# South Asia Biosafety Program

**NEWSLETTER FOR PRIVATE CIRCULATION ONLY - NOT FOR SALE** 



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#### ANNOUNCEMENT

# **Charting a New Future with a New Name**

Dr. Morven McLean and Dr. Andrew Roberts, Agriculture & Food Systems Institute

Astute readers of this month's South Asia Biosafety Program (SABP) Newsletter might notice a new logo and website on this issue. That is because on May 1, 2020, the organization that leads SABP unveiled a new name that symbolizes and unifies our purpose as an independent and unaffiliated, non-profit science institute. The name is Agriculture & Food Systems Institute (AFSI), and it will be used as we move forward, building on our history, scientific capabilities, and successes.

Under our management, and supported by the United States Agency for International Development, SABP started its mission to facilitate the implementation of transparent, efficient, and responsive regulatory frameworks for products

of modern biotechnology in South Asia in 2005. For over 15 years, SABP has worked to assist South Asian countries to further strengthen institutional governance of biotechnology by providing technical assistance to the biosafety risk assessment and research communities.

The SABP Newsletter has been published monthly since May 2005, with over 175 issues sharing information and activities in South Asia. It is circulated electronically and in print to over 25,000 organizations and individuals in the region and internationally. As a subscriber to the SABP Newsletter, you may also regularly use the many resources we provide as global public goods and services. We would like to assure you that our eLearning portal, databases, and other resources will continue to be accessible on our new website, foodsystems.org. As part of this transition, we have also implemented a number of changes to enhance

> the user experience on our website, and more projects are in the pipeline.

> As part of the Agriculture & Food Systems Institute, the SABP team will continue to further its mission and implement programs in South Asia.

We are continually pursuing scientific advancement, which is why our new name and the changes that come with it are both important and exciting. With your continued support, we will build on our foundation of impactful scientific research, knowledge sharing, and outreach toward an even better future.



Dr. Morven McLean, Chief Executive Officer, AFSI & Dr. Vibha Ahuja, Senior Advisor, SABP, at the 5th Annual South Asia Biosafety Conference (September 11-13, 2017 in Bangalore, India).



Dr. Aparna Islam, Country Manager, SABP, Dr. Bhavneet Bajaj, Scientific Program Manager, AFSI, and Dr. Vibha Ahuja, Senior Advisor, SABP, at the 7th Annual South Asia Biosafety Conference (September 14-16, 2019 in Dhaka, Bangladesh).



Dr. Andrew Roberts, Vice President & Dr. Bhavneet Bajaj, Scientific Program Manager, AFSI, at the 6th Annual South Asia Biosafety Conference (September 15-17, 2018 in Dhaka, Bangladesh)



Dr. Aparna Islam, Country Manager & Dr. Vibha Ahuja, Senior Advisor, SABP, at the 7th Annual South Asia Biosafety Conference (September 14-16, 2019 in Dhaka, Bangladesh).

# Agricultural Biotechnology and Biosafety in South Asia: Progress and Prospects – A Valuable Resource on Biosafety Regulation in SAARC Member States

**Experts and regulators from six** 

SAARC Member States—Bangladesh,

Bhutan, India, Nepal, Pakistan,

and Sri Lanka—participated in the

consultation meeting.

Dr. Vibha Ahuja, South Asia Biosafety Program and Biotech Consortium India Limited Dr. Bhavneet Bajaj, Agriculture & Food Systems Institute

Dr. Aparna Islam, South Asia Biosafety Program

Agricultural Biotechnology and Biosafety in South Asia: Progress and Prospects, published by the SAARC Agriculture Center (SAC), is a collection of papers and proceedings of the SAARC Regional Consultation Meeting that was organized under the auspices of the South Asia Biosafety Program (SABP), in partnership with the SAC, in June 2019.

Experts and regulators from six SAARC Member States—Bangladesh, Bhutan, India, Nepal, Pakistan and Sri Lanka—participated in the consultation meeting and contributed country papers on agricultural biotechnology and biosafety regulations, from their respective countries. These

papers depict common challenges faced by countries in the South Asian region and approaches being followed to address them. The meeting was an excellent platform for sharing experiences in the field of biosafety, and the book is a good resource for the same.

In addition to country papers, focal point experts, as representatives of the participating SAARC Member States, provided their valuable insight towards enabling cooperation in biosafety regulation and efforts to harmonize risk assessments in the South Asian region. The case study of efforts by the South Asian Regional Standards Organization

(SARSO) on developing a SAARC standard on risk assessment of foods derived from modern biotechnology served as an example to move in this direction. Personal interaction among experts furthered potential fruitful collaborations between participating countries in this regard.

Editing the country papers was a great experience, not only in terms of interactions with the expert authors from the participating

SAARC Member States, but it was also an opportunity to know more about the biosafety regulatory structure in each of these countries. All contributors did a commendable job of articulating the structural organization and role of governance bodies involved in various aspects of biosafety

regulation, as well as identifying areas for potential cooperation with other Member States to harmonize technical requirements for biosafety risk assessments.

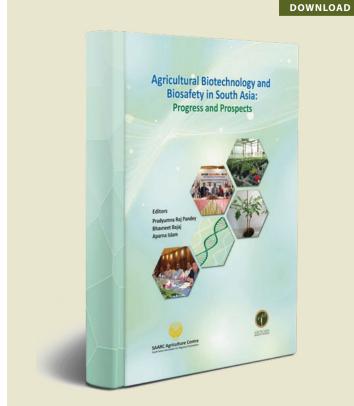
The book, a very valuable resource, serves not only as a compendium for understanding the regulatory frameworks for biotechnology in SAARC countries, but also provides updated information on efforts that each of these countries are making towards regional cooperation and harmonization in biotechnology risk assessment.



Dr. Vibha Ahuja, Senior Advisor, SABP at the SAARC Regional Expert Consultation Meeting on the Progress and Prospects of Agricultural Biotechnology and Biosafety in South Asia (June 18-20, 2019 in Dhaka, Bangladesh)



Dr. Aparna Islam, Country Manager, SABP, at the SAARC Regional Expert Consultation Meeting on the Progress and Prospects of Agricultural Biotechnology and Biosafety in South Asia (June 18-20, 2019 in Dhaka, Bangladesh)



Agricultural Biotechnology and Biosafety in South Asia: Progress and Prospects is available online at:

foodsystems.org/publication/agbiotechsa/

For details on how to purchase a copy, please contact the SAARC Agriculture Center (www.sac.org.bd)

### **USDA Publishes New Biotechnology Rule**

On May 18, 2020, the United States Department of Agriculture (USDA) published a final rule, updating and modernizing its biotechnology regulations under the Plant Protection Act. The Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) rule "will bring USDA's plant biotechnology regulations into the 21st century by removing duplicative and antiquated processes in order to facilitate the development and availability of these technologies through a transparent, consistent, science-based, and risk-proportionate regulatory system." The final rule "puts in place a more efficient process to identify plants that would be subject to regulation, focusing on the properties of the plant rather than on its method of production. APHIS will evaluate plants developed using genetic engineering for plant pest risk under a new process called a regulatory status review, regulating only those that plausibly pose an increased plant pest risk."

For more information, please visit:

SECURE Rule Website - https://bit.ly/2LFDoD6

SECURE Rule Full Text - https://bit.ly/2WEwDb0 | SECURE Rule FAQ - https://bit.ly/2WGtFTj

ANNOUNCEMENT

## **Biosafety Guidelines for Research Related to COVID-19 in India**

In the wake of the severe acute respiratory syndrome CoV-2 (SARS CoV-2/COVID-19) pandemic, several public and private institutions in India have initiated extensive research efforts towards development of rapid diagnostic methods, prophylactics, and therapeutics for detection, prevention, treatment, and management of COVID-19 infections.

The following guidelines were released in April 2020 for ensuring biosafety during research activities involving COVID-19 in India, including the sharing of biospecimens and data among various stakeholders:

- The Interim Guidance Document on Laboratory Biosafety to Handle COVID-19 Specimens was released on April 8, 2020. In compliance with Environment Protection Act, 1986 and on the basis of recommendations of the Review Committee on Gene Manipulation (RCGM), the Department of Biotechnology (DBT) released a guidance document, which provides an interim guideline on laboratory biosafety (in tune with the international norms), to be followed when handling and processing clinical samples/infectious virus for diagnostic testing, and research and development (R&D) work to develop new diagnostics/ therapeutics for COVID-19. Key issues addressed include:
  - All laboratories engaged in R&D work on suspected/confirmed COVID-19 samples should follow precautions as enlisted for Risk Group 3 or 4 organisms in the Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017.
  - Basic minimal procedure to be followed include risk assessment and mitigation measures, routine laboratory measures, specimen and nucleic acid storage, viral isolation, disinfectant and lab waste management, and specimen packaging and labelling.
  - All specimens being transported should have appropriate packaging, labelling, and documentation, as per the World Health Organization (WHO) Guidance on Regulations for the Transport of Infectious Substances 2017-2018.
  - · Institutional Biosafety Committees (IBSC) should update the status of such work in the organization quarterly, along with details of inventory and biosecurity information.
  - · For work related to COVID-19, RCGM may constitute an empowered committee, if necessary, to visit the laboratory to ensure due diligence to protocols and other requirements.

As per the provisions of Rule 1989 under EPA, all IBSCs and host institutions involved in research, development, and handling of COVID-19 specimens are required to comply with these guidelines with immediate effect. IBSCs are advised to refer to the WHO and CDC Interim Laboratory Biosafety Guidelines for further information.

The Government of India, through an empowered committee led by Niti Aayog, released the Guidelines for Sharing of Biospecimen and Data for Research Related to COVID-19 on April 21, 2020, with an objective to provide a basic framework for sharing of biospecimens and data generated from research among various stakeholders, such as national and public research institutions, healthcare facilities, and private entities working in collaboration with government departments and involved in research activities related to COVID-19. These guidelines have been aligned with the existing international framework of the Biological Weapons Convention, to which India is a signatory. These guidelines are consistent with the national guidelines/policies and regulatory framework related to the conduct of scientific research, clinical trials, medical practice, and data privacy.

These guidelines lay out effective and standard procedures for sample collection, storage, and transparent sharing of data, without compromising the research interests of sample providers and confidentiality of the study participants. An internal governance mechanism has also been established to consider specific legal and commercial requirements, such as intellectual property rights and publications related to COVID-19 research work.

Guidelines have annexures covering the following:

- · Interim Guidance Document on Laboratory Biosafety to Handle COVID-19 Specimens
- Guidelines for Sample Collection
- Request Form for Access to Biological Samples
- · Request Form for Access to Clinical Samples
- · Process Flow for Access to COVID-19 Resources

These guidelines are obligatory for compliance to biorepositories and hospitals to share the biospecimen as per the procedure and timelines as prescribed in these guidelines.

For more information, please visit: https://bit.ly/2zQSHWR | https://bit.ly/2ydH38j

# **CALENDAR OF EVENTS**

EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
India Bio @ Bengaluru Tech Summit	Department of Information Technology Biotechnology and Science and Technology, Government of Karnataka	September 21-23, 2020 Bengaluru, Karnataka	http://www.indiabio.in/
4 <sup>th</sup> International Conference on NANOFORAGRI 2020 - Application of Nanotechnology for Sustainable, Productive and Safer Agriculture and Food System	The Energy and Resources Institute	November 5-6, 2020 Gurugram, Haryana	https://www.teriin.org/ event/4th-international- conference-nanoforagri-2020- application-nanotechnology- sustainable
INTERNATIONAL			
24 <sup>th</sup> Meeting of the Subsidiary Body on Scientific, Technical, and Technological Advice	Secretariat of the Convention on Biological Diversity	August 17-22, 2020 Montreal, Canada	https://www.cbd.int/ meetings/?thm=CPB
5 <sup>th</sup> International Conference on Genome Editing and Gene Therapy	Meetings International	August 19-20, 2020 Osaka, Japan	https://www.meetingsint.com/ conferences/genomeediting
3 <sup>rd</sup> Meeting of the Subsidiary Body on Implementation	Secretariat of the Convention on Biological Diversity	August 24-29, 2020 Montreal, Canada	https://www.cbd.int/ meetings/?thm=CPB
Workshop on Fall Armyworm Control: Challenges and Opportunities for the Use of Biopesticides	International Centre For Genetic Engineering and Biotechnology (ICGEB)	September 9-11, 2020 Cape Town, South Africa	https://www.icgeb.org/ activities/meeting-and-courses/
7 <sup>th</sup> Plant Genomics and Gene Editing Congress: Asia	Global Engage Ltd.	September 14-15, 2020 Bangkok, Thailand	http://www.global-engage.com/ event/plant-genomics-asia/
10 <sup>th</sup> Meeting of the Conference of the Parties Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety	Secretariat of the Convention on Biological Diversity	October TBD, 2020 Kunming, China	https://www.cbd.int/ meetings/?thm=CPB
The 3 <sup>rd</sup> Asian Horticultural Congress 2020 (AHC 2020)	Horticultural Science Society of Thailand, International Society for Horticultural Science, Department of Agriculture, Department of Agricultural Extension, Ministry of Agriculture, Kasetsart University, and VNU Exhibitions Asia Pacific	December 15-17, 2020 Bangkok, Thailand	http://ahc2020.org/



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







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#### **UNITED STATES**

safety of novel foods and feeds, and environmental protection.

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