Introduction to ILSI’s Food Allergy Programmes

IUNS 20th International Congress of Nutrition 2013
19 September 2013
Food Allergy Session

Prof. Diána Bánáti
Executive & Scientific Director, ILSI Europe
Through history...

Hippocrates (460-370 BC)
First reported that “cow’s milk could cause gastric upset and urticaria”

Galen (131-210 BC)
Described a case of intolerance to goat’s milk

Lucretius (96-55 BC)
“What is food to one might be fierce poison to others”
Food allergy is of high importance

Allergens are a continuing safety concern to both allergic consumers and the food industry

• 17 million consumers in Europe suffer from food allergies
• Anaphylaxis: the most severe manifestation of an allergic reaction – foods account for 25-60 %
• Peanuts are the leading cause of severe allergic reactions, followed by tree nuts, shellfish, fish, and eggs
• Consumer health protection lies with avoidance
Effective management of allergens still poses major scientific challenges

<table>
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<tr>
<th>Question</th>
<th>Answer</th>
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<tr>
<td>Which allergens are of public health concern?</td>
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<td>How do we measure the real incidence and health impact of allergic reactions in Europe?</td>
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Why do we need to manage food allergens? (1/2)

• To ensure that food-allergic consumers can make safe choices by having both:
  • the right allergen information about foods (credible, trustworthy, accurate)
  • access to food products which are safe and the right information about their condition (e.g. severity, which foods to avoid)
Why do we need to manage food allergens? (2/2)

• Better Quality of Life among people with food allergy

• Consistent approach to allergen management across industry
  • Harmonised application of precautionary labelling; i.e. “may contain” means the same on any product

• Improved understanding of and trust in allergen labelling
The “riddle”...

May contain

Puede contener

可能含有

“………”

tartalmazhat

peut contenir des

Μπορεί να περιέχει

kan

Può contenere
What does it mean in practice? (1/2)

• Zero risk is not possible in practice
  • Food allergens cannot be excluded from the food supply

• “Precautionary labelling” (such as “may contain”) is a potentially valuable mitigating measure but has severe limitations
  • Credibility in inverse proportion to extent of use
  • Therefore need to find a balance that maximises its protective value
Precautionary labelling: Use and effectiveness

Graph, courtesy of R. Crevel
What does it mean in practice? (2/2)

• Build a **risk management framework** based on
  • Identifying the range of allergen doses over which precautionary labelling minimises the overall number of reactions,
  • Choosing realistic, achievable **reference doses**, providing a high degree of protection and resulting in no severe reactions and few mild, self-limiting reactions
  • Communicating these conditions to people with food allergies and those who look after them.
ILSI Europe and its work on Food Allergy
ILSI Europe’s mission
To provide science that improves public health and well-being

- SCIENCE-DRIVEN organisation
- Addressing COMPLEX scientific issues
- Thanks to renowned EXPERTS and scientists
- With COMPLEMENTARY experiences
The ILSI family: a worldwide network
14 branches, 3 entities

5 branches with focus on Food Allergy
Task Force Portfolio

3 pillars, 21 task forces, 32 expert groups

Food Safety
- Addition of Nutrients to Food
- Risk Assessment of Foods*
- Emerging Microbiological Issues
- Environment and Health
- Food Intake Methodology
- Functional Foods
- Novel Foods and Nanotechnology
- Packaging Materials
- Process-related Compounds and Natural Toxins
- Risk Analysis in Food Microbiology
- Threshold of Toxicological Concern

Nutrition
- Dietary Carbohydrates
- Eating Behaviour and Energy Balance
- **Food Allergy**
- Metabolic Imprinting
- Nutrient Requirements
- Nutrition and Immunity
- Nutrition and Mental Performance
- Obesity and Diabetes
- Prebiotics
- Probiotics
- **Public Health** *

Societal aspects
- Consumer Science

* These task forces have not started yet
ILSI Europe
Food Allergy Task Force

► Created: June 1995

► Why? Allergens were an increasing concern for both consumers and the food industry supplying food to consumers


► Objectives
  a) Consider the public health impact of allergenic foods and how it can be mitigated
  b) Identify gaps in knowledge which hinder risk assessment & management of food allergens. Propose work to address identified gaps in knowledge
Food Allergy Task Force: Science-based approaches to allergen risk management

Hazard identification: Which allergenic foods?

Application of Scientific Criteria [on-going]

Scientific Criteria [complete]

Hazard characterisation: How much is too much to how many?

Application of Scientific Criteria [complete]

Eliciting doses [complete]

FARRP / ILSI-NA

Food Intake Methodology Task Force

Education

Allergic reactions Registries [complete]

Risk characterisation: What is population impact of a given amount of allergen?

Exposure assessment: How many are at risk? How much are they exposed to?

Action levels [on-going]

NEW!! [on-going]

Allergenicity & processing

Coeliac and wheat allergy [complete]

Scheme, courtesy by R. Crevel
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
- Can estimate potency such as ED10, ED05, and sometimes ED01

In collaboration with
ILSI Europe Workshop
“From Thresholds to Action levels” (2012)

3 papers submitted in Q2 2013:

- **Paper 1:** Advances in the risk management of unintended presence of allergenic foods in manufactured food products – an overview

- **Paper 2:** Development and evolution of risk assessment for food allergens

- **Paper 3:** Translating reference doses into allergen management practice: challenges for stakeholders
ILSI Europe
EG “Scientific criteria applying to food allergens”

- **2007 - 2008**: Criteria for identifying allergenic foods of public health importance
- **2008 - 2010**: Evaluation of scientific criteria for identifying allergenic foods of public health importance
- **2010-2011**: Application of Scientific criteria to food allergens of public health importance
- **2012-....**: Prioritization with respect to public health relevance of allergenic foods

- **Björksten et al., 2008.** Criteria for identifying allergenic foods of public health importance. *Regul. Toxicol. and Pharmacol.* (51) 42-52
- **Y.J. Chung et al.,** Application of Scientific criteria to food allergens of public health importance. *In press*

- ✓ Focus on QUALITY OF EVIDENCE of data
- ✓ 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
EG “Allergenicity and processing”

• Goal
To better understand the impact of processing on the allergenic potential of certain food allergens

• Desired outcome
  a) Develop a framework for risk managers to identify whether the applied processing parameters are to be considered as mitigating factor or rather an aggravating factor for a given allergen
  b) Establish clear, agreed and reasonable assessment tools

First face to face meeting was on 16 July 2013
Integrated Approaches to Food Allergen and Allergy Risk Management

- **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. on making “may contain” transparent) [M24, Q1 2015]
- Organise Consensus Workshops followed by publication (e.g. on thresholds and action levels)
- Produce publications and disseminate [M24, Q1 2015]
ILSI Europe
Close collaborations

European Commission

TNO innovation for life

EUFIC European Food Information Council

Health Canada

Food Standards Agency

BfR Bundesinstitut für Risikobewertung

ILSI Health and Environmental Sciences Institute (ILSI - HESI)
In summary

• The nature of food allergens precludes their exclusion, or even minimising their presence in the food supply, making zero risk unachievable

• Clear definition of risk management objectives is a prerequisite to successfully achieving them and avoiding unintended (and undesirable) consequences

• Minimising the number of reactions from the unintended presence of allergens is proposed as the overall risk management objective, based on
  • Highly protective reference doses as the threshold for precautionary labelling
  • Excellent communication of risk management framework and its implications to all stakeholders
Other ILSI Branches work on Food Allergy
HESI PATC
(Protein Allergenicity Technical Committee)

Areas of Interest / Research

• Biochemical Parameters associated with allergenic proteins
• Sequence Homology / Bioinformatics evaluations

• Animal Models for predicting human food allergy
• In Vitro Models for predicting allergy
• Detection Methods to support endogenous allergen assessments
HESI PATC Research
2012-2014

- Intra- and Inter-laboratory evaluation of a more physiologically based SGF assay (Academic Medical Center/University of Amsterdam; Bayer SAS)
- Purpose: Address requests by EU guidance to provide a more physiologically relevant pepsin digestion assay to assess novel protein digestion potential.
- 2D-DIGE phase 2 validation with rice (Dr. Reiko Teshima, Japan National Institute of Health Sciences)
- Ring-trial assessment of the 2D-DIGE method (two-dimensional difference in gel electrophoresis) to quantify rice allergens of several rice varieties.
- Evaluation of mouse epidermal stem cells as an in vitro model to predict protein allergenicity (Dr. Raymond Pieters, Utrecht University)
- Quantitative determinations of endogenous soybean allergens (Dr. Jay Thelen, University of Missouri)
Global PATC Impact

HESI PATC Contact:
Nancy G. Doerrer, MS (HESI)
doerrer@hesiglobal.org
ILSI Brasil Activities

• Workshop on Food Allergy
  – May 9th 2013, in São Paulo
  – Regulatory issues, differences among Allergy, Hypersensitivity and Intolerance; Cross Contamination; Allergen management in Food Industry

• Symposium on Allergen management in Food Industry
  – August 8th 2013, in São Paulo
  – Regulatory issues, differences among Allergy, Hypersensitivity and Intolerance; Thresholds and Food Allergens; Allergen Management in Food Industry
Food Allergy

@ ILSI North America
Threshold dose for peanut: Risk characterization based upon diagnostic oral challenge of a series of 286 peanut-allergic individuals

Steve L. Taylor\textsuperscript{a,}\textsuperscript{a}, D.A. Moneret-Vautrin\textsuperscript{b}, Rene W.R. Crevel\textsuperscript{c}, David Sheffield\textsuperscript{d}, Martine Morisset\textsuperscript{b}, P. Dumont\textsuperscript{b}, Benjamin C. Remington\textsuperscript{a}, Joseph L. Baumert\textsuperscript{a}

\textsuperscript{a}Food Allergy Research and Resource Program, Department of Food Science and Technology, University of Nebraska-Lincoln, Lincoln, NE, USA
\textsuperscript{b}Department of Internal Medicine, Clinical Immunology and Allergology, University Hospital, Nancy, France
\textsuperscript{c}Safety and Environmental Assurance Centre, Unilever, Colworth Science Park, Sharnbrook, Bedford MK44 1LQ, United Kingdom
\textsuperscript{d}Statistics Group, Unilever, Colworth Science Park, Sharnbrook, Bedford MK44 1LQ, United Kingdom
Technical Committee on Food and Chemical Safety

WORKSHOP ON
FOOD ALLERGY: FROM THRESHOLDS TO ACTION LEVELS
13–14 SEPTEMBER 2012, READING, UNITED KINGDOM

Organised by ILSI Europe in collaboration with:

ILSI
ILSI Europe
Nebraska Lincoln
ILSI North America
farrp
ILSI Japan
### Estimated Annualized Burden Hours—Continued

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<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
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<th>Total burden (in hours)</th>
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**Dated:** December 10, 2012.

**Ron A. Otten,**
**Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OAD), Office of the Director.**

[FR Doc. 2012-30113 Filed 12-13-12; 8:45 am]

**BILLING CODE 4162-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2012–N–0711]

**Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds; Establishment of Docket**

**AGENCY:** Food and Drug Administration, HHS

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**Instructions:** All submissions received must include the Agency name and Docket No. FDA–2012–N–0711. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

**Docket:** For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number(s), found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Sean McDaid, Chief, Office of Food Safety, FDA.

**Definition:** FDA defines a major food allergen as “[m]ilk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans” and also as a food ingredient that contains protein derived from such foods. The definition excludes any highly refined oil derived from a major food allergen and any ingredient derived from such highly refined oil.

**FALCPA** provides two mechanisms through which ingredients may become exempt from the major food allergen labeling requirement. An individual may petition for an exemption by providing scientific evidence, including the analytical method used, that an ingredient “does not cause an allergic response that poses a risk to human health.” (21 U.S.C. 403(w)(6)(C)).

Alternatively, an individual may submit
Food Allergy

@ ILSI Argentina
EpA2NA Study
(Food Allergy Epidemiology in Argentine Children)

Objectives: The EpA2NA study is a national multi-center project, which goal is to collect the first epidemiological data about food allergies in children from Argentina.

This will allow us to know our reality in order to adopt fundamental guidelines and develop prevention policies.
Expected outcomes: To have a realistic diagnosis of the food allergies situation is of vital importance in order to establish adequate measures from the primary prevention standpoint.

Current data is from different countries, with different cultures and genetics, and that is the reason why is difficult to compare them. This project will allow us to get essential information about this pathology in our country, its prevalence and foods groups involved.
Aims of the session

• Overview of the global effort to review new low dose challenge data and tools to analyse these data and apply them to quantitative risk assessment
Aims of the session

Allergens Prevalence
Clare E.N. Mills, Institute of Inflammation and Repair, University of Manchester, UK

Probabilistic Risk Assessment in Setting Allergen Thresholds
Steve Taylor, Food Allergy Research & Resource Program, University of Nebraska, USA

The Consumer Perspective - Living with Uncertainty
Audrey Dunn Galvin, School of Applied Psychology, University College Cork, IE

Protein Allergenicity
Gregory S. Ladics, DuPont Company, USA (Co-Chair, HESI Protein Allergenicity Technical Committee)
www.ilsie.eu

Meet us at booth #47