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Report Highlights:

The Government of Bangladesh has demonstrated a willingness to adopt and implement modern agricultural policy frameworks and guidelines that supports the safe and appropriate use of science and technology, including biotechnology, to help meet agricultural challenges and address the country's food security concerns. With innovative biotechnology support from the international scientific community, Bangladesh is seeking to play a role in the advancement of modern biotechnology research and currently conducts trials of new genetically engineered (GE) varieties of essential trait-based crops, such as rice, potato, brinjal (eggplant), tomato, papaya, wheat, and cotton. However, the regulatory process for biotechnology in Bangladesh is at times inefficient. Delays in the approval process of certain GE varieties in Bangladesh are the cause of frustration amongst the agricultural science and technology community. Bangladesh's research and development of animal biotechnology continues 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 economic and social 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, 2014[1]. At the same time, Bangladesh's regulatory framework for biotechnology has expanded greatly with the introduction of new rules and guidelines[2].

Bacillus thuringiensis (Bt) brinjal (eggplant) is an example of Bangladesh's success in adopting modern agricultural biotechnology. According to a recent report from Cambridge University, nearly 21,000 Bangladeshi farmers are planting Bt brinjal. Farmers' acceptance of the GE variety has steadily increase since it was commercially introduced in 2013. The Cambridge report states farmers have been able to increase revenue by 21.7 percent ($664 USD per hectare) and increase yields by 19.6 percent relative to non-bt varieties of brinjal. 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 modern biotechnology is widely accepted in Bangladesh's academic and research communities, there is some 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 safely conduct biotechnology research and development and will encourage the private industry to invest into the development of plant varieties that are able to meet the plant pest and plant disease challenges commonly found in Bangladesh.

Farmers have long awaited the approval of "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 are transparent and science-based. The research and development of animal and microbial biotechnology in Bangladesh is still far behind countries with a modern agricultural industry.

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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
BRRI	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) 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 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 by farmers. Scientists proposed that Bt *Chega* variety be released into commercial production but not yet applied for variety release approval. At present, three other Bt eggplant varieties are undergoing GOB approval process for release for 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 and then released into limited commercial production (See policy section for more on the approval process).

Agricultural scientists of the Biotechnology Division, BARI, continue to test the presence of inserted gene traits (genetic purification) in the commercialized Bt eggplant varieties. 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 in the prepared Bt brinjal (presence negative).

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 is still 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 is also involved in late-blight-resistant (LBR) transgenic potato development through the introgression of a single RB gene into two popular potato varieties (Cardinal and Diamant). After successfully completing contained field trials in multiple locations, the researchers identified a 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 Biotechnology Division 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 trials by MSU to see the efficacy against Phytophthora isolates. The best performing GE events DIA-MSU-UB #1 and DIA-MSU-UB #2 will be imported to Bangladesh for continued confined field trials. After the approval of BCC, the NCB approved the importation of these events for contained trials on March 4, 2020.

Papaya:

The Biotechnology Division of BARI is advancing in its interest in 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 BRRI completed the biosafety evaluation of Golden Rice line GR2E BRRI dhan 29. The environmental and food safety assessment dossier was submitted to the National Committee of Biosafety (NCB) through the National Technical Committee of Crop

Biotechnology (NTCCB) of Ministry of Agriculture on November 26, 2017, for approval of environmental release and use in food and feed. The National Committee on Biosafety (NCB) and Biosafety Core Committee (BCC) under the Department of Environment are still reviewing the dossier. The last meeting between BRRI and NCB took place in the spring of 2020 but no outcome was announced. The COVID-19 pandemic has impacted the committees' ability to render a decision on Golden Rice. The process has been delayed for nearly 3 years without approval.

The confined field trials (CFT) of Golden Rice IR112060 GR2-E:2-7-63-2-96 during Boro rice cultivation season (November to April) of 2016-17 and 2017-18 revealed that yield of GR2E was 13.3 percent higher than BRRI dhan29 in 2016-17 and approximately 3.8 percent lower than control in 2017-18. The selected best single line IR112060 GR2E:2-7-63-2-96 was also evaluated in multi-locations (eight locations) CFT during Boro 2018-19. Similar results were found in this season as well. 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 BRRI dhan29. Therefore, BRRI recommended that GR2E introgression line IR112060 GR2E:2-7-63-2-96 can be used for the purposes of breeding advancement as well as variety release in future based on its consistent performance across locations and seasons.

BRRI 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+-0.12 mg/g). As the genes are endosperm specific, so, it expressed only in grain, not in other parts of the plant. Food, feed and environmental assessments 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.

Scientists of the biotechnology division, BRRI are involved in upgrading the most popular rice variety BRRI dhan29 into saline tolerant transgenic rice variety through transforming BRRI dhan29 with salt tolerant gene *GlyI (Glyoxalase I)* and *GlyII (Glyoxalase II)* via the Agrobacterium-mediated transformation method. The plants from T_1 confirmed with both *GlyI* and *GlyII* gene specific primers. Seed from the derived line is ready for T_2 plantation.

BRRI, biotechnology division is also involved in the development of salt tolerant transgenic rice varieties by crossing transgenic rice plants containing salt tolerant gene AeMDHAR (Monodehydroascorbate reductase (MDHAR)) from mangrove plant (Acanthus ebracteatus) with BRRI dhan28 and BRRI dhan29. Putative transformants were confirmed by PCR 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 *Vacoular 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 BRRI, 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 its 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 introduced 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 an 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 1950 Bt. A contained greenhouse trial to test the efficacy of the introduced *Bt* varieties was successfully completed. On March 4, 2020, CDB received National Committee on Biosafety's (NCB) approval to start a confined field trials (CFTs) for the crop year 2020-21. 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 Bangladesh Seed Development Corporation (BADC) is producing foundation and certified seed to sell to farmers. The current fiscal year (FY) 2020-2021 (July-June), BADC produced foundation seeds totaling in 120 kilogram (kg) of seed. BADC-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 commercially sold 199.1 kg of Bt *Begun* 2 and 85.6 kg of 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 $10 (USD) per kilogram (kg) to the dealer and $11.29 (USD) per kilogram (kg) at the farmer's level.

It is estimated that 21,000 farmers are producing Bt brinjal on their farms. In area coverage, it is estimated that approximately 6 percent 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: Foundation seed production by BADC

Year	Bt Brinjal 2 (kg)	Bt Brinjal 4 (kg)	Total Bt Brinjal (kg)
2017-18	76	58	134
2018-19	95	84	179
2019-20	191.9	85.6	277.5
2020-21	60	60	120

Table 3: Breeder seed distribution by BADC

Year	Bt Brinjal 2 (kg)	Bt Brinjal 4 (kg)	Total Bt Brinjal (kg)
2017-18	76	58	134
2018-19	95	84	179
2019-20	191.9	85.6	277.5
2020-21	On going	On going	

Table 4: Seed distribution to the farmers

Year	Seed distribution to farmers (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
Total	21.77	591.56	507.3	1120.63

Note: BARI – Bangladesh Agricultural Research Institute
DAE – Department of Agriculture Extension
BADC – Bangladesh Agriculture Development Corporation
Source: GFSS, USAID.

Table 5: 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
2019-2020	100	8913	19000	26913
Total	1696	20678	32830	55104

Note: BARI – Bangladesh Agricultural Research Institute
DAE – Department of Agriculture Extension
BADC – Bangladesh Agriculture Development Corporation
Source: GFSS, USAID.

Table 6: Bangladesh – Bt brinjal adoption coverage

FY Year	Total (ac)
2013-2014	6.66
2014-2015	36
2015-2016	25
2016-2017	1251.2
2017-2018	3439

2018-2019	3716
2019-2020	4771

Source: GFSS, 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 (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.

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.

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 the 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, 2005 Animal Quarantine Act, and the 2017 Packaged Food Labeling Regulations from BFSA.

Table-4: Bangladesh – Ministry Responsible in Biotechnology

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

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.

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 doesn't export either the 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 their import data is not available. As there is no agency of the government to directly regulate biotech-derived food ingredients, therefore there is no official source of name of those ingredients. A list of 76 products type food products (Link) standards is regulated and monitored by Bangladesh Standard and Testing Institute (BSTI) of Ministry of Industry, where there is possibility of having microbial biotech-derived food ingredients.

d) TRADE BARRIERS: There is 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. The food production and its ingredients standardizations are regulated by Bangladesh Standard and Testing Institution (Link) under Ministry of Industry. Food quality is regulated by Bangladesh Food Safety Authority (Link) of Ministry of Food.

b) APPROVALS: BSTI is responsible for the clearance of imported food products based on national standards, CODEX, and other international standards. Food ingredients importing 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 National Board of Revenue sends the imported food ingredient product sample to the BCSIR for certification.

To provide the "Release Letter for Imported Food Products" (Link), BSTI follows June 2020, List of Bangladesh Standards(BDS) on Agricultural and Food Products, Updated June 2020 (Link) for the mandatory 76 types of agricultural and food products (Link). Bangladesh Food Safety Authority is responsible for ensuring the quality of food falls within the regulation of 2017, Use of Food Additives Regulations, (Bengali) (Link)

Necessary documents for customs clearance and laboratory testing

Following documents need to be submitted:

(a) Updated trade license;
(b) Letter of Credit;
(c) Invoice;
(d) Bill of lading (BL);
(e) Import Registration Certificate;
(f) Radiation certificate;
(for powder milk/food products);
(g) Attested Tax Identification number (TIN) certificate;
(h) Certificate of Analysis (Chemical analysis);
(i) Health certificate;
(j) Country of Origin;

(Note: Necessary Documents may vary with product)

c) LABELING and TRACEBILITY:

BSTI and BFSA follows 2017, Packaged Food Labeling Regulations, (Bengali) (Link) for food products and the food ingredients used in food industry. In addition, there is no separate labeling regulation 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's Food and Bacteriology Division (Link) perform product standard test through following laboratories.

1. Cereal and Bakery Lab.
2. Processed Food products and Fruit Drinks Lab.
3. Water and Beverages lab.
4. Microbiological lab.
5. Oils and Fats Products lab.
6. HPLC lab.
7. Instrumental lab.
8. GC-MS lab.

BSTI testing parameters:

1. Microbiology
2. Melamine
3. Aflatoxin
4. Preservative
5. Vitamin

Test Items:

Sugar, Chillis (Whole & Ground), Soybean Oil, Mustard Oil, Turmeric Powder, Honey, Suji, Banaspati, Red Flour (Atta), White Flour (Maida), Water, Carbonated Beverage, Cake, candy, Ice-Cream, Pasteurized Milk, Toffees, Yoghurt & Sweetened Yoghurt, Whole Milk Powder & 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 Squash, Fruit Syrup, Fruit Cordial, Edible Jell, Soft Drink Powder etc.

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

b) MARKET ACCEPTANCE and STUDIES: There is no study available related to market acceptance of microbial biotechnology.

Attachments:

No Attachments