



SOUTH ASIA
BIOSAFETY PROGRAM

October 2012

Vol.8 No.10

NEWSLETTER

for private circulation only - not for sale

www.cera-gmc.org

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 national governmental agencies to facilitate the implementation of transparent, efficient and responsive regulatory frameworks for products of modern biotechnology that meet national goals as regards the safety of novel foods and feeds and environmental protection.

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 Bangladesh and address policy issues within the overall context of economic development, international trade, environmental safety and sustainability.

MEETING OF SCIENTIFIC ADVISORY COUNCIL OF PM ON BIOTECHNOLOGY AND AGRICULTURE

Press Information Bureau, Government of India, Ministry of Science & Technology

Scientific and technological breakthroughs of a transformational nature relevant to economic and social development happen only once in a while. The emergence of such technologies evokes responses according to a pattern: initial excitement, followed by strong expression of concern and then emergence of a balanced perspective. Transformational technologies in the past, such as the steam engine, electricity and other sources of energy, vaccines and immunization and the Internet have all followed this trend. Molecular biology and biotechnologies, developed through major investments in science and technology globally, have a transformational potential for benefitting agriculture and health and it is time now to evolve a balanced perspective.

The members of the Scientific Advisory Committee (SAC) to the Prime Minister deliberated on the important issue of the application of biotechnology for social and economic advancement of the country particularly in the area of agriculture. There are uncertainties in some segments of society that need to be objectively and fairly addressed. The members of the SAC are concerned that a science informed, evidence based approach is lacking in the current debate on biotechnologies for agriculture. There are some key aspects that merit consideration.

Do we need new technologies for agriculture? Indian agricultural productivity is seen by the less discerning to be adequate for today's needs but what is ignored is that vast numbers of our countrymen are unable to consume the required food and nutrients because of difficult access. As our current efforts to address the issue of access bear fruit, the need for food and quality nutrients will grow rapidly. Land availability and quality, water, low productivity, drought and salinity, biotic stresses, post harvest losses are all serious concerns that will endanger our food and nutrition security with potentially serious additional effects as a result of climate change. Accordingly, strategies for agriculture in future must be based on higher yields, concomitant with reduction in resource inputs. This will require a judicious blend of traditional breeding and new technologies, non-transgenic and transgenic. This situation in developed countries, such as in Europe, is quite in contrast, as there is no dearth of food and a small proportion of people engaged in agriculture.

The assessment of safety and efficacy of biotechnology products has to be evaluated through an appropriate regulatory system on a case-by-case basis, as for drugs and vaccines. In general, endorsement or opposition to a generic technology is scientifically not rational and safety and efficacy must be judged on a product basis. The need

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GMOs IN THE PIPELINE

FAO e-mail conference

From 5 November to 2 December 2012 the **FAO Biotechnology Forum** is hosting its next e-mail conference, which has the provisional title "*GMOs in the pipeline: Looking to the next five years in the crop, forestry, livestock, aquaculture and agro-industry sectors in developing countries*". Its goal is to inform the debate about genetically modified organisms (GMOs) in the pipeline, considering the specific kind of GMOs that are likely to be commercialised in developing countries over the next five years and to discuss their potential implications. The conference is open to everyone, is free and will be moderated. To subscribe to the conference, send an e-mail to listserv@listserv.fao.org with the following one line in the body of the message (leave the subject line blank):

subscribe biotech-room2-L firstname lastname

Where firstname and lastname refer to the person's first and last name. For example, if the subscriber's name is John Smith, then the line should be:

subscribe biotech-room2-L John Smith

A background document is being prepared and will be sent to Forum members before the conference begins and placed on the Forum website, at <http://www.fao.org/biotech/biotech-forum/en/>. For more information, contact biotech-mod2@fao.org.

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for an appropriate regulatory mechanism in the country has been rightly emphasized in the Swaminathan Committee Report. The existing system based on Review Committee on Genetic Manipulation (RCGM) and Genetic Engineering Approval Committee (GEAC) has given us large experience and its operational guidelines are generally sound and as per the best international norms such as the guidelines by the Organisation for Economic Co-operation and Development (OECD). The effort now should be on effective implementation. Regulatory systems evolve with experience and review based redesign. Little is served by focusing on the flaws only.

The proposed Bill for establishment of a national Biotechnology Regulatory Authority of India (BRAI), 2012 is with the Parliament, it deserves to be examined on a priority basis. The key characteristics of an effective regulatory system hardly need reiteration; sound scientific expertise within the organization and through independent panels, access to scientific tools for assessment of safety and efficacy and processes that ensure transparency, freedom from conflict and competence. This can only be delivered by a robust and independent system. The focus of the regulatory authority has to be on assessment of safety and efficacy. Commercialization and deployment of agricultural biotechnology products requires expertise in social and economic evaluation and post-deployment surveillance. This requires effective inputs of central and state agriculture ministries.

The experience with the deployment of genetically modified (GM) crops worldwide is growing at a steady pace and should be taken into consideration. GM crops of maize, soya, potato, sugar beet, canola, cotton and alfalfa are grown across the globe covering 160 million hectares by 2011. While each concern must be addressed through a scientific approach, we believe the performance of GM crops released through oversight by regulators has been very positive. This view has been endorsed by major scientific bodies of the world. This is clearly true of our own experience with the introduction of Bt cotton in India wherein the benefits have been major. It is our view that biotechnology research and development should target important national needs, products should be developed under careful regulatory oversight and deployed in a way that access and affordability to the entire farming community, particularly small and marginal farmers, is ensured.

There are other relevant issues that merit attention. Some of the opposition to GM crops in the country results from fear of domination by multinational companies. One way to address this concern is to invigorate and further strengthen the relevant scientific capacities of our institutions in the public sector, universities and Indian companies. The current debate, unfortunately, is demoralizing and isolating our scientists in the sector whose skills have been built with painstaking effort and large investment. The policy confusion will also keep the brightest away from this field of research. Our scientists are fully aware of the social realities in this country and have widely endorsed the judicious adoption of traditional breeding with biotechnologies, non-transgenic and transgenic, as appropriate. There is concern about the

costs at which seed is available to our farmers, particularly poor farmers. This requires an appropriate public policy and action. Industry must shoulder responsibility by ensuring this through constructive dialogue with the government. Market mechanisms alone will not be sufficient.

The precautionary approach is inherently sound but it must be applied through a science based safety assessment and social and economic analysis for deployment. We make the following recommendations for kind consideration:

1. The current regulatory system for recombinant products administered under Rules (1989) of EPA Act, 1986 should be reformed till BRAI is in place.
 - i. RCGM and GEAC should be the sole authority for biosafety and bio-efficacy assessment of all recombinant products. Decisions on commercial use of biotechnology produced crops should be taken by agriculture ministries/departments of central and state governments as per existing policies and regulations on crops. For medical products Central Drugs Standard Control Organization (CDSCO) of Ministry of Health and Family Welfare, Government of India would approve commercialization as of now.
 - ii. High level dialogue with state governments to streamline clearances for conduct of multi-location "confined field trials" – a scientific prerequisite in all countries for meaningful decision making on approvals or otherwise.
 - iii. A Biotechnology Regulatory Secretariat with a high level of scientifically and technically trained manpower should be established to support RCGM and GEAC.
 - iv. GEAC and RCGM should have full time Chairpersons. The Chairman of GEAC, may be of Special Secretary status for a three year period and RCGM one level lower. Chairman of RCGM should be the Co-Chair in GEAC and not the expert nominee of the Department of Biotechnology. For greater synergy at least three members should be common between RCGM and GEAC.
 - v. The public needs to be informed of every decision.
2. The Bill pending with Parliament, i.e., BRAI 2012, should be debated with an open mind. It would be appropriate if the administrative organization could be the Cabinet Secretariat because of the involvement of multiple ministries. The Bill, when examined by appropriate parliamentary committee, would be opened up for wider debate and discussions for shaping the draft legislation into a model regulatory framework.
3. The capacity for regulatory testing of new technologies in agriculture in public sector laboratories should be strengthened, supplemented with a system of notification and accreditation. This can be initiated even while the BRAI becomes a reality.
4. Research and infrastructure of state agricultural universities and colleges be strengthened for addressing



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the location-specific needs of the states and regions and generate expertise.

5. Priority should be given to strengthen state government departments and laboratories dealing with agriculture inputs, including GM or non-GM seeds, extension and education of farmers through major programmes and investments for capacity building tailor made to the needs of the region.

OPENING OF THE CENTRE FOR MEDICAL BIOTECHNOLOGY - BANGLADESH

On August 5, 2012 a medical biotechnology sensitization workshop was held on the occasion of the grand opening of the Centre for Medical Biotechnology under Management Information System, Directorate General of Health Services at the Institute of Public Health (IPH) Bhaban, Mohakhali, Dhaka.

Dignitaries from the Ministry of Health and Family Welfare; Directorate General of Health Services; Directorate General of Drug Administration; and of the Bangladesh Medical Association (BMA) were present as were leading professionals and biotechnologist from Bangabandhu Sheikh Mujib Medical University; the International Centre for Diarrhoeal Disease Research, Bangladesh; Bangladesh Institute of Research and Rehabilitation in Diabetes, Endocrine and Metabolic Disorders; and Bangladesh Institute of Health Sciences. Representatives of the pharmaceutical industries also attended and spoke on the occasion.

The keynote speaker, Prof. Dr. A.K. Azad, Additional Director General, DGHS and Line Director, Management and Information System and e-Health and member of the Biosafety Core Committee (BCC), highlighted the use of biotechnology in medical science and, in particular, the benefits of biotechnology in the drug industries. Pointing out that the Centre for Medical Biotechnology was developed based on the National Guidelines on Medical Biotechnology 2010, he said that, in a traditional system, marketing a new drug requires ten to twelve years, needs trial volunteers and carries risks of adverse effects during the trial. He opined that a biotech drug can be even less expensive, citing a US example that in the US, seven of twenty best-selling drugs are biotech drugs. He spoke about the importance of medical biotechnology in Bangladesh and described present activities and future plans

of the Centre for Medical Biotechnology. He expressed the hope that Bangladesh could profit from the sale to foreign markets of stem cells collected from the umbilical cords of newborns. Using bioinformatics, he said antibiotic resistance could be predicted as much as ten years in advance and, using biotechnological tools, it was also possible to find out exact causes of any disease. He also said he hoped that, with government and national/international agency support, the Centre would be able to perform a full complement of activities. Prof. Azad sought more involvement by the private sector in the newly established Centre.

Dr. A.K. Saha, the Centre's Program Manager, presented a status paper on research and development activities on medical, plant and animal biotechnology being carried out at various universities, National Agricultural Research System (NARS) institutes and other related national and international institutes working in Bangladesh. The Centre for Medical Biotechnology has the scope and role of promoting medical biotechnology in the government as well as in private sectors.

In his inaugural speech the Health Minister welcomed medical biotechnology to health care services and pointed out that the present government is very much supportive of the emerging field of medical biotechnology and said the establishment of the Centre was the first step in the government's initiatives saying it was just the beginning and the Centre would facilitate the initial advanced diagnostic testing and research of different institutes. He suggested that authorities establish a strong collaboration with international centres to strengthen the activities of its centre. Other invited guests and speakers at the opening stressed the importance of medical biotechnology to Bangladesh.

Senior Health Secretary, Mr. H. Kabir in his remark disclosed that a regulatory body will be formed to oversee medical biotechnology activities so that ethical, religious social discrimination and privacy concerns could be avoided or minimized.

The workshop concluded with remarks by Prof. Dr. K. M. Sefayetullah, Director General of Health Services who chaired the workshop and inaugural ceremony.

For details on the Centre for Medical Biotechnology contact Dr. Ashish Kumar Saha, Program Manager or Dr. S.A.A. Ashrafi, Deputy Program Manager, e-Health, Management Information System, Director General of Health Services Mohakhali, Dhaka-1212, Email: dr.ashrafi@mis.dghs.gov.bd, Website: www.dghs.gov.bd.



TILLING IN EXTREMIS

Wang TL, Uauy C, Robson F, Till B

Targeting induced local lesions in genomes (TILLING), initially a functional genomics tool in model plants, has been extended to many plant species and become of paramount importance to reverse genetics in crops species. Because it is readily applicable to most plants, it remains a dominant non-transgenic method for obtaining mutations in known genes. The process has seen many technological changes over the last 10 years; a major recent change has been

The Reading List

. . . new and notable articles

the application of next-generation sequencing (NGS) to the process, which permits multiplexing of gene targets and genomes. NGS will ultimately lead to TILLING becoming an *in silico* procedure. We review here the history and technology in brief, but focus more importantly on recent developments in polyploids, vegetatively propagated crops and the future of TILLING for plant breeding.

PLANT BIOTECHNOLOGY JOURNAL (2012) SEP;10(7):761-72. DOI: 10.1111/j.1467-7652.2012.00708.x. EPUB 2012 JUN 1. <http://onlinelibrary.wiley.com/doi/10.1111/j.1467-7652.2012.00708.x/abstract>

CALENDAR OF EVENTS

Event	Organized by	Date and Venue	Website
INDIA			
Panel Discussion on the Importance of Agriculture and Technology in India	IndoAsiancommodities.com	October 16, 2012 New Delhi	http://www.indoasiancommodities.com/
Third National Symposium on Agriculture Production and Protection in Context of Climate Change	The Society of Agricultural Professionals, Chandra Shekhar Azad University of Agriculture and Technology, Kanpur, Uttar Pradesh, and Birsa Agricultural University, Kanke, Ranchi	November 3 - 5, 2012 Ranchi	http://www.baujharkhand.org/Downloads/online%20circular%20for%203rd%20national%20symposium.pdf
Practical Course in Plant Biotechnology	Barwale Foundation	November - December, 2012	http://www.barwalefoundation.org/html/announcement-2.htm
44th Annual National Conference of the Nutrition Society of India (NSI)	Nutrition Society of India	November 16 - 17, 2012 Tirupati	http://www.nutritionocietyindia.org/
Winter school on "Molecular Breeding Approaches for Genetic Enhancement in Oilseed Crops"	Directorate of Oilseeds Research	December 1 - 21, 2012, Hyderabad	http://dor-icar.org.in/media/docs/winter-school-dec-2012.pdf
International symposium Food Security Dilemma: Plant Health and Climate Change Issues	Bidhan Chandra Krishi Viswavidyalaya	December 7 - 9, 2012 Kalyani, West Bengal	http://www.bckv.edu.in/userfiles/file/Final_Circlr_%20Int_Symp_AAPP.pdf
AgTech Global Summit - 2012	Bejo Sheetal Bio-Science Foundation and Maryland India Business Round Table	December 9 - 13, 2012, Aurangabad	
National Convention on India Cotton: Gearing Up for Global Leadership	The Gujarat Association For Agricultural Sciences, Navsari, Indian Society For Cotton Improvement, Mumbai; Navsari Agricultural University, Surat; and Central Institute For Cotton, Research, Nagpur	December 18 - 20, 2012 NAU, Surat	http://www.nau.in/announce.php?id=686
INTERNATIONAL			
1st International Conference for GM Crops and Food	Faculty of Agriculture, Cairo University	November 27 - 29, 2012 Cairo, Egypt	http://www.icgmc.com/
International Scientific Workshop "Non-target Organisms and GM Crops: Assessing the Effects of Bt Proteins"	European Food Safety Authority (EFSA) and the Netherlands Commission on Genetic Modification (COGEM)	November 29 - 30, 2012, Amsterdam, The Netherlands	http://www.cogem.net/index.cfm/en/symposium/
Theoretical and Practical Course "Detection of GMOs in Food and Agricultural Products"	International Centre for Genetic Engineering and Biotechnology (ICGEB)	January 6 - 10, 2013 Doha, Qatar	http://www.icgeb.org/meetings-2013.html
World Soybean Research Conference IX	Hosted by the Protein Research Foundation, the Oil and Protein Seeds Development Trust, and organized by Paragon Conventions	February 17 - 22, 2013 Durban, South Africa	http://www.wsrc2013.co.za/
Strategic Approaches in the Evaluation of the Science Underpinning GMO Regulatory Decision-making	ICGEB	July 1 - 5, 2013 Trieste, Italy	http://www.icgeb.org/tl_files/Meetings/2013/TS_BIOSAFETY_1-5%20July_2013.pdf

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