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### **Report Highlights:**

Bangladesh is pursuing advanced biotechnological crop research. In June 2023, the Bangladesh Academy of Science submitted a “Standard Operating Procedures for Research and Release of Genome Edited Plants of Categories SDN-1 and SDN-2 in Bangladesh” to the Bangladesh Agricultural Research Council, Ministry of Agriculture. This SOP is currently under review by the Ministry of Agriculture. Additionally in 2023, the Cotton Development Board released two bollworm resistant hybrid Bt cotton varieties for limited cultivation. Scientists from various organizations are engaged in developing climate resilient gene transferred and gene edited rice, eggplant, tomato, and potato varieties.

## **Executive Summary:**

Bangladesh is advancing towards the recognition of innovative biotechnology. In June 2023, a Bangladesh Academy of Science lead expert team submitted a “Standard Operating Procedures for Research and Release of Genome Edited Plants of Categories SDN-1 and SDN-2 in Bangladesh” to the Bangladesh Agricultural Research Council, Ministry of Agriculture (MOA). The MOA is currently conducting stakeholder meetings and is reviewing the SOPs.

Ten years after releasing the first Bt Brinjal variety in Bangladesh, the Cotton Development Board received approval for two bollworm resistant hybrid Bt cotton varieties. Bangladesh officials, regulators, and scientists are showing strong interest in modern science-based crop research.

The public research institutions and universities of Bangladesh are making continued progress in cultivating climate resilient crops through precision biotechnology. Even though the vitamin A enriched Golden Rice has been waiting for regulatory approval for six years, rice scientists have initiated more research to develop climate smart biotic and abiotic stress resistant rice varieties. The research for beta carotene-fortified eggplant, and leaf curl virus resistant tomato and the confined field trials for developing late blight resistant potato are progressing under the supervision of biosafety regulators.

However, no national or international life science corporations have submitted applications for the authorization of any events for commercial use. The uncertainty of government approval for Golden Rice, the delay in the approval process due to the limited capacity of the government’s biosafety regulatory authority, and lack of awareness of the importance of approval and commercial use of GE products are the main factors preventing local industry from pursuing transboundary movement and commercial use approval. The research and development of animal and microbial biotechnology in Bangladesh is underdeveloped.

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### List of Acronyms

BARI	Bangladesh Agriculture Research Institute
BCC	Biosafety Core Committee
BG	Biosafety Guidelines
BPH	brown planthopper
BRRRI	Bangladesh Rice Research Institute
BSO	Biological Safety Officers
BSTI	Bangladesh Standardization and Testing Institute
Bt	Bacillus thuringiensis
CDB	Coton Development Board
CFT	Confined Field Trial
Codex	Codex Alimentarius
CPB	Cartagena Protocol on Biosafety
CS	Certified Seed
DU	University of Dhaka
ERA	Environmental Risk Assessment
FBC	Field Level Biosafety Committee
GE	Genetically Engineered
GI	Glycemic Index
IBC	Institutional Biosafety Committee
IPPC	International Plant Protection Convention
JKAL/ JKAGL	JK Agri Genetics Limited
LMOs	Living Modified Organisms
MAB	Marker Assisted Backcross
MDHAR	Monodehydroascorbate reductase
MOA	Ministry of Agriculture
MOEFCC	Ministry of Environment, Forest, and Climate Change
MOFL	Ministry of Fisheries and Livestock
MOH	Ministry of Health
NBF	National Biosafety Framework
NIB	National Institute of Biotechnology
NTCCB	National Technical Committee on Crop Biotechnology
NTCFLB	National Technical Committee on Fisheries and Livestock Biotechnology
NTFBB	National Task Force on Biotechnology of Bangladesh
RIB	Refuge in Bag
SBE	Starch branching enzymes
SP	Separate Pack
TGMS	Thermo-sensitive Genic Male Sterile
TLS	Truthfully labeled seed
ToLCV	Tomato Leaf Curl Virus
USAID	U.S. Agency for International Development

## CHAPTER 1: PLANT BIOTECHNOLOGY

### PART A: PRODUCTION AND TRADE

#### a) PRODUCT DEVELOPMENT:

The Cotton Development Board (CDB), the Bangladesh Agricultural Research Institute (BARI), the Bangladesh Rice Research Institute (BRRI) and National Institute of Biotechnology (NIB) are the leading advanced crop biotechnology research organizations in Bangladesh. Public universities, including the University of Dhaka (DU), are also conducting limited genetically engineered (GE) biotechnology research.

#### *Cotton*

The Cotton Development Board's (CDB) application to release the hybrid GE *Bacillus thuringiensis* (Bt) Cotton hybrid varieties JKCH 1947 Bt and JKCH 1050 Bt, developed by JK Agri Genetics Ltd. (JKAL or JKAGL), India, was approved by the National Committee on Biosafety (NCB) on May 31, 2023.

In crop year 2023-24, the CDB started limited cultivation for demonstration trials of two Bt cotton varieties on 138 farmers' plots (0.25 acres/plot) and 30 on farm research plots (0.11 acre/plot) covering a total 37.8 acres located in 13 cotton production zones and five cotton research centers; Jashore, Chuadanga, Kushtia, Jhenaidah Rangpur, Bogura, Rajshahi, Thakurgaon, Dhaka, Mymensingh, Khagrachari, Bandarban, Rangamati, Gazipur, and Dinajpur districts..

After a successful confined field trial (CFT) in a single location in December 2020, the CDB received approval in September 2021 to continue with multilocation CFTs. Based on the success of CFTs, the CDB's Institutional Biosafety Committee (IBC) and the National Technical Committee on Crop Biotechnology (NTCCB) recommended the field release of JKCH 1947 Bt and JKCH 1050 Bt in 2022.

**Table 1: Yield and Yield Contributing Characters of Bt cotton and Non-Bt cotton**

Variety	Plant height (cm)	Boll per Plant (Number)	Individual Boll Weight (g)	Seed Cotton Yield (g/plant)
JK 1947 Bt	105.9	4.9	4.0	19.6
JK 1050 Bt	123.2	8.7	3.15	27.4
CB-9 (non-Bt)	99.3	2.75	4.07	11.2

Source: Cotton Development Board

The official approval of Bt cotton's limited release for cultivation at the field level was notified with conditions issued by Ministry of Environment, Forest and Climate Change (MOEFCC), on May 31, 2023 (see Appendix A).

#### *Eggplant*

BARI was the first public institute to release four GE *Bacillus thuringiensis* (Bt) eggplant (brinjal) (Bangla name "begun") varieties in Bangladesh in 2013.

BARI and Maharashtra Hybrid Seeds Company Limited signed an agreement for technical cooperation for the introgression of the *CryIAc* gene in two popular eggplant varieties: BARI Begun-10, and BARI Begun-11. These two events are helping develop wilt tolerant and year-round Bt eggplant varieties. Maharashtra Hybrid Seeds Company is currently conducting the research and there is possibility of handing over the seed in 2024.

In 2019, the National Institute of Biotechnology (NIB) started developing beta carotene-fortified eggplant through genetic transformation by multiple genes. NIB obtained seven transgenic eggplant lines and second-generation research is going on.

### ***Tomato***

Tomatoes are one of the most important year-round vegetable crops in Bangladesh. However, tomato leaf curl virus (ToLCV) causes serious yield loss and is the biggest threat to domestic tomato production in the country. In response, BARI is leading an effort to develop a ToLCV-resistant tomato variety started in 2009. Researchers inserted two reporter genes, viz. *gusA* and *Cycle 3 gfp (gfpC3)*, into each of the binary vector backbones, using potato *Ubi3* and *CaMV35S* promoter-terminator cassettes for optimization of the tomato transformation protocol.

### ***Potato***

BARI has been working with Michigan State University since 2021 under the Feed the Future Biotechnology Potato Partnership project, funded by the U.S. Agency for International Development (USAID) to develop a late blight resistant 3R-gene GE potato variety truncated *Rpi-mcq1*, *Rpi-blb2*, and *Rpi-vnt1.1*. These three genes have been isolated from wild potatoes and inserted in farmers' preferred Diamant variety. Based on the application submitted to NTCCB in August 2022, and the NCB approval, BARI started CFTs at four research stations (Gazipur, Rangpur, Munshiganj and Chattogram) in 2023.

### ***Rice***

The Plant Breeding Division of BRRI completed the biosafety evaluation of Golden Rice line GR2E BRRI dhan29 and submitted the dossier in November 2017 to the NTCCB of the Ministry of Agriculture (MOA) for the environmental and food safety assessment. The National Committee on Biosafety (NCB) and the Biosafety Core Committee (BCC) are reviewing the dossier. The process has been delayed for more than six years without approval. For additional information on the history of Golden Rice development in Bangladesh, refer to the [2022 Agricultural Biotechnology Annual Report](#).

In addition to their work on Golden Rice, BRRI is advancing in developing first-generation CRISPR/Cas9 target gene-edited rice lines with traits to effectively fight against rice blast disease, insect-like brown planthopper (BPH), and salinity intrusion.

The research division is developing salt tolerant rice by knocking out the *OsRR22* gene. The division is also applying CRISPR/Cas9-targeted mutagenesis on the fragrance gene *BADH2* to develop more high yielding aromatic rice varieties.

With an aim to develop heat or temperature adaptive/tolerant rice variety, BRRI is developing thermo-sensitive genic male sterile (TGMS) lines employing the CRISPR/Cas9 gene editing technology to modify the gene *TMS5*. BRRI is also using CRISPR/Cas9 mediated genome editing to transform the

resistant gene OsERF922 for developing a rice blast disease resistant variety. The rice transformation research was completed in 2022 and sequencing and artificial inoculation is in progress. The scientists are also working to knock out CYP71A1 (encoding tryptamine 5-hydroxylase) by CRISPR/Cas9 to develop brown planthopper (BPH) resistant rice variety.

Scientists of the Biotechnology Division of BIRRI are involved in upgrading the most popular rice variety BIRRI dhan29 into a saline tolerant transgenic rice variety transforming with salt tolerant genes *GlyI* (*Glyoxalase I*) and *GlyII* (*Glyoxalase II*). They are also developing another salt tolerant transgenic rice variety through crossed between transgenic rice plant containing salt tolerant gene AeMDHAR (Monodehydroascorbate reductase (MDHAR)) from mangrove plant (*Acanthus ebracteatus*) and BIRRI dhan28 and BIRRI dhan29. The salt tolerant GE rice variety will be beneficial to farmers in coastal areas where sea level rise and salinity intrusion are major threats from climate change.

The development of a saline tolerant transgenic rice variety from BIRRI dhan86, BIRRI dhan87 and BIRRI dhan89 through the isolation and cloning of the most promising salt tolerant Vacuolar H<sup>+</sup> - ATPase subunit c gene (PVA1) is progressing.

A research team of the Department of Biochemistry and Molecular Biology, University of Dhaka (DU) developed some drought and salt-tolerant and high-yielding commercial rice lines from two varieties BIRRI dhan27 and BIRRI dhan55 using cloning and transformation technologies. In 2022, DU signed an MOU with the National Institute of Biotechnology (NIB) for laboratory and field support for testing the performance of these lines following a biosafety protocol. In 2022, NIB applied to the NTCCB of the MOA for contained trial approval (Table 2). Finally, in September 2023, BCC recommended starting the contained trial and the application is waiting final approval from NCB.

**Table 2: NIB Events Submitted for Field Trials**

Event No.	Name of the gene	Rice Variety	Stage	Lines	Traits
1	At-HRD cDNA	BIRRI Dhan 27	T <sub>5</sub>	300	Drought and salt tolerant at seedling and reproductive-needs half water for same yield
2	PDH-AtHRD cDNA	BIRRI Dhan 27	T <sub>3</sub>	50	Drought and salt tolerant at seedling and reproductive
3	Rice SNAC1 cDNA	BIRRI Dhan 55	T <sub>5</sub>	300	Drought and salt tolerant at seedling and reproductive
4	RD29-Rice SNAC1	BIRRI Dhan 55	T <sub>4</sub>	300	Drought-inducible promoter-drought tolerant at seedling and reproductive
5	Rice G-protein βsubunit cDNA	BIRRI Dhan 55	T <sub>5</sub>	300	Salt and heat tolerant at seedling and reproductive

Rice with a low Glycemic Index (GI) value and high amylose content rice is preferred by diabetic patients to avoid a sudden rise in glucose in the bloodstream. The NIB crop biotech division is developing high amylose content and resistant starch in high-yielding rice through multiplex CRISPR/Cas9.

b. COMMERCIAL PRODUCTION:

**Eggplant**

The first GE crop in Bangladesh, Bt eggplant is in mass commercial production with seed production occurring. BARI produces breeder seeds and sells them to the Bangladesh Agricultural Development Corporation (BADC) and NGOs for distribution. BADC produces foundation seeds on its own farms and supplies to contract growers to produce certified seeds (CS) and truthfully labeled seeds (TLS). These seeds are then sold to farmers. The Department of Agricultural Extension (DAE) encourages and helps farmers cultivate Bt eggplant.

From June 2022 to July 2023, BADC produced 1019 kilograms (kg) of seed for seed dealers and farmers (Table 1). The dealer price for Bt eggplant foundation seed was BDT 1500 /kg (\$14/kg) and TLS price was BDT 1400/kg (\$13/kg). Dealers sold foundation seed to the farmers with a retail price of BDT 1700/kg (\$15/kg) and TLS seeds at BDT 1600/kg (\$14/kg).

In 2022-2023, based on the volume of seed sold to farmers, Bt eggplant was cultivated on 6885 acres of land, covering about 8.1 percent of total winter season eggplant acreage (Table 3). This is a decline of 15 percent in planted area due to decreased seed supply to the farmers. DAE didn't supply seeds to farmers in 2022-23 due to lack of funding.

**Table 3: Bt Brinjal Seed Production**

Year	Breeder Seed Produced by BARI (kg)		Foundation Seed Produced by BADC (kg)
	With project funds	With GoB funds	With GoB funds
2013-14	8.10		
2014-15	90		
2015-16	661	75	
2016-17	1068	475	284
2017-18	67	450	134
2018-19	78		179
2019-20			278
2020-21	90		213
2021-22	75		275
2022-23	498		1019

Source: Feed the Future South Asia Eggplant Improvement Partnership, USAID

Note: BADC produced Bt *Begun 4* seed for marketing

**Table 4: Seed Distributed to Farmers**

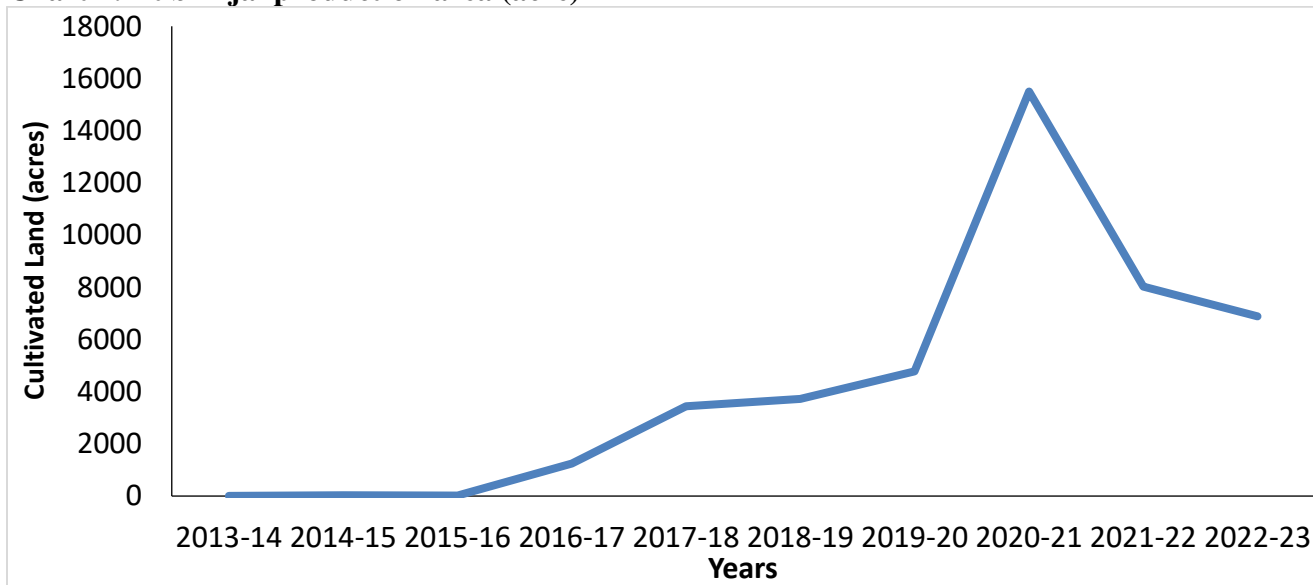
Year	Seed Distributed (kg)			
	BARI	DAE	BADC	Total



2013-14	0.6	0	0	0.6
2014-15	3.24	0	0	3.24
2015-16	2.5	0	0	2.5
2016-17	5.12	120	0	125.12
2017-18	5.81	152.02	194.3	352.13
2018-19	2.5	141.54	134	278.04
2019-20	2	178	179	359
2020-21	17.5	734	277	1029
2021-22	260	0	275	925
2022-23	185	0	274	459

Source: Feed the Future South Asia Eggplant Improvement Partnership, USAID

**Chart 1: Bt brinjal production area (acre)**



Source: Feed the Future South Asia Eggplant Improvement Partnership, USAID

Note: Acreage is estimated on the basis of volume of seed sold and seed packet weight is 10 g recommended for 0.15 - 0.20 acres of land.

**c. EXPORTS:**

The GoB has not initiated any third country application process to export GE crops.

**d. IMPORTS:**

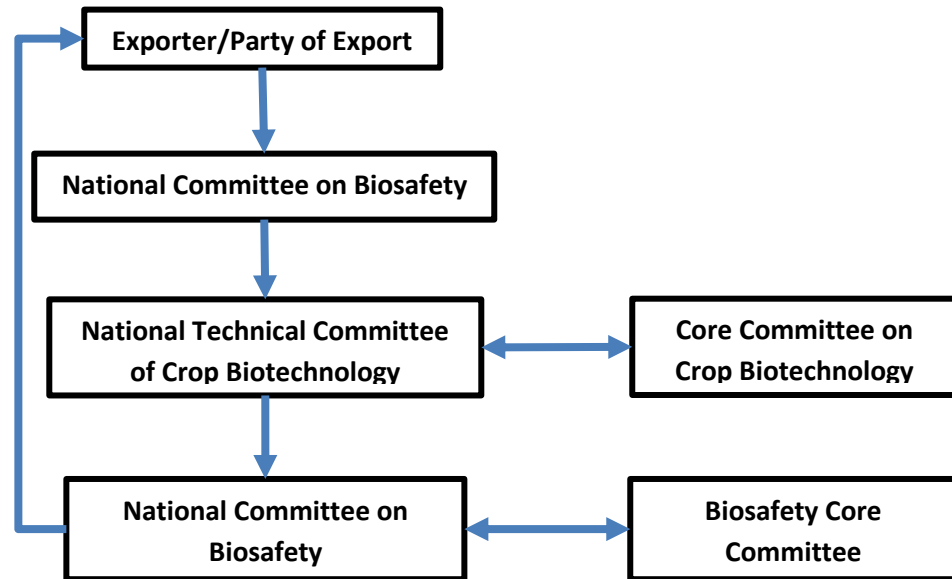
According to the [2012 Bangladesh Biosafety Rules](#), the MOEFCC must approve a GE product before it can be imported and commercially sold or cultivated within Bangladesh (see Regulatory Framework section below). Contacts have not reported any third country applications for importation for commercial food, feed use or cultivation purpose.

The 2007 Biosafety Guidelines (BG) Chapter III, notes that an exporter or the country of export needs to apply for approval to export a GE product to Bangladesh. Following Article 11 of the Cartagena Protocol on Biosafety, the 2017 User’s Guide to the Biosafety Regulatory Process for Genetically

Engineered Plants in Bangladesh, explains the process of getting import permit to import “living modified organisms” (LMOs) (in this case analogous to seeds of GM plants) for the purpose of direct use as food, animal feed or for processing. An applicant needs to apply for an import permit through the NCB of MOEFCC. Based on the final decision of Biosafety Core Committee (BCC), the NCB will issue the notification of approval for single import/multiple import/the duration of the approval.

As a signatory of the Cartagena Protocol on Biosafety (CPB), Bangladesh follows the requirement for Advanced Informed Agreement (AIA) whenever an LMO is going to be imported from another country, with the intention of releasing the LMO into the environment in the country of import. In the case where Bangladesh is the country of import, the application may come from an exporter or from the party where the export originates. The application for import of a biotech crop should be submitted to the MOEFCC NCB in the then be forwarded to the MOA for review by the NTCCB.

**Chart 2: AIA Procedure When Country is the Importer**



e. **FOOD AID:**  
Bangladesh doesn't import GE products as food aid.

f. **TRADE BARRIERS:**  
No life sciences companies have applied for GE product approval. The GoB is not encouraging local private life science companies to do GE research and apply for the release and cultivation approvals. Imported GE products require the GOB's approval, but importers of bulk commodities are not encouraged to go through the approval process for importing or use for commercial processing or marketing purposes. Labeling requirements and GE product certification (Non-transgenic certification) could create challenges for importers.

**PART B: POLICY**

a. REGULATORY FRAMEWORK:

The National Task Force on Biotechnology of Bangladesh (NTFBB), led by the Prime Minister, is the apex body of five national-level biotechnology committees that provides final approval for all biotechnology-related policies. The five national-level biotechnology technical committees cover biodiversity, biosafety, crop biotechnology, livestock and fisheries biotechnology, and medical biotechnology. Among other functions, these national committees receive and review biotechnology applications.

An unofficial translation of the 2012 Bangladesh Biosafety Rules notes that: “The Ministry of Environment and Forests shall follow the [Environmental Conservation] Act and other concerned rules formulated under the Act, if any, and the provisions of the [Biosafety] Guidelines in case of issuing approval.” Moreover, the document states, “an individual or a firm shall not import, export, buy, or sell any genetically modified organism or products or use them [without any approval from the Ministry of Environment and Forests].” Bangladesh is a signatory of the Cartagena Protocol on Biosafety, and the 2007 Biosafety Guidelines (BG), closely follows the GE application approval processes contained in the Cartagena Protocol.

MOEFCC is the lead ministry in charge of implementing the Cartagena Protocol and established the NCB as the final decision-making body for approving biotechnology applications. The NCB includes 21 members from various ministries including the MOA, Ministry of Science and Technology (MOST), Ministry of Fisheries and Livestock (MOFL), and heads of national research institutes and departments. Other important committees include:

- Biosafety Core Committee (BCC), which provides the NCB with technical comments and recommendations on GE applications and advises on other GE issues;
- Institutional Biosafety Committee (IBC), which evaluates and monitors research and development activities in research institutions; and
- Field Level Biosafety Committee (FBC), which monitors field trials for GE plants, animals, or fish.

Information on the biotechnology approval process can be found in Section 3.1.8 of the 2007 BG, entitled “Procedures and Guidelines for Obtaining Permission in Favor of Working with GMOs.” GE applications are divided into three categories: 1) GE plants, animals, and fish, 2) GE products used for food, feed, or processing, and 3) laboratory research. Each category provides information on data requirements, field trials, or other provisions. Section 4.1.4.5 of the 2007 National Biosafety Framework provides some information on how many days it will take for a decision to be made on a biotechnology application. However, the overall timeline is unclear and could be 360 days or more.

The 2007 National Biosafety Framework and 2017 User’s Guide to Biosafety Regulatory Process for Genetically Engineered Plants in Bangladesh provide information on the step-by-step approval procedure for CFTs, cultivation, and importation of “living modified organisms” (LMOs) (in this case analogous to seeds of GE plants) for direct use as food, feed, or processing.

According to the User’s Guide, a biotech application for CFTs or experimental cultivation can be submitted to the IBC and an application for the approval of importation can be submitted to

NCB/MOEFCC directly. The IBC forwards the application to the national technical committee for evaluation. Applications may be submitted at any time of the year.

The subject-oriented national technical committees review the dossiers for field trials and cultivation and submit any recommendations or concerns to the NCB. After evaluating the application, in most cases, the NCB sends the dossier to the BCC for further review and recommends a decision. The BCC reviews the application, analyzes, and evaluates any relevant information, including the data supplied by the applicant. Following the technical review report, the case is presented to the NCB, which provides the final decision.

After obtaining approval from the NCB, according to an unofficial translation of the 2012 BR, “[the] application may be filed to the Ministry of Commerce or other concerned authorities to permit import and export or use commercially under the existing import and export policies of the country.” Current import and export policies that regulate trade and may trigger additional approvals for GE products include: 2021-24 Import Policy Order; 2021-24 Export Policy Order; 2018 Plant Quarantine Rules; and 2005 Animal Quarantine Act; and 2017 Packaged Food Labeling Regulations from the Bangladesh Food Safety Authority (BFSA).

**Table 6: Ministries Involved in Biotechnology**

<b>Ministry</b>	<b>Responsibility/Role</b>
Ministry of Environment and Forest and Climate Change (MOEFCC)	<p>Leads the NCB. The Secretary of MOEFCC is the Chairperson of the NCB.</p> <p>Leads the National Technical Committee on Biodiversity.</p> <p>Houses the BCC.</p> <p>Competent national authority and focal point to implement the CPB of Biosafety.</p> <p>Lead Ministry for implementing the Bangladesh Biosafety Rules, 2012.</p>
Ministry of Agriculture (MOA)	<p>Leads the NTCCB, which evaluates and recommends a decision on GE crop applications.</p> <p>The Secretary of MOA is the chairperson of the NTCCB.</p>
Ministry of Fisheries and Livestock (MOFL)	<p>Leads the National Technical Committee on Fisheries and Livestock Biotechnology (NTCFLB), which evaluates and recommends a decision on GE animals and animal products applications.</p> <p>The Secretary of MOFL is the chairman of the NTCFLB.</p>

Ministry	Responsibility/Role
Ministry of Health (MOH)	<p>Leads the National Technical Committee on Medical Biotechnology (NTCMB), which evaluates and recommends a decision on GE medical applications.</p> <p>The Secretary of MOH is the chairman of the NTCMB.</p>

Links to Bangladesh’s regulations, policies, and other documents on biotechnology are below:

- [2007 National Biosafety Framework](#)
  - The National Biosafety Framework (NBF) is a combination of policy, legal, administrative, and technical instruments to ensure an adequate level of protection in the field of the safe transfer, handling, and use of GMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.
- [2007 Biosafety Guidelines of Bangladesh](#)
  - The Biosafety Guidelines are applicable to all research and development activities of modern biotechnology conducted in laboratories of the government research institutes, state enterprises, universities, international organizations located in Bangladesh, private companies, or non-governmental organizations. The guidelines contribute to ensuring an adequate level of protection in the laboratory, field trial, safe transfer, handling, use and trans boundary movement, transit, handling, and use of GMOs/LMOs as part of modern biotechnology.
- [2012 National Biotechnology Policy \(Bangla\)](#)
- [2012 National Biotechnology Action Plan](#)
- [2012 Bangladesh Biosafety Rules \(Proposed for Amendments\)](#)
- [2013 Bangladesh Standard for Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants;](#)
  - The 2013 Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants is consistent with Codex standards. The document notes it was written to “provide technical guidance on the safety assessment process for whole foods, food products, and foods used as ingredients, that are derived from GE plant sources.” The guideline states that the Bangladesh Standardization and Testing Institute (BSTI) has the lead in assessing the safety of GE foods derived from GE plants.
- [Work Plan for the National Biotechnology Policy](#)
- [2016 Guidelines for the Environmental Risk Assessment \(ERA\) of Genetically Engineered Plants \(Bangla\)](#)
  - Used for planning and conducting an environmental risk assessment for an open release in Bangladesh. These guidelines cover both GE plants domestically developed for cultivation and propagable forms of GE plants imported for food, feed, and processing. This will not be applicable to non-propagable GE plants for direct use in food, feed, or processing (e.g., flour, starch, crushed meal, and oil derived from GE plants), environmental introduction of non-plant genetically engineered organisms (e.g., recombinant micro-organisms), and experimental GE plants for confined field trials.

- [2017 User’s Guide to Biosafety Regulatory Process for Genetically Engineered Plants in Bangladesh,](#)
  - Provides guidance on submitting an application for confined field trials or importation of LMOs for direct use as food, animal feed or for processing or cultivation.
- [2017 Training manual on biosafety](#)
- [2018 Emergency Response Procedures for GMOs in Bangladesh](#)
- [2019 Monitoring and Enforcement Manual for GMO \(draft\)](#)
- [2019 Manual on GMO Detection and Good Laboratory Practice \(draft\)](#)
- [2019 Harmonization of Bangladesh’s Food Safety Standards with Codex Standards and other International Best Practices \(draft\)](#)
- [2020 Biosafety Policy of Bangladesh \(draft\)](#)
- [2020 Biosafety Guideline of Bangladesh \(draft\)](#)
- [2021 National Biotechnology Policy \(draft\)](#)
- [2021 National Biotechnology Policy Action Plan \(draft\)](#)
- [Guidelines for Monitoring Confined Field Trial \(CFT\) of Genetically Engineered Plants in Bangladesh \(draft\)](#)

The MOEFCC drafted a 2020 Biosafety Policy of Bangladesh, which is subject to GoB approval and the ministry has published [standard operating procedures \(SOP\)](#) for:

- SOP -1: Transport of Genetically Engineered Plant Material
- SOP-2: Storage of Genetically Engineered Plant Material
- SOP-3: Compliance Management of Current Season Field Trials of Genetically Engineered Eggplant
- SOP-3: Compliance Management of Current Season Field Trials of Genetically Engineered GE Cotton
- SOP-4: Termination/Harvest and Disposition of Genetically Engineered Plant Material
- SOP-5: Post-Harvest Management of Field Trial Sites of Genetically Engineered Eggplant
- SOP-5: Post-Harvest Management of Field Trial Sites of Genetically Engineered GE Cotton
- SOP-6: Contents, placement, and renewal of compliance document binder

**Table 7: Terms Used in Different Acts and Rules**

<b>Legal Term (in official language)</b>	<b>Legal term (in English)</b>	<b>Laws and Regulations where Term is Used</b>	<b>Legal Definition (in English)</b>
Cowligoto vabe poribortito gene	Genetically Modified Organism	2012 Bangladesh Biosafety Rules <a href="#">(Proposed for Amendments)</a>	Any creature created through application of biotechnology

Genetically Modified Organism	Genetically Modified Organism	2018 Plant Quarantine Rules	An organism synthesized or innovated by altering its genetic structure using genetic engineering
Transgenic	Transgenic	2018 Plant Quarantine Rules	The material used to make cells or microorganisms of a species by inserting one or more genetic material of different species'
Genetically Modified Food	Genetically Modified Food	2017 Packaged Food Labelling Act	If the agricultural product is produced through a change in hereditary traits, the expression "Genetically Modified Food" should be mentioned on the label of the packaging.

**b. APPROVALS/AUTHORIZATIONS:**

In 2013, four varieties of Bt eggplant seed were developed by the Bangladesh Agricultural Research Institute (BARI) and have been approved for commercial production. The varieties include: 1) BARI Bt *begun-1* (Bt Uttara); 2) BARI Bt *begun-2* (Bt Kajla); 3) BARI Bt *begun-3* (Bt Nayantara); and 4) BARI Bt *begun-4* (Bt Iswardi/ISD 006).

**c. STACKED or PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS:**

No separate regulations exist, so developers need to follow the same biosafety rules for approval.

**d. FIELD TESTING:**

The National Technical Committee on Agriculture Biotechnology and NTCFLB provide a recommendation to the NCB on whether to allow field testing for GE plants or animals. The FBC monitors the field trials and collects data during the biotechnology approval process.

**e. INNOVATIVE BIOTECHNOLOGIES:**

Although researchers have started using genome editing tools for crop variety development, Bangladesh has not yet decided to regulate innovative biotechnology. A Bangladesh Academy of Science lead expert team submitted a “Standard Operating Procedures for Research and Release of Genome Edited Plants of Categories SDN-1 and SDN-2 in Bangladesh” to the Bangladesh Agricultural Research Council, Ministry of Agriculture in June 2023. The Ministry is following the review process by consulting with the related research organization and experts.

f. COEXISTENCE:

Currently there are no specific regulations or policies that address coexistence.

g. LABELING AND TRACABILITY:

An unofficial translation of the 2012 BR states: “The box or package carrying the Genetically Modified Organism or products shall bear the complete information of its identification on them or bear labeling that states that the product is Genetically Modified Organism or that has been produced from Genetically Modified Organism, and it shall be done additionally, whatever stated in other Acts on the matter.”

Additional requirements are specified in Section 3.2.2.4 of the 2007 BG and the 2006 Product Labeling Policy. These rules are not functional for GE products because there are no GoB approved packaged or processed commodities derived from GE raw materials. Farmers usually do not sell vegetables with labels. Most consumers buy loose vegetables from the wet markets and Bt brinjal is sold without special labeling.

h. MONITORING AND TESTING:

On behalf of the NCB, the Field Level Biosafety Committee monitors approved GE crops for performance and impact on biodiversity and the environment. The country tests GE traits of plant varieties that are imported for field trials, research, and commercial release. An applicant must submit information on testing methodologies and reference materials supplied by the developer. The NCB published [SOPs](#) on the transportation, storage, harvest, and compliance management of current season monitoring, termination-harvest and disposition, and post-harvest management.

The IBC FBC and Biological Safety Officers (BSOs) ensure safe management of biosafety activities in the laboratories and in the field. Per the 2007 BG, “the IBC and BSOs will ensure that all personnel working on genetic engineering are well aware of the risks and hazards involved in their work and that the facilities and instruments governing ambient Biosafety are in order. The BSO will adopt a system of reporting laboratory accidents, occupational hazards and the subsequent emergency measures undertaken in dealing with such incidents.”

i. LOW LEVEL PRESENCE (LLP) POLICY:

Currently there are no regulations or policies that address low level presence.

j. ADDITIONAL REGULATORY REQUIREMENTS:

Variety registration is required for approved GE crop variety seed marketing. The 2007 BG and the 2012 Bangladesh Biosafety Rules need to be followed for seed registration and marketing. According to the 2018 Seed Policy of Bangladesh (Draft), all plant varieties need to be registered with the National Seed Board before commercial production and marketing. Except for controlled crops (rice, wheat, jute, potato, and sugarcane), registration does not involve additional testing.

According to Section 3.2.2.3 of the 2007 BG, the country of export must certify that a GE product used for food, processing, or feed is “fit for consumption” and either “does not contain harmful ingredients” or “is free from all kinds of harmful germs.” Moreover, the certificate should mention the “age group for which the item is eligible for consumption.”



k. INTELLECTUAL PROPERTY RIGHTS (IPR):

Bangladesh lacks effective legislation or enforcement mechanisms to protect intellectual property rights. Due to the lack of proper enforcement, IPR infringement is very common in different product markets. Bangladesh has the Department of Patents, Design, and Trademarks, and the Copyright Office. It has international membership in the World Intellectual Property Organization and acceded to the Paris Convention on Intellectual Property in 1991 and Trade-Related Aspects of Intellectual Property Rights agreements. Bangladesh has national regulations on IP, including: 2023 Patents and Designs Act; 2015 Trademark Rules; 2009 Trademark Act; 2000 Copyright Act; and 2013 Geographical Indication (Registration and Protection) Act.

l. CARTAGENA PROTOCOL RATIFICATION:

Bangladesh is a signatory to the Cartagena Protocol. It ratified the protocol in 2004. The 2012 BR and 2007 BG create a framework to implement the Cartagena Protocol.

m. INTERNATIONAL TREATIES and FORUMS:

Bangladesh is a member of the International Plant Protection Convention (IPPC) and Codex Alimentarius (Codex). Activity in these two international bodies has been limited.

n. RELATED ISSUES: No information available.

***PART C: MARKETING***

a. PUBLIC/PRIVATE OPINIONS:

There is a general recognition within Bangladesh's scientific and policy community that agricultural biotechnology is a tool to ensure food security in light of the country's growing population. Nevertheless, some local advocacy groups publicly question GE technology.

b. MARKET ACCEPTANCE/STUDIES:

Bangladeshi citizens are not well informed about GE products. The quality of publicly disseminated information is not always accurate or supported with sound science.

GE seeds for planting may experience difficulty gaining market acceptability unless proper knowledge sharing and extension activities are conducted by multinational seed companies. The lack of purchasing power in the farming sector, due to the predominance of small and marginal farmers, may also restrict the wider use of GE seeds, which farmers believe cost more than non-GE varieties.

## ***CHAPTER 2: ANIMAL BIOTECHNOLOGY***

### ***PART D: PRODUCTION AND TRADE***

#### **a. PRODUCT DEVELOPMENT:**

Bangladesh has not conducted cloning or GE animal research. The private sector is unable to engage in genetic engineering or cloning because of the lack of policies in place. The private sector has not expressed interest in GE animal research to date. The Bangladesh Livestock Research Institution may, in the future, undertake research. According to the 2012 Action Plan of the National Biotechnology Policy, the GoB expressed interest in supporting GE animal research for Bangladesh research institutions, although it is unclear whether financing is available or not.

b. **COMMERCIAL PRODUCTION:** No information available.

c. **EXPORTS:** Bangladesh does not export any GE animals or animal products.

d. **IMPORTS:** Bangladesh does not import any GE animals or animal products.

e. **TRADE BARRIERS:** No information available.

### ***PART E: POLICY***

#### **a. REGULATORY FRAMEWORK:**

The 2012 BR and 2007 BG also apply for GE animal research, commercialization, and trade. The 2006 National Guidelines for Fish and Animal Biotechnology establish objectives to promote the: 1) acquisition of knowledge of and skills in animal and fish biotechnology; and 2) development of biotechnology tools in the fields of fisheries and livestock to optimize safety and acceptability. As there are no applications submitted to the NCB for the approval of GE livestock and fisheries products, the NTCFLB is essentially inactive.

b. **APPROVALS/AUTHORIZATIONS:** No information available.

#### **c. INNOVATIVE BIOTECHNOLOGIES:**

Bangladesh has not decided to regulate innovative biotechnology, such as genome editing, in animals.

d. **LABELING AND TRACEABILITY:** No information available.

e. **INTELLECTUAL PROPERTY RIGHTS (IPR):** No information available.

#### **f. INTERNATIONAL TREATIES and FORUMS:**

Bangladesh is member of the World Organization for Animal Health and Codex. Participation in these two international bodies has been limited.

g. **RELATED ISSUES:** No information available.

### ***PART F: MARKETING***

a. PUBLIC/PRIVATE OPINIONS:

Most Bangladeshis have little or no knowledge about GE animals. For an often religiously conservative society such as Bangladesh, public perception of animal biotechnology and cloning is likely to be sensitive.

b. MARKET ACCEPTANCE/STUDIES: No information available.

## ***CHAPTER 3: MICROBIAL BIOTECHNOLOGY***

### ***PART G: PRODUCTION AND TRADE***

#### a) COMMERCIAL PRODUCTION:

Bangladesh does not commercially produce any food ingredients derived from microbial biotechnology.

#### b) EXPORTS:

Bangladesh does not export GE microbes nor any product that contains microbial biotech-derived food ingredients to the United States or any other country.

#### c) IMPORTS:

Bangladesh imports microbial biotech-derived food ingredients, but import data is not available. There is no agency directly regulating biotech-derived food ingredients. A [list of 88 product standards](#) (English) is regulated and monitored by the BSTI, where there is a possibility of having microbial biotech-derived food ingredients.

#### d) TRADE BARRIERS:

There are no known trade barriers that affect U.S. exports of microbial biotech-derived food ingredients or processed food products containing microbial biotech-derived food ingredients.

### ***PART H: POLICY***

#### a) REGULATORY FRAMEWORK:

Processed food and food ingredients for commercial production are regulated by various government agencies based on national and international standards. [BSTI](#) (Bangla) regulates food and non-food and ingredient standardizations. [BFSA](#) (Bangla) regulates food safety.

#### b) APPROVALS:

BSTI is responsible for the clearance of imported food products based on national standards, CODEX, and other international standards. Food ingredient imports for industrial food production are tested and certified by the Institute of Food Science Technology Laboratory of Bangladesh Council of Scientific and Industrial Research (BCSIR). The Customs House of the National Board of Revenue sends the imported food ingredient product sample to BCSIR for certification.

To provide a “[Release Letter for Imported Food Products](#),” BSTI follows the [September 2023, List of Bangladesh Standards on Agricultural and Food Products](#). BFSA is responsible for ensuring the quality of food falls within the regulation of the [2017 Use of Food Additives Regulations](#) (Bangla).

Documents required for customs clearance and laboratory testing:

- Updated trade license
- Letter of Credit
- Invoice
- Bill of lading (BL)
- Import Registration Certificate
- Radiation certificate (for powdered milk/food products)
- Attested Tax Identification number (TIN) certificate
- Certificate of Analysis (Chemical analysis)
- Health certificate
- Country of Origin

Note: Required documents may vary by product

c) LABELING and TRACEABILITY:

BSTI and BFSA follow the [2017 Packaged Food Labeling Regulations](#) (Bangla) for food products and food ingredients used in food industry. There are no separate labeling regulations available for food ingredients derived from microbial biotechnology.

d) MONITORING AND TESTING:

Microbial biotechnology products and ingredients are tested only when imported. BCSIR is assigned to test food ingredients and the [BSTI Food and Bacteriology Division](#) performs standard tests through following laboratories:

- Cereal and Bakery Lab
- Processed Food products and Fruit Drinks Lab
- Water and Beverages Lab
- Microbiological Lab
- Oils and Fats Products Lab
- HPLC Lab
- Instrumental Lab
- GC-MS Lab

Testable products include, sugar, chilis (whole and ground), soybean oil, mustard oil, turmeric powder, honey, suji, banaspati, red flour (atta), white flour (maida), water, carbonated beverages, cake, candy, ice cream, pasteurized milk, toffee, yoghurt, milk powders, skim milk powder, infant formula, biscuits, chanachur, noodles, instant noodles, white bread, lachsa shemai, fruit juice, fruits drinks, jam, jelly, marmalade, pickles, sauce, tomato ketchup, tomato paste, chutney, fruit syrup, fruit cordial, edible jelly, and soft drink powders.

e) ADDITIONAL REGULATORY REQUIREMENTS:

No known additional regulatory requirements.

f) INTELLECTUAL PROPERTY RIGHTS (IPR):

Please refer Chapter 1, Part B, Section k of this report.

g) RELATED ISSUES: No information available.

***PART I: MARKETING***

a) PUBLIC and PRIVATE OPINION:

The public is generally not aware of products that use microbial biotechnology ingredients.

b) MARKET ACCEPTANCE and STUDIES:

There are no studies available related to market acceptance of microbial biotechnology.

## Appendix A

**People's Republic of Bangladesh**  
**Ministry of Environment, Forest and Climate Change**  
**Environment -2 Branch**

No. 22.00.0000.073.06.020.21 (Part-1)-153

Date: 31 May, 2023

In light of the 14th meeting of the National Committee on Biosafety (NCB), application from the Bangladesh Cotton Development Board for hybrid cotton variety JKCH 1947 Bt and JKCH 1050 Bt imported from JK Agri Genetics Limited (JKAL or JKAGL) of India to release for limited field level cultivation is approved with the following condition:

- 1) In accordance with the proposal of Cotton Development Board, opinion from National Institute of Biotechnology and Department of Livestock Services and recommendation from the Ministry of Agriculture, hybrid Bt Cotton variety JKCH 1947 Bt and JKCH 1050 Bt may be released for limited cultivation at the field level under a specific action plan;
- 2) Before releasing on the field level, associated ministries and institutions must notify the NCB and BCC by devising reports on the field production planning, field biosafety management planning, emergency response planning, safety measures like: isolation distance management planning, border row management planning, techniques for protection of local and indigenous variety and wild plants;
- 3) The Cotton Development Board ought to present the NCB with the proposition to form a field level biosafety committee, so as to monitor the biosafety measures in the regions where limited cultivation will be conducted. The committee members should be the local officer of the Department of Agricultural Extension and Department of Livestock Services, Scientific officer of Cotton Development Board, and district and division level officer of the Department of Environment;
- 4) In case of refuge as separate pack (SP), for purity terms of transgenics/transgenes, Bt cotton seed pack having minimum of 90% seeds positive for each transgene. Separate refuge non-Bt. Cotton seed pack with transgene positive seeds not exceeding 5%;
- 5) In case of refuge in bag (RIB), for purity terms of transgenics/transgenes, Bt cotton RIB seed pack having minimum of 90% and maximum of 95% seeds positive for each transgene. The RIB seed packet shall contain minimum of 5% and maximum 10% non-Bt. Cotton seeds.
- 6) The non-Bt seeds provided along with Bt. Seeds either as "Refuge as Separate Pack (SP)" or as RIB shall be of a non-Bt hybrid that is an isogenic version of the corresponding "Bt hybrid or of a non-Bt. Hybrid with similar flowering period and fiber traits as that of 'Bt. Hybrid' per the label claim.

- 7) Each packet must be labeled with the description of Bt Cotton hybrid including transgene's name, and NCB's approval. Other than that, the method of sowing, pest management, suitable for which agricultural climate should be written on the packet;
- 8) Bt cotton susceptibility of bollworms must be checked regularly, and the report to NCB if resistance grows;
- 9) The Cotton Development Board must submit the research report to NCB regarding the impact of Bt cotton on non-target insects or crops;
- 10) Farmers in designated areas for limited cultivation should be trained on eco-friendly cultivation and biosafety measures. Biosafety and Bt cotton cultivation regulations guidelines or leaflets should be distributed to the concerned farmers;
- 11) If there is any risk created to the environment and public health due to Bt cotton cultivation, the applicant organization and the relevant ministry must implement emergency plans with immediate measures, so as to prevent the spread of such threats and alleviate its adverse effects. In case of any adverse environmental impact or situation arising out of release at field level, the applicant organization/institution shall be held liable under Biosafety Rules;
- 12) Annual report on Bt cotton cultivation (amount of cultivation, area covered, bollworm resistance, yield, training of farmers etc.) must be submitted to NCB by January 31 of the following year;
- 13) As per the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD), monthly report detailing the biosafety measures taken for the environment at the point of release should be submitted to the NCB and BCC for publication in the Biosafety Clearing House;
- 14) The committee may issue necessary directions and new conditions from time to time based on the report submitted to the NCB and the biosafety guidelines.

**Attachments:**

No Attachments