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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 national governmental agencies to facilitate the implementation of transparent, efficient and responsive regulatory frameworks for products of modern biotechnology that meet national goals as regards the safety of novel foods and feeds and environmental protection.

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 Bangladesh and address policy issues within the overall context of economic development, international trade, environmental safety and sustainability.

SEMINAR ON UNDERSTANDING THE BANGLADESH GUIDELINES FOR THE SAFETY ASSESSMENT OF FOODS DERIVED FROM GENETICALLY ENGINEERED PLANTS

A seminar on understanding the Bangladesh Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered (GE) Plants, held at the Bangladesh Standards and Testing Institution (BSTI) on February 7, 2012, was attended by scientists and staff of BSTI, members of the Biosafety Core Committee (BCC) of Bangladesh and members of the drafting committee for the Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants (the Guidelines). Mr. A.K. Fazlul Ahad, Director General, BSTI chaired the inaugural ceremony. Mr. Monowar Islam, Director General, Department of Environment (DoE) was the guest of honour.

During his welcome address, Dr. Syed Humayun Kabir, Director (Standards), BSTI, told the audience that the Guidelines were developed through a stakeholder consultation process and were approved by the National Committee on Biosafety (NCB) and therefore, now was the time to implement them. He also pointed out that the Guidelines may be adopted as a national standard by BSTI for the assessment of foods derived from genetically engineered plants.

After the welcome address Dr. Andrew Roberts, Deputy Director, Center for Environmental Risk Assessment (CERA) of the ILSI Research Foundation outlined the objective of the seminar and introduced the program's international speakers. Mr. Monowar Islam, Director General, DoE thanked BSTI and South Asia Biosafety Program (SABP) for holding such an important seminar. He said that the Guidelines had been developed through joint initiatives of Bangladesh Agricultural Research Council (BARC) and DoE. He continued, saying he hoped that the Guidelines would be useful for developers as well as regulators in making decisions on the safety assessment of foods derived from GE plants. Mr. Islam reiterated that the Guidelines had already been approved by the NCB and in his speech requested BSTI also adopt the Guidelines as the standard for the safety assessment of GE plant-derived foods. Mr. A.K. Fazlul Ahad pointed out that BSTI is the lone institute in Bangladesh that has authority to set standards for food and other commodities and to issue certificates in favour of specific products. To this he added the simple fact that BSTI staff have no experience in the safety assessment of foods derived from GE plants. In this context, Mr. Ahad suggested the seminar would be immensely beneficial. The inaugural ceremony ended with a thank you by Dr. Md. Khalequzzaman A. Chowdhury, Member Director (Crops) at BARC and convenor of the drafting committee for the Guidelines.

Two scientific sessions followed the inaugural ceremony. The first, a review of biosafety obligations and regulations of biotechnology in Bangladesh, was given by Prof. M. Imdadul Hoque, SABP Bangladesh Country Coordinator. Prof. Hoque described the developments of different biosafety regulatory documents, including the Biosafety Guidelines of Bangladesh and the National Biosafety Framework. He outlined the different obligations under the Cartagena Protocol and identified the regulatory committees described in the Guidelines.

The second session, by Mr. Mohammed Solaiman Haider, Deputy Director, DoE and Member Secretary, NCB and BCC, described the development process of the Guidelines. He echoed the point that the Guidelines were developed through a series of stakeholder consultations with members of the drafting committee being taken from different stakeholder groups including National Agricultural Research System (NARS) institutes, BSTI, DG/Foods, DG/Health, Institute of Public Health and from universities. Mr. Haider described the salient features of the Guidelines including the scope and objectives.

Dr. Vibha Ahuja, General Manager, Biotech Consortium India Ltd. gave a presentation on the International Consensus on Food Safety Assessment of Novel Foods and the Codex Alimentarius Guidelines. Dr. Ahuja provided background on foods derived from GE plants and internationally accepted approaches to assessing food safety. She gave a comparative account of the development of crops

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using conventional breeding methods as well as through genetic engineering.

Dr. B. Sesikeran, Director, National Institute of Nutrition gave a presentation on India's Regulatory Guidelines for Safety Assessment of GM Crops. Pointing out that genetic modification "does not result in food which is inherently less safe than that produced by conventional means," he counseled that the risk-associated characteristics assessed for GM food are equivalent to the same characteristics for a conventional counterpart. Dr. Sesikeran also described the present status of pre-approval food testing in India.

Dr. Donald J. MacKenzie, Pioneer Hi-Bred, USA spoke about conducting food safety assessments under the Guidelines. He reviewed the essential elements of GE food safety assessment with an overview on assessing the potential toxicity and potential allergenicity of GE foods and their compositional analysis. He also talked about the outcome of the FAO/WHO consultation held in 2000, CODEX guidance (2003) and the acute oral toxicity testing of new proteins in the diet.

Two presentations made up the second session. Dr. Syed Humayun Kabir, Director (Standards), BSTI gave a detailed description of how a national standard is established in Bangladesh. He detailed how BSTI, the National Standards Body (NSB) of Bangladesh, plays a leading role in all matters related to standardization, testing, certification and metrology. He explained that standards are developed at national, regional and international levels. Going on, he said Bangladesh standards are developed by considering national perspective, manufacturers needs, industrial development, health and welfare of the public and promotion of export. BSTI performs functions such as standards development, product certification, management system certification, laboratory testing, metrology and calibration.

In the final presentation, Dr. Roberts reviewed the proposed process for implementation of the Guidelines. He briefly reviewed the topics presented earlier, and reinforced the need for an official standard and regulatory process to implement the Guidelines.

Finally, a panel discussion session was held where all speakers and invited guest from BCC and drafting committee members took part. The discussion ranged from issues related to molecular biology to the assessment of food safety and the role of BSTI in formulating a national standard. The discussion was lively and regarded as useful by all participants. The seminar closed with Dr. Roberts providing thanks to the speakers and participants.

DEVELOPMENT OF GENETICALLY ENGINEERED TREES: ISSUES AND CHALLENGES

Dr. O.P. Govila, former Professor of Genetics, Indian Agricultural Research Institute

Crop improvement facilitated by genetic engineering is one of the most significant developments in agricultural biotechnology, as evidenced by the growth of the area under cultivation with genetically engineered (GE) crops across the world. This rose from 1.7 million hectares in 1996 to 160 million hectares in 2011. Compared with advances made in field crops as seen over more than 15 years of successful commercial use, applications of genetic engineering in trees have lagged behind. This is mainly due to longer rotation times of the crop, significant hurdles to overcome with regard to efficient tissue culture and propagation technologies and also environmental concerns.

Conventional tree breeding has been used extensively in tree improvement programmes, however there are some desirable traits that are not available in the tree species of choice. These include herbicide and insect resistance, modified lignin and cellulose content and, more recently, research focused on traits in forest trees associated with the wood secondary cell wall that have the potential to make transformational changes to wood-based products. The increasing interest in the current trend towards a bio-based economy that derives resource materials from plant matter rather than petrochemicals is another important area of research. Some of the traits that have been targeted for development of GE trees and examples are given in Table 1.

TABLE 1: TRAITS BEING TARGETED FOR GENETIC MODIFICATIONS IN GE TREES

TRAITS	EXAMPLES
Disease tolerance	GE *papaya* against ringspot virus
Herbicide tolerance	Overexpression of in *Populus alba* × *P. grandidentata* against glyphosate -the active ingredient in Roundup® herbicide
Abiotic (*i.e.*, cold, wet, drought and freezing) stress tolerance	Genetically modified *Eucalyptus*
Pest resistance	Bt resistance in *Pinus radiata*
Modified wood fiber quality and quantity	Decreased lignin content in *Pinus radiate*
Nutrient uptake	*Populus* with enhanced nitrogen uptake
Altered growth rate	GS1 expression in *Populus*
Altered reproductive development (Flowering Control)	Overproduction of PtCENL1 –studies in nascent stages in *Populus*
Modified versions of fruit or flowers	GE *Citrus* to lower the liminoids to improve the quality of fruit juice

It has been reported that more than 700 field trials of GE trees have been carried out in the past 25 years in countries including Australia, Belgium, Brazil, Canada, China, France, Finland, Germany, Norway, Portugal, Spain, Sweden, The Netherlands, UK and USA. In the United States, GE papaya and, in China, GE poplar are two examples of successfully commercialized GE trees.

The general regulatory framework for GE trees is similar in many respects to that for crops and deals with two major areas of concern, food safety and environmental consequences. Some of the considerations in the regulation of horticultural trees are different from those of forestry trees, where food safety is rarely a problem and therefore the focus of GE tree regulation is the environment. A review of regulatory approaches to GE trees in various countries indicates that while regulatory systems may vary by country, usually GE trees fall under the same general set of regulations as for crops and other plants. However, the protocols for safety assessment and the conduct of confined field trials may be modified to recognize the longer lifespan of trees and the associated longer term deregulation problems.

In India, research institutions like the Indian Institute of Horticultural Research, Bangalore; the Institute of Forest Genetics and Tree Breeding, Coimbatore; Institute

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The Reading List

. . . new and notable articles

RNA INTERFERENCE IN PLANT PARASITIC NEMATODES: A SUMMARY OF THE CURRENT STATUS.

Lilley CJ, Davies LJ, Urwin PE.

RNA interference (RNAi) has emerged as an invaluable gene-silencing tool for functional analysis in a wide variety of organisms, particularly the free-living model nematode *Caenorhabditis elegans*. An increasing number of studies have now described its application to plant parasitic nematodes. Genes expressed in a range of cell types are silenced when nematodes take up double stranded RNA (dsRNA) or short interfering RNAs (siRNAs) that elicit a systemic RNAi response. Despite many successful reports, there is still poor understanding of the range of factors that influence optimal gene silencing. Recent in vitro studies have highlighted significant variations in the RNAi phenotype that can occur with different dsRNA concentrations, construct size and duration of soaking. Discrepancies in methodology thwart efforts to reliably compare the efficacy of RNAi between different nematodes or target tissues. Nevertheless, RNAi has become an established experimental tool for plant parasitic nematodes and also offers the prospect of being developed into a novel control strategy when delivered from transgenic plants.

PARASITOLOGY. 2012 JAN 5:1-11. [EPUB AHEAD OF PRINT]

GM WHEAT DEVELOPMENT IN CHINA: CURRENT STATUS AND CHALLENGES TO COMMERCIALIZATION.

Xia L, Ma Y, He Y, Jones HD.

Genetic modification facilitates research into fundamental questions of plant functional genomics and provides a route for developing novel commercial varieties. In 2008, significant financial resources were supplied by the Chinese government for research and development (R&D) into genetic modification of the major crop species. This project was aimed at providing an opportunity for crop improvement while accentuating the development of a safe, precise, and effective wheat genetic transformation system suitable for commercialization. The focus here is on one of the key crops included in this project, wheat, to provide an insight into the main transformation methods currently in use, the target traits of major importance, and the successful applications of wheat genetic improvement in China. Furthermore, the biosafety and regulatory issues of major concern and the strategies to produce 'clean' transgenic wheat plants will also be discussed. This commentary is intended to be a helpful insight into the production and commercialization of transgenic wheat in China and to put these activities into a global context.

JOURNAL OF EXPERIMENTAL BOTANY 2011 DEC 15. [EPUB AHEAD OF PRINT]

ASSESSMENT OF THE HEALTH IMPACT OF GM PLANT DIETS IN LONG-TERM AND MULTIGENERATIONAL ANIMAL FEEDING TRIALS: A LITERATURE REVIEW.

Snell S, Bernheim A, Bergé J-B, Kuntz M, Pascal G, Paris A, Ricroch AE.

The aim of this systematic review was to collect data concerning the effects of diets containing GM maize, potato, soybean, rice, or triticale on animal health. We examined 12 long-term studies (of more than 90 days, up to 2years in duration) and 12 multigenerational studies (from 2 to 5 generations). We referenced the 90-day studies on GM feed for which long-term or multigenerational study data were available. Many parameters have been examined using biochemical analyses, histological examination of specific organs, hematology and the detection of transgenic DNA. The statistical findings and methods have been considered from each study. Results from all the 24 studies do not suggest any health hazards and, in general, there were no statistically significant differences within parameters observed. However, some small differences were observed, though these fell within the normal variation range of the considered parameter and thus had no biological or toxicological significance. If required, a 90-day feeding study performed in rodents, according to the OECD Test Guideline, is generally considered sufficient in order to evaluate the health effects of GM feed. The studies reviewed present evidence to show that GM plants are nutritionally equivalent to their non-GM counterparts and can be safely used in food and feed.

FOOD AND CHEMICAL TOXICOLOGY. 2011 DEC 3. [EPUB AHEAD OF PRINT]

FIELD TRIALS AND TRIBULATIONS-MAKING SENSE OF THE REGULATIONS FOR EXPERIMENTAL FIELD TRIALS OF TRANSGENIC CROPS IN EUROPE.

Gómez-Galera S, Twyman RM, Sparrow PA, Van Droogenbroeck B, Custers R, Capell T, Christou P.

Transgenic plants that are being developed for commercial cultivation must be tested under field conditions to monitor their effects on surrounding wildlife and conventional crops. Developers also use this opportunity to evaluate the performance of transgenic crops in a typical environment, although this is a matter of commercial necessity rather than regulatory compliance. Most countries have adapted existing regulations or developed new ones to deal specifically with transgenic crops and their commodities. The European Union (EU) is renowned, or perhaps notorious, for having the broadest and most stringent regulations governing such field trials in the world. This reflects its nominal adherence to the precautionary approach, which assumes all transgenic crops carry an inherent risk. Therefore, field trials in the EU need to demonstrate that the

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of Himalayan Bioresource Technology, Palampur; Rubber Research Institute, Kottayam, etc. have begun researching and developing GE trees. Many tree species including eucalyptus, bamboo, casuarina, apple, papaya, pomegranate and mulberry are being developed for improved traits with GE rubber already having been approved for the conduct of confined field trials.

With research efforts initiated towards development of GE trees for both horticultural and forestry uses in India, there is a need to develop appropriate protocols to take these initiatives forward through the regulatory process.

READING - *continued from page 3*

risk associated with deploying a transgenic crop has been reduced to the level where it is regarded as acceptable within the narrowly defined limits of the regulations developed and enforced (albeit inconsistently) by national and regional governments, that is, that there is no greater risk than growing an equivalent conventional crop. The involvement of national and regional competent authorities in the decision-making process can add multiple layers of bureaucracy to an already-intricate process. In this review, we use country-based case studies to show how the EU, national and regional regulations are implemented, and we propose strategies that could increase the efficiency of regulation without burdening developers with further unnecessary bureaucracy.

PLANT BIOTECHNOLOGY JOURNAL 2012 DOI: 10.1111/J.1467-7652.2012.00681.X. [EPUB AHEAD OF PRINT]

CALENDAR OF EVENTS

Event	Organized by	Date and Venue	Website
INDIA			
Seed Industry Program 2012	Cornell University, College of Agriculture and Life Sciences Manager - Center For Executive Education Sathguru Management Consultants	March 5 - 8, 2012 Goa	http://www.nsai.co.in/Events/upload/brochure.pdf
National Seminar on New Frontiers and Future Challenges in Horticultural Crops	College of Agriculture, PAU, Ludhiana Sponsored by National Horticulture Mission	March 6 - 8, 2012 Ludhiana	http://web.pau.edu/coa/content/userfiles/10.pdf
Workshop on Commercialization Of Biotechnology	Department of Biotechnology, Government of India and Biotech Consortium India Limited	March 12, 2012 New Delhi	http://www.bcil.nic.in
International Symposium on New Paradigms in Sugarcane Research	Society for Sugarcane Research and Development and Sugarcane Breeding Institute	October 15-18, 2012 Coimbatore	http://www.sugarcane.res.in/images/sbi/Centenary/1st_circular_int_symposium.pdf
Biosafety Workshop on Problem Formulation: A Strategic Approach to Risk Assessment of GMOs	International Centre for Genetic Engineering and Biotechnology (ICGEB) in collaboration with the Ministry for Environment, for the Protection of the Territory and for the Sea, Government of Italy	April 16 - 20, 2012 Trieste Italy	http://www.icgeb.org/tl_files/Meetings/2012/ICGEB%20TS%20BSF%2016-20%20April%202012.pdf
Workshop on Biosafety of Genetically Engineered Crops: Best Practices from Laboratory to Farmer's Fields	ICGEB in collaboration with GENETECH, Colombo, Sri Lanka, University of Colombo, Sri Lanka, Michigan State University, USA, The National Science Foundation, Colombo, Sri Lanka and Embassy of USA, Colombo, Sri Lanka	May 21 - 25, 2012 Colombo, Sri Lanka	http://www.icgeb.org/meetings-2012.html
12th International Symposium on Biosafety of Genetically Modified Organisms (ISBGMO12)	International Society for Biosafety Research	September 17 – 20, 2012 St Louis, Missouri, USA	http://www.isbgmo.com/

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