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.

THE STATUS AND IMPACT OF BIOSAFETY REGULATION IN DEVELOPING ECONOMIES SINCE RATIFICATION OF THE CARTAGENA PROTOCOL

Morven McLean, **Mary-Ellen Foley**, and **Eija Pehu**

JOINT DEPARTMENT DISCUSSION PAPER 3, AGRICULTURE AND RURAL DEVELOPMENT & ENVIRONMENT DEPARTMENTS, THE WORLD BANK

Common to all of the countries where genetically engineered (GE) crops are cultivated is a system to regulate these products and particularly to ensure their evaluation for human health and environmental safety (commonly referred to as biosafety) prior to any commercial release. This paper explores how the Cartagena Protocol to the Convention on Biological Diversity, as well as other important drivers, have affected the regulation of GE crops in developing countries. It examines the impact of biosafety regulation on research and development of GE crops and on product approvals. Finally, it identifies opportunities to advance biosafety regulation in those developing countries that wish to access the potential benefits of agricultural biotechnology.

The early adopters of GE crops, like the United States, Canada, and Argentina, developed regulatory systems to respond to the impending release of GE crops for cultivation. In most developing countries, however, the establishment of national biosafety regulatory systems was a by-product of the ratification of the Cartagena Protocol on Biosafety and its entry into force in 2003. The Cartagena Protocol is the only international environmental agreement that is concerned exclusively with products of modern biotechnology. Its interpretation and implementation have had a significant impact on biosafety regulation, especially in developing countries. Over the past decade, more than 140 developing countries or countries with transitional economies have received assistance to develop or implement national biosafety frameworks. Only a small number of developing countries have moved beyond these projects to operationalize their biosafety regulatory systems effectively, so that they may be considered functional—that is, they implement regulatory submission, assessment, and decision-making processes in a consistent, transparent, and predictable manner.

As is true for capacity development in other regulatory arenas, progress in biosafety regulation in developing countries is often impeded by limited political and financial commitments from national governments and by insufficient technical, human resource, and institutional capacity for implementation. It is also confounded by competing or redundant capacity building projects and the absence of products to regulate. Only a limited number of developing countries have substantive public sector research programs in agricultural biotechnology or are considered markets of interest for private sector investments in this area. In effect, there is limited demand to drive regulatory development (or reform) forward, and policy makers' attention is necessarily redirected to other priorities. Private sector developers of GE crops are generally disinterested in entering markets, even those in which farmers demand GE crops, unless the biosafety regulatory system is operational and predictable. More critically, public sector and donor initiatives that focus on improving the productivity of staple crops using biotechnology will be unsuccessful unless there is a clear path for improved crop varieties actually to move from laboratories to field trials to farmers.

Even with these challenges, there are opportunities to advance biosafety regulation in ways that could particularly benefit developing countries. These opportunities include:

- Revisiting the context for biosafety regulation of GE crops to ensure that both the risk assessment and any non-safety considerations that are used to inform decisions are not defined solely by environmental protection goals but also by

(continued on page 2 - see STATUS)

Crops - *continued from page 1*

other development priorities, such as improving agricultural productivity, food security, and rural development.

- Rationalizing environmental risk assessment information and data requirements to focus exclusively on issues that are relevant to assessing plausible adverse environmental impacts of GE crops. Improved and cost-effective approaches to biosafety regulation generally, and risk assessment particularly, can be pursued without compromising environmental protection and management goals.
- Incorporating the assessment of environmental benefits of GE crops in agricultural ecosystems in addition to the standard evaluation of potential adverse environmental impacts.
- Aggressively pursuing harmonization of risk assessment requirements and processes between countries—for example, by recognizing scientific opinions arising from risk assessments by other regulatory authorities, establishing regional approaches to risk assessment, or, more ambitiously, adopting decisions taken by other governments where appropriate.

- Improving biosafety capacity building so that it moves past the development of national biosafety frameworks and associated short-term technical training to pursue sustained commitments to operationalize, monitor, and improve the regulatory systems that are put into place. Capacity-building programs should promote the rationalization of biosafety regulation and opportunities to strengthen the scientific and knowledge base in ways that will provide benefits that extend beyond the often transient need for biosafety risk assessment and decision making.

The entire document can be downloaded as a PDF from **The World Bank website.**

ESTABLISHMENT OF MEDICAL BIOTECHNOLOGY (MBT) PROGRAM UNDER THE DIRECTORATE GENERAL HEALTH SERVICES (DGHS), MINISTRY OF HEALTH AND FAMILY PLANNING, BANGLADESH

Under the Health, Population and Nutrition Sector Program 2011-16, a new program called Medical Biotechnology (MBT) has been included in the Operational Plan of Health Information System (HIS) and e-Health. The importance of this program is revealed in the government's policy decision for rapid deployment of medical biotechnology, to confront the country's future health, nutrition and livelihood challenges. The government constituted a National Taskforce on Biotechnology with the Prime Minister as chair and adopted the National Biotechnology Policy and several sector-specific National Biotechnology Guidelines including National Guidelines on Medical Biotechnology. The latter has been published as a government gazette and spells out MOHFW's deliverables for the next 25 years. By this time, the MOHFW will have held a number of workshops for medical doctors and teachers to orient and sensitize them on the subject. Considering that more thrust is required for timely implementation of the government's policy decision in this regard, the Operational Plan of HIS and e-Health included two objectives under the MBT component:

1. Achievement of the short and medium term deliverables mentioned in the National Guidelines on Medical Biotechnology; and
2. Creation of conditions for achieving the long term deliverables of the National Guidelines on Medical Biotechnology.

The activities will be carried out as per instructions provided in the National Guidelines on Medical Biotechnology. Following will be the deliverables in the short and medium term (1 to 10 years):

1. Center for Medical Biotechnology will be established;
2. Situation analysis of medical biotechnology will be carried out and medical biotechnology plan will be developed;
3. Sensitization/orientation training/workshops, updating medical curriculum with focus on medical biotechnology will be held, medical biotechnology resources in medical libraries will be developed, postgraduate and technologist courses and career group for medical biotechnology will be identified gradually; orientation of the core group members and concerned officials on medical biotechnology will be given;
4. Institutional capacity will be built through development of lab facilities, clinical services and epidemiological surveillance for medical biotechnology;
5. R&D environment will be created through supporting related research projects;
6. Steps will be taken to open Department of Medical Biotechnology in the National Institute of Biotechnology and establishing a Centre of Excellence for medical biotechnology;
7. Appropriate communication programs with potential entrepreneurs of medical biotechnology will be carried out;
8. Appropriate public awareness programs will be conducted;
9. Measures will be taken to develop and enforce standards, codes of practice and regulatory framework for medical biotechnology.

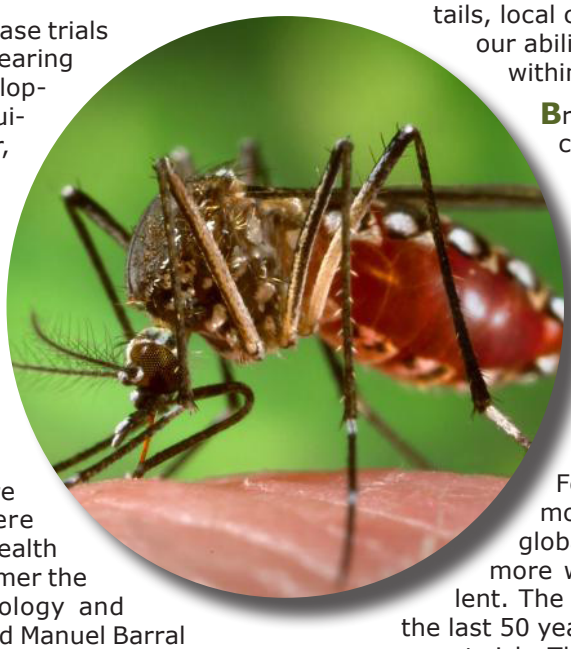
Conditions will be created for achieving the following long term vision (25 years or more) of National Guidelines on MBT:

1. To attain medical biotechnology initiatives and infrastructures at globally competitive level;

2. To make medical biotechnology industries, laboratories and services capable to compete globally and keep pace with global development trends;
3. To produce high quality medical biotechnology products and services for local market as well as for export to the global market; and
4. To make availability of a world-class higher education and research base to serve the rapidly growing medical biotechnology needs both in home and in abroad.
5. Effective leadership, monitoring and supervision will be ensured.

MOSCAMED PREPARES FOR NEXT PHASE IN THE DEVELOPMENT OF OXITEC'S TRANSGENIC MOSQUITOES IN BRAZIL

9 July 2012



Following successful open release trials in Brazil, Moscamed are now gearing up for the next phase of development in combatting the mosquitoes which spread dengue fever, with the launch of their new mosquito production facility. On Saturday 7 July 2012 Moscamed formally opened their new facility, which will enable production of Oxitec's mosquitoes to be scaled up to an initial level sufficient for a town of approximately 50,000 people. The opening was attended by the Minister of Health of Brazil, Alexandre Padilha. Other attendees were Jorge Solla the Secretary of Health of the State of Bahia, Paulo Camer the Secretary of Science, Technology and Innovation of State of Bahia and Manuel Barral representing Ministry of Science and Technology.

The Minister of Heath of Brazil stated he was supporting the project and saw this technology as an important new tool for the country in the fight against dengue.

The evaluation of Oxitec mosquitoes in Brazil is called 'Project Aedes Transgenico' (PAT) and is being carried out by Moscamed and the University of Sao Paulo in collaboration with Oxitec and is supported by the State of Bahia government. The project commenced in 2010 and the first outdoor releases took place in February 2011. Phase 1 of the project involved successful transfer of transgenic mosquito production from UK to Brazil with the establishment and local optimization of mass rearing methodologies. In Phase 2 the team demonstrated success in controlling the mosquitoes that spread dengue fever in Itaberaba, a densely populated suburb in Bahia state.

Dr Margareth Capurro of the University of Sao Paulo, who is leading the project, said;

"After a long period of contained evaluation work, we started a series of releases in Brazil in February 2011 in the outdoor environment. Then, from December 2011 we commenced a suppression trial and showed that, in the area where we were releasing the sterile male mosquitoes, we could control the mosquito that spreads dengue fever. This was done in a suburb of Juazerio, Bahia state where mosquitoes are at a very high level all year round. When we started the trial we were seeing *Aedes aegypti* in about half of the traps we set in and around people's homes. Now we see hardly any. Comparing the area of release to the adjacent area where no releases were made, we have reduced the population of *Aedes aegypti* by 85%. We are very excited by the result'

Dr Aldo Malavasi the President of Moscamed added;

'Dengue represents a major health challenge for Brazil. The Oxitec sterile insect approach has great potential and, as Moscamed are the experts in using sterile insects in Brazil, we have taken the lead in coordinating the evaluation of this approach. Transparency and community engagement have been at the forefront of every stage of this process and we have been delighted by the response from the local community. We have also had excellent support and advice from political, scientific and health leaders at both state and federal level. Now, with the roll-out of our new production facility, with the employment and expert training that entails, local communities stand to benefit even more from our ability to control this disease spreading mosquito within Brazil."'

Brazil has a mature regulatory system for genetically modified organisms (GMO's) and its by-products, with a long history of open releases of genetically modified plants in agriculture. All activities have been carried out under regulatory permits and in close consultation with national and local stakeholders.

ABOUT DENGUE FEVER

Dengue Fever is a virus spread by the bite of an infected mosquito. There is neither medication nor a vaccine to prevent Dengue Fever. Effective measures to control the dengue mosquito *Aedes aegypti* are urgently required as globally the disease is becoming geographically more wide-spread, more prevalent and more virulent. The incidence of dengue has increased 30 fold in the last 50 years and, according to WHO, now 2.5Bn people are at risk. The severe form of dengue, known as Dengue Haemorrhagic Fever, was first recognized as recently as the 1950s but today has become has become a leading cause of hospitalization and death among children in Asian and Latin American countries.

ABOUT OXITEC (WWW.OXITEC.COM)

Oxitec is developing and commercialising an effective and environment-friendly proprietary technology for the control of significant insect pests. Oxitec's technology has the potential to make a major contribution for both global health and agriculture by combating insects responsible for serious diseases such as dengue fever as well as agricultural damage. The proprietary technology builds on inventions from the University of Oxford and employs genetics and molecular biology to enhance the existing radiation based Sterile Insect Technique (SIT), and to extend the control method to a broader range of insect pests.

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ABOUT MOSCAMED (HTTP://WWW.MOSCAMED.ORG.BR)

Moscamed is a leading exponent of the Sterile Insect Technique (SIT), an environmentally friendly and proven technique to control insect pests. Moscamed provide both monitoring services and carry out SIT programmes for the control of fruit flies in Brazil.

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CALENDAR OF EVENTS

Event	Organized by	Date and Venue	Website
INDIA			
National Workshop on Biotechnology: Its Applications and Bio-safety Concerns	Shivrath Center of Excellence in Clinical Research	July 28, 2012 Ahmedabad	A joint venture with Gujarat State Biotechnology Mission, Department of Science and Technology, Government of Gujarat and ffiliated to Gujarat University.
TERI-ITEC Courses 2012-13 Course II - Applications of Biotechnology and its Regulation	The Energy and Resources Institute and Indian Technical and Economic Cooperation (ITEC), Ministry of External Affairs	August 13 - 31, 2012 Gurgaon	http://www.teriin.org/index.php?option=com_events&task=details&sid=505
Agritech Asia 2012 National Convention – The Next Frontier of Agri-Business and Technology	*Vibrant Gujarat*	September 3 - 5, 2012 Gandhinagar	http://www2.kenes.com/agritech-asia/Pages/Home.aspx
6th International Congress on Legume Genetics and Genomics	International Crops Research Institute for the Semi-Arid Tropics	October 2 - 7, 2012 Hyderabad	http://www.icrisat.org/gt-bt/VI-ICLGG/homepage.htm
Silver Jubilee International Symposium on "Global Cotton Production Technologies vis-à-vis Climate Change"	Cotton Research and Development Association and CCS Haryana Agricultural University, Hisar	October 10 - 12, 2012 Hisar	http://crdaindia.com/?view=news&page_id=16
International Symposium on New Paradigms in Sugarcane Research	Society for Sugarcane Research and Development and Sugarcane Breeding Institute	October 15 - 18, 2012 Coimbatore	http://www.sugarcane.res.in/images/sbi/Centenary/1st_circular_int_symposium.pdf
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 and Birsa Agricultural University	November 3 - 5, 2012 Ranchi	http://www.baujharkhand.org/Downloads/online%20circular%20for%203rd%20national%20symposium.pdf
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			
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 5 – 10, 2012, Michigan, USA	http://worldtap.msu.edu/short-courses/biosafety/
ABIC 2012: The XII International Conference for Agriculture Biotechnology	ABIC Foundation	September 2 - 5, 2012 Rotorua, New Zealand	http://www.abic2012.com/
Commercialization of Biotech Crops: Learning from Asia	Asia BioBusiness Pte. Ltd., the Southeast Asian Regional Center for Graduate Study and Research in Agriculture and the International Service for the Acquisition of Agri-Biotech Applications	September 3 - 7, 2012 Los Baños, The Philippines	http://www.asiabiobusiness.com/?page_id=335
12th International Symposium on Biosafety of Genetically Modified Organisms (ISBGMO12)	International Society for Biosafety Research	September 16 – 20, 2012 St Louis, Missouri, USA	http://www.isbgmo.com/
Sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (MOP-6)	Convention on Biological Diversity (CBD) and MoEF	October 1 - 5, 2012 Hyderabad	http://www.cbd.int/doc/?meeting=MOP-06
Eleventh meeting of the Conference of the Parties to the Convention on Biological Diversity (COP-11)	CBD and MoEF	October 8 - 19, 2012 Hyderabad	http://www.cbd.int/doc/?meeting=cop-11

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Center for Environmental Risk Assessment

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