

# Agricultural BioTech Regulatory Network

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## ABTR Network Expert Advances Safety Assessment Techniques for GM Crops

The Agricultural BioTech Regulatory Network proudly announces four new publications on the safety of biotechnology-derived crops co-authored by member consultant Sue MacIntosh (MacIntosh & Associates, Inc.).

International expert Sue MacIntosh explores allergenicity assessment techniques and insect resistance management for crops improved through biotechnology. These technical reports advance the current state of knowledge in two critical fields of GM crop safety.

Evaluation of Protein safety in the Context of Agricultural Biotechnology<sup>1</sup> describes a weight-of-evidence approach to protein safety with emphasis on proteins introduced using modern biotechnology. The testing approach utilizes a two-tier system, first for hazard identification and second, if a hazard is found, a description of options for full characterization of the hazard. Hazard identification focuses on physiological, chemical and biochemical aspects of the protein using techniques to explore protein structure, function and mode-of-action. Hazard characterization includes toxicology tests in rodents or other animals and hypothesis-based tests using information from the hazard identification process. Examples illustrate this testing paradigm. Contact Marci Levine, PhD, ILSI (+1 610-365-8117, [mlevine@ilsi.org](mailto:mlevine@ilsi.org)) for a copy of the article.

Current and Future Methods for Evaluating the Allergenic Potential of Proteins<sup>2</sup> reviews current and emerging techniques for evaluating allergenicity of novel proteins. This report summarizes an international workshop of experts hosted by The Health & Environmental Sciences Institute's Protein Allergenicity Technical Committee (HESI PATC) in October 2007. New methods reviewed include expanded options for evaluation of bioinformatics results, proteomics approach, cell-based techniques, and animal models. Look for individual manuscripts published as a supplement to Molecular Nutrition & Food Research, in early 2009.

Scientific Advancement of Novel Protein Allergenicity Evaluation (2000-2007)<sup>3</sup> summarizes activities of HESI PATC, is an industry-supported team founded in 2000 to advance the science of conducting, interpreting and applying risk assessments for the allergenic potential of agricultural biotechnology products. Since 2000, HESI PATC has convened workshops and meetings of allergy experts and government authorities and has supported various research initiatives. The results of this effort have been published in peer-reviewed scientific journals and have been shared through outreach activities in the US, Japan, South Korea, Brazil, Argentina, Finland, and the European Union. Contact Nancy Doerrler, HESI (+1 202-659-3306, [ndoerrler@hesiglobal.org](mailto:ndoerrler@hesiglobal.org)) for more information.

Growers around the world have rapidly embraced genetically improved crops that control insects over the past 12 years. Integration of Insect-Resistant Genetically Modified Crops within IPM Programs provides an overview of how insect-resistant crops fit within the principles of integrated pest management (IPM) systems. A chapter entitled GM Crops and Insect Resistance Management (IRM)<sup>4</sup> provides historical perspective on insect resistance in the lab and field, as well as the theory, concepts and practices used to delay resistance to Bt crops, and the role of government regulations surrounding resistance management. Available from Springer publishers (<http://www.springer.com/life+sci/zoology/book/978-1-4020-8372-3>).

#### References:

<sup>1</sup> Delaney, B., Astwood, J.D., Cunny, H., Eichen Conn, R., Herouet-Guicheney, C., MacIntosh, S., Meyer, L.S., Privalle, L., Gao, Y., Mattsson, J., & Levine, M. 2008. Evaluation of protein safety in the context of agricultural biotechnology. *Food & Chem Tox* 46:871-897.

<sup>2</sup> Ladics, G., Herouet-Guicheney, C., McClain, S., MacIntosh, S., Privalle, L., Thomas, K., & Woolhiser, M. 2008. Current and Future Methods for Evaluating the Allergenic Potential of Proteins: International Workshop Report 23 - 25 October 2007. *Food & Chem Tox. In Press*.

<sup>3</sup> Thomas, K., MacIntosh, S., Bannon, G., Herouet-Guicheney, C., Holsapple, M., Ladics, G., McClain, S., Vieths, S., Woolhiser, M., & Privalle, L. 2008. Health & Environmental Sciences Institute (HESI)'s Protein Allergenicity Technical Committee (PATC) Scientific Advancement of Novel Protein Allergenicity Evaluation (2000-2007). *Food & Chem Tox*, 46:3219-3225.

<sup>4</sup> Ferré, J., Van Rie, J., MacIntosh, S., 2008. GM Crops and Insect Resistance Management (IRM), In: *Integration of Insect-Resistant GM Crops within IPM Programs*, (Romeis, J., Shelton, A.M., Kennedy, G.G., Eds.) Springer US.

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Established in 2006, the ABTR Network is a unique global network of independent regulatory affairs managers/services serving the agricultural biotechnology industry from product conception through commercialization.

Services cover the entire range of regulatory support required for AgBiotech projects, including project management, project evaluation, risk assessments, contained/confined use permits; field trial permits / notifications; regulatory files; commercial permits; movement of biological materials; compliance audits; compliance systems; training; quality control; study design; documentation systems; regulatory strategies; regulatory management; issue management; communication; emergency response & public advocacy.

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