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BANGLADESH

Obituary Note for Dr. Md. Kamrul Islam

Dr. Rakha Hari Sarker, Country Coordinator, South Asia Biosafety Program and Professor, Department of Botany, University of Dhaka

Dr. Md. Kamrul Islam, Principal Scientific Officer of the Cotton Development Board of Bangladesh, passed away on 13 November 2024 at a private hospital in Dhaka. He is survived by his mother, wife, son, brothers, and several family members.

Dr. Islam joined the Cotton Development Board as a Scientific officer in 1993 and was promoted to the position of Principal Scientific Officer in 2022. He was very involved in the field release processes of two boll-warm resistant hybrid cotton varieties (Bt cotton) in Bangladesh in May 2023. He played a major role in developing the biosafety capacity at the Cotton Development Board and towards the various trials required for the biosafety approval for Bt cotton. Additionally, he worked with the team at the South Asia Biosafety Program (SABP) to create the Standard Operating Procedure (SOP) for the release of Bt cotton in Bangladesh.

The Cotton Development Board is deeply saddened by the loss of such a skilled and talented researcher. The SABP team wishes to express its deep gratitude to Dr. Md. Kamrul Islam for his outstanding contribution towards the development of biosafety regulatory capacity at the Cotton Development Board, as well as for his pioneering role in realizing genetically engineered cotton in Bangladesh. As a colleague and friend, he will be greatly missed.

BANGLADESH

Innovations in Biotechnology: The Rise of Bt Cotton

Silme Subha Karim, 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.

WHAT IS BT COTTON?

Bt cotton plants are transgenic, as they contain a number of foreign gene(s) that originate from the soil-dwelling bacteria called *Bacillus thuringiensis*. This bacterium has had its DNA introduced into the Bt cotton to modify the genetic makeup of plants and generate certain proteins that are detrimental to specific insects, such as harmful caterpillar pests, including tobacco budworm, beet armyworm, cotton bollworm, and many more. The Bt cotton cultivars, which are commercially available, generate either or both vegetative and crystal insecticidal proteins (Cry and Vip), which are utilized against these caterpillar pests (*Bt Cotton*, n.d.).

DEVELOPMENT OF BT COTTON THROUGH GENETIC MODIFICATION

By introducing certain foreign DNA from *Bacillus thuringiensis* bacteria into the genome of the cotton plant, biotechnologists produced Bt cotton. This DNA alteration provides a transgenic technology to control pests by enabling the plant to produce Cry proteins, which are useful against specific pests. The *Cry* genes are introgressed into high-yielding cotton cultivars by breeders at seed corporations using conventional or traditional plant breeding strategies. This strategy integrated the advantageous Cry protein gene into commercially viable cotton cultivars while maintaining key agronomic traits like yield, harvestability, and fiber quality.

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To demonstrate the safety and efficacy of this technology, the transgenic varieties are tested in field trials. China and India top the world in both adoption and acreage of Bt cotton, which has been widely used since the 1990s and now accounts for the majority of cotton production worldwide.

GLOBAL ADOPTION OF BT COTTON

Cotton accounts for around 38% of the global fiber economy, making it a crop that has substantial economic significance due to its high demand in textile manufacturing. As indicated by some reports, China is the world's leading cotton manufacturer, followed by the USA and India. One bale of cotton weighs 480 pounds, and in 2021, China, the world's largest cotton producer, harvested over 6.4 million tons of cotton (*Cotton Production by Country 2024*, n.d.). The depletion of several hundred acres of crops due to insect infestation demonstrates a significant loss for the producers, in addition to the industry, since cotton is a remarkable cash crop. 79% of the cotton produced worldwide is genetically modified. Many different countries, including the USA, Australia, China, South Africa, Argentina, Mexico, India, Indonesia, and others, cultivate Bt cotton for commercial purposes. In the USA, the very first commercial Bt cotton cultivar was introduced in 1993. In 1995, 1.8 million acres of Bt cotton were planted because this crop's compatibility and reliability were confirmed by a number of the USA's governmental bodies. Bt cotton cultivation grew significantly, increasing from 15% of US cotton acreage in 1997 to 37% by 2001. By 2024, 90% of US cotton fields were planted with genetically engineered or insect-resistant seeds (*Recent Trends in GE Adoption*, 2024).

THE TIMELINE OF THE INTRODUCTION OF BT COTTON INTO COMMERCE

- **In 1901**, the sotto (sudden-collapse) illness was originally associated with the bacteria *Bacillus thuringiensis* (Bt), as claimed by the Japanese researcher Shigetane Ishiwatari.
- **In 1911**, another scientist identified the bacterium that was responsible for killing a Mediterranean flour moth and re-established Bt. The pest was named *Bacillus thuringiensis* after the German town Thuringina, where it was originally discovered.
- **In 1915**, Berlin announced that a crystal existed inside Bt.
- **In 1920**, cultivators began to utilize Bt as a pesticide.
- **In 1956**, scientists discovered that the parasporal crystal presented the primary insecticidal function against lepidopteran pests. Expanded interest in the biological processes, crystalline structure, and fundamental mechanisms of Bt resulted from this discovery. Further studies on Bt began.
- **In 1958**, Bt was utilized for commercial purposes in the USA.
- **In 1961**, Bt was listed as a pesticide.
- **In the 1980s**, as pests grew more resistant to artificial insecticides and scientists discovered that the toxins were damaging the ecosystem, the implementation of Bt broadened. As it is organic, Bt only impacts particular insects and does not linger in the ecosystem. As a result, authorities and the commercial sector began to fund studies and research on Bt.
- **In 1995**, the potential for transferring the genetic material that encodes the crystals within a plant became achievable through technological advances in molecular biology.
- **In 1996**, Bt cotton was introduced in US agriculture.

BT COTTON PRODUCTION IN DIFFERENT YEARS IN DIFFERENT COUNTRIES

YEAR	COUNTRY	AREA *(MHa = million hectares, ha = hectares)*
2001	China	1.5 MHa
	Australia	0.1 MHa
2002-2003	India	38,038 ha
	USA	2 MHa
2004	India	100,000 ha
2005	India	1.3 MHa
	Australia	0.3 MHa
	China	3.3 MHa
	Colombia	<0.1 MHa
2007	China	3.8 MHa
	India	3.72 MHa
	USA	3.88 MHa
2009	India	8.4 MHa
	Burkina Faso	0.1 MHa
	Colombia	<0.1 MHa
2011	India	10.6 MHa
	USA	2.4 MHa
2012	India	10.8 MHa
	Pakistan	2.8 MHa
	Burkina Faso	0.3 MHa
	Myanmar	0.3 MHa
	Colombia	<0.1 MHa
	Sudan	<0.1 MHa
2014	India	11.6 MHa
	China	3.9 MHa
	Pakistan	2.9 MHa
2016	USA	3.70 MHa
	Brazil	0.79 MHa
	Mexico	0.097 MHa
	Australia	0.405 MHa
2017	India	11.4 MHa
	USA	4.58 MHa
	Brazil	0.94 MHa
	Mexico	0.110 MHa
	Australia	0.432 MHa

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YEAR	COUNTRY	AREA *(MHa = million hectares, ha = hectares)*
2018	India	11.6 MHa
	USA	5.06 MHa
	China	2.93 MHa
	Pakistan	2.8 MHa
	Brazil	1 MHa
2021	India	~12.2MHa
	USA	2.3 MHa
	China	3.2 MHa
	Brazil	1.4 MHa
2023	India	11.3 MHa
	USA	4 MHa
	China	3.3 MHa
	Bangladesh	15.3 ha

Table 1: Bt Cotton Production in Different Years in Different Countries

Between 2007 to 2009, Bt cotton was grown significantly in China, the USA, and India. In India, Bt cotton production increased dramatically, achieving 7.6 million hectares (ha) by 2008.The table above shows India cultivating Bt cotton in an area of 8.4 million hectares (MHa) by 2009, which made India the world leader in the production of Bt cotton. India remained the global leader, employing Bt cultivars on more than 95% of its cotton land (12.2 MHa) in 2023 (Table 1.1). As of 2023, India is the largest Bt cotton producer globally, cultivating approximately 12.2 MHa of Bt cotton or genetically modified cotton.

China and the USA expanded their cultivation of Bt cultivars at large levels, accounting for most of their cotton cultivars. Over 3.3 MHa of Bt cotton was grown in China, the world's second largest grower of Bt cotton. Even though China is a major contributor, India continues to produce the most Bt cotton worldwide (Table 1). Countries such as Sudan, Burkina Faso, along with Myanmar, have comparatively smaller amounts of Bt cotton production as compared with India, China, and the USA, although specific information on the lowest producers of Bt cotton are not always available.

BT COTTON APPROVALS IN BANGLADESH

The introduction of Bt cotton in Bangladesh marks a significant milestone for the country's agricultural sector. The approval by the National Committee on Biosafety (NCB) of the two Bt hybrids, JKCH 1947 Bt and JKCH 1050 Bt, on 7 May 2023, reflects a progressive step towards sustainable farming practices. With the adoption of Bt cotton in the 2023-2024 growing season, Bangladeshi farmers are poised to benefit from cultivating Bt cotton to control pests like the bollworm, leading to reduced pesticide use, better yields, and improved profitability. The adoption of Bt cotton in Bangladesh is a testament to the country's functional and well-structured regulatory framework, guided by the *Bangladesh Biosafety Guidelines* under the auspices of the Ministry of Environment, Forests, and Climate Change. The process involved active participation from the Institutional Biosafety Committee (IBC) of the Cotton Development Board (CDB), the National Technical Committee on Crop Biotechnology (NTCCB) at the Ministry of Agriculture, and its Core Committee at the Bangladesh Agricultural Research Council (BARC). Additionally, the Biosafety Core Committee (BCC) of the Department of Environment and the National Committee on Biosafety (NCB) played pivotal roles in ensuring thorough scientific evaluation and compliance with national and international standards.

The Cotton Development Board carried out field trials of these Bt cotton types at the Bangladesh Agricultural Research Institute (BARI). JK Agri Genetics, based in Hyderabad, India, is the source of the two Bt cotton types. These pest-resistant cotton cultivars are engineered to yield an insecticide that efficiently suppress bollworms, providing increased defense against these detrimental pests.

RISK ASSESSMENT OF BT COTTON

Prior to the approval of any GM crop, it is a prerequisite to go through the biosafety of the GM crop. Therefore, before open cultivation was approved, several safety issues were evaluated. The possible toxicity and allergenicity of Cry proteins, the hazards of cross-pollination and gene flow, the continuing presence of Bt proteins in the soil, and the effect on non-target organisms are considered for the safety evaluation of Bt cotton.

a. Safety of Bt Cry Proteins

Certain pests like bollworms are selectively targeted by the Cry proteins expressed in Bt cotton. These Cry proteins are produced in GM cottons as pre-protein, which gets active in target insects after exposure to the alkaline gut environment and certain midgut epithelial receptors. On the other hand, non-target organisms, such as humans and animals, have an acidic pH in the stomach (pH = 1.5) and lack receptors. Thus, the Cry proteins do not harm them. Moreover, Cry proteins break down quickly in the soil and do not have adverse effects on the environment. More than 100 years of safe Bt microbial spray application for pest management around the world provides justification for this assertion.

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b. Gene Flow and Cross Pollination

For every certified Bt crop, concerns of transgene transfer from Bt crops to associated weeds through pollen flow have been thoroughly investigated. Studies show that there is no appreciable risk of Bt *Cry* genes transferring to weedy or wild relatives of crops such as potatoes, corn, and cotton. The reasons for this low risk include habitat separation, phenological variations, and sexual incompatibility. There is no danger of gene flow to the weed *Gossypium comstocksii* in India since it is isolated from cultivated cotton, both geographically and reproductively. Furthermore, it is thought that there is very little horizontal gene transfer from Bt crops to soil microbes because *Bacillus thuringiensis* and its *Cry* genes are naturally found in the soil. Nonetheless, to minimize the gene flow, SOPs for cultivation and post-harvest monitoring are followed.

c. Bt Proteins' Fate in Soil

Due to pollen deposition, above-ground tissue disintegration following harvest, and leaching from Bt crop roots, questions have been raised about the possible effects of Bt proteins on soil microbes. According to investigations, exposure can happen through the consumption of either living or dead Bt roots or when soil-secreted proteins are consumed. However, according to regulatory evaluations, there is no expectation of Bt insecticidal proteins accumulating through the food chain as they do not bioaccumulate. Research indicates that once proteinaceous resources, such as Bt Cry proteins, are exposed to the surroundings, they are rapidly broken down by microbial, abiotic, and metabolic processes. Although some data indicate that bound proteins may bind to soil, upon elution, bound proteins are rapidly broken down by bacteria *(*Manjunath, n.d.*)*.

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d. Effect on Non-Target Organisms

There have been concerns about the exposure of non-target organisms to Bt Cry proteins from transgenic plants and possible negative consequences. Research on mice, rats, and rabbits given high doses of Cry1Ac protein did not reveal any acute toxicity, and the animals' body weight and food consumption were significantly similar to those of the control groups. According to proximate analysis, there are no significant variations in the protein, carbohydrates, ash, and moisture content in Bt cotton when compared to its non-Bt counterpart.

Biosafety studies carried out in India, according to the Department of Biotechnology, have demonstrated that Bt cotton seed meal is safe for fish, birds, cows, goats, and rabbits, with outcomes similar to control animals. Furthermore, research on the effects of Bt cotton leachate on soil microflora and creatures showed no distinctions between soils from Bt and non-Bt plants. The United States Environmental Protection Agency (EPA) concluded that, at label use rates of registered Bt active components, the toxicity and infectivity of Cry proteins to non-target animals, such as fish, birds, aquatic invertebrates, and honeybees, are negligible.

RISK MANAGEMENT OF BT COTTON

The purpose of Bt cotton insect resistance management or IRM techniques is to stop pests from becoming resistant to Cry proteins. Important factors include allowing resistance to be prolonged by gene stacking.

CASE STUDY: RISK ASSESSMENT OF MON 15985 BT COTTON IN KENYA

Discussed here is a case study of genetically engineered Bt cotton, MON 15985, which is resistant to particular lepidopteran pests, such as the African bollworm and cotton semilooper. This is often referred to as BollGard II cotton. A pair of genes from the *Bacillus thuringiensis* bacteria, *Cry1Ac* and *Cry2Ab2*, were introduced to generate this variety. These genes synthesize proteins that are nontoxic to fishes, humans, birds, and beneficial insects but hazardous to lepidopteran larvae. Two alterations led to the development of MON 15985: *Cry1Ac* (MON 531) and *Cry2Ab2* (MON 15947), which were brought together to create a stacked event that strengthened protection against pests.

With regard to food safety, feed safety, and environmental safety, MON 15985 cotton is considered as safe as traditional cotton. There are no recognized concerns related to its introduction or placement in the market. The applicant satisfied the requirements of the 2016 ruling, secured an Environmental Impact License from the National Environment Management Authority (NEMA), and accomplished National Performance Trials monitored by the Kenya Plant Health Inspectorate Service (KEPHIS) in a number of agro-ecologies.

The proposal for the release into the environment and commercialization of the MON 15985 event and its varietal equivalents for cultivation, food, feed and processing, import, export, and transit was approved by the Kenyan National Biosafety Authority (NBA) on behalf of the Monsanto Kenya, Ltd.

The approval of Bt cotton MON 15985 is conditioned on the following requirements and remains effective for ten years in Kenya:

1. Adhere strictly to all applicable national and country laws, the *Biosafety Act*, and the regulations.
2. Labeling Bt cotton commodities and seeds appropriately, in compliance with the Biosafety (Labeling) Regulations.
3. Provide the authority annual updates on the general surveillance or observations and the targeted monitoring of Bt cotton cultivars.

Bt cotton is an extensively studied biotech product that has been approved by several regulatory agencies around the world after safety evaluations compliant with their biosafety requirements. Its cultivation has spread to several nations since it was first introduced in the USA in 1996. The primary benefits of Bt cotton include reduction of loss due to pest infestation, less pesticide use, environmental friendliness, enhanced farmer earnings, and efficient bollworm control. Newer traits, including stacked transgenic technologies, are being continuously developed to provide durable resistance in the field.

CONCERN	POTENTIAL ADVERSE EFFECTS	LIKELIHOOD	RISK	RISK MANAGEMENT	CONCLUSION
Substantial Equivalence	Differences in composition compared to the conventional or traditional cotton	Unlikely	Negligible	None	Acceptable
Gene Safety	Toxicity or allergenicity of Cry proteins	Unlikely	Negligible	Post-release monitoring	Acceptable
Gene Flow	Out-crossing with wild relatives or conventional varieties	Likely	Negligible	Post-release monitoring	Acceptable
Persistence and Invasiveness	Increased fitness or invasiveness	Unlikely	Low	Agronomic practices, herbicides	Acceptable
Target Organisms	Insect resistance in bollworm	Likely	Moderate	Structured refuge, stewardship	Manageable
Non-Target Organisms	Impact on beneficial insects and biodiversity	Unlikely	Negligible	Post-release monitoring	Acceptable

Table 2: Risk Assessment Summary of MON 15985 Bt Cotton

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BANGLADESH

The Bangladesh Biosafety Portal: An Updated and Informative Online Resource to Strengthen Biosafety Compliance in Bangladesh

Dil Afroj Moni, Program Officer, South Asia Biosafety Program (SABP)

Homepage of the Bangladesh Biosafety Portal (bangladeshbiosafety.org) with main menu options visible (10 December 2024).

In order to effectively implement research and development of agricultural biotechnology activities in Bangladesh, scientists and regulators need to adhere to biosafety considerations. The Bangladesh Biosafety Portal acts as a helpful resource to understand the regulatory system in the country and the intricate interaction among the various rules, policies, SOPs, and governmental plans for the environment, agriculture, food, science, and technology.

The Bangladesh Biosafety Portal (**bangladeshbiosafety.org**) stands out as a highly informative website that offers a comprehensive collection of documents on Bangladeshi biosafety regulations. Launched in 2017 by the South Asia Biosafety Program (SABP), it provides a wealth of information and links to national and international technical resources, descriptions of the regulatory processes, and the structure and composition of Bangladesh's regulatory committees. The portal was first updated in 2021, which further enriched the portal with new information, including regulatory documents on agriculture, biodiversity, biotechnology, the environment, and food safety. In the 2021 update, SABP made a concerted effort to transform the portal into a user-friendly repository, housing essential documents for easy access by researchers and regulators. This design allows users to find all the necessary information in one platform and also provides access to similar documents from other countries, as well as international resources, facilitating biosafety research and the decision-making process.

The Bangladesh Biosafety Portal is an online resource that compiles all relevant documents on biosafety and related subjects, including the environment, biotechnology, agriculture, and food.

In 2024, SABP took another initiative to revise the portal with new information and documents. Several new resources were added to the relevant sections of the portal. One of the documents that has been added to the portal is the recently approved "*Standard Operating Procedures for Research and Release of Genome Edited Plants of Categories of SDN-1 and SDN-2 in Bangladesh*." It was approved by the Ministry of Agriculture, Government of the People's Republic of Bangladesh in December 2023, keeping in mind the potential and applications of the adoption of genome editing technology for improving plant productivity and addressing other challenges in agriculture.

Agricultural researchers can benefit from the third installment of the SABP Resource Book Series, *Frequently Asked Questions: Genome Edited Plants*, published on 4 April 2024. This document was added to the portal and featured on the homepage.

The Bangladesh Biosafety Portal is an online resource that compiles all relevant documents on biosafety and related subjects, including the environment, biotechnology, agriculture, and food. Under the biosafety regulatory documents section, one can find the *National Biosafety Policy (2024)*, which was gazetted on 22 August 2024. The Agricultural Policy Documents section contains the *National Seed Policy (2018)* in both Bangla and English, along with the *National Seed Rules (2020)*, *Bangladesh Good Agricultural Practices Policy (2020)*, and *National Agricultural Extension Act (2020)*. The Biotechnology Policy Documents section contains the most recent and final version of the draft of the *National Biotechnology Policy (2024)* and the *Action Plan of the National Biotechnology Policy (2024)*. In the Environment/Biodiversity Documents section, the *National Adaptation Plan of Bangladesh 2023-2050* was added. In the Standard Operating Procedures section, the draft version of *SOP 3: Compliance Management of Current Season Monitoring of GE Cotton* and *SOP 5: Post Harvest Management of GE Cotton* was replaced with the final versions. The Bangladesh Decision Documents section now contains the approval document for Bt cotton, which was approved in 2023.

The menu at the top of the home page links to the Agriculture & Food Systems Institute's e-learning modules, *SABP Newsletter*, and the Biosafety Research in Bangladesh Grants Program (BRBGP). The sections on Bangladesh Biosafety Regulation, International Resources, and Useful Web Links can also be accessed using this menu. The Bangladesh Biosafety

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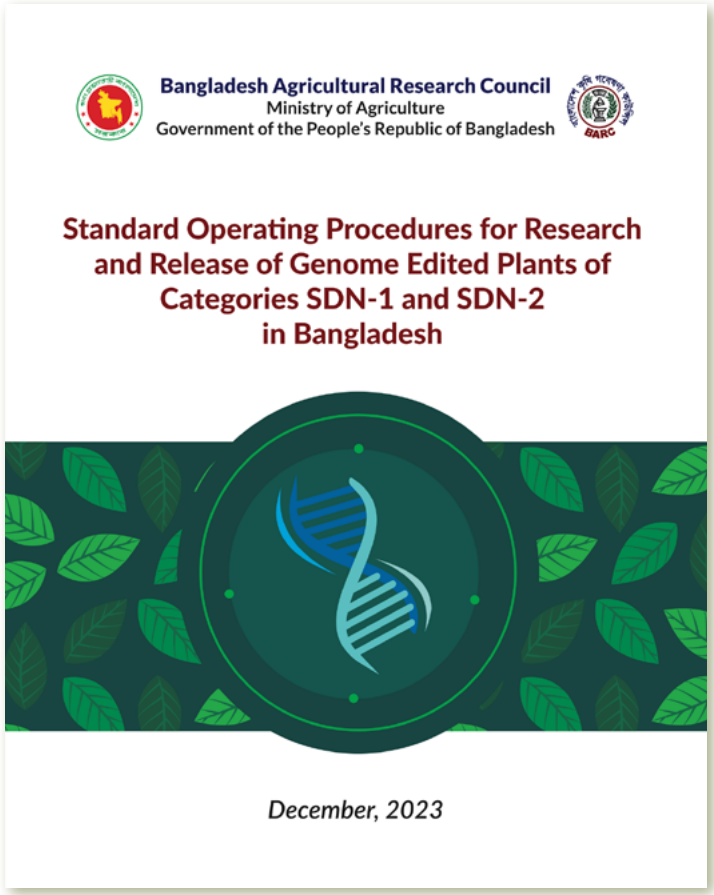
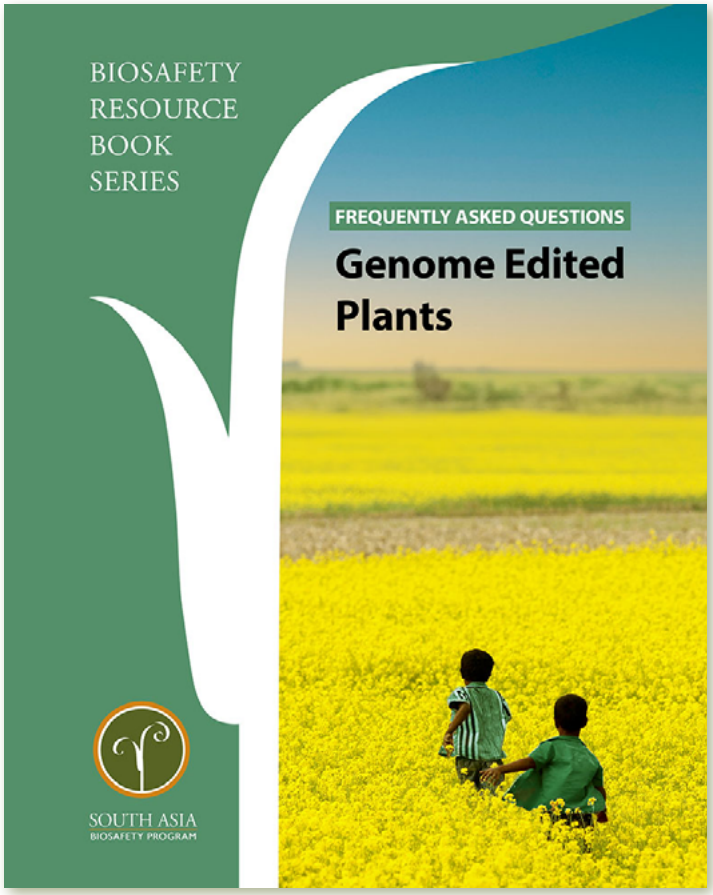
The expanded menu interface for the Bangladesh Biosafety Regulation section of the Bangladesh Biosafety Portal (10 December 2024).

Regulation tab contains two sections–Bangladesh Laws & Regulatory Documents and SABP Resource Books. The Bangladesh Laws & Regulatory Documents are further classified into ten categories, namely agriculture policy documents, biosafety regulatory documents, biotechnology policy documents, environment/biodiversity documents, environmental safety documents, food safety regulatory documents, standard operating procedures (SOPs), Bangladesh decision documents, Bangladesh regulatory processes, and Bangladesh regulatory committees. Within any of these sections, the user can see the list of all documents in one place or filter according to the categories, as well as search using relevant keywords. In each category, the user will see the list of documents, including the year and status of the document, available language(s), and a short description to provide necessary information on the specific document. The International Resources tab not only contains the international guidelines but also acts as a repository for crop biology documents from Australia, India, Canada, and the OECD. To date, 61 crop biology documents, including banana, barley, cotton, maize, and others, have been incorporated into the portal. This tab also contains a link to the comprehensive AFSI Crop Composition Database (CCDB). The Useful Web Links tab lists government organizations dealing with the biosafety of GE crops, intergovernmental organizations assisting in biosafety issues, and other organizations concerned with biosafety and biotechnology.

Ever since its establishment, the portal has functioned as a platform for sharing regulatory information in conjunction with the resources offered by SABP to enhance the capacity of stakeholders. Since the update in 2021, about 45,450 active users have accessed the portal to retrieve information (as of 10 December 2024). With the new changes, it is anticipated that the portal will help regulators and researchers improve compliance and advance agricultural biotechnology in Bangladesh.



Cover of the Standard Operating Procedures for Research and Release of Genome Edited Plants of Categories of SDN-1 and SDN-2 in Bangladesh.



Cover of Frequently Asked Questions: Genome Edited Plants

INDIA

Synthetic Biology, Gene Drives, and Digital Sequence Information: Outcomes from COP 16 and COP-MOP11

Dr. Vibha Ahuja, Chief General Manager, Biotech Consortium India Limited

16th Meeting of the Conference of the Parties (COP 16) to the Convention on Biological Diversity (CBD) Stock-Taking Plenary in Cali, Colombia (31 October 2024).
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The Sixteenth Meeting of the Conference of the Parties to the Convention on Biological Diversity (COP 16) and concurrent meetings of its two protocols, the Cartagena Protocol on Biosafety (COP-MOP11) and Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization (COP-MOP5), were held from 21 October-1 November 2024 in Cali, Colombia. The key outcomes on three topics relevant to the biotech sector—synthetic biology, gene drives, and digital sequence information—are summarized in this article.

SYNTHETIC BIOLOGY

Recognizing synthetic biology as a unique opportunity in relation to the three fundamental objectives of the Convention on Biological Diversity (CBD) and in implementing the Kunming-Montreal Global Biodiversity Framework (KMGBF), discussions included consideration of its potential benefits while considering the risks. A new thematic action plan will be developed by an expert group to help address the capacity-building, technology transfer, and knowledge-sharing needs of the Parties and indigenous peoples and local communities (IPLCs). To address inequity in the participation of developing countries in the synthetic biology field, capacity-building initiatives will help countries assess and apply synthetic biology technologies, with an aim to foster innovation while safeguarding biodiversity.

GENE DRIVES

A new voluntary guidance on assessing the risks posed by living modified organisms (LMOs) containing engineered gene drives was agreed by the Parties. The new guidance prioritizes scientific transparency and accuracy in risk assessments, an essential step toward unified safety standards for managing LMOs worldwide. The new guidance materials bring together the best available scientific resources and guidance materials available for environmental risk assessment while also emphasizing the precautionary approach. The voluntary nature of these guidelines allows individual countries to tailor assessments to national contexts, considering ecological variables unique to their environments.

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DIGITAL SEQUENCE INFORMATION

Discussions at COP16 focused on advancing the operationalization of the multilateral mechanism, including a global fund, to share the benefits from uses of digital sequence information (DSI) on genetic resources more fairly and equitably. This decision addresses how industries benefiting from DSI, such as industry sectors including pharmaceuticals, biotechnology, animal and plant breeding, etc., should share those benefits with developing countries and indigenous peoples and local communities (IPLCs).

It was agreed that the "Cali Fund" should be set up and that large companies and other major entities benefiting commercially from the use of DSI should contribute based on a percentage of their profits or revenues. It was agreed that academic, public research institutions, and other entities using DSI but not directly benefiting should be exempt. Funds will be used to support the implementation of the "Global Biodiversity Framework," and developing countries will benefit by using a large part of this fund, according to the priorities of those governments. At least half of the funding is expected to support the self-identified needs of IPLCs, including women and youth within those communities, through governments or by direct payments through institutions identified by IPLCs. Some funds may support capacity building and technology transfer. Monitoring and reporting is an important component of the agreed mechanism.

Further Reading

What COP 16 Has Delivered: **https://www.cbd.int/article/agreement-reached-cop-16**
Decision Documents: **https://www.cbd.int/meetings/COP-16**

New Biological Diversity Rules 2024: Key Updates and Implications

Dr. Suhas Nimbalkar, Partner & Consultant - IP & Regulatory Affairs, eitimo Ventures LLP
Dr. Vibha Ahuja, Chief General Manager, Biotech Consortium India Limited

The *Biological Diversity Rules, 2024*, follow the recent amendments to the *Biological Diversity Act, 2002*, which came into force in April 2024. These amendments, including the *Biological Diversity (Amendment) Act, 2023*, seek to ensure that India's biological resources are used sustainably while benefiting from innovations in biotechnology and related fields. These updated regulations will come into effect on 24 December 2024, which is 60 days after their notification in the *Official Gazette* (G.S.R.665(E), 22 October 2024). This article details the key highlights of the *2024 Biodiversity Rules.*

The *Amended Biological Diversity (BD) Rules, 2024* provide much-needed clarity on the implementation of the amended *Biological Diversity Act.* Further clarity and sector-specific solutions would be required to realize smooth implementation of the rules.

KEY CHANGES INTRODUCED IN THE 2024 BIODIVERSITY RULES

Updating of the Online Application Portal: The *2024 Rules* introduced many more forms for seeking approvals through a centralized online platform for submitting applications to the National Biodiversity Authority (NBA), and hence, the portal will need upgrades and revamping.

Streamlined Access Process: Individuals and organizations seeking to access biological resources for commercial utilization, as well as for research or bio-surveys, must now submit their applications through the new online portal using the applicable Forms.

Emphasis on Transferring/Sharing Research Results: The *Amended Act 2023* places more emphasis on the transfer of information to entities falling under Section 3(2), i.e., foreign-controlled entities. Hence, for those wishing to transfer research results based on biological resources from India to foreign entities, the application process has been updated and categorized to distinguish them by the purpose for which such information (i.e., the results of the research) will be used. The *2024 Rules* introduces the following four new forms for these different scenarios:

- Form 3: For sharing or transferring results of research for commercial or non-commercial purposes.
- Form 4: For registration of a transferee intending to use the results for further research.
- Form 5: For commercial utilization of research results by the transferee.
- Form 6: For the transferee's use of research results to secure intellectual property rights (IPR).

Prior Approval for Intellectual Property (IP) Protection: The *2024 Rules* now specify the procedure for obtaining prior approval from the NBA before filing for intellectual property protection. The procedures are different for Indian entities (Section 7) and foreign entities (Section 3(2)). The procedure is divided into three categories:

- For foreign entities: Prior approval required before granting IPR.
- For Indian entities: (1) Registration with NBA for IPR acquisition and (2) Approval from NBA for the commercialization of IPR thus obtained.

Monitoring and Regulation of Foreign Biological Resources: The new rules also bring some clarity on the measures for monitoring the use of biological resources or associated traditional knowledge obtained from foreign countries within India. The Rules prescribe that anyone utilizing the bioresources obtained from outside India need to declare the same to the NBA in Form10.

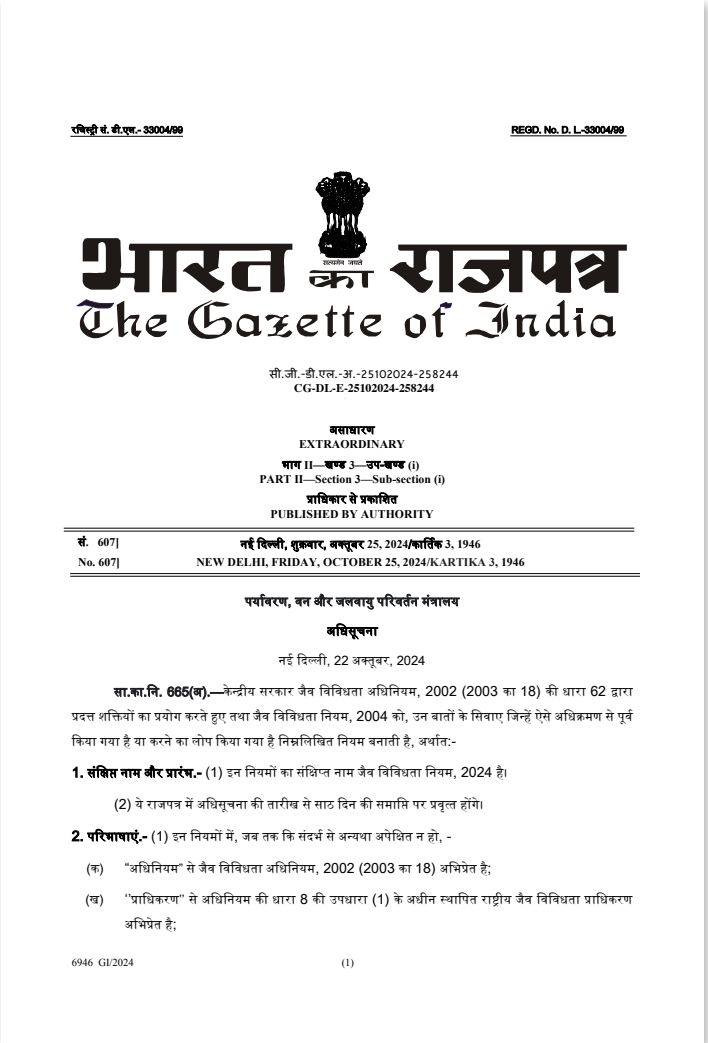
Exemption for Cultivated Medicinal Plants: A new provision now allows entities to claim exemption for accessing cultivated medicinal plants, providing clarity on who and what qualifies for an exemption under the rules. However, this exemption is conditional on obtaining certification from the Biodiversity Management Committees (BMCs), which are tasked with issuing such approvals.

Decriminalization and Push for Regularization of Past Violations: The *Amended Biological Diversity (BD) Rules* introduce a provision for the decriminalization of past violations, encouraging the regularization of non-compliance with biodiversity regulations that occurred before the enforcement of the updated rules.

Implications for Entities Accessing Information on Bioresources to Seek IPR: Under the new *Biological Diversity (BD) Rules, 2024*, entities seeking to access research results related to Indian biological resources will face additional obligations, particularly when it comes to the use of digital sequence information (DSI) in inventions for obtaining intellectual property rights (IPR). Entities will now be required to comply with specific regulations and seek approval from the NBA before utilizing Indian biological resources or DSI in their inventions.

Procedural Implications for Accessing Indian Biological Resources: Key procedural changes under the new rules that will impact how entities operate include:

- The introduction of new forms for registration and approval, each associated with specific activities.



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भारत का राजपत्र
The Gazette of India

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असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 607] नई दिल्ली, शुक्रवार, अक्तूबर 25, 2024/कार्तिक 3, 1946
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पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय

अधिसूचना

नई दिल्ली, 22 अक्तूबर, 2024

सा.का.नि. 665(अ).—केन्द्रीय सरकार जैव विविधता अधिनियम, 2002 (2003 का 18) की धारा 62 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए तथा जैव विविधता नियम, 2004 को, उन बातों के सिवाए जिन्हें ऐसे अधिक्रमण से पूर्व किया गया है या करने का लोप किया गया है निम्नलिखित नियम बनाती है, अर्थात:-

1. संक्षिप्त नाम और प्रारंभ.- (1) इन नियमों का संक्षिप्त नाम जैव विविधता नियम, 2024 है।

(2) ये राजपत्र में अधिसूचना की तारीख से साठ दिन की समाप्ति पर प्रवृत्त होंगे।

2. परिभाषाएं.- (1) इन नियमों में, जब तक कि संदर्भ से अन्यथा अपेक्षित न हो, -

(क) "अधिनियम" से जैव विविधता अधिनियम, 2002 (2003 का 18) अभिप्रेत है;

(ख) "प्राधिकरण" से अधिनियम की धारा 8 की उपधारा (1) के अधीन स्थापित राष्ट्रीय जैव विविधता प्राधिकरण अभिप्रेत है;

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Cover page for the the Biological Diversity Rules, 2024 in the Gazette of India.

Continued on page 9

Continued from page 8

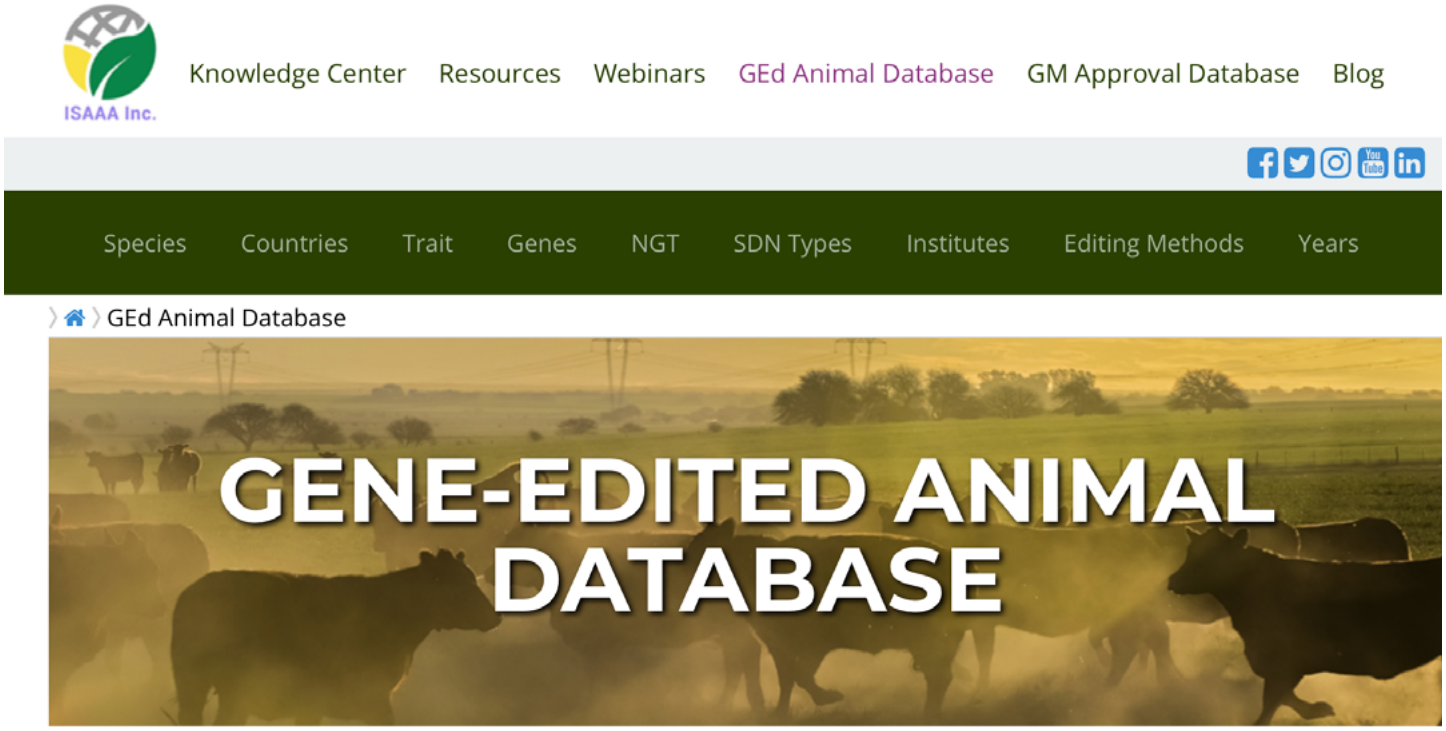
- Fee structures for submitting applications and forms have been updated, ensuring that the process is financially supported.
- Timelines have been specified for responding to queries raised by the regulatory authorities and actions for not honoring the timelines have also been clearly spelled out.
- Adjudicating officer and violations: Under the *BD Rules, 2024*, violations of Sections 3, 4, 6, and 7 of the *Biological Diversity Act* are required to be placed before an adjudicating officer, who holds the powers of a civil court to determine penalties.

The *Amended Biological Diversity (BD) Rules, 2024* provide much-needed clarity on the implementation of the amended *Biological Diversity Act*. Further clarity and sector-specific solutions would be required to realize smooth implementation of the rules.

RESOURCE

Gene-Edited Animals for Agricultural Applications Database

Dr. Vibha Ahuja, Chief General Manager, Biotech Consortium India Limited



Landing page for the Gene-Edited Animals for Agricultural Applications Database (10 December 2024).

The *Gene-Edited Animal Database (GEAD)*, available through the International Service for the Acquisition of Agri-biotech Applications (ISAAA), provides detailed information about animals developed through gene editing for agricultural applications based on the scientific report titled *New Genomic Techniques (NGT) in Animals and Their Agri/Food/Feed Products* (Van Eenennaam A.L. 2023. New Genomic Techniques (NGTs) Animals and their Agri/food/feed products. EFSA supporting publication 2023: 20(9):EN-8311. 82 pp. doi:10.2903/sp.efsa.2023.EN-8311).

GEAD presents 16 entries of gene-edited animals that have undergone the regulatory process and 192 entries that did not go through the regulatory process.

As of September 2024, GEAD presents 16 entries of gene-edited animals that have undergone the regulatory process and 192 entries that did not go through the regulatory process. The regulatory documents are included in the database based on publicly available English (or translatable) decision documents of each approving country.

Some of the key features of the GEAD include:

User-Friendly Interface: Web design for ease of access and navigation across different devices and screen sizes using a phone, tablet, or laptop.

Search Engine Optimization (SEO)-Enhanced Content: Database content designed to rank higher in search engine results through strategic use of keyword prominence and proximity, keyword links, accordion navigation, and breadcrumbs, among others.

Advanced Search and Filtering Options: Database entries can be narrowed down based on specific criteria, such as species, country, trait category, target gene, NGT used, SDN type, institute or developer, editing method, year, and foreign DNA, if present.

Comprehensive Data Collection: Information sourced from a scientific report and regulatory documents, ensuring the accuracy and reliability of the database.

The database can be accessed at **https://www.isaaa.org/animalbiotechdatabase/default.asp**

CALENDAR OF EVENTS

EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
International Conference on Plant Health Asia: Research Priorities and Partnerships	Vignan's Foundation for Science, Technology & Research (VFSTR), Asia-Pacific Association of Agricultural Research Institutions (APAARI), and EUPHRESCO III: A Global Network for Phytosanitary Research Coordination	17-18 December 2024 Guntur	https://www.apaari.org/international-conference-on-plant-health-asia-research-priorities-and-partnerships/
AGRI PITCHFEST 2.0	Tamil Nadu Agricultural University	30 December 2024 Coimbatore	https://tnau.ac.in/news-2/
National Symposium on Hybrid Technology for Enhanced Crop Productivity	Trust for Advancement of Agricultural Sciences (TAAS)	8-10 January 2025 New Delhi	https://www.taas.in/ForthcomingEvents.aspx?id=46
International Conference on Trailblazing Trends in Sustainable Climate Resilient Precision Agriculture Through Artificial Intelligence and Remote Sensing	Centre of Excellence on Soil & Water Management Research Testing and Training Centre at Junagadh Agricultural University	23-24 January 2025 Junagadh	https://www.ictpairs.in/
ICAR-Sponsored Winter School: Frontier Technologies in Crop Improvement, Production, and Extension for Horticultural Research & Its Industrial Application	Indian Council of Agricultural Research (ICAR) Central Potato Research Institute	12 February-4 March 2025 Shimla	https://cpri.icar.gov.in/
International Conference: One Health Perspectives in Global Plant Protection Research	Tamil Nadu Agricultural University	19-21 February 2025 Coimbatore	https://tnau.ac.in/news-2/
National Conference-cum-Workshop on Sustainable Biotech Solutions for Global Challenges	Jamia Hamdard University	19-21 February 2025 New Delhi	http://jamiahamdard.edu
XVII Agricultural Science Congress	National Academy of Agricultural Sciences and G B Pant University of Agriculture & Technology	20-22 February 2025 Pantnagar	http://www.17asc2025.in/ https://www.gbpuat.ac.in
Indian Seed Congress 2025: Emerging Technologies - Propelling Seed Revolution	National Seed Association of India	23-25 February 2025 New Delhi	https://isc.nsai.co.in/
Second International Conference on Biological Control: Biocontrol Contributions to One Health (2icbc2025)	Society for Biocontrol Advancement (SBA) and the ICAR–National Bureau of Agricultural Insect Resources	25-28 February 2025 Bengaluru	https://www.nbair.res.in/

SOUTH ASIA BIOSAFETY PROGRAM

The South Asia Biosafety Program (SABP) is an international development program implemented in India and Bangladesh by the Agriculture & Food Systems Institute (AFSI). 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.

Agriculture & Food Systems Institute

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