



SOUTH ASIA
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.

Over the next three years, SABP will work 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.

COMPLETION OF SABP IN BANGLADESH

Donald J. MacKenzie, Ph.D., Executive Vice President, AGBIOS

September 30, 2006, marked the end of USAID support for SABP activities in Bangladesh and it is worth reflecting on some of the achievements of the past 20 months. Since the start of the program in February 2005, hundreds of scientists and professionals have participated in various workshops and discussion meetings on recent developments in agricultural biotechnology and biosafety regulation. The participants have included officials from the Department of Agriculture Extension, scientists from National Agricultural Research Systems, university and college level instructors and researchers, private sector scientists and numerous students. The program also provided funding for establishment of the Bangladesh Biotechnology Information Centre, which has worked to raise the awareness and understanding of biotechnology issues among local journalists working in print and electronic media. In addition, the program provided training to a number of Bangladeshi scientists and policymakers on biosafety and the safety assessment of foods derived from genetically modified crops by supporting their attendance at training workshops held in India, Sri Lanka and the Philippines.

All of these activities have been with the full support and active participation of the Bangladesh Agricultural Research Council, whose partnership has been essential to the overall success of the program. In particular we would like to thank Dr. Md. Nurul Alam, Executive Chairman, for his leadership and commitment to the program's objectives, and to Dr. Md. Abdur Razzaque, Member Director (Crops), and Dr. Khalequzzaman A. Chowdhury, Chief Scientific Officer

(Crops), for their tireless dedication in helping to organize and in participating in various training activities.

In a relatively short time, the program has had some significant impacts. By all accounts, senior level policymakers have become more aware of the potential benefits of biotechnology for Bangladesh agriculture and have often voiced their support of rapid introduction of useful new transgenic varieties. And during our workshops we have also heard from numerous agricultural extension personnel the desire to give some of these new products a try, and to see for themselves how they perform at the field level and whether they will be of any value to Bangladeshi farmers.

To date, Bangladesh has authorized the importation of a number of transgenic plant lines for contained experimental use in laboratories and greenhouses. These include potato resistant to late-blight disease caused by *Phytophthora infestans*, insect-resistant Bt brinjal, enhanced provitamin-A 'Golden Rice', insect-resistant chickpea, and papaya resistant to disease caused by papaya ringspot virus. However, such greenhouse trials have only limited utility in assessing agronomic performance or field-level disease resistance, and it is doubtful that any meaningful biosafety data are being collected. What is required is a system to permit the introduction of new transgenic lines into small-scale experimental open field trials in a controlled manner that mitigates any risk to the environment.

Through the South Asia Biosafety Program, there have been training workshops on risk assessment and risk management approaches to dealing with experimental field trials, including practical training on assessing field trial applications and designing appropriate field inspection and monitoring protocols. In addition, we have provided assistance to the Bangladesh Agricultural Research Council in their preparation of standard operating procedures and codes of conduct for experimental field trials.

In short, Bangladesh has all of the expertise and tools necessary to begin field testing of new transgenic plant varieties. This fact, together with a positive viewpoint among top-level policymakers and the desire of scientists and agricultural extension officers to test new biotechnology products, should provide the necessary encouragement to regulatory officials to make the necessary decisions. All too often, biosafety concerns and speculation about potential risks to the environment or human health from new biotechnology products can result in a 'paralysis of analysis' and a lack of decisiveness. However, nothing is without risk, and there are also risks associated with not adopting new technologies, including risks to food security and risks to the environment and health from existing agricultural practices.

In closing, AGBIOS wants to recognize the diligent and very professional efforts of Prof. Imdadul Hoque who has served as the SABP Country Coordinator for Bangladesh. Prof. Hoque has been instrumental in building our working relationship with the Bangladesh Agricultural Research Council, the Ministry of Agriculture, and the Ministry of Environment and Forests. Without his hard work and organizational skills we would not have been able to successfully deliver this program.

CALENDAR OF EVENTS (INDIA)

Event	Organization	Date	Place
Second Asian Graduate Course on Production and Use of Food Composition Data in Nutrition	National Institute of Nutrition (ICMR) and International Nutrition Foundation. For more information go to ftp://ftp.fao.org/ag/agn/infoods/asia_food_comp06.pdf	November 5-25, 2006	National Institute of Nutrition, Hyderabad, India
Cartagena Protocol on Biosafety: from decisions to diagnostics	National Bureau of Plant Genetic Resources (NBPGR), New Delhi. For more information contact: director@nbpgr.ernet.in gurinder.randhawa@rediffmail.com	November 23-30, 2006	National Bureau of Plant Genetic Resources, New Delhi

OUTCOMES OF THE SABP POLICY DIALOGUE, AUGUST 24-25, 2006, IN NEW DELHI.

Guillaume Gruere, Ph.D., IFPRI and Purvi Mehta Bhatt, SABP

The International Food Policy Research Institute under SABP, in collaboration with the Research and Information System for Developing Countries (RIS) organized a two day policy dialogue in New Delhi on August 24 and 25, 2006 (see the September issue for more on the dialogue). The dialogue was designed to provide a platform for economic experts to interact with stakeholders and to discuss economic considerations related to biosafety and biotechnology regulations in India. The dialogue was attended by representatives from public, private, NGO (CSO) and international development agencies. This note summarizes the six main policy recommendations formulated by the participants to the dialogue.

First, India has developed a very sophisticated and stringent regulatory framework. But by adding layers of complexity to the approval process, which have translated into high costs for developers, it is increasingly likely to delay the approval of future important technologies. The high costs and long lags due to the regulatory approval requirements add to the high costs and long duration of biotechnology research and increasingly constitute a challenge for Indian biotechnology companies.

Second, the relevance and economic feasibility of the proposed mandatory labeling regulation of GM food and feed in India is largely questioned by economists. A new economic study of the potential benefits and costs of mandatory labeling in India showed that mandatory labeling cannot be economically justified as a public policy. First, it would not correct any market failure, and it would entail certain costs. Second, it would not provide social benefits that outweigh the costs. In fact, voluntary labeling of non-GM products, as presented in the draft regulation of the Philippines, would likely be more appropriate for India. At the same time, India does not currently have and is not likely to quickly develop the national capacity to effectively implement and enforce the proposed stringent mandatory labeling regulation for GM food.

Third, the compliance and enforcement of post release regulations of GM crops has to be addressed particularly with regard to insect resistance management and control of illegal seeds. Currently a large majority of Bt cotton growers do not plant a non-Bt variety as an insect refuge area. An economic study showed that a zero refuge policy can be sustainable in the case of the Chinese cropping system,

but this result cannot simply apply to India's agriculture. More research is needed on this issue, and more capacity is needed to increase the awareness on the use of refuge. In addition, results from an economic study in Western India have showed that illegal trade in Bt cotton seeds could be avoided with proper state enforcement strategy, and that illegal seeds are not socially optimal, because they erode returns to developers with the risk of discouraging them to develop new crops. There is a need to strengthen the state level capacities for enforcement and implementation of post release regulations.

Fourth, the existing research and application capacity, including capacity for developing crops of Indian priority, and the consumers' and farmers' capacity to understand and adopt the technology needs to be strengthened. India would benefit from more economic research to assess future trends – consumers, markets and economic effects of agricultural biotechnology. Moreover, most public institutions lack experience, skills and motivation to develop the expertise needed for product delivery capacity. Capacity development at the level of all stakeholders, including extension workers, agri-dealers, farmers, and state level regulators is considered one of the keys in making the technology successfully reach the farms.

Fifth, participants to the dialogue regretted the lack of clear policy on GM food and international trade. Rules on GM food import approval have been changing back and forth and need to be rapidly clarified. They should be based on international food safety standards and set up efficiently in order to avoid the disruption of important trade flows for India's growing food sector. In addition, segregation strategies for non-GM crops should be encouraged to maintain export opportunities to all sensitive markets while allowing the use of safe GM technology for Indian farmers covering the domestic market, particularly with the future release of new transgenic food and feed crops.

Sixth, India would benefit from a broader cooperation among the different ministries involved in biotechnology policies, including the Ministries of Health, Trade, Agriculture, Environment & Forest, Science & Technology, etc. The implementation of trade related regulations of GM food should depend on policies of the Ministry of Trade, and its commitments to the World Trade Organization and other trade agreements. Similarly, the Ministry of Agriculture and their policies towards GM crops and initiatives at forums like the FAO should have their specific role in the regulatory process. The role of the Ministry of Environment and Forest as a regulator should be an important determinant in the process. Each Ministry should have a specific role, but also interact with other Ministries.

(continued on page 3 - see Outcomes)

Outcomes - continued from page 2

Overall, the dialogue participants expressed the need for a convergence between the Government of India's objectives on the development of biotechnology as a tool to increase agricultural productivity, its biotechnology and biosafety regulations, and the capacity it provides for safe access to approved biotechnology innovations to all Indian farmers.

The complete results of the dialogue will be published in a volume of proceedings that will be disseminated to relevant policy makers in India. Presentations made at the dialogue are available on the SABP website at http://agbios.com/sabp_main.php?action=ActivitiesPage

BIOSAFETY GUIDELINES OF BANGLADESH APPROVED

Prof. M. Imdadul Hoque

With the aim of providing a favourable environment for researchers to carry out research in different disciplines of modern biotechnology in a safe and sound manner, the government of Bangladesh has approved the Biosafety Guidelines of Bangladesh.

The Guidelines, submitted by the Ministry of Environment and Forests, were given final approval at the meeting of the National Taskforce on Biotechnology of Bangladesh (NTFBB), held on July 19, 2006, and chaired by Prime Minister Begum Khaleda Zia.

The Biosafety Guidelines were developed by the Ministry of Science and Technology in 1999 and gazetted as a government document by the same ministry in June 2000. However, after the Government of Bangladesh signed the Cartagena Protocol it decided that the Guidelines should be revised by the Ministry of Environment and Forests. The Ministry formed an Expert Committee comprising researchers, policymakers and representatives of NGOs to review and finalize the Guidelines.

The Biosafety Guidelines are for all research and development activities of modern biotechnology conducted in the laboratories of government research institutes, state enterprises, universities, international organizations located in Bangladesh, private companies and non-governmental organizations. The Guidelines are to be used in laboratories and field trials, trans-boundary movement, transit, handling and use of all GMOs/LMOs that may have adverse effects on the conservation and sustainable use of biological diversity. The objective of the Guidelines is to ensure an adequate level of protection against adverse effects taking into account risks to human and animal health.

Under the Guidelines the Ministry of Environment and Forest (MOEF) will be the competent national authority and national focal point to implement the Cartagena Protocol and will establish a National Committee on Biosafety (NCB) in order to ensure environmentally safe management of modern biotechnological development. A Biosafety Core Committee (BCC) is to assist and accelerate the functions of NCB. In order to ensure safe management of biosafety activities in laboratories and in the field there will be committees under the NCB, such as the Institutional Biosafety Committee (IBC), Field Level Biosafety Committee (FBC) and there will be designated Biological Safety Officers (BSO) in each research establishment of the country.

The Guidelines set out the risk assessment and risk management procedures. Depending on how and where GMOs/LMOs will be used, specific criteria for risk assessment in five

major areas have been suggested. These areas are: laboratory use, field use, direct use of foreign GMOs/LMOs in the environment, industrial use and products intended for release into the market. Procedures and guidelines for obtaining permission for various dealings with GMOs/LMOs, such as, laboratory use, field release, release into the market, have also been provided.

The Guidelines give the procedures for physical, chemical and biological containment in order to avert the adverse impacts of modern biotechnological research work. They categorize laboratory work into minimum, low, considerable and high biosafety risk levels and describe the precautionary measures that should be taken to avert such risks.

The detailed guidelines are available at http://www.doe-bd.org/biosafety_guidelines_draft.pdf

KANNADA MEDIA WORKSHOP

Dr. T.M. Manjunath and Bhagirath Choudhary, ISAAA

The International Service for the Acquisition of Agri-biotech Applications (ISAAA) along with the Karnataka Media Academy (KMA) organized a one-day media workshop on agricultural biotechnology for Kannada and English writing journalists on September 20, 2006, in Bangalore, Karnataka.



Panel discussion at Kannada media workshop.

Topics included how modern agricultural biotechnology is based on sound science; the development of beneficial traits; the development of regulatory protocols and the stringent biosafety tests required before approval for commercialization; the increase in the area planted in biotech crops over the past ten years; the social, economic and environmental benefits to farmers of biotech crops; biotech crop research; and concerns regarding safety.

For more information contact b.choudhary@isaaa.org

GOLDEN RICE IN 3 YRS: MK ANWAR

The Daily Star - September 27, 2006

Agriculture Minister MK Anwar yesterday said Golden Rice, a genetically modified crop enriched by Vitamin A, is expected to be released in Bangladesh within the next two or three years.

See the full article at: http://agbios.com/sabp_main.php?action=ShowNewsItem&id=7875

COURT: WITHHOLD APPROVAL FOR GENETICALLY MODIFIED PRODUCTS

The Hindu - September 24, 2006

New Delhi: The Supreme Court on Friday asked the Genetic Engineering Approval Committee not to give approval for genetically modified products until further orders.

A Bench comprising Chief Justice Y.K. Sabharwal, Justice C.K. Thakker and Justice R.V. Raveendran gave this direction on an application filed by Aruna Rodrigues and three others seeking a ban on release of genetically modified organism/seeds having the potential of causing major health hazards.

Counsel Prashant Bhushan alleged that the Government's policy was to give speedy clearance for genetically modified organisms (GOM) even before putting in place a mechanism to test their bio-safety value. He pleaded for stay on grant of fresh approvals and on all field trials of genetically modified crops.

The Bench said: "We are not inclined to direct stoppage of all field trials at this stage without [knowing] the stand of the respondents.

At the same time, we deem it appropriate to direct the GEAC to withhold the approvals until further directions are issued on hearing all concerned. The Government would also consider associating independent experts in the field with the GEAC." It directed that the matter be listed after two weeks.

In their public interest litigation, the petitioners said GMO seeds were a pest-resistant, high producing variety with the inherent drawback of passing on strands of pesticide to human body that could in future blow up into major health problems. The hazards included new allergies, greatly increased resistance to antibiotics, and severe toxicity to humans, animals and micro-organisms, resulting in a serious import [impact] on human health, and loss of wildlife and biodiversity.

In a fresh application, they said genetic engineering, if allowed unchecked, would change the molecular structure of the world's food.

INDIAN AG MINISTER: AGRICULTURAL RESEARCH SYSTEM TO BE STRENGTHENED

Government of India Press - September 29, 2006

The National Agricultural Research System (NARS) needs to be strengthened to meet the existing challenges of food production. Taking this into consideration The Government has accorded the much-needed thrust to research and development efforts in the recent past, which will be further augmented in the ensuing XIth Plan.

This was stated here today by Shri Sharad Pawar, Minister of Agriculture, Consumer Affairs, Food and Public Distribution while inaugurating an international conference on "Recent Scientific Developments in Agricultural Biotechnology: Sharing Experiences and Knowledge" which is sponsored by International Life Sciences Institute-India (ILSI-India), and ILSI-International Food Biotechnology Committee (ILSI-IFBiC) and co-sponsored by Ministry of Agriculture and Cooperation, Government of India.

Shri Pawar enumerated key issues for increasing food production like strengthening and streamlining of transgenic research programme, capacity building and human

resource development for effective utilisation of genetic transformation strategies for improving crop and ensuring proper flow of scientific and technical information as well as genetic materials for development and testing of transgenic crops. He also pointed out the need for creating confidence among consumers about the safety of genetically modified foods.

Expressing concern over the decreasing availability of water for agricultural purposes, the minister underlined the need for developing transgenic crops tolerant to increased drought conditions and less water requirement for extending area under cultivation and consequent increase in total food production.

India had taken up an ambitious programme on agricultural biotechnology to ensure food security and is among the 21 countries in terms of acreage under GM crops. While Bt cotton has been commercialized many transgenic crops including brinjal, rice, tomato resistant to leaf-curl virus, tomato with delayed ripening and improved shelf-life, potato with enhanced levels of essential amino acids, pigeonpea resistant to bollworm are in the pipe line for development.

Besides many genes of agronomic and nutritional importance have been already cloned and are being introduced into crop species including cereals, pulses, oilseeds, fruits and vegetable crops, Shri Pawar added.

Speaking on the occasion, Shri D.H. Pai Panandiker, Chairman, ILSI-India underlined the need for use of bio-fertilizers and bio-pesticides and called for policy initiatives for increased use of these items for environmental protection and soil restoration.

We welcome reader comments or suggestions.

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