“Food Allergy: From Thresholds to Action Levels”

Workshop objectives

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Risk assessment of allergenic foods: Evolution

Hazard identification

- Early 1990s: Nordic list

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
Background and origin of Expert Group

• Food allergen risk assessment at the heart of ILSI Food Allergy Task Force since its inception

• Significant Task Force contribution to
  – Identifying the data requirements (type, quality, volume)
  – Developing the tools to analyse those data meaningfully
An idea whose time had come

- Risk management of allergens was failing to achieve its objectives
  - Allergic consumers disliked precautionary labelling because of its pervasiveness
  - 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?
Why formulate action levels?

- Greater consistency of allergen management and labelling for consumers.
- Well-defined and consistent standards for allergen management for the food industry
- Better allergen management for all food industry
- Safer products for food-allergic consumers
Objective of the Expert Group

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

Leading to

• clear, agreed and reasonable harmonised standards which will
  – benefit allergic consumers and food manufacturers
  – And serve as a scientific source for regulatory instances when considering setting thresholds for allergens.
The Expert Group’s role

- **EG’s task was to:**
  - consider the available data and tools and
  - propose how these could be used to derive thresholds for managing allergens.

- **EG was formed of four groups of stakeholders:**
  - Regulators
  - Clinicians/health care practitioners
  - Patient group representatives
  - Industry
What the Expert Group did

• Reviewed current schemes with particular emphasis on how levels have been defined.
• Considered extent to which levels are adequately protective
  – what is the evidence base?
  – what pieces of evidence need to be considered?
  – What risk assessment approaches have been used?
  – What possible uncertainty factors could affect the data and how should they be handled
• Formulated an approach to derive action levels for additional allergens (EU list in first instance).
The workshop

• During workshop, presentations to illustrate the journey the EG has taken and resulting proposals

• Report of this work distributed
  – very much work in progress.
  – will form basis for one or more peer-reviewed publication(s), based on workshop outcomes and conclusions
  – you have been invited to participate and contribute.
Some questions for the workshop to consider

• Could stakeholders agree that a consistent, transparent set of reference doses (as a basis for action levels) would be a desirable outcome, in principle?

• Are data from food challenge studies the appropriate foundation from which these action levels can be derived? If not, what type of data would be?

• Do sufficient data exist to move forward and better estimate the risk to the allergic population for the allergens specified in the report?

• If there are sufficient data, do the proposed reference doses constitute a reasonable first pass to minimise risk to the allergic consumer while maintaining food choices?