

A View Toward the Future of Food Allergen Management

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Food Allergies Are a Serious Public Health Concern

- Numerous consumers have IgE-mediated food allergies on a worldwide basis – perhaps 6-8% or more in some countries
- The prevalence of food allergies is growing rapidly
- The prevalence of multiple food allergies is also increasing
- Reactions can occasionally be quite severe, even fatal
- The prevalence of severe reactions is also increasing rapidly
- Reactions happen immediately after ingestion
- Threshold dose for provoking a reaction is quite low (but not zero)
- Avoidance is the only current strategy for reaction prevention
- Allergic consumers are diligent label readers



3 Key Elements of Public Health Risk for Food Allergy

Prevalence

Severity

Potency

The **Single** Key Element of Food Allergen Risk Management

Potency

If allergen residue levels are kept below some “safe” level, then reactions will rarely happen, those reactions will be mild and transitory, and severe/fatal reactions will never occur

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It's all that simple and it's all that hard

Food Allergen Risk Management

The focus should always be on the food-allergic consumer

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What Do/Should Food Allergic Consumers Want?

- Abundant, varied, and safe food supply
- Clear labels (including precautionary labels – PAL)
- Labels linked to risk
- Food companies that have the capability to provide safe foods for allergic consumers or who will clearly label foods that are not safe
- Scientific- and risk-based regulatory enforcement

How Do We Get There?

First and Foremost

- We have to agree on what is safe – a level of allergen residue that protects all allergic consumers from severe reactions and the vast majority of consumers from any reaction
- “We” starts with food-allergic consumers – the key stakeholder

How Do We Get There?

- We have to have a system to convert that safe level into clear, risk-based food labels that are easily interpretable by allergic consumers
- Ideally we have international harmonization on the definition of safe (and on the implementing system)
- We must have appropriate regulatory enforcement tools (detection methods and well trained auditors)

How Do We Get There?

- Food companies, on a global basis, must acknowledge that undeclared food allergens are a public health risk and must develop a food allergy safety culture within their organizations
- The global food industry must be trained and competent in the management of food allergens to assure that all food manufacturers can consistently make safe foods
- Note: This approach focuses on the packaged food industry but restaurants/other retailers could follow

Where Do We Stand Now?

- On the precipice in my view
- We have developed much of the needed data, methods and risk assessment approaches
- We have the technical elements of a risk management system – VITAL
- It seems that we only need to realize that we have all of these inputs and use them to initiate the system
- But recognition probably precedes consensus
- We have the knowledge to improve the lives of food-allergic consumers starting tomorrow. Will we?

Where Do We Stand Now?

Data, Methods and Risk Assessment

- Individual thresholds on 1000s of food-allergic subjects
- Modeling approaches to use those data to predict population thresholds
- Population thresholds allow us to predict safe doses
- Suitably sensitive, specific analytical methods
- Excellent consumption data for some countries
- Quantitative risk assessment and simple safety assessment methods

Where Do We Stand Now?

Data, Methods and Risk Assessment

Food Industry

- Hazard assessment tools
- Safety assessment approaches
- Lateral flow devices
- 3rd party labs for quantitative analysis
- Confirmatory methods (mass spectrometry)
- Identification of allergen GMPs
- Identification of allergen preventive controls
- Ability to develop allergen control plans

Where Do We Stand Now? Implementation System

- VITAL
- Could be expanded beyond PAL decisions to become an industry safety assessment system
- VITAL Calculator links analytical data to Reference Doses predicted from population thresholds
- Needs to be more widely implemented by food industry
- Could be linked with hazard assessment and allergen control plan targets
- Could also be used by global regulatory agencies

Why Haven't We Implemented a System When We Have So Much Data?

- Lack of consensus on safety of Reference Doses
- Public health authorities need to be the leaders for implementation, not the laggards
- Public health authorities in some countries continue to attempt the impossible (regulate to zero) and end up chasing phantom hazards while real hazards can pass through unnoticed
- Food industry will be reluctant if regulatory risk persists

Can We Move Ahead?

- Uncertain, global consensus and international collaboration are challenging
- Consumers must accept safe Reference Doses
- Public health authorities must move first but consumers probably need to push them
- Codex Alimentarius Commission and Codex Committee on Food Labelling could play important role
- Food industry must move beyond paranoia and toward risk-based approach

What Happens If We Delay?

- Use of PAL proliferates globally
- PAL not risk-based because we don't have a risk-based system
- Consumers stress about unexpected reactions
- Consumers denied access to many safe foods
- Regulators and food companies issue recalls for safe products because they are chasing zero
- But the world of food is not universally safe

Teenager's Fatal In-Flight Reaction Raises Food Allergy Labeling Loophole



Photograph: theguardian.com

“Daddy, help me, I can't breathe”: Family blames mislabeled food for death of 15-year-old with sesame allergy

Boy, 3, Allergic to Dairy, Dies After Eating Grilled Cheese at Pre-K



Photograph: Living Allergic ,November 16, 2017

Tragic Spring: 3 Food Allergy-Related Deaths

After 11-year-old boy's sudden death, mom warns about food allergies

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