SOUTH ASIA
BIOSAFETY PROGRAM

February 2008
Vol.4 No.2

NEWSLETTER

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SABP

The South Asia Biosafety Program (SABP) is an international developmental program initiated with support from the United States Agency for International Development (USAID). The program is implemented in India and Bangladesh and aims to work with the local governments to facilitate implementation of transparent, efficient and responsive regulatory frameworks that ensure the safety of new foods and feeds, and protect the environment.

SABP is working with its in-country partners to:

- Identify and respond to technical training needs for food, feed and environmental safety assessment.
- Develop a sustainable network of trained, authoritative local experts to communicate both the benefits and the concerns associated with new agricultural biotechnologies to farmers and other stakeholder groups.
- Raise the profile of biotechnology and biosafety on the policy agenda within India and address policy issues within the overall context of economic development, international trade, environmental safety and sustainability.

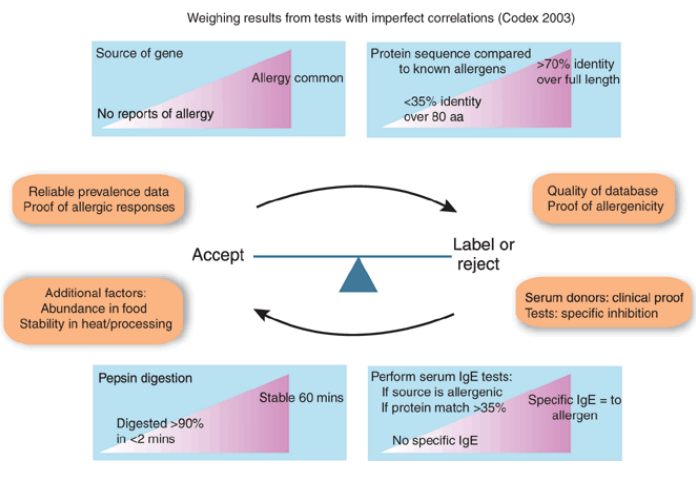
PAPER 'ALLERGENICITY ASSESSMENT OF GENETICALLY MODIFIED CROPS – WHAT MAKES SENSE?'

Richard E. Goodman, Ph.D., Professor - Food Science & Technology, Food Allergy Research & Resource Program, University of Nebraska - Lincoln

In January 2008, Nature Biotechnology (NBT) published a peer reviewed Research Perspective (Goodman, Vieths, Sampson, Hill, Ebisawa, Taylor and van Ree, 26(1):73-81) describing the methods and merits of the current evaluation process for assessing the potential allergenicity of transgenic crops under the Codex Alimentarius guidelines (2003). The Codex guidelines were developed under the auspices of the Food and Agricultural Organization (FAO) of the United Nations and are followed by regulators in the European Union, the United States, Japan and many other countries. The authors of the NBT paper are clinical and/or laboratory allergy experts who primarily focus on food allergy, characterization of allergens and food allergy risk assessment. Two authors were primary contributors in the first published allergenicity assessment (Metcalfe *et al.*, 1996 Crit. Rev. Food Sci Nutr 36(S):165-186). The purpose of the NBT publication was to review the utility and predictive value of the steps used in recent assessments and to identify steps that are not working.

All foods carry some risk of allergy for a few individuals. Therefore the goal of regulators must be to minimize the possibility that new transgenic crops might significantly increase the risks of food allergy, relative to the risks presented by existing foods. But, the goal cannot be to eliminate all risks of allergy, or to demand that each transgenic crop be less allergenic than the non-transgenic counterpart.

The schematic interpretation of Codex (reprinted with permission from NBT) outlines the primary predictive steps in the assessment and describes appropriate cautions and tests needed to evaluate risks. Proteins produced from genes isolated from organisms that are highly allergenic are to be tested for IgE binding using serum donors allergic to the source. Proteins with amino acid sequences highly identical to known allergens are tested for IgE binding using sera from donors allergic to the known allergen. When indicated, those serum tests should reduce the greatest risk of food allergy for individuals most at risk (those with existing allergies). To put the risk in context, fewer than 200 individuals are thought to die each year in the U.S. (population 300 million) after eating the food that contains the allergen they already knew causes them to react. For most, exposure was due to the consumption of food prepared with the allergenic ingredient, but not labeled and the individual was thus unaware of risk. Most fatal reactions are caused by peanuts, crustacean shellfish, or commonly allergenic tree nuts. The first two steps of the assessment should eliminate most significantly risky transgenic crops. Additional steps include evaluating the stability of the introduced protein in pepsin at pH 1.2 or 2, and evaluating the abundance of the protein. Highly stable and abundant proteins are more likely to sensitize consumers and may become important food allergens.



Schematic interpretation of the weight-of-evidence approach described by the Codex Alimentarius Commission Guidelines for Allergenicity Assessment in 2003. In the figure, the four main areas of evidence are depicted with a graphic representation of the evidence representing maximum risk on the right (high side of the triangles). The weight of the evidence in each of the areas is influenced by the quality of the factors depicted in the yellow boxes. On the basis of the imperfect nature of the test methods available to distinguish between allergenic and nonallergenic proteins, scientific interpretation is necessary to reach a balanced and useful conclusion regarding the potential risks of allergy associated with each new food product. (Figure courtesy of the author and Nature Biotechnology)

The NBT paper also provides critical evaluation of three steps in the evaluation process that have not proven predictive. One is the use of short (six to eight) amino acid sequence matches as a trigger for human serum testing. There are no published examples of six or eight amino acid matches that identified probable cross-reactive allergens that were not also identified by at least 35 per cent sequence identities over 80

(continued on page 2 - see Allergenicity)

THE CALENDAR

CALENDAR OF EVENTS

Event	Organization	Date	Place
INDIA			
Workshop on Agricultural Biotechnology: A hands on training in advanced tissue culture and molecular biology techniques	The Energy and Resources Institute, New Delhi	February 18 - 23 2008	TERI, New Delhi
14th National Level Symposium, "Biotechcellence"	Centre for Biotechnology, Anna University	February 22 - 24, 2008	Chennai
Workshop-cum-Training on Bioinformatics Applications in Agricultural Research	Indian Agricultural Research Institute	February 25 - 27, 2008	New Delhi
Training course on "Management Development for Extension Professionals"	Indian Agricultural Research Institute	February 28 – March 19, 2008	New Delhi
Regional workshops on "Management and Monitoring of Field Trials of Genetically Modified Crops"	Ministry of Environment & Forests, Department of Biotechnology and Biotech Consortium India Limited	February – March 2008	Nagpur and Hyderabad
The National Workshop on the Status and Perspective of Biotechnology in Animal Feeds and Feeding	Animal Nutrition Association (For details refer to: http://ivri.nic.in/others/an_dbt_workshop_11_3_8.pdf or contact: Dr. K. Sharma at ksharma52@gmail.com)	March 11 - 12, 2008	Centre of Advanced Studies in Animal Nutrition, IVRI, Izatnagar
BANGLADESH			
Implementing National Biosafety Framework and Biosafety Guidelines of Bangladesh	Bangladesh Agricultural Research Council (BARC) and South Asia Biosafety Program (SABP)	February 17, 2008	BARC, Dhaka
Compliance Management Workshop for Confined Field Trials of Transgenic Crops	BARC and SABP	February 18 - 20, 2008	BARC, Dhaka
Role of Plant Scientists in Food Security and Disaster Management	Bangladesh Botanical Society	March 8 - 9, 2008	Jahangirnagar University, Savar, Dhaka
Plant Tissue Culture and Biotechnology Conference	Bangladesh Association for Plant Tissue Culture and Biotechnology	April 11 - 13, 2008	Botany Department, Dhaka University

Allergenicity - *continued from page 1*

or more amino acids. Examples of false positive matches are described along with resulting unwarranted testing demands. Second, no animal model has been demonstrated to provide good positive and negative predictive values in identifying whether dietary proteins are allergenic or not-allergenic for humans. While some of the animal models can provide important information about mechanisms of allergenicity, none have been demonstrated to provide significant predictive power. Third, broadly targeted serum testing recommended by the FAO/WHO (2001) has not been demonstrated to be predictive and has the potential to produce false positives and therefore rejection of relatively non-allergenic products.

The paper discusses the lack of clear scientific justification for requiring comparative serum IgE testing for differences in endogenous allergens between the transgenic crop variety and non-transgenic counterpart. Current non-transgenic crop varieties represent variation in endogenous allergen expression that has been demonstrated to represent two to four or more fold differences in allergenicity. Therefore testing for relatively limited differences in allergen expression is not justified with few exceptions. Finally, there are no cases demonstrating that transgenic crops that have undergone assessment following the recommendations of Codex (2003) and the NBT paper have caused increased allergies. Instead, a number of potential transgenic products described in scientific literature have failed or would have to undergo serum IgE testing in order to be approved for market.

See the full paper at
http://www.nature.com/nbt/journal/v26/n1/pdf/nbt1343.pdf

ISAAA BRIEF 37-2007 GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS

ISAAA - February 13, 2008

After a dozen years of commercialization, biotech crops are still gaining ground with another year of double-digit growth and new countries joining the list of supporters, according to a report released today by the International Service for the Acquisition of Agri-biotech Applications (ISAAA). In 2007, biotech crop area grew 12 per cent or 12.3 million hectares to reach 114.3 million hectares, the second highest area increase in the past five years.

In addition to planting more biotech hectares, farmers are quickly adopting varieties with more than one biotech trait. These "trait hectares" grew at a swift 22 per cent, or 26 million hectares, to reach 143.7 million hectares – more than double the area increase of 12.3 million hectares. New crops were also added to the list as China reported 250,000 biotech poplar trees planted. The insect-resistant trees can contribute to reforestation efforts.

(continued on page 4 - see ISAAA Brief 37)

SPOTLIGHT ON THE WORLDWIDE WEB

Over the next number of newsletters we will be spotlighting some important websites, created by the Department of Biotechnology (DBT) and the Ministry of Environment and Forests (MoEF), that provide information on genetically modified organisms.

This month we feature India Biosafety Clearing House (http://indbch.nic.in/). In the months ahead we will look at the websites of National Research Centre on Plant Biotechnology; Department of Agriculture and Cooperation, Ministry of Agriculture, Government of India; and Biotech Consortium India Limited (BCIL). - Editor

India Biosafety Clearing House

(http://indbch.nic.in/)

India is a signatory to the Cartagena Protocol on Biosafety and ratified it on January 23, 2003.

The India Biosafety Clearing House (IND-BCH) has been established as per Article 20 of the Cartagena Protocol on Biosafety, in order to facilitate the exchange of scientific, technical, environmental and legal information on living modified organisms (LMOs).

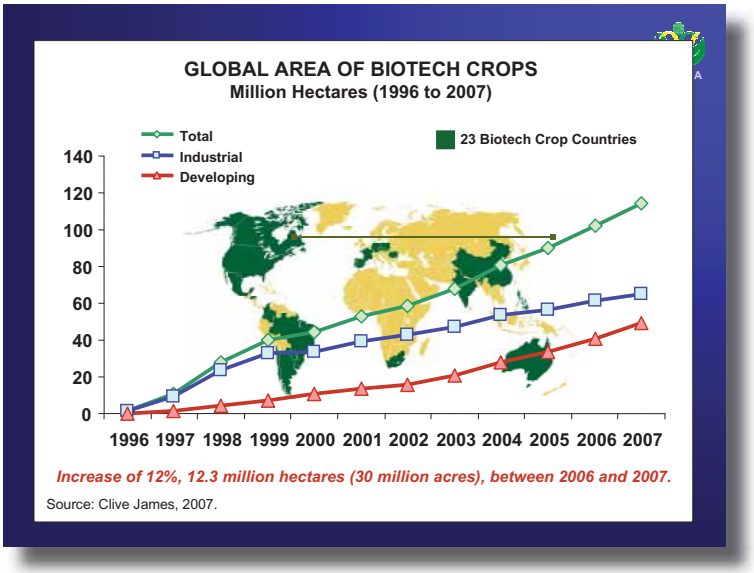
Among other things, you can find links to The Cartagena Protocol on Biosafety and the Convention on Biological Diversity and the Central Portal of its Biosafety Clearing House (BCH), which is an information exchange mechanism established to assist Parties to implement its provisions and to facilitate sharing of information on, and experience with, LMOs.

The India Biosafety Clearing House has website databases for information on:

- National Contacts
- Laws and Regulations
- Decisions and Declarations
- Capacity Building
- Roster of Experts

ISAAA Brief 37 - *continued from page 2*

Further, 2 million more farmers planted biotech crops last year to total 12 million farmers globally enjoying the advantages from the improved technology. Notably, 9 out of 10, or 11 million of the benefiting farmers, were resource-poor farmers, exceeding the 10-million milestone for the first



time. In fact, the number of developing countries (12) planting biotech crops surpassed the number of industrialized countries (11), and the growth rate in the developing world was three times that of industrialized nations (21 per cent compared to 6 per cent.)

Details about ISAAA Brief 37 can be found at http://www.isaaa.org

FIRST DOCUMENTED CASE OF PEST RESISTANCE TO BIOTECH COTTON

Science Daily – February 8, 2008

Researchers at the University of Arizona (UA) in the U.S. have reported the discovery of the first known insect pest to have developed resistance to a Bt crop in the field. Bt crops are genetically engineered to contain different types of insecticidal toxins from "Bt" bacteria; the crops have been grown in the U.S. since 1996. The Bt-resistant insect discovered is a bollworm, or *Helicoverpa zea*. It was found in more than a dozen Bt cotton fields in the Southern U.S. states of Mississippi and Arkansas between 2003 and 2006. The variety of Bt cotton was one that produced only one type of Bt toxin: Cry1Ac. "What we're seeing is evolution in action. This is the first documented case of field-evolved resistance to a Bt crop," says lead researcher Bruce Tabashnik, a UA entomologist. Tabashnik emphasized, however, that: "The resistance occurred in one particular pest in one part of the U.S. The other major pests attacking Bt crops have not evolved resistance. And even most bollworm populations have not evolved resistance." The researchers' study was funded by the U.S. Department of Agriculture (USDA) and was based on an analysis of published data from monitoring studies of six major caterpillar pests of Bt crops in Australia, China, Spain, and the U.S. Bt crops in the U.S. are supposed to be planted alongside "refuges" of non-Bt crops, designed to "dilute" populations of Bt-resistant insects that might develop. In bollworm, however, hybrid offspring produced by matings between susceptible and resistant moths are resistant. Such a dominant inheritance of resistance was predicted to make resistance evolve faster. The UA researchers found that bollworm resistance evolved fastest in the U.S. states with the lowest abundance of refuges. The researchers' findings have been published in the February edition of the journal Nature Biotechnology.

See the full article at:
http://www.sciencedaily.com/releases/2008/02/080207140803.htm

The following publication may be of interest to readers of the SABP newsletter.

A special issue of **AgBioForum**, "Biofortified Food Crops: Progress and Prospects in Developing Countries", was published recently. It includes the following articles:

- Addressing Micronutrient Deficiencies: Alternative Interventions and Technologies;
- Patterns of Political Response to Biofortified Varieties of Crops Produced with Different Breeding Techniques and Agronomic Traits;
- Political Actors on the Landscape;
- Crop Case Study: GMO Golden Rice in Asia with Enhanced Vitamin A Benefits for Consumers;
- Biofortification for China: Political Responses to Food Fortification and GM Technology, Interest Groups, and Possible Strategies;
- Biofortified Crops and Biotechnology: A Political Economy Landscape for India;
- Socioeconomic and Political Concerns for GM Foods and Biotechnology Adoption in the Philippines;
- Assessing the Prospects for the Adoption of Biofortified Crops in South Africa;
- Biofortified Foods and Crops in West Africa: Mali and Burkina Faso; and
- Patterns of Political Support and Pathways to Final Impact.

AgBioForum Volume 10, Number 3, 2007 can be seen online at http://www.agbioforum.org/

We welcome reader comments or suggestions. E-mail your letters to: nringma@agbios.com **Mail your letters to:** The Editor, SABP Newsletter, P.O. Box 475, Merrickville, Ontario, K0G 1N0 Canada

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