Good food, Good life

Proven Practices for Allergen Management

Selecting Raw Materials and Product Development

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Food Safety Summit

AllforQuality
Our foundation for trust

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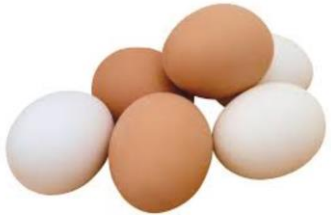
Impact of Food Allergies

Those seen

And unseen…

Hundreds of Foods Can Cause an Allergic Reaction













Global Regulations Vary

Food Allergens

Crustacean Shellfish | Egg | Fish | Milk | Peanut | Soy | Tree Nuts | Sesame | Wheat | Cereals w/ Gluten | Sulfites | Buckwheat | Celery | Lupin

Molluscan Shellfish | Mustard | Bee Pollen/ Propolis | Beef | Chicken | Latex (Natural Rubber) | Mango | Peach | Pork | Royal Jelly | Tomato

For information on recent updates to the International Chart please check here.

Food Allergens	Crustacean Shellfish	Egg	Fish	Milk	Peanut	Soy	Tree Nuts	Sesame	Wheat	Cereals w/ Gluten	Sulfites	Buckwheat	Celery	Lupin	Molluscan Shellfish	Mustard	Bee Pollen/ Propolis	Beef	Chicken	Latex (Natural Rubber)	Mango	Peach	Pork	Royal Jelly	Tomato
USA[1]	X	X	X	X	X	X	X	X	X		X													
Canada	X	X	X	X	X	X	X	X	X	X	X				X	X								
EU[2]	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X								
Australia/NZ	X	X	X	X	X	X	X	X	X	X	X			X	X		X						X	
Argentina	X	X	X	X	X	X	X			X	X													
Bangladesh	X	X	X	X	X	X	X	X		X	X		X			X								
Belarus	X	X	X	X	X	X	X	X		X	X		X	X	X	X								
Bolivia	X	X	X	X	X	X	X		X	X	X													
Botswana	X	X	X	X	X	X	X			X	X													
Brazil	X	X	X	X	X	X	X		X	X	X								X					

https://farrp.unl.edu/IRChart/

US Regulated Food Allergens – FALCPA (Food Allergen Labeling and Consumer Protection Act

INGREDIENTS: SUGAR, NONFAT MILK, CORN SYRUP SOLIDS, COCOA, HYDROGENATED VEGETABLE OIL (COCONUT AND/OR PALM KERNEL AND/OR SOYBEAN), DAIRY PRODUCT SOLIDS, 2% OR LESS OF CELLULOSE GUM, DIPOTASSIUM PHOSPHATE, NATURAL AND ARTIFICIAL FLAVORS, SODIUM CASEINATE, SALT, SODIUM ALUMINOSILICATE, MONO- AND DIGLYCERIDES, SUCRALOSE.
CONTAINS: MILK.
MAY CONTAIN SOY AND WHEAT.

INGREDIENTS: MILK, SUGAR, CORN SYRUP, REESE'S PEANUT BUTTER SWIRL [PEANUTS, SUGAR, PEANUT OIL, DEXTROSE, SALT, TBHQ (PRESERVATIVE)], REESE'S PEANUT BUTTER CUPS {MILK CHOCOLATE [SUGAR, COCOA BUTTER, CHOCOLATE, NONFAT MILK, MILK FAT, CORN SYRUP SOLIDS, SOY LECITHIN, PGPR (EMULSIFIER)], PEANUTS, SUGAR, DEXTROSE, SALT, TBHQ (PRESERVATIVE)}, CREAM, DUTCHED COCOA (PROCESSED WITH ALKALI), **LESS THAN 2% OF:** WHEY, MONO AND DIGLYCERIDES, VEGETABLE GUMS (GUAR, CAROB BEAN, TARA), CARRAGEENAN, VITAMIN A PALMITATE, NATURAL FLAVORS.

Recent Changes- FALCPA Guidance

- **Definition for milk and eggs- includes other domesticated animals (previously defined as cow's milk and chicken eggs)**
- **Tree nut list**
  - Almond
  - Black Walnut
  - Brazil Nut
  - California Walnut
  - Cashew
  - Filbert/Hazelnut
  - Heartnut/Japanese Walnut
  - Macadamia Nut/Bush Nut
  - Pecan
  - Pine Nut/Pinion Nut
  - Pistachio
  - Walnut (English, Persian)

- Frequently Asked Questions: Food Allergen Labeling Guidance for Industry | FDA

What About Gluten?

- Wheat, wheatberries, rye, barley, spelt, triticale, farro all examples of gluten containing grains

- <20 ppm gluten to be gluten free, and food does not contain an ingredient that is:
  a) a gluten-containing grain (e.g. wheat, barley, rye)
  b) derived from a gluten-containing grain that has not been processed to remove gluten (e.g., wheat flour)
  c) derived from a gluten-containing grain that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food

- Special considerations for fermented or hydrolyzed foods
- Additional record keeping

Reviewing Raw Materials- Questions to Consider

Is the allergen information I have from my supplier accurate and up to date?

Does this change the allergen profile of an existing product?

Would a consumer expect this allergen or cross contact in this product?

Does this add a new allergen to the factory?

Collecting Accurate Ingredient Allergen Information

1. **Do you have an agreement with your supplier to be notified if there are changes to allergen information? Do you require allergen information be updated on a regular frequency?**

2. **Allergens inherent to the material- *including processing aids derived from allergens must be labeled***
   - *Ask about local allergens plus what may be considered an allergen in countries you produce product for*
   - *Form of allergen could dictate labeling requirements (RBD oil)*
   - *Species for fish, crustaceans, tree nuts*

Collecting Accurate Ingredient Allergen Information

1. **Is there cross contact? Is Precautionary Allergen Labeling required?**
   - Consider source of cross contact- Ag co-mingling, from the line, from the facility
   - Nature of cross contact material- homogeneous, inhomogeneous
   - Controls is place to prevent and minimize cross contact
   - Precautionary statements on ingredients: need justification on carry forward or not

2. **Claims on Label?**
   - May need to ask additional, open-ended questions to assess, especially if product will carry special claims like gluten free, vegan, dairy free, etc

Changing the Allergen Profile of an Existing Product

Expected Allergens and Cross Contacts?

npr

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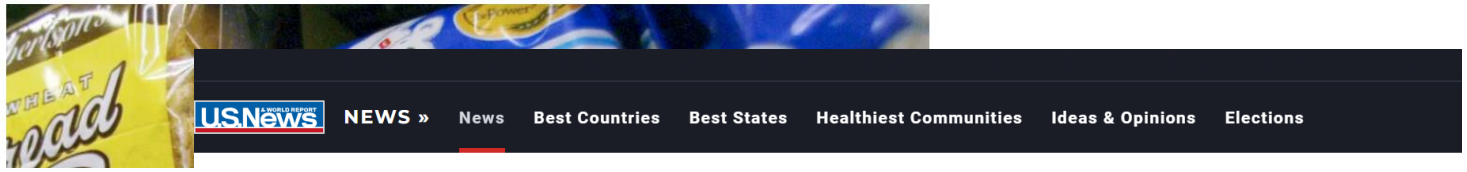
HEALTH

FDA warns top U.S. bakery not to claim foods contain allergens when they don't

JUNE 26, 2024 · 1:46 AM ET

By The Associated Press



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Home / News / Health News / Some Chocolate Products Lab...

Some Chocolate Products Labeled 'Dairy-Free' Contain Milk, FDA Finds

By HealthDay | Sept. 19, 2024, at 6:08 a.m.

Save Comment

Cross Reactivity

- Allergic Reactions- caused by immune response to certain proteins

- What happens when similar proteins are found in other foods? Or the same due to genetic engineering?








Unexpected Allergens in the Supply Chain

FDA Investigates Low Levels of Peanut Residue Found in Limited Flour and Flour Products

Does this add a new allergen to the factory…?

Start this discussion during product development!

Management of change is critical for adding allergens to a factory

Allergen Detection Methods

Food Safety Summit 2025, Chicago IL

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Overview

- When to use allergen detection methods
- What types of detection methods are available ?
- Detection methods are not equal
- Working with an analytical lab

When to use allergen detection methods

- Allergen detection methods are **not a primary control** for allergens.
- The primary use of allergen detection methods is **in support of an allergen control plan (ACP)**.
- When and how detection methods are used should be clearly **defined as part of your allergen control plan**.
- Ideally, tests should **not** be used outside this plan.
- **Awareness** of the types of method and how they work is therefore crucial to the success of your ACP.

Purpose of allergen analysis

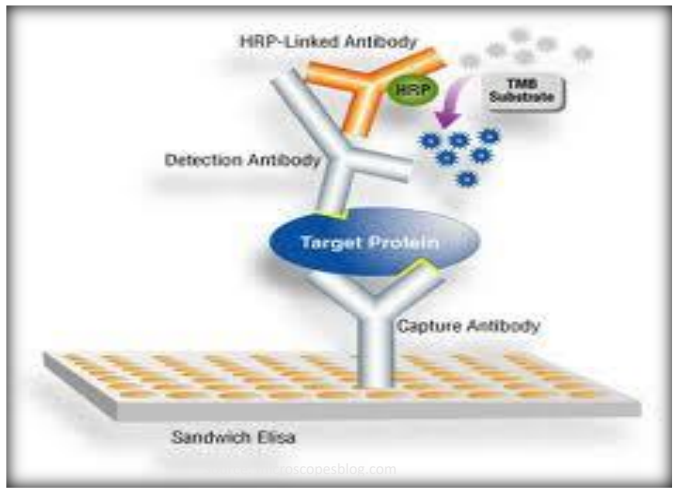
- Allergen control programs
  - ➢ Ingredient Qualification
    - Supplier qualification
    - Ingredient verification (particularly for free-from claims)
  - ➢ Support Cleaning Programs
    - Equipment swabs
    - CIP rinse water
  - ➢ Finished product confirmation (particularly for free-from claims)
- Consumer complaint investigation
- Regulatory enforcement

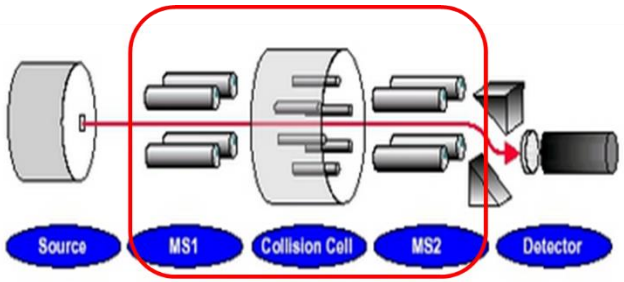
Validation and Verification

- Using allergen detection methods to **check another process**.
- **Validation** – using testing to demonstrate that the cleaning process in your ACP removes allergens when performed as specified.
  - May be performed once if nothing changes.

- **Verification** – Periodic checking that the cleaning is being performed as described in the ACP.
  - Periodic

What type of detection methods are available ?

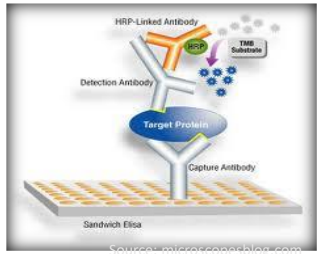


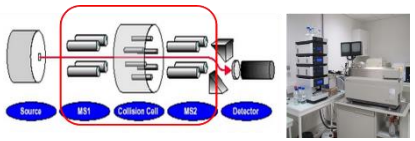


Types of detection method

- All detection methods use ‘target’ molecule(s) to represent the allergenic foodstuff.
  - E.g. the presence of specific peanut proteins, peptides or DNA demonstrates the presence of peanut.

- **Immunological methods** – proteins
- PCR – DNA
- MS - peptides





ELISA - principles

- Uses **antibodies** which recognize one or more proteins chosen from an allergenic food.
- The **binding of antibodies** to allergenic food in the sample is then detected by a (usually color-changing) enzyme assay using an enzyme linked to the antibody.
- **Calibration** is performed using a standard curve generated using **manufacturer-supplied standards.**
- **Different types of ELISA** (direct, indirect, sandwich) exist – the type can affect utility.

ELISA and ELISA-Based Technologies

- Many **commercial kits** available, some labs also offer 'in house' ELISA methods.
- **Most used** method for allergen detection.
- Usually **specific and sensitive.**
- **Fast** turnaround.
- Due to the need for conditions allowing antibody binding and enzyme-linked detection, limited to a **few extraction conditions.**

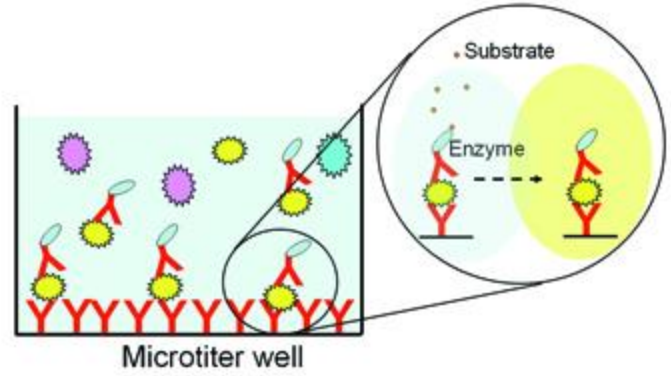
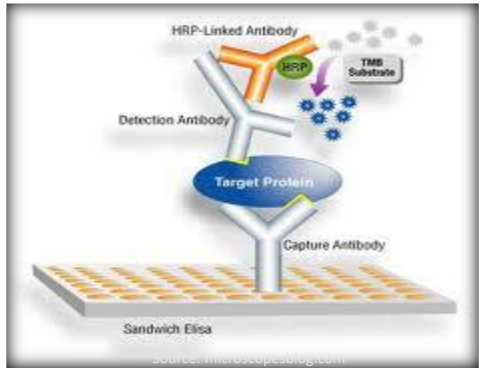


Figure 2: Principle of an ELISA: Allergens are detected by a specific enzyme-labeled antibody and a specific capture antibody on the wall of a microtiter well. After conversion of a substrate by the enzyme, a colored product is formed. The color is read in a microplate-compatible spectrophotometer.



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Lateral Flow devices

- Also uses **antibodies.**
- Used primarily for **sanitation assessment.**
- Often combined with **swabbing**.
- **Rapid** (approx. 10 min).
- Sensitive.
- Typically qualitative (+ or -) only.
- Typically **no lab equipment needed.**

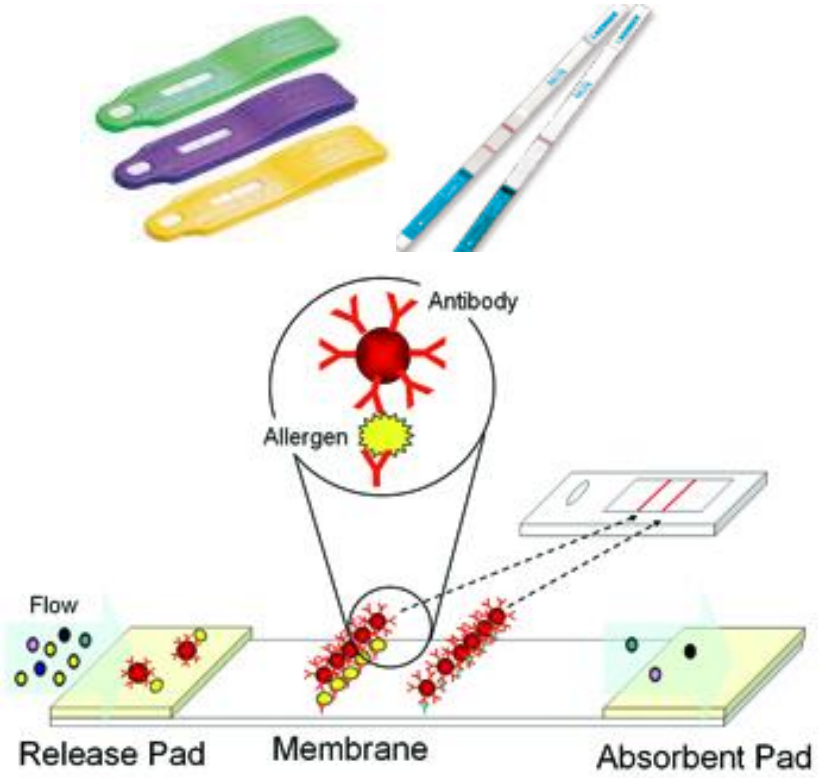

Figure 1: Principle of a strip test: Anti-allergen antibody-coated colored beads form a complex with allergens in the sample and anti-allergen antibodies on the strip. This leads to a colored test line indicating a positive (i.e., allergen-containing) sample. A colored control band indicates correct performance of the test.

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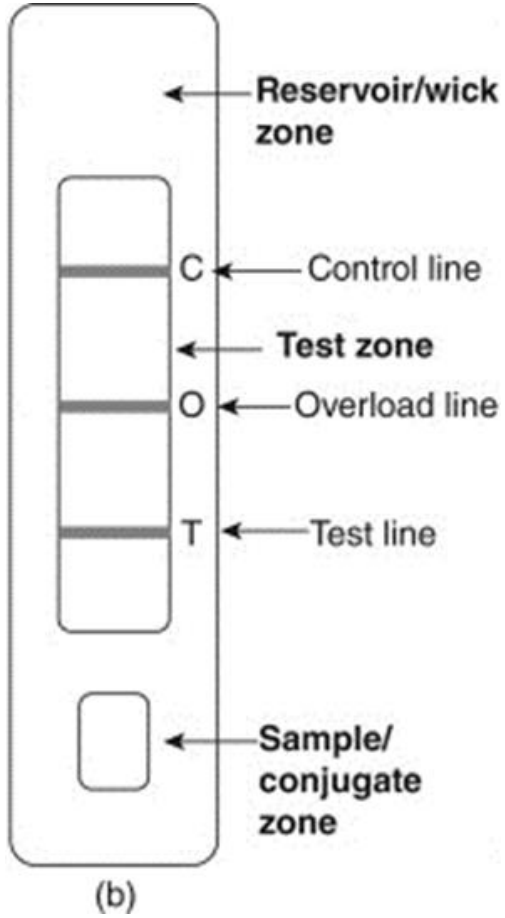
A word of caution

- **Overloading** a LFD can cause a **false negative** result (due to the 'hook effect').
- Some manufacturers therefore include an '**overload line**' between the test and control lines.



Analysis for general soiling

- Methods that are **not designed for specific detection** of allergenic foods, but detect **more general soiling**.
- These can still be useful in **cleaning / surface validation**.
- Usually combined with **swabbing.**
- Usually **inexpensive and quick.**
- Two main types :
  - **Protein**
  - **ATP**

Detection methods are not equal

- Allergen detection is **imperfect**.
- Different methods use different extractions, have different target molecules, different detection, different antibody-detector coupling etc.
- Different methods function better or worse under **different circumstances**.
- **Processing** and **matrix** matter.
- Ideally, you should check how well the method works under the circumstances in which you will use it (**method validation**).

Detection methods are not equal

Peanut ELISA kit	Spiked whole peanut in cumin (mg.kg^{-1})		
	4	**1000**	**200000**
1	65.0 (317.5)	43.3 (235)	24.9 (179)
2	91.4	78.6	na
3	113.1	42.1	na
4	19.8	17.3	na
5	52.8	29.4	na
6	nd	18.1	2.2

Working with an analytical lab

- Manufacturers may have different relationships with **analytical laboratories**
  - Vendor
  - Run analyses
  - Advice/guidance
  - Method validation
- Especially given the **imperfect nature** of allergen detection, your analytical lab partner is **important**.
- The lab you're working with have vast, important experience of **working with these methods**, and of **validating methods**.

A word on ISO 17025

- ISO 17025 is a standard applied to a laboratory **for a given method**.
- It is **NOT** a general laboratory certification.
- Methods for which a laboratory has ISO 17025 certification are usually described as '**under scope**'.
- **Ask if the method they are running is under their ISO 17025 scope**.

Thank you for your attention

Embracing Change: Considerations for Allergen Control Program Updates

Scott Hegenbart
Manager of Regulatory Affairs

Disclaimers

Scott Hegenbart is employed by Conagra Brands, Inc., a food company that manufactures and distributes a variety of food products.

Scott’s presentation reflects his own insights and observations of the Food Industry and do not necessarily reflect specific practices and policies of Conagra Brands.

Who is Scott Hegenbart?

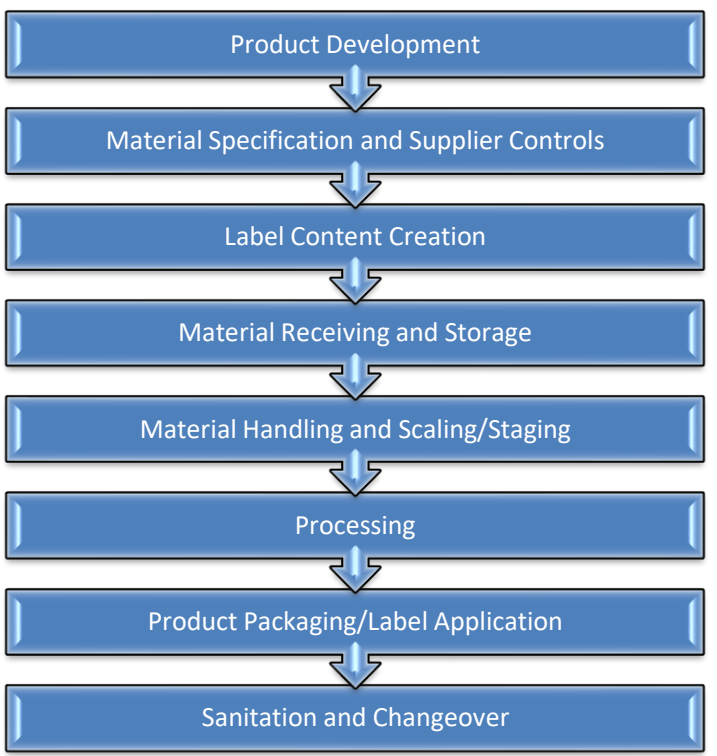
- Manager of Regulatory Affairs at Conagra Brands, Inc. in Omaha, NE
- Scott Hegenbart earned his bachelor’s degree in both Chemistry and Speech Communication from Iowa State University
- Scott began his food industry career working in various quality assurance and research and development positions. He also has extensive experience in the food industry media where he has authored more than 200 articles on topics including product development, ingredient technology and food safety
- In addition to his work with Conagra Brands, Inc., Scott has shared his food science and communications expertise as a trainer and consultant

Creating an Allergen Program

- Applicable to all preventive control based plans
- Determining allergen controls:
  - Map your process flow
  - Identify the potential allergen hazards
  - Devise allergen controls

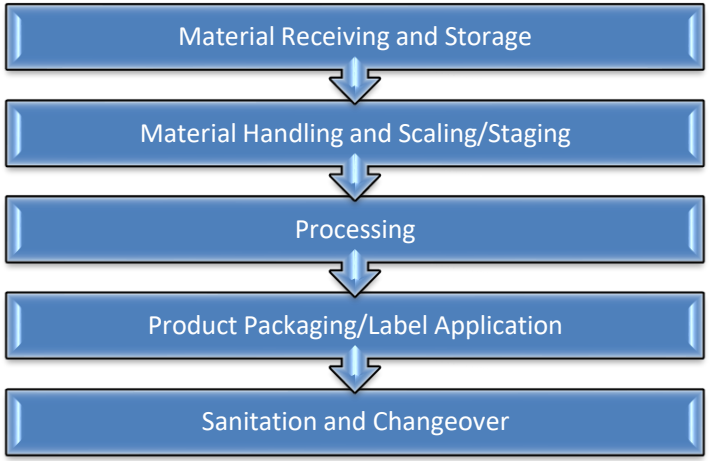
Tasks performed during development

Tasks supporting production



Incorporating Allergen Changes

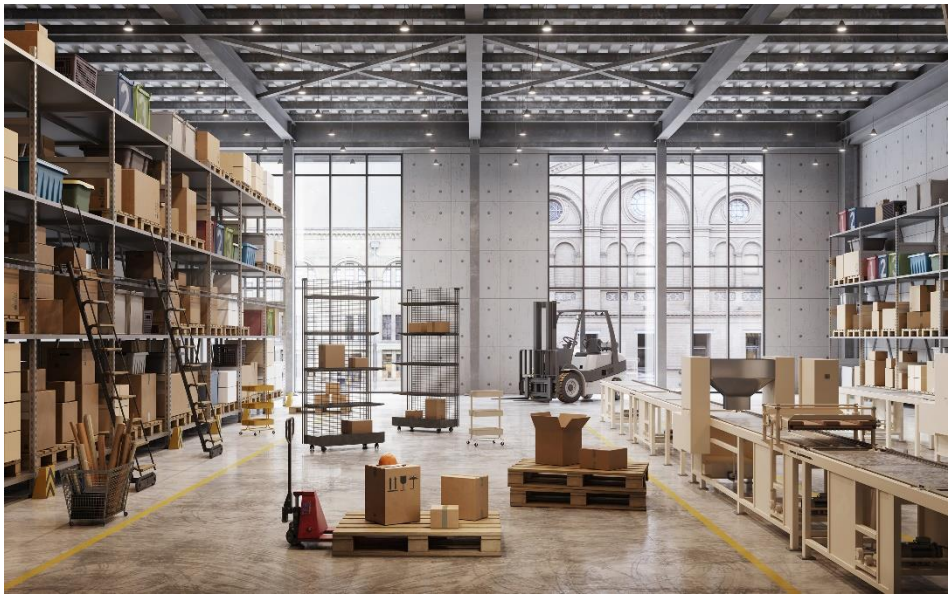
- R&D has already made the change
- The challenge of changing allergen profiles
- Revising allergen controls:
  - Follow the process
  - Identify the new/changed potential allergen hazards
  - Update allergen controls



Material Receiving and Storage

Receiving new ingredients:

- Have new data so the facility can match the new item to the paperwork?
- The ingredient containers must be marked with the item number and ingredient declaration
- Consider what else needs to be modified or updated for the new allergen



Material Receiving and Storage

Storing:

- Minimize cross-contact during storage
- Identifying allergens – allergens should be clearly marked
- Allergens should be segregated in designated and identified storage areas
- On warehouse racks, allergens should be stored below non-allergens

Guidelines for allergen ID

1. Clear text
2. Color coding
3. Common icons

Material Receiving and Storage

Receiving new pre-printed packaging:

- Have new proofs of new or modified ingredient declarations
- Affirm the content of pre-printed packaging material is correct
- Affirm any bar codes or data matrices scan correctly
- Check for mixed packaging
- Make an imprint visible on each pallet for in-process identification

Material Handling and Scaling/Staging

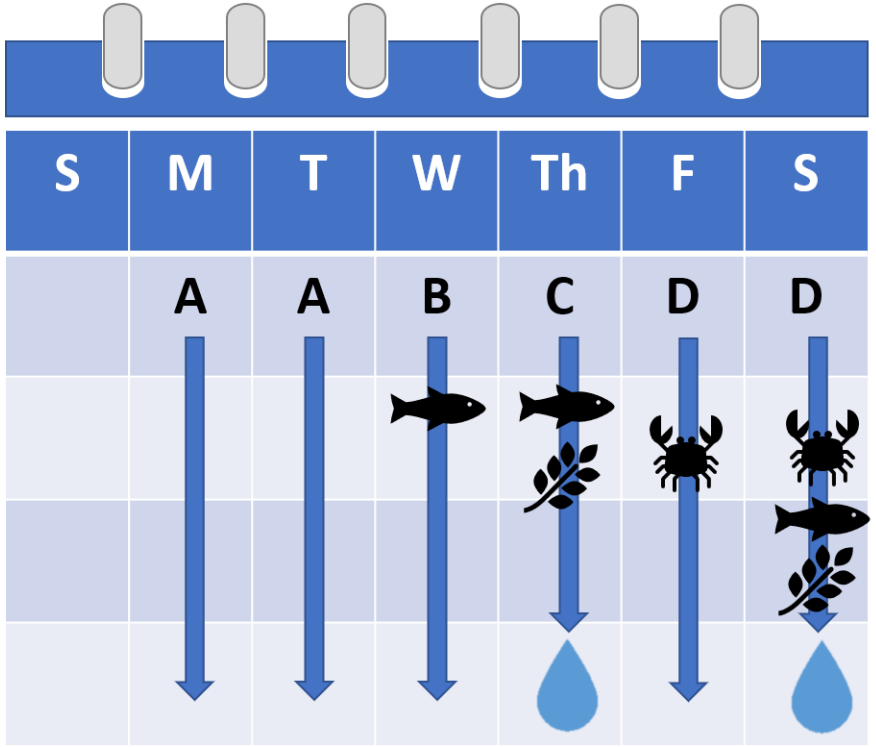
- Cross-check formula to assure it matches scheduled product
- Only deliver allergen ingredients to scaling area immediately before use
- Batched ingredients should be clearly identified and segregated
- Have a sensible re-work handling procedure
  - Ideally, use re-work the same day generated
  - Clearly identify re-work
  - Only use in same product, or product with matching allergen profile

Processing—Pre-Op

- Where possible, dedicate equipment and personnel to specific allergenic products
  - Can dedication be maintained with a new allergen?
  - Processing equipment
  - In-process totes
  - Clearly identify and use color coding
- Introduce allergen ingredients into products as late in the process as possible
- Avoid cross-contact through line cross-over
  - Redesign layout
  - Conveyor covers
- Schedule manufacturing of allergenic products just prior to the end of manufacturing cycle that is followed by full sanitation

Processing—Scheduling

- “Progressive Scheduling” minimizes allergen changeovers
- Products with no allergens should be run first
- Products with more allergens should be run successively
- New allergen must be integrated into the schedule



Fish
Crustacean
Wheat
Allergen
Sanitation

Processing—Operations

- Cross-check formula against schedule
- Post product and allergen notification
- Affirm correct materials brought to line
- Personnel practices to maintain segregation

Product Packaging/Label Application

Before and during production

- If the new allergen is in an existing product, prepare a hard-cutover of the old formula and package with the new formula and package
- Clear line of packaging at changeover
- Confirm packaging on the line matches scheduled product
- Packaging cross-checks to verify materials
  - Record packaging identification and capture imprint
  - Scanning technology may help perform checks, but must be managed correctly
  - Scanning systems are a final verification, they should not be the only verification

Product Packaging/Label Application

After production

- Return packaging to designated location
- Stretch wrap on partial pallets to avoid label mixing
- Make a sample label or carton visible on the exterior of the pallet
- If you find old packaging for the previous formula, it must be destroyed to retain continuity

Sanitation and Changeover

- Equipment must be cleaned when changing allergens by establishing a Standard Sanitary Operations Procedure (SSOP)
- FSMA established “Sanitation Controls” as its own preventive control category
- A new allergen may be in a form that is more challenging to clean and the SSOP may need updating

Sanitation and Changeover

General SSOP components

- Type of cleaning: Wet clean vs. dry clean
- In all cases, start by clearing the line of all packaging, ingredients, leftover product, etc.
- Subsequent steps should emphasize challenging cross-contact locations:
  - Product catch points
  - Shared connections
  - Equipment should be designed to minimize these challenges
- Document SSOP completion

Sanitation and Changeover

Thoughts on verification and validation

- At a minimum, inspect the line visually
- Any testing should be implemented after a sound history of successful visual inspection
- Create a plan to appropriately incorporate testing that will yield useful information

A Final Word

Train!

- Allergen control includes many manual practices
- Awareness of any new allergens is vital to maintain segregation
- Consistent execution is critical
- Make sure to teach the “why”

Thank you!

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