

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.

DRAFT GUIDELINES FOR THE CONDUCT OF CONFINED FIELD TRIALS OF REGULATED, GENETIC ENGINEERED (GE) PLANTS IN INDIA

Department of Biotechnology (DBT) Guidelines for Research in Transgenic Crops, 1998 extensively provide for approval procedures for research, greenhouse design, *etc.* However, in view of increase in the number of field trials being conducted for several crops with new genes/events, DBT has initiated an exercise to develop guidelines for conducting field trials of regulated, genetically engineered plants in India.

Comments are invited from all the stakeholders on the above guidelines. Comments will be received up to January 15, 2008, following which the guidelines will be finalized. The Guidelines can be viewed at http://www.igmoris.nic.in/field_trials_guidelines/Guidelines.pdf.

DRAFT STANDARD OPERATING PROCEDURES AND RECORDING FORMATS FOR CONFINED FIELD TRIALS

DBT has initiated an exercise for development of Standard Operating Procedures (SOPs) for field trials of regulated genetically engineered plants. To begin, SOPs have been drafted for transport, storage, management, harvest or termination and post harvest management of confined field trials of genetically engineered cotton. Formats for recording the information during the conduct of field trials have also been drafted.

Comments are invited from all the stakeholders on the above SOPs, which can be viewed at http://www.igmoris.nic. in/field_trials_guidelines/SOP.htm. Comments will be received up to January 15, 2008, following which the SOPs will be finalized. Comments can be sent to:

Dr. K.K. Tripathi, Member Secretary, RCGM and Advisor, Department of Biotechnology Block-II, CGO Complex, Lodhi Road New Delhi – 110 003 Telefax: 011-24361559 Email: kkt@dbt.nic.in

DRAFT PROTOCOLS FOR ASSESSMENT OF TOXICITY AND ALLERGENICITY IN TRANSGENIC CROPS

As recommended by the Review Committee on Genetic Modification (RCGM), Department of Biotechnology constituted a sub-committee to review the existing protocols on toxicity and allergenicity testing of transgenic crops *vide* letter no. No.BT/03/105/2007-PID dated 02.07.2007 under the chairmanship of Dr. B. Sesikeran, Director, National Institute of Nutrition. After deliberating in detail on the state-of-theart information available for the assessment of toxicity and allergenicity of the genetically modified crops, the committee has recommended the following:

- Acute oral toxicity test should be undertaken with purified protein and sub-chronic 90 day toxicity be undertaken with whole plant material, along with daily intake food/feed.
- ii) Allergenicity testing should comprise a battery of tests including amino acid sequence homology using bioinformatics tools from the allergen databases, pepsin digestibility and protein thermal stability. These tests should be mandatory and the use of other tests viz. serum testing (specific/targeted) and use of animal models should be recommended on a case by case basis, based on the source of the gene/protein and the results of the above three mandatory tests.
- iii) The following protocols may be deleted:
 - a) Primary skin irritation test of transgenic seed and vegetables in rabbit.
 - b) Irritation to mucous membrane test of transgenic seed in female rabbit.
 - c) Skin sensitization test of transgenic seed in guinea pigs (OECD 406).
 - d) Passive cutaneous anaphylaxis.
 - e) Prausnitz Kustner (PK) test.
 - f) Radioallergosorbent (RAST) inhibition test.
 - g) ELISA for measurement of antibodies.
- iv) The protocols to be adopted for testing of all new materials have been developed and placed at the links below. Any additional tests may be specified on a case by case basis.
- v) Indian Council of Medical Research (ICMR) Guidelines for the Safety Assessment of Foods Derived from

CALENDAR OF EVENTS			
INDIA			
Event	Organization	Date	Place
National Consultation on Liability and Redress in the Context of the Cartagena Protocols on Biosafety	Biotech Consortium India Limited (BCIL) and Ministry of Environment and Forests (MoEF)	January 7, 2008	New Delhi
Orientation Programme on Biotechnology, Biosafety and IPRs	Institute of Public Enterprise, Osmania University	January 31 - February 1, 2008	Hyderabad
National Consultation on Insect Resistance Management (IRM) Strategies in Bt Cotton	BCIL and MoEF	January 21 - 22, 2008	New Delhi
National Symposium on Plant Biotechnology for Conservation, Characterization and Crop Improvement	Mohanlal Sukhadia University	February 8 - 10, 2008	Udaipur

Draft Protocols - continued from page 1

Genetically Engineered Plants may be used for further guidance while reviewing the protocols.

vi) The crop specific sub-committees set up by RCGM would provide detailed compositional considerations to be tested for each crop.

Comments are invited from all the stakeholders on the protocols suggested by the sub-committee. The protocols can be viewed at **http://www.igmoris.nic.in/Protocols. htm**. Comments will be received up to January 15, 2008, following which these protocols will be finalized. Comments can be sent to:

Dr. K.K. Tripathi, Member Secretary, RCGM and Advisor, Department of Biotechnology Block-II, CGO Complex, Lodhi Road New Delhi – 110 003 Telefax: 011-24361559 Email: kkt@dbt.nic.in

GOVERNMENT OF INDIA APPROVES THE NATIONAL BIOTECHNOLOGY DEVELOPMENT STRATEGY

The National Biotechnology Development Strategy has been approved by the Government of India. The strategy is an outcome of a two-year-long nationwide consultation process with multiple stakeholders including concerned ministries, universities, research institutes, private sector, civil society, consumer groups, non-government and voluntary organizations and international bodies. The draft strategy, which was posted on the web (http://dbtindia.nic.in/biotechstrategy/National%20Biotechnology%20 Development%20Strategy.pdf), received over 300 comments from all sectors of society. The strategy was finalized after careful scrutiny of the comments.

The key elements of the strategy are:

• The Government recognizes that biotechnology is a sunrise sector and hence, needs focused attention.

- Approval has been accorded for the broad framework of the National Biotechnology Development Strategy and the strategic focus on sectors proposed therein.
- The strategy, while enabling the full utilization of currently available opportunities in manufacturing and services, will lay a strong foundation for discovery and innovation, effectively utilizing novel technology platforms with potential to contribute to long term benefits in agriculture, animal productivity, human health, environmental security and sustainable industrial growth.
- The cornerstone of the strategy is the focus on building coherence and connectivity between disciplines and to bring together variegated skills across sectors to enhance synergy.
- The strategy seeks to address a number of challenges relating to the biotechnology sector in terms of reasearch and development, creation of investment capital, technology transfer, absorption and diffusion, intellectual property rights, regulatory issues, building public confidence, and tailor made human capital for all these aspects.
- The stated vision of the strategy is responsible use of life sciences and biotechnology to promote balanced growth of all sections of society.

Addressing regulation, the strategy calls for the establishment of a National Biotechnology Regulatory Authority

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SPOTLIGHT ON THE WORDWIDE WEB

Over the next number of newsletters we will be spotlighting some important websites, created by the Department of Biotechnology (DBT) and the Ministry of Environment and Forests (MoEF), that provide information on GMOs.

This month we feature the the Ministry of Environment and Forests, Government of India (http://envfor. nic.in). In the months ahead we will look at the websites of Capacity Building on Biosafety; India Biosafety Clearing House; National Research Centre on Plant Biotechnology; Department of Agriculture and Cooperation, Ministry of Agriculture, Government of India; and Biotech Consortium India Limited (BCIL). - Editor



Government of India - Ministry of Environment & Forests

(http://http://envfor.nic.in)

I mplementation of policies and programmes relating to conservation of the country's natural resources including lakes and rivers, its biodiversity, forests and wildlife, ensuring the welfare of animals and prevention and abatement of pollution are the primary concern of the Ministry of Environment & Forests under the Government structure. While implementing these policies and programmes, the Ministry is guided by the principle of sustainable development and enhancement of human well-being. The Ministry also serves as the nodal agency in the country for the United Nations Environment Programme (UNEP), South Asia Co-operative Environment Programme (SACEP), International Centre for Integrated Mountain Development (ICIMOD) and for the follow-up of the United Nations Conference on Environment and Development (UNCED). The Ministry is also entrusted with the issues relating to multilateral bodies such as the Commission on Sustainable Development (CSD), Global Environment Facility (GEF) and of regional bodies like Economic and Social Council for Asia and Pacific (ESCAP) and South Asian Association for Regional Co-operation (SAARC) on matters pertaining to environment.

The principal activities undertaken by the Ministry are:

- · Conservation and survey of flora, fauna, forests and wildlife;
- Prevention and control of pollution;
- · Afforestation and regeneration of degraded areas;
- Protection of the environment; and
- Ensuring the welfare of animals.

These objectives are well supported by a set of legislative and regulatory measures, aimed at the preservation, conservation and protection of the environment. Besides the legislative measures, a National Conservation Strategy and Policy Statement on Environment and Development, 1992, National Forest Policy, 1988, a Policy Statement on Abatement of Pollution, 1992 and a National Environment Policy, 2006 have also been evolved.



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(NBRA). The NBRA would be set up as an independent, autonomous and professionally led body to provide a single window mechanism for biosafety clearance of genetically modified products and processes. DBT has been entrusted with the responsibility of setting up the NBRA. Existing mechanisms, however, would continue until a full-fledged body is created with the required infrastructure and fully functional autonomy.



The following papers were published recently and may be of interest to readers of the SABP newsletter.

NUTRITIONAL AND SAFETY ASSESSMENTS OF FOODS AND FEEDS NUTRITIONALLY IMPROVED THROUGH BIOTECHNOLOGY: CASE STUDIES: EXECUTIVE SUMMARY OF A TASK FORCE REPORT BY THE INTERNATIONAL LIFE SCIENCES INSTITUTE, WASHINGTON, D.C.

Journal of Food Science - Volume 72 Issue 9 Page R131-R137, November/ December 2007

During the last two decades, the public and private sectors have made substantial international research progress toward improving the nutritional value of a wide range of food and feed crops. Nevertheless, significant numbers of people still suffer from the effects of undernutrition. In addition, the nutritional quality of feed is often a limiting factor in livestock production systems, particularly those in developing countries. As newly developed crops with nutritionally improved traits come closer to being available to producers and consumers, we must ensure that scientifically sound and efficient processes are used to assess the safety and nutritional quality of these crops. Such processes will facilitate deploying these crops to those world areas with large numbers of people who need them. This document describes five case studies of crops with improved nutritional value. These case studies examine the principles and recommendations published by the International Life Sciences Institute (ILSI) in 2004 for the safety and nutritional assessment of foods and feeds derived from nutritionally improved crops (ILSI 2004). One overarching conclusion that spans all five case studies is that the comparative safety assessment process is a valid approach. Such a process has been endorsed by many publications and organizations, including the 2004 ILSI publication. The type and extent of data that are appropriate for a scientifically sound comparative safety assessment are presented on a case-by-case basis in a manner that takes into account scientific results published since the 2004 ILSI report. This report will appear in the January issue of Comprehensive Reviews in Food Science and Food Safety.

For more information go to: http://www.blackwell-synergy.com/ doi/abs/10.1111/j.1750-3841.2007.00579.x

Council for Agricultural Science and Technology Paper Addresses the Implications of Gene Flow related to Commercial Use of Biotech Crops

December, 2007 - Ames, Iowa. The Council for Agricultural Science and Technology (CAST) is releasing a new Issue Paper, Implications of Gene Flow in the Scale-up and Commercial Use of Biotechnology-derived Crops: Economic and Policy Considerations.

Gene flow is a natural occurrence in the biological world and always has been. The introduction of biotechnology-derived crops, however, has caused an increased interest in understanding and managing gene flow. According to Task Force Chair David Gealy, USDA–ARS, "Humans have selected, adapted, and improved crops from diverse species for numerous purposes. Many useful traits are being imparted into biotech and nonbiotech crops, most of which are likely to impact the dynamics of gene flow very little, especially outside of agricultural fields. Precommercialization procedures that take into account the specific trait being introduced will help to insure that impacts of gene flow remain low." The Issue Paper:

- Describes biological traits being imparted into biotech crops and their gene flow ramifications.
- Explains the phenomenon of adventitious presence and how it relates to gene flow.
- Discusses containment approaches for the mitigation of gene flow.
- Summarizes existing regulatory and risk assessment mechanisms for biotech crops.
- Discusses potential economic implications of biotech crops in the marketplace.
- Explores future policy and research issues.
- For more information go to: http://www.cast-science.org/

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, KOG 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 KOG 1NO Canada Tel: +613-269-7966 Email: info@agbios.com

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