard to reach areas), testing CIP final rinse water (when possible), push-through material is commonly done for allergen assessment

Possible Detection Methods

- Enzyme Linked Immunosorbent Assay (ELISA)
- General Protein Tests
- ATP/Bioluminescence Tests
- Polymerase Chain Reaction (PCR)

How To Decide What Test to Use in a Specific Situation?

- The specificity of the test method is one concern – general protein, allergenic source protein, DNA, or ATP
- The sensitivity of the test method is a second concern;
 - Will the method support the corporate target level?
 - Can you correlate the method results to the corporate target level?

Picking the Best Test Method

General Comments

- Recommended to validate removal of allergenic residue using specific ELISAs
 - ATP and general protein tests do not detect proteins from allergenic sources specifically so the effectiveness of these tests ALONE as the sole approach must be carefully examined
- Surrogate testing (protein, ATP) can be helpful in some cases
 - ATP or general protein swabs can provide a good quick check on sanitation effectiveness during routine cleaning



Re-Validation

- No fixed acceptable frequency of testing, experience is the best teacher
- More frequently in early stages of product manufacturing
- Depends on level of confidence in product, process, SSOP, test methods, etc.

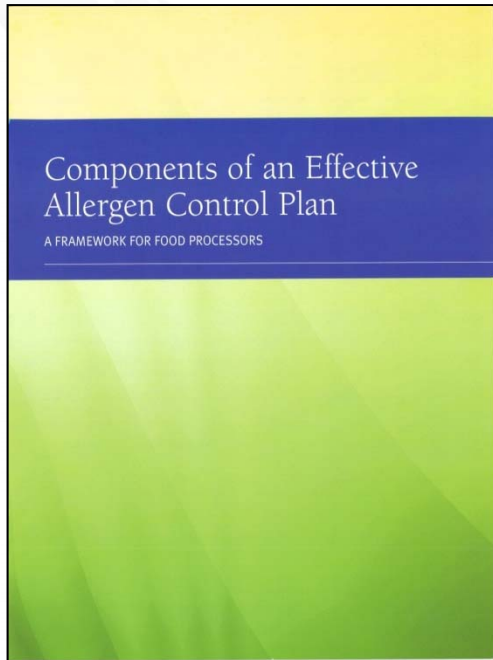
Prevent Re-Contamination

- Protect clean equipment and areas
- Follow procedures, in sequence
- Control people and activities
- Remove allergen ingredients
- Label and seal clean systems
- Communicate during and after cleaning
- Re-inspect prior to start-up
- Flush and examine first product

Change Management

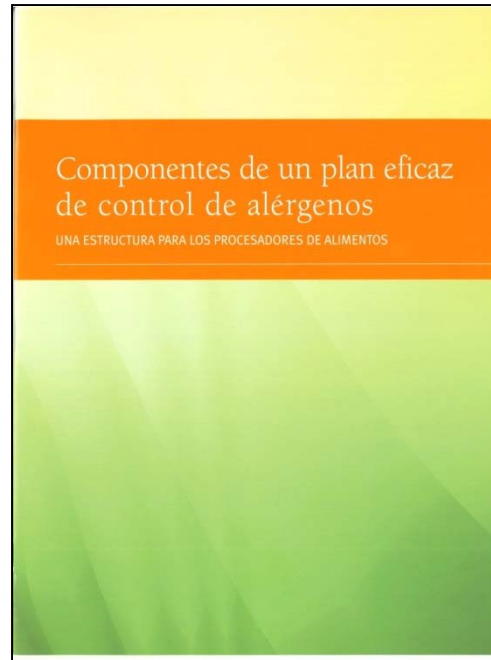
- When ***anything*** changes, then you **must** re-evaluate the entire allergen control plan
 - Re-Validate by doing a new Quantitative Risk Analysis
 - Does the existing Allergen Control Plan still work with the new conditions?

FARRP



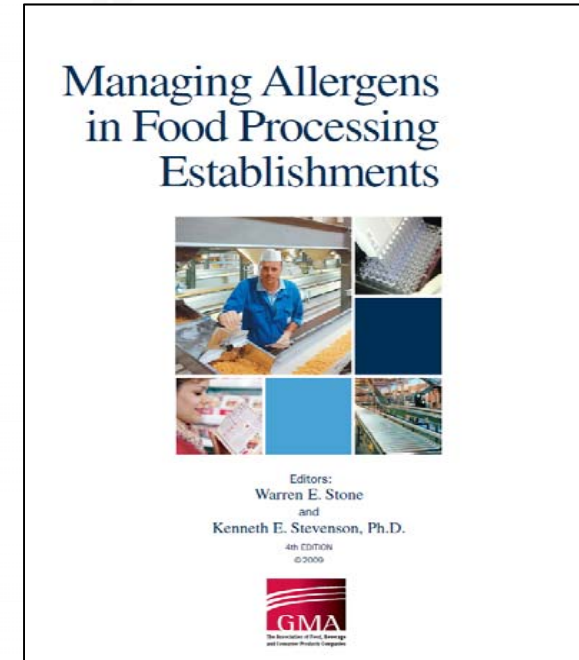
English Version

<http://farrp.unl.edu/allergencontrolfi>



Spanish Version

GMA



<http://www.gmaonline.org/forms/store/ProductFormPublic/managing-allergens-in-food-processing-establishments>

Thank You for Your Attention

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