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Report Highlights:

Development of the Bangladesh biotechnology sector is progressing slowly in general, but strong interest of the Government of Bangladesh (GOB) will help to drive the development and commercial application of *agricultural* GE biotechnology in particular. Scientific research is increasing to develop numerous genetically engineered (GE) crops which have higher yields, use fewer inputs, or adapt to climate changes, each of which help to ensure food security. The GOB is developing a regulatory framework and approval process for all GE products developed domestically or by a third country.

Section I. Executive Summary:

In Bangladesh, biotechnology research and development is drawing on both national and international collaborations. To ensure food security, the Government of Bangladesh is accelerating deregulation, research, and marketing of GE crop varieties. Since approval of Bt brinjal (eggplant) in 2013, trials have been satisfactory and brinjal seed is already being distributed to farmers. Additional GE research now includes development of new GE varieties of rice, potatoes, and cotton: field trials have begun for Golden rice and initial development has begun for a new GE potato variety having late blight resistance. In addition, also at initial trial stage is a rice variety having higher saline tolerance. For cotton, GOB is launching a new initiative to develop an improved Bt Cotton variety.

Although the 2012 Bangladesh Biosafety Rules (2012 BR) and 2007 Biosafety Guidelines of Bangladesh (2007 BG) officially created a regulatory framework and approval process for all GE products developed domestically or by a third country, in fact the biosafety rules are incomplete and insufficient to effectively regulate imports of GE commodities. At the same time, the public needs to be better informed about biotechnologies: information based on sound science needs to be disseminated to farmers, consumers, policymakers, and regulators. Activities on outreach and risk communication are necessary to prepare science-based regulation and to raise acceptance and interest on GE commodity consumption.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

- a) **PRODUCT DEVELOPMENT:** The government of Bangladesh's Seventh Five Year Plan (2016–2020) acknowledges that the effects of climate change threaten food security and the agricultural economy of Bangladesh. In particular, a rise in sea level and unusual weather patterns will affect crop production and food security, which ultimately causes malnutrition and poverty. To mitigate these negative affects of climate change, policy planners and scientist are committing to develop genetically engineered (GE) crop varieties which are saline and drought tolerant as well as disease resistant.

The Bangladesh Agricultural Research Institute (BARI) is the only research institute that has developed and commercialized a GE product in Bangladesh. Although other Bangladeshi universities and public sector research institutes, such as the Bangladesh Rice Research Institute (BRRI), have biotechnology departments, they receive few government funds for research and what funds they do get are sourced from a variety of ministries or institutes and are not coordinated at the national level.

BARI was the developer for Bangladesh of Bt (*Bacillus thuringiensis*) eggplant (brinjal) (local name "*Begun*") (see commercial section below). In its first year, 2014-15, BARI produced 90.75 kg of seed. In the second year it produced 966.5 kg of seed of four Bt brinjal varieties. These new seeds were distributed to farmers and public organizations to conduct field demonstrations and especially to support farmers affected by flooding. The biotechnology division reported that current seed production levels can provide Bt brinjal for nearly one-third of the total winter brinjal crop area. (11,000 ha out of 29,000 ha total, using 90% germination rate and 80 cm x 70 cm spacing). The Bt brinjal seeds are selling at BDT 5000 per kg, or US \$63 per kilogram.

The biotechnology division and seed technology division at BARI jointly targeted the production of 1.5 MT breeder seed in 2016-17. BARI has also applied to release another three Bt brinjal varieties: BARI Bt *begun-5* (Dohazari); BARI Bt *begun-6* (Khatkhatia); and BARI Bt *begun-7* (Singnath). One source indicates these will be released in 2017 if approved by Department of Environment. And a confined field trail on another two Bt brinjal lines (local variety "Islampuri" and "Chega") is progressing toward homozygosity, the development stage at which the varietal traits can be held constant.

BARI was involved in researching a late blight resistant (LBR) potato called BARI Potato-8 (Diamant) using single RB gene technology. After several years of confined and multi-location field trial and toxicological risk analysis, BARI noted that that they are preparing to submit in December 2016 a request for deregulation to release variety (see the Regulatory Framework section for further details on the approval process). In October 2015, the Tuber Crop Research Center of BARI started a collaborative research project to develop a late blight resistant potato variety using 3-gene technology. BARI is also researching a variety of tomato having resistance to leaf curl virus.

The BIRRI is involved in the Golden Rice Project coordinated by the International Rice Research Institute (IRRI). BIRRI is working with IRRI to develop and conduct field trials of provitamin A (beta carotene) enriched GR2-E Golden Rice based on experience with BIRRI dhan 29, a widely grown high-yielding boro rice variety. After successfully completing confined field trials in 2016, BIRRI has requested approval from the national committee on biosafety to conduct multi-location confined field trials at different regional stations. The Annual Report July 2015 - June 2016 of BIRRI reported that total carotenoid content in milled rice after two months of storage at ambient temperature ranged from 8.4 – 14.4 mg/g (micrograms/gram), with an average value of 11.2 ± 1.12 mg/g; this value would meet the target (10 mg/g) needed to address vitamin-A deficiency. The biotechnology division of BIRRI is also conducting collaborative research to develop a salt-tolerant rice variety. BIRRI's application for import research materials to conduct research is under review at Ministry of Agriculture.

At the same time, the Department of Biochemistry and Molecular Biology at Dhaka University (DU) is conducting a contained trial in the transgenic green house at BIRRI for developing salt tolerant HYV rice by infusing the pea DNA Helicase gene. The department is also doing research using gene transcription to improve yields as well as stress tolerance, thus increasing water use efficiency. In particular the department is using transcription factors of the Stress-Responsive Nucleus Accumbens-associated Protein 1 gene from rice to confer drought and salt tolerance; plasma membrane and vacuolar sodium hydrogen antiporter to sequester salt; and transcription factors Guanine nucleotide-binding proteins (G protein) beta to confer salt, drought and heat tolerance. Meanwhile, the Department of Botany at DU is researching fungal resistant peanut, lentils and chickpeas, and a mung bean resistant to yellow mosaic virus.

Other research initiatives include: The Bangladesh Institute of Nuclear Agriculture Research project on GE rice, including researching saline tolerance, flood tolerance, drought tolerance, early maturing/high yielding traits, and iron bio fortification. And the Department of Biotechnology at Bangladesh Agricultural University is doing biotech

- b) **COMMERCIAL PRODUCTION:** In October 2013, four varieties of Bt brinjal seed were approved by the National Committee on Biosafety, which is located in the Ministry of Environment and Forests (MOEF). In early 2014 the GOB distributed Bt brinjal seeds to 20 farmers. In 2015, seeds were distributed to 19 districts and more than 100 farmers. And now in 2016 contacts report that roughly 23,000 brinjal farmers are estimated to be cultivating Bt brinjal on 4,500 hectares this winter using seed supplied by BARI.

Separately 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 Bangladesh Agricultural Development Corporation . They are targeting the production of 30 kg of seed for commercial distribution. Bt brinjal that is being produced now can be sold in local markets.

- c) **EXPORT:** According to sources, the GOB has not begun any third country application process in order to export Bt brinjal.
- d) **IMPORT:** According to Bangladesh Biosafety Rules 2012 (see Gain Report BG4005), a GE

product needs to be approved by the Ministry of Environment and Forests before it can be imported and commercially sold or cultivated within Bangladesh (see Regulatory Framework section below). The Cotton Development Board of Bangladesh is planning for the second time to apply to the Ministry of Agriculture for an agreement with Mahyco, India to import seed of Bt Cotton variety Bollgard II. The board applied for approval to conduct a contained trial at BARI facility in year 2017; the trial will be of two genes (Cry1Ac and Cry2Ab), which are based on Boalgard II Bt cotton. The first initiative for developing Bt cotton was not successful in contained field trials. Post contacts have not reported any third country applications for import at this time.

- e) **FOOD AID:** Regarding the monetization of food aid, historically Bangladesh has imported conventional crops such as wheat.
- f) **TRADE BARRIERS:** Biosafety Guidelines 2007 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 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 an early stage of development, but the national government seeks to accelerate that development. Bangladesh already has published various regulations, policies, and other documents on biotechnology such as the “2012 National Biotechnology Policy”; “2014 Action Plan of the National Biotechnology Policy 2012”; the “2007 National Biosafety Framework” (See Gain Report BG4007); the “2007 Biosafety Guidelines of Bangladesh” (See Gain Report BG4006); and the “2012 Bangladesh Biosafety Rules” (See Gain Report BG4005). Guidelines for Environmental Risk Assessment will be published soon, and the Ministry of Environment and Forests reportedly is drafting a Bangladesh Biosafety Policy.

Previously, the GOB published “Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants”. That document attempts to meet Codex standards and “to provide technical guidance on the safety assessment process for whole foods, food products, and food ingredients which are derived from GE plant sources.” The Bangladesh Standardization and Testing Institute leads the safety assessment of foods derived from GE plants.

The National Task Force on Biotechnology Development, led by the Prime Minister of Bangladesh, is the apex body of five national-level biotechnology committees that provide final approval on all biotechnology-related policies. The five national-level biotechnology technical committees receive and review biotechnology applications pertaining to crops, livestock and fisheries, and medical products. (See matrix in Table 1 below).

Regarding the approval of imported and domestically developed GE products, an informal

translation of the 2012 Bangladesh Biosafety Rules (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].” Note: Bangladesh is a signatory to the Cartagena Protocol (CP) on Biosafety and closely follows the GE application approval processes contained in the CP.

The Ministry of Environment and Forests is the lead ministry in charge of implementing the CP. It established the National Committee on Biosafety (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: 1) Biosafety Core Committee, which provides the NCB with technical comments and recommendations on GE applications, and advises on other GE issues; 2) Institutional Biosafety Committee, which evaluates and monitors research and development activities in research institutions; and 3) Field Level Biosafety Committee, which monitors field trials for GE plants, animals, or fish.

Information on the biotechnology approval process is in section 3.1.8 of the 2007 Biosafety Guidelines (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 3.2.2 of the 2007 BG provides some information on how many days it will take for a decision to be made on a biotechnology application from a third country. However, the overall timeline is unclear and could be 12 months or longer.

Although the 2007 Biosafety Guidelines do not provide much information on the step-by-step approval procedure, according to contacts a national technical committee (see Table 1) will review the dossier and submit any recommendations or concerns to the National Committee on Biosafety (NCB). Afterward, in most cases the NCB will send the dossier to the Biosafety Core Committee for review and decision. The NCB provides a final decision on the GE application. If approved, four copies of the permit will be issued (please see section 3.1.10 of the 2007 BG).

A biotech application can be submitted to the Secretary (chairman) of the NCB or to one of the Secretaries of a national technical committee (see Table 1 below). Applications 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.

After obtaining approval from the NCB, according to an informal translation of the 2012 Biosafety Regulations, “[the] application may be filed with the Ministry of Commerce or other concerned authorities to import and export 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: Import Policy Order 2012-15, Export Policy Order 2012-15, 1996 Plant Quarantine Rules, (amended up to 1989), and the 2005 Animal Quarantine Act.

Table-1: Bangladesh: Ministry Responsible for development and regulation of Biotechnology

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

b) **APPROVAL:** Four varieties of Bt eggplant seed were developed by BARI and have been approved for limited 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). According to contacts, 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).

c) **STACKED or PYRAMIDED EVENT APPROVALS:** No regulations exist at this time.

- d) **FIELD TESTING:** The National Technical Committee on Agriculture Biotechnology, National Technical Committee on Fisheries Biotechnology, or the National Technical Committee on Animal Biotechnology provide a recommendation to the National Committee on Biosafety whether to allow field testing for GE plants or animals. The Field Level Biosafety Committee monitors the field trials and collects data during the biotechnology approval process.
- e) **INNOVATIVE BIOTECHNOLOGIES:** No information available
- f) **COEXISTENCE:** Currently, there are no specific regulations or policies that address coexistence.
- g) **LABELING:** An informal translation of the 2012 Biosafety Rules 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 a Genetically Modified Organism or that has been produced from a Genetically Modified Organism.” Additional requirements are specified in section 3.2.2.4 of the 2007 Bio Safety Guidelines (2007 BG), and the 2006 Product Labeling Policy. Compliance with these rules is not feasible for GE product because no GOB-approved packaging exists for GE raw materials. Farmers sell product in bulk and consumers buy unpackaged products in wet markets. Small quantities of unpackaged Bt brinjals are known to be sold in village markets without government interference.
- h) **MONITORING AND TESTING:** On behalf of the National Committee on Biosafety, the Field Level Biosafety Committee monitors approved GE crops and animals for performance and impact on biodiversity or the environment.
- i) **ADDITIONAL REGULATORY REQUIREMENTS:** Registration of seed variety 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 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, 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.”
- j) **INTELLECTUAL PROPERTY RIGHTS:** Bangladesh lacks effective legislation or enforcement mechanisms to protect intellectual property rights.
- k) **CARTAGENA PROTOCOL RATIFICATION:** Bangladesh is a signatory to the Cartagena Protocol on Biosafety (CP). It ratified the protocol in 2004. The 2012 BR and 2007 BG create a framework to implement the CP.
- l) **INTERNATIONAL TREATIES/FORA:** 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.

PART C: MARKETING

- a) **PUBLIC/PRIVATE OPINION:** 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. In Fall 2013, media reports indicate some of these groups legally challenged the GOB on whether it could release Bt eggplant.
- b) **MARKET ACCEPTANCE/STUDIES:** Because reliable information is limited, many Bangladeshi citizens are not well informed about the issues involved with biotechnology. Publically disseminated information is not always accurate or supported with sound science. As a result, gaining future market acceptance will depend on efforts to inform and educate the public about the safety and benefits of biotechnology products.

In particular, enterprises and institutions promoting GE seeds for planting need to address apprehensions about multinational seed companies in order to achieve market acceptance. In addition, the lack of purchasing power 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. According to the 2012 Action Plan of the National Biotechnology Policy, the GOB will support GE animal research at Bangladesh research institutions, one of which is the Bangladesh Livestock Research Institute. Funding of such research is still pending. Domestic research is the only livestock biotechnology activity currently: Bangladesh does not import or export any GE animals or animal products.
- b) **COMMERCIAL PRODUCTION:** No information available.
- c) **EXPORT:** No information available.
- d) **IMPORT:** No information available.
- e) **TRADE BARRIERS:** No information available.

PART E: POLICY

- a) **REGULATORY FRAMEWORK:** The 2012 Bangladesh Biosafety Rules (2012 BR) and 2007 Biosafety Guidelines (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: (i) acquisition of knowledge and skills in animal and fish biotechnology and (ii) development of biotechnology tools in the fields of fisheries and livestock subject to optimum safety and acceptability.
- b) **INNOVATIVE BIOTECHNOLOGIES:** The country has not decided to regulate innovative biotechnology like genome editing in animals.
- c) **LABELING AND TRACEABILITY:** No information available.
- d) **INTELLECTUAL PROPERTY RIGHTS (IPR):** No information available
- e) **INTERNATIONAL TREATIES/FORA:** Bangladesh is a member of the World Organization for Animal Health (OIE) and the Codex Alimentarius (Codex), although its activity in these two international bodies has been limited.
- f) **RELATED ISSUES:** No information available.

PART F: MARKETING

- a) **PUBLIC/PRIVATE OPINION:** Most Bangladeshis have little or no knowledge about GE animals. For a 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.