VOL 14 NO. 11 NOVEMBER 2017

South Asia Biosafety Program

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Outcomes from SABC Workshop 3: Intersection of the Cartagena Protocol and the Indian Biosafety Regulatory System

The workshop was attended by 30

participants, including members of

regulatory committees and scientists from

public, private, and other organizations.

The objective of the workshop *Intersection of the Cartagena Protocol* and the *Indian Biosafety Regulatory System*, held September 12, 2017 during the 5th Annual South Asia Biosafety Conference (SABC), was to promote dialogue about how living modified organisms (LMOs) for

food, feed, and processing (FFP) and non-LMOs for FFP (including non-propagable LMOs/ products derived from LMOs) might be best addressed under India's biosafety regulatory framework. The program included a series of presentations to establish common context for the subsequent breakout group discussions,

which were in turn informed by three case studies with a common set of questions. The workshop was attended by 30 participants, including members of regulatory committees and scientists from public, private, and other organizations.

Prior to the breakout session, participants were addressed by Dr. Amita Prasad, Additional Secretary, Ministry of Environment, Forest &

Climate Change (MoEF&CC), who stated that the time has arrived to reevaluate and update *Rules, 1989*. She indicated that these rules were progressive when first released, but, almost 30 years later, it is apparent that there are policy gaps. Dr. Prasad encouraged the workshop participants to consider this during their

deliberations, and to provide guidance to MoEF&CC on what needs to be done to modernize *Rules, 1989*, including potentially reducing the regulatory burden for products of modern biotechnology.

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The workshop participants actively discussed the case studies in groups, and then in plenary. There were significant points of consensus that should be useful to MoEF&CC as it seeks to update *Rules*, 1989:

- Non-LMOs for FFP clearly fall outside the scope of the Cartagena Protocol and should be excluded from Rules, 1989.
- LMOs for FFP and non-LMOs for FFP have already been assessed and approved in (at a minimum) the country of export. This means that decision documents, regulatory summaries and similar informational resources are available on the websites of regulatory agencies, the Biosafety Clearing House, as well as from databases created by agencies such as the OECD and the ILSI Research Foundation. Participants agreed that this information should be used in decision-making by the Genetic Engineering Approval Committee (GEAC) or the Food Safety and Standards Authority of India (FSSAI), and they may in fact be sufficient for that purpose.
- GM foods should be regulated by the same authority responsible for regulating non-GM foods, as there are no environmental or



biodiversity considerations involved in the safety assessment of GM foods (including LMOs for FFP or products derived from LMOs).

- Accidental releases of LMOs for FFP should to be dealt with in a manner different from LMOs for intentional release. These situations are low exposure scenarios, and data generated by developers in the country of export is generally considered sufficient to resolve them.
- Non-LMOs for FFP, where there is detectable transgenic protein, could be practically addressed by requiring the inclusion of a "may contain" list of the potential transgenic events and references to the regulatory approvals undertaken by the country of export (and other countries as well).
- Non-LMOs for FFP with no detectable DNA or protein should be exempted from further regulation after the first decision to permit import is made (as was the case in India with soybean oil).

INDIA

Presentations Posted from the South Asia Biosafety Conference

In case you missed it... 35 experts presented during 5 plenary sessions at the South Asia Biosafety Conference in September 2017. You can now view the presentations shared by these specialists on regulation and capacity building initiatives in South Asia; crop biotechnology and biosafety; soil and plant microbiomes; synthetic biology; and new applications of biotechnology. Be sure to watch the Lighting Round videos which featured the latest from young scientists and researchers.

Video and PDF presentations are available at http://ilsirf.org/event/sabc2017/









Recent Regulatory Approval of Genetically Engineered Crops in Bangladesh

The National Committee on Biosafety (NCB) is the highest Biosafety Regulatory Authority in Bangladesh. This committee meets to review decisions on importation, field trial, and environmental release of

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genetically engineered organisms, including crops, in Bangladesh. The NCB considers recommendations from the Biosafety Core Committee (BCC), which is a technical committee headed by the Director General of the Department of Environment (DOE).

The most recent meeting of the NCB occurred on October 8, 2017, during which the NCB approved a number of

applications for the importation and contained trials of insect resistant cotton, Fe and Zn rich rice, and salinity tolerant rice.

These decisions represent the ongoing commitment of the Government of Bangladesh to advance useful research for the development of agriculturally beneficial biotechnologies while complying with domestic and international obligations related to ensuring the safety of genetically engineered plants. They may be summarized as follows.

- Permission for the importation of four varieties of cotton from JK Agri-Genetics Limited (JKAL): Bangladesh Cotton Development Board has applied for the importation of four transgenic hybrid lines containing Cry1Ac Truncated Event-1 from JK Agri Genetics Limited (JKAGL), India, which confers resistance against cotton bollworm. The Cotton Development Board will perform contained trials in the greenhouse of the Bangladesh Agricultural Research Institute (BARI) to evaluate the potential of these hybrids before continuing with confined field trials.
- Permission for the importation of Fe and Zn enriched transgenic BR 29 rice: Bangladesh Rice Research Institute has received permission for the importation and contained trials of Fe and Zn enriched transgenic BR 29 rice Event IRS495-274 from the International Rice Research Institute (IRRI). BRRI will import seeds of 24 breeding lines of Event IRS495-274 and two null segregants from IRRI and will perform contained trials to evaluate these lines at the BRRI greenhouse.
- Permission for the importation of salinity tolerant transgenic IR64 rice seeds: Bangladesh Rice Research Institute has received permission for the importation and contained trials of salinity tolerant transgenic IR64 seeds developed by Arcadia Bioscience Inc., USA. As per the application, BRRI will import 913 gms of transgenic seeds and 220 gms of wild type IR64. The proposed contained trials will be performed at the BRRI greenhouse.



FAO Regional Meeting on Agricultural Biotechnologies in the Asia-Pacific

Reproduced from FAO.org (originally published September 13, 2017).

The Food and Agriculture Organization of the United Nations (FAO) Regional Meeting on Agricultural Biotechnologies in Sustainable Food Systems and Nutrition in the Asia-Pacific took place on September 11-13, 2017 in Kuala Lumpur, Malaysia. The meeting was hosted and coorganized by the Government of Malaysia.

It was the first of four regional meetings that FAO is planning to organize in 2017-2018 as a follow-up to the FAO International Symposium on The Role of Agricultural Biotechnologies in Sustainable Food Systems and Nutrition, which took place on February 15-17, 2016 at FAO Headquarters, Rome.

The regional meeting brought together about 200 representatives of governments, intergovernmental organizations, private sector entities, academia and research institutions, as well as civil society organizations and producer organizations. The meeting encompassed a wide spectrum of available biotechnologies used in forestry, crops, livestock, and aquaculture/fisheries, from low- to high-tech.

The 2.5-day meeting consisted of presentations by 42 speakers and moderated discussions during 9 plenary and 6 parallel sessions dedicated to a wide range of issues concerning agricultural biotechnologies in the region, including the following:

- investments:
- dissemination, adoption, and use of biotechnologies (and their social and economic impacts);
- regional innovation opportunities;
- regulation, policies, and intellectual property rights;
- genetic resources for food and agriculture;

- nutrition:
- climate change; and
- south-south cooperation.

Ahead of the meeting, the FAO Regional Office for Asia and the Pacific produced four short videos with real examples of biotechnologies being applied to meet the needs of smallholders in the Asia-Pacific. They covered the use of:

- artificial insemination and semen sexing in dairy cows for milk production in Nepal:
- DNA-based diagnostics and probiotics for disease management in shrimp populations in Thailand;
- DNA marker-assisted selection to develop Swarna-Sub1, a rice variety tolerant to floods in India; and
- tissue culture for propagating tree planting stock for agroforestry in Thailand.

On the first day of the meeting, FAO also released a news story titled "Improved access to agricultural biotechnologies needed to help defeat hunger, malnutrition and poverty in the Asia-Pacific region."

The meeting website provides links to a wide range of material related to the event, including links to the press release, the new videos, frequently asked questions (FAQs), as well as the final agenda, abstracts of presentations made, and additional materials from the meeting.

> See http://www.fao.org/asiapacific/events/ detail-events/en/c/1440/ for more information.

EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
Training Programme: Use of Biotechnological and Conventional Tools in Understanding Virus-Host	ICAR-Indian Agricultural Research Institute	November 7-27, 2017 New Delhi	http://bit.ly/2wavDwz
TERI-ITEC Courses 2017-18: Course IV - Applications of Biotechnology and its Regulation	The Energy and Resources Institute	November 20- December 8, 2017 Gual Pahri, Gurgaon	http://www.teriin.org/events/ upcoming
Fostering Innovations in Fisheries and Aquaculture: Focus on Sustainability and Safety	ICAR-Central Institute of Fisheries Technology and Asian Fisheries Society Indian Branch (AFSIB)	November 21-24, 2017 Bengaluru	http://bit.ly/2wqW3g7
Training Workshop: Strengthening Capacities of Enforcement Agencies for Transboundary Movement of LMOs	ICAR-National Bureau of Plant Genetic Resources (ICAR-NBPGR)	November 22-23, 2017 Raxaul, Bihar	http://bit.ly/2xmaTpo
IPSACON2017 - XXXIV Annual Conference of the Indian Poultry Science Association	Indian Poultry Science Association and ICAR-National Institute of Animal Nutrition and Physiology	November 28-30, 2017 Bengaluru	http://bit.ly/2yx1yre
PulSym2017 National Symposium on Pulses for Nutritional Security and Agricultural Sustainability	Indian Society of Pulses Research and Development and ICAR-Indian Institute of Pulses Research	December 2-4, 2017 Kanpur	http://bit.ly/2ACtJWC
National Symposium on Sustainable Disease Management: Approaches and Applications	G.B. Pant University of Agriculture and Technology, Pantnagar	December 21-23, 2017 Pantnagar	http://bit.ly/2mlTt7k
1st National Biotechnology Conclave 2017: Accelerating the Biotech Ecosystem in India	Confederation of Indian Industry (CII)	December 22, 2017 New Delhi	http://www.cii.in/
7 th International Botanical Conference	Bangladesh Botanical Society	December 2-3, 2017 Dhaka, Bangladesh	http://www.bdbotsociety.org
INTERNATIONAL			
Asia Forum on Environmental Release & Safety Management of LMOs	Korea Biosafety Clearing House and Korea Research Institute of Bioscience & Biotechnology	November 22-24, 2017 Jeju Islands, South Korea	http://bit.ly/2yA7jEw
Meeting of the Ad Hoc Technical Expert Group on Synthetic Biology	CBD Secretariat	December 5-8, 2017 Montreal, Canada	https://www.cbd.int/meetings/



The South Asia Biosafety Program (SABP) is an international developmental program implemented in India and Bangladesh 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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