



# The Visible Threat: How to Prevent Undeclared Allergens

Speakers: Laura Dunn Nelson & Holly Mockus  
March 9, 2016



# Today's Speakers



Laura Dunn Nelson  
Business Development



Holly Mockus  
Product Manager



# Agenda

---

- Regulatory Overview
- Allergen Plans, Procedures, & Testing
- Allergen Validation
- People Make It All Happen
- Q & A

# Regulatory Overview



# Regulatory Allergens – United States



# Regulatory Allergens – Europe





# Regulatory Allergens – Canada



Canada specifically defines tree nuts as almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, or walnuts



Sesame

Mustard

# Regulatory Allergens – Japan

Labeling	Name of Specified Ingredients	
<b>Mandatory by Cabinet Office Ordinance (7 items)</b>	1. Shrimp/prawn 2. Crab 3. Wheat 4. Buckwheat 5. Egg 6. Milk 7. Peanuts	
<b>Recommended by Notice (20 items)</b>	1. Abalone 2. Squid 3. Salmon roe 4. Oranges 5. Cashew nut 6. Kiwifruit 7. Beef 8. Walnuts 9. Sesame 10. Salmon 11. Mackerel 12. Soybeans 13. Chicken 14. Bananas 15. Pork 16. "Matsutake" mushrooms 17. Peaches 18. Yams 19. Apples 20. Gelatin	





# US Allergen Facts and Figures

#2



#1



#3

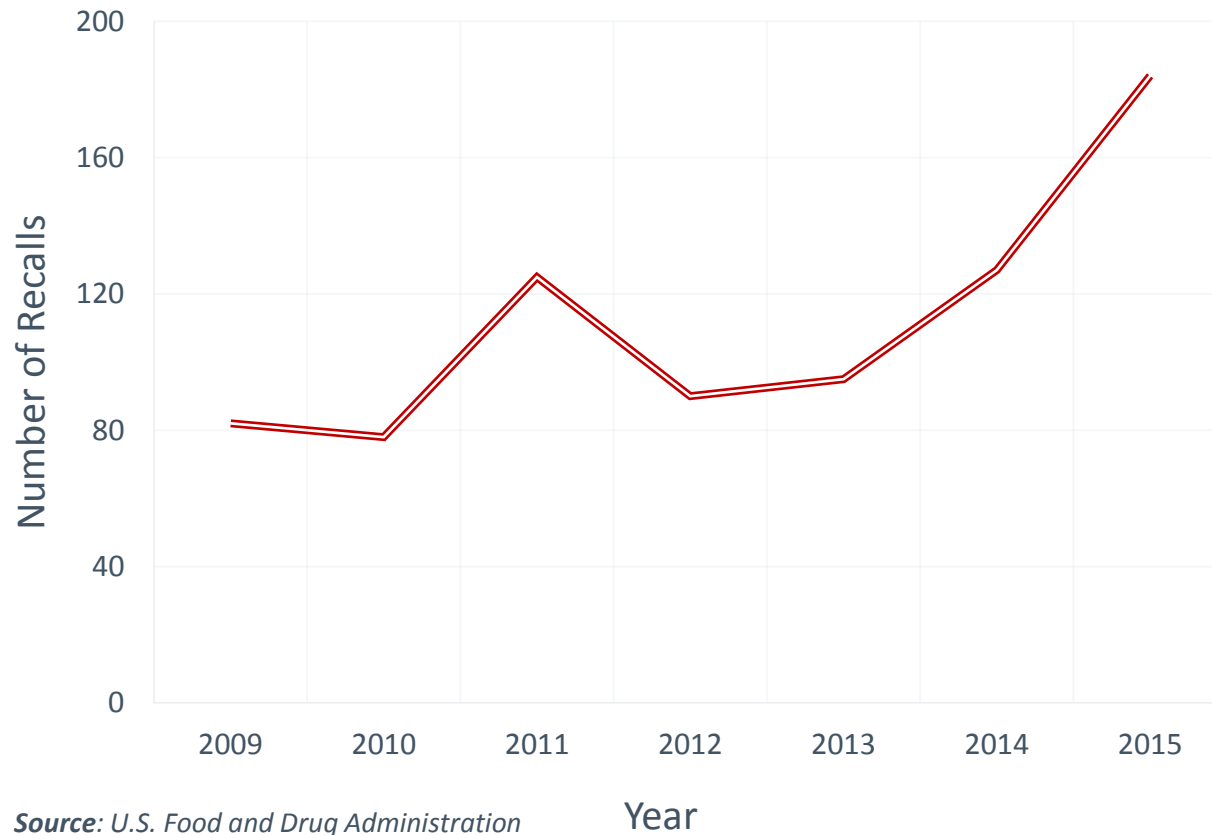


- About 15 million sufferers in the US – 6 million are children
- 38.7% of food-allergic children have a history of severe reaction
  - 30.4% of these children are allergic to multiple foods

- Each year in the U.S., it is estimated that anaphylaxis to food results in:
  - **30,000** emergency room visits
  - **2,000** hospitalizations
  - **150** deaths

# Food Allergen Related Recalls

## Food Allergy-related Recalls Shoot Up



Undeclared allergen recalls reached an all-time high in 2015 and nearly doubled since 2009

Source: U.S. Food and Drug Administration

# Common Causes

- Wrong package or label
- Terminology
- Failure to carry forward information from an ingredient final label
- Ingredient mislabeled from supplier
- Cross-contact



# Food Allergen Related Recalls

## 3 years (2010-2012)

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

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

## 2015

Food Type	# of Recalls
Snack	54
Bakery	36
Dressing/Spice	31
Meal	30
Dairy	12
Candy	11

Allergen	# of Recalls
Milk	49
Peanut	47
Treenuts	27
Egg	17
Sulfites	16
Soy	14
Wheat	2
Shellfish	2
Wheat	1
Multiple	28

# FSMA Legislation

## Food Safety Modernization Act of 2011

Section 101 – FDA employees (inspectors and officers) will have **access to records**

- “Applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation...(including paper and electronic formats) at any location”
- FDA inspectors will have access to all food safety plans and **allergen control plan records**, employee training records, **sanitation and chemical usage records, pre-op inspection records**, supplier audit records, product labels, supplier ingredient records and labels and food safety testing records



**FDA FOOD SAFETY**  
MODERNIZATION ACT

# FSMA Legislation

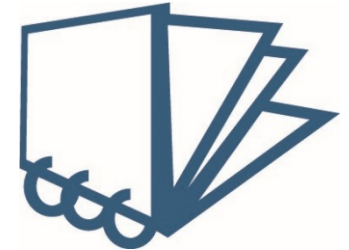
Section 103 – hazard analysis & risk-based preventive controls

(b) **Owner, operator or agent in charge of a facility** shall:

- (1) identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility including (A) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, **allergens**, and unapproved food and color additives; and (B) hazards that occur naturally, or may be unintentionally introduced; and
- (2) identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism; and
- (3) develop a **written** analysis of the hazards

# Direction to Food Safety Leaders

- Food safety leaders should:
  - **Explain** the impact of the Food Safety Modernization Act changes to their “owner, operator, or agent in charge” of their facility to allow for adequate planning for additional capital and testing expenses
  - **Update** their allergen control plans
  - **Assess** the adequacy of all procedures and the effective completion of documentation





# Allergen Plans, Procedures & Testing



# Allergen Control Plan Components

- New Product Development
- Allergen Risk Assessment
- Supplier Control Plan
- Engineering & System Design
- Receiving & Storage
- Scheduling
- Processing Operations Allergen Control Plan
  - Allergen Containment
  - Rework, trim, recycled and Hold Material
  - Packaging Operations
- Labeling
- Maintenance
- Sanitation
- Consumer complaints
- Training
- Auditing / Verification



# Ingredient Receiving and Storage

- Receiving – review allergen label of all ingredients and review ingredient statements on packaging lots
- Labeling – label allergens on ingredients so it is easy for employees to read
- Storage – do not store an allergen over a non-allergen or a different allergen



# Allergen Labeling

---

- Know the allergen labeling regulations in the country your food will be sold
- Know the exact term required by regulation (calcium caseinate, dairy, milk)
- Know your ingredients and supplier programs for allergen management
- Review all new packaging labels at point of receipt in the facility
- Review each new lot of packaging labels
- Assure the right label is put on the right food – most common cause of recalls!
  - Manual checklist for operators
  - Verified by QA
  - Automation can help – barcode scanners linked to formulas

# Scheduling Allergens

---

- Schedule allergens last before sanitation
- Create product changeover matrix for personnel to understand cleaning requirements between products
- Schedule allergen products for longer runs to minimize cost of sanitation and risk of cross-contact
- Charge the cost of allergen sanitation validation to the allergen containing product
- Best practice is to program a scheduling system to schedule allergens according to changeover matrix and verify manually

# Implementing

- Our responsibility: we cannot hide behind an allergen disclaimer on our packaging
- No second chances - labelling, recipe or sanitation errors
- Must have constant reinforcement and vigilance
  - Team Training
  - Regular Recipe and Label Checks
  - Effective Cleaning and Verification
  - Validations



# Benefits of Allergen Testing

- **It protects your consumers!**
- For gluten free claims on packages it provides substantiation of the health claim to prevent a disease
- It demonstrates compliance with the intent of the Food Safety Modernization Act (FSMA) in the U.S. and similar legislative and regulatory expectations globally
- Protects your company and limits your liability by demonstrating due diligence
- Gives you, the food safety leader, data and insight to conduct a proper risk assessment





# Allergen Validation



# Challenges of Allergen Testing

---

- Management fear and legal implications
- Defining a sufficient number of samples
- Testing the most high risk situations
- Matrix effects with ELISA methodology
- Dose makes the poison – we rely on published literature and expert resources to understand the amount of allergen protein that can cause harm to the consumer
- Allergen testing does not prevent human error in sanitation or prevent putting the wrong label on the food

# Allergen Sanitation Validation

- The equipment and facility should be designed for adequate sanitation and accessible for inspection
- Use pre-operational visual inspection with a checklist – **if it looks clean it generally tests clean!**
- Periodically validate allergen changeover sanitation procedures with revalidation for new products or other critical changes using allergen-specific ELISA kits
- Conduct allergen sanitation validation for shared lines with report documented for regulatory or third party audit review



# Allergen Validation Procedure

- Select the formula containing the maximum amount of the allergen of concern
- Food Contact Surface Allergen Validation
  - Pre and Post Sanitation swabbing
  - Intensive sanitation corrective action must take place and re-test until acceptable results are obtained before production
  - Repeat for 3 consecutive sanitation cycles
- Finished Food Allergen Validation
  - Collect the first finished item produced post allergen sanitation
  - All products (the entire sample lot clean up to clean up) must be held (or destroyed for short shelf-life product) awaiting the lab results
  - If one product sample is positive, immediately destroy held product



Almond	
Casein	
Crustacea	
Egg	
Gluten	
Hazelnut	
Mustard	
Peanut	
Soy	
Total Milk	



# Allergen Validation Test Kits

- **Neogen's Reveal**<sup>®</sup> for food allergen kit is an easy-to-use and interpret strip test that screens samples for food allergen at 5 ppm in 10 minutes or less. If the test detects at least 5 ppm, two lines will form on the test device. The formation of only one line indicates a negative test result
- **Neogen's Veratox**<sup>®</sup> for food allergen kits are quantitative tests that compare up to 19 samples at a time against 5 test controls. Through the use of a microwell reader, the tests provide accurate sample results in parts per million
- Reference: [www.neogen.com/FoodSafety/FS\\_FA\\_Index.html](http://www.neogen.com/FoodSafety/FS_FA_Index.html)



# Allergen Validation Steps

- Only use certified allergen-free swabs (some generic swabs use recycled milk cartons that contain milk residues)
- Swab equipment surfaces and hard to clean niches **BEFORE** and **AFTER** sanitation to validate cleaning
- Equipment swabbing can be done in “safe mode” with start up on the same allergen containing product
- If one piece of equipment fails, change the Sanitation Standard Operating Procedure (SSOP) and revalidate
- Once each piece of equipment has validated cleaning SSOPs, testing of the non-allergen product can be used to further support the validation of the swabs

# Clean In Place (CIP) Systems



- Methods to validate allergen are removed using automated sanitation CIP systems
  - Periodically verify location and chemical delivery of spray nozzles
  - Periodically disassemble and swab test for allergens in piping, spray nozzles, pumps, or other niches
  - Test final rinse water for the allergen
  - Conduct allergen validation prior to reuse of cleaning chemicals



# Some Pitfalls to Watch Out For!

---

- Allergen sample contamination – use aseptic techniques just like micro sampling
- Cleaning in the “niches”
- First food through validation approach vs. harborages
- Cooking, baking, frying effects on detection of allergenic proteins
- Matrix effects – chocolate, highly colored foods, hydrolyzed/highly processed ingredients, protein isolates
- Raw agricultural commodities and the 1% rule
- Storage of kits and swabs when not in use
- Limits of ELISA methodology

# Allergen Testing Benefits Far Outweigh the Challenges

- The fundamental principle that we uphold in food safety is to **understand the hazard of concern** and **develop methods to prevent, eliminate, or reduce the hazard** to an acceptable level
- Sanitation validation testing provides the data to assess the hazard and reduce it to an acceptable level
- Bottom line: the benefits of using allergen testing to validate sanitation effectiveness outweigh the challenges



# Who to Trust for Your First Allergen Sanitation Validation?

- Confidential Analysis
- Expert Allergen Consulting
- Allergen 101 and Sanitation Training
- Support Allergen Threshold Studies
- Reference: [www.farrp.unl.edu](http://www.farrp.unl.edu)



# Allergen Control Plan Training

- **Introduction to Food Allergens (14:31 minutes)**
  - Identify the most common food allergens
  - Understand that a person who is allergic to a specific ingredient has to avoid all foods that contain the ingredient
  - Explain why it's so important to properly label foods that contain allergenic ingredients
- **Proper Handling of Food Allergens (21:51 minutes)**
  - Define the term "cross contact," and how cross contact can happen
  - Discuss how to help prevent cross contact in receiving and storage
  - Explain how cross contact happens during formulation, and how to properly handle ingredients
  - Identify preventative measures for preventing cross contact during processing and product labeling
  - Understand how proper cleaning and sanitation can help control the spread of allergens
- **Add Allergen Specific Training for each location**
- **Training with testing to VERIFY understanding**

# People Make It All Happen



# FSMA Legislation

## Food Safety Modernization Act of 2011

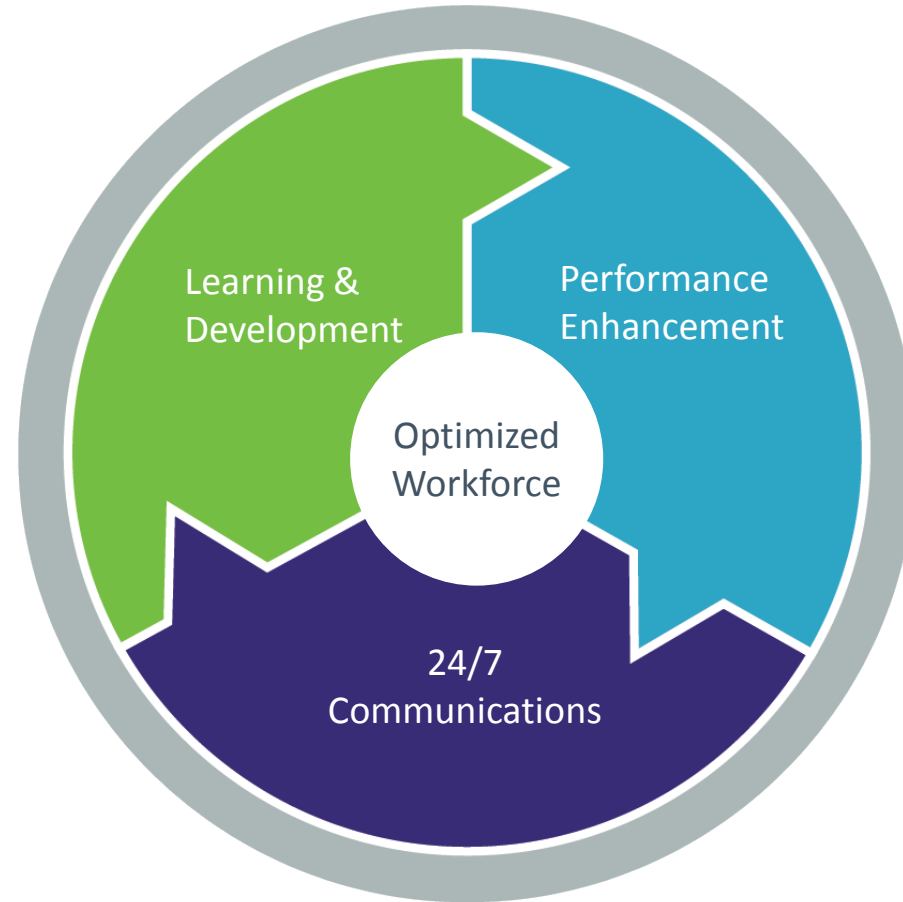
Section 101 – FDA employees (inspectors and officers) will have **access to records**

- “Applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation... (including paper and electronic formats) at any location”
- FDA inspectors will have access to all food safety plans and **allergen control plan records**, **employee training records**, **sanitation and chemical usage records**, **pre-op inspection records**, supplier audit records, product labels, supplier ingredient records and labels and food safety testing records



**FDA FOOD SAFETY**  
MODERNIZATION ACT

# Closed Loop Approach Needed to Engage Workforce





# Harness the Power of Your Workforce!

## Learning and Development Areas:

- What allergens are used
- How are they handled
- Spill clean up
- Importance of labeling
- Segregation practices
- Traffic patterns
- Color coding
- Rework
- Repackaging
- Finished goods labels
- Risks and benefits

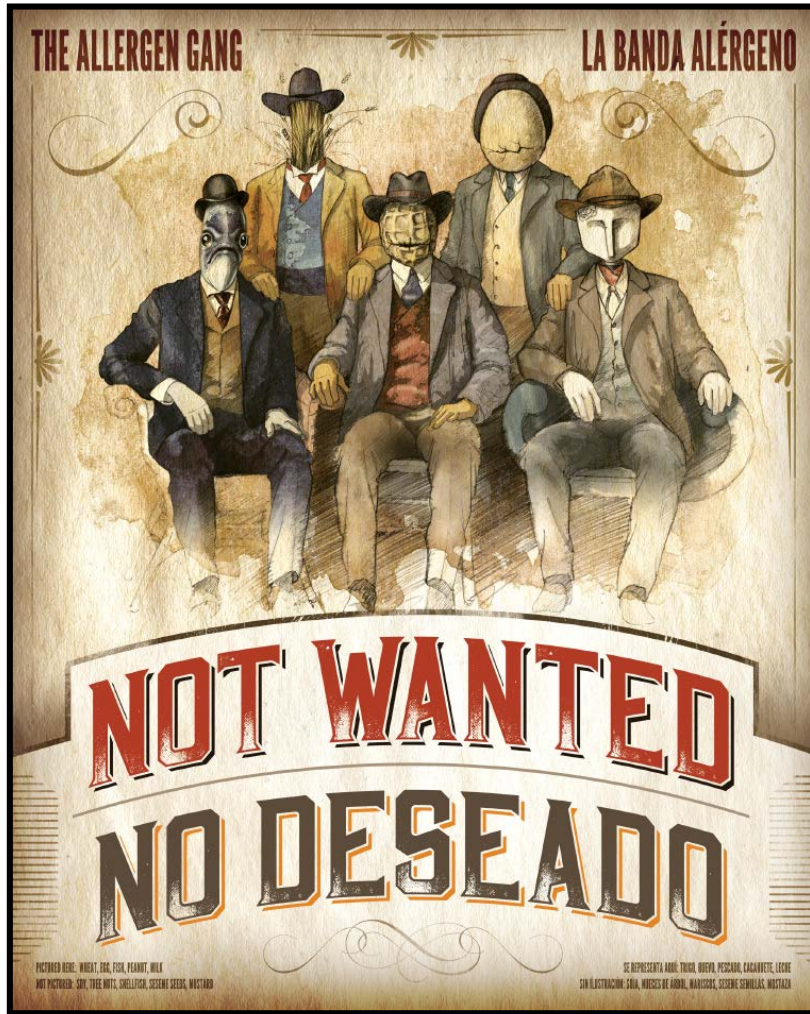


# Measure

- Track and trend
- React to data
  - Don't just collect to collect
- Consider context / continuity
- Corrective actions are important
- Documentation is critical
- Celebrate!
- Have fun.....



# Keep Allergens Top of Mind with 24/7 Communications



## Reinforcement

- Posters
- Signage
- Huddle Talks
- Observations
  - Praise
  - Correct
  - Observe again
- Metrics
  - Pivot when necessary

# Webinar: 24/7 Communications

- 24/7 Communications: When Training Alone Isn't Enough
- Wednesday, March 23<sup>rd</sup>
- 10:00 am PT | 12:00 pm CT | 1:00 pm ET
- Speakers: Marcus Slaughter, Dawn Foods  
Holly Mockus, Alchemy  
Jeff Moores, Alchemy



Register on our website under Upcoming Webinars



# Resource: PCQI Certification Onsite Training

## BACKGROUND





- New FSMA regulations require that key personnel in charge of managing the Food Safety Plan at a company must be a “Preventive Control Qualified Individual.”
- The Food Safety Preventive Controls Alliance (FSPCA) has partnered with the FDA to develop course curriculum to meet the “Preventive Control Qualified Individual” requirements.
- Companies have a specific amount of time to comply depending on their size.
- Alchemy will offer an FSPCA-approved classroom training to be PCQI certified.



## WHO SHOULD ATTEND

- QA Directors and Managers
- QA Supervisors
- Operations Managers
- SQF/BRC Practitioners and Auditors

## LOCATIONS

-  **Glendale, CA**  
March 16-18 **SOLD OUT!**
-  **Philadelphia, PA**  
April 19-21
-  **Portland, OR**  
May 24-26
-  Visit link below for more details and locations

THANK YOU