Food Allergy: From Thresholds to Action Levels

ILSI Europe Food Allergy Task Force

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Scientific Project Manager

2013 ILSI Annual Meeting Miami, FL
Food Allergy field before 1990’s……
# Risk assessment of allergenic foods: Evolution

## Hazard identification
- **Early 1990s**: Nordic list
- **1995**: FAO-WHO consultation – **Codex List (1999)**

## Hazard characterisation
- **1997**: Peanut threshold study (Hourihane et al)
- **1999**: 1st Threshold conference
- **2002**: Dose-distribution feasibility (Bindslev-Jensen et al)
- **2007**: Considerations on use and interpretation of dose-distribution data (Crevel et al)

## Risk assessment
- **2008**: FDA Threshold Working Group: “the quantitative risk assessment-based approach provides the strongest, most transparent scientific analyses to establish thresholds for the major food allergens”
- **2009**: Europrevall-FSA workshop (Madsen et al)
- **2011**: VITAL Scientific Expert Panel

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*Image [Link](https://www.ilsi.org) [Source](https://www.ilsi.org) [Ethics](https://www.ilsi.org) [Editorial](https://www.ilsi.org) [Policy](https://www.ilsi.org)*
The Facts

- **Global** and **growing** importance to public health
  - 17 million consumers in Europe suffer from food allergies
  - Affects consumers quality of life (mainly children)
  - Greater demands on health service resources

- Consumer health protection lies with **avoidance**
With whom do we work?

European Commission

TNO innovation for life

EUFIC

European Food Information Council

Health Canada
Santé Canada

Food Standards Agency

BfR

farrp

food allergy research & resource program

EAACI

ILSI Health and Environmental Sciences Institute (ILSI - HESI)
Expert Group “From Thresholds to Action Levels”
An idea whose time had come!

- Risk management of allergens was **failing**…
  - Allergic consumers disliked precautionary labelling and the way it limited food choices
  - It was **losing credibility** and hence effectiveness
- Yet…
  - We had **more data** than ever and both its volume and quality were growing
  - **Tools** to analyse these data were available and their use was beginning to be well understood

- So what was holding things back?
Objective of the Expert Group

- To develop a **consensus on quantitative action levels** for use in the management of allergenic foods

  - Clear, agreed and reasonable harmonised standards which will
    - Benefit allergic consumers and food manufacturers
    - Serve as a scientific source for regulatory instances when considering setting thresholds for allergens.
Methodology

a. Use as a model the VITAL review report (Allergen Bureau)

b. Particularly explore:
   o Quality of threshold data gathered, including the reliability of analytical methods used
   o Consumer behaviour: how do allergic consumers make their food choices, e.g. interpreting labelling?
   o Uncertainty factors: factors that effect sensitivity
   o Geographical variation in prevalence
   o Identify research gaps

c. Use probabilistic risk assessment models with data from various countries (e.g. NL, DK, USA, etc.)
Workshop
“From thresholds to action levels”

❖ Aim:
To illustrate the journey the EG has taken and seek endorsement of resulting proposals by a wider group of stakeholders

❖ In collaboration with:
Overall Conclusions

- Sufficient data exist to generate reasonably reliable dose distributions.
- Existing data are also of sufficiently good quality for this purpose.
- Data come from allergic human subjects; no need for extrapolation as in other safety studies.
- Exclusion of those with history of severe reactions won’t have much effect on distributions (small numbers).
- Can estimate ED10, ED05, and sometimes ED01.
Expert Group Output

In 2013:

- **Paper 1**: Establishment of reference doses for food allergens in line with standard toxicological principles (i.e. NOAEL, LOAEL, referencing dose, etc.)
- **Paper 2**: Model for translating reference doses to action levels
- **Paper 3**: Intake data requirements for use in food allergen risk assessment
- **Paper 4**: Clinical implications of defined reference doses

In the near future:

- **Paper 5**: Best relevant data for acute exposure to food allergens
Other Projects of the Food Allergy Task Force
**“Scientific criteria applying to food allergens”**

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<td>Criteria for identifying allergenic foods of public health importance</td>
<td>Evaluation of scientific criteria for identifying allergenic foods of public health importance</td>
<td>MINI -WORKSHOP Application of Scientific criteria to food allergens of public health importance</td>
<td>Prioritization with respect to public health relevance of allergenic foods</td>
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- Y.J. Chung *et al.*, Application of Scientific criteria to food allergens of public health importance. *(In press)*

- Focus on QUALITY of EVIDENCE
- Focus on ASSESING the quality of evidence
- Focus on the PUBLIC HEALTH IMPORTANCE of the criteria
- Create a TOOL to prioritise the inclusion of allergens in risk assessment

**ILSI Europe**
Allergenicity and processing

Goal
To increase the knowledge of the impact of different types of processing on the allergenic potential of certain allergens

Desired outcome
a. Develop a framework that can help risk managers to identify whether the applied processing parameters are likely to as mitigate or aggravate the allergenicity of particular foods
b. Establish clear, agreed and reasonable assessment tools
iFAAM Partner (2013-2017)

Integrated Approaches to Food Allergen and Allergy Risk Management (iFAAM)
Coordinator: University of Manchester, UK (Prof Clare Mills)

❖ How will ILSI Europe contribute?
Key role on Task Stakeholder Platform and Engagement within the dissemination work package

✓ Set up Experts Groups to address particular elements of the project
e.g. Expert Group on making “may contain” transparent
✓ Organise Consensus Workshops followed by publication
e.g. Consensus on Thresholds and action levels
✓ Produce publications and disseminate
e.g. reports. Peer-reviewed articles, monographs, etc.
Food Allergy field in 2013
## Acknowledgements – Task Force

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<tr>
<th>Name</th>
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Thank you for the attention!

The ILSI Europe team