



Peanuts in Wheat Flour: A Lesson for Agricultural Commingling

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Outline

- A brief primer on food allergies
- Should we have really been surprised? Was peanut in wheat flour really unexpected?

Our experiences with agricultural commingling and allergens

- Peanut in wheat flour – the story
- The ongoing U.S. regulatory response

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Why Should Millers Be Concerned About Food Allergies?

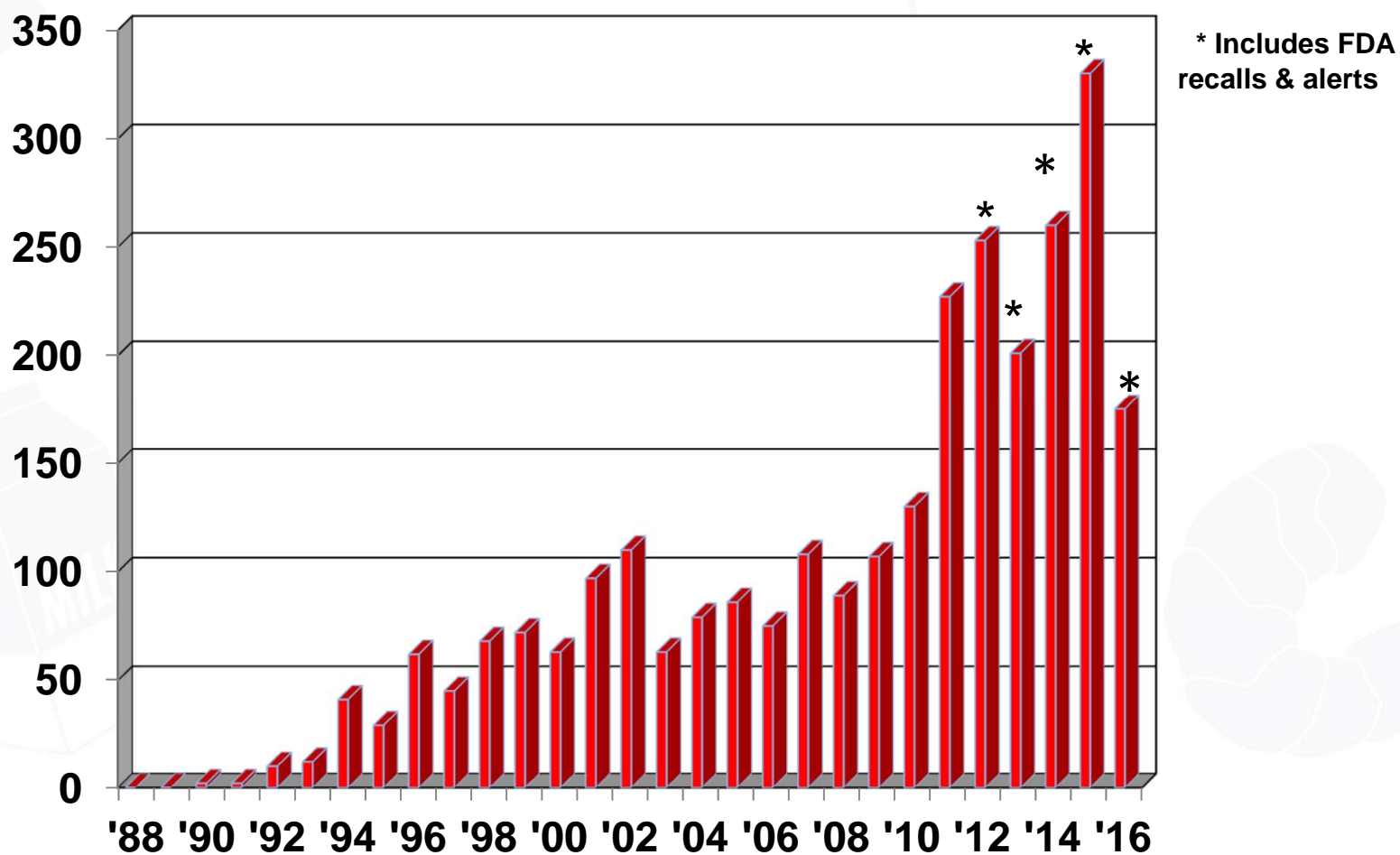
Why Should Food Allergies & Sensitivities be a Priority Concern for Millers?

- Allergic consumers expect it (very aware; high expectations)
- Estimated 10-14 million U.S. consumers have food allergy; similar prevalence in Canada
- Reactions can occasionally be quite severe, even fatal
- Reactions happen immediately after ingestion
- Threshold dose for provoking a reaction is quite low
- Avoidance is the only strategy for reaction prevention
- Allergic consumers are diligent label readers

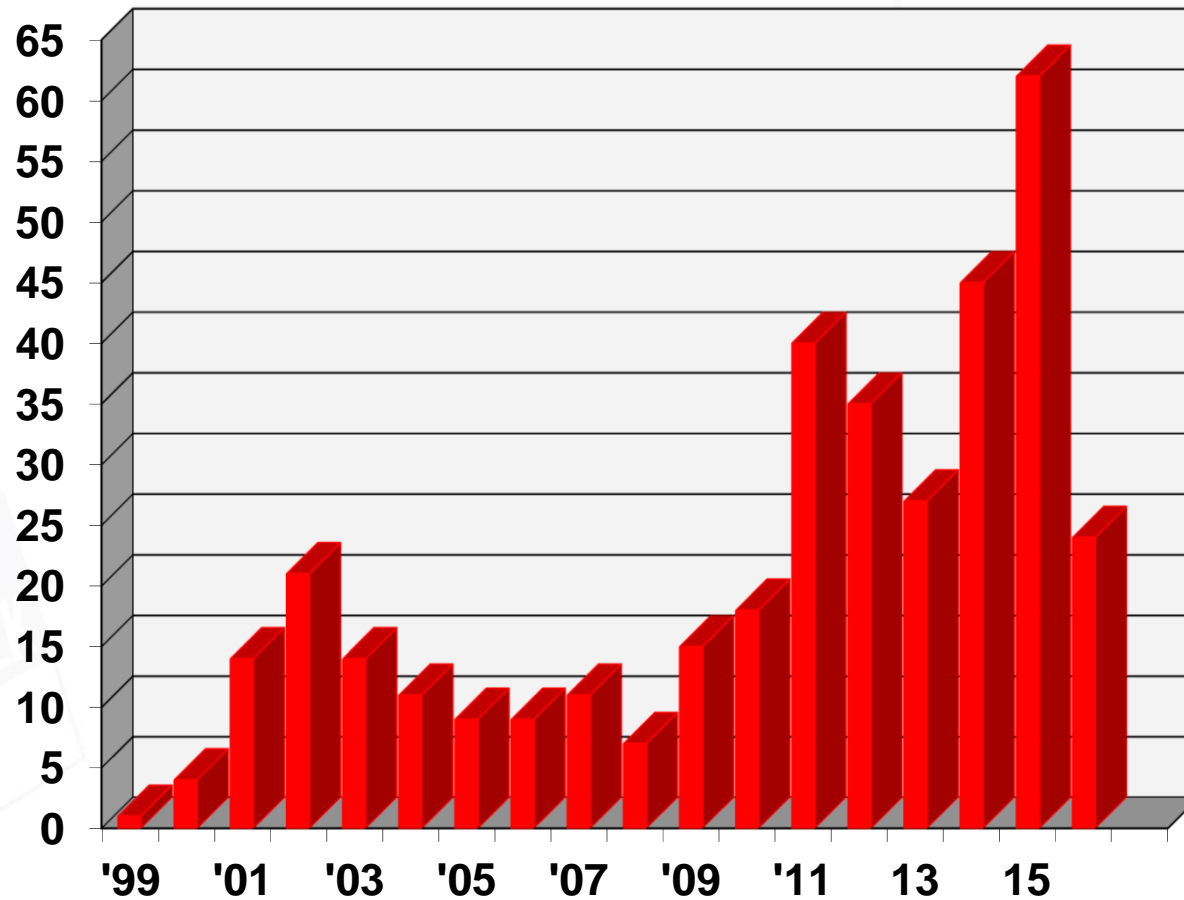
The Risks of Uncontrolled Allergens

- Regulatory risk – undeclared allergens can lead to product recalls, FDA audits, etc.
- Business risk - loss of customers, law suits, failed audits (SQF, etc.), cost of product recalls, loss of consumer confidence, loss of retail space for products with your ingredients, allergen control/sanitation, down time, etc.
- Health risk – undeclared allergens can cause consumers to have reactions (some of which can be severe and even fatal!)

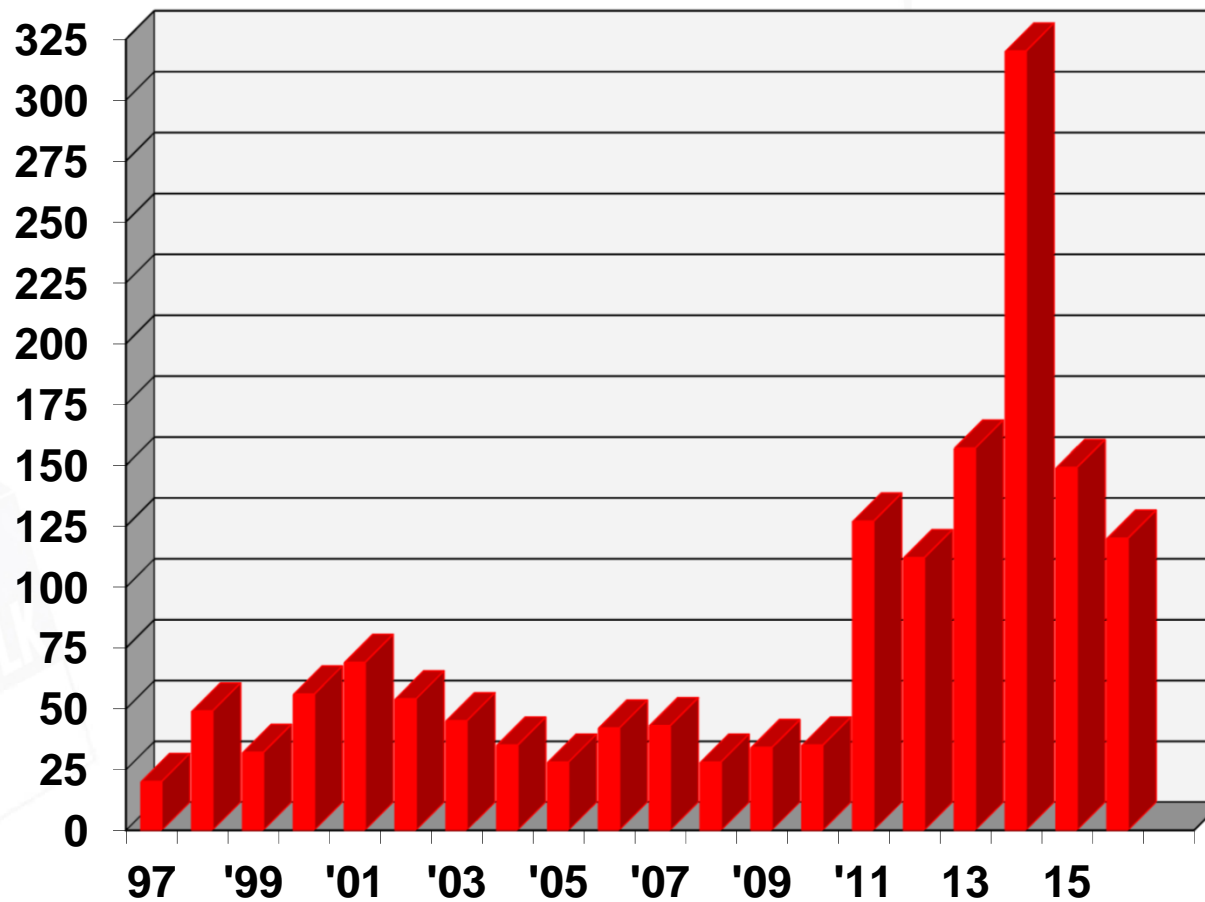
U.S. FDA Food Allergen Recall Incidents Calendar Years: 1988-2016



FSIS/ USDA Food Allergen Recalls Calendar Years 1999-2016



Canadian Food Inspection Agency: Food Allergen Recalls Calendar Years 1999-2016



Typical Symptoms of IgE-Mediated Reactions

Skin:

- Urticaria (hives)
- Eczema (rash)
- Angioedema (swelling)
- Pruritis (itching)

GI Tract:

- Nausea
- Vomiting
- Abdominal pain
- Diarrhea

Respiratory:

- Asthma
- Rhinitis (runny nose)
- Laryngeal edema (swelling of the throat)

Cardiovascular:

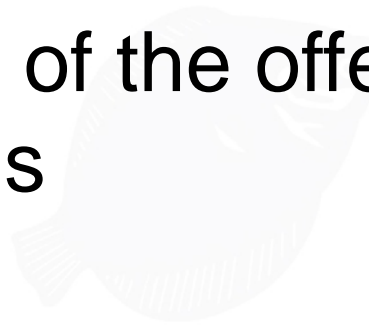
- Hypotension (low blood pressure)

Multiple Organ Systems:

- Anaphylaxis or Anaphylactic shock

Exquisite Sensitivity of Some Food-Allergic Individuals

- Trace amounts of the offending food will trigger reactions



How Much is Too Much?

Milligram amounts!
(ppm concentrations)



Dose of Peanuts Causing Reactions in Peanut-Allergic Individuals



0.2mg
(0.05 mg)

0.4mg
(0.1 mg)

1.0mg
(0.25 mg)

5.0mg
(1.25 mg)

25mg
(6.25 mg)

100mg
(25 mg)

400mg
(100 mg)

Lowest Eliciting Dose in mg whole peanut (**mg peanut protein**)

Percent of Peanut-Allergic Population That Would React To Dose

0.3%

1%

4.25%

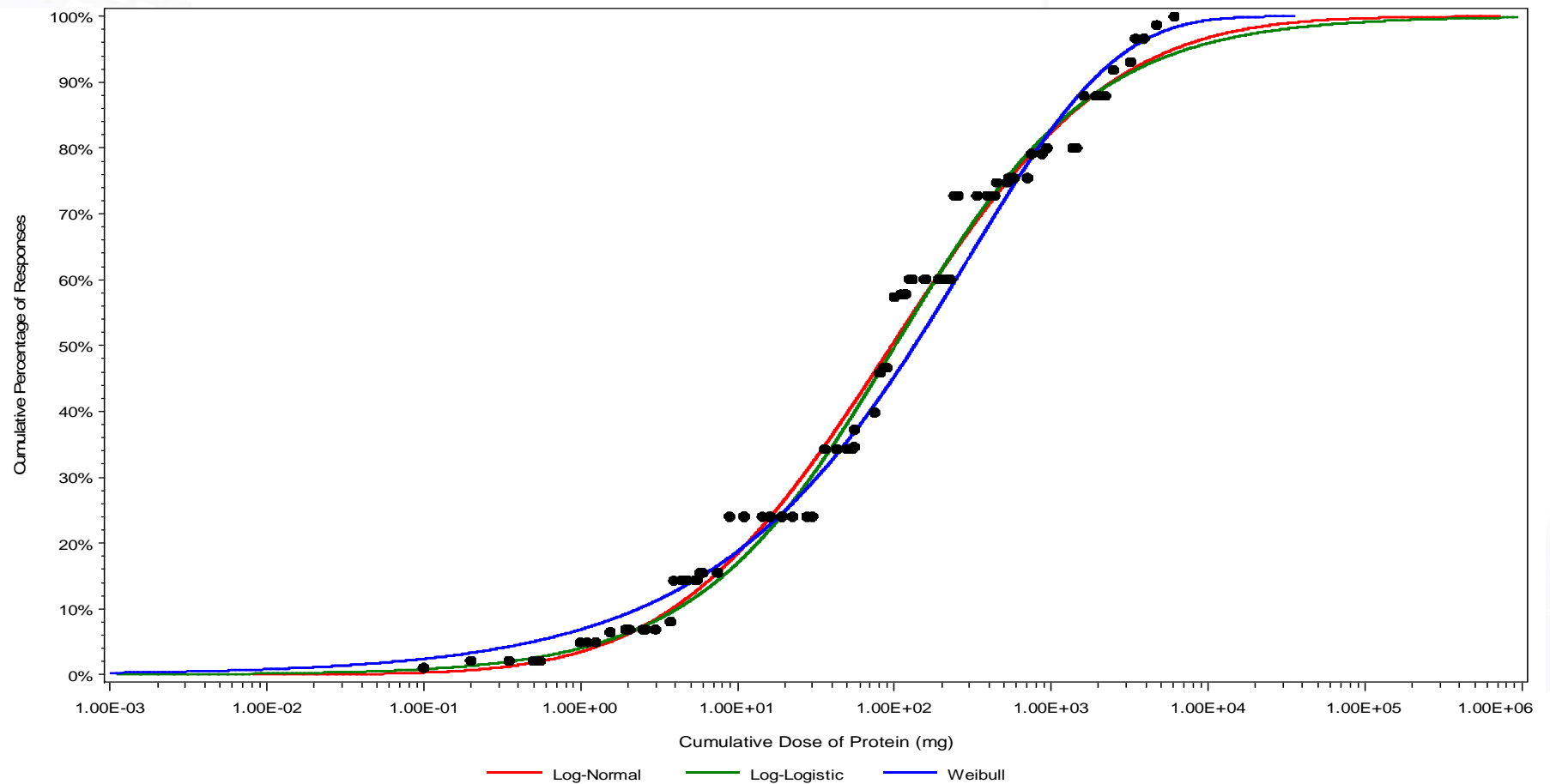
14%

30%

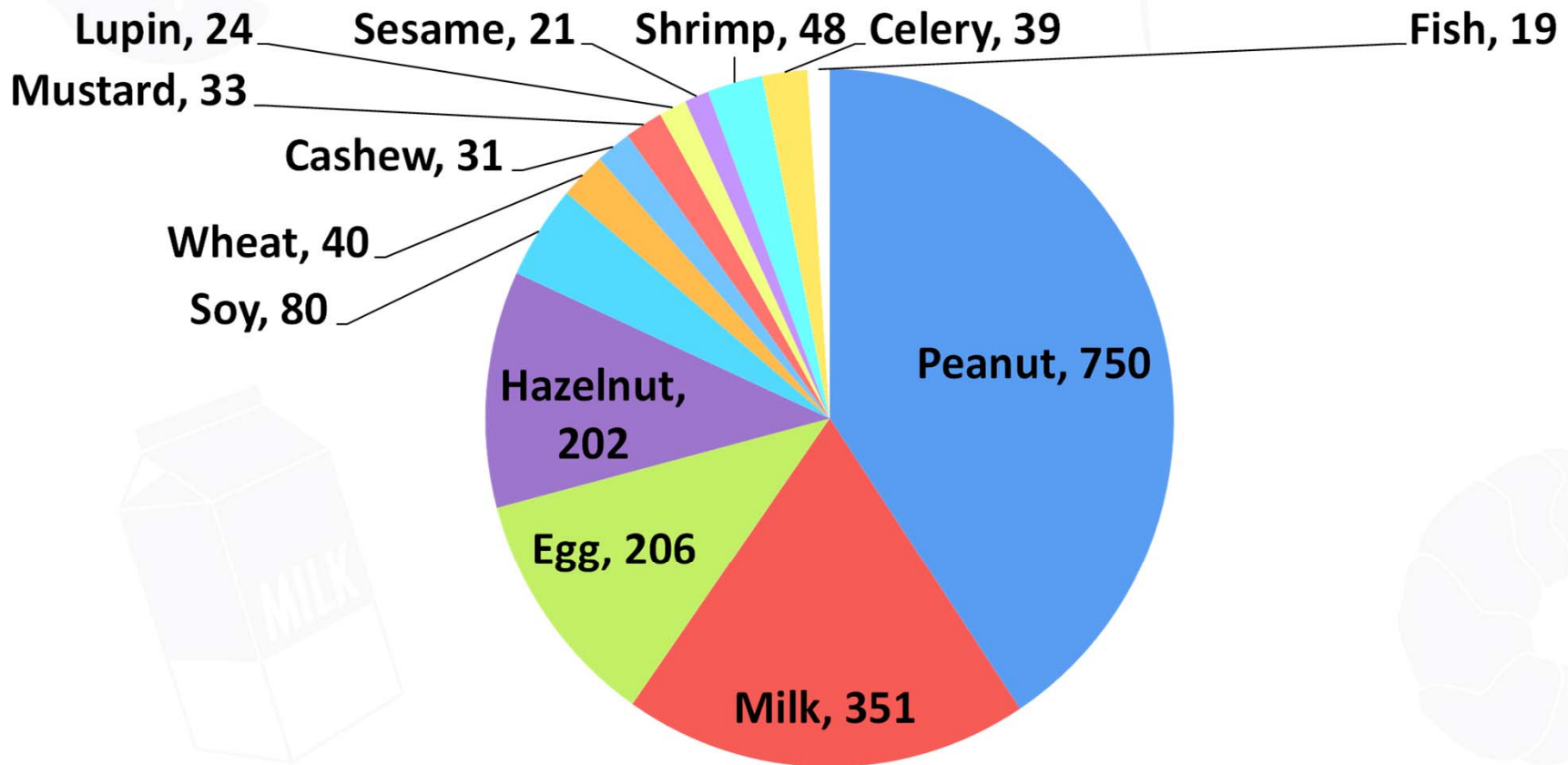
50%

Ballmer-Weber and Hourihane

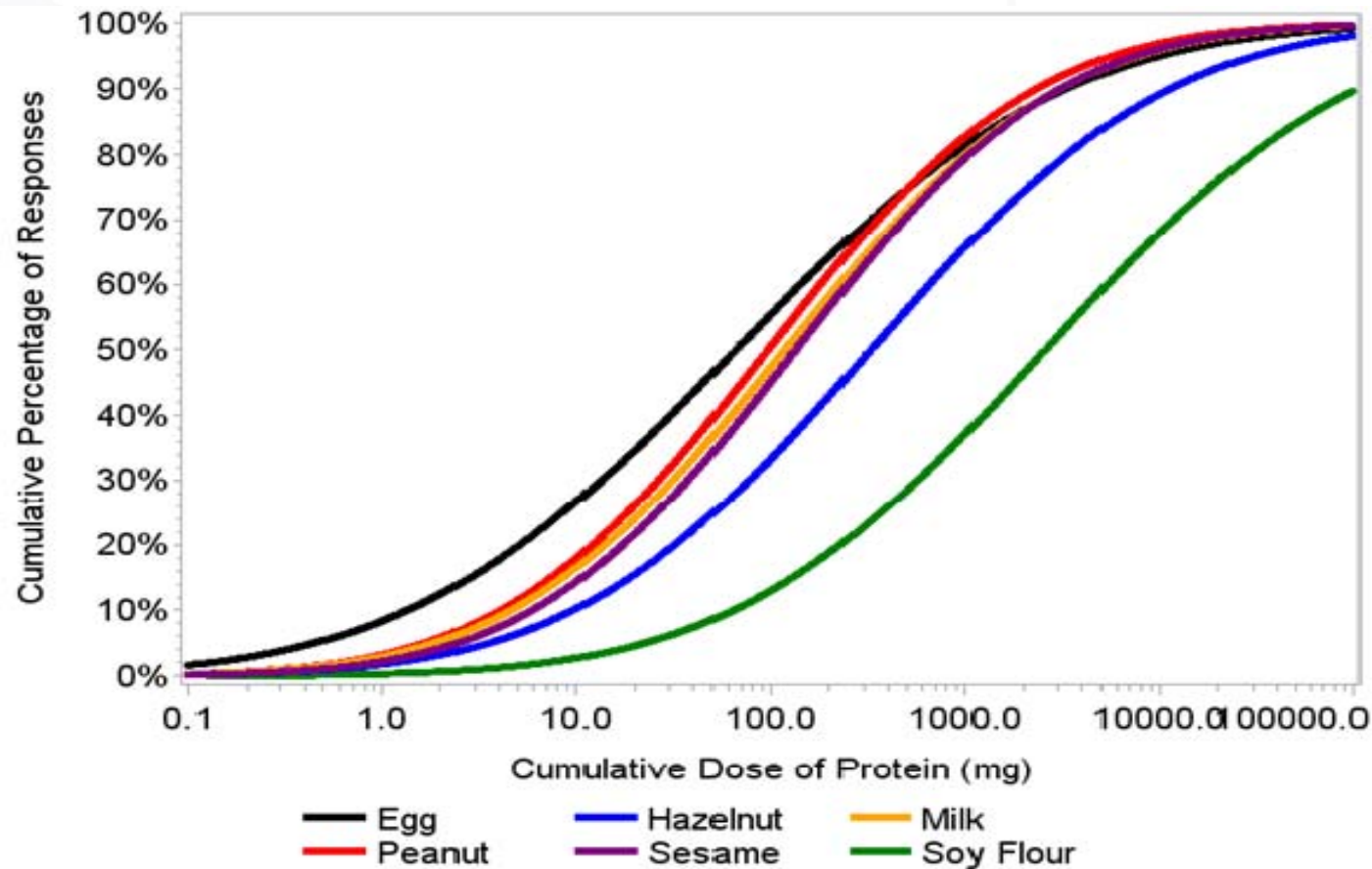
Peanut Threshold Population Distribution (expressed as mg peanut protein)



Number of Available Threshold Data Points



Dose Distributions for Various Food Allergens: Not all food allergens are created equal



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Unexpected Sources of Gluten

- Mixed grains and other commodity crops
- Gluten-free oats
- Fermented ingredients: enzymes, bacterial cultures, etc.
- Yeast
- Whey protein concentrate
- Flavors
- Products made in shared frying oil
- Bacon!!
- Tea!!!!
- Spices especially from international sources
 - Cumin

Unexpected Sources of Peanut

- Pickle relish
- Honey
- Baby carrots
- Chocolate liquor
- Herbal tea bags
- Mosquito coils – is inhaling smoke dangerous?
- Lawn aeration treatments
- Foam insulation for buildings
- Gum Arabic (gum acacia)
- Spices
 - Cumin (ground and whole seed)
 - Garlic powder

Commodity Commingling Common Examples

- Wheat in oats
- Soy in wheat
- Soy in corn
- Wheat in millet
- Wheat in sorghum
- Peanut in wheat
- Many others

Commodity Commingling Sources

- Grown on the same farms
- Harvested at the same time of year
- Harvested with shared equipment
- Transported in the same trucks
- Stored at the same grain elevators
- Shipped in the same rail cars
- Impossible to separate

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The Peanut in Wheat Flour Story in North America

Initial Peanut in Wheat Flour Situation

- March 2016 – A restaurant chain decides that they want to sell peanut/nut-free cookies in their outlets; ask bakery supplier to produce the cookies
- Bakery makes the cookies and sends for analysis; unexpectedly low ppm levels of peanut are found
- Bakery has retains of ingredients and finds peanut residues in wheat flour
- Wheat flour from a milling facility in Georgia

Peanut in Wheat Flour – Recalls Begin

- Bakery informs miller of situation
- Bakery tests other bakery products and find peanut residues in several products
- Bakery files RFR report with FDA
- Results in several recalls of products made by bakery but distributed by other companies
 - i.e restaurant chains and retail companies.

Peanut in Wheat Flour – The Mill

- Mill uses mixture of Georgia soft wheat and northern hard red spring wheat
- Mill has a limited number of retain flour samples from dates involved in bakery products (basically months of March/April)
- Mill had shipped flour to numerous bakeries during the fateful month, mostly by truck
- Over half of mill retain samples contain detectable peanut at levels up to ~25 ppm peanut

Peanut in Wheat Flour – The Mill

- FDA visits mill takes limited number of samples and finds similar low levels of peanut in some of these samples
- Even though allergy risk appears to be low, FDA proposes that mill should do Class II recall of the flour from March/April
- Mill proceeds with Class II recall and notifies all customers who received wheat flour during the critical period; customers advised to test finished products and consult with FDA

Peanut in Wheat Flour – 2nd Wave

- Various companies test finished products; most find low levels of peanut but some samples contain higher levels
- Only one company has sufficient data to track the mill's flour by date and truck load and they find detectable peanut only in certain loads from certain dates
- Quantitative risk assessments done by FARRP reveal low risk but near 1% due to high levels of wheat flour incorporated into certain products

Peanut in Wheat Flour – 2nd Wave

- Risk Ex. 1: cookies
 - Assume 25 ppm peanut (6.25 ppm peanut protein) in wheat flour
 - 35-70% wheat flour in cookie formulations
 - Assume 50% = 3.1 ppm peanut protein in cookie
 - Average consumption = 30g

$30\text{g} \times 3.1 \text{ ppm peanut protein in cookie} = 0.09 \text{ mg peanut protein}$

$\text{ED01} = 0.2 \text{ mg peanut protein}$

Peanut in Wheat Flour – 2nd Wave

- Risk Ex. 2: pretzels
 - Assume 25 ppm peanut (6.25 ppm peanut protein) in wheat flour
 - 90% wheat flour in pretzel formulations = 5.6 mg peanut protein
 - Average consumption = 30g

30g x 5.6 ppm peanut protein in pretzel = 0.2 mg peanut protein

ED01 = 0.2 mg peanut protein

Peanut in Wheat Flour – 2nd Wave

- One company receives 2 alleged consumer complaints about donuts from affected lot but other companies have no complaints
- Despite low risk and existence of USDA Grain Standards, FDA prompts Class I recalls for undeclared peanut in numerous products from multiple companies – cookies, pretzels, crackers, etc.

Peanut in Wheat Flour – 3rd Wave?

- So far, FDA has made no effort to expand this investigation to other lots from the Mill, other flour mills, or other flour-containing products; seem to be considering it as an isolated event
- But in reality, it is likely not isolated
- Milling industry has been observed occasional peanuts in cleaning house
- Root cause remains unknown
- But, affected baking companies have low tolerance for recalls and are beginning to test flour

Past Examples of Potential Business Risk

- Major restaurant chain tried to source soy-free breading for fried items (unsuccessful)
- Major retail grocery chain wanted to declare presence of soy in wheat-derived bakery products (FARRP talked them out of the idea)
- Food company investigating allergen control changeover found even higher risk from commodity contamination of soy in wheat
- Major restaurant chain tried to make peanut-free cookies (the recent recall)

Past Examples of Potential Business Risk

- CFIA conducted random allergen testing of wheat-based products and found undeclared soy; several recalls sought; at least one was conducted; source of soy residue was clearly commodity contamination
- Irish Food Safety Authority tested wheat- and corn-based imported products for soy residues and found presence of undeclared soy; no recalls but posted notices on their public web site
- FSAI has asked EFSA to investigate threshold levels and desirability of action levels; EFSA agrees (2012)
- FDA supports recalls for wheat flour-based products containing low levels of peanut despite knowledge that it is commodity comingling

Food Allergies and Commodities

- Does any real risk exist?
- Quantitative risk assessment can now be used to evaluate magnitude of risk
- QRA not yet fully supported by FDA or CFIA

Development of Risk Assessment Approaches for Food Allergens

- 2007 workshop on risk assessment approaches
 - EuroPrevall, ILSI-EU and UK FSA
 1. Safety Assessment Approach
 2. Benchmark Dose (BMD) and Margin of Exposure (MoE) Approach
 3. Probabilistic Approach
- Workshop concluded that the BMD/MoE and probabilistic approaches had the most merit
 - Rely upon low-dose extrapolation from dose-distributions of clinical thresholds rather than a single point estimate

Risk Assessment

- a function of the exposure dose (mg of protein from the allergenic source) compared to the threshold dose (mg of protein from the allergenic source)

Exposure Dose < Threshold Dose = no predicted reaction

Exposure Dose \geq Threshold Dose = a predicted reaction

- Quantitative risk assessment can evaluate the risk on an individual or population basis

Input Parameters:

- Clinical threshold data from low-dose food challenges
 - *Note: data from food-allergic individuals rather than extrapolation from animal models as in classical toxicological approaches
- Exposure Assessment
 - Food intake
 - Level of contamination

Secondary Input Parameters

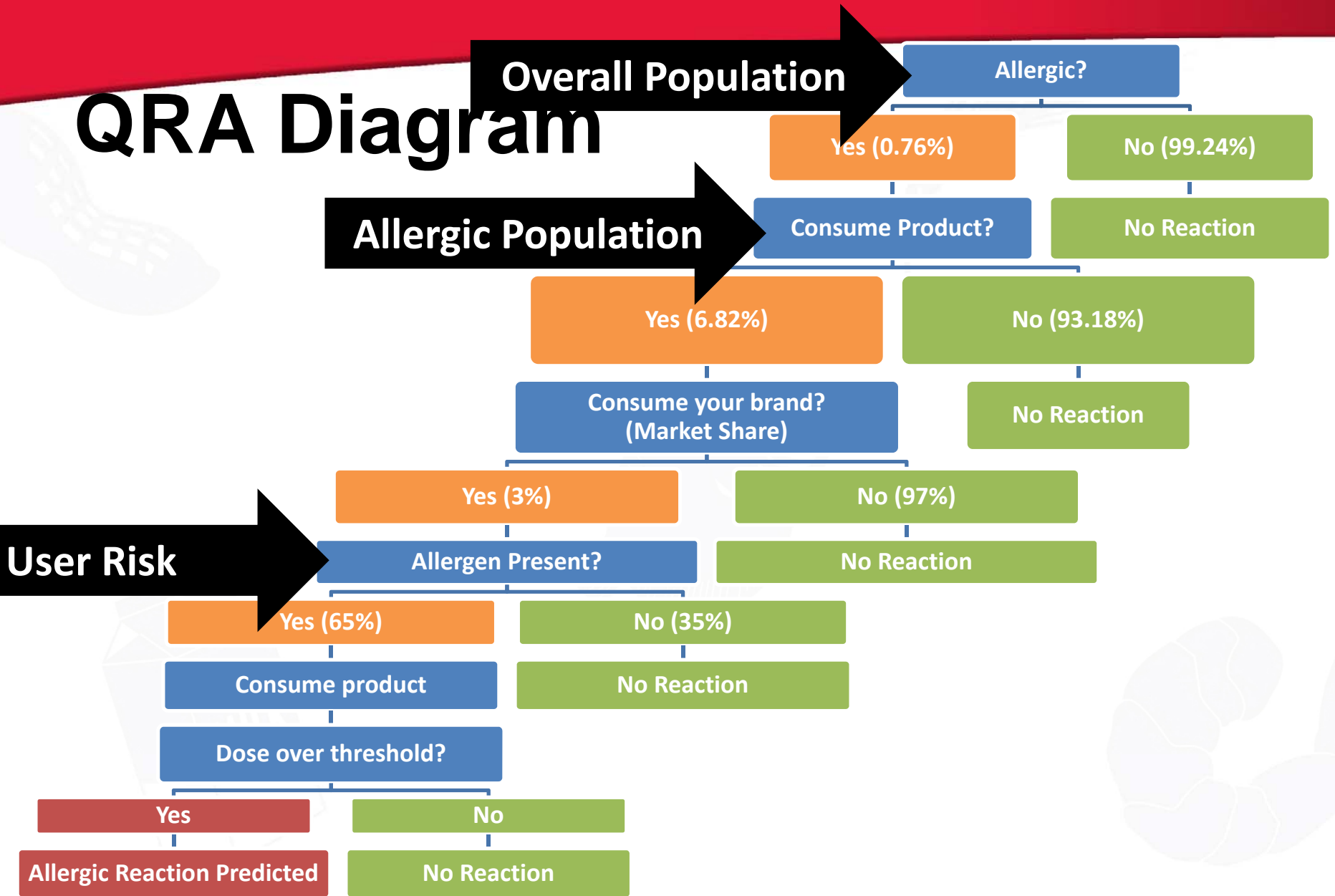
- Prevalence of the Food Allergy
- Market Share for Specific Product in Category
- Number of Packages of Food Manufactured
- Propensity to Buy Advisory Labeled Products



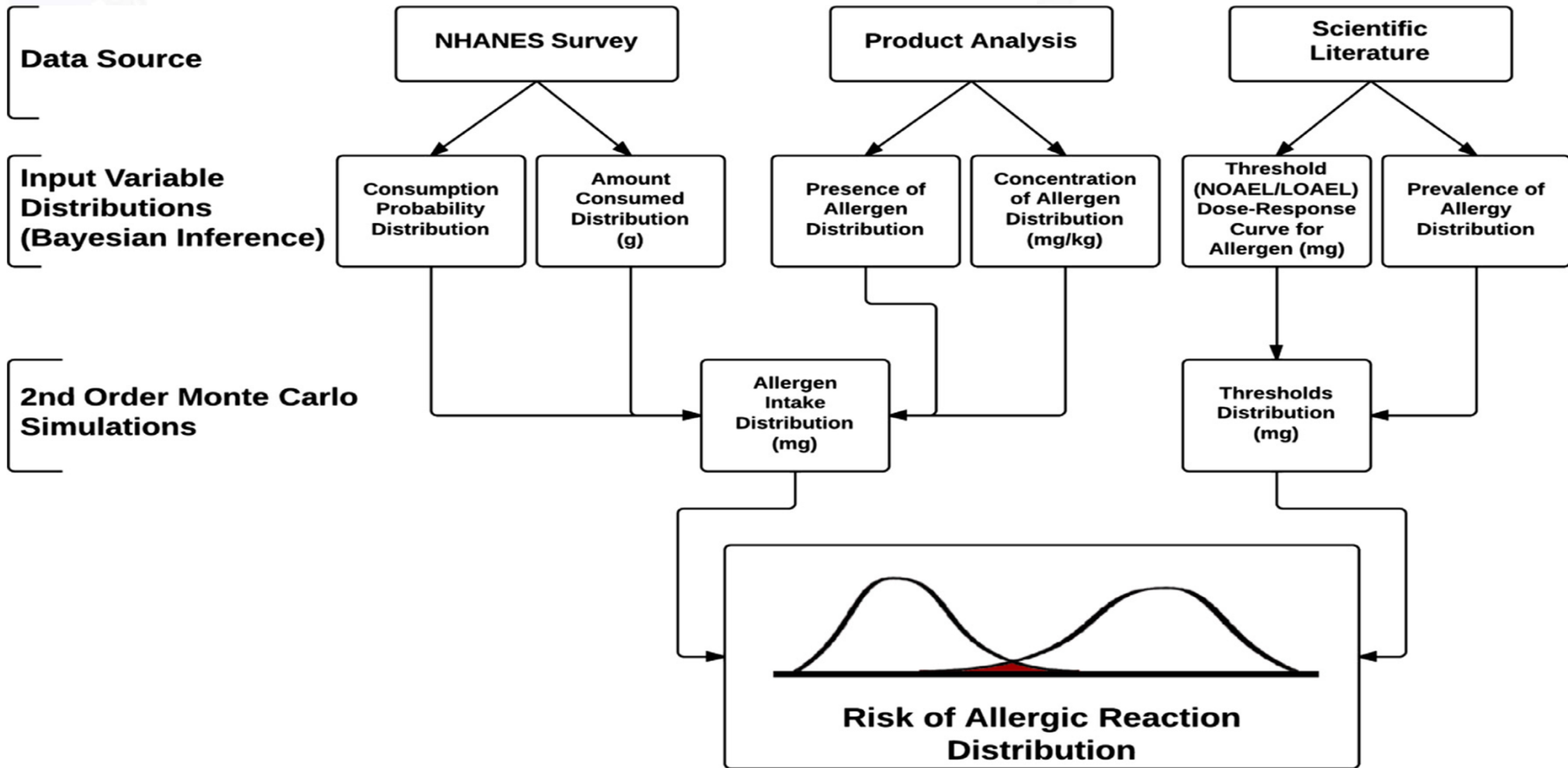
Expressions of Risk

- **User Population Risk**
 - Assumes everyone is allergic and consumes the product
- **Allergic Population Risk**
 - Assumes everyone is allergic but a specific percent (%) consume the product
- **Overall Population Risk**
 - Assumes a percent (%) of people are allergic and a specific percent (%) consume the product

QRA Diagram



Quantitative Risk Assessment



Conclusions

- QRA provides an in-depth analysis not available with previous methods
 - Integrates variability and uncertainty of inputs into the risk assessment model for a more realistic estimate of potential risk
- QRA is flexible and applicable to a wide range of scenarios
- QRA enables risk assessors to make an informed decision based on the true risk of a product

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Thank You for Your Attention

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