GLOBAL FOOD PROTECTION INSTITUTE

A COMMUNITY OF ACTION
ADVANCING FOOD PROTECTION

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Preventive Controls Symposium: Sept 24, 2012, Hyatt Fair Lakes, Fairfax, VA

The development and implementation of threshold levels, or reference doses, remain in the formative stage for a variety of reasons. Current research could be used to establish levels for many of the known major allergens, but consensus on the use of these levels is only beginning to emerge from the medical/scientific community. More research is needed; funding for research will need to be identified; and issues related to the individuals selected for clinical trials will need to be addressed. Educational awareness training for the affected populations (consumers, physicians, regulators, industry, etc.) is another challenge, as many are largely unaware of the threshold concept and advances in research, and have held a *strict avoidance* mentality for years. The regulatory framework for implementing reference doses to food labeling will also pose challenges and the regulatory implementation process is likely to be methodical.

Reference dose testing in the clinical setting is not routinely performed. Food challenges are time-consuming and would be a costly new mandate for the health-care system. Efficient, cost-effective approaches for determining the threshold dose of the individual patient must still be developed. Medical professionals must then be able to counsel patients effectively based upon this new information. Similarly, without regulatory and medically recognized reference doses demonstrating acceptable levels of risk for major allergens, manufacturers and the food service industry may not be willing to embrace and practice the concept. The industry relies upon commercial test methods to detect allergen residues to validate their allergen control programs. While substantial progress has been made in the development and use of these tests, further efforts remain to develop methods for allergenic foods where methods are lacking, to improve and standardize existing methods, and to reduce the cost of such methods thereby expanding their use, especially by smaller manufacturers.

Consensus statement:

The establishment of threshold levels for major food allergens will significantly streamline activities conducted by the food industry and regulatory bodies, and will improve the daily lives of affected consumers. What is more, thresholds will help FDA issue science-based, appropriate Performance Standards for allergens as mandated by the Food Safety Modernization Act.

Considerable progress on thresholds has been made in the past 5-7 years thanks to the efforts of clinicians, public health officials (including the FDA Threshold Working Group), academic scientists such as FARRP and TNO, consumer organizations and the food industry. These efforts, and the scientific data gathered to date, represent an appropriate foundation from which to move forward.

It is therefore our consensus that a stakeholder workshop be convened in 2013, so as to continue to build upon the considerable progress to date. Specifically, the goals of the 2013 workshop will be to:

- Leverage physician/clinician groups, food industry, academia, federal regulators, and consumer groups;
- Develop standardized terminology and clinical protocols;
- Plan educational/awareness efforts aimed at those subscribing to a *zero tolerance* mindset*;*
- Investigate funding sources/opportunities for future research; and
- Assess the effectiveness and use of allergen test kits.