

Good afternoon, I'm Alison Kretser, Director of Science Programs at ILSI North America. The ILSI North America Food and Chemical Safety Committee has had a long interest in food allergens. As one example, the Committee commissioned an evaluation of a clinical peanut data set containing diagnostic oral challenges of a series of 286 peanut-allergic individuals. This work focusing on the threshold dose for peanut was published in 2010. The peanut dataset was robust enough to demonstrate that no differences were observed in estimates of population threshold doses in peanut-allergic patients with histories of severe reactions compared to those with histories of less serious reactions.

Today my comments will cover four issues under the IOM Committee's statement of task which are of greatest interest to ILSI North America and as a co-sponsor we would like to see these areas addressed in the final report: allergen thresholds, prevalence, major food allergens and education.

### Allergen Thresholds

Establishment of allergen thresholds presents the opportunity to enhance the quality of life for food allergic individuals by reducing the use of precautionary labeling, thereby improving consumer confidence in food labeling, improving supermarket food choices, while maintaining food safety. In response to a 2012 FDA Federal Register Notice, ILSI North America communicated their support for threshold development based on the advances in dose-distribution modeling of controlled food challenge results and the increased availability of low-dose challenge data. Development of reference values in this manner has garnered support from food allergy and risk assessment experts from around the world, as evidenced by the outcome of the "Workshop on Food Allergy: From Thresholds to Action Levels" held in 2012, hosted by ILSI Europe and co-sponsored by ILSI North America, Food Allergy Research Resource Program (FARRP), Health Canada, and ILSI Japan.

Based on the success of these efforts, the greatest advancement would be to have access to clinical datasets from allergy clinics across the US through the establishment of a nationally comprehensive food allergen database. With availability of large datasets, the development of adverse effect distribution curves using advanced mathematical modeling for all of the 8 major allergens becomes possible and would further advance risk assessment.



One of the major questions that is often asked when discussing the establishment of allergen thresholds is cumulative exposure during the course of single eating occasion, i.e., whether an allergic individual may exceed a threshold in a given meal composed of several foods and whether this would be considered a health hazard. It is common in risk assessments to employ uncertainty factors to account, not only for the differences in severities of reactions among food allergic individuals, but also to account for uncertainties in exposure assessment. Uncertainty factors used to establish allergen thresholds will not only account for these scenarios, but will be based on objective, reversible reactions that do not require pharmaceutical intervention. Therefore, any allergen thresholds that may be established will be protective of the food allergic population based on global, clinical, and scientific data.

### Prevalence

ILSI North America believes it is critically important to have a greater understanding of the prevalence of allergic reactions for the eight major food allergens. This will lead to a better understanding of the magnitude of risk. Currently, our ability to identify the prevalence of allergic reactions to the eight major food allergens is lacking or inadequate. We encourage the Committee to engage with those involved with the EuroPrevall study to use a similar framework to determine prevalence rates in the US and Canada. In addition, collecting data from clinical studies will help characterize food allergies and provide information on prevalence. It's critical to recognize the importance of prevalence information and the health impact on the US and Canadian population. In our following comments, we would like to discuss additional tools that may help in our understanding of prevalence rates for food allergens.

The development of a set of validated questionnaires for use in epidemiologic studies of food allergy would be a huge step forward. Currently food allergy research at the population level is severely hampered by the lack of validated tools to measure food allergy prevalence and to link food allergy with other relevant exposures and outcomes. A validated food allergy questionnaire would allow for a vast increase in the quantity and quality of data available for food allergy research.

Introducing the development of a standard reporting form for use in the emergency room, urgent care setting or physician's office to document the incidence of a food allergic episode would be extremely valuable. Without this information, we have little knowledge of the allergen or allergens that cause the



most severe reactions or the frequency in which these allergic reactions occur. The tools we have today have disparate methods to identify food allergy and none of the current questionnaires have been validated against diagnosis of food allergy.

### Major food allergens

Moving to the topic of major food allergens, there is a need for development of a systematic scientific process to determine the criteria for which a food allergen should be categorized as a major food allergen. Three key criteria to establish the public health importance of an allergenic food are potency, severity and prevalence as identified in workshop proceedings published by ILSI Europe in 2012. The workshop participants developed a systematic scientific process for the application of scientific criteria for identifying allergenic foods of public health importance.

### Education

On education, the development of guidance that educates providers and the public on food allergies could be one step towards creating a safe environment for food allergic children. Such guidance would need to be accessible to a diverse spectrum and audience of caregivers and convey factual information in a manner that is readily comprehensible and deemed credible considering the broad array of information sources existing today in the social media. The Voluntary Guidelines for Managing Food Allergies in Schools and Early Care and Education Programs published by the CDC in 2013 could serve as reference model for developing the content for this type of guidance. Convening workshops that engage different stakeholders is another important step that can be taken in order to disseminate information, engage critical thought, and facilitate the development of education tools that promote a safe environment for food allergic children. For example, the

“Workshop on Food Allergy: From Thresholds to Action Levels” included presentations by clinical, industry, regulatory, and consumer stakeholders to enable a dialogue on allergen risk management. A safe environment can be established through education and executed through effective communication. The absence of product labels for some foods or in certain scenarios, such as eating occasions outside the home, present challenges to creating a safe environment. Creating a safe environment requires two steps: the application of science-based risk management decision-making and the consideration of



communicating risk through uniform use of terminology on the label text or otherwise used to communicate risk to the consumer. This was outlined in one of three manuscripts stemming from this workshop. As with establishing the criteria that define major food allergens, it will also be important for all stakeholders to have common understanding of the risk assessment, management and communication processes. One of the manuscripts from this workshop provides a framework that outlines the challenges necessary to overcome in order to advance allergen management programs that are productive of health and promoting of a safe environment for food allergic individuals.

In closing, ILSI North America would like to remind the Committee members there is a long list of questions under the Statement of Task to tackle in a relatively short period of time, just 16-18 months. We would urge you to prioritize this list to have the greatest impact on public health. We hope that the final report will provide a call to action to raise awareness on the true impact of food allergies which could precipitate food allergy research and ultimately improve the lives of individuals with food allergies. Thank-you for this opportunity to provide oral comments as you begin this important work.



## References:

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