

Meeting Report: “Food Allergens: Best Practices for Assessing, Managing, and Communicating the Risks”

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SUMMARY

Stakeholders with a wide variety of viewpoints related to food allergen control met on 14–15 October 2015 in Burr Ridge, Illinois to discuss best practices related to assessment, management, and communication of risks. Among the approximately 160 participants were clinicians, researchers, regulators, public health advocates, and representatives of the food manufacturing and food service industries. The consumer was also well represented: Many attendees had personal or family struggles with food allergies. The efforts of many individuals in food industries, academia, and government, particularly those passionately concerned about food allergies because of personal

experience, have improved knowledge and practices related to food allergens in the past few decades. Significant challenges still exist; however, which triggered the creation of several working groups among the meeting participants. These working groups welcome other interested participants as they develop tools to share best practices across the food manufacturing industry and within the food service sector. The meeting was sponsored by the Institute for Food Safety and Health (Illinois Institute of Technology), with organizational assistance from the Food Research Institute (University of Wisconsin-Madison) and funding through a USDA NIFA grant.

Overview of food allergy, food allergen, and regulatory perspectives

The first day began with a discussion of food allergies and allergens and some of the regulatory considerations in their management. Steve Taylor provided a historical perspective of food allergens and discussed how food allergy deaths in the 1980s spurred a “chaotic awakening” in the food industry and led to the formation of advocacy organizations. He discussed the challenges of developing analytical methods appropriate for use in food matrices and asked how the food service industry might apply what they have learned in successfully tackling the challenges of going “gluten-free” towards the related issues of food allergen control. The need to disseminate best practices and research the behavior of people with food allergies, two recurring themes of the meeting, were also introduced in Taylor’s talk.

The impact on public health of the prevalence of food allergies was the focus of the presentation by Ruchi Gupta (Northwestern University). She presented work demonstrating that the risk for food allergy is higher (and rate of diagnosis lower) among African-American and Asian-American children as well as children in lower-income families. The emotional, financial, and practical impacts on the family of having a child with a food allergy were also highlighted in her talk.

David Fleischer (University of Colorado) discussed the challenges and promise of recent clinical trials investigating immunotherapy to treat established food allergies. He described the difficulties in conducting immunotherapy studies and finding therapies that achieve long-term tolerance to allergens.

Jennifer Thomas (FDA) stated that current FDA tools related to food allergen control are limited primarily to labeling and manufacturing controls. She described how FSMA would bring new tools to the FDA to control food allergen risks in packaged foods, including mandatory recall powers. In addition, the FSMA preventive controls final rule published in September 2015 recognizes the importance of allergens as hazards and will require all firms to have written allergen control plans by 2018.

Byron Beerbower (Michigan Department of Agriculture and Rural Development) described how establishing food service worker training requirements in Michigan involved well-orchestrated efforts to achieve consensus among groups with different positions (e.g., industry vs. parents of children with allergies). Rather than requiring restaurants to reinvent the wheel, Michigan allows them to use existing allergen training, such as the ServSafe Allergen Training program, according to Beerbower.

Jennifer Jobrack, of Food Allergy Research & Education (FARE), discussed efforts to improve accessibility to epinephrine in public places where food allergic reactions

may occur. FARE’s efforts have resulted in guidelines or statutes that explicitly allow or require epinephrine in schools in all but a few states. FARE is also working to ensure that all ambulances and airlines carry epinephrine and to eliminate barriers to its use in those environments.

Best practices for risk assessment, management, and communication for the packaged food industry

The second session of the meeting focused on best practices to control food allergens in the packaged food industry.

Current recall data in the U.S. and other regions was mined by Steven Gendel (IEH Laboratories and Consulting group; former Food Allergen Coordinator at the FDA) to investigate which food allergens cause food manufacturers the most problems. During the first half of 2015, most FDA-reported food recalls were associated with allergens, with milk and peanut triggering more recalls in the U.S. than other allergens. Worldwide, milk is the allergen leading to the most recalls, according to Gendel.

Susan Estes (PepsiCo) discussed best practices used by the food industry to control food allergens, which she summarized as (1) correctly listing allergens on the label and (2) keeping other allergens out. The importance of knowing every supplier, including each location supplying product, is paramount. She also described how attention to packaging and labeling controls is critical, since most food allergen recalls are linked to labeling that does not correctly reflect the allergen content of the product inside.

Tim Adams, of Kellogg’s, highlighted his company’s approach to allergen sanitation, including protocol validation, auditing, and verification activities. He illustrated the importance of sampling appropriately in environmental testing: If the expected allergen is a particulate (for example, a peanut) rather than a powder (such as non-fat dry milk), the sampling plan should be very different.

Best practices for food allergen cleaning in the manufacturing environment were discussed further by Lauren Jackson (FDA), who outlined steps in developing an allergen cleaning and sanitation program, and described how allergen-cleaning validations should be performed. Ms. Jackson also described considerations for environmental testing for food allergens and highlighted a variety of possible analytical methodologies to use in food allergen detection.

Joe Baumert discussed a data-driven approach to establish risk-based thresholds for food allergens. Threshold dose data from individuals in double-blind, placebo-controlled challenge studies can be combined and statistically modeled to establish population thresholds. Mr. Baumert commented that more data is needed before thresholds can be set with confidence.



Best practices for risk assessment, management, and communication for the food service industry

David Crowthorn (National Restaurant Association) stressed the importance of increasing food allergen awareness in the food service industry. He cited results of a survey of small regional food service operators, which showed that while a large percentage of those surveyed believed that food allergy knowledge was important, a much lower percentage trained staff on food allergen control. This gap is at least partially due to a lack of suitable training materials. To meet this need, the National Restaurant Association partnered with FARE to develop an evidence-based online food allergen training program (ServSafe Allergen Training), which has certified approximately 10,000 food service workers in the two years since its launch.

Hal King (Public Health Innovations, LLC, formerly of Chick-fil-A) discussed his experiences managing food allergens in the context of a large fast-food chain. Mr. King discussed the importance of notifying customers when ingredient changes are made to regular menu items and described novel ways, such as the use of mobile apps, to make it easy for customers to find ingredient information related to the “Big 8” allergens for each menu item. Surveillance of the supply chain is critical in order to know exactly what is in each ingredient, used in each menu item, with only pre-approved vendors being used, without exception, at his former company.

Having a daughter with celiac disease has provided Carlyn Berghoff, CEO of Chicago’s renowned Berghoff restaurants, with acute awareness of the problems associated with food allergens and given her a passion for food safety. Translating what she learned at home to her restaurants, including careful design of menus, recipe reviews, education, and a caring approach toward customers, her company’s business has improved, she reported.

From the state regulatory perspective, Adam Inman (Kansas Department of Agriculture) explained how safe food microbiological practices don’t always translate into safe food allergen practices. Training is key, he stressed, and food service establishments should not rely upon inspectors for training. Some states, including Michigan, Massachusetts, and Rhode Island, have already mandated food allergen training for food service workers.

In addition to ServSafe’s course, other food allergen training materials for food service workers are being developed. Katherine Brandt and Suzanne Driessen of the University of Minnesota Extension Service used formal instructional design principles to develop a food allergen-training course. Their course was designed to appeal to oral-culture learners by inclusion of a compelling first-person narrative by a food-allergic individual.

Best practices for risk assessment, management, and communication at home and in other community settings

The final session of the meeting discussed best practices for food allergen control at home and in various community settings.

Michael Pistiner, physician and cofounder of Allergy-Home, drew upon personal experience to illustrate anaphylaxis from a parent's perspective. Parents of children with food allergies must serve as coordinator, advocate, role model, and educator. Physicians have inadequate time to educate parents, according to Pistiner, so many parents have clear deficits in knowledge. The constant need to straddle the line between anxiety and risk taking contributes to emotional and social effects for the entire family.

Kathryn Whiteside (University of Michigan) described tools available at the University of Michigan that students use to manage their food allergies on campus. Making information about food allergens in menu items available online and in a mobile app can help students easily identify safe food options without drawing attention to themselves. Gluten-free pantries, clearly marked signage, and using the name of the allergens in names of dishes are other techniques they have implemented at the University of Michigan to help manage food allergies.

Knowing what is in the food your children eat when they are outside the home is also a big concern for parents. Inspired by her sister Rachel's life-threatening anaphylactic reaction, high-school student Lauren Maunus and her mother, Debbie Maunus, became advocates for those with food allergies, joining forces with Robin Safley of the Florida Department of Agriculture to improve school menu transparency in Florida. Ms. Maunus and Ms. Safley discussed how their efforts resulted in all schools in Florida now having the ability to publish their school menus online and on mobile devices, using a database system.

Challenges moving forward

The personal impact of food allergies and its motivating force were mentioned by numerous speakers throughout the meeting. Many of the successes highlighted during presentations were attributed to the passion of those directly affected by food allergy.

While the meeting highlighted progress made toward improving control of food allergens and keeping those with food allergies safe, challenges remain. Multiple speakers mentioned the need for more appropriate use of precautionary allergen labeling and for more research related to behaviors of patients and their families in managing food allergies, as well as the continuing need to build awareness about food allergies across all levels of the food manufacturing and food service industries.

Meeting follow-up

Several working groups were organized during the meeting to document food allergen best practices for use by small food manufacturers and to establish basic food allergen controls for food service establishments. Those interested in participating in the working groups are encouraged to contact the meeting organizers, Kathiravan Krishnamurthy (kkrishn2@iit.edu), Tong-Jen Fu (tongjen.fu@fda.hhs.gov), or Lauren Jackson (lauren.jackson@fda.hhs.gov).

Meeting proceedings will be published on the IFSH website, and a book by the meeting speakers is in preparation and will be available through Springer (contact Tong-Jen Fu (tongjen.fu@fda.hhs.gov) for more information).

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