

Required Report: Required - Public Distribution

Date: February 09,2020

Report Number: BG2019-0007

Report Name: Agricultural Biotechnology Annual

Country: Bangladesh

Post: Dhaka

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

Bangladesh is a role model of acceptance and advancement of modern agricultural biotechnology. As an emerging economy and developing country, Bangladesh's citizens and policy makers are aligned in the same goal of reaching a sufficient food security status to feed a population of 165 million people. With innovative biotechnology support from the world scientific community, Bangladesh is progressing gradually to initiate research and trials of new genetically engineered (GE) varieties of essential trait-based crops, such as rice, potato, brinjal (eggplant), tomato, papaya, wheat, and cotton. Bangladesh's research and development of animal biotechnology continue to be limited.

Executive Summary:

In an effort to reduce poverty levels, Bangladesh is focused on creating a vibrant and productive agricultural sector. In its *Perspective Plan of Bangladesh (2010-2021) (Vision 2021)*, which is the country's principal guiding document, the Government of Bangladesh (GOB) identifies food security as a primary goal and commits to encouraging research and development in the agricultural sector.

Bangladesh's agricultural biotechnology sector is in the nascent stage of development, but the GOB seeks to move forward in developing and commercializing biotechnology through its National Biotechnology Policy, 2012, and an Action Plan of the National Biotechnology Policy, 2014¹. At the same time, Bangladesh's regulatory framework for biotechnology has expanded greatly with the introduction of new rules and guidelines².

Bangladesh has had success in the development of GE vegetables, such as *Bacillus thuringiensis* (Bt) brinjal (eggplant). Consumers overwhelmingly accept eating the GE vegetable, as it does not test positive for presence of the Bt gene after it has been cooked. Farmers also are interested in producing the Bt eggplant, as it reduces production costs and increases yield. As a result, seed demand and supply are increasing without sellers experiencing any negative feedback. This success also encourages scientists and policy makers to become further involved in developing more GE varieties, including a saline-tolerant rice variety, wheat-blast-resistant wheat variety, and late-blight-resistant potato variety.

While biotechnology is widely accepted in Bangladesh, there are multiple local non-government organizations (NGOs) that have launched marketing campaigns against biotechnology in hopes of swaying public opinion. Nevertheless, a majority of Bangladeshi consumers see biotechnology as helpful in increasing agricultural productivity and assisting in the control of pests and diseases.

GE crops that could see approval in the near future include "Golden Rice" and three more Bt brinjal (eggplant) varieties. 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 cover all aspects of the value chain. Bangladesh is an active member of international standard setting bodies for biotechnology.

¹ World Trade Organization, Trade Policy Review, Report by the Secretariat, February 2019

² Bangladesh Biosafety Rules, 2012; the Bangladesh Standard for Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2013; the Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016; the User's Guide to Biosafety Regulatory Process for Genetically Engineered Plants in Bangladesh, 2017; and the Biodiversity Act, 2017.

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List of Acronyms

APHIS	Animal and Plant Health Inspection Services
BADC	Bangladesh Seed Development Corporation
BARI	Bangladesh Agricultural Research Institute
BB	Bacterial Blight
BBSRC	Biotechnology and Biological Sciences Research Council
BSMRAU	Bangabandhu Sheikh Mujibur Rahman Agricultural University
BCC	Biosafety Core Committee
BDT	Bangladeshi Taka (Currency)
BG	Biosafety Guidelines
BR	Biosafety Rules
BRRRI	Bangladesh Rice Research Institute
BSO	Biological Safety Officer
Bt	Bacillus thuringiensis
CDB	Cotton Development Board
CPB	Cartagena Protocol on Biosafety
DAE	Department of Agricultural Extension
FBC	Field Level Biosafety Committee
GAIN	Global Agriculture Information Network
GE	Genetically Engineered
GFSS	Global Food Security Strategy
GOB	Government of Bangladesh
IBC	Institutional Biosafety Committee
IBGE	Institute of Biotechnology and Genetic Engineering
IPR	Intellectual Property Right
JKAL	JK Agri-Genetics Ltd
LBR	Late Blight Resistant
ToLCV	Tomato Leaf Curl Viruses
MOA	Ministry of Agriculture
MoEFCC	Ministry of Environment, Forest and Climate Change
MOFL	Ministry of Fisheries and Livestock
MOH	Ministry of Health
MSU	Michigan State University
MTA	Material Transfer Agreement
NCB	National Committee of Biosafety
NIAB	National Institute of Agricultural Botany
NSB	National Seed Board
NTCCB	National Technical Committee of Crop Biotechnology
NTCFLB	National Technical Committee on Fisheries and Livestock Biotechnology
NTCMB	National Technical Committee on Medical Biotechnology
NTFBB	National Task Force on Biotechnology of Bangladesh
TCRC	Tuber Crop Research Center
UD	University of Dhaka

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) biotech research.

Eggplant:

BARI was the first public institute to release four GE *Bacillus thuringiensis* (Bt) eggplant (brinjal) (Bangla name Begun) varieties in Bangladesh in the year 2013. After confined field trials of another two Bt eggplant lines, Bt *Chega* and Bt *Islampuri*, scientists found Bt *Chega* to be preferred. Scientists proposed that Bt *Chega* variety be released into commercial production but not yet applied for variety release approval. At present, another three Bt eggplant varieties are undergoing the government approval process for release into commercial cultivation. The proposed varieties are BARI Bt *Begun-5* (Local variety Dohazari), BARI Bt *Begun-6* (Khatkhatia), and BARI Bt *Begun-7* (Singnath). The proposed varieties are under consideration for approval by the Biosafety Core Committee, and following their review, it will go to the National Committee of Biosafety (NCB) for final approval to release into limited commercial production (See policy section for more on the approval process).

Scientists of Biotechnology Division, BARI, are testing to ensure that the inserted gene traits are present (genetic purification) in the released Bt eggplant varieties and lines and also to measure gene flow in the Bt eggplant cultivation area. Detection of Bt *protein* in the cooked fruits of Bt eggplant varieties and lines (unapproved varieties) were tested by scientists and found that *Cry1Ac* protein was degraded negative. The tissue specific expression of *Cry1Ac* crystal protein (from *Bacillus thuringiensis*) in the different plant parts and seasonal abundance of *Cry1Ac* protein in Bt eggplant were analyzed. The researcher found that Bt protein concentration varied from 17.53-33.58 µg/g (Microgram/gram) (Dry Weight [DW]) irrespective of different plant parts of four Bt eggplant varieties which are above the critical level to control brinjal fruit and shoot borer effectively.

Wheat:

A wheat blast pathogen appeared in Bangladesh in 2016, impacting production in Bangladesh's 19 wheat growing districts. As a result, Bangladesh's Institute of Biotechnology and Genetic Engineering (IBGE) and Bangabandhu Sheikh Mujibur Rahman Agricultural University (BSMRAU) collaborated with The Sainsbury Laboratory and The National Institute of Agricultural Botany (NIAB) from the United Kingdom (UK) to start a Biotechnology and Biological Sciences Research Council (BBSRC) 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 5 S-genes (negative regulators of wheat blast disease) in the genomes of wheat cv. Fielder (a British wheat variety) and barley. The primary screening revealed that some of the gene edited transformants are resistant to wheat blast fungus at the seedling stage. The new variety is still in the development stage and is years away from possible commercialization.

The Biotechnology Division of BARI is also involved in DNA marker-assisted transfer of salt tolerant Nax (Nax 1 and Nax2) genes into wheat varieties BARI Gom-25 and BARI Gom-26 in collaboration with Commonwealth Scientific and Industrial Research Organization (CSIRO), Australia. The work for molecular genotyping of selected lines for confirming the presence of Nax genes are in progress.

Tomato:

Tomato (*Solanum lycopersicum* L.) is one of the most important year-round vegetable crops in Bangladesh. However, Tomato Leaf Curl Viruses (ToLCV) cause serious yield losses and are considered as the biggest threat to tomato production in the country. IN response to the viruses, the Biotechnology Division of BARI is leading an effort in the development of a tomato variety that is ToLCV-resistant. Researchers are at the process of constructing modular vectors in-house for efficient transformation of tomato plants.

Potato:

The Biotechnology Division of BARI also started late-blight-resistant (LBR) transgenic potato development in 2005 through the introgression of single RB gene into two popular potato varieties (Cardinal and Diamant). After passing a long road by doing contained, confined and multi-location confined field trials, the researchers identified vector backbone in the selected clone. Without stopping the program, the Ministry of Agriculture decided to continue the program for removal of the vector backbone from the single RB gene hybrid LBR potato clone D951 (137) through backcrossing with the recipient potato parent, Diamant. A confined field trial is planned this year with the minitubers obtained from the backcrossed seeds.

The Tuber Crop Research Center (TCRC) of BARI is working with Michigan State University (MSU) 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. Till now 10 3R-gene events have been selected as late blight resistant with a single insert of the tDNA. These 10 events were evaluated at confined field conditions at MSU to see the efficacy against *Phytophthora* isolates. The best performing two GE events DIA-MSU-UB #1 and DIA-MSU-UB #2 will be imported to Bangladesh for contained use and confined field trial. The National Technical Committee on Crop Biotechnology (NTCCB) approved the importation of these events for trial.

Papaya:

The Biotechnology Division of BARI is advancing with a target for developing Papaya Ringspot Virus (PRSV) resistant transgenic papaya and bacterial wilt tolerant transgenic brinjal varieties. No further information is currently available.

Rice:

The plant breeding division of BARI completed the biosafety evaluation of Golden Rice line GR2E BARI dhan 29. The dossier was submitted to the NCB through the National Technical Committee of Crop Biotechnology (NTCCB) on November 26, 2017 for approval of environmental release and use in food and feed under Bangladesh Biosafety Rules, 2012. The National Committee on Biosafety and Biosafety Core Committee (BCC) are still reviewing the dossier. The process has been delayed for nearly 2 years without approval.

Confined field trials of Golden Rice IR112060 GR2-E:2-7-63-2-96 during Boro rice cultivation season (November to April 2017) 2017 revealed that yield of BRR1 dhan29 (8.64 ton per hectare [t/ha]) is 0.57 t/ha higher than Golden Rice (8.07 t/ha). Other traits like plant height and weight are almost identical with slight variations. There is no significant difference in insect pest infestation between transgenic golden rice and non-transgenic rice BRR1 dhan29. Food, feed and environmental assessment for regulatory approval found that GR is as safe as regular rice. The proximity analysis didn't show significant difference in results comparing non-transgenic rice. The sixteen type of food safety assessments didn't found toxicity and allergenicity on GR rice. The assessment conclude that GR could supplement 40-50% of the estimated average requirement for vitamin A.

Scientists of the biotechnology division, BRR1 are involved in upgrading the most popular rice variety BRR1 dhan29 into saline tolerant transgenic rice variety through transforming BRR1 dhan29 with salt tolerant gene *GlyI* (*Glyoxalase I*) and *GlyII* (*Glyoxalase II*) by Agrobacterium-mediated transformation method. The plants from T₁ confirmed with both *GlyI* and *GlyII* gene specific primers. Seed from the derived line is ready for T₂ plantation.

BRR1, biotechnology division is also involved in development of 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 BRR1 dhan28 and BRR1 dhan29. Putative transformants were confirmed by PCR with gene specific primers and. Plants containing AeMDHAR were used for two backcrossing and 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 also involved in developing bacterial blight (BB) disease resistant rice variety with introgression of three BB resistant genes (Xa4, Xa13 and Xa21). The development process of salt tolerant transgenic rice variety is also under progress through isolation and cloning of salt tolerant gene *Vacuolar H⁺ ATPase (PVA1)*.

Department of Genetic Engineering and Biotechnology, Shahjalal University of Science and Technology is involved in Agrobacterium mediated transformation of PsCIPK and PsCBL genes to enhance salt and submerge tolerance in Indica rice (*Oryza sativa* L.).

With greenhouse support of the Biotechnology Division of BRR1, the Department of Biochemistry and Molecular Biology of University of Dhaka has been working to characterize high-yielding rice varieties containing the salt tolerant PDH45 gene. The PDH45 gene contained salt tolerant transgenic rice lines were tested for salinity and drought tolerance at the seedling stage in a contained facility. Considering their salinity tolerance at the seedling stage, nine (9) transgenic lines e.g. 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.

Cotton:

The Cotton Development Board (CDB) has persevered to introduce Bt cotton in Bangladesh through a Material Transfer Agreement (MTA) with foreign seed companies. With the permission of the NCB in October 2017, CDB signed MTA with JK Agri-Genetics Ltd (JKAL), India to obtain Bt cotton hybrid varieties containing truncated *Cry1Ac Bt* gene. With the permission of the Institutional Biosafety Committee of the Cotton Development Board, the CDB began a contained trial on August 7, 2018 with two Bt hybrid cotton varieties: JKCH 1947 Bt and JKCH 1050 Bt. A contained trial to test the efficacy of the introduced *Bt* varieties was successfully completed and a confined field trial was approved by National Technical Committee on Crop Biotechnology. (NTCCB). The CDB is hoping to start planting in February 2020. The goal is development of an efficient GE cotton variety which is resistant to Bollworm and Spodoptera / Armyworm.

b) COMMERCIAL PRODUCTION:

Eggplant:

The first GE crop (i.e., eggplant) in Bangladesh is advancing towards mass commercial production. The biotechnology and seed technology divisions of the BARI are producing breeder seeds. The Bangladesh Seed Development Corporation (BADC) is producing foundation and certified seed to sell to farmers. The current fiscal year (FY) 2019-2020 (July-June), BARI has a stock of breeder seed totaling in 1,513 kilogram (kg) of seed, and BADC has a stock totaling in 179 kg of foundation seed. BARI-produced seed will be distributed to farmers who are engaged in field demonstrations controlled by Department of Agricultural Extension, Ministry of Agriculture.

In FY 2019-2020, BADC is commercially selling 179 kg of Bt *Begun 2* and Bt *Begun 4* through 8,500 seed dealers. BADC sells the foundation seed to the farmers through local seed dealers (authorized listed sellers), and the price of the seed is approximately \$11.22 (USD) per kilogram (kg).

It is estimated that 20,602 farmers are producing Bt brinjal on their farms. In area coverage, it is estimated that 4.56% of 80,000 acres of brinjal are cultivated with Bt brinjal.

Table 1: Bangladesh - Bt Brinjal seed production

Year	Breeder Seed (kg) Produced by BARI		Foundation Seed (kg) Produced by BADC
	With Project fund	With GOB fund	With GOB fund
2013-2014	8.10		
2014-2015	90		
2015-2016	661	75	
2016-2017	1068	475	284
2017-2018	67	450	95 (76+58)
2018-2019	78	No Fund	179 (95+84)
Seed in Stock	1513		179

Source: Presentation of Global Food Security Strategy (GFSS), USAID in 6th Biosafety Conference, Bangladesh.

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

Table 2: Bangladesh - Bt brinjal adoption at farmers field

FY Year	Number of Farmer's trial			Total Farmers (no)
	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	19430	27612
2018-2019	125	7077	13400	20602
Total	1596	20678	32830	55104

Note: BARI – Bangladesh Agricultural Research Institute

DAE – Department of Agriculture Extension

BADC – Bangladesh Agriculture Development Corporation

Source: GFSS, USAID.

Table 3: Bangladesh – Bt brinjal adoption coverage

FY Year	Area Cultivated (acre, ac)			Total (ac)
	BARI	DAE	BADC	
2013-2014	6.66	0	0	6.66
2014-2015	36	0	0	36
2015-2016	25	0	0	25
2016-2017	21.2	1200	0	1251.2
2017-2018	95.86	1403.2	1943	3442.06
2018-2019	20.63	2335.4	1340	3696.03

Note: BARI - Bangladesh Agricultural Research Institute

DAE - Department of Agriculture Extension

BADC - Bangladesh Agriculture Development Corporation

Source: GFSS, USAID.

- c) EXPORTS: According to sources, the GOB has not initiated any third country application process to export GE crops.
- d) IMPORTS: According to the 2012 Bangladesh Biosafety Rules (BR) (see Global Agriculture Information Network (GAIN) Report [link](#)), a GE product needs to be approved by the Ministry of Environment, Forest and Climate Change (MOEFCC) 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 import for commercial use as food or feed at this time.
- e) FOOD AID: Bangladesh imports only wheat as food aid. The Plant Quarantine Wing of Ministry of Agriculture added a new import condition which requires non-transgenic confirmation on the phytosanitary certificate, but this certification does not seem to be impeding the import of U.S. wheat.

- f) **TRADE BARRIERS:** The 2007 Biosafety Guidelines (BG) notes 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 seeks to move forward in developing and commercializing biotechnology. Bangladesh has published various regulations, policies, and other documents on biotechnology including the following: the 2007 National Biosafety Framework (NBF) (See Report [link](#)), 2007 BG of Bangladesh (See Report [link](#)), 2012 National Biotechnology Policy (Bangla) (See [link](#)), 2012 Bangladesh Biosafety Rules (See GAIN Report [link](#)), 2013 Bangladesh Standard for Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants (See GAIN Report [link](#)), 2014 Action Plan of the National Biotechnology Policy 2012 (See GAIN Report [link](#)), 2016 Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants (See [link](#)), and 2017 User's Guide to Biosafety Regulatory Process for Genetically Engineered Plants in Bangladesh (See [link](#)).

The MoEFCC is also crafting a Bangladesh Biosafety Policy, which is subject to GOB approval. The MoEFCC also published manuals of standard operating procedures of:

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

The 2017 User's Guide to Biosafety Regulatory Process on Genetically Engineered Plants in Bangladesh (See [link](#)), provides guidance on the process of submitting an application. The 2016 Guideline for the ERA of Genetically Engineered Plants is used for planning and conducting an environmental risk assessment of an open release in Bangladesh. This guideline covers both the 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.

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.

The National Task Force on Biotechnology of Bangladesh (NTFBB), led by the Prime Minister of Bangladesh, is the apex body of five national-level biotechnology committees that provides final approval on all biotechnology-related policies. For example, the NTFBB approved the 2012 National Biotechnology Policy and other ministry level policies, such as the 2007 BG. The five national-level biotechnology technical committees cover biodiversity, biosafety, crop biotechnology, livestock and fisheries biotechnology, and medical biotechnology (see matrix in Table 1 below). 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.

The MOEFCC is the lead ministry in charge of implementing the CPB and established the NCB as the final decision-making body on 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; 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 as long as 360 days, if not more.

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

According to the aforementioned User’s Guide, a biotech application for confined field trial or experimental cultivation can be submitted to Institutional Biosafety Committee (IBC) and application for the approval of import can be submitted to NCB/MoEFCC directly. The IBC forwarded the application to the one of the Secretaries of a national technical committee (NTCCB/NTCFLB/NTCMB) (see Table 1 below) for evaluation. Applications allegedly may be submitted at any time of the year. Reportedly, the NCB is in the process of developing application forms that will need to be filled out to complete the biotechnology application process.

One of the subject oriented national technical committees (see Table 1) review the dossier for field trials, cultivation and submit any recommendations or concerns to the NCB. After evaluating all types of application, in most cases, the NCB sends the dossier to the BCC for further review and recommend a decision. BCC reviews the application, analyzes, and evaluates relevant information including the data supplied by the applicant. After having technical review report of BCC, the case is presented to the NCB meeting. The NCB provides the final decision on the GE application.

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 require additional approvals for GE products include: 2015-18 Import Policy Order, 2015-18 Export Policy Order, 2018 Plant Quarantine Rules, and 2005 Animal Quarantine Act.

Table-4: Bangladesh – Ministry Responsible in Biotechnology

Ministry	Responsibility/Role
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 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</p>

Ministry	Responsibility/Role
	<p>decision on GE medical applications.</p> <p>The Secretary of MOH is the chairman of the NTCMB.</p>

- b) APPROVALS: 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). Contacts report that BARI applied to deregulate another three Bt eggplant varieties BARI Bt *begun-5* (Bt Dohazari); BARI Bt *begun-6* (Bt Khatkhatia), and BARI Bt *begun-7* (Bt Singnath). At present, the application is waiting for the approval of the NCB. Golden Rice is also in the approval process to release for commercial cultivation.
- c) STACKED or PYRAMIDED EVENT APPROVALS: No regulations exist at this time.
- d) FIELD TESTING: The National Technical Committee on Agriculture Biotechnology (NTCAB), National Technical Committee on Fisheries and Livestock Biotechnology (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 decided to regulate innovative biotechnology like genome editing in plants.
- 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 product because there are no GOB approved packaged processed commodities derived from GE raw materials. Farmers usually do not sell vegetables with labelling. Most consumers buy loose vegetables from urban wet markets; Bt brinjals are sold without special labeling.
- h) MONITORING AND TESTING: On behalf of the NCB, the Field Level Biosafety Committee monitors approved GE crops for the performance and impact on biodiversity or the environment. The country tests GE traits of plant variety that are imported for field trial, research and commercial release. An applicant must submit information of testing methodologies and reference materials supplied by the developer. National Committee of Biosafety published Standard Operating Procedure (SOP) ([link](#)) on the transportation, storage, harvest, and management of GE eggplant of Bangladesh.

The Institutional Biosafety Committee (IBC), Field Level Biosafety Committee (FBC) and Biological Safety Officers (BSO) ensure safe management of biosafety activities in the laboratories and in the field. Per the 2007 BG “The IBC and BSO 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 (See GAIN Report [link](#)), and 2012 Bangladesh Biosafety Rules (See GAIN Report [link](#)) 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 (NSB) 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 in 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. There is a strong structure of Intellectual Property Right (IPR) law in the legal system of the country. Nonetheless, because of the lack of proper enforcement, practice to infringe IPR is very common in different product markets. The country has the Department of Patents, Design and Trademarks (DPDT) and the Copyright Office. It has international membership in World Intellectual Property Organization (WIPO), acceded to the Paris Convention on Intellectual Property in 1991, and Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreements. The country has national regulation and act of patent and design “2003 Patents and Designs Act (revised)” and “1911 Patents and Designs Act”, trademark “2015 Trade Mark Act (revised), and 2009 Trade Mark Act and 2003 Revised”, and copyright “2000 Copyright Act and 2013 Geographical Indication (Registration and Protection) Act”. Experts believe that IP laws in Bangladesh are in a very premature form and IP rights are not very protective for producer or inventor of all sectors and service market. The perception and practice of IPR is very weak among the consumer, producer, inventor and law enforcement department. Therefore, U.S. GE product exporters will face various hurdles in IPR in the long run to keep business sustainable.
- l) **CARTAGENA PROTOCOL RATIFICATION:** Bangladesh is a signatory to the Protocol on Biosafety (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 offers a tool to provide food security to 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. Gaining future market acceptance will greatly depend on education efforts.

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 expresses interest in supporting GE animal research for Bangladesh research institutions, although it is unclear whether financing will be available. Bangladesh does not import or export any GE animals or animal products.

b) COMMERCIAL PRODUCTION: No information available.

c) EXPORTS: No information available.

d) IMPORTS: No information available.

e) TRADE BARRIERS: No information available.

PART E: POLICY

- a) **REGULATORY FRAMEWORK:** The 2012 BR and 2007 BG also apply for approving GE animal research, commercialization, and trade (see previous sections on Regulatory Framework, Field Testing, and Monitoring and Testing). The 2006 National Guidelines for Fish and Animal Biotechnology establish objectives to promote 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 subject to optimum safety and acceptability. Because there is no application submitted to the NCB for the approval of GE livestock and fisheries product, NTCFLB is almost inactive, only existing in the guideline and regulation aspect.
- b) **APPROVALS:** No information available.
- c) **INNOVATIVE BIOTECHNOLOGIES:** The country has not decided to regulate innovative biotechnology like genome editing in animal.
- 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 (OIE) 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.

Attachments:

No Attachments