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 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.

INTRODUCTION OF A BILL TO SET UP BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA (BRAI)

On April 22, 2013, in the Lok Sabha (lower house of the Indian parliament) Shri Jaipal Reddy, India's Minister of Science and Technology, introduced the *Biotechnology Regulatory Authority of India Bill, 2013*. Its purpose is to promote the safe and responsible use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures by setting up an independent statutory regulatory authority, the Biotechnology Regulatory Authority of India (BRAI).

Modern biotechnology offers opportunities to address important needs related to health, food production and the environment and is recognised globally as a rapidly advancing science. India has been active in the research and development of biotechnology for the last two decades and Indian industry has also made a foray into modern biotechnology. Concomitant to these developments, there are public concerns about the human, animal and environmental safety of organisms and products derived from modern biotechnology.

According to the Bill's statement of objectives and reasons, the BRAI is proposed to be a statutory independent regulator that would be a nodal agency of the Government of India to ensure comprehensive safety assessment of organisms and products of modern biotechnology. It will function as the competent national authority for biotechnology regulation to ensure the health and safety of the Indian people is safeguarded and to protect the environment. It will subsume the functions of the existing multiple competent bodies under R*ules for Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/ Genetically Engineered Organisms or Cells, 1989* notified under the *Environment (Protection) Act, 1986* so as to keep pace with regulatory measures with the rapid technology advancement in the field of biotechnology.

The salient features of the BRAI Bill are:

(a) establishment of the Biotechnology Regulatory Authority of India to regulate the research, transport, import, manufacture and use of organisms and products of modern biotechnology;

(b) constitution of Inter-Ministerial Governing Board to oversee the performance of the Authority;

(c) constitution of Biotechnology Advisory Council to render strategic advice to the Authority on matters relating to developments in modern biotechnology and their implications in India;

(d) provision for an eminent biotechnologist in the position of Chairperson and have four members with expertise in the areas of health care, agriculture, environment and molecular biology.

(e) provision for Regulatory Divisions of the Authority dealing with agriculture, forest and fisheries, human health and veterinary products and industrial and environmental applications for the implementation of safety assessment procedures and processes;

(f) constitution of Risk Assessment Unit comprising scientific officers, product rulings committee and environmental appraisal panel for elaborate risk assessment process involving scientific experts and representatives of concerned ministries including a special public review system for the evaluation of applications before final approvals;

(g) constitution of the State Biotechnology Regulatory Advisory Committee to act as the nodal agency between the State Government and the Authority in respect of matters related to the regulation of modern biotechnology;

(h) provision for the notification by the Authority of accredited laboratories and research institutions by the Authority for the purposes of proposed legislation;

(i) provision for Biotechnology Regulatory Appellate Tribunal consisting of full-time Chairperson who has been a Judge of the Supreme Court of India or a Chief Justice of a High Court and part-time expert members not exceeding five to hear the appeals against the decision or order or direction of the Authority;

(j) provision for offences and penalties for contravening the provisions of the proposed legislation;

(k) empowerment of the Central Government to supersede the Authority in certain circumstances.

(continued on page 2 - see BRAI)

BRAI - *continued from page 1*

It has been stated that commercialization of biotechnology products in agriculture and health care would be subject to all other laws whether Central or State, for the time being in force and the rules and regulations made thereunder. The organisational plan of the Authority also provides collaborative arrangements, co-ordination and mechanisms with other existing regulatory agencies.

A copy of the Bill and the notes on clauses explaining in detail various provisions in the Bill can be accessed at http://164.100.47.4/newlsbios_search/intsessionreport3.aspx.

The Partnership for Biosafety Risk Assessment and Regulation is a cooperative project funded by the World Bank and managed by the Center for Environmental Risk Assessment. In partnership with the OECD Environment Directorate and developing country partners, the aim of the project is to provide support for building biosafety capacity with the intention of facilitating partner countries' participation in the OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology. The program was launched in 2011, and partner countries include Bangladesh, Kenya, Paraguay, Tanzania, Uganda, Uruguay and Vietnam. In April 2012, the Working Group held its 27th meeting, and the Partnership Program was able to support the participation of two delegates from Bangladesh: Mr. M. Solaiman Haider of the Bangladesh Department of Environment and Professor Zeba Seraj Islam of the University of Dhaka and member of the Bangladesh Biosafety Core Committee. Below is a report of the highlights of the meeting provided by Professor Seraj.

SUMMARY OF THE 27TH WORKING GROUP MEETING ON THE HARMONISATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY

Under the Joint meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, Environment Directorate and part of the OECD's Global Forum on Biotechnology (GFB)

A summary record of the 26th Working Group (WG) meeting indicated major accomplishments and available information:

- Development and availability of environmental documents such as, Fostering Innovation for Green Growth, Food and Agriculture, and Energy, developed jointly with the International Energy Agency (IEA). Documents are accessible at www.oecd.org/green-growth and/or www.oecd.org/croissanceverte.
- The three-year, joint OECD/World Bank/CERA Partnership for Biosafety Risk Assessment and Regulation, officially launched in October 2012, which contributes to the GFB. The GFB allows participation by non-OECD economies in both environmental safety (biosafety) and novel food/feed programmes, the latter is also under the Joint meeting.
- Information about a Biotechnology Update newsletter produced twice a year by the OECD Internal Coordination Group for Biotechnology (ICGB). ICGB co-ordinates activities related to biotechnology developed by different directorates and bodies at OECD. The newsletter is useful not only for OECD personnel but for the wider biotechnology community as a whole.
- The OECD Environment Working Paper No. 40 Adaptation and Innovation – An Analysis of Crop Biotechnology Patent Data.
- A workshop at OECD on the "Safety of Transgenic Crops and Products".

Declassification of Documents Since the 26th Meeting: the Consensus Biology Documents on *Cucurbita* and *Brassica* crops, which were prepared and finalized previously, were declassified and published.

Opening of the 27th Meeting: The current status of biotechnological products and their regulatory oversight was presented by representatives of 16 member and observer countries. Bangladesh and Moldova were welcomed into the group for the first time as observers.

Environmental Use of Micro-organisms: A state-of-the-art workshop overview of the environmental uses of micro-organisms, focusing on concrete or expected developments in the field of transgenic organisms, was earlier organized by OECD to support the development of the work programme.

Consensus LLP Document: A document on low level presence (LLP) of transgenes in seeds and commodities in the context of environmental risk/safety assessment and availability and use of information was agreed upon and will begin the process for declassification.

Format for Environmental Considerations for Release of Transgenic Plants: Formulation of a general propose format for developing environmental considerations for risk safety assessment for the release of transgenic plants was discussed. It was agreed that a problem formulation approach to risk assessment would be followed. A steering group was organized to begin drafting sections of the document based on this outline.

Consensus Biology Documents: Several Consensus Biology Documents on crops, trees and animals at various stages of finalization were discussed: sorghum, sugarcane, tomato, cassava, cowpea, eucalyptus, salmon, and mosquito.

Updating the Points to Consider for Consensus Documents on the Biology of Cultivated Plants: Delegates agreed to provide comment in order to update this guidance document.

OECD Database: Delegations were invited to submit new entries to the Secretariat at any time to update the database http://www2.oecd.org/biotech/

Unique Identifier for Transgenics: It was agreed to discuss with the UNEP-CBD Secretariat the request at COPMOP6 for the OECD to develop Guidance Documents on Unique Identifiers for transgenic (a) micro-organisms and (b) animals.

New Plant Breeding Techniques: It was agreed by the WG that a workshop on New Plant Breeding Techniques will be held in conjunction with the 28th WG meeting.

The meeting ended with the announcement that the 28th WG meeting will take place in February, 2014.

The Reading List

. . . new and notable articles

FATE OF ARTIFICIAL MICRORNA-MEDIATED RESISTANCE TO PLANT VIRUSES IN MIXED INFECTIONS

Martínez F, Elena SF, Daròs JA

Artificial microRNAs (amiRNAs) are the expression products of engineered microRNA (miRNA) genes that efficiently and specifically down-regulate RNAs that contain complementary sequences. Transgenic plants expressing high levels of one or more amiRNAs targeting particular sequences in the genomes of some RNA viruses have shown specific resistance to the corresponding virus. This is the case of the *Arabidopsis thaliana* transgenic line 12-4 expressing a high level of the amiR159-HC-Pro targeting 21 nucleotides in the Turnip mosaic virus (TuMV; family Potyviridae) cistron coding for the viral RNA silencing suppressor HC-Pro that is highly resistant to TuMV infection. In this study we explored the fate of this resistance when the *A. thaliana* 12-4 plants are challenged with a second virus in addition to TuMV. The *A. thaliana* 12-4 plants maintained the resistance to TuMV when this virus was co-inoculated with Tobacco mosaic virus, Tobacco rattle virus (TRV), Cucumber mosaic virus (CMV), Turnip yellow mosaic virus, Cauliflower mosaic virus (CaMV), Lettuce mosaic virus or Plum pox virus. However, when the plants were pre-infected with these viruses, TuMV was able to co-infect 12-4 plants pre-infected with TRV, CaMV, and, particularly, with CMV. So, pre-infection by another virus jeopardizes the amiRNA-mediated resistance to TuMV.

PHYTOPATHOLOGY. 2013 APR 25. [EPUB AHEAD OF PRINT] HTTP://APSJOURNALS.APSNET.ORG/DOI/ABS/10.1094/PHYTO-09-12-0233-R

GENOMIC MISCONCEPTION: A FRESH LOOK AT THE BIOSAFETY OF TRANSGENIC AND CONVENTIONAL CROPS. A PLEA FOR A PROCESS AGNOSTIC REGULATION

Ammann K.

The regulation of genetically engineered crops, in Europe and within the legislation of the Cartagena Biosafety Protocol is built on false premises: The claim was (and unfortunately still is) that there is a basic difference between conventional and transgenic crops, this despite the fact that this has been rejected on scientifically solid grounds since many years. This contribution collects some major arguments for a fresh look at regulation of transgenic crops, they are in their molecular processes of creation not basically different from conventional crops, which are based in their breeding methods on natural, sometimes enhanced mutation. But the fascination and euphoria of the discoveries in molecular biology and the new perspectives in plant breeding in the sixties and seventies led to the wrong focus on transgenic plants alone. In a collective framing process the initial biosafety debates focused on the novelty of the process of transgenesis. When early debates on the risk assessment merged into legislative decisions, this wrong focus on transgenesis alone seemed uncontested. The process-focused view was also fostered by a conglomerate of a) concerned scientists and b) biotechnology companies, both with a vested interest to at least tolerate the rise of the safety threshold in order to secure research money (a) and to discourage competitors of all kinds (b). Policy minded people and opponent activists without deeper insight in the molecular science agreed to those efforts without much resistance. It is interesting to realize, that the focus on processes was uncontested by a majority of regulators, this despite of serious early warnings from important authorities in science, mainly of US origin. It is time to change the regulation of GM crops towards a more science based process-agnostic legislation. Although this article concentrates on the critique of the process-oriented regulation, including some details about the history behind, there should be no misunderstanding that there are other important factors responsible for the failure of this kind of process-oriented regulation, most importantly: 1) The predominance of politics in the decision making processes combined with the lack of serious scientific debates on regulatory matters within the European Union and also in the Cartagena system, 2) the obscure and much too complex decision making structures within the EU, 3) the active, professional, negative and intimidating role of fundamental opposition against GM crops on all levels dealing with flawed science, often declared as better parallel science published by 'independent' scientists.

NEW BIOTECHNOLOGY (2013) MAY 14. PII: S1871-6784(13)00060-5. DOI: 10.1016/J.NBT.2013.04.008. [EPUB AHEAD OF PRINT] HTTP://WWW.SCIENCEDIRECT.COM/SCIENCE/ARTICLE/PII/S1871678413000605

SITE-DIRECTED NUCLEASES: A PARADIGM SHIFT IN PREDICTABLE, KNOWLEDGE-BASED PLANT BREEDING

Podevin N, Davies HV, Hartung F, Nogué F, Casacuberta JM

Conventional plant breeding exploits existing genetic variability and introduces new variability by mutagenesis. This has proven highly successful in securing food supplies for an ever-growing human population. The use of genetically modified plants is a complementary approach but all plant breeding techniques have limitations. Here, we discuss how the recent evolution of targeted mutagenesis and DNA insertion techniques based on tailor-made site-directed nucleases (SDNs) provides opportunities to overcome such limitations. Plant breeding companies are exploiting SDNs to develop a new generation of crops with new and improved traits. Nevertheless, some technical limitations as well as significant uncertainties on the regulatory status of SDNs may challenge their use for commercial plant breeding.

TRENDS IN BIOTECHNOLOGY. 2013 APR 16. PII: S0167-7799(13)00065-6. DOI: 10.1016/J.TIBTECH.2013.03.004. [EPUB AHEAD OF PRINT] HTTP://WWW.SCIENCEDIRECT.COM/SCIENCE/ARTICLE/PII/S0167779913000656

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CALENDAR OF EVENTS

Event	Organized by	Date and Venue	Website
INDIA			
AP-TEC 2013@TIRUPATI	Confederation of Indian Industry	June 6 - 8, 2013 Tirupati, Chittoor, Andhra Pradesh	http://ow.ly/hOefY
XIII National Seed Seminar on Innovations in Seed Research and Development	Indian Society of Seed Technology and University of Agricultural Sciences, Bangalore	June 8 - 10, 2013 Bangalore	http://www.iari.res.in/
BIO-AGRI 2013 Towards Productive Efficiencies & Farmers Growth	The Associated Chambers of Commerce and Industry of India (ASSOCHAM)	June 19, 2013 New Delhi	http://www.assocham.org/events/showevent.php?id=845
ICAR Sponsored Summer School on New Horizons in Biotic Stress Management in Rice under Changing Climate Scenario	Central Rice Research Institute	September 10 - 30, 2013 Cuttack	http://www.crri.nic.in/Summer%20School%20Brochure_CRRI%202013.pdf
INTERNATIONAL			
World Biotechnology Congress (WBC 2013)	Eureka Conference	June 3 – 6, 2013 Boston, Massachusetts USA	http://www.worldbiotechcongress.com/confprog.htm
International Workshop on Comparative Approaches to Safety Assessment of GM Plant Materials	AgriFood Health and Quality National Service (SENASA, Ministry of Agriculture), Argentina, and ILSI Argentina	June 26 - 28, 2013 Buenos Aires, Argentina	
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_Rev7Feb2013.pdf
Biosafety: An International Short Course in Environmental Aspects of Agricultural Biotechnology	Michigan State University College of Agriculture and Natural Resources in Collaboration with the Plant Breeding and Genetics Program	August 4 – 9, 2013 East Lansing, Michigan, USA	http://worldtap.msu.edu/short-courses/biosafety/
International Conference on Genetic Engineering and Genetically Modified Organisms	OMICS Group	August 12 - 14, 2013 Raleigh, North Carolina, USA	http://www.omicsgroup.com/conferences/genetic-engineering-genetically-modified-organisms-2013/

Reading List - *continued from page 3*

TRANSGENE-BASED, FEMALE-SPECIFIC LETHALITY SYSTEM FOR GENETIC SEXING OF THE SILKWORM, *BOMBYX MORI*

Tan A, Fu G, Jin L, Guo Q, Li Z, Niu B, Meng Z, Morrison NI, Alphey L, Huang Y

Transgene-based genetic sexing methods are being developed for insects of agricultural and public health importance. Male-only rearing has long been sought in sericulture because males show superior economic characteristics, such as better fitness, lower food consumption, and higher silk yield. Here we report the establishment of a transgene-based genetic sexing system for the silkworm, *Bombyx mori*. We developed a construct in which a positive feedback loop regulated by sex-specific alternative splicing leads to high-level expression of the tetracycline-repressible transactivator in females only. Transgenic animals show female-specific lethality during embryonic and early larval stages, leading to male-only cocoons. This transgene-based female-specific lethal system not only has wide application in sericulture, but also has great potential in lepidopteran pest control.

PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES OF AMERICA. 2013 APR 23;110(17):6766-70. DOI: 10.1073/PNAS.1221700110. EPUB 2013 APR 8 HTTP://WWW.PNAS.ORG/CONTENT/110/17/6766.ABSTRACT?SID=E7A39C03-2750-4F5C-9B18-09EEF56C5DB3

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