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**Report Highlights:**

The Government of Bangladesh has demonstrated a willingness to adopt and implement a modern agricultural policy framework and guidelines which support the safe and appropriate use of science and technology, including biotechnology, to help meet agricultural challenges. With support from the world's scientific community, Bangladesh is seeking to play a role in the advancement of biotechnology research of new genetically engineered (GE) crop varieties, including rice, potato, eggplant, tomato, wheat, and cotton. GE research on various rice traits is widening with an aim to develop climate smart varieties, which is essential for the Bangladesh rice sector. However, the regulatory process for gene edited biotechnology in Bangladesh is at times insufficient, and the scientific community is demanding revisions to the existing guidelines and rules for a more efficient approval process for future GE crops. Bangladesh's research and development of animal and microbial biotechnology continues to be limited.

**Executive Summary:**

In an effort to reduce poverty levels, Bangladesh is focused on creating a vibrant and climate smart agricultural sector. In the country's principal guiding documents: "Perspective Plan of Bangladesh (2021-2041)"; Vision 2041"; Sustainable Development Goal (SDG) 2030"; and the "8th Five Year Plan July 2020- June 2025," the Government of Bangladesh (GoB) identifies ensuring food security as a primary goal and commits to investing funding to bolster research and development to create a climate resilient agricultural sector.

Bangladesh's agricultural biotechnology sector is in a nascent stage of development, but the GoB seeks to move forward in developing and commercializing modern biotechnology products through its draft National Biotechnology Policy (2020) and draft Action Plan of the National Biotechnology Policy (2020). In order to keep pace with scientific advancements, Bangladesh needs to update its regulatory system.

*Bacillus thuringiensis* (Bt) brinjal (eggplant) is an example of Bangladesh's success in adopting modern agricultural biotechnology. Over 65,000 Bangladeshi farmers planted Bt brinjal in 2021. Farmers' acceptance of the GE crop has steadily increased since it was commercially introduced in 2013, with farmers seeing increased revenues and yields. This success also encouraged scientists and policy makers to become further involved in developing more GE varieties, including saline-tolerant, stress-tolerant, and insect resistant rice, blast-resistant wheat, late-blight-resistant potato, and bollworm resistant cotton. Farmers have also long awaited the approval of "Golden Rice" which is still pending.

While modern biotechnology is widely accepted in Bangladesh's academic and research communities, there is some, albeit limited, pause in the political community as government officials respond to consumer concerns. Transparent, science-based, and efficient biosafety laws and regulations will enable the GoB to conduct biotechnology research and development and will encourage industry to invest in the development of plant varieties that are able to meet the plant pest and plant disease challenges commonly found in Bangladesh.

The regulatory system in Bangladesh is slowly modernizing, but it still has a long way to go to achieve a coherent set of rules and regulations that are welcoming to scientific innovation, transparent, and science-based. The research and development of animal and microbial biotechnology in Bangladesh is still underdeveloped.

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## **CHAPTER 1: PLANT BIOTECHNOLOGY**

### **PART A: PRODUCTION AND TRADE**

- a. **PRODUCT DEVELOPMENT:** Bangladesh Agricultural Research Institute (BARI) and Bangladesh Rice Research Institute (BRRI) are the leading advanced crop biotechnology research organizations in Bangladesh. Public universities, such as the University of Dhaka (UD) and Bangabandhu Sheikh Mujibur Rahman Agricultural University (BSMRAU), are also conducting limited genetically engineered (GE) biotechnology research.

#### ***Eggplant***

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

Agricultural scientists in the Biotechnology Division of BARI, continue to test for the presence of inserted gene traits in commercialized Bt eggplant varieties. Scientists tested for Bt protein in the cooked fruits of Bt eggplant varieties and lines and found the *CryIAc* protein was degraded in the cooked Bt brinjal fruits (negative presence). The division started following a stewardship approach for the maintenance and purification of BT eggplant varieties. ELISA tests confirmed 100 percent presence of the Bt gene (*CryIAc*) in the Bt eggplant varieties, with the amount of Bt protein in the range of 14.36 - 25.26 parts per million. In 2021-22, the division has continued stewardship, maintenance, and breeder seed production, testing the purity of Bangladesh Agricultural Development Corporation (BADC) produced seed and selecting the parents for further Bt variety development.

BARI and Maharashtra Hybrid Seeds Company Limited signed an agreement for technical cooperation for the introgression of the *CryIAc* gene to two popular eggplant varieties: BARI Begun-10, and BARI Begun-11. These two events will help 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 2023.

As per the BARI Biotechnology Annual Report 2021, non-Bt brinjal plants were planted at the border of the Bt brinjal field as refuge, isolation distance was maintained, border crops (i.e. non-Bt) were infested by Brinjal fruit and shoot borer, but Bt brinjal plants were not infested. There was a presence of insects, including honeybees, ants, white flies, jassids, epilachna beetles, and butterfly in the Bt brinjal field, indicating that there were no adverse effects of the Bt gene on biodiversity. Observers noted normal growth, flowering, and fruiting in the Bt eggplant, and farmers noted the comparative lack of insecticide needed for the Bt fields. Finally, there was no taste difference between the Bt and non-Bt varieties.

#### ***Wheat***

A wheat blast pathogen appeared in Bangladesh in 2016, impacting production in Bangladesh’s 20 wheat growing districts. As a result, Bangladesh’s Institute of Biotechnology and Genetic Engineering and BSMRAU collaborated with the Sainsbury Laboratory and the National Institute of Agricultural Botany in the United Kingdom to start a Biotechnology and Biological Sciences Research Council project in 2017. The project’s goal is to develop a wheat blast-resistant wheat variety using CRISPR-Cas9 genome editing. The researchers successfully edited

five S-genes (negative regulators of wheat blast disease) in the genomes of wheat cv. Fielder (a British wheat variety) and barley and developed and screened more than 7,000 edited lines of wheat. Although the edited barley plants showed high resistance to wheat blast fungus, the edited wheat lines at the reproductive stage did not; the reason is under investigation. However, an international wheat blast research team led by BSMRAU successfully utilized CRISPR technology for the development of a rapid and convenient detection method for wheat blast fungus in field-infected plants, seed lots, and alternate hosts.

Scientists from Bangladesh and Australia, from the Australian Center for International Agricultural Research, the Commonwealth Scientific and Industrial Research Organisation, the University of Western Australia, and the Bangladesh Wheat and Maize Research Institute have made significant progress toward introducing salt-tolerant wheat to help farmers in Bangladesh coastal zones. They conducted a field evaluation with 20 wheat lines in three salinity-rich sites in Patuakhali, Khulna, and Satkhira districts from 2019-2022. Among the 20 lines, 12 were salt-tolerant developed through the back cross breeding method where BARI Gom 25 and BARI Gom 26 were crossed as recurrent parents with two salt tolerant Australian wheat lines as donor parents (Nax1 and Nax2 lines). Salt tolerant gene insertion was confirmed through DNA marker assisted breeding by the BARI Biotechnology Division.

Eight Nax lines were better than their parents, with Bio 12 Nax being the highest yielder. BWMRI preserved all 12 lines for future use as salt tolerant breeding materials and some will begin the variety release process.

### ***Tomato***

Tomato (*Solanum lycopersicum* L.) is 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, the Biotechnology Division of BARI is leading an effort to develop a ToLCV-resistant tomato variety. Several experiments are ongoing. 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***

The Biotechnology Division of BARI is working with Michigan State University under the Feed the Future Biotechnology Potato Partnership project, funded by the U.S. Agency for International Development to develop a late blight resistant 3R-gene GE potato variety truncated Rpi-mcql, Rpi-blb2, and Rpi-vnt1.1. These three genes have been isolated from wild potatoes and inserted in farmers' preferred Diamant variety. The division started a contained trial of the two GE events, DIA-MSU-UB015 and DIA-MSU-UB255, in April 2021. Researchers used mini-tubers of potato event 1 (DIA-MSU-UB015), event 2 (DIA-MSU-UB255), and the non-GE potato variety "Diamant" in the trial. Results revealed no significant phenotypically differences between the two events compared to non-GE Diamant and the GE Diamant events showed strong resistance, as compared to non-GE Diamant. The biotech division has applied for multi-location confined field trial (CFT) to the biosafety regulatory authority and waiting for the approval.

## ***Rice***

The Plant Breeding Division of BIRRI completed the biosafety evaluation of Golden Rice (GR) line GR2E BIRRI dhan 29. The National Committee on Biosafety (NCB) and the Biosafety Core Committee (BCC) are reviewing the dossier. The process has been delayed for five years without approval.

Here is a brief history of the GR research and approval process:

- April 2015: GR event imported from IRRI Philippines
- 2015 Aus rice season: Conducted contained trial (170 lines)
- 2016 Boro rice season: CFT (23 lines)
- 2017 Boro rice season: CFT in multiple locations (88 lines)
- 2018 Boro rice season: CFT in multiple locations (11 lines)
- 2019 Boro rice season: CFT in multiple locations (11 lines)
- November 2017: BIRRI submitted an application for the environmental and food safety assessment of GR2E Golden rice to Ministry of Agriculture National Technical Committee of Crop Biotechnology (NTCCB) and forwarded it to the NCB of the Ministry of Environment, Forest, and Climate Change (MOEFCC). The NCB then sent the application to the BCC.

CFTs of GR IR112060 GR2-E:2-7-63-2-96 during the 2016-2017 and 2017-2018 Boro rice seasons (November to April) revealed that the yield of GR2E was 13.3 percent higher than BIRRI dhan29 in 2016-2017 and approximately 3.8 percent lower than the control in 2017-2018. The selected best single line IR112060 GR2E:2-7-63-2-96 was also evaluated in CFT in eight locations during the 2018-2019 Boro rice season, with similar results. Other traits, such as plant height and weight were almost identical. There is no significant difference in insect pest infestation between transgenic golden rice and non-transgenic rice BIRRI dhan29. Therefore, BIRRI recommended that GR2E introgression line IR112060 GR2E:2-7-63-2-96 could be used for breeding advancement and variety release.

BIRRI found no sequence homology structural alerts for potential toxicity and allergenicity of the ZmPSY1 protein. Feeding trials with mice at 100 mg/kg did not result in evidence of toxicity. Nutritional composition of GR2E such as fiber, polysaccharide, ash, crude fat, protein, minerals, carotenoids, and straw composition were analyzed and revealed similarities in every aspect to the control except the carotenoid factor (in milled rice  $16.0 \pm 0.12$  mg/g). As the genes are endosperm specific, it expressed only in the grain. Food, feed, and environmental assessments for regulatory approval found that GR is as safe as regular rice. The proximity analysis did not show significant differences as compared to non-transgenic rice.

BIRRI also introgressed GR2E into BIRRI popular varieties through the marker assisted backcross technique. The introgression started in 2016 with BIRRI dhan49, BIRRI dhan62, and Boro season rice variety BIRRI dhan28, and researchers developed 94 fixed lines. Contained trials started in 2022.

The second phase of introgression was in 2019 into six varieties: transplanted Aus season rice variety BRRI dhan48; transplanted Aman season rice varieties BRRI dhan71 and BRRI dhan87; and Boro season rice varieties BRRI dhan67, BRRI dhan84, and BRRI dhan89. BC<sub>3</sub>F<sub>2</sub> in transplanted Aman was developed in 2021. The Breeding Division also introgressed high iron and zinc traits into six varieties of Aus, Aman, and Boro rice through marker assisted backcross.

Scientists of the Biotechnology Division of BRRI are involved in upgrading the most popular rice variety BRRI dhan29 into a saline tolerant transgenic rice variety with salt tolerant genes *GlyI* (*Glyoxalase I*) and *GlyII* (*Glyoxalase II*) via the agrobacterium-mediated transformation method. T<sub>4</sub> plants were confirmed by the GlyI specific primer.

The Biotechnology Division is also involved in the development of salt tolerant transgenic rice varieties by crossing transgenic rice plants containing the salt tolerant gene AeMDHAR (Monodehydroascorbate reductase) from mangroves (*Acanthus ebracteatus*) with BRRI dhan28 and BRRI dhan29. Three BRRI dhan28 plants were confirmed with gene specific primers. The salt tolerant GE rice variety will likely be widely used by Bangladeshi farmers in the coastal areas where rising sea levels are the biggest threat to production.

The Research Division is involved in developing a bacterial blight disease resistant rice variety with introgression of three blight resistant genes (Xa4, Xa13, and Xa21). The development process of a salt tolerant transgenic rice variety is also under progress through the isolation and cloning of salt tolerant gene Vacuolar H<sup>+</sup> ATPase (PVA1). In addition, in 2020-2021, the division worked on other various introgression projects.

The Biotechnology Division is also working with high yielding aromatic rice and blast resistant rice variety development through CRISPR Cas-9 and on variation identification, isolation, and cloning of various genes, including drought tolerant genes from wheat.

The Department of Biochemistry and Molecular Biology of the University of Dhaka has been characterizing high-yielding rice varieties containing the salt tolerant PDH45 gene. It tested salt tolerant transgenic rice lines with the PDH45 gene for salinity and drought tolerance at the seedling stage in a contained facility. Considering its salinity tolerance at the seedling stage, nine transgenic lines (PDH\_BR47-2, PDH\_BR47-3, PDH\_BR47-1, PDH\_BR29-2, PDH\_BR29-4, PDH\_BR36-2, PDH\_BR36-3 PDH\_BR28-1, and PDH\_BR28-3) were evaluated separately under salt stress tests at the reproductive stage. The Department signed a memorandum of understanding with the National Institute of Biotechnology (NIB) for the screening of rice transgenic lines identified through various research specially helicase lines (PDH45), G-protein, SNAC1, OsNHX1, and amiRNA-DST). The Department is preparing the regulatory dossier for CFTs at the NIB.

### ***Cotton***

The Cotton Development Board (CDB) has introduced Bt cotton in Bangladesh through a material transfer agreement with foreign seed companies. With the permission of the NCB, in October 2017, CDB signed an agreement with JK Agri-Genetics to obtain Bt cotton hybrid varieties containing a truncated *CryI*Ac Bt gene and *nptII*. With the permission of the CDB Institutional Biosafety Committee, the CDB began a contained greenhouse trial in August 2018

with two Bt hybrid cotton varieties, JKCH 1947 Bt and JKCH 1050 Bt. The GE traits of the event JKCH-1947 Bt are Lepidopteran insect resistance and antibiotic resistance, introduced via microparticle bombardment of the plant cells. BARI's Department of Entomology conducted bioassays to test the bollworm resistance of these Bt cotton hybrids. Results of the study showed that JKCH 1947 Bt and JKCH 1050 Bt were bollworm resistant.

After a successful 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 Institutional Biosafety Committee and the NTCCB recommended the field release of JKCH 1947 Bt and JKCH 1050 Bt. The CDB is waiting for a final recommendation from the BCC and final approval from NCB for the field release.

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

<b>Variety</b>	<b>Plant height (cm)</b>	<b>Boll per Plant (Number)</b>	<b>Individual Boll Weight (g)</b>	<b>Seed Cotton Yield (g/plant)</b>
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

**b. COMMERCIAL PRODUCTION:**

***Eggplant***

The first GE crop in Bangladesh has advanced toward mass commercial production. BARI is producing breeder seed, BADC is producing foundation and certified seed to sell to farmers, and the Department of Agricultural Extension (DAE) encourages and helps farmers to cultivate Bt eggplant. Bt eggplant seed production, cultivation area, and production is gradually increasing as farmers prefer it due to increased yield and lower plant protection costs (Table 2).

From June 2021 to July 2022, BARI, DAE, and BADC distributed seeds totaling in 925 kilograms (kg) (Table 3). The seed price is approximately BDT 900 – 950 /kg (\$8.78-9.22/kg) for dealers and BDT 1000 – 1070 /kg (\$9.7-10.39/kg) at retail.

In 2021-2022, approximately 27,825 farmers are producing Bt eggplant on 2,782 acres of land, covering about 3.5 percent of total eggplant acreage (Table 4), with a decline in planted area due to decreased seed production; please note that production is not yet finalized (Figure 1).



**Table 2: 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

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

Note: BADC produced Bt *Begun 2* and Bt *Begun 4* seed for marketing

**Table 3: 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	390*	275	925

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

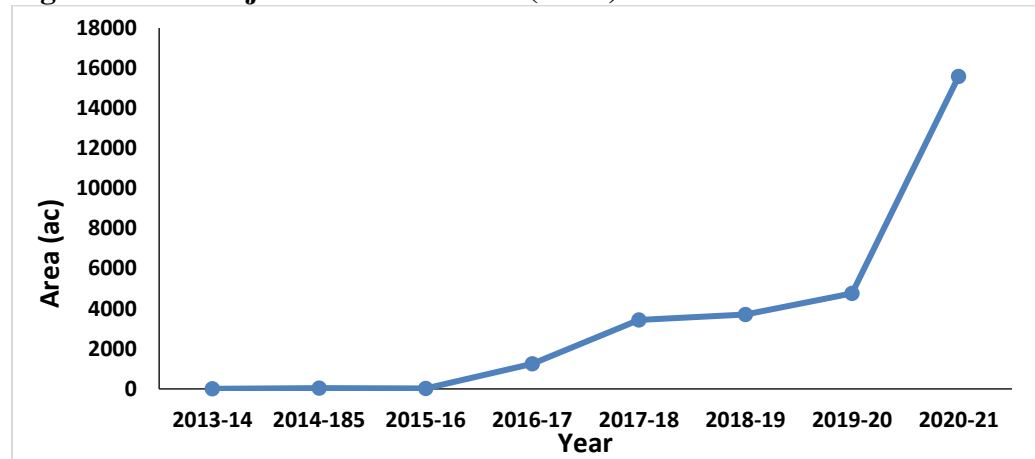
Note: \* in process

**Table 4: Bt brinjal Adoption by Farmers**

FY Year	Number of Farmer's Trials			Total Farmers (number)
	BARI	DAE	BADC	
2013-2014	20	0	0	20
2014-2015	108	0	0	108
2015-2016	250	0	0	250
2016-2017	512	6000	0	6512
2017-2018	581	7601	19,430	27,612
2018-2019	125	7077	13,400	20,602
2019-2020	100	8913	19,000	26,913
2020-2021	875	36,700	27,720	65,290
2021-2022	125		27,700	27,825

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

**Figure 1: Bt Brinjal Production Area (acres)**



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

- 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](#), 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 or feed use. The Plant Quarantine Wing (PQW) of the Ministry of Agriculture is authorized to issue import permits with the requirements of non-transgenic confirmation in the phytosanitary certificate. But PQW does not add this condition to the import permit if the importer confirms in writing that the imported product is non-transgenic.
- e. **FOOD AID:** Bangladesh imports only wheat as food aid. PQW does not require non-transgenic confirmation on the phytosanitary certificate, if the importer confirms that the importing product is non-transgenic.
- f. **TRADE BARRIERS:** The 2007 Biosafety Guidelines (BG) note that an exporter or the country of export needs to apply for GE product approval. Because life science companies apply for GE product approval, it is unclear how to initiate the process in Bangladesh. Likewise, the requirement that a country of export must legally ensure the accuracy of biotech applications adds additional confusion. Labeling requirements and other certifications (see Additional Requirements) may also create challenges.

## ***PART B: POLICY***

- a. **REGULATORY FRAMEWORK:** The agricultural biotechnology sector in Bangladesh is in a nascent stage of development, but the national government is seeking to move forward in developing and commercializing biotechnology.

**Table 5: 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.

Bangladesh has published various regulations, policies, and other documents on biotechnology including:

- [2007 National Biosafety Framework](#)
- [2007 Biosafety Guidelines](#)
- [2012 National Biotechnology Policy](#) (Bangla)
- [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 of an open release in Bangladesh. This guideline covers both GE plants domestically developed for cultivation and propagable form 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
- [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 GLP](#) (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 National Biotechnology Policy](#) (draft)
- [2020 National Biotechnology Policy Action Plan](#) (draft)
- [2020 Biosafety Guideline of Bangladesh](#) (draft)
- [Guidelines for Monitoring Confined Field Trial \(CFT\) of Genetically Engineered Plants in Bangladesh](#) (draft)

The MOEFCC is also crafting a Biosafety Policy, which is subject to GoB approval and has published standard operating procedures for:

- Transport of Genetically Engineered Plant Material
- Storage of Genetically Engineered Plant Material
- Termination/Harvest and Disposition of Genetically Engineered Plant Material
- Compliance Management of Current Season Field Trials of Genetically Engineered Eggplant
- Post-Harvest Management of Field Trial Sites of Genetically Engineered Eggplant

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.

Regarding the approval of imported and domestically developed GE products, an informal translation of the 2012 BR 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 (CPB), and the 2007 BG closely follows the GE application approval processes contained in the CPB.

- MOEFCC is the lead ministry in charge of implementing the CPB and established the NCB as the final decision-making body for approving biotechnology applications. The NCB includes 21 members from various ministries such as the Ministry of Science and Technology, Ministry of Agriculture, Ministry of Fisheries and Livestock, and heads of national research institutes and departments. Other important committees include the:
  - 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
  - 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 one of the Secretaries of a national technical committee for evaluation. Applications may be submitted at any time of the year.

The subject-oriented national technical committees review the dossier 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 informal 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. These include: 2015-18 Import Policy Order; 2015-18 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 5: 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 Chairman 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 chairman 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 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>

b. APPROVALS/AUTHORIZATIONS: Four varieties of Bt eggplant seed were developed by 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 regulations exist at this time.

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: The country has not yet decided to regulate innovative biotechnology such as genome editing in plants. However, researchers have started using genome editing tools for crop variety development, making an assessment urgent.

f. COEXISTENCE: Currently, there are no specific regulations or policies that address coexistence.

g. LABELING AND TRACABILITY: An informal 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, processed commodities derived from GE raw materials. Farmers usually do not sell vegetables with labeling. 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. 2007 BG of Bangladesh and 2012 Bangladesh Biosafety Rules should be followed for seed registration and marketing. According to the 2018 Draft Seed Policy of Bangladesh, 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 World Intellectual Property Organization and acceded to the Paris Convention on Intellectual Property in 1991 and Trade-Related Aspects of Intellectual Property Rights agreements. The country has national regulations, including: 2003 Patents and Designs Act (revised); 1911 Patents and Designs Act; 2015 Trade Mark Act (revised); 2009 Trade Mark Act and 2003 Revised; 2000 Copyright Act; and 2013 Geographical Indication (Registration and Protection) Act.

l. **CARTAGENA PROTOCOL RATIFICATION:** Bangladesh is a signatory to the CPB. It ratified the protocol in 2004. The 2012 BR and 2007 BG create a framework to implement the CPB.

m. **INTERNATIONAL TREATIES and FORUMS:** Bangladesh is a member of the International Plant Protection Convention (IPPC) and the 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:** Because there is a dearth of reliable information, many Bangladeshi citizens are not well informed. 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 apprehensions about multinational seed companies are addressed. 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 are higher priced vis-à-vis non-GE varieties.

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

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

- a. **PRODUCT DEVELOPMENT:** Reportedly, Bangladesh has not conducted cloning or GE animal research. Since the private sector has no capacity to engage in genetic engineering or cloning, the only future possibility is for public sector research. The Bangladesh Livestock Research Institution may, in the future, undertake such research efforts. 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. Because 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:** The country 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. Activity 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](#) (Bangla) 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 negatively 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 production and ingredient standardizations. [BFSA](#) (Bangla) regulates food quality.
- 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 [January 2022 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 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 per 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 see Chapter 1, Part B, Section k.
- 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.

**Attachments:**

No Attachments