SOUTH ASIA
BIOSAFETY PROGRAM

February 2007
Vol.3 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.

CONCLUSIONS & RECOMMENDATIONS FROM THE INTERNATIONAL CONFERENCE ON RECENT SCIENTIFIC DEVELOPMENTS IN AGRICULTURAL BIOTECHNOLOGY: SHARING EXPERIENCES AND KNOWLEDGE

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The International Conference on 'Recent Scientific Developments in Agricultural Biotechnology: Sharing Experiences and Knowledge', organized by ILSI-India and ILSI-International Biotechnology Task Force, was held on October 29 and 30, 2006, in New Delhi. The conference was co-sponsored by Ministry of Agriculture, Government of India (GOI), Department of Science and Technology (DST) and Department of Biotechnology (DBT) of the Ministry of Science and Technology, GOI, and the Planning Commission. It was inaugurated by Shri Sharad Pawar, Union Minister of Agriculture.

The Perspective

Indian agriculture has completed one cycle of the Green Revolution, which started about 35 years ago. It was mainly led by dwarf hybrid varieties of wheat and rice. During these years food grains production increased 123 per cent to 208 mt (2005-06). Yield per hectare of both rice and wheat has nearly doubled. In spite of this, present yield in respect of rice is about two-fifths that of the United States (US) and, of wheat, one-third that of the United Kingdom.

Demand for agricultural products, however, is increasing at two and a half per cent per year partly due to population growth and partly to improvement in incomes. It is targeted that food grains production will cross 320 mt by 2011-12 (Eleventh Five-Year Plan) and horticulture production will double.

It would be difficult to reach these targets in present conditions characterized by sub-soil water depletion, deficiency of micronutrients in soil. The increased use of agro-chemicals have caused tremendous damage to environment and human health and have led to widespread pest and weed resistance. Even conventional biotechnology intended to promote use of biofertilizers and biopesticides has made limited progress. A technology deficit has emerged in agriculture and the food curve has become nearly flat.

2011-12 Food Grain Production Targets in India	
Crop	**in Metric Tons (mt)**
Rice	129
Wheat	125.5
Pulses	23.5
Total	**320**

The New Technology Tool

With this perspective, it is necessary to look closely at crop biotechnology, including transgenic crops, marker–assisted breeding, and structural and functional genomics, as the new tool to galvanize agriculture.

Biotechnology has an implicit advantage over conventional breeding. Gene transfer is for specific traits and the gestation period to incorporate these traits is much shorter. Hence conventional breeding has to be complemented by tissue culture and molecular breeding. These new tools can not only increase production in a sustainable manner but also enrich the quality of products and reduce costs.

It was in 1996 that the first transgenic plants were released for commercial cultivation in the US. The first generation transgenics were mainly designed for herbicide tolerance and insect/virus protection. The second generation transgenics are more comprehensive and aim at higher yield, drought resistance, fortification of foods, healthy oil content, biofuel, pharmacological applications, and so on.

The benefits of agriculture biotechnology actually realized at present are:

- Improved insect and weed control
- Higher yields
- Reduced use of agro chemicals
- Lower cost

Worldwide there is rapid increase in transgenic crop cultivation. Last year, the total area under transgenics was 90 million ha in 21 countries cultivated by 8.5 million farmers. A little less than a half of the total area under transgenics is in the US followed by Argentina, Canada, Brazil, China and India, in that order. The four major crops that have been commercialized are soybean, maize, cotton and canola.

(continued on page 2 - see Conclusions)

ACTIVITIES

CALENDAR OF EVENTS

INDIA

Event	Organization	Date	Place
Regional Workshops on Issues related to Cartagena Protocol on Biosafety in association with State Agricultural Universities	Ministry of Environment & Forests (MoEF) and BCIL	February 2007	Hyderabad and Junagarh, Gujarat
Awareness workshops on GM crops with a focus on post release monitoring	Ministry of Agriculture (MoA) and BCIL	February-March 2007	Hyderabad, Chennai and Aurangabad
National Consultation on Safety Assessment of GM Food Crops	Department of Biotechnology and BCIL	February-March 2007	New Delhi, Dharward and Coimbatore
Training programmes on "Detection of LMOs"	Central Food Technological Research Institute (CFTRI)	April 9-13, 2007	CFTRI, Mysore

BANGLADESH

Event	Organization	Date	Place
Conference on Promoting Biotechnology in Bangladesh: National and International Perspectives	Ministry of Science, Information and Communication Technology, Dhaka University, BRAC University, Bangladesh Academy of Sciences, ICDDR,B and Incepta Pharmaceuticals. For more information please go to http://www.gnobb.org/ or http://www.promotebio-techbd.net/	April 6-8, 2007	BRAC Centre and ICDDR,B, Dhaka

Conclusions - *continued from page 1*

In India, 14 food crops have been approved for field trials by the public and private sector with insect resistance, herbicide tolerance, viral and fungal disease resistance and stress tolerance as the target traits. These crops include rice, chickpeas, potato, mustard, tomato, brinjal, cauliflower, cabbage, pigeonpeas, groundnut, maize, okra and sorghum. Bt Cotton has already been commercialized and brinjal is awaiting approval.

Commercialization of Bt cotton has led to tremendous expansion in area under Bt cotton. From less than 29 thousand acres in 2002-03, the area under Bt cotton has gone up to 35 million acres in 2006-07 (estimated). Currently more than one million farmers are engaged in the cultivation of Bt cotton.

Progress With Caution

Progress in respect of gene technology has been slow because of apprehension about the safety of genetically modified (GM) foods and concerns about environment.

GM foods, it is feared, can be anti-nutritional, toxic and allergenic. Food and Agriculture Organization of the United Nations/World Health Organization, Organization of Economic Cooperation and Development, International Food Safety Authorities Network, and a variety of expert groups have made intensive studies about the health and environmental aspects of genetically modified organisms (GMOs). All products have passed risk assessments and it has been found that they are not likely to present risks for human health. Commercialization of alfalfa, canola, carnation, chicory, cotton, flax, linseed, green pepper, maize, melon, papaya, potato, rice, soybean, squash, sugar beet, sunflower, tobacco, tomato and wheat, is now allowed in a number of countries.

Risk assessment for food safety is based on substantial equivalence model for which a number of compositional parameters are tested (*e.g.* proximates, fibre, minerals, vitamins, fatty acids, amino acids, secondary metabolites and crop specific anti-nutrients). Substantial equivalence model is followed in most countries though there are national differences in biotech policies. Tolerance limits for the presence of GMOs vary from one per cent in Australia and the European Union to five per cent in Japan. China has zero tolerance.

To inform the consumer about the presence of GMOs some countries have encouraged labeling of these products. The Ministry of Health, GOI, has issued draft provisions for labeling of GM foods.

There are no globally recognized standard methods for testing for GMOs and the number of reference materials for products of modern biotechnology are limited. Each laboratory may have its own validation criteria and protocols for determining GM content.

Ecological hazards are implied and yet there is no evidence for actual damage to environment. More than 50,000 tests in the field have been carried out around the world and these have given no indication of real danger or consequences that had not been predicted.

There are extensive regulations in India for rDNA/GMO and products under the Rules of EPA (1986) and adequate infrastructure is also in place to prevent damage to human health and environment. It needs to be recognized that the implied risks in the application of biotechnology to agriculture are minimal and the benefits enormous.

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Conclusions - *continued from page 2*

Access to Technology

Research in agricultural biotechnology applications in India began more than two decades ago. Since 1984 the DBT, DST, Council of Scientific and Industrial Research, Indian Council of Agricultural Research, and University Grants Commission have been assisting research and monitoring progress of crop biotechnology, in addition to the initiatives taken by the private sector. Intensive research is undertaken at plant molecular biology centres, universities and other institutions. In the private sector a number of companies have transgenic lines in advanced stages of development for field trials for a variety of crops.

The pace of progress in biotech applications in agriculture is governed by knowledge production and knowledge transfer. Both are facilitated when GMOs become acceptable. In that situation, private sector will be an equally dependable source of biotechnology innovations.

Although research is undertaken by different institutions and organizations in the public and private sector there are hardly any linkages *inter-se*. It would be useful to forge relationships through public-public and public-private partnerships to share experiences and knowledge. This is particularly important now when a number of products are at advanced stage and have to be commercialized

Since indigenous research is limited, cross border transfer of technology is critical to keep up with world developments. There are internationally accepted regulations that govern technology transfer generally, for example, Trade-related Aspects of Intellectual Property Rights (TRIPS), Convention on Biological Diversity, *etc*. Subject to these international regulations, technology transfer can take a variety of forms since research is at public and private sector levels, and the objectives can be both commercial and altruistic.

There are multiple owners of technology involving considerable transaction costs and possible hold ups leading to a situation that has been described as 'crisis of the anti-common'. Consequently there is serious underutilization of a valuable resource. Management of intellectual property rights (IPRs) has therefore become a critical issue.

There are a variety of ways in which institutions and firms can obtain biotechnology genes and tools:

- For free, if the transfer is done on humanitarian basis as, for instance, in the case of golden rice.
- For purchase, acquired on license with conditions for commercialization, or secured through joint ventures, and so on.
- Technology transfer may be institutionalized as for instance, PIPRA, (Public Sector Intellectual Property Resource for Agriculture) or AATF (African Agricultural Technology Foundation) set up by the Rockefeller Foundation to assist countries that have limited access to IPRs.

The success of biotech applications must be judged by the number of products that can make it to the market. For this it is important to discover the right genes to develop the best product. Apart from technology it necessitates good project management and an efficient regulatory system.

Steps to Gene Revolution

It is important to devise a systematic, coordinated approach to application of biotechnology to agriculture to get the best returns. The success of the Eleventh Five-Year Plan will depend to a large extent on achieving a four per cent annual growth in agriculture. Hence emphasis in the immediate future will have to be placed on technologies that enhance yields while developing a system that will ensure food security. It is in this perspective that the following steps must be vigorously pursued.

There are a variety of ways in which institutions and firms can obtain biotechnology genes and tools:

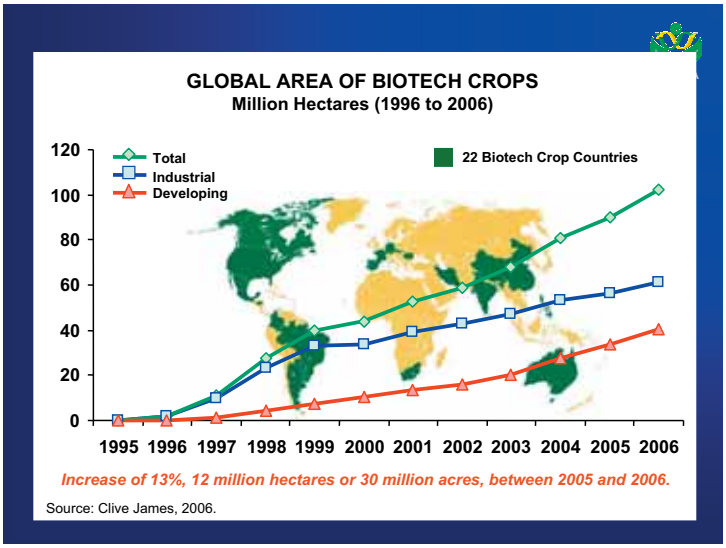
i. National biotechnology regulations need to be harmonized with Codex. This will facilitate introduction of biotechnology and also minimize disruption to external trade.
ii. There is need to exercise prioritization focused on outcome. Hence crops in respect of which research is already undertaken and field trials are under way have to have the first priority.
iii. While indigenous discovery of new genes should be encouraged, wherever there is need for a product to achieve food or nutritional security, external sourcing of important genes through licensing arrangements should be immediately explored.
iv. It would be useful to evolve a scientific and globally acceptable system of deregulation of bio-safe events.
v. It is necessary to encourage public-private partnerships to facilitate commercialization of research and post-release monitoring.
vi. The proposed autonomous National Biotechnology Regulatory Authority should be set up as soon as possible to approve biotechnology products.
vii. Greater attention should be given to capacity building and providing adequate facilities for researchers and a mechanism should be developed to share information about research done by different organizations.
viii. An interdisciplinary collegium should be set up to explore possibilities of comprehensive interdisciplinary scientific applications.
ix. Institutions like PIPRA and AATF are good vehicles for transfer of technology. A similar institution at the international level should be set up to facilitate technology transfer. This institution should develop guidelines for licensing and retaining rights if the technology transfer is for public benefit and also provide funding for such transfer.
x. It is extremely important to educate the consumer who is currently exposed to considerable misinformation and disinformation about the safety of genetically modified foods and the farmer about efficient use the new farm technology and thus create conducive conditions for acceptance of GMOs in the country.

ISAAA BRIEF 35 - GLOBAL BIOTECH AREA SURGES PAST 100 MILLION HECTARES ON 13 PER CENT GROWTH

Source: Clive James, ISAAA, 2006

Farmers' continued rapid adoption of biotech crops around the globe in 2006 is driving multiple adoption milestones for the technology-enhanced crops that produce greater yields of food, feed, fibre and fuel, according to an annual report released by the International Service for the Acquisition of Agri-Biotech Applications (ISAAA).

At the beginning of the second decade of biotech crop adoption, biotech crop area jumped 12 million hectares or 13 per cent to reach 102 million hectares, breaking the 100 million hectare mark for the first time and achieving the second highest growth in the past 5 years. Growth for the period 1996 to 2006 is equivalent to an unprecedented 60-fold increase, the highest adoption rate of any crop technology. Additionally, the number of farmers planting biotech crops surged past 10 million for the first time, to 10.3 million, from 8.5 million farmers in 2005.



Clive James, chairman and founder of ISAAA and author of the report, expects these adoption levels to continue accelerating throughout the second decade of commercialization. By 2015, ISAAA predicts more than 20 million farmers will plant 200 million hectares of biotech crops in about 40 countries.

"More than 90 percent or 9.3 million farmers growing biotech crops last year were small, resource-poor farmers from the developing world, allowing biotechnology to make a modest contribution to the alleviation of their poverty," James said. "Millions of small, resource-poor farmers will turn to the potential biotech crops offered in the next decade."

In fact, the report indicated that the growth of biotech crop adoption was substantially higher in the developing world at 21 per cent versus the industrialized nations where adoption grew 9 per cent. Developing countries now account for 40 per cent of the global biotech crop area.

More detail about ISAAA Brief 35 can be found at http://www.isaaa.org/Resources/Publications/briefs/default.html

THREE-DAY BIOTECHNOLOGY CONFERENCE PLANNED FOR DHAKA

A three-day conference on "Promoting Biotechnology in Bangladesh: National and International Perspective" sponsored by the Bangladesh Ministry of Science, Information and Communication Technology, Dhaka University, BRAC University, Bangladesh Academy of Sciences, International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) and Incepta Phamaceuticals will be held on April 6, 7 and 8, 2007 at the BRAC Centre and ICDDR,B with the following objectives:

1. Scientific capacity assessment within the country in terms of identifiable research outputs of government, non-government and private institutes working on biotechnology-related activities.
2. Establishment of international linkages with centers of scientific excellence and arranging collaboration with the help of expatriate scientists.
3. Prioritization of research goals, activities and strategies for implementation of deliverable outputs in tune with some of the millennium development goals.

It is expected that the deliberations from the seminar will result in the production of a targeted plan of action for biotechnological research activities for national development. The three-day programme will include:

- Scientific presentations;
- National case studies of India, Malaysia, Pakistan and Turkey;
- Presentations from Goverment of Bangladesh departments, research institutes, education and industries;
- Education and training programmes;
- Presentation of a position paper on the state of biotechnology including the National Institute of Biotechnology and its promotion;
- Discussions and recommendations on biotechnology policy and its implementation in Bangladesh;
- Avenues for capacity building.

More information about this conference is available at www.gnobb.org and at http://www.promotebiotechbd.net

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

SABP CONTACTS

South Asia

Dr. Vibha Ahuja
Deputy General Manager
Biotech Consortium India Limited
Anuvrat Bhawan, 5th Floor
210, Deendayal Upadhyaya Marg
New Delhi 110 002 India
Tel: 23219064-67
Email: vibhaahuja@biotech.co.in

Others

AGBIOS
106 St. John Street
P.O. Box 475
Merrickville, Ontario
K0G 1N0 Canada
Tel: +613-269-7966
Email: info@agbios.com

To receive an electronic copy of this newletter send your name and e-mail address to: info@agbios.com