

# A View Toward the Future of Food Allergen Management

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3<sup>rd</sup> Food Allergen Management Symposium  
Melbourne, VIC, Australia  
May 14, 2019

# 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

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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
- 3<sup>rd</sup> 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

[farrp.unl.edu](http://farrp.unl.edu)