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Report Highlights:
Bangladesh is a role model of acceptance and advancement of modern biotech in daily life. As an emerging economy and developing country, the country'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 biotech 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), and cotton. The government is also supporting scientists in this advancement, but regulatory policies are not fully developed to cover all aspects of production and marketing.

Executive Summary:
Research and development of desirable traits in staple and commercial GE crops is continuing to advance. The scientific community's involvement in modern biotech research is expanding, and interest in working with foreign private companies is increasing. Although, government funding for research is limited. Bangladesh became a leader in GE vegetables, such as Bacillus thuringiensis (Bt) brinjal (eggplant) production, for commercial use and consumption. Consumers overwhelmingly accept eating the vegetable, as it is 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. Without foreign funding, the government also introduced Bt cotton. Authorities are also busy deregulating other GE crops like Golden Rice and three more Bt brinjal 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.

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List of Acronyms

BADC	Bangladesh Seed Development Corporation
BARI	Bangladesh Agricultural Research Institute
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
DAP	Diammonium Phosphate
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
IPR	Intellectual Property Right
MOA	Ministry of Agriculture
MoEFCC	Ministry of Environment, Forest and Climate Change
MOFL	Ministry of Fisheries and Livestock
MOH	Ministry of Health
MOP	Muriate of Potash
MTA	Material Transfer Agreement
NCB	National Committee of Biosafety
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

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 biotech research organizations in Bangladesh. Some public universities also conduct limited Genetically Engineered (GE) biotech research.

BARI was the first public institute to release four GE eggplant (brinjal) 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* was uniform and homozygous. Scientists proposed that Bt *Chega* variety be released into commercial production. 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.

Scientists of Biotechnology Division, BARI, are testing to ensure that the inserted gene traits are present (purification) in the released Bt eggplant varieties 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 and seasonal abundance of *Cry1Ac* protein in Bt eggplant was analyzed and found that Bt protein concentration varied from 19-32 µg/g (Dry Weight [DW]) irrespective of different plant parts of four Bt eggplant varieties.

The Tuber Crop Research Center (TCRC) of BARI is working to develop a late blight resistant 3-R-gene GE potato variety truncated Rpi-mcq1, Rpi-bib2, and Rpi-vnt1.1. This summer, Michigan State University conducted efficacy test trials against the Phytopthora Infestans isolates of 16 3-R-Gene events. The best performing events will be imported to Bangladesh in August to September 2019. Afterwards, they will be contained and confined, and regulatory field trials of the GE Diamant variety will be released in Bangladesh.

The plant breeding division of BRRI is conducting multiple trials of Golden Rice BRRI dhan 29 in different locations of the country. BRRI has completed the biosafety evaluation of Golden Rice line GR2E BRRI dhan 29 and has submitted an application to the NCB through the National Technical Committee of Crop Biotechnology (NTCCB) for environmental release and use in food and feed under Bangladesh Biosafety Rules, 2012. All relevant data was presented by BRRI to the Biosafety Core Committee (BCC) on September 23, 2018. The Committee is currently reviewing the data.

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 BRRI dhan 29 (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 (centimeter, cm), tiller number (no), panicle (no), and 1000 grain weight (gram, gm) are almost identical with

slight variations. There is no significant difference in insect pest infestation between transgenic golden rice and non-transgenic rice BRRI dhan 29.

Table 1: Bangladesh - Confined field trial of golden rice during Boro season 2017-18

Genotypes	Plant height (cm)	Tiller (no)	Panicle (no)	1000 grain weight (gm)	Yield (t/ha)
IR112060 GR2-E:2-7-63-2-96	106.85	14.55	13.48	19.55	8.07
BRRI dhan 29	106.42	14.38	13.35	20.53	8.64

Reference: BRRI (2018), BRRI Annual Research Report 2017-18, Bangladesh Rice Research Institute, Bangladesh.

The biotechnology division of BRRI is collaborating with Arcadia Bioscience to develop a salt tolerant transgenic rice variety. The salt tolerant transgenic IR64 rice lines were imported from Arcadia Bioscience. These lines are screen tested in greenhouses, and the first screening at the seedling stage has been completed.

Scientists of the biotechnology division, BRRI are involved in developing saline tolerant BRRI dhan 29 through transformed BRRI dhan 29 with salt tolerant gene *GlyI* and *GlyII*. They confirmed three plants with both *GlyI* and *GlyII* gene specific primers.

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 their salinity tolerance at the seedling stage, five transgenic lines PDH_BR47-1, PDH_BR47-2, PDH_BR29-2, PDH_BR28-3, and PDH_BR36-2 were selected for reproductive stage characterization.

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 a MTA with JK Agri-Genetics Ltd, India to obtain Bt cotton hybrid varieties containing truncated *Cry1Ac* 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 varieties: JKCH 1974 Bt and JKCH 1050 Bt. In this contained trial, a bioassay test will be done to determine the efficacy of the introduced Bt varieties. Moreover, yield and fiber quality of these two varieties will be compared with a popular local variety. The goal is development of an efficient GE cotton variety which is resistant to Bollworm and Spodoptera/Army worm.

Table 2: Bangladesh - Bt Cotton development activities

Dates	Activities
January 09, 2017	Applied for NCB permission to conduct contained trial with Bt Cotton hybrids from JK Agri-Genetics Ltd.

June 20, 2017	Applied to get approval for MTA with JK Agri-Genetics Ltd.
October 08, 2017	Obtained approval from NCB
January 25, 2018	Obtained permission for MTA with JK Agri-Genetics Ltd.
February 02, 2018	Signed MTA with JK Agri-Genetics
April 05, 2018	Received import permit
July 23, 2018	Received JKCH 1947 Bt and JKCH 1050 Bt hybrid seed
August 07, 2018	Initiated contained trial

Source: Cotton Development Board.

b) COMMERCIAL PRODUCTION: The first GE crop in Bangladesh is advancing towards mass commercial production from farm to fork. Seed multiplication is continuing through increased interest of farmers. 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 last fiscal year (FY) 2017-2018 (July-June), BARI produced 517 kilogram (kg) of seed, and BADC produced 95 kg of foundation seed. The biotech division alone produced 67 kg of seed, and the seed technology division produced 450 kg of seed. BARI-produced seed will be distributed to farmers who are engaged in field demonstrations controlled by upazila (sub-district) agriculture offices and those that received permission from the upazila agriculture officer. For FY 2018-2019, BARI has a target to produce 60 kg of four varieties of breeder seed. This amount is lower than last year, as the seed technology division has not allocated any Government of Bangladesh (GOB) funding for seed production.

In 2016, 150 gm of Bt brinjal breeder seed of two varieties (BARI Bt *begun* 2 and BARI Bt *begun* 4) were purchased by the public seed producing and distributing authority, the BADC. In FY 2018-2019, BADC is planning to produce and commercially sell 90 kg of Bt *Begun* 2 and Bt *Begun* 4 through 8,500 seed dealers. BADC sells the seed to the farmers through local seed dealers (authorized listed sellers), and the price of the seed is Bangladeshi Taka (Currency) (BDT) 700 (US $8.43) per kilogram (km).

It is estimated that 150,000 farmers are producing brinjal on their farms, and 23% of them are producing Bt Brinjal. In area coverage, it is estimated that 5.95% of 80,000 acres of brinjal are cultivated with Bt brinjal.

Table 3: 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 (Target)	60	No Fund	90 (30+60)
Seed in Stock	1400		0

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

Table 4: Bangladesh - Bt brinjal adoption at farmers field

FY Year	No 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
Total	1471	13601	19430	34502

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 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
Total	194.07	2603.2	1943	4760.92

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

In October 2018, the Ministry of Agriculture decided to distribute BDT 800 million (US$ 9.6 million) to 700,000 small and subsistence farmers through the provision of cash and in-kind support like seed and fertilizer. The purpose is to inspire farmers to produce wheat, maize, mustard, peanuts, dal, Bt brinjal, boro rice, winter mung beans, summer mung beans, and summer sesame in the March-May 2019 season. GOB will provide 20 kg of wheat, 5 kg rice, 2 kg maize, 1 kg mustard, 10 kg peanuts, 1 kg summer sesame, 5 kg summer mung bean, 8 kg grass pea, 7 kg of cowpea and 20 kg of BT brinjal seeds for cultivation on 33 decimals (1/3 of an acre) of land. As input support, GOB will give 20 kg of Diammonium Phosphate (DAP) and 10 kg of Muriate of Potash (MOP) fertilizer for rice, wheat, maize, summer sesame, mustard, and Bt

brinjal cultivation and 10 kg of DAP, 5 kg of MOP fertilizer for cultivation of peanuts, summer mung beans, winter mung beans, grass pea, and cowpea.

c) EXPORTS: According to sources, the GOB has not initiated any third country application process to export Bt brinjal.

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: Regarding the monetization of food aid, historically Bangladesh has imported conventional crops such as wheat. As Bangladesh imports only wheat as food aid so there is no evidence of impeding GE food aid. Until now the country doesn't officially approve imported GE product for consumption and use therefore importing GE food aid for the first time will be trapped in GOB's bureaucratic approval process which will hamper the objectives of aid distribution.

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 2012 National Biotechnology Policy (Bangla) (See link), 2014 Action Plan of the National Biotechnology Policy 2012 (See GAIN Report link), 2007 National Biosafety Framework (NBF) (See GAIN Report link), 2007 BG of Bangladesh (See GAIN Report 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), 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 User's Guide to Biosafety Regulatory Process on Genetically Engineered Plants in Bangladesh (See Link), published in 2017, provides guidance on the process of submitting an application. The Guideline for the ERA of Genetically Engineered Plants, published in 2016, 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 trails.

The Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, published in 2013, 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 trails, 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 user's guide, a biotech application for confined field trail 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-6: 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: 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 performance and impact on biodiversity or the environment. The country test GE traits of plant variety that is imported for field trail, research and commercial release. Applicant has to submit information of testing methodologies and reference materials supplied by the developer. The users destroy unapproved and field trial failed materials as per the 2007 BG.

Institutional Biosafety Committee (IBC), Field Level Biosafety Committee (FBC) and Biological Safety Officers (BSO) monitor all together to 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 seeds. According to the 1992 Seed Policy of Bangladesh, all plant varieties need to be registered with the National Seed Board (NSB) before commercial production. 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 market. The country has 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", copyright "2000 Copyright Act and 2013 Geographical Indication (Registration and Protection) Act. The 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, US GE product exporter will face various hurdles in IPR in the long run to keep business sustainable.

l) CARTAGENA PROTOCOL RATIFICATION: Bangladesh is a signatory to the 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 publically 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. As because there is no application submitted to the NCB for the approval of GE livestock and fisheries product, so NTCFLB is almost inactive, they exist only in the guideline and regulation.

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.