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.

## THE NATIONAL PHYTOTRON FACILITY

Dr. K.V. Prabhu, National Phytotron Facility, IARI, New Delhi

The National Phytotron Facility (NPF) at the Indian Agricultural Research Institute (IARI), is a controlled environment plant research facility designed to enable its users to perform studies on plants under specified environmental conditions like temperature, light, humidity and filtered air quality. The Facility's design automatically makes it suitable for the containment of genetically modified organisms (GMOs).

The Facility is open to users from the National Agricultural Research System and other institutions (public or private) engaged in transgenic plant research. The NPF was opened to users in November 1998, who are allowed to initiate experiments after their proposals have been approved by the Institutional Biosafety Committee.

Transgenic cotton in a greenhouse at the NPF.

Infrastruture: The NPF is a professionally managed independent unit in a 2700m$^2$ centrally air conditioned building. The 1125 kW electrical demand of the facility is met by the Delhi Vidyut Board through an 11 kV dedicated sub-station with standby power generation equipment. Water for the facility is from ground water sources and is provided through a 25000 litres per day water softening plant.

Growth chambers housed in the NPF.

Growth Chambers: There are 12 growth chambers with a floor area of 1.39 m$^2$ each, eight with a floor area of 3.36 m$^2$ each and two with a floor area of 6.72 m$^2$ each. The ranges of micro-climatic parameters achievable in the growth chambers are as follows:

- Temperature: 4°C to 45°C
- Relative Humidity: 30 to 95%
- Lights: 0 – 124 k lux (1470 $\mu Em^{-2}s^{-1}$) through 81 steps
- Carbon Dioxide: Resultant (from growing plants) to 3000 ppm
- Air Flow: Vertical current upward

Greenhouses: There are ten attached greenhouses, each with a floor area of 9 m x 4.5 m, on the south facing side of the building with individual access from the building. Each greenhouse is constructed with a roof made of 6 mm twin wall polycarbonate sheet and three sides of 5 mm clear window glass. The greenhouses have a closed loop temperature control system to maintain the temperature in the range of 10°C to 40°C. Relative humidity can be maintained in the range of 40 to 80%. Photoperiod control exists.

Tissue Culture Facility: There is a compact tissue culture area, spanning about 60 m$^2$, comprising three independent culture rooms, a media room and a media preparation room with clean environment and temperature control features. Transformation can be carried out safely in the facility without exposing the experimenter or the environment to any hazards.

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ACTIVITIES

## CALENDAR OF EVENTS

**INDIA**

| Event | Organization | Date | Place |
|---|---|---|---|
| Consultation on Safety Assessment of GM Food Crops | Department of Biotechnology and Biotech Consortium India Limited (BCIL) | June 2, 2007 | University of Agricultural Sciences, Dharwad |
| Training workshop on biosafety issues for the members of SBCCs, DLCs and IBSCs | Ministry of Environment & Forests( MoEF), BCIL and Government of Karnataka | June 7, 2007 | Hotel Atria, Bangalore |
| Training workshop on biosafety issues for the members of SBCCs, DLCs and IBSCs | MoEF, BCIL and Department of Environment & Forests, Government of Tamil Nadu | June 8, 2007 | Hotel Taj Connemara, Chennai |

**NPF -** *continued from page 1*

The greenhouses are suitable for Biosafety Level 3 (BL3) work, and can be easily maintained without external exposure. Effluents can be treated from individual potted plants. Each growth chamber is suitable for BL3 and the supportive laboratory facilities at the NPF make the growth chamber experiments convenient to maintain, while preventing any escape of the gene or the GMO to the outside environment. [Information on containment and biosafety levels will be provided in next month's issue of the SABP newsletter.]

Similarly, basic infrastructural provision with adequate equipment has been made for laboratory work in three rooms to support research in the areas of genetics, plant biotechnology, plant physiology and biochemistry. This enables significant information generation on the genetically modified plants under contained conditions in the facility.

## PAKISTAN REGIONAL CONSULTATION ON TRANSGENIC COTTON

Ijaz Ahmad Rao, Bahawalpur, Pakistan,
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The Common Fund for Commodities approved the project 'Regional Consultation on Biotech Cotton for Risk Assessment and Opportunities for Small Scale Cotton Growers - CFC/ICAC'. The main objective of the project was to organize a consultation aimed at discussing all aspects of transgenic cotton. The International Service for the Acquisition of Agri-biotech Applications served as the Project Executing Agency. The National Institute for Biotechnology and Genetic Engineering (NIBGE), Faisalabad, Pakistan hosted the consultation. Forty-three international participants from 27 countries plus 73 participants from Pakistan attended the meeting.

Crop biotechnology applications and uses include tissue culture/embryo culture, DNA marker assisted technologies, diagnostics and genetic engineering tools. However, genetic engineering is the most visible commercial use of the technology in agriculture. Nine countries have commercialized transgenic cotton so far, and around 36% of the world cotton area in 2006/07 was planted to transgenic varieties.

Acceptance of transgenic cotton depends on a range of issues related to agronomic factors, environmental concerns, farming systems and long-term sustainability of the technology. The technology developers and users have a challenge to maintain high quality stewardship programs to protect sustained use of the technology. Political support and national investment in biotechnology are also crucial for safe and economical use of biotechnology applications.

Concerns and apprehensions about the safety and sustainability of currently available transgenic products in cotton have been raised. Most safety issues have been adequately addressed at the scientific level. Continuing research and integrating public awareness into the scientific process from the very beginning can effectively address many other concerns.

The first generation products have agronomic benefits in the form of lower insecticide use and better weed control, although better weed control may be accompanied by increased herbicide use.

The regulatory process for development, approval, testing and commercialization of transgenic products is cumbersome and expensive and limits the spread of the technology to developing countries. Countries like China (Mainland), India and Pakistan have developed their own genes against bollworms and sucking insects and are developing genes against other pests. The developed infrastructure may lower the cost of the technology. China (Mainland) already has 80% of the transgenic cotton area under a locally developed Bt gene.

It is important to incorporate the technology into locally adapted germplasm, as locally developed varieties are usually the most suited to the prevailing environmental conditions, cropping systems and biotic constraints such as pests, and have production of higher quality. Also, more researchers need to be involved in the regulatory bodies set up by governments.

China and India have seen tremendous increases in yields since the adoption of transgenic cotton. Small growers in South Africa have equally benefited from this technology, as did the growers in areas of Colombia with a high incidence of target pests. However, the insect resistant transgenic varieties may not bring the same benefits to growers in areas or countries where the cost of controlling the target insects is lower than the cost of the technology fee. The experience in India shows that the Bt expression decreases as the crop matures, so the level of protection by the transgene decreases at later stages of plant development. The expression decrease needs to be monitored, particularly in long-duration varieties or growing conditions similar to Northern India and Pakistan.

Biotechnology research in cotton is limited due to a lack of technical staff, high cost of research and development work, controversies and opposition from policy makers, lack

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**Pakistan -** *continued from page 2*

of financial support from governments, political skepticism that biotechnology is an economic manoeuver by developed countries and private companies, costly risk management studies, narrow scope of *Cry* genes and technical complexity. Limitations could be alleviated through regional and international cooperation and networking.

The Government of Pakistan established the 'Pakistan Biosafety Rules' in April 2005. The government also published the 'National Biosafety Guidelines' in May 2005. Roles of various organizations have been established, setting the stage for commercial use of biotechnology applications. Local researchers have developed a modified form of the *Cry1Ac* gene that has been extensively tested throughout the main cotton growing areas. The data show significant savings to growers in insecticide applications in spite of the fact that drought and temperature affected expression of the transgene. Farmers are demanding transgenic varieties, but the government is still considering commercial release approval of transgenic varieties.

The rate of adoption of cotton in producing developing countries is slow due to various policy-related, regulatory, technical, and trade constraints. Partnerships and international cooperation could help allow stakeholders to work more effectively for improving understanding of the technology and its commercial use.

## BIOTECHNOLOGY WILL DOMINATE THE 21ST CENTURY: NAMO NARAYAN MEENA

Government of India Press Release – May 9, 2007

Union Minister of State for Environment and Forests, Shri Namo Narayan Meena said biotechnology will dominate the 21st century just as information technology dominated the last century. Addressing the 10th meeting of the Consultative Committee of the Ministry of Environment and Forests, last night, he informed the meeting that the stay on Genetic Engineering Approval Commttee has been vacated today during judicial hearing. The entire research activities of the country which were at a standstill, will get momentum and Genetic Engineering Approval Committee (GEAC) will be able to work speedily. Shri Meena assured along with treating this field as a priority area with investments, priority will be given to proper risk assessment and appropriate measures to mitigate its adverse impacts.

Before the presentation on living modified organisms (LMOs) and genetically modified organisms (GMOs) , he said in biopharma and bio-seeds industries , the turnover has already crossed a billion mark and the growth rate is estimated as 40 per cent. Referring to the approval of the transgenic crop Bt cotton and 20 recombinant therapeutic products in India, he said 62 hybrids of cotton have been approved for commercial cultivation across nine cotton growing states (Andhra Pradesh, Gujarat, Haryana, Karnataka, Madhya Pradesh, Punjab, Rajasthan and Tamil Nadu) after reviewing the performance and other criteria.

The area under cotton cultivation has increased from 72,000 acres in 2002 to 93 lakh acres in 2006. Overall production has gone up to 24.4 million bales in 2005-06 as compared to 15.8 million bales in 2001-02. The productivity has increased from 308 kg per hectare to 450 kg per hectare during the same period. The Minister of State added the pesticide usage has also come down by 2260 MT during 2005-06. Though there has been overall acceptance of the Bt technology by cotton growing farmers, the issues and concerns raised are being examined by the Regulatory Agencies. He said Bt cotton is the first GM crop in the country, which enables us to pass through the learning phase. Sale of illegal/spurious seeds, insect resistant management, compliance of conditions, *etc.*, are various issues that will be taken care of by the Ministry.

This Ministry is the nodal ministry for implementation of Cartagena Protocol on Biosafety. This is an international agreement under Convention on Biological Diversity, The Ministry is also implementing a World Bank GEF capacity building project on biosafety that includes strengthening the national capacity for effective legislative framework, operational mechanism, establishing biosafety data base and supporting a network for research in the area of risk assessment and monitoring.

The committee members appreciated the presentation on biosafety regulation of LMOs as well as GMOs in India. They inquired about the authority that will monitor and control biosafety assessments of transgenic crops. Welcoming the higher production of Bt cotton, members suggested improving the quality of long staple in cotton.

Earlier, members also sought the action taken on the projects and progress, which were discussed during the last consultative committee meeting. Concluding the meeting, Shri Meena said that biotechnology has the potential for ensuring food security, decreased pressure on land use, increased crop yields and reduced use of water and agrochemicals in agriculture. Genetic engineering offers benefits for agriculture, medical treatments, new industrial products, improved fibers and fuels, S/shri Mahaveer Bhagora, Dushyant Singh, Basudeb Barman, from Lok Sabha and Shri R. Shunmugasundaram from Rajya Sabha attended the meeting.

## SC ALLOWS FIELD TRIALS OF GM SEEDS

Press Trust of India - May 8, 2007

The Supreme Court today allowed the centre to conduct approved field trials of genetically modified (GM) seeds in the country subject to certain restrictions.

A three-member bench headed by Chief Justice K.G. Balakrishnan permitted field trials of GM crops, which were earlier approved by the the Genetic Engineering Approval Committee (GEAC) in April and May 2006, provided it fulfilled certain conditions.

The government should increase the isolation distance up to 200 metres between the GM-planted fields and other fields, and a protocol for testing for contamination up to 0.01% for neighbouring fields was established, the apex court said.

It also said a designated scientist should be made responsible for ensuring that all the conditions were complied with during the field trials of GM seeds.

While the court allowed the commercial release of four approved Bt cotton varieties, it said no new species should be introduced.

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**Field Trials -** *continued from page 3*

The bench said GEAC, the GM regulatory authority under the Union Ministry of Environment and Forests, should submit detailed data, if any, about the effects of GM crops, *i.e.* the toxicity and allergic reactions before the court.

The apex court, on a public interest litigation filed by Aruna Rodrigues and others, had on September 22 last year directed GEAC not to clear any GM crop for fresh field trials.

On May 1 last year, it had also said the GEAC and not the Review Committee for Genetic Manipulation (RCGM) under the Department of Biotechnology should be responsible for field trials and approval of GM crops.

## PAPER 'A REVIEW OF INTERNATIONAL LABELING POLICIES OF GM FOOD TO EVALUATE INDIA'S PROPOSED RULE' NOW AVAILABLE

A paper, 'A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule', by Dr. Guillaume P. Gruère, Environment and Production Technology Division, International Food Policy Research Institute, and Dr. S.R. Rao, Department of Biotechnology, Ministry of Science and Technology, Government of India, which was published in the latest edition of AgBioForum (http://www.agbioforum.org/v10n1/v10n1a06-gruere.htm) is available to download as a PDF from the SABP website at http://www.agbios.com/docroot/articles/07-132-001.pdf

This paper provides a comprehensive review of existing international labeling policies of genetically modified (GM) food and associated relevant international agreements in order to evaluate India's proposed mandatory labeling rule. Existing evidence from developed countries shows that mandatory labeling regulations have resulted in no additional consumer choice or information. Among the few developing countries with labeling policies, most have not effectively implemented their regulations. We show that India's proposed labeling rules for GM food would be among the most stringent globally and could potentially result in low consumer benefits at a high cost both domestically and internationally. India's proposed regulation also lacks a number of elements to be implemented. However, these conclusions are based on experiences from other countries and limited available information from India. More studies are needed to evaluate the potential economic effects of GM food labeling in India.

## BIOTECH INDUSTRY TO TOUCH $5 BILLION IN THREE YEARS

Times of India - May 7, 2007

The domestic biotechnology sector, which closed at $1.5 billion mark in 2005-06, is expected to touch $5 billion by 2010. The sector is growing at a compount annual growth rate of 35%. Biotechnology by definition is the exploitation of biological process for industrial and other purpose.

At present, India has over 300 biotech firms focusing on different aspects of value chain and their number is going to more than double in next three to four years, says a release from Associated Chambers of Commerce and Industry in India (ASSOCHAM).

In a paper by ASSOCHAM on Biotechnology Future, it has been pointed out that although clearly much smaller in size than the information technology and business process outsourcing sectors, the domestic biotechnology sector is witnessing similar growth and growth prospects. For instance during FY 05-06, the sector closed at around $1.5 billion, and grew by 35% for the second year in a row.

See the full article at: http://www.agbios.com/sabp_main.php?action=ShowNewsItem&id=8446

## TOWARD A BANANA-BASED VACCINE FOR HEPATITIS B

Science Daily - May 1, 2007

Bananas have emerged as the best candidate to deliver a bite-sized vaccine for hepatitis B virus (HBV) to millions of people in developing countries, according to an article scheduled for the June 1 issue of ACS' Biotechnology Progress, a bi-monthly journal co-published with the American Institute of Chemical Engineers.

In the article, India's V.A. Bapat and colleagues update and review worldwide research on efforts to genetically engineer plants as biofactories for the production of vaccines. They focus on transferring genes to produce HBV vaccine, noting that there already are 350 million carriers of hepatitis B worldwide, with 1 million new cases annually. An estimated 75 million to 100 million of those infected individuals may die from liver cirrhosis or liver cancer as a result, the article adds.

The authors explain that plant-based production of an oral hepatitis B vaccine has economic and other advantages over the existing injectable vaccine. Researchers so far have successfully engineered several plants , including banana, potato, lettuce, carrot, and tobacco, to produce HBV vaccines. They explain why banana appears to be the ideal production and delivery vehicle for HBV vaccine, and the further research and development needed to exploit bananas in the global battle against HBV.

Article: "Production of Hepatitis B Surface Antigen in Recombinant Plant Systems: An Update", Biotechnology Progress

Note: This story has been adapted from a news release issued by American Chemical Society.

**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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