Using Contamination Data for Exposure Assessment

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Exposure Assessment

- Exposure assessment has 2 main components:
  - Food intake (amount and frequency)
  - Level of contamination in the food (and frequency)

- Both of these factors can be used in food allergy risk assessment to generate an allergen intake distribution
  - Quantitative risk assessment such as probabilistic modelling can be used to statistically predict the probability of an allergic reaction occurring

- Accurate exposure assessment is an important component of the overall risk assessment
  - Must ensure that the consumption data is reflective of the entire population of consumers
  - Contamination data must be carefully calculated or analytically assessed
Exposure Assessment: Using Contamination Data

- The concentration of allergenic food residue (or protein from the allergenic source) can be determined either by calculation or by quantitative analysis.

- Quantitative analysis commonly conducted on ingredients or finished food products that may contain an unintended allergenic residue.
  - Ideally the analytical method used to determine the concentration of the unintended allergenic residue would detect proteins from the allergenic source.
    - Total protein
    - A certain protein fraction from the allergenic source (e.g. casein)
    - A specific allergen (e.g. Ara h 2 from peanut)
Exposure Assessment: Using Contamination Data

• Immunochemical methods have become the standard method used by food industry

• Detect protein(s) from the allergenic source of interest

• Sufficiently sensitive (low ppm limits of detection)

• Rapid analytical assessment – 5 min-1 hr analytical process

• Suitable for food-processing settings

Source: microscopesblog.com

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Using ELISAs for Contamination Assessment

- Differences do exist between commercial ELISA methods
  - Antibody Specificity – total protein vs. allergen
  - Polyclonal vs. Monoclonal
  - Calibrators
  - Effects of Processing on Detection
  - Extraction Methods
  - Sensitivity Limits

- These differences need to be fully understood and carefully considered to ensure that the results are meaningful and can be applied to the risk assessment
Using ELISAs for Contamination Assessment

- Analytical data from commercial ELISA methods can be reported in units of ppm whole food (e.g. whole peanut), ppm protein (e.g. casein), or ppm of a specific allergenic protein (e.g. Ara h 1 from peanut).

- It is important to understand what calibrators are used in the commercial ELISA kit and what units the results are reported in so that proper conversions to concentration of protein from the allergenic source can be derived.
  - Allows for comparison to the threshold data in units of mg protein.
Importance of Appropriate Conversion Factors

- Assessment of the concentration of milk residue serves as a good example
  - Commercial ELISA detection for milk allergen residue reported in units of ppm:
    - Non-fat dry milk (NFDM)
    - β-lactoglobulin (BLG)
    - Casein

- Misinterpretation of the analytical results could have significant effects on the overall risk assessment
Importance of Appropriate Conversion Factors

- NFDM contains 35% milk protein
  - 1 ppm NFDM = 0.35 ppm milk protein

- Casein accounts for 80% of the total milk protein
  - 1 ppm casein = 1.25 ppm milk protein

- BLG accounts for 10% of the total milk protein
  - 1 ppm BLG = 10 ppm milk protein
Importance of Appropriate Conversion Factors

- Example
  - 1 ppm milk protein in a food product
  - Estimated consumption = 50 g food product
  - Exposure Dose = 0.05 mg milk protein
    - Exposure dose is below the recommended Reference Dose of 0.1 mg milk protein

- If the result of an ELISA reported in units of ppm BLG were misinterpreted for ppm milk protein
  - 1 ppm BLG = 10 ppm milk protein
    (Ex. misinterpreted as 1 ppm milk protein)
  - Estimated consumption = 50 g food product
  - Exposure Dose = 0.5 mg milk protein
    - Exposure dose is above the recommended Reference Dose of 0.1 mg milk protein

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Sampling Considerations

- Selecting a sufficient number of samples that represent the distribution of the expected concentration is somewhat straightforward when the contamination is homogeneously distributed throughout the product of interest.

- Sampling is more challenging when the source of contamination is particulate.
  - Likelihood and size distribution of particulate contamination, along with dose distribution (based on the expected size distribution) can be included as input variables in risk quantitative risk assessment models.
Conclusions

- Exposure assessment is an important part of risk assessment

- Both food intake and level of contamination must be accurately assessed in order to determine realistic exposure to that allergenic food residue

- Analytical assessment to determine the concentration of allergenic residue present in a food product can be utilized
  - Differences in analytical methods need to be fully understood and carefully considered to ensure proper comparison of the exposure dose to the proposed Reference Doses