

Formation of the NCFST Allergen Task Force Steering Committee

Several interesting ideas were generated during the Food Allergen Workshop hosted by the National Center for Food Safety and Technology (NCFST) on Oct. 28, 2004. As a result, it was decided that an Allergen Task Force would be formed in order to better define the direction of NCFST activities and to help align resources. NCFST will continue to conduct research in the areas of processing effects on allergens, cleaning and validation of processing lines, and bioinformatics. A potential new venture for the Center may be involvement in the development of analytical standards.

NCFST has partnered with the International Life Sciences Institute (ILSI) in the formation of the allergen task force. The Center will also have significant interaction with the Food Allergy Research Consortium, established by the National Institute of Allergy and Infectious Diseases, National Institutes of Health, particularly with respect to the role that food processing may have in the development of antigenicity and the severity of food allergic reactions.

The Center has identified potential members for the Steering Committee, which will advise on the formation of the task force. The Center has invited the following individuals to join the Allergen Task Force Steering Committee: Robert Buchanan and Don Zink, CFSAN/FDA; Catherine Nnoka, ILSI; Sue Hefle, Food Allergy Research and Resource Program; and Mark Moorman of Kellogg's.

If you would like to participate, please do not hesitate to contact Peter Slade, Ph.D., NCFST/IIT, Acting Director of Research, at (708) 563-8172 or at slade@iit.edu. Full details will be posted on the NCFST website, www.ncfst.iit.edu.

Allergen Taskforce Meeting March 11, 2005

Please call Peter Slade, Ph.D., NCFST/IIT, at (708) 563-8172 or e-mail him at slade@iit.edu for further details.

Goal 1. To address short-term issues relating to the Food Allergen Labeling and Consumer Protection Act (FALCPA)

Objectives:

- To identify best practices for allergen removal and residue testing, including effects of processing on allergenicity and development of standard materials
- To develop a system for evaluating FALCPA exemption claims (e.g., criteria for assessing analytical methods)
- To develop tools for inspectors (e.g., guidance, checklists, training)
- To identify issues relating to other industry segments (e.g., retail, "biotech" products, etc.)

Goal 2. To consider aspects required for risk analysis in the medium- to long-term range.

Objectives:

- To identify data gaps and research needs associated with determining threshold levels and assessing exposure
- To evaluate alternative allergen risk management tools such as application of the FSO concept
- To identify key elements of risk communication

ILSI Meeting on Food Allergens

Martin Cole, Ph.D., Director of NCFST, Peter J. Slade, Ph.D., NCFST/IIT and T.J. Fu, Ph.D., NCFST/FDA attended a meeting of the Subcommittee on Food Allergy hosted by the Food, Nutrition and Safety Program, International Life Sciences Institute (ILSI), in Washington D.C., Dec. 2, 2004. Several representatives from industry, FDA and the National Institutes of Health/National Institute of Allergy and Infectious Diseases (NIH/NIAID) were present.

The group heard a report from a representative from ILSI Europe on European food allergy activities. This included details of the "Report on ILSI Europe EuroPrevall" program that aims to deliver information and tools necessary for policy makers, regulators and the food industry to effectively manage food allergies across Europe and

hence deliver an improved quality of life to food allergic consumers. Other details from Europe included a summary of the Third Food Allergy Research and Resource Program (FARRP) Scientific Roundtable on Thresholds entitled "How Much is Too Much?" held in Mallorca, Spain, Oct. 3-5, 2004.

Douglas Park, Ph.D., CFSAN/FDA, gave a presentation on "Necessity of Method Validation: Increased Reliability of Analytical Results for Food Allergens" in which details of recent FDA comparative evaluations of test kits were provided. Over lunch, Fu, NCFST/FDA, gave a comprehensive overview of "NCFST Research on Food Allergens and the Effects of Food Processing on Food Allergens," a detailed account of allergen determinations using various methods following different food

processing procedures.

Following his analysis of outstanding food allergen and processing issues, Cole led a roundtable discussion on the potential for collaboration between NCFST and its industry members with key stakeholders such as ILSI, FARRP, FDA and the National Institutes of Health. Cole outlined the process for the formation of the Allergen Task Force at NCFST, which will be led by Slade. The NCFST Allergen Task Force Steering Committee was formed to prepare for the first meeting of the full task force early in the New Year.

For more information on allergen research at NCFST and the NCFST Allergen Task Force, please contact Peter J. Slade, Ph.D., Acting Director of Research at NCFST, at (708)563-8172 or slade@iit.edu.

NCFST Allergen Workshop

The Food Allergen Labeling and Consumer Protection Act (FALCPA) was signed Aug. 2, 2004. The labeling requirement, which will become effective January 2006, requires a label to disclose certain allergenic ingredients. There are eight major food allergens. The food ingredients subject to this law are those that contain protein derived from major food allergens and include incidental additives and flavors. In the event of incorrect labeling, the food label is corrected and a recall of the product may occur.

An allergen workshop was held at NCFST on Oct. 28, 2004 with the purpose of sharing CFSAN progress and priorities on allergens, reviewing existing work on allergens at NCFST and determining the future role and direction of NCFST in allergens and processing. An FDA report is due out in February 2006 that will describe types of advisory labeling ("may contain" labeling), describe how food allergic consumers would like cross-contact information placed on labels and give the extent to which advisory labeling may be used. The report will also identify ways in which foods are unintentionally contaminated during manufacturing and processing and estimate how common these practices are with breakdowns by food type.

Betty Harden, Special Assistant to the Office of Compliance Director, CFSAN, identified the CFSAN food allergen priorities. Inspections related to food allergens are being conducted to ensure that firms are complying with practices to reduce or eliminate cross-contacts and ensure that major food allergens are properly labeled. A CFSAN ad hoc working group is in the process of making recommendations for the development of possible threshold(s). FDA believes there is a possibility of revising current GMPs to deal more effectively with cross-contact and mislabeling issues.

Three test kits, Biokits Peanut Assay (Tepnel Biosystems Ltd., Flintshire, UK), RIDASCREEN[®] FAST Peanut (R-Biopharm AG, Darmstadt, Germany), and Veratox[®] for Peanut Allergen (Neogen Corp., Lansing, MI, USA) were approved as Performance Tested Methods. They were

proven to be reliable for the detection of peanut proteins in breakfast cereals, cookies, ice cream, and milk chocolate. Users can decide which method to use based on validated performance results, cost, time, and ease of use. FDA intends to use these kit methods for detection of peanut proteins in various food matrices until collaborative validation studies are completed, said Douglas Park, Ph.D., Division of Natural Products, CFSAN/FDA.

Park still has more work to do on allergens. He will conduct collaborative validation studies (harmonized protocols AOAC/IUPAC/ISO/Codex) for peanut test kit methods. He will also conduct method evaluation studies for other food allergens, i.e., milk, egg, wheat, etc. He will work with other organizations in the preparation of standards/reference materials for food allergens.

Mark Moorman, W.K. Kellogg Institute for Food and Nutrition Research, gave industry's perspective on the allergen issue. He said that the obligation of industry is to have accurate ingredient statements on their labels. Companies must obtain information from the supplier on ingredient formulation, allergens in other products on the same manufacturing line, and the presence of allergenic ingredients within the facility. The highest percentage of recalls is due to the omission of an allergenic ingredient from the label. The food manufacturer must take care to avoid cross contact with allergenic ingredients. Lauren Jackson, Ph.D., NCFST/FDA, and her team are collaborating with Kellogg's in conducting some sanitation studies on allergens to determine the effects of cleaning on removal of peanut allergens from food-contact surfaces.

Sue Hefle, Associate Professor and Co-Director of the Food Allergy Research and Resource Program (FARRP), University of Nebraska, works on thresholds and detection issues. The FARRP laboratory routinely analyzes retail samples that contain 1-5 ppm allergenic food and hasn't had any consumer complaints associated with foods containing these low levels of aller-

gen contamination. There are levels below which food-allergic patients will not react (thresholds). Severe reactions have usually been associated with higher levels of contamination.

"Non-zero thresholds for allergens do exist," said Hefle. "Many foods containing low levels of allergens do exist on the market now and apparently do not cause illness."

In determining threshold limits, the aim should be to protect the vast majority of food allergic consumers. Eliciting dose levels for allergens are an important part of risk assessment for the food industry and regulatory agencies. This can also reduce the "may contain"- type labeling. Determination of doses provides more accurate information to the food-allergic consumer as to their possible sensitivity level.

The FARRP clinical threshold research for the egg allergen has been completed. The threshold research for peanut and shrimp is underway. Studies on soybean have just begun.

The food industry and regulators are using allergen detection kits. "We don't have commercial test kits for all of the allergenic foods yet or the threshold," said Hefle.

NCFST researchers presented some of their work being done on allergens. Steve Gendel, Ph.D., NCFST/FDA, discussed the database "Bioinformatics for Food Safety" (BIFS). He has developed the BIFS Allergen database containing amino acid sequences of animal food allergens, plant and non-food allergens. He is in the process of completing an analysis of allergen sequences- protein families, motifs, and peptide distributions. T.J. Fu, Ph.D., NCFST/FDA, is working on determining the effects of processing on allergens.

There was excellent feedback on the content and timelines of the meeting. During the concluding session of the workshop, it was agreed to establish a NCFST/ industry task force in order to better coordinate the many research efforts in the area.