3M℠ Health Care Academy

3M Food Safety presents

Validation and Verification of Food Allergen Control Approaches and Programs

Food Allergen Control Series Part 2 of 2

Agenda

I. About 3M Food Safety

II. Presentation by Dr. Steve Taylor

III. Question & Answer session

IV. Closing comments

3M Science. Applied to Life.™

Your trusted partner in food safety.

- Over 30 years in food safety industry.
- Global experience. Local support.
- Trusted by top food companies, validated around the world.

Every day, 3M Food Safety solutions and people help food and beverage processors around the world maintain the highest food safety standards and provide the highest levels of service and technical support.

3M Food Safety Solutions

Quality Indicator Testing

3M™ Petrifilm™ Plates

Pathogen Testing

3M™ Molecular Detection System

Allergen Testing

3M™ Allergen Protein ELISA and Rapid Kits

Sample Handling

3M™ Sample Handling and Media Solutions

Hygiene Monitoring

3M™ Clean-Trace™ Hygiene Monitoring System

UHT Beverage Testing

3M™ Microbial Luminescence System

Keep up with professional development, even with your busy schedule.

Continue your education and stay current on the latest food safety topics and find the answers you need, all from one convenient source: 3M℠ Health Care Academy. It's a vault of valuable resources to help deepen your expertise and improve food safety and quality within your company—organized, updated and accessible anytime... from anywhere.

Access On-Demand Education

Register for on-demand courses at no cost to you. See and hear experts discuss relevant industry topics, track your progress and receive a certificate for your participation.

Register for Upcoming Events

Continue your education through live webinars or in-person seminars.

Video Library

Explore our video library to learn more about industry trends and 3M Food Safety products.

Educational Resources

Access scientific articles, studies, white papers and more.

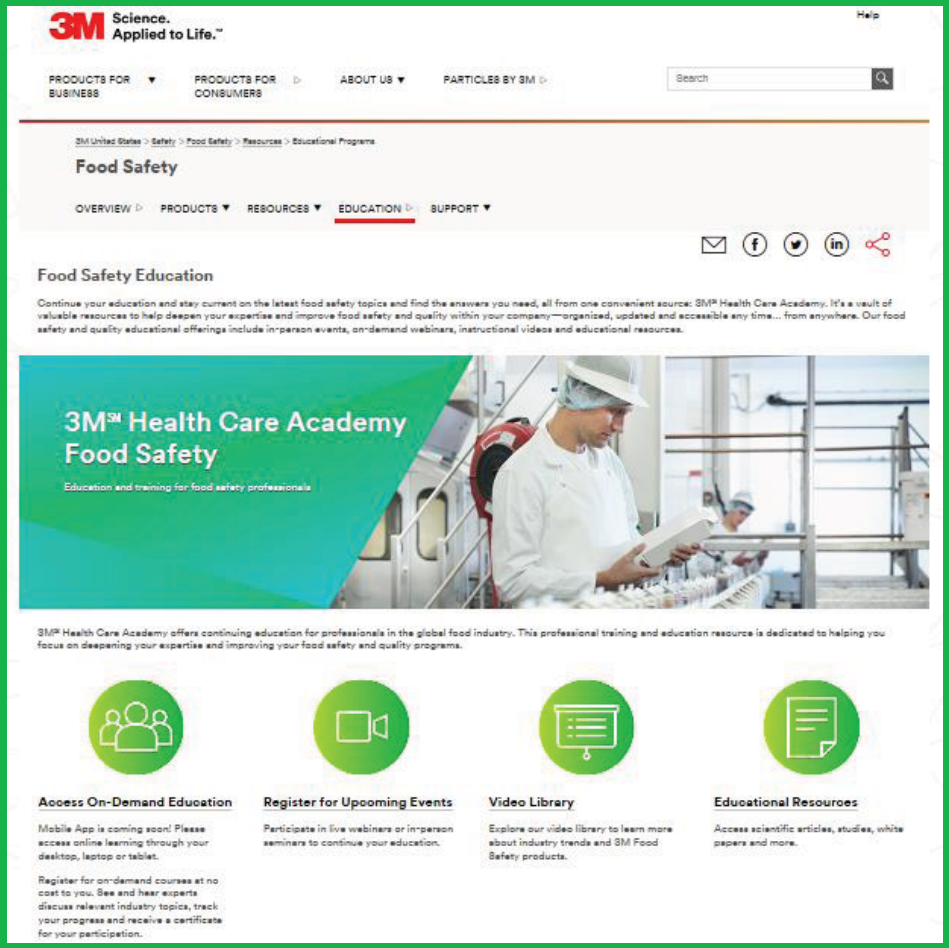
How to get started.

① Go to 3M.com/foodsafety/education

② Create a login username and password.

③ Follow the links to find the resources that fit your needs.

One-stop education.
It's that easy.



Validation and Verification of Food Allergen Control Approaches and Programs

Today you'll learn about:

- Essentials of allergen control and where risks occur
- Allergen control strategies for food processing operations, packaging, and cleaning and sanitation
- Guidance for choosing the right test methods for verification and validation of sanitation standard operating procedures (SSOPs)
- The FARRP approach to validation of allergen control plans

Steve Taylor, Ph.D.
Food Allergy Research and Resource Program (FARRP)

- Founding Director (retired) of the Food Allergy Research and Resource Program and is a Professor Emeritus with the Department of Food Science and Technology the University of Nebraska-Lincoln
- His research interests involve food allergies and allergy-like illnesses including immunochemical methods for the detection of allergens and allergenic foods and implementation of risk assessment approaches for allergenic foods
- In addition to research, Dr. Taylor is heavily involved in outreach to the food industry and has helped countless companies on a wide range of allergen-related topics

Validation and Verification of Food Allergen Control Approaches and Programs

Steve Taylor, Ph.D.
Professor & Co-Director
Food Allergy Research & Resource Program
University of Nebraska-Lincoln

3M Food Allergen Control Symposium
April 4, 2019
St. Paul, MN

Food Safety Modernization Act (FSMA)

- Hazard Analysis and Risk-Based Preventive Controls (HARPC)
- Food allergens are chemical hazards
- If a facility handles any food allergens:
  - Food allergens are almost certainly a hazard requiring control
  - Food allergen controls are applicable
  - A food safety plan is required

- Food allergens can be managed with a combination of GMPs and preventive controls

Preventive Controls & Allergens

- Written Hazard Analysis: allergens as chemical hazards
- If undeclared allergens are reasonably likely to occur, must have a food safety plan with allergen controls

Allergen Controls:

1. **Labeling** the food to properly indicate allergen-containing ingredients
2. Preventing allergen **cross-contact** (**HARPC**)

FDA Enforcement of FSMA

- Some inspections barely focus on allergens and predominantly focus on bacterial pathogens
- When FSMA allergen inspections are conducted, they have focused on GMP considerations
- Only recently have FSMA allergen inspections begun to focus more on Risk-Based Preventive Controls (RPC) and on allergen control plans (ACP)
- Expect more of that focus moving forward as FDA trains more inspectors to conduct ACP-based inspections
- Expect some variability and arguments as inspectors get aligned

Updated GMPs & Allergens

Personnel	• Hygienic practices • Outer garments to protect against cross-contact
Plant construction and design	• Operating practices/design: separation of operations • Ventilation to minimize dust which would result in cross-contact
Sanitary operations	• Clean utensils/equipment; storage of clean equipment • Food-contact and non-contact surfaces
Equipment and utensils	• Cleanable and maintained • Seams: smoothly bonded & maintained
Processes and controls	• Raw material and rework storage • Manufacturing, processing, packing and holding conducted to minimize cross-contact
Warehousing and distribution	• Storage and transportation to protect against cross-contact

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

Keys to Development of an Effective Allergen Control Plan

Focus on the Big 8

Essentials of Allergen Control

- Form an allergen control team
- Conduct a hazard assessment to identify critical allergenic ingredients, formulations, unit operations, and preventive control locations
- Quantitative risk assessment helps to determine the extent of the concern

Essentials of Allergen Control

- Develop an allergen process flow diagram (allergen map)
- Identify the areas where preventive controls can be implemented; what is a preventive control and what is GMP?
- Develop an allergen control plan (ACP) specific to each processing facility and each product
- Review the ACP on some regular basis and especially for new products, introduction of new processing capabilities, new ingredients
- Incorporate ACP into overall Food Safety Plan

Where Risks Occur

- Research and Development
- Engineering and System Design
- Raw Materials/Suppliers/Co-Packers/Purchasing
- Operations/Manufacturing
- Packaging and Labeling
- Cleaning/Sanitation
- Human Error/Training

It is everyone's job; we are all in this together (team effort)

Where Risks Occur

- Research and Development
- Engineering and System Design
- Raw Materials/Suppliers/Co-Packers/Purchasing
- Operations/Manufacturing
- Packaging and Labeling
- Cleaning/Sanitation
- Human Error/Training

Where can Preventive Controls be Implemented?
Preventive Controls vs. GMPs

Engineering Design & Maintenance

- Purchase, design, modify equipment using sanitary design principles
  - Ensure equipment is easy to clean, inspect and disassemble if necessary
- Prevent cross-contact at line cross-overs
- Assess the need to segregate adjacent processing lines with physical barriers, etc.
  - Assess the risk of dust as a source of allergen cross-contact
- Assure that maintenance procedures will not allow cross-contact

Receiving

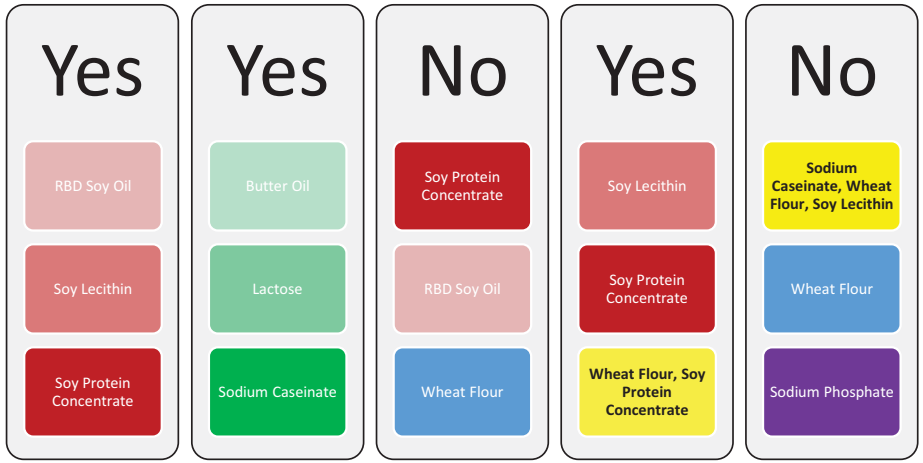
- Review and inspect incoming shipments of raw materials for allergen information
- Develop a company-wide system for tagging all raw materials for easy identification in your facilities (Ex. color coding, symbols/icons, etc.)
- Assure that each incoming container is appropriately tagged and placed in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

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

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/)

Operation Strategies - Staging

- Use clearly designated staging areas for allergenic ingredients/products
  - ➢ Use segregated/color coded utensils to avoid allergen cross contact
  - ➢ Could also consider dedicating utensils to a line with the same allergen profile
- Assure that the correct ingredients are assembled and incorporated into the formulation
- Clearly label opened, partially used ingredient bags and return these items to the appropriate storage area

http://remcoproducts.com/

Operation 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”

Operations Strategies

- Where processing lines are in close proximity, install a physical barrier between lines if needed
- Avoid situations where product flow might allow allergen cross-contamination such as line cross-over
- Ensure that traffic patterns for raw materials, packaging supplies and employees are limited during manufacturing of allergenic formulations to minimize cross-contact
- Restrict employees to allergen-only areas or require change of clothing for shared staff (maintenance); allow easy identification of those employees

Packaging Strategies

- Check labels or packages to assure that the labeling statement is entirely correct before start-up of a new formulation
- Check to assure that there are no mixed bundles of labels/packages
- Develop procedures (e.g. bar code readers) to assure that the product ends up in the package with the correct label
- Remove all packaging materials from the area during allergen changeovers
- Remove obsolete stock and destroy immediately

Cleaning & Sanitation Strategies

- Shared processing equipment must be cleaned effectively between formulations when allergens differ or allergen to non-allergen
- 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'
- But how to validate and verify??

Food Safety Modernization Act

- FSMA guidance does not mandate how SSOPs should be validated or verified but companies should be able to defend selected approaches
- FDA is unlikely to mandate use of allergen testing
- Visually clean will likely be sufficient but documentation for validation of cleaning effectiveness is an issue
- Allergen testing will likely be an aid to validation of effectiveness of ACP
- Can include quantitative ELISAs, LFDs, PCR, general protein, ATP, mass spectrometry as appropriate and available
- Testing can also aid in verification because it establishes the documentation

Food Safety Modernization Act

- Will put focus on validation and verification of allergen control approaches
- Have food companies be able to validate ACP effectiveness? Can testing help?
- Have they made the best testing method choices?
- Can they document that visibly clean is a good standard?
- Can they document ACP effectiveness?
- How much is too much?
- How clean is clean enough?
- Will food companies be able to verify allergen control?

Allergen Preventive Controls - Background

- When allergens first became an issue in the early to mid-1990s, the food industry had no tools to detect allergens; big reason for genesis of FARRP
- At that time, allergen control plans did not exist
- Out of necessity, visually clean became a standard approach to assessment of effectiveness of SSOPs on shared equipment
- Visually clean turned out to be an excellent approach in many situations and remains an element of allergen control today
- Visually clean is especially appropriate for particulates

More Recent Developments

- Sensitive and specific tests for allergen residues have been developed – ELISA and other
- Lateral flow strip ELISA available for in-plant use
- Allergen control has become a key part of overall food safety plan for many companies
- But elements of allergen control and validation of its effectiveness differ among companies
- Allergen control now a key part of auditing too
- Auditing organizations have differing expectations

Possible Detection Methods to SSOP Validations

- **Quantitative Methods:**
  - Enzyme Linked Immunosorbent Assay (ELISA)
  - Polymerase Chain Reaction (PCR)
  - Mass Spec Methods (LC-MS/MS)

- **Qualitative Methods:**
  - Lateral Flow Devices (ELISA LFD)
  - General Protein Tests
  - ATP/Bioluminescence Tests

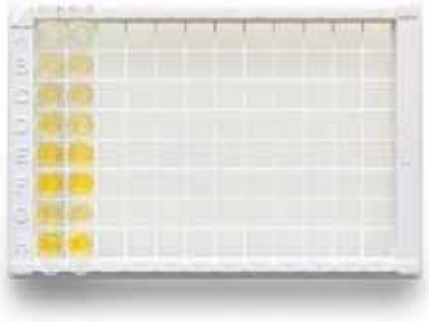
Validation of SSOP Effectiveness

- What can you test?

  - Equipment surfaces – LFD or protein or ATP
  - Rinse water from CIP – LFD or protein or ELISA
  - Push-through material – ELISA or LFD?
  - In-process product – ELISA or LFD?
  - Finished product – ELISA
  - Mass spectrometry – still in development

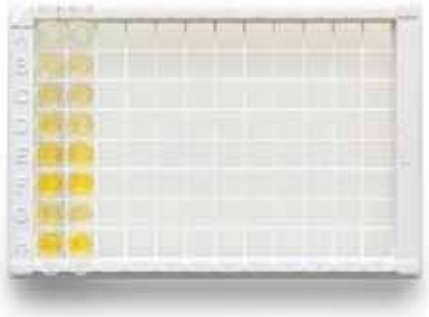
Picking the Best Test Method
General Comments

- 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
- LFD or ELISA are the better choice



Picking the Best Test Method
General Comments

- Make sure that the test method is fit for purpose – analyze a positive control
- Processing esp. heat can affect detection
- Fermentation or hydrolysis can affect detection
- Matrix effects can occur esp. with ingredients
- Understand reporting units and conversion factors
  - e.g. 1 ppm BLG = 28 ppm NFDM
- All ELISAs or LFDs are not created equal



Common Gaps

- Inadequate packaging controls
- Lack of documentation on effectiveness of allergen control plan
- Poor choices of analytical methods for documentation
- Use of advisory labeling as a substitute for Good Manufacturing Practices
- Inadequate knowledge of suppliers and associated allergen risks

FARRP Approach on Allergen Validation

The FARRP Approach

- Step 1 – Know Your Allergens

➢ Allergen load is extremely important; focus on allergenic ingredients of highest protein load

➢ Allergen form is also important
particulate vs. non-particulate
liquid, dry, powder, paste, etc.

Allergen Load

- Some ingredients contain high level of allergenic protein e.g. casein, gluten, soy flour
- Other ingredients contain modest level of allergenic protein e.g. lactose
- Some ingredients contain low to very low level of allergenic protein e.g. soy lecithin, fish oil, butter

Allergen Composition

- Almond Pieces?
- Almond Powder?
- Almond Butter?

❖Consider:

Difficulty to clean and potential risk factors.

How much equipment will be exposed?

Know Your Allergens

- Be able to identify ingredients derived from commonly allergenic sources
- Assess the allergen load of these ingredients to determine if hazard exists
- Understand allergen control practices of your suppliers and then their suppliers
- Analysis can help to identify potentially hazardous ingredients but use intelligently

The FARRP Approach

- Step 2 – Develop SSOP for each line and each allergenic ingredient

  - Focus on shared processing lines and equipment as these represent a major risk for cross contact
  - First, evaluate your current approach to cleaning of shared lines/equipment; it might be good enough

The FARRP Approach

- Step 2 – Develop SSOP for each line and each allergenic ingredient

  - If several ingredients have similar form (dry powders) then you can assume that cleaning is equivalent
  - If several lines have identical set-ups, then same SSOP should work for all
  - Focus on allergenic ingredients of highest protein load
  - But may need some evidence that this is right choice

The FARRP Approach

- Step 3 – Validate the SSOP for each line
  - But perhaps not every allergenic ingredient
  - Be prepared to make a good argument for selection of testing one allergen but not others
  - Be really careful about skipping analysis for minor ingredient that is highly allergenic, e.g. peanut
  - Minor allergenic ingredients e.g. soy lecithin can be ignored based on calculations, expert opinion letters

The FARRP Approach

- Step 3 – Validate the SSOP for each line
  - Run the allergenic formulation
  - Test the dirty equipment (positive control)
  - Do the SSOP
  - Determine if equipment is visually clean
  - Perform allergen-specific ELISA swabs/lateral flow strips on equipment surfaces, CIP rinse water, etc. (multiple swabs are advised)
  - If non-detect, you pass and can run next product
  - If allergen detected, more cleaning is needed

The FARRP Approach

- Step 3 – Validate the SSOP for each line

  - Repeat the whole cycle again
  - If you get non-detect on two successive runs, then you have a validated SSOP
  - Develop an approach to determine that SSOP is performed each time
  - Not necessary to do allergen swabs each time once validation is complete

The FARRP Approach

- Step 3 – Validate the SSOP for each line

  - Can use allergen swabs to validate that visually clean, ATP, or general protein is a sufficient approach
  - Can use ATP as a first pass assessment; if ATP is positive, then allergen swab will be positive

The FARRP Approach

- Step 4 – Re-Validate the SSOP

  - Re-validate periodically using allergen swabs; frequency is not fixed
  - Re-validate when anything changes: formulation, equipment matrix, processing conditions, SSOP parameters, allergen test kit
  - Keep records of all test results

The FARRP Approach

- Step 5 – Validate Overall ACP

  - When you are 99.9% sure that you will get BLQ result, do finished product testing by quantitative ELISA – this is the ultimate assessment
  - Repeat finished product testing periodically

The FARRP Approach

- Special Situation: What to do when you cannot consistently get non-detect with allergen swab
  - Test finished product (especially if you expect uniform distribution); remember swabs are very sensitive
  - Do a quantitative risk assessment to judge extent of risk
  - Use advisory labeling if risk is too high

Key Decisions in ACP Validation

- Establish corporate target level (ppm allergen residue)
- Use quantitative information for risk assessment
- Selection of test method(s)
- Sampling strategy (what to test, how often to test)

Target Level

- Regulatory action levels (thresholds) do not exist only in Japan (10 ppm). Thus, need to establish a corporate target level that protects consumers
- In FARRP expert opinion, BLQ (below limit of quantitation) by allergen-specific test does protect consumers (<2.5 or <5 ppm)
- Recommended corporate target levels – 2.5, 5.0, or 10 ppm

farrp.unl.edu

Steve Taylor, Ph.D.
Food Allergy Research and Resource Program (FARRP)

Ask the Expert

Live Q&A

Validation and Verification of Food Allergen Control Approaches and Programs

Today you've learned about:

- Essentials of allergen control and where risks occur
- Allergen control strategies for food processing operations, packaging, and cleaning and sanitation
- Guidance for choosing the right test methods for verification and validation of sanitation standard operating procedures (SSOPs)
- The FARRP approach to validation of allergen control plans

3M Science. Applied to Life.™

Complex testing made simple.

Now you can master the complex world of food allergen testing. Streamline your process and get accurate results with 3M™ Allergen Testing.

When you see how simple it is, you'll know it's worth it.

3M Food Safety Allergen Testing

3M Science. Applied to Life.™

Versatility across sample types.

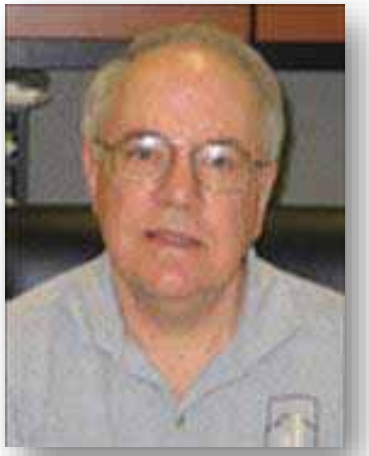
3M™ Allergen Testing Products can be used to detect allergenic proteins in:

- Clean-in-place final rinse water
- Environmental swab samples
- Food ingredients and processed food products

Thank you.

Food Allergy Research and Resource Program
farrp.unl.edu

3M Food Safety
3M.com/foodsafety



Dr. Steve Taylor
FARRP
U. of Nebraska-Lincoln

John David
3M Food Safety