

# South Asia Biosafety Program

NEWSLETTER FOR PRIVATE CIRCULATION ONLY – NOT FOR SALE



**BSAFE Foundation Webinar Discusses the Status of Golden Rice in Bangladesh**

PAGE 3

**Experience at AFSI's Webinar on Microbial Biotechnology for the European Union**

PAGE 4

**Department of Biotechnology (DBT) Releases Biotech-PRIDE Guidelines: Enabling Sharing, Access, and Storage of Data**

PAGE 5

**Calendar of Regional and International Events**

PAGE 6

## BANGLADESH

### Public Research Delivers Plant Science Innovation to Improve Food and Nutrition Security

Dr. Donald J. MacKenzie, Institute for International Crop Improvement, Donald Danforth Plant Science Center



**Virus-resistant cassava approved for environmental release in Kenya (18 June 2021)**

**Pod borer-resistant cowpea commercial launch in Nigeria (29 June 2021)**

**Golden Rice commercial propagation permit in the Philippines (21 July 2021)**

Recent regulatory approvals and deployment milestones for virus resistant cassava, pod-borer resistant cowpea, and Golden Rice.

The past several weeks has seen some remarkable developments in getting plant biotechnology into the hands of smallholder farmers. Recent regulatory approvals and deployment milestones have included the environmental release authorization of virus resistant cassava by Kenya on 18 June,<sup>1</sup> the first seed sales of pod-borer resistant (PBR) cowpea in Nigeria on 29 June,<sup>2</sup> followed shortly by the approval for commercial propagation of Golden Rice<sup>3</sup> and the food and feed approval of Bt eggplant<sup>4</sup> (brinjal) in the Philippines on 21 July. Also in July was the registration in Indonesia of Bio Granola, the first potato cultivar with engineered resistance to late blight disease caused by *Phytophthora infestans*.

Each of these developments is noteworthy, but collectively, they represent a major accomplishment for the various national agricul-

tural research organizations and international partners who have been working over many years to achieve impact from innovation. Cassava event 4046, with resistance to *Cassava brown streak virus* via RNA interference technology, is only the second transgenic food crop to be granted environmental release authorization in Kenya, the other being Bt maize event MON 810, which was approved in 2016 but is still not in farmers' hands. With the environmental release approval of event 4046 in hand, the next step is National Performance

Trials and registration of new cassava varieties containing the event for release to farmers.

PBR cowpea event 709A, which expresses the Cry1Ab protein from *Bacillus thuringiensis* to control *Maruca vitrata*, is the first wholly public sector developed genetically engineered food crop to be released in

Continued on page 2

Continued from page 1

Africa. Uncontrolled, the legume pod-borer can result in yield losses of 80 percent or more, so the new PBR cowpea variety (SAMPEA 20-T) has been eagerly awaited by Nigerian farmers who will be able to reduce the number of insecticide applications per season from about eight to two, while realizing significantly improved yield. As noted by Kano State Governor, Dr. Abdullahi Umar Ganduje during the commercial launch, "Today, Nigeria is recognized as the first country in the world to release a cowpea variety that is resistant to *Maruca*, the destructive insect that had been a nightmare to farmers on the African continent. This is a landmark event that will help Nigeria achieve food security and increase farmers income."<sup>5</sup> Event 709A was granted a permit for commercial production in January 2019 by the National Biosafety Management Agency of Nigeria, and the first variety containing event 709A was registered by the National Committee on Naming, Registration and Release of Crop Varieties in December 2019.

With its recent approval of Bt eggplant event EE-1 for food, feed, or for processing, the Philippines becomes only the second country after Bangladesh to have issued a positive regulatory decision on Bt eggplant. Since first adopted in 2014, the cultivation of Bt brinjal in Bangladesh has grown substantially and shown both increased yield (ca. 20 percent) and income (ca. 22 percent) for farmers using the technology.<sup>6</sup>

The issuance of the permit for commercial propagation of Golden Rice event GR2E to the Philippine Rice Research Institute (PhilRice) represents a major milestone towards achieving impact in helping combat vitamin A insufficiency. Studies have shown that a one-cup portion of cooked Golden Rice contains enough beta-carotene to meet up to 50 percent of the estimated average requirement (EAR) of vitamin A for children aged six months to five years, the group most at risk of vitamin A insufficiency in the Philippines. Notwithstanding the success of vitamin A supplementation and food fortification programs, only two out of 10 Filipino households currently meet the EAR for vitamin A intake in their daily diet.<sup>7</sup>

Similarly in Bangladesh, while having made significant progress over the past two decades in reducing poverty and undernutrition, the country is still facing high levels of micronutrient deficiencies. Even with food fortification and a vitamin A supplementation program, more than 20 percent of pre-school age children are vitamin A deficient.<sup>8</sup> Golden Rice can provide low-income households with a sustainable way of meeting their vitamin A needs through their own food production.

The data supporting the food and feed safety of Golden Rice are irrefutable, having been certified by regulatory agencies representing Australia, Canada, New Zealand, the Philippines, and the United States. Considering that all the involved regulatory bodies have generally based their assessment on risk analysis principles and guidelines developed through the Codex Alimentarius Commission, it is unsurprising that without exception, assessors found that "food derived from line GR2E is considered to be as safe for human consumption as food derived from conventional rice cultivars."<sup>9</sup>

With respect to environmental safety, an evaluation of the agronomic and phenotypic data generated for GR2E rice in different germplasm backgrounds, grown at multiple locations under a range of environmental conditions in the Philippines and in Bangladesh did not identify trends of significant differences with the recurrent parental variety. The genetic modification did not have an unintended, unexpected, effect on plant growth habit and general morphology, vegetative vigour, or grain yield. The Philippines Department of Environment and Natural Resources, Biosafety Committee, after a thorough scientific review and evaluation, "recommended the issuance of a biosafety permit for this regulated event since it poses no significant adverse effect to the environment."<sup>10</sup>

**For those of us involved in plant science research, we should feel greatly encouraged by recent events and redouble our efforts to move research results from "lab to land".**

The regulatory decisions taken in Kenya, Nigeria, and the Philippines were not easy ones, facing at times significant ideological opposition. These decisions required not only courage on the part of regulators but also adherence to scientific principles and to review procedures laid out in national legislation and regulations. The importance of science in regulatory decision-making is perhaps no better articulated than by the Honorable Matia Chowdhury, MP and former Minister of Agriculture for Bangladesh, who noted "We will be guided by the science-based information, not by the nonscientific whispering of a section of people. Good science will move on its own course keeping the anti-science people down. As human beings, it is our moral obligation that all people in our country should get food and not go to bed on an empty stomach. Biotechnology can play an important role in this effort."<sup>11</sup>

For those of us involved in plant science research, we should feel greatly encouraged by recent events and redouble our efforts to move research results from "lab to land". And for governments striving to meet the goals of zero hunger and achieving food and nutrition security, the gap between innovation and impact must be urgently, and significantly, reduced. Addressing unnecessary regulatory hurdles and delays is part of the solution.

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## BSAFE Foundation Webinar Discusses the Status of Golden Rice in Bangladesh

Md. Abdul Kader, M. Abdul Momin, and Azizur Rahman Anik, Healthier Rice Project, Bangladesh Rice Research Institute



Speakers at the BSAFE Foundation Webinar (July 27, 2021)

In a country like Bangladesh, rice is not just the staple food, it is also part of people's livelihood, where "to eat" means "to eat rice." On a global level as well, nearly half of the world's population get a lion share of their daily calorie needs from rice. However, it is also not a coincidence that many countries that depend on rice for nourishment are also among the poorest in the world, especially in Asian countries where people have to put in a lot of hard, physical labour to make three (sometimes fewer) meals a day, and rice features prominently because it is one of the cheapest sources of energy that can keep a human body up and running for a long day's hard toil.

"For a long time, rice has been labelled as merely a source of carbohydrate," said Dr. Md. Shahjahan Kabir, Director General of Bangladesh Rice Research Institute (BRRRI), in a webinar on July 27, 2021. "The fact that it contains other key nutrients such as protein, vitamins, and minerals, including zinc and iron, which have long been unknown to a lot of people. It's high time that everyone knows about the nutritional value of our staple crop," said the BRRRI DG at the webinar organized by Bangladesh Safe Agro Food Efforts (BSAFE) Foundation, a fast-emerging policy think-tank in Bangladesh that deals with food security and safety.

In Bangladesh, micronutrient deficiencies have been a longstanding public health concern and one of these micronutrients is vitamin A, a lack in the body of which is among the leading causes for childhood blindness, stunted growth, and weakened immune system. This is quite understandable because rice does not have vitamin A. So, in a country where the poor depend mainly on rice and cannot afford (often expensive) nutritious food (such as meat, milk, eggs, and vegetables), vitamin A deficiency will be prevalent.

As a response to this problem, in 2014, BRRRI, with technical and resource support from the International Rice Research Institute (IRRI),

developed Golden Rice that contains beta carotene (precursor of vitamin A) in the grain. Since no rice in the world contains beta carotene, it could not have been achieved through traditional breeding methods. Therefore, a certain gene was brought over from maize and added to a popular local variety (BRRRI dhan29) using genetic modification technology to develop Golden Rice, so that anyone who eats this rice can avail themselves of the beta carotene in it.

After years of rigorous research, scientists from BRRRI have reached the conclusion that not only is Golden Rice absolutely safe for human consumption and the environment, it can also provide 30-50% of the daily average vitamin A requirement of children. Its proponents, which also include scientists from the Philippines Rice Research Institute (PhilRice), therefore conceived Golden Rice as a tool to fight vitamin A deficiency (VAD) in children living in poor, marginalized settings and as a sustainable, cost-effective complementary solution to the existing government-run interventions, such as capsule feeding and edible oil fortification. The Philippine government, after being fully convinced with the research outcomes about its safety, recently cleared the way for Golden Rice to be commercially cultivated in the country.

At the webinar, Dr. Kabir also said that scientists at BRRRI are now working to develop biofortified nutritious non-transgenic rice with enhanced levels of protein and transgenic rice with enhanced levels of zinc and iron to support the government's nutritional targets. BRRRI is also developing low GI (glycemic index) rice for diabetes patients.

"If we are talking about taking nutrition to a wider population, nothing can be better than rice. It's our staple food, which means everyone eats rice. So, if we can improve the nutritional content of rice, it will be the most cost-effective way of carrying nutrition to a wider mass," said Dr. Md. Khalilur Rahman, the Director General of Bangladesh

*Continued on page 4*

Continued from page 3

National Nutrition Council (BNNC), the apex policymaking body in the country's nutrition sector.

"The honorable prime minister of Bangladesh declared 2015 to 2025 as the decade of nutrition, which means that ensuring nutrition for all will be one of the main national focus over the next few years. Key policy documents, such as SDG, National Agricultural Policy 2018, and Election Manifesto of the ruling party and the National Plan of Action for Nutrition (NPAN2) also emphasize the role of biofortification of food crops to improve the nutritional status of the people of the country," said the BNNC DG while speaking at the BSAFE webinar.

Despite the clear-cut potential benefits that Golden Rice can bring and the fact that it has been a ready product for many years, it is still to reach the farmers' fields and the consumers' plates. BRRI applied for the biosafety approval of Golden Rice in December 2017 with the ministry of environment. However, despite there being regulatory bindings that any such applications must be processed within 180 days, the application has been pending with the National Committee on Biosafety (NCB) under the Ministry of Environment for nearly four years. The NCB has asked a total of 13 questions on nutritional efficacy, bioavailability, and biosafety in two separate

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instalments during 2019-20 and BRRI, the applicant, has given appropriate evidence-backed responses to those in due time. But, the NCB has not been able to make a decision in about four years.

"It's hard to understand why it would take so long for the regulators to make a decision on this," said Prof. Dr. Rakha Hari Sarker from the Department of Botany at Dhaka University, who is also the head of the Institutional Biosafety Committee at Dhaka University and member of the Core Committee on the National Technical Committee on Crop Biotechnology, while speaking at the BSAFE Webinar.

"Many countries in the world have been consuming genetically modified (GM) products without any problem. In Bangladesh, we already have a GM crop, Bt eggplant, since 2014. Nobody has reported any problem from consuming it. There is insulin, which is a GM product. Most of the soybean oil and maize found in the local market imported from developed countries are also GM products. We are consuming all of these without any problem whatsoever. It's really hard to understand why our regulators would have a problem with Golden Rice. Even the covid-19 vaccines that everyone is taking now are products of genetic modification."

## STUDENT SHOWCASE

### Experience at the Agriculture & Food Systems Institute's Webinar on Microbial Biotechnology for the European Union

Ifthikhar Zaman, Biotechnology Program, BRAC University

## STUDENT SHOWCASE

To encourage written discourse on topics related to biosafety and biotechnology among the younger generation, the *SABP Newsletter* dedicates space in select issues to spotlight pieces written by students residing in South Asia. Since articles with the "Student Showcase" tag are meant to reflect the actual views and capabilities of the author(s), they are not revised for content and only lightly edited to conform with the newsletter's style guide.

The Agriculture & Food Systems Institute (AFSI) organized the webinar "Microbial Biotechnology for the European Union" on July 8, 2021. Four discussants talked about microbial biotechnology, the EU green deal, alternative food source, regulatory aspects, and the impact of the biotech industry on the economy, etc.

It was one of the best discussions I have participated in as it discussed major issues with efficient details. The webinar began with a good account of the history of microbial biotechnology, its production procedures, and its products by Dr. Markus Wyss, Strain Director, Global Regulatory Affairs, DSM Nutritional Products Ltd., who also talked about safety assessment and regulatory context in the EU, which shed light on hurdles on research translation. He suggested revision of the EU GMO regulatory framework to have a separate regulation for microbial products for food and feed. He pointed out that as time changes, the laws have to keep up with it. The talk set the tone of the webinar for a better understanding of the topic and further elaboration of this matter.

The next panelist, Dr. Elke Duwenig, Senior Expert Global Regulatory/Public & Government Affairs Biotechnology, Nutrition & Health, BASF, talked about various issues ranging from the EU Green Deal, sustainability, microbial biotechnology products like vitamin B2, green transformation requirements, and the vastness of biotech application, etc. In her discussion, biotechnology came out as a way forward to achieve the EU green deal, a unified approach to go climate neutral by 2050 with a circular economy and sustainable food system. She also

reiterated the need to change the EU regulatory path. She focused on enabling biotechnology everywhere to meet the deadline for the green deal and unifying everyone to give this technology a chance.

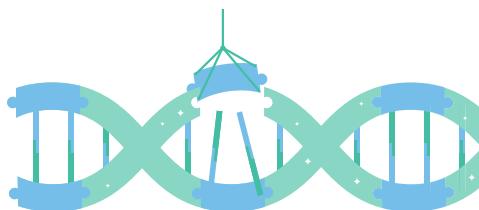
The third talk was given by Seren Kell, Science, and Technology Manager, The Good Food Institute Europe. She highlighted how fermentation changed food biotechnology. She gave an overview of how fermentation works to make alternative proteins and various foods. Producing animal products without actually farming the animals is a

marvel of biotechnology. She also gave exciting statistics on the increasing rate of fermentation-powered alternative protein startups and investments. Indicating increasing acceptance and demand among the general people, she explained the need to change the current agricultural practice to become an efficient system

to feed 10 billion people by 2050. This will on one hand help to feed people sufficiently and in a financially feasible manner, and on the other hand, improve the environment. Later, she also briefed attendees on the regulatory situation in some EU countries.

The final panelist, Prof. Dennis Ostwald, CEO and Founder, WifOR Institute, talked about trade and the economy. He put forward statistics on job opportunities, GDP contribution, and economic growth. He pointed out that around one million people are directly or indirectly connected to this field and the EU biotechnology industry amounted to €79 billion. This job sector and the GDP contribution from it has been ever-growing since 2008, with healthcare biotechnology playing a major role. He mentioned that, though there are many positive effects, many

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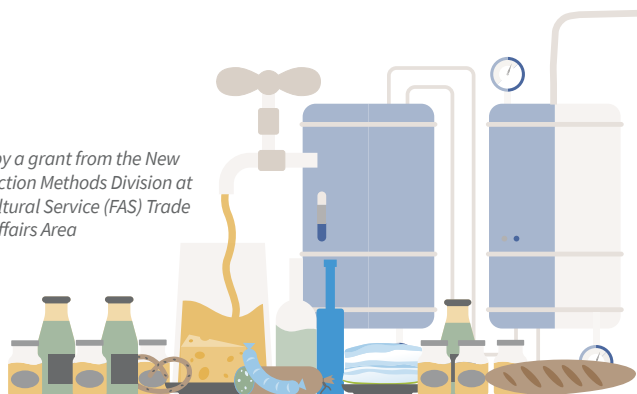


# Microbial Biotechnology for the European Union

July 8, 2021

This event is supported by a grant from the New Technologies and Production Methods Division at the USDA Foreign Agricultural Service (FAS) Trade Policy and Geographic Affairs Area

foodsystems.org



**Science & Technology of Microbial Biotechnology**  
Markus Wyss  
Strain Director  
Global Regulatory Affairs,  
DSM Nutritional Products Ltd.



**Products of Microbial Biotechnology and the Green Deal**  
Elke Duwenig  
Senior Expert - Global Regulatory/  
Public & Government Affairs  
Biotechnology, Nutrition & Health, BASF



**Customers & Consumers - Products of Microbial Biotechnology & Food Trends**  
Seren Kell  
Science & Technology Manager  
The Good Food Institute Europe



**Trade of Products of Microbial Biotechnology**  
Dennis Ostwald  
CEO and Founder  
WifOR Institute

Event flier for AFSI's webinar on Microbial Biotechnology for the European Union (July 8, 2021)

politicians are still not focusing on biotech. To harness the benefits, he suggested placing biotech in all policies. He also suggested awareness of the economic and environmental values, as well as the social impact of this technology, which will have a positive impact on the minds of political decision-makers.

The webinar had four interesting talks, building the story from research to approval of its product. The webinar focused on how the EU's biotechnology sector is performing, the bottlenecks, and solutions to overcome them. With growing pollution and the growing population, it is high time to invest our time and money in the biotech sector. To combat the climate crisis, to feed people, and to protect the environment, GMOs are a great solution. Unfortunately, European countries do not allow the cultivation of GMOs that have a negative impression on the public's mind. However, this scenario needs to change. When Dr. Andrew F. Roberts pointed out the public distrust, Prof. Dennis Ostwald gave a master plan on how

**The more people know about the science and safety of GMOs, the better we can implement our research to improve both human life and the environment.**

to deal with it—informing the entire society about the benefits/risks and keeping different stakeholders' concerns in mind when working with decision-makers in making rational decisions will be a great way to achieve the required change the EU needs to adopt GMOs, and that would help to attain the green deal. Dr. Elke Duwenig and Seren Kell

pointed out the history of public fear of new technology and the fact that not most people are against GMOs, only some. To inform those, discussions on how regulatory authorities and safety measures work may play a vital role. The importance of open access to research publications was also mentioned, to let Asian countries take the benefit of this technology.

Clear communication is the key to solve any problem. We need to remember that general people are the consumers, and policymakers will work in the direction of people's satisfaction. So, the more people know about the science and safety of GMOs, the better we can implement our research to improve both human life and the environment.

INDIA

## Department of Biotechnology (DBT) Releases Biotech-PRIDE Guidelines: Enabling Sharing, Access, and Storage of Data

Recent advances in various disciplines of biological research have resulted in the generation of a wealth of information, which requires integrative analysis. The enormity of data has necessitated the formulation of enabling mechanisms for effective data sharing and data driven research. To facilitate and enable the sharing and exchange of biological information and data generated through research conducted within the country, the Department of Biotechnology has released *Biotech-PRIDE (Biotech-Promotion of Research and Innovation through Data Exchange)* guidelines in conformity with the *National Data Sharing and Accessibility Policy (NDSAP), 2012*. These guidelines will be implemented through the Indian Biological Data Centre (IBDC). The guidelines have been harmonized with relevant extant norms of government and international agreements.

This guidance document is specifically applicable to high throughput and high volume data like nucleic acid and protein sequences generated by instruments like next-generation sequencers, microarrays, and mass spectrometry; biomolecular structures as determined by X-ray crystallography, Nuclear Magnetic Resonance (NMR), CryoEM, etc.; images of the whole body (like CT scans, PET scans, X-rays, and MRI images), organs and cells; and flow cytometry data. These guidelines envisage bridging other existing biological datasets/data centres with the IBDC, which will be called Bio-Grid. Sharing a wide range of large scale data advances the understanding of the molecular and biological processes. This will contribute to human health, agriculture, animal husbandry, and fundamental research and thus, will extend societal benefits.

**CALENDAR OF EVENTS**

EVENT	ORGANIZED BY	DATE	WEBSITE
<b>INDIA</b>			
Webinar 3: Enabling Policies for Genome Editing in Agriculture (part of the webinar series on Applications of Gene Editing in Sustainable Agriculture and Food Security in Asia-Pacific Region)	Asia-Pacific Association of Agricultural Research Institutions (APAARI), Korea Biosafety-Clearing House, Biotech Consortium India Limited, and Asia-Pacific Consortium on Agricultural Biotechnology and Bioresources (APCoAB)	August 18, 2021 Virtual	<a href="https://zoom.us/join/joinMeeting/register/tJAqdumsqDooGNApndwbg1Zt6ldtYcsrLM5y">https://zoom.us/meeting/register/tJAqdumsqDooGNApndwbg1Zt6ldtYcsrLM5y</a>  <a href="https://www.apaari.org/">https://www.apaari.org/</a>  <a href="https://www.biotech.co.in/en">https://www.biotech.co.in/en</a>
International e-Conference on Postharvest Disease Management and Value Addition of Horticultural Crops	ICAR-Indian Agricultural Research Institute	August 18-20, 2021 Virtual	<a href="http://www.uhsbagalkot.edu.in/">http://www.uhsbagalkot.edu.in/</a>
International Horticulture Conference – Next Generation Horticulture (NEXTGEN – HORT)	Tamil Nadu Agricultural University	September 16-19, 2021 Coimbatore	<a href="https://tnau.ac.in/news-events/">https://tnau.ac.in/news-events/</a>
Global Rice Conference	Tamil Nadu Agricultural University	September 24–25, 2021 Thanjavur, Tamil Nadu	<a href="https://tnau.ac.in/news-events/">https://tnau.ac.in/news-events/</a>
International Conference on Future Challenges and Prospects in Plant Breeding	Tamil Nadu Agricultural University	October 6-7, 2021 Coimbatore	<a href="https://tnau.ac.in/news-events/">https://tnau.ac.in/news-events/</a>
International Conference on Agricultural Genomics - Progress and Prospects	Tamil Nadu Agricultural University	October 21–23, 2021 Coimbatore	<a href="https://tnau.ac.in/news-events/">https://tnau.ac.in/news-events/</a>
<b>INTERNATIONAL</b>			
International Agriculture Innovation Conference 2021	International Association for Agricultural Sustainability and Waseda Business School	September 3-4, 2021 Tokyo, Japan	<a href="https://app.glueup.com/event/2021-international-agriculture-innovation-conference-32451/home.html">https://app.glueup.com/event/2021-international-agriculture-innovation-conference-32451/home.html</a>
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 (SCBD)	October 11-24, 2021 Kunming, China (tentative dates)	<a href="https://www.cbd.int/meetings/?thm=CPB">https://www.cbd.int/meetings/?thm=CPB</a>
Workshop on Fall Armyworm Control: Challenges and Opportunities for the Use of Biopesticides	International Centre for Genetic Engineering and Biotechnology	November 16-18, 2021 Cape Town, South Africa	<a href="https://www.icgeb.org/activities/meeting-and-courses/">https://www.icgeb.org/activities/meeting-and-courses/</a>



**SOUTH ASIA**  
BIOSAFETY PROGRAM

The South Asia Biosafety Program (SABP) is an international development program implemented in India and Bangladesh with support from the United States Agency for International Development (USAID). 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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