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BIO SAFETY

Newsletter

A QUARTERLY NEWSLETTER

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From the Desk of Editor

Biotechnology has great promises for the sectors of medicine, agriculture and industry. However the application of biotechnology in these sectors is replete with several biosafety concerns towards environment and human health. Adopted in January 2000 as a supplement to the Convention on Biological Diversity, the Cartagena Protocol on Biosafety addresses the safe transfer, handling, and use of Living Modified Organisms (LMOs), focusing specially on transboundary movements.



To prepare a level playing field, it is desirable to ensure that the recipient countries have both the opportunity and the capacity to assess risks involved in the use of the products of modern biotechnology. It has been well recognized that successful implementation of the Protocol is contingent on the development of national biosafety capacity in countries that have yet to establish, or are in the process of establishing, biosafety systems. Even though we have in India such regulations ever since 1989 the Capacity Building remains a priority concern.

This has been mostly necessitated by rapid increase in research and development of transgenics and their exploitation for commercial purposes in the recent past. To keep pace with the developments in the field of biotechnology as well as associated safety concerns, capacity building for various stakeholders in different areas becomes important. Keeping this in view, Ministry of Environment and Forests (MoEF) is implementing a Global Environment Facility-World Bank (GEF-WB) project for capacity building on biosafety, focusing on institutional strengthening, information dissemination and training. As part of the project activities, a quarterly newsletter on activities related to the project and information on biosafety has been planned with an objective to serve as a knowledge support for various stakeholders. I am pleased to introduce the first issue of the newsletter and hope that it will help in our efforts for information sharing and general awareness.

Desh Deepak Verma
Project Director & Joint Secretary
Ministry of Environment & Forests

Message



It is widely believed today, biotechnology is a sunrise sector of the modern era, which is likely to affect different facets of human life, particularly agriculture, healthcare and nutrition. With the advent of new transgenic crop varieties and recombinant medicines, there is a promise of food security and freedom from hunger, malnutrition and disease, especially in developing countries. However, while recognizing the tremendous potential of this sector for the good of society, there are real or perceived apprehensions of adverse affects to society associated with the use of their technologies. India has developed scientific and regulatory competence in selected biotech areas that provide the ground conditions for the propagation of biotechnology along with biosafety issues. In the context of biosafety, capacity building means the strengthening and/or development of both human resources and the institutional and infra structural capacities which ensure that, in the wake of the emerging biotechnological advance countries, in particular, developing countries, are able to cope with the developments through effective implementation of existing or proposed biosafety guidelines. The GEF-World Bank Biosafety capacity building project would accelerate the process of enhancing the capacity for biosafety in the country.

I am sure that the newsletter has been structured to provide a useful forum for discussion and exchange of information. I wish the venture all success.

Prodipto Ghosh
Secretary
Ministry of Environment & Forests



Message

The use of biotechnology products and processes in diverse application areas affecting our life is playing an important role towards sustainable development. But such widespread applications have raised new challenges such as biosafety. India has been practicing conventional biotechnology for several decades whereas modern biotechnology involving Genetically Modified Organisms is rather new. In spite of the obvious advantages of GMOs in both agriculture and healthcare, there are concerns about the potential risks associated with their use for human health, environment and biological diversity. There have also been initiatives to harmonize biosafety regulations by international organizations. Although, India has framed the required Rules for Biosafety Regulations, its implementation capacity needs to be strengthened. Ministry of Environment & Forests, keeping this in view, has initiated programmes for capacity building in the area of biosafety. The Newsletter, as a part of the GEF-World Bank Capacity Building Project on Biosafety, will go a long way in information sharing in the area.

I do hope that this Newsletter would provide an excellent opportunity to collate a range of thoughts, share experiences and build ideas on capacity building in biosafety.

Suresh Chandra
Special Secretary
Ministry of Environment & Forests



GEF-WORLD BANK CAPACITY BUILDING PROJECT ON BIOSAFETY



The Capacity Building Project will enhance India's national capacity in order to implement the Cartagena Protocol on Biosafety. This Project will address the capacity building needs of the country for implementing the national biosafety framework related to the transboundary movement of LMOs in the context of the Cartagena Protocol and coordination of the implementation of the Biosafety Clearing House (BCH).

Component 1: Strengthening the institutional and legal framework to improve capacity and coordination in decision making at the Federal and State levels and in relevant specialized agencies

In order to improve capacity and coordination in decision making on issues relating to LMOs, the GEF resources will be used to strengthen institutional framework within as well as across the concerned Ministries. This component will be achieved *inter alia* through training for core capacity development in relevant Ministries and State Agencies and other specialized organizations.

Component 2: Improving capacity for risk evaluation and management

GEF resources will be used specifically for training experts in molecular genetics to detect and track LMOs presented under AIA. The capacity developed will increase India's potential to monitor in-country movements of LMOs. GEF support will also be used to develop field capacity to monitor possible gene flow between introduced LMOs and semi domestic and wild relatives. Capacity enhancement would be done for transboundary movement of LMOs at points of entry.

Component 3: Strengthening laboratories/ institutions for analytical evaluation of GM ingredients and for certification services

This outcome will be achieved through:

- Identification of laboratories/ institutions for analytical

evaluation of GM ingredients.

- Training the personnel for certification services.
- Infrastructure and equipment for the identified laboratories/institutions.
- Risks related to LMOs, including labelling issues, traceability etc.

Following four Institutions are being strengthened for the purpose:

- (1) Central Food Technological Institute, (CFTRI) Mysore, Karnataka
- (2) National Bureau of Plant Genetic Resources (NBPGR), New Delhi
- (3) National Research Center on Plant Biotechnology (NRCPB), New Delhi
- (4) G.B. Pant University of Agriculture and Technology, Pantnagar, Uttaranchal

Component 4: Biosafety Clearing House and Enhanced information sharing and public awareness

A Biosafety Clearing House (BCH) is being set up for information sharing for implementation of the Cartagena Protocol on Biosafety. A Project website and a quarterly newsletter on biosafety are being published for wider dissemination of information.

Component 5: Project Coordinating and Monitoring Unit (PCMU)

PCMU provides the technical and administrative assistance for implementing the project.

National Bureau of Plant Genetic Resources (NBPGR), New Delhi

A nodal institute at national level for acquisition and management of indigenous and exotic plant genetic resources for food and agriculture, will be involved in development of biology document for rice; development and standardization of diagnostic tools for detection of LMOs and the traits expressed by them. Organization of training courses/workshop on biosafety and training for resource personnel.

Central Food Technological Research Institute, (CFTRI), Mysore

A national institute that covers every field of scientific investigation connected with foods and their relationship to humans, including food biotechnology. CFTRI would validate the commercially available immuno diagnostic strip test methods for on the spot testing of imported LMOs and organizing related training programmes.

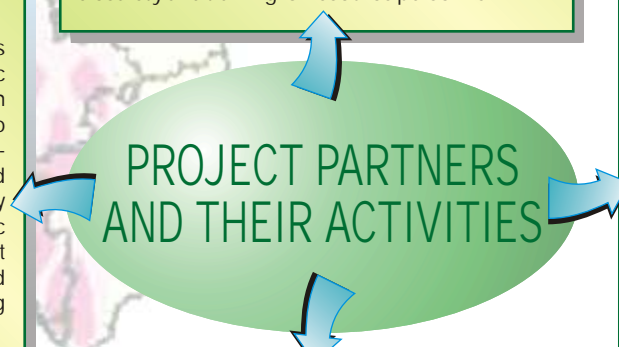
G. B. Pant University of Agriculture and Technology, Pantnagar

The institute will provide facilities for testing GM seeds, to validate commercially available diagnostic kits against defined targets used globally and at national level; to prepare standard operating procedures for the seed production sector and testing analysis of GM procedures in the field and made available to seed certification lab and ports authorities for quick immunological detection and to impart manpower training for assistance in enforcing biosafety regulations.

National Research Center on Plant Biotechnology (NRCPB), New Delhi

A national lead center for plant molecular biology and biotechnology research will create an integrated data-base on post release risk assessment and monitoring transgenics.

PROJECT PARTNERS AND THEIR ACTIVITIES



CARTAGENA PROTOCOL ON BIOSAFETY

The Cartagena Protocol on Biosafety was negotiated and adopted under the aegis of Convention on Biological Diversity (CBD) on January 29, 2000. The objective of Protocol is to ensure an adequate level of protection in the field of safe transfer, handling and use of LMOs taking also into account risks to human health, and specifically focusing on transboundary movement.

The Protocol entered into force on September 11, 2003 and India ratified the Protocol on January 23, 2003. As on date 117 countries have ratified the Protocol.

REGULATORY FRAMEWORK FOR GMOS AND PRODUCTS THEREOF IN INDIA

India has regulatory framework for handling GMOs and products thereof consisting of rules notified in 1989 under Environment (Protection) Act, 1986 and guidelines issued subsequently. The Ministry of Environment and Forests (MoEF) and the Department of Biotechnology (DBT) are the nodal Ministries for implementation of the regulations. There are six Competent Authorities to handle various aspects viz. the Recombinant DNA Advisory Committee (RDAC); Institutional Biosafety Committee (IBSC); Review Committee on Genetic Manipulation (RCGM); Genetic Engineering Approval Committee (GEAC); State Biotechnology Coordination Committee (SBCC) and District Level Committee (DLC)

Progress of National Regulatory Reforms

Report of Task Force on Agriculture Biotechnology

The Department of Agriculture & Cooperation, Ministry of Agriculture, Government of India had set up a Task Force on Agriculture Biotechnology under the Chairmanship of Prof. M. S. Swaminathan, to draft a long term policy on application of biotechnology in agriculture. The report was submitted in May 2004. The major recommendation of the report included setting up of an autonomous regulatory commission, National Biotechnology Regulatory Authority to deal with various issues related to the environment, protection, affordability and human health. The full text of the report is available at <http://agricoop.nic.in/TaskForce/tf.htm>

Report of the Task Force on Recombinant Pharma

Ministry of Environment and Forest, Government of India had constituted a Task Force on Recombinant Pharma Sector under Dr. R. A. Mashelkar, Director General, Council of Scientific and Industrial Research and Secretary Ministry of Science & Technology, which submitted its report in March 2005. The major recommendations of the report included setting up of a transparent and streamlined regulatory mechanism and process for the use of Living Modified Organisms (LMOs) in the pharmaceutical industry during the

various stages of research, testing, manufacture, marketing, import and use. The full text of the report is available at http://envfor.nic.in/divisions/csurv/geac/draftreport_rpharma.pdf

Draft National Biotechnology Development Strategy

The Department of Biotechnology (DBT), Government of India recently announced the National Biotechnology Development Strategy to provide a framework for development of biotechnology in the country by charting out an integrated 10 years road map. The Strategy includes implementation of recommendations of the Swaminathan Committee for agri-biotech and the Mashelkar committee for bio-pharma. The Strategy also includes defining clearly the biosafety evaluation procedure and setting up of new guidelines and a competent single National Biotechnology Regulatory Authority with separate divisions for different products. A special regulatory cell would be created by the DBT to build capacity in the country for scientific risk assessment, monitoring and management, to foster international linkages, support biosafety research; to obtain and review feedback from different stakeholders and provide support to industry and Research & Development institutions. The full text of the Strategy is available at <http://www.dbtindia.nic.in/biotechstrategy/Biotech%20strategy.doc>



under Bt cotton cultivation has been estimated to be 9.0 million Ha in 2004 amounting to 28% of the global area under cotton.

India is the world's third largest cotton producer and has adopted the technology of genetic modification of cotton since 2002.

The Government of India through Genetic Engineering Approval Committee (GEAC), Ministry of Environment & Forests had approved three Bt cotton hybrids developed by MAHYCO based on MON 531 event which is developed by Monsanto for commercial cultivation for a period of three years after extensive field trials. Subsequently, more hybrids of Bt cotton for same event have been approved for different regions. As of now twenty hybrids of Bt cotton have been approved for commercial cultivation. The area under Bt cotton has increased to 13,00,000 acres in 2004 from 72,000 acres in 2002. Companies such as Nath Seeds, Syngenta and J.K. Agrigenetics are developing transgenic cotton using different genes/events.

Cotton (*Gossypium*), family Malvaceae, is grown commercially in over 88 countries with a combined production of 54 million metric tonnes of seed cotton and 18 million metric tonnes of cotton lint. Cotton production is majorly affected by the pests. To fight against these pests genetically modified (GM) cotton has been developed for resistance against insects by incorporating

insecticidal proteins from *Bacillus thuringiensis*. GM cotton has also been developed for herbicide tolerance. Since its introduction in 1996 in USA, Bt cotton has found extensive acceptance world over. Currently, Bt cotton is grown in most of the major cotton growing countries, including USA, Australia, South Africa, Argentina, Mexico, Indonesia and India. The total area



HIGHLIGHTS OF EVENTS



Name	Organized by	Date and venue	Objectives
Launching workshop of GEF-World Bank Aided Capacity Building Projection on Biosafety	MoEF (in association with BCIL)	November 13-14, 2003 New Delhi	To launch the project and discuss the project outline and plan of action.
Bio-safety for monitoring and evaluation of transgenic plants	MoEF and G.B. Pant University of Agriculture and Technology	January 27-February 1, 2005 Pantnagar, Uttaranchal	Hands on training on molecular testing methods of transgenic plants and creating awareness about the biosafety issues related to the use of transgenic crop plants.
Series of workshops on biosafety issues related to transgenic crops with a focus on Bt cotton	MoEF and BCIL	January-March, 2005 Ahmedabad, Nagpur, Hyderabad, Coimbatore, Hisar and Ludhiana	Sharing experiences of growing Bt cotton by various stakeholders in six Bt cotton growing states in central and southern India and creating awareness about rules and regulations in three northern states where large scale trials were underway
National Seminar on Biosafety of Genetically Modified Organisms	MoEF and Delhi University Botanical Society	March 10-11, 2005 New Delhi	Sharing experience on Genetically Modified Organisms and its biosafety issues
Biosafety Concerns of Transgenics and Detection of LMOs	MoEF and NBPGR	March 14-21, 2005 New Delhi	Hands on training on ELISA/PCR based detection protocols for LMO and lectures addressing different biosafety concerns
Workshop on Capacity Building on Biosafety	MoEF (in association with BCIL)	March 23-24, 2005 New Delhi	Planning a coordinated approach for capacity building in the context of implementing provisions of Cartagena Protocol on Biosafety
National Consultation on Liability and Redress in the context of Cartagena Protocol on Biosafety	MoEF, JNU and BCIL	March 28-29, 2005 New Delhi	Deliberations on approach to be followed by India for the negotiations for liability and redress regime for transboundary movement of LMOs.
National Consultation on Liability and Redress in the context of Cartagena Protocol on Biosafety	MoEF and RIS	May 24, 2005 New Delhi	Discussions on Precautionary principle and compliance, liability and redress, capacity building and socioeconomic concerns.

UPCOMING EVENTS

Name	Organized by	Date and venue
International Conference on Food Derived from GM Crops: Issues for Consumers, Regulators and Scientists	Indian Council of Medical Research AGBIOS Inc., Canada and Biotech Consortium India Limited	September 26-27, 2005 New Delhi
National Seminar on Transgenic Crops in Indian Agriculture: Status, Risks and Acceptance	National Society of Plant Sciences, in collaboration with Department of Plant Breeding and Department of Biotechnology and Molecular Biology, CCS Haryana Agricultural University	November 10-11, 2005 Hisar
Symposium on Biotechnology for Better Nutrition, XXXVII Annual Meetings of The Nutrition Society of India	National Institute of Nutrition, Hyderabad	November 17, 2005 Hyderabad

RECENTLY RELEASED REPORTS

- i) Global status of commercialized biotech/GM crops (2004) by C. James, Chair, ISAAA Board of Directors (www.isaaa.org)
- ii) The global diffusion of Plant Biotechnology: International Adoption and Research in 2004 by C. Ford Runge and Barry Ryan (<http://www.apec.umn.edu/faculty/frunge/globalbiotech04.pdf>)
- iii) Benchmark document on the needs and present status of the capacity building in biosafety of GM crops in Asia (2004) by FAO Regional Office for Asia and the Pacific Bangkok ([http://asiabionet.org/activities second FP March 2004/doc Revised %20 Proceedings Second % 20 Focal % 20 Point % 20 Meeting % 20 RL % 20 ED1. pdf](http://asiabionet.org/activities%20second%20FP%20March%202004/doc%20Revised%20Proceedings%20Second%20Focal%20Point%20Meeting%20RL%20ED1.pdf))
- iv) The state of food and agriculture 2003-2004 (2004) by Food and Agriculture Organization of the United Nations, Rome. (<http://www.fao.org/docrep/006/Y5160E/y5160e01.htm>)

Training Needs Assessment Survey

As part of the GEF-World Bank Project on Biosafety of MoEF, Biotech Consortium India Ltd. (BCIL), is undertaking a survey to assess training needs for capacity building in the area of biosafety related to use of LMOs/GMOs. The objective of the survey is to make a realistic assessment of the training needs prior to initiating steps for countrywide training programmes under the project. The assessment is proposed to be done through a process of consultation with key stakeholders representing Central and State Governments, research scientists, industry, social organizations and NGOs.

A questionnaire has been placed on www.envfor.nic.in and www.biotech.co.in. All concerned with the subject are requested to kindly download, complete and return the same at the earliest (at hota@nic.in and vibhaahuja@biotech.co.in or fax 011-23219063).

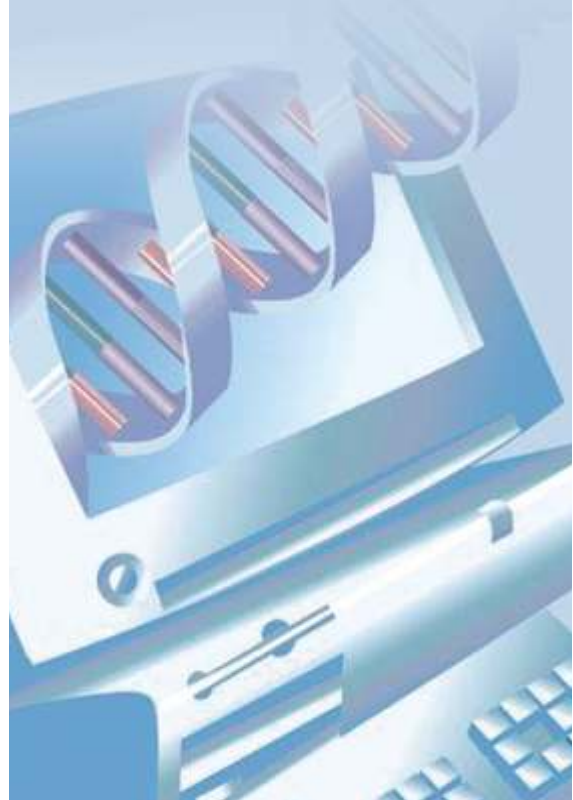


Links for further reading

<http://www.biodiv.org> gives information about the Cartagena Protocol on Biosafety, including background and full text of the agreements, articles, updated list of signatures and ratifications, documents of various meetings held, the Biosafety Clearing House and a database of biosafety capacity-building activities.

<http://www.agbios.com>, is dedicated to providing public policy, regulatory, and risk assessment expertise for products of biotechnology and offers access to a database of safety information on all GM plant products

<http://www.agbiosafety.unl.edu>, site of University of Nebraska, offers up-to-date information on current issues in biotechnology and food safety and a searchable database of safety information on GM crops.



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Special Secretary, MoEF

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Biosafety Information Resource Centre (BIRC)

The BIRC is an online searchable database containing electronic catalogues of biosafety-related publications and information resources (including: news services, e-mail Listservs, online databases and search engines, reports and case studies, journals and newsletters, as well as teaching materials manuals, toolkits and presentations). Its objective is to increase the accessibility and utilization of available biosafety information and resources by policymakers, educators, researchers and the general public.

Biosafety Capacity-Building Network

The Biosafety Capacity-Building Network is an interactive forum that links individuals from Government agencies and relevant organisations active in biosafety capacity-building activities. The primary purpose of the Network is to facilitate active interaction and exchange of information and experience among Network members with a view to promoting partnerships, complementarity and synergies between various biosafety capacity-building initiatives. After registration, members of the Network have access to an interactive collaborative portal for the Network.

For more information visit :

<http://bch.biodiv.org/informationsharing/default.shtml>



Project website :

<http://www.enfor.nic.in/divisions/csurv/biosafety/default.htm>

Disclaimer : The information in this newsletter has been compiled from various sources and does not necessarily depict views of the Ministry of Environment & Forests, Government of India.