

# South Asia Biosafety Program

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for June 2017

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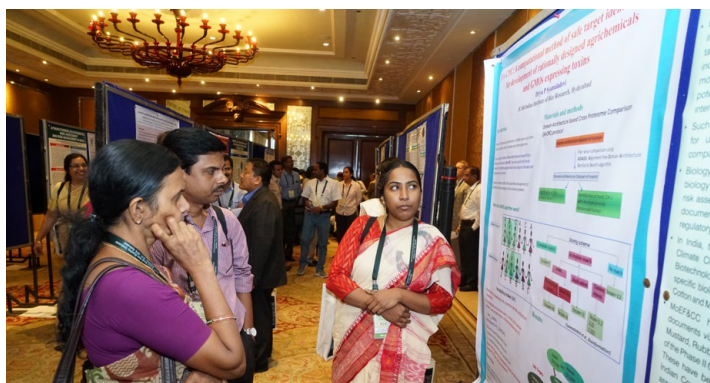
Presentations are now available from the

## 4<sup>th</sup> Annual South Asia Biosafety Conference

<http://sabc.biotech.co.in/>

INDIA

### South Asia Biosafety Conference Poster Winners Receive Sponsorship to ISBR



The South Asia Biosafety Program, the ILSI Research Foundation and the Biotech Consortium India Limited (BCIL) organized the 4<sup>th</sup> Annual South Asia Biosafety Conference (SABC) in Hyderabad, India from September 19-21, 2016. This conference provided an opportunity to hear from leading scientists representing regulatory agencies, public sector research institutions, and the private sector in South Asia and internationally. The conference was held at the Taj Krishna in Hyderabad.

The conference featured four plenary sessions, addressing the status and current progress of biosafety regulations for South Asian countries, new technologies (such as gene editing and gene drives), methods and

best practices for meeting regulatory challenges and engaging with stakeholders, and practical experience and guidance for putting together biosafety dossiers.

The SABC Poster Program provided an opportunity for individuals to share their research, findings and achievements with colleagues at the conference. Presenting a poster is a noteworthy way to share expertise or accomplishment. Poster presenters had dedicated time to present and discuss their work with the diverse group of conference attendees. Read on to learn more about the Poster Program winners, who received sponsorship to the International Society for Biosafety Research!

## Congratulations to Lourdes Taylo Winning 1<sup>st</sup> Place at the SABC Poster Program



**1ST PLACE WINNER:** Lourdes D. Taylo

**ORGANIZATION:** Crop Science Cluster-Institute of Plant Breeding, UP Los Banos College, Laguna, Philippines

**POSTER TITLE:** *Baseline Susceptibility to Bt Cry1Ac Protein of Eggplant Fruit and Shoot Borer (EFSB), Leucinodes orbonalis Guenée (Lepidoptera:Crambidae) in the Philippines*

**POSTER ABSTRACT:** The use of Bt technology is one of the innovative options for the management of the eggplant fruit and shoot borer (EFSB), the major insect pest of eggplant in Asia. Bt eggplant from event EE-1 produces the insecticidal crystal protein (Cry1Ac) from *Bacillus thuringiensis* (Bt) that has been shown to be highly effective in preventing damage by EFSB. To ensure the durability of this product, one of the requirements for resistance management is to determine the sensitivity of EFSB to Cry1Ac over time. Nine EFSB field populations were collected during growing the seasons of 2012 to 2013. Neonates were exposed to artificial diet treated with increasing Cry1Ac concentrations and dose-response curves for lethality and growth inhibition, evaluated after 7d, were determined. Median lethal concentrations 52 (LC50) for the different populations ranged from 0.12 to 0.18 ppm (0.07-0.51, 95% fiducial limit) for nine populations of EFSB. Although interpopulation variation in susceptibility to Cry1Ac was observed, the magnitude of the differences was small (< 2-fold). Interpopulation

susceptibility to Cry1Ac indicated by growth inhibition was measured in terms of molting inhibitory concentration (MIC50). Results ranged from 0.04 to 0.21 ppm, also a small (5-fold) variation. These bioassay results document that the EFSB populations tested were very susceptible to Cry1Ac prior to commercial deployment of Bt eggplant in the Philippines.

**1ST PLACE PRIZE:** Congratulations to Lourdes who will be sponsored to participate in the 14<sup>th</sup> International Symposium on the Biosafety of Genetically Modified Organisms (ISBGMO), to be held in Guadalajara, Mexico in 2017. ISBGMO is a biennial, international meeting organized by the International Society for Biosafety Research (ISBR), which offers a unique opportunity to share information and experiences as well as engage in open and meaningful dialogue on biosafety research, risk analysis, policy and regulatory matters. This 1<sup>st</sup> place prize also includes:

- Economy class airfare to Guadalajara
- Standard hotel accommodations during ISBGMO
- Per diem allowances in an amount to be determined by SABC
- Payment of the winner's ISBGMO registration fee
- A two-year membership to ISBR

### LOURDES' EXPERIENCE AT THE SOUTH ASIA BIOSAFETY CONFERENCE:

"The 4<sup>th</sup> South Asia Biosafety Conference (SABC) sponsored by the Biosafety Consortium India Ltd. (BCIL) in cooperation with the LSI Research Foundation was successfully held on 19-21 September 2016 at the Taj Krishna, Hyderabad, India. The scientific conference was attended by scientists, technology developers, students, risk assessors and regulators from India, Bangladesh, Bhutan, Sri Lanka, Philippines, South Africa, Kenya, and the United States. Plenary talks focused on the safe and effective use of genetically engineered (GE) products as well as biosafety regulatory frameworks and experiences in South and Southeast Asia and Africa. Concurrent scientific sessions discussed the innovations in biotech research and development in potato, chickpea, rice, silk moths and emerging new plant breeding technologies (NPBT) namely, gene drives and CRISPR-Cas 9.

Common among the speakers were the challenges (social, cultural and political) faced in their country, with opposition to the technologies. Although the biosafety regulatory policies are robust and systematic, with expert scientists possessing deep knowledge of the science, the process of approval for GE crops are much delayed. Nevertheless, the scientists as well as research institutions are still painstakingly doing their work in the laboratory or in confined field trials on agricultural biotechnology with the hope that their product will reach the farmers and consumers in the end. Although there were already developed products utilizing new plant breeding techniques, regulatory policies on how these GE organisms will be evaluated is a pressing issue that needs to be addressed by the regulators.

**"These sessions provided an avenue for collaboration among countries on how the area of regulation can be strengthened."**

It was noteworthy that the government of Bangladesh had the strong political will to approve the commercial cultivation of Bt brinjal much earlier than India or the Philippines resulting in increasing benefits among its own resource-poor farmers and consumers. We in the Philippines, as prime movers of Bt eggplant, welcomed the reversal of the Supreme Court decision, but still need to face the hurdles of more rigid regulatory agencies as part of the newly-formed Joint Department Circular evaluating any GE products.

Regulatory dossiers for environmental risk analysis to be submitted for evaluation by risk assessors should be concise, complete and reader-friendly as to not delay the process of evaluation and approval. A problem formulation approach should be used to guide the evaluator about the rationale of product development. This presentation is very useful for us who will be submitting an application for propagation.

Improving the science communication of the technology highlighting its potential impacts and economic, health and environment safety will hope to break the barrier of the perceived fears, confusion and misconceptions by the general public and decision making policies of government officials.

I commend BCIL, UNEP, GEF, ICAR Indian Institute of Vegetable Research and the Ministry of Environment, Forest and Climate Change for preparing crop specific biology documents which will be very helpful in our preparation of regulatory dossier for Bt eggplant."



## Congratulations to Mark Gabriel S. Sagarbarria Winning 2<sup>nd</sup> Place at the SABC Poster Program



**2ND PLACE WINNER:** Mark Gabriel S. Sagarbarria

**ORGANIZATION:** Crop Science Cluster-Institute of Plant Breeding, UP Los Banos College, Laguna, Philippines

**POSTER TITLE:** *Mitochondrial cytochrome oxidase I (COI) DNA Sequence and Morphometric Traits of Eggplant Fruit and Shoot Borer, Leucinodes orbonalis Guenée (Lepidoptera: Crambidae) in Southern Luzon, Philippines*

**POSTER ABSTRACT:** The eggplant fruit and shoot borer (EFSB), *Leucinodes orbonalis*, is the most important insect pests of eggplant in the Philippines and many parts of SE Asia. A sample of 360 EFSB male adults and F1 4th instars were collected in six municipalities in two provinces in Southern Luzon, Philippines: Laguna and Quezon. Sequence analysis of mitochondrial DNA (mt) cytochrome oxidase I (COI) gene and the morphology of male genitalia of *L. orbonalis* were measured and analyzed to characterize the local EFSB population structure. This knowledge is important in designing an Insect Resistance Management plan for Bt eggplant. Both analyses confirmed that all EFSB samples from Laguna and Quezon belong to the *L. orbonalis* species. No statistically significant difference was observed among populations within a province in all genital traits measured. However, genital traits of Laguna EFSB were statistically larger than Quezon. The mtDNA sequence analysis revealed five haplotypes among Southern Luzon populations which were homologous (99~100%) with the published COI sequence of *L. orbonalis* from NCBI (KP260782.1). These haplotypes showed very low nucleotide diversity ( $\pi = 0.00021$ ) and overall mean distance ( $0.003 \pm 0.001$ ). Topologies from neighbor-joining trees indicate all five haplotypes cluster in a single clade with populations from India, where *L. orbonalis* may have originated and been introduced to the Philippines by trade.

**2ND PLACE PRIZE:** The second place winner of this competition received a USD \$100 cash prize and a two year membership for ISBR, which aims to promote scientifically sound research that supports biosafety assessment by improving communication among scientists who study plants, animals, and microbes with new characteristics due to altered DNA and produced using modern biotechnology. Congratulations to Mark!

**MARK'S EXPERIENCE AT THE SOUTH ASIA BIOSAFETY CONFERENCE:** "The 4<sup>th</sup> South Asia Biosafety Conference was the first international event I have attended. I was too caught up in preparing for presenting our poster there that the whole purpose of the conference had only really weighed down on me during the event, as the first few speakers were on the stage. Everyone was there to talk about issues regarding the regulation and risk assessment of genetically engineered organisms, and biosafety issues in general. It was amazing to me that there were over 200 participants, including various scientists, researchers, regulators and policy makers that gathered to tackle the various issues of biosafety that have risen due to the advent of modern biotechnology.

Though my colleagues and I were not from South Asia, we were able to learn so much from the conference. It was great to hear from other countries about their policies and regulatory frameworks regarding biosafety and GMOs, to hear what policies work for them, and to learn from them and to compare their regulations with that of our own country. It was great to hear their stories and challenges they have faced from products of modern biotechnology that no one has ever had experience with, such as GM trees like plums, and the use of gene drives in snails and mosquitoes. The topics discussed would surely provide insights when faced with future regulatory challenges and biosafety assessments of GMOs.

One of the most important topics discussed, and a lesson learned for me, was to assess all of our tools used in the genetic improvement of crops. All of the tools from traditional plant breeding techniques to modern biotechnology are important, but must be wisely utilized. With the availability of knowledge and resources on gene editing and other systems like CRISPR-Cas9, many scientists are looking to utilize these technologies to improve our crops. However, we must first assess if our objective or desired product can be attained through more conventional methods that do not require genetic engineering, to avoid cumbersome regulatory work and regulatory backlog. It is more important to consider the 'product' rather than the 'process'.

All in all, the conference was amazing and eye-opening. I was able to learn a lot about regulatory frameworks and dossiers, biosafety assessments, new genetic engineering technologies, and how these technologies are currently being utilized to address climate change, invasive species, food security, human nutrition, and so much more.

**"Above all, I have learned how important it is to communicate among scientists and the public about our research, to build support for our science, so that the world may benefit from it."**

The conference was definitely successful as so many relevant topics on biosafety were discussed. I hope to see that this will continue annually, to support biosafety as our science progresses."

**Interested in learning more about the International Society for Biosafety Research?**

View <http://isbr.info/>

## Environmental Risk Assessment of Genetically Modified Organisms: Past, Present and Future

Join over 500 of biosafety's best and brightest at the 14<sup>th</sup> International Symposium on the Biosafety of Genetically Modified Organisms (ISBGMO14) in Mexico. ISBGMO14 offers a unique opportunity to share information and experiences as well as engage in open and meaningful dialogue on biosafety research, risk analysis, policy and regulatory matters. Advance the standing of biosafety research around the world and shape the ways in which GM technology is applied and regulated - at ISBGMO14!

**Symposium Objective:** Over the course of four days, attendees will learn from the past, discuss the present and look ahead to future opportunities and challenges associated with GM technology.

**Who Should Attend:** ISBGMO14 brings together academics, technology developers, regulatory authorities, non-government organizations and other credible stakeholders involved in all aspects of biosafety and offers a unique opportunity to share information and experiences and engage in open and meaningful dialogue on biosafety research, risk analysis, policy and regulatory matters.



**Save the date for June 4-8, 2017 in Guadalajara, Mexico**

ISBGMO14 is organized by the International Society for Biosafety Research (ISBR), which aims to promote scientifically sound biosafety research and provides a fair and welcoming exchange platform for scientists, regulators and technology developers - improving communication and promoting a multidisciplinary approach to biosafety research.

**Visit <http://isbr.info/ISBGMO14> for more information**

## INDIA

### Strengthening Environmental Risk Assessment of GE Plants: Adoption of New Guidelines

A set of three guidance documents viz., *Guidelines for Environmental Risk Assessment (ERA) of Genetically Engineered (GE) Plants, 2016*, *A Stakeholders Guide* and *Risk Analysis Framework, 2016* have been prepared by the Ministry of Environment, Forest and Climate Change (MoEF&CC) in association with the Department of Biotechnology, Ministry of Science and Technology. These documents were prepared as part of a series of activities under the risk assessment and risk management component of the UNEP/GEF supported Phase II Capacity Building Project on Biosafety, being implemented by MoEF&CC.

A multi-disciplinary expert committee was involved in the preparation of these documents under the chairmanship of Dr. C.R. Babu, Emeritus Professor, Centre for Environmental Management of Degraded Ecosystems, School of Environmental Studies, University of Delhi and Member, Genetic Engineering Appraisal Committee (GEAC) and co-chaired by Dr. K. Veluthambi, Professor (Retired), School of Biotechnology, Madurai Kamaraj University, Madurai and Co-Chair, GEAC. The members of the expert committee reviewed the international best practices being followed and critically examined information collected from peer reviewed publications and documented experiences. In addition, baseline information was compiled in resource documents which included: (1) multi-country comparison of information and data requirements for ERA of GE plants, (2) review of conformity of India's regulatory system for GE plants with the Cartagena Protocol on Biosafety and (3) post release monitoring of GE plants.

The Genetic Engineering Appraisal Committee, the apex regulatory committee for commercialization of GE plants in India, adopted these guidance documents at its 130<sup>th</sup> meeting held on August 11, 2016. These documents have been prepared as a step towards further strengthening the environmental safety assessment process of GE plants in India through a structured and systematic approach.

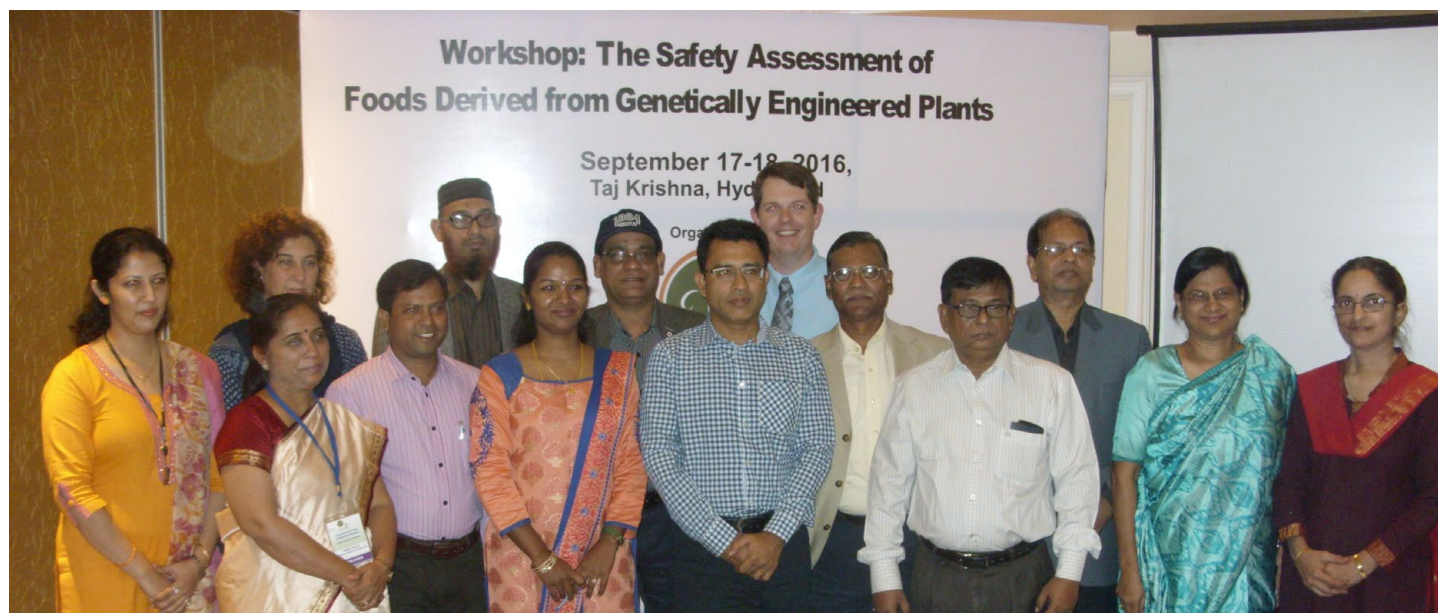


**Dr. Amita Prasad, Chairperson, GEAC and Additional Secretary, MoEF&CC, released the newly adopted guidance documents at the 4<sup>th</sup> Annual South Asia Biosafety Conference on September 19-21, 2016 in Hyderabad, India.**



## Workshop on the Safety Assessment of Foods Derived from Genetically Engineered Crops

Prof. Dr. M. Imdadul Hoque, University of Dhaka and Bangladesh Country Coordinator, South Asia Biosafety Program (SABP)



The Bangladesh Agricultural Research Council (BARC) has taken the initiatives to formulate the **Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered (GE) Plants**. At the request of BARC, the South Asia Biosafety Program (SABP) developed the zero draft of these guidelines following the CODEX principles. SABP also provided technical assistance to finalize the guidelines. During its 3<sup>rd</sup> meeting, the National Committee of Biosafety (NCB) endorsed the guidelines and requested the Bangladesh Standards and Testing Institution (BSTI) to adopt the guidelines as their standards. The BSTI, following their rules and regulations, adopted the guidelines (BDS 1873:2013).

Following the recommendation of the Biosafety Core Committee (BCC), the National Committee of Biosafety endorsed an ad hoc 12-member technical committee headed by the Director General of BSTI as the convener of this committee and included relevant members, namely, Prof. Dr. Zeba Islam Seraj, University of Dhaka; Mr. Mohammed Solaiman Haider, Department of Environment (DOE); Prof. Dr. Emdadul Haque Chowdhury, Bangladesh Agricultural University and BSTI; and Prof. Dr. M. Imdadul Hoque. The other members of this committee represented government departments, including: Member Director (Crops), Bangladesh Agricultural Research Council (BARC); Head, Biotechnology Division of Bangladesh Agricultural Research Institute (BARI); Assistant Director General, Directorate of Health; Chief Chemist, Directorate of Foods; Head, Food Microbiology Laboratory, Bangladesh Council of Scientific and Industrial Research (BCSIR); and the Director General, National Institute of Biotechnology (NIB).

SABP organized a two-day workshop on September 17-18, 2016 at the Taj Krishna Hotel, Hyderabad, India with the aim of providing training for the Bangladesh Food Safety ad hoc Committee. The workshop was conducted by Dr. Andrew Roberts, ILSI Research Foundation; Dr. Vibha Ahuja, Biotech Consortium India Ltd.; Dr. Monica Garcia-Alonso, Estel Consult; and Dr. Vasanthi Siruguri, National Institute of Nutrition. The first day was focused on introductory material, including concepts and principles of safety assessment, host and donor organisms as well as nutritional

and compositional analysis. The second day was focused on molecular characterization, toxicity and allergenicity.

In his introductory remarks, Dr. Roberts explained the objectives of the workshop specifically designed for the members of the Bangladesh GE food safety assessment ad hoc committee. Participants were able to review internationally accepted approaches to the risk assessment of genetically engineered crops and foods and apply them with practical examples and discussion exercises.

In her presentation, Dr. Ahuja shared the history of crop improvement, advantages of GE crops over traditional breeding, the need for food safety assessment, internationally recognized safety assessment processes, as well as regulators requirements.

Dr. Siruguri gave a detailed account on the assessment of possible allergenicity of foods derived from GE crops. She pointed out that the GE foods that are to be commercialized should be assessed for allergenicity, except where there is a history of safe consumption e.g., viral coat proteins. Considering the source, amino acid sequence homology and pepsin digestibility are the basic tools for safety assessment. She shared that serum screening may not be warranted in most cases and also mentioned that in the future, animal models could be a valuable tool for predicting allergenicity, but currently they are inadequate.

In addition to the presentations, the participants were divided into different groups for group exercises on toxicity, modification methods, molecular characterization, inheritance and stability studies and internet based exercise on allergenicity studies.



EVENT	ORGANIZED BY	DATE	WEBSITE
<b>INDIA</b>			
1 <sup>st</sup> International Agrobiodiversity Congress (IAC 2016)	Indian Society of Plant Genetic Resources (ISPGR) and Bioersity International	November 6-9, 2016 New Delhi	<a href="http://www.iac2016.in/">www.iac2016.in/</a>
International Conference on "Pulses for Nutritional Security and Agricultural Sustainability"	Indian Society of Pulse Research and Development in association with Indian Institute of Pulses Research, Kanpur	November 12-14, 2016 New Delhi	<a href="http://www.iipr.res.in/pdf/events_201115.pdf">www.iipr.res.in/pdf/events_201115.pdf</a>
ICAR Winter School – Development and Utilization of Genetic and Genomic Resources through Biotechnology for Biotic and Abiotic Stress Management and Quality Improvement in Field Crops	University of Agricultural Sciences, Dharwad	December 1-21, 2016 Dharwad	<a href="http://www.uasd.edu">www.uasd.edu</a>
International Conferences on Nutraceuticals and Functional Foods – The Challenges and Opportunities along with The XIII Convention of the Indian Society of Agricultural Biochemists	Indian Society of Agricultural Biochemists, C.S. Azad University of Agriculture and Technology, Kanpur and Anand Agricultural University, Anand, Gujarat	December 6-8, 2016 Anand, Gujarat	<a href="http://www.aau.in/sites/default/files/Broucher_1_seminar_biochem_baca_dec_15.pdf">www.aau.in/sites/default/files/Broucher_1_seminar_biochem_baca_dec_15.pdf</a>
International Symposium on Eco-Efficiency in Agriculture and Allied Research	Crop and Weed Science Society (CWSS) and Bidhan Chandra Krishi Viswavidyalaya (BCKV)	January 20-23, 2017 Nadia, West Bengal	
<b>INTERNATIONAL</b>			
Symposium on Export Control of Emerging Biotechnologies: International Biosecurity and Prevention Forum (IBPF)	International Biosecurity and Prevention Forum (IBPF) and the James Martin Center for Nonproliferation Studies (CNS)	October 18-20, 2016 California, USA	<a href="https://ibpfsymposium.org/">https://ibpfsymposium.org/</a>
8 <sup>th</sup> International Plant Tissue Culture & Biotechnology Conference	Bangladesh Association for Plant Tissue Culture & Biotechnology (BAPTC&B) and University of Dhaka	December 3-5, 2016 Dhaka, Bangladesh	<a href="http://www.bap tcb.org/">www.bap tcb.org/</a>
13 <sup>th</sup> Meeting of the Conference of the Parties to the Convention on Biological Diversity (COP13) & the 8 <sup>th</sup> Meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COPMOP8)	Secretariat of the Convention on Biological Diversity (SCBD)	December 4-17, 2016 Cancun, Mexico	<a href="http://www.cbd.int/meetings/">www.cbd.int/meetings/</a>



**SOUTH ASIA**  
BIOSAFETY PROGRAM

**The South Asia Biosafety Program (SABP)** is an international developmental program implemented in India, Bangladesh and Pakistan with support from the United States Agency for International Development. SABP aims to work with national governmental agencies and other public sector partners 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.



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