ILSI North America

The North American branch of the International Life Sciences Institute (ILSI North America) is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply.
Technical Committee on Food and Chemical Safety

Operational Research Vision Statement:

The Committee promotes a science-based determination of the chemical safety of foods to support the advancement of public health.
ILSI North America Technical Committee on Food and Chemical Safety

Abbott Nutrition
DR Pepper Snapple Group
MARS Incorporated
PEPSICO
Cargill
General Mills
Mondelez International
Hillshire Brands
The Coca-Cola Company
Kellogg's
MONSANTO
senomyx
ConAgra Foods
kraft foods
Nestle
valspar
Unilever
Project - Risk Assessment Approaches to Food Allergen Thresholds

• Work Sessions
  • FDA, FARRP, Clinical Allergist, Risk Assessment Experts, FAAN

• Task 1
  • Literature review and available peanut allergen data-mining to develop a dose-response curve for risk characterization of sensitized population.

• Task 2
  • Acquire other data sets (additional peanut data sets, data sets for milk, egg and wheat).
Project - Risk Assessment Approaches to Food Allergen Thresholds

- Research Foundation
- ILSI
- Research Foundation
- Global Threshold Project
Project Risk Assessment Approaches to Food Allergen Thresholds

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Threshold dose for peanut: Risk characterization based upon published results from challenges of peanut-allergic individuals
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b Safety & Environmental Assurance Centre, Unilever, Colworth Science Park, Sharnbrook, Bedford, MK44 1LQ, United Kingdom
Threshold dose for peanut: Risk characterization based upon diagnostic oral challenge of a series of 286 peanut-allergic individuals

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A R T I C L E   I N F O

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A B S T R A C T

Clinical records of 286 consecutive patients reacting positively with objective symptoms to double-blind, placebo-controlled oral peanut challenges at University Hospital, Nancy, France were examined for individual No Observed Adverse Effect Levels (NOAELs) and Lowest Observed Adverse Effect Levels (LOAELs). After fitting to a log-normal probability distribution model, the ED_{10} and ED_{95} were 14.4 and 7.3 mg (expressed as whole peanut), respectively, with 95% lower confidence intervals of 10.7 and 5.2 mg, respectively. Compared to results from a previous study where the ED_{10} was based upon individual peanut thresholds gleaned from 12 publications, a statistically significant difference was observed between the ED_{50}'s, but not the ED_{10}'s of the two probability distribution curves. The Nancy patient group contains more sensitive subjects than the group from the published literature thus contributing to the observed differences. Minimum eliciting dose-distributions for patients with histories of more severe reactions (grade 4 or 5; 40 subjects) did not differ significantly from those of patients with histories of less severe reactions (grades 1–3; 123 subjects). These data and this modeling approach could be used to establish
FCS Sponsored Scientific Session

Toxicology Forum 35th Annual Winter Meeting

Food Allergens: Thresholds for Adverse Reactions
WORKSHOP ON
FOOD ALLERGY: FROM THRESHOLDS TO ACTION LEVELS
13 –14 SEPTEMBER 2012, READING, UNITED KINGDOM

Organised by ILSI Europe in collaboration with:

ILSI
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farrp
food allergy research & resource program

ILSI
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Japan
### Estimated Annualized Burden Hours—Continued

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

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**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, FDA

**FOR FURTHER INFORMATION CONTACT:**

**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.

**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)).
Thank you!