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South Asia Biosafety Program

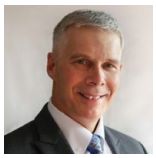
NEWSLETTER for private circulation only – not for sale

Hear from leading scientists representing regulatory agencies, public sector research institutions, and the private sector at the

4th Annual South Asia Biosafety Conference

September 19-21, 2016 in Hyderabad, India


Dr. Barwale Zehr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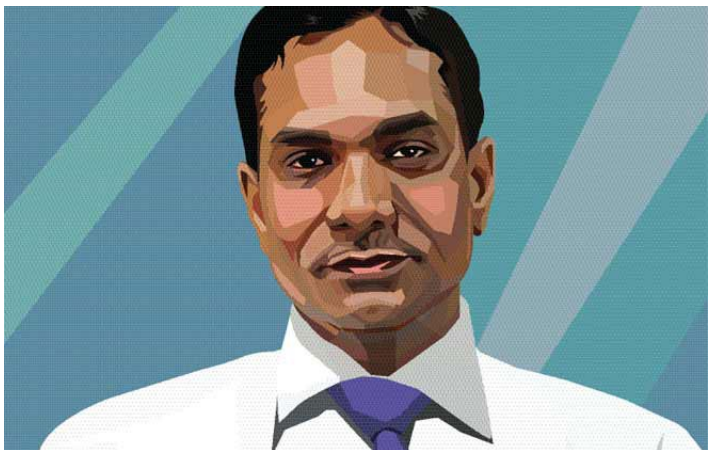
Follow along to #SABC2016 on Twitter for live tweets during the conference.

INDIA

Record caFe: We're Open to Private Partnership for GM Crop Research: ICAR DG

Ms. Vivian Fernandes, Author, Financial Express, Reproduced from the Financial Express Article Originally Published on August 18, 2016



Trilochan Mohapatra took over as secretary, department of agricultural research and education, and director general, Indian Council of Agricultural Research (ICAR) in February. A molecular geneticist, he is known for developing the first high-yielding basmati rice variety resistant to bacterial leaf blight and for genome sequencing of rice and tomato. In an interview with Vivian Fernandes, he adds that we need PPPs in biotech and for seed multiplication. Excerpts:

With weather getting more erratic and population set to increase, how is ICAR preparing for food and nutrition security? Agriculture contributes to GHG emissions, particularly low-land rice. It emits methane, which is more earth warming than carbon dioxide. Direct-seeded rice (without transplantation) and System of Rice Intensification (SRI) can help reduce these emissions. But these cannot be applied in every situation

Continued on page 2

Continued from page 1

as rice is cultivated in a variety of ecologies, from upland to deep water. Even with rice-wheat system in the Indo-Gangetic Plain (IGP), where there is no water stagnation, we have to reduce emissions.

Will it happen through conservation agriculture? With conservation agriculture you retain soil moisture, sequester carbon in the soil instead of releasing it in the atmosphere (as smoke and soot), and reduce the use of chemical fertilisers. We can have C4 crops like maize, sorghum and sugarcane, which are more efficient in photosynthesis than rice and wheat. But there are research efforts to bring C4 photosynthesis to rice as well. It is one of the areas ICAR is focusing on. There are several institutions engaged in changing the anatomy of the rice plant to increase the concentration of CO2 in the tissue so more photosynthesis can occur.

Why can't we use the tools of (GM)? Without recombinant DNA technology, it can't happen. Even the regulatory environment is not favourable…At this point, we have limitations but we are overcoming them. Science should not stop. When it comes to commercialisation, one can see what best can be done. But this is at the concept validation stage. Experiments should continue.

ICAR was at the forefront of the Green Revolution. Why is it missing in action in the gene revolution? Not exactly, activities have been going on. There is a need to improve efficiency and speed. There are many laboratories which are involved in validation of gene functions. But the public system cannot match private companies in funding, infrastructure and the critical mass of people focused on a project.

What are ICAR's focus areas in agri-biotech? We are testing genes for C4 photosynthesis in rice. We are trying to improve nitrogen use efficiency (a) through nitrogen-fixing bacteria, (b) plant and rhizobia interaction, and (c) by manipulating host genetic mechanisms. With regard to phosphorus use efficiency, the genes and markers are available and we are doing the breeding. We have had very good success.

ICAR has more than 100 institutes. Why can't it focus on a few critical crops like pulses? In pulses, the problem of pod borer is serious. We have a focused programme on GM pulses where we can use Bt genes, which has been proven safe in cotton (against bollworm). We are making tur resistant to pod borers. That is happening at Assam Agricultural University, Jorhat… It is doing work on chickpea (chana). The Indian Institute of Pulses Research, Kanpur, has identified 6-7 events (mutated transgenic cells). Event selection will happen next. In 3-4 years, we should be able to deliver it to the farmers if the regulatory system approves.

Political leaders are wary of GM technology because they see it as the preserve of private companies. If ICAR gets into the field, will there be less resistance? DU (South Campus) has created transgenic mustard with NDDB funding. It has gone through all the tests. It is a product of the public system. The bio-safety dossier is ready. Once it is placed in the public domain and comments come, the Genetic Engineering Appraisal Committee (GEAC) will, probably, take a final call. That should happen ideally before the mustard sowing season in October.

Is hybrid vigour in it proven? They have recorded more than 20% heterosis (yield enhancement). But I am not really worried by heterosis in this particular hybrid (Dhara Mustard Hybrid 11) as we can back-cross and generate better ones if this seed is deregulated and allowed for cultivation. This has happened in (Bt) cotton. More than 1,500 hybrids have been released in 10 years. It is a record for India. Public and private can join and create newer combinations.

You told reporters recently there should be PPPs in research. Can you elaborate? We need PPPs in biotech and for seed multiplication. Gone are the days when the public system could meet all the seed needs of the country. Today, the National Seed Corporation and state seed corporations cannot supply enough because seed replacement rates are increasing. Some farmers want to change them every year. The second area is having partnerships for GM research … partnering with multinationals, if they can put in money and we can do research together to solve a particular problem.

It happened in Bt brinjal… There the event was provided (by Mahyco India) and it was back-crossed. It was not at the stage of gene discovery.

Political leaders are reluctant to allow private companies to charge for plant traits. The agriculture ministry virtually issued a compulsory licence on Bt cotton using the Essential Commodities Act. It capped the trait fees. In fact, a former IAS official, Pravesh Sharma, said the government should acquire critical technologies and provide them free to farmers… That is one way to deal with it. But we can partner from the very beginning and have an understanding on how to share credit, and how to make it (a desirable trait) a thing of public good.

Is there such a mindset in ICAR? This is what our mindset is. Certainly, there must be partners who are ready for it. We need to develop more transgenic events than the public system is handling at this time. Also, bio-safety study is not easy. The public system can involve the private sector.

Why can't ICAR do field trials on behalf of private trait developers? If I have a sponsored project, I will be very happy. For (GM) mustard we did field trials in Punjab, Delhi and Bharatpur. There are a few issues. For event selection and confined field trials, state government NOC is required. What we are planning is to create sites, where selections can happen before it goes to GEAC. When the event is approved, we have to go back to GEAC. We have to see ways and means to rationalise that process.

Have you spoken to the Department of Biotechnology and the ministry of environment? We are discussing. Two rounds of meetings are over. There is quite a bit of evolution. The agriculture minister says whatever has been approved by the environment ministry for release, we will not have difficulty in promoting that.

Agri-biotech is an important area of science. Because of the uncertainty, are you finding it difficult to attract talent? This is one point which is being discussed among scientists and also the political leaders. This is a wonderful science, it has tremendous potential.

What about golden rice fortified with beta carotene for vitamin-A? I don't know when it will go to consumer. ICAR has it. It is sitting there. The day we get approvals, we will do the needful.

Politicians are wary of agri-biotech. Shouldn't ICAR educate them? This country needs an awareness programme for the public, the political system and even educated people like scientists … even they do not understand. We have discussed this with the department of biotechnology and the National Academy of Agricultural Sciences.

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CDSCO and DBT have released a revised version of the Guidelines for Similar Biologics in India, 2016

The "Guidelines on Similar Biologics" prepared by the Central Drugs Standard Control Organization (CDSCO) and the Department of Biotechnology (DBT) address:

- The regulatory pathway regarding the manufacturing process and the safety, efficacy and quality aspects for Similar Biologics, defined as a product which is similar in terms of quality, safety and efficacy to an approved Reference Biological product based on comparability.
- The pre-market regulatory requirements including the comparability exercise for quality, preclinical and clinical studies and post market regulatory requirements for Similar Biologics.

To view the guidelines, please visit: http://bit.ly/2cJhmBh

Spotlight on the Institutional Biosafety Officers: Mr. Kumaraswamy and Dr. Mohammad Akram

"The IBO program has been highly useful in making ICAR-IIOR ready to comply with regulatory requirements in developing transgenic crops."

INSTITUTIONAL BIOSAFETY OFFICER: Mr. Kumaraswamy, H. Hosur.

JOB TITLE: Scientist (Biotechnology)

ORGANIZATION: ICAR- Indian Institute of Oilseeds Research, Hyderabad

BIOGRAPHY: Mr. Kumaraswamy, H. Hosur received his M.Sc. in Biotechnology from the University of Agricultural Sciences, Bangalore, India in 2001. He served as an examiner of Patents and Designs in the Indian Patent Office at Chennai from 2002-2005. From 2005-2008, while serving as a Scientist (Biotechnology) in the Intellectual Property (IP) Management Division of the Council of Scientific and Industrial Research (CSIR) at Head Quarters in New Delhi, he handled drafting, litigation and prosecution of more than 500 patent cases of CSIR research laboratories in the area of biotechnology and molecular biology. In 2008, he joined as a Scientist (Biotechnology) at ICAR-Indian Institute of Oilseeds and presently is working in the area of genomics assisted genetic improvement of Sesame (*Sesamum indicum*).

Mr. Kumaraswamy has more than thirteen years of experience in the field of biotechnology and molecular biology. He has six years of experience in IP protection and management, which enabled him to develop critical analysis and in-depth understanding of government regulatory requirements. He has more than seven years of research and development experience while working on a wide array of crops including rice, wheat, safflower and sesamum. Mr. Kumaraswamy has published nearly 10 research papers in peer-reviewed journals. He has examined patentability of nearly 400 patent applications related to foods, drugs, pharmaceuticals and agrochemicals. He has also obtained a law degree from the Faculty of Faw, University of Delhi. He is acquiring state-of-the-art skills and knowledge during his Ph.D. studies at the National Research Centre on Plant Biotechnology, New Delhi, India. Presently, he is preparing his thesis.

His current areas of his interest include development and utilization of Simple Sequence Repeat (SSR) markers in crop improvement; genomics and phenomics assisted crop improvement in sesame; molecular diversity studies, population structure, association mapping and biostatistics; and DNA finger-prints and DNA barcodes for identifying public-domain varieties of sesame.

THE VALUE OF THE IBO PROGRAM: "This program has been very helpful in understanding and analysis of various issues related to the regulatory approval of transgenic crops being developed at my institute. At present, ICAR-IIOR is in the process of developing transgenic castor for resistance to semi-looper, a lepidopteron insect, and transgenic sunflower for resistance to sunflower necrosis disease (SND). The standard operating protocols thoroughly discussed and developed during the IBO program are being used at various stages of developing transgenic plants, namely, labelling, location layout, transportation and storage in inoculation chambers, culture chambers, and glass houses, as well as safe handling and disposal of transgenic materials. Knowledge of environmental risk assessment, problem formulation, practical exercises and dossier preparation has been further disseminated to researchers and students of the institute by organizing in-house workshops. In total, the IBO program has been highly useful in making ICAR-IIOR ready to comply with regulatory requirements in developing transgenic crops."

"After attending this programme, my understanding enhanced many folds on the use of SOPs and the biosafety issues in the development of transgenic plants/crops."

INSTITUTIONAL BIOSAFETY OFFICER: Dr. Mohammad Akram

JOB TITLE: Principal Scientist (Plant Pathology)

ORGANIZATION: ICAR-Indian Institute of Pulses Research, Kanpur

BIOGRAPHY: Dr. Akram's specialization is plant pathology and diagnostic; diversity and management of plant viruses; and molecular characterization of pathogens. His current areas of research include development of polymerase chain reaction (PCR) based diagnostics for major viruses and fungi of pulses; characterization of emerging viruses in pulses through next generation sequencing (NGS) and identification of stable sources of resistance in mungbean and urdbean against major pathogens. He has received many awards including the Young Scientist Award 2003-2004 in the field of Plant Protection by the National Academy of Agricultural Sciences, New Delhi; the Science Award 2004-2005 (Young Scientist Award Category) by the Council of Science and Technology, Uttar Pradesh, Government of Uttar Pradesh; the Lal Bahadur Shastri Young Scientist Award Biennium 2005-2006 in the field of Plant Protection by the Indian Council of Agricultural Research, New Delhi; and the Best Scientist Award-2015 by ICAR-Indian Institute of Pulses Research, Kanpur. He has published approximately 45 research papers in National Academy of Agricultural Sciences (NAAS) rated journals and 50 popular articles, book reviews, and bulletins. He has guided over 15 Postgraduate students.

THE VALUE OF THE IBO PROGRAM: "Research management in laboratories, especially on the hazardous chemicals, pathogenic microorganisms, DNA recombinant technology etc., needs to ensure the safety of researchers/ technicians/ research fellows/ students, environment and animals. There is lot of literature available on the Good Laboratory Practices (GLP) to avoid the hazards to the researchers, human beings, environment and animals. But to follow the GLP, the first and most important issue is the availability of the standard infrastructure which includes the protected space, quality equipments, resource management, discipline and standard operating protocols/ procedures. Several ICAR institutions have very good facilities to do the high quality research on plants/crops, animals and fish and are involved in developing transgenics.

The main aim of developing transgenic crops is to boost productivity and production of various crops so that the income of the growers is enhanced. Additionally, it is also to reduce the application of the chemical pesticides thereby reducing the environmental pollution. There is a need to create awareness on the use of standard operating procedures (SOPs) for developing the transgenic crops in accordance with the biosafety rules and regulation in the National Agricultural Research System (NARS) of the country. There is also a need to make the public aware on the safety and other benefits of the transgenic products so that their release is not opposed.

ICAR has initiated the programme on "Biosafety Awareness and Compliance Readiness" in collaboration with the ILSI Research Foundation, USA and Biotech Consortium Limited (BCIL), New Delhi to train 20 scientists from 10 ICAR institutes since 2015. I come from the ICAR-

Continued on page 4

Continued from page 3

Indian Institute of Pulses Research, which is part of this programme. After attending this programme, my understanding enhanced many folds on the use of SOPs and the biosafety issues in the development of transgenic plants/crops. All of us trainees are directly involved in developing the SOPs keeping in view the kind of crops and the conditions of the ICAR Institutes along with the experts from the ILSI Research Foundation and BCIL. I hope this programme will continue to train the other scientists of ICAR and also to create awareness on the biosafety issues related to transgenic plants/crops not only in the scientific community but also with the general public of the country."

Interested in learning more about the IBO Program and available resources? Visit the ICAR Biosafety Portal, an online resource to strengthen compliance with the regulatory framework and also to effectively facilitate research and development of agricultural biotechnology activities in ICAR through the regulatory process for the benefit of farmers and society, at http://biosafety.icar.gov.in/

GEAC Invites Comments on the Safety Assessment Report on GE Mustard

The Genetic Engineering Approval Committee (GEAC) of the Ministry of Environment, Forest & Climate Change, India, invites comments on the Food and Environmental Safety Assessment (AFES) Report submitted by the Sub-Committee for environmental release of GE Mustard (Brassica juncea) hybrid DMH-11 and use of parental events (varuna bn 3.6 and EH2 modbs 2.99) for development of new generation hybrids developed by Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi, South Campus, on or before October 5, 2016.

To provide feedback, please visit: **http://bit.ly/2cM0hqq**

BANGLADESH

Consultation Meeting on the Safety Assessment of Foods Derived from GM Plants

Dr. Tahmina Islam, Department of Botany, University of Dhaka, Dhaka

A consultation meeting on the safety assessment of foods derived from genetically modified (GM) plants was held at the Bangladesh Food Safety Authority (BFSA) on August 29, 2016. Prof. Dr. M.A. Malek, Member, BFSA, presided over the meeting. Participants were selected from among the biotech researchers working in the National Agricultural Research System (NARS) institutes and universities, including: Prof. Dr. Zeba Islam Seraj, Dhaka University; Prof. Dr. M. Imdadul Hoque, Dhaka University,and Country Coordinator, South Asia Biosafety Program (SABP); Dr. Tahmina Islam, Dhaka University; Dr. Md. Abdullah Yousuf Akhond, Biotechnology Division, Bangladesh Agricultural Research Institute (BARI); Mr. Md. Golam Sarwer, Bangladesh Standards and Testing Institution (BSTI); Prof. Dr. Md. Kamrul Hassan, National Food Safety Consultant (Horticulture), FAO; Md. Moinul Haque, BFSA; and Prof. Dr. Md. Iqbal Rouf Mamun, BFSA were in attendance.

In Dr. Malek's welcoming address, he mentioned that the Bangladesh National Parliament has passed the Food Safety Act, 2013 on October 10, 2013 after repealing and re-enacting the existing outdated laws in this regards. By passing the act, provisions were made for the establishment of an efficient, effective, scientifically based Authority and for regulating the activities relating to food production, import, processing, stockpiling, supplying, marketing and sales. It was also enacted to ensure the people's right to access safe food through appropriate application of scientific processes and state of the art technology. Obligated by the citizens' aspirations and being respectful towards the present Government's desire, the Bangladesh Food Safety Authority was established on February 2, 2015, with the commitment to make a united start with full strength and unstinting efforts.

Dr. Malek shared that as many as 18 different organizations, including various government ministries, departments, city corporations, Pourashava (municipalities), and district magistrates are involved with the BFSA. The Authority whole-heartedly welcomes the all out support of all food control agencies, food business operators and people of the country towards the landmark goal of establishing a modern and technological food safety system in Bangladesh to contribute to the Government's Vision 2021.

The Food Safety Act not only focuses on the safety of traditional foods, but also has the responsibility to ensure the safety of foods derived from GM plants. Therefore, this meeting provided an opportunity to discuss the issues related to the safety assessment of foods derived from GM plants.

Mr. Alam, Director of BFSA, gave a short presentation highlighting the current and future activities of BFSA. In his presentation, Mr. Alam pointed out the various articles of the Food Safety Act where the provisions for assessment of GM foods are addressed.

Continued on page 5

Continued from page 4

After the presentation, the Chair requested Prof. Hoque to give a short presentation on the safety assessment of foods derived from GM plants, including their benefits and potential risks. He described the global status of biotech crops and how the foods derived from GM crops are being assessed internationally. He also described the guidelines for the safety assessment of foods derived from GM plants, including its development process, which has been adopted by the Bangladesh Standards and Testing Institution (BSTI) as their standard. He described the salient features of these guidelines and the guiding principles for the assessment of GM plants derived foods.

A lively discussion followed the presentations. In his concluding remarks, the Chair thanked all participants for sparing their valuable time for this meeting. He mentioned that this is just a preliminary meeting on this important issue and there are plans to hold such consultation meetings more frequently in the future so that the regulators may have better understanding about the foods dervied from GM crops and their safe use.

PAKISTAN

Capacity Building Session with Biosafety Regulators in Islamabad

Dr. Sammer Yousuf, Assistant Professor, H.E.J. Research Institute of Chemistry, University of Karachi, Karachi

A two-day event entitled, "Capacity Building Session with the Biosafety Regulators", was held on August 11-12, 2016 at the Serena Hotel, Islamabad, Pakistan. This event was jointly organized by the Pakistan Biotechnology Information Center (PABIC), the Pakistan Agriculture Research Council (PARC), the Forman Christian College (A Chartered University), Lahore, and the United States Department of Agriculture, Foreign Agricultural Service US Embassy, Islamabad, Pakistan. Top biotechnologists and regulators from different countries including Pakistan, Philippines, Malaysia and Austria, participated in this capacity building event.

The event was attended by more than 70 participants, including researchers, members of institutional biosafety committees and regulators, representatives of various private sector seed companies and university faculty.

The inauguration ceremony was honored by the presence of His Excellency Sikandar Hayat Khan Bosan, Federal Minister for National Food Security and Research and Mr. Syed Abu Ahmad Akif, Secretary Ministry of Climate Change, as the Chief Guest and the Guest of Honor, respectively. Excellency Sikandar Hayat Khan Boson also launched the ISAAA Brief 51. Before the launch, Prof. M. Iqbal Choudhary, Director, PABIC, briefed the audience regarding important facts and figures in the ISAAA Brief written by Dr. Clive James and informed them that it is the 20th Anniversary of the global commercialization of biotech crops. While addressing the inaugural session, the Minister shared that the rapid adoption of GM crops in industrial and developing countries clearly shows the importance of this technology. He enumerated the challenges faced by the country in the form of energy crisis, food security, rapid urbanization and climate change, adding that in the face of such challenges, the country took a bold step towards biotechnology. The Minister expressed pleasure at the progress made in the field of biotech crops, in the form of gene manipulations through exotic means, and thereby using them in crops to gain positive results which include insect resistance, protection from disease, and drought soil salinity.

During the technical sessions, Dr. Yousuf Zafar, Department of Technical Cooperation, Vienna International Centre, talked about the regulatory issues related to new gene editing technology. This was followed by a comprehensive talk on Philippines' experience with biosafety regulation of GMOs delivered by Ms. Julieta Fe L. Estacio, Project Development Officer, Department of Science and Technology and Head Secretariat, National Committee on Biosafety of the Philippines and Department of Science and Technology (DOST) Biosafety Committee. Dr. Asif Ali, Vice Chancellor, Muhammad Nawaz Sharif Agriculture University Multan, talked in detail about the issues of food security and climate change in Pakistan. Dr. Shahid Manssor, Director, National Institute for Biotechnology and Genetic Engineering (NIBGE), talked about capacity building related to the biosafety evaluation of transgenic plants. This was followed by a comprehensive talk from Dr. Qaiser Khan, Head, Environmental Biotechnology Division, NIBGE, regarding the toxicological risk assessment of genetically modified crops and related available facilities in NIBGE. While Dr. Tayyab Hassnain, Director, Centre of Excellence in Molecular Biology (CEMB) talked about biosafety issues. Dr. Mahaletchumy Arujanan, Executive Director, Malaysian Biotechnology Information Centre, delivered a detailed training lecture entitled, "Fighting the GM Debate as an Underdog", for scientists as effective science communicators. She explained in detailed about the required acts needed for scientists to communicate with people in society as well as with the media.

The event ended with a long discussion among the speakers and participants about the further improvements required for the existing biosafety clearance system of GMOs in Pakistan. The participants urged that since the agriculture is the backbone of national economy, it is imperative to adopt science based agriculture at the national level in order to meet the constantly growing food, fiber and fodder demands in Pakistan. However, lack of coherent policies and clear implementation strategy to adapt agri-biotech need to be properly addressed and improved in order to feed the growing population and to provide raw material for high value exports.

CALENDAR OF EVENTS

EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
Technical Workshop on "Practical Considerations of Applications of Genome Editing"	Department of Biotechnology (DBT), Government of India and Biotech Consortium India Limited	September 23, 2016 Hyderabad	www.bcil.nic.in
International Conference on Food, Water, Energy Nexus in Arena of Climate Change	Anand Agricultural University and National Council for Climate Change Sustainable Development and Public Leadership (NCCSD)	October 14-16, 2016 Anand, Gujarat	http://bit.ly/1qpcp1y
1st International Agrobiodiversity Congress (IAC 2016)	Indian Society of Plant Genetic Resources (ISPGR) and Bioversity International	November 6-9, 2016 New Delhi	www.iac2016.in/
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	www.iipr.res.in/pdf/events_201115.pdf
INTERNATIONAL			
4th Annual South Asia Biosafety Conference	SABP, Center for Environmental Risk Assessment (CERA), ILSI Research Foundation, Biotech Consortium India Limited (BCIL)	September 19-21, 2016 Hyderabad, India	http://sabc.biotech.co.in/
Workshop on Environmental Release of Engineered Pests: Building an International Governance Framework	OECD and Genetic Engineering and Society Center, North Carolina State University	October 5-6, 2016 North Carolina, USA	https://research.ncsu.edu/ges/oecd-crp-meeting/
4th Asia Pacific International Food Safety Conference & 7th Asian Conference on Food and Nutrition Safety	ILSI Southeast Asia Region and Southeast Asia Association for Food Production	October 11-13, 2016 Penang, Malaysia	www.apacfoodsafety2016.com
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	https://ibpfsymposium.org/
8th 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	www.baptcb.org/

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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