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BIOSAFETY PROGRAM

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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.

QUARANTINE AND TRANSBOUNDARY MOVEMENT OF TRANSGENICS

Dr. Ravi K. Khetarpal, Head, Plant Quarantine Division, National Bureau of Plant Genetic Resources, New Delhi

Under the aegis of Convention on Biological Diversity (CBD; Article 19.3) the Cartagena Protocol on Biosafety, was adopted in 2000 to provide for the safe transfer, handling and use of living modified organisms (LMOs) in recognition of the potential risk arising from them. A lot of information on biosafety concerns regarding the effect of LMOs on safety, health and the environment has been generated and discussed in the recent past. The Protocol promises to provide an international regulatory framework for the biotechnology industry that protects the interests of international trade in genetically modified (GM, transgenic) crops while taking care of environmental protection.

The transboundary movement of any planting material poses the environmental risk of introducing exotic pests and diseases; moving transgenic planting material and crops has the added risk of introducing a new or unwanted transgene. Quarantine and trade related issues are country specific but also need to adhere to international norms. Unfortunately, few details are provided in the CBD on the methodology of quarantine processing and related issues that are important during transboundary movement of transgenics.

The import of transgenics is initiated with the issuance of an import permit by most importing countries. This involves a prior risk assessment based on the transgenes to be imported and a pest risk analysis (PRA) as per the International Standard of Phytosanitary Measures (ISPMs) of the International Plant Protection Convention (IPPC), which is the standard-setting organization of the World Trade Organization under the Agreement on Application of Sanitary and Phytosanitary (SPS) Measures. In particular, the IPPC has a standard (ISPM 11) on risk analysis that includes guidelines on risk assessment for LMOs when a transgenic crop may have the potential of becoming a pest.

The Biosafety Clearing House can provide technical information to the importer if there isn't a national mechanism for the risk assessment of imported transgenes or if additional information on risk assessment is required. Risk assessment is carried out on a case-by-case basis. It is the obligation of the exporter to notify the regulator in the country of import of the intended shipment of transgenic planting material. The regulatory decision on imports should be made in accordance with the risk assessment and the precautionary principle.

The imported consignment must be accompanied by a phytosanitary certificate as per IPPC norms. The imported transgenic seed samples can be subjected to the detection of transgene(s) and quarantine pests simultaneously. Pest detection involves specialized physical, chemical, biochemical, serological and molecular techniques, depending on the pests to be detected and the crops involved. The number and size of samples to be tested is based on whether the material will be imported in small quantities for research purposes or in bulk for sowing or consumption. In the case of import of planting material, a post-entry quarantine may be warranted. The detection of transgenes in the seed material may or may not be mandatory and is country-specific. Many serological (ELISA-based) and molecular (PCR-based) techniques are available to detect transgenes. Based on the health of the planting material, disinfestation treatments are imparted prior to the release of the consignment.

Although it may appear to be a simple and routine job, the ground reality is very different. A number of issues need to be addressed to ensure safe transboundary movement of transgenics. We will explore these issues in next month's newsletter.

CALENDAR

CALENDAR OF EVENTS

Event	Organization	Date	Place
INDIA			
Workshop on Global Food Security and Rising Food Prices	The Energy and Resources Institute (TERI)	May 26, 2008	New Delhi
Regional consultations on the proposed National Biotechnology Regulatory Authority (NBRA)	Department of Biotechnology (DBT) and Biotech Consortium India Limited (BCIL)	June 2008	Bangalore, Hyderabad, Chennai, Mumbai/ Ahmedabad and Kolkata
Workshop on Guidelines for Conducting Confined Field Trials of GE Crops and Standard Operating Procedures (SOPs)	National Seed Association of India and BCIL	June and July, 2008	Hyderabad and Aurangabad
SAU Workshops on Management and Monitoring of Field Trials of Genetically Modified Crops	Ministry of Environment and Forests, DBT and BCIL	June to August, 2008	State Agricultural Universities in 12 States
Symposium on Food Safety Assessment of Genetically Modified Crops	Indian Council of Medical Research, BCIL and AGBIOS	July 8, 2008	NIN, Hyderabad
GLOBAL			
First Global Conference on GMO Analysis	European Network of GMO Laboratories and the European Commission	June 24 to 27, 2008	Villa Erba, Como, Italy
10th International Symposium on the Biosafety of Genetically Modified Organisms	International Society for Biosafety Research (ISBR)	November 16 to 21, 2008	Wellington, New Zealand

BANGLADESH NCB APPROVES TRANSGENIC EGGPLANT FIELD TRIALS

On May 5, the inaugural meeting of the National Committee on Biosafety of Bangladesh (NCB) approved the application for confined field trials of transgenic eggplant submitted by the Bangladesh Agricultural Research Institute (BARI). These trials, to be held in three locations, will be the first to be held in Bangladesh and their approval follows on from the gazetting of the Biosafety Guidelines and the National Biosafety Framework of Bangladesh, which established the NCB as the apex body for the regulation of deliberate introduction of GM organisms into the environment.

The NCB is comprised of 21 members, including the Secretaries of the relevant ministries (Environment, Science, Agriculture, Fisheries, and Health) together with the Executive Chairman of the Bangladesh Agricultural Research Council and the Directors General of the various agricultural research institutes. Also on the NCB are the Directors of the Directorate of Food and the Department of Environment, which has the major responsibility for implementing the Biosafety Framework in Bangladesh. Also at this meeting, discussion was held on the formation of the Biosafety Core Committee (BCC) and the Field Level Biosafety Committee (FBC), which will be responsible for scientific evaluation of applications for environmental release of GM organisms and for the monitoring of these organisms. Appointment of members to these committees will be made by the Chair of the NCB, the Secretary of the Ministry of Environment and Forests.

The confined field trials of GM eggplant will be planted in May at three sites in Bangladesh, all under the supervision of BARI scientists. This material has been engineered to be resistant to the eggplant fruit and shoot borer and the trials are needed in order to determine the efficacy of the GM plants against this very damaging pest. Conditions have been placed on the trial to ensure that there will be no spread of genetic material from the trial site and no persistence of the plants in the environment once the trial is terminated. The protocol for the trial was considered by a Technical Committee in the Department of Agriculture prior to being submitted to the NCB for approval and follows internationally recognized approaches to managing such trials.

BANGLADESH LAUNCHES BIOSAFETY EDUCATION MATERIALS

In a launching ceremony held on May 10, 2008, the Department of Environment (DOE) of Ministry of Environment and Forests (MOEF) unveiled its recently gazetted Biosafety Guidelines of Bangladesh and National Biosafety Framework (NBF). It was attended by more than 100 participants from different universities, NARS institutes, various ministries, NGOs and from the private sectors.

After the launching ceremony, a round table meeting was chaired by the Director General of DOE. The main focus of the discussion was the significance of implementing the NBF to ensure the safe development of biotechnology in Bangladesh. The importance of working together to create a regulatory system that allowed scientists and industry to realise the benefits of modern biotechnology, while protecting human health and the environment, was stressed. The steps taken by the DOE to develop the NBF and related Biosafety Guidelines were applauded, but it was also recognised that there was still much to be done.

INDIA DEVELOPS PCR-BASED RAPID DIAGNOSTIC KITS FOR FIVE GM CROPS

Seedquest - April 7, 2008

The global area under commercial cultivation of genetically modified (GM) crops is increasing at a very fast pace. In India too, there has been a dramatic increase in commercial cultivation of Bt cotton. There is an urgent need for upgrading the analytical methods for the GM detection to check the authorized GM crops being cultivated and to solve the legal

(continued on page 4 - see India)

SPOTLIGHT ON THE WORLDWIDE WEB

Since September 2007 we have 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 Biotech Consortium India Limited (BCIL) (http://bcil.nic.in/). - Editor

Biotech Consortium India Limited (BCIL)

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

Biotech Consortium India Limited (BCIL) was incorporated as a public limited company in 1990 under the Indian Companies Act 1956. It is promoted by the Department of Biotechnology, Government of India and financed by the All India Financial Institutions including IDBI, ICICI, IFCI, UTI and IFCI Venture Capital Funds Limited (formerly RCTC) and the corporate sector including Ranbaxy Laboratories, Glaxo India, Cadila Laboratories, Lupin Laboratories, Kothari Sugars and Chemicals, Rallis India, SPIC, Madras Refineries, Zuari Agro, EID Parry, ACC and Excel Industries.

Over the past decade and a half, BCIL has been actively involved in technology transfer, project consultancy, fund syndication, information dissemination, and manpower training and placement related to biotechnology. It has assisted scientists, technologies, research institutions, universities, first entrepreneurs, the corporate sector, national and international organizations, central government, various state governments, banks and financial institutions.

The services of BCIL are aimed at facilitating accelerated commercialization of biotechnology by:

- establishing linkages among the various stake holders including industry, research and development institutions, government, financial institutions and international agencies and providing access to technologies;
- creating awareness about business opportunities, IPR protection, regulatory and biosafety requirements;
- preparing feasibility and detailed project reports; and
- arranging financial support and manpower training and placement.

The website provides, among other things:

- a descriptions of its services including technology transfer, project consultancy, certification services, information services, biosafety, human resource development, and project management;
- information about its Biotechnology Club, which keeps its members updated on major developments in biotechnology;
- web links to the various Department of Biotechnology websites; and
- information about its publications, which include a Biotech Directory, the Value Added Technology Information Services (VATIS) Update and the Biotech Bulletin.

India - *continued from page 2*

disputes as well as to meet the labeling and international trade requirements.

Diagnostic kits based on polymerase chain reaction (PCR) have been developed for five GM crops. Bt cotton (Bollgard I) with *cry1Ac* gene was the first GM crop to be commercialized in India in March 2002 and Bt cotton (Bollgard II) with *cry1Ac* and *cry2Ab* for insect resistance has also been commercialized. Revealing this at a press conference in New Delhi today, Union Minister for Science and Technology and Earth Sciences, Shri Kapil Sibal said that these diagnostic kits developed at the National Bureau of Plant Genetic Resources (NBPGR) under a collaborative research project funded by Department of Biotechnology (DBT) are ready for commercial launch and will be of immense use to meet the regulatory obligations and legal requirements as well as helping to address consumer concerns.

The other four food crops, *viz*., Bt brinjal and Bt cauliflower with *cry1Ac* gene, for insect resistance, GM mustard with *barnase/ barstar* gene for male sterility and GM tomato with *osmotin* gene for drought and salinity tolerance are either in field trials or in advanced stages of testing in contained field trials.

Crop	Transgene/promoter/ endogenous gene	Trait
Cotton (Bollgard I)	cry1Ac/CaMV 35S/Sad1	Insect resistance
Cotton (Bollgard II)	cry1Ac & cry2Ab/CaMV 35S/ Sad1	Insect resistance
Bt brinjal	cry1Ac/CaMV 35S	Insect resistance
Bt cauliflower	cry1Ac/CaMV 35S/ SRK1	Insect resistance
Mustard	barnase & barstar/CaMV 35S/ HMG	Male sterility
Tomato	osmotin/CaMV 35S/ LAT52	Salinity and drought tolerance

The kits can detect specific transgenes, *cry1Ac*, *cry2Ab*, *barnase/ barstar*, and *osmotin* gene, individually as well as along with CaMV35S promoter and endogenous genes, Sad1 in cotton, SRK1 in cauliflower, HMG in mustard, Lat52 in tomato.

The diagnostic kits are reliable, sensitive and efficient, as more than one target sequence can be detected in a single assay, the sensitivity of the kits is upto 0.1%. They are user friendly and would require merely 4 hours time to complete the assay from the DNA and 8-10 hours from the plant tissue. The kits are cost effective and the cost per assay will range from Rs. 50 to 60 only.

NBPGR, New Delhi, has been designated by DBT as a Referral Centre for Molecular Diagnosis of Transgenic Planting Material.

A special issue of the journal Pest Management Science, focusing on glyphosate-resistant weeds and crops, was published in April 2008. This issue may be of interest to readers of the SABP newsletter.

PEST MANAGEMENT SCIENCE

Volume 64 Issue 4 , Pages 317 - 496 (April 2008)
Special Issue: Glyphosate-Resistant Weeds and Crops

Articles in this issue include:

- Editorial: Glyphosate-Resistant Weeds and Crops;
- Glyphosate: a once-in-a-century herbicide;
- Glyphosate-resistant crops: adoption, use and future considerations;
- New multiple-herbicide crop resistance and formulation technology to augment the utility of glyphosate;
- Characterization and plant expression of a glyphosate-tolerant enolpyruvylshikimate phosphate synthase;
- Economic impacts of glyphosate-resistant crops;
- The control of Asian rust by glyphosate in glyphosate-resistant soybeans;
- Evolved glyphosate-resistant weeds around the world: lessons to be learnt;
- Glyphosate-resistant weeds of South American cropping systems: an overview;
- Resistance to glyphosate from altered herbicide translocation patterns;
- Weed species shifts in glyphosate-resistant crops;
- US grower perceptions and experiences with glyphosate-resistant weeds;
- Simulation modelling to understand the evolution and management of glyphosate resistance in weeds;
- A risk calculator for glyphosate resistance in *Lolium rigidum* (Gaud.);
- Sustainable use of glyphosate in North American cropping systems;
- Managing the risk of glyphosate resistance in Australian glyphosate-resistant cotton production systems;
- Glyphosate sustainability in South American cropping systems;
- Gene flow from glyphosate-resistant crops;
- Fate of glyphosate in soil and the possibility of leaching to ground and surface waters: a review;
- Integrating soil conservation practices and glyphosate-resistant crops: impacts on soil;
- Herbicides, glyphosate resistance and acute mammalian toxicity: simulating an environmental effect of glyphosate-resistant weeds in the USA;
- Comparison of herbicide regimes and the associated potential environmental effects of glyphosate-resistant crops versus what they replace in Europe; and
- Glyphosate applied at low doses can stimulate plant growth.

For more information go to: http://www3.interscience.wiley.com/journal/117934749/issue

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