



SOUTH ASIA
BIOSAFETY PROGRAM

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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.

GUIDELINES AND STANDARD OPERATING PROCEDURES FOR CONFINED FIELD TRIALS OF REGULATED GENETICALLY ENGINEERED PLANTS IN INDIA

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

Mendelian principles provided a scientific basis for the theory and practice of plant breeding. In plant breeding, whenever an improved variety is developed, it has been a normal practice to check for its agronomic performance and carry out evaluation in different environments through multi location trials to ensure that the traits in the new variety are economically superior to the existing varieties. After a few years of multi-location trials for reliable performance, the variety is released to farmers for cultivation.

Genetic engineering or transgenic technology is similar to conventional breeding in terms of the objective of generating more useful and productive crop varieties containing a new combination of genes, but it expands the possibilities by enabling introduction of useful genes not just from within the crop species or from closely related plants, but from a wide range of other organisms. It allows the transfer of one or more genes, in a controlled and predictable way, that are not available to conventional plant breeders. However this has resulted in concerns being expressed about the potential risks associated with the impact on human health, the environment and biological diversity. Questions focus on increased toxicity and allergenicity, the impact of introduced traits introgressing into other related species through outcrossing, the potential buildup of resistance in insect populations to engineered insecticidal traits, and the unintended secondary effects on non-target organisms.

In view of the above, field trials involving genetically engineered (GE) crops assume great significance as they

represent the first controlled introduction of a GE crop into the environment which take place after experiments in laboratory/glass house contained facilities, but before the environmental release declaring the product to be bio safe. Accordingly, regulatory frameworks in various countries provide guidance for the conduct of field trials (CFTs) of GE crops.

In India, guidelines for research in transgenic plants issued in 1998, included considerations to be followed for conducting limited field experiments of GE crops, *i.e.*, strip trials, multi location research trials and large scale trials on the lines of varietal testing in plant breeding. Bt cotton containing *cry1Ac* was one of first crops permitted for field testing and evaluation. As a member of the Monitoring cum Evaluation Committee, I was involved in development of formats for monitoring as well as participating in field visits across the country to review the performance of Bt cotton. In fact the first monitoring was done by our team. Bt cotton was finally approved for commercial cultivation in 2002. As the regulatory agencies in India have been following individual genotype based approval, the number of trials to be monitored, particularly those of various Bt cotton hybrids containing the approved genes/events, increased substantially. The focus of these trials was primarily on testing agronomic performance, while due care was maintained in ensuring required isolation distance and observing parameter such as yield, efficacy, quality of produce, effects on beneficial insects, *etc.*



Dr. O.P. Govila inspecting a confined field trial.

With the successful adoption of Bt cotton in India, the research and development efforts received added momentum and field trials of several different crops with new genes/events are being planned and applications have been submitted to regulatory agencies. Simultaneously, the Genetic Engineering Approvals Committee (GEAC) has adopted an event-based, rather than genotype based, approval system for GE crops.

(continued on page 4 - see Guidelines)

CALENDAR OF EVENTS

Event	Organization	Date	Place
INDIA			
2nd International Food Regulatory Summit, 2008 - "Delivering Consumer Choice, Health and Safety".	Confederation of Indian Industry in cooperation with Food and Agriculture Organization of the United Nations (FAO)	October 16 - 17, 2008	Radisson MBD Hotel, Noida
SAU workshops on 'Management and Monitoring of Field Trials of Genetically Modified Crops'. Organized by Ministry of Environment & Forests (MOEF), Department of Biotechnology (DBT) and Biotech Consortium India Limited (BCIL).	Workshops are being held October - December, 2008, at the following SAUs: <ul style="list-style-type: none"> - Rajendra Agricultural University, Samastipur, Bihar - Indira Gandhi Krishi Vishwavidyalaya, Raipur, Chhattisgarh - Orissa University of Agriculture & Technology, Bhubaneswar, Orissa - Bidhan Chandra Krishi Viswavidyalaya, Nadia, West Bengal - Birsa Agricultural University, Ranchi, Jharkhand - Jawaharlal Nehru Krishi Viswavidyalaya, Jabalpur, Madhya Pradesh - University of Agricultural Sciences, Bangalore - Chaudhary Charan Singh Haryana Agricultural University, Hisar, Haryana - Punjab Agricultural University, Ludhiana, Punjab - Dr. Panjabrao Deshmukh Krishi Vidyapeeth, Akola, Maharashtra - Acharya NG Ranga Agricultural University, Hyderabad, Andhra Pradesh - Tamil Nadu Agricultural University, Coimbatore, Tamil Nadu - Sardarkrushinagar-Dantiwada Agricultural University, Dantiwada, Gujarat - Rajasthan Agricultural University, Bikaner - Narendra Deva University of Agriculture & Technology, Faizabad, Uttar Pradesh - CSK Himachal Pradesh Krishi Vishwavidyalaya, Palampur, Himachal Pradesh 		
Sensitization workshop on "Biosafety Issues Related to Practicing Agricultural Biotechnology" for the news media, policy makers, scientists and extension officials of North zone.	G.B. Pant University of Agriculture and Technology (GBPUAT) and International Service for the Acquisition of Agri-Biotech Applications (ISAAA)	November 3 - 4, 2008	GBPUAT, Pantnagar
BANGLADESH			
International Symposium on Regulatory and Safety Issues in the Commercialization of Biotechnology Research in the Developing World.	International Centre for Genetic Engineering & Biotechnology (ICEGB) and BRAC University. For more information e-mail biotechsypm2008@yahoo.com	December 2 - 4, 2008	BRAC University, Dhaka
4th International Botanical Conference.	Bangladesh Botanical Society	January 16 - 18, 2009	Botany Department, Dhaka University
INTERNATIONAL			
10th International Symposium on the Biosafety of Genetically Modified Organisms.	International Society for Biosafety Research (ISBR)	November 16 - 21, 2008	Wellington, New Zealand

PLANT BIOTECH BONANZA

Nature Biotechnology - October 2008

The US Senate has recommended up to \$30 million to develop biotech crops for Africa and Asia in its 2009 budget. If approved, this will be the tenth consecutive year—except 2008—in which Congress has appropriated funds for such projects. The US Agency for International Development (USAID) controls the money and focuses on developing genetically engineered varieties of crops that affect incomes of small-scale farmers. In the past, the agency has funded research on insect-resistant cowpeas for West Africa and virus-resistant papaya for the Philippines and Bangladesh. Next year's focus: drought- and salt-tolerant rice and wheat. USAID biotech funding is prioritized well but may be spread too thin, say experts. "It takes roughly \$10–20 million to get to a genetically modified crop," says Florence Wambugu, CEO of Africa Harvest Biotech Foundation International in

Nairobi. "It would appear that [USAID] money has been spread across many areas, and it may be of greater benefit to focus on specific areas, especially where there is synergy with other funds." The \$30 million isn't guaranteed yet: the Senate's recommendation must be passed by the full Senate, agreed upon by the House of Representatives and signed by the incoming president.

We welcome reader comments or suggestions.

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CREAM OF THE (WEB) CROP

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THIS MONTH'S PICK:

International Portal on Food Safety, Animal and Plant Health website

<http://www.ipfsaph.org/En/default.jsp>

The International Portal on Food Safety, Animal and Plant Health (IPFSAPH) is a joint undertaking between a number of SPS-recognized standard-setting organizations and international agencies. It was developed by the Food and Agriculture Organization of the United Nations (FAO) in association with Codex Alimentarius, the Secretariat of the International Plant Protection Convention (IPPC) and the World Organization for Animal Health (OIE).

The goal of IPFSAPH is to facilitate trade in food and agriculture products and support the implementation of the World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) Agreement by providing a reliable single access point for authorized international and national information across the sectors of food safety,

animal and plant health. This cross-sectoral approach aims to avoid information gaps resulting from the dispersal of data sets across diverse organizations.

The portal is targeted at individuals from national government agencies, scientific and private sector institutions, as well as regional and international organizations.

IPFSAPH contains official information related to food safety, animal and plant health. It includes international and national standards, recommended codes of practice, laws, regulations, trade notifications, risk assessments, maximum residue limits, national contact point details and related supporting documentation.

Records in the portal are taken from nearly 50 different competent national institutions, standard setting bodies, international and regional agencies. New datasets are added as they become available. The majority of content is updated automatically from original sources (e.g., trade notifications, pest and disease alerts). New releases of the portal are published nearly every week.

Documents are available in their original language. Where the original language is not English, French or Spanish summaries in those languages are provided. The site is navigable in English, French and Spanish.

The portal actively encourages the inclusion of national documentation relevant to the SPS Agreement. For more information, please contact the portal at: IPFSAPH@fao.org.

IPFSAPH HOME PAGE

ADVANCED SEARCH PAGE

www.ipfsaph.org

Guidelines - continued from page 1

In view of this, Dr. K.K. Tripathi, Advisor, Department of Biotechnology (DBT) and Member Secretary, Review Committee on Genetic Manipulation initiated the exercise of supplementing the 1998 guidelines with detailed guidance on conduct of field trials of GE crops. I was invited to participate in this exercise and, in particular, to advise on the feasibility of implementing the new set of guidelines and Standard Operating Procedures (SOPs).

SCOPE AND KEY FEATURES OF NEW SET OF GUIDELINES AND SOPs FOR THE CONDUCT OF CFTs OF REGULATED, GE CROPS

SCOPE OF NEW GUIDELINES - Guidelines for CFTs of GE plants are based on three considerations. Firstly, CFTs are carried out on a small scale. Secondly, CFTs are an experimental activity conducted to collect data on potential biosafety impacts. Finally, the trial is conducted under conditions known to prevent i) pollen or seed mediated dissemination of experimental plants, ii) persistence of the GE plant or its progeny in the environment and iii) introduction of GE plant or plant products into the human food or livestock feed.

MAIN FEATURES OF GUIDELINES - The CFTs have to be conducted for three seasons/years (Biosafety Research Level -BRL I + I by RCGM and BRL II by GEAC) along with food and feed safety wherever required and data on ecotoxicology and field observation. An elaborate application form has been provided to get relevant information from the applicant about the unmodified species (through biological documents) and its modified GE version (through laboratory experimentation)

LETTER OF AUTHORIZATION - After technical review, successful applicants are issued a letter of authorization to conduct CFTs with the following conditions/requirements for compliance and reporting such as (only a broad list is provided):

- i) Restrictions on size and number of CFTs with a simplified field protocol, storage and transport details, field maps, etc.
- ii) Records and reporting by applicant a) compliance records, b) field trial report and c) to provide mandatory information on planting, harvest, accidental release.
- iii) Information on reproductive isolation of CFT.
- iv) Disposal of material from CFT.
- v) Post harvest land use and monitoring.

COMPLIANCE AND REPORTING BY THE PERMITTED PARTY - THE SOPs - The guidelines include SOPs to carry out each activity in CFT of GE material (SOPs on storage, transport, conduct of field trials, harvest and termination and post harvest monitoring). Finally, for each of these activities eight recording forms have been provided to the permitted party for recording compliance, making reporting simpler.

MONITORING OF CFTs - The monitoring guidelines are intended to provide guidance to designated members of monitoring teams who have been given the responsibility of determining whether conduct of a CFT, including the condition of trial site, storage facility, and availability of relevant documentation and records are in compliance with the term and conditions of the permit. The guidance in this document is consistent with the Guidelines and SOPs. Appropriate forms have been provided for monitoring teams for reporting to the regulatory authorities.

My first reaction to the draft documents was that these might be difficult to follow in India, but as I read the drafts, I found them very systematic and easy to follow. I presented the guidelines and SOPs in three regional workshops organized by the Ministry of Environment and Forests, DBT and Biotechnology Consortium India Limited wherein the scientists from national agricultural research system (NARS) of India viz. agricultural research institutions and state agricultural universities across the country, participated. I was extremely pleased that at the end of these workshops, the key stakeholders were convinced about the need and importance of following new set of guidelines and SOPs in conduct of confined field trials.

The scope and key features of guidelines are presented in the box at left.

Following the adoption of the new set of guidelines, they were implemented by the regulatory agencies. I was invited to be a part of this exercise and it may be a coincidence that I was a member of the first team that monitored confined field trials as per the new set of guidelines, in the same way that I was involved in monitoring the first field trial of Bt cotton containing *cry1Ac* gene in 1999. Now that the whole process is in place and the permitted parties have started following the new guidelines it is hoped that the biosafety issues concerning GE plants will be addressed in a more scientific manner in India.



Two recent article in the online journal **GMO Safety** may be of interest to readers of the SABP newsletter.

WESTERN CORN ROOTWORM IN GERMANY: PEST CONTROL WITH SIDE-EFFECTS

August 21, 2008

The number of pests found is increasing. Incorrect treatment of the maize seed causes bee deaths.

TEN YEARS OF Bt MAIZE CULTIVATION: HORIZONTAL GENE TRANSFER OF No SIGNIFICANCE

May 30, 2008

Scientists from France and Switzerland have been studying soil bacteria from a field where genetically modified Bt maize has been growing for ten years: transgenic plants play no part in the spread of antibiotic resistances.

See the full articles at <http://www.gmo-safety.eu/en/news/>



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