Thinking About Allergen Testing

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First Principles

- Undeclared food allergens are a significant hazard
  - Undeclared allergens remain the major cause of food recalls

- You can not test-in allergen safety
  - You need to have an effective allergen control program before thinking about testing
    - Program = Plan + Execution
Why test?

- Most common allergen problems do not need testing for either prevention or response
  - Examples:
    - Putting food in the wrong package or using the wrong label
    - Not reading information from your suppliers
    - Not reviewing your own labels

- Testing should be used to verify and validate your internal allergen controls
  - Example:
    - To validate cleaning SOPs
Why test?

- Testing is critical for supply chain control
  - Once an undeclared allergen gets in the supply chain it cannot be removed
  - There is nothing equivalent to a microbial kill step for allergens
  - Dilution is not a solution

- The only way you can be sure that testing is done right is to do it yourself (in house or in your contact lab)
  - To ensure
    - Use of appropriate tests
    - Validation of tests for your specific matrix
    - Use of appropriate controls
  - Supplier COAs or LOGs don’t usually provide this information
What about thresholds?

- The first question to ask is – thresholds for what?
  - Final product or ingredients or environmental swabs?
  - For which form of an allergen?
    • Examples: Whole milk or whey or casein; intact or hydrolyzed?

- The available clinical data that might be used to establish regulatory thresholds do not address many critical issues
  - Allergen form
    • Including differences for particulate vs. soluble allergens
  - Matrix effects
What about thresholds?

- The most widely cited threshold suggestions were derived using data that are not public and calculations that have not been fully described
  - Including data from clinical testing where the material used was not well controlled
  - Thresholds expressed as total dose, not concentration
  - They were developed to provide guidance on the use of advisory labels (i.e., “may contain”) not for allergen control
  - They address food as consumed, not ingredients
  - They explicitly exclude particulate allergens
  - They are useful for risk assessment when problems are discovered
    - i.e., recall classification
Practical Thoughts

- Be sure that the testing you do is actually capable of finding problems should they occur
  - Do not rely on the LOD or LOQ claimed by a kit manufacturer
    - These are usually matrix-free values
    - Issues like extraction efficiency are critical in determining actual values in your application

- Both product and environmental testing should occur at high frequency until you have enough data to make informed decisions on what it looks like to be “in control”

- Testing for supply chain control should occur all the time for vulnerable ingredients
  - This testing should include testing for allergens that are not “reasonably likely” because these can indicate EMA
Practical Thoughts

- Regulatory authorities are doing random testing
  - You want to prevent and find problems before they do

- For Dietary Ingredients
  - Beware of ingredients produced primarily for use as processing aids
  - Using a contract manufacturer carries an additional set of risks
  - Be sure you have data to back up any label claims
    • Particularly “free from” claims
Thank You

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