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Report Highlights:

The biotechnology sector is in a nascent stage of development, but the Government of Bangladesh (GOB) seeks to move forward in developing and commercializing agricultural biotechnology. The GOB has established a regulatory framework and approval process for all GE products developed domestically or by a third country. GE products need to be approved before they are imported, sold commercially, or cultivated in Bangladesh.

Section I. Executive Summary:

The biotechnology sector is in a nascent stage of development, but the Government of Bangladesh (GOB) seeks to move forward in developing and commercializing agricultural biotechnology, such as Bt eggplant which was approved in 2013. The Bangladesh Biosafety Rules (BR), 2012 and Biosafety Guidelines of Bangladesh (BG), 2007 officially created a regulatory framework and approval process for all GE products developed domestically or by a third country. GE products need to be approved before they can be imported, sold commercially, or cultivated in Bangladesh. Due to the information gap on agricultural biotechnology, disseminating information based on sound science will be critical to educate the public as new technologies are developed and commercialized.

Section II. Author Defined:

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a. Product Development

The Bangladesh Agricultural Research Institute (BARI) is the only research institution that has developed and commercialized a GE product in Bangladesh. Although other Bangladeshi public sector research institutes, such as the Bangladesh Rice Research Institute (BRRI), and universities have biotechnology departments, government funding for biotechnology research is generally miniscule. Currently, various ministries/institutions provide funding without any coordination at the national level.

The BARI recently developed and received approval for *Bacillus thuringiensis* (Bt) eggplant (*brinjal*) (see commercial section below). This project received support by the U.S. Agency for International Development (USAID) through the Agricultural Biotechnology Support Project II (ABSP II). Another USAID (ABSP II) funded project includes the University of Wisconsin at Madison and BARI, who are jointly researching a late blight resistant (LBR) potato called BARI Potato-8 (Diamant); after several years of confined field trials and toxicological risk analysis, BARI noted that it plans to apply for farm level field trials next year (see the Regulatory Framework section for further details on the approval process). BARI is also researching a leaf curl virus resistant tomato.

The BRRI is involved in a GE Golden Rice Project funded by the Rockefeller Foundation, Bill & Melinda Gates Foundation (Grand Challenges in Global Health Initiative), USAID, the Philippine Department of Agriculture, HarvestPlus, the European Commission, Swiss Federal Funding, and Syngenta Foundation. The breeding division at IRRI is working with the BRRI to conduct confined field trails for beta-carotene-enriched (Vitamin A, Iron and Zinc contained) BRRI Dhan 29, also called Golden Rice 2 (GR2) Event "R" (GR2-R). Moreover, BRRI scientists are developing drought and saline tolerant GE rice by inserting the Trehalose Phosphate Synthase Phosphatase (TPSP) gene from E. coli into certain rice varieties. The Bangladesh Institute of Nuclear Agriculture Research (BINA) is conducting various projects on GE rice, including researching saline tolerance, submergence, drought tolerance, early maturing/high yielding traits, and iron bio fortification.

Various universities are conducting GE plant research. The Department of Biochemistry and Molecular Biology (DBMB) at the University of Dhaka (DU) is developing a salt tolerant rice using the Helicase gene (the product is currently undergoing field trials) as well as a low lignin jute. In collaboration with the Bangladesh Jute Research Institute, the department is also developing a stem rot and insect resistant jute. The Department of Botany at DU is researching fungal resistant lentils and chickpeas and a yellow mosaic virus resistant mungbean. The Department of Biotechnology at Bangladesh Agricultural University is working on drought tolerant potatoes and virus and/or insect resistant garlic, cucumbers, chili, papaya, and eggplant.

b. Commercial Production:

In October 2013, four varieties of Bt eggplant seed were approved by the National Committee on Biosafety (NCB), which is located in the Ministry of Environment and Forests (MOEF). After approval, in early 2014, the GOB initially distributed Bt eggplant seeds to 20 farmers. Later, seeds were distributed to 19 districts and more than 100 farmers. Official contacts noted that BARI plans to provide Bt eggplant breeder seed to the Bangladesh Agricultural Development Corporation (BADC), which will mass produce seed for commercial distribution and sale throughout Bangladesh, possibly within the next year. Bt eggplant that is currently being produced 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 eggplant.

d. Import:

According to Bangladesh Biosafety Rules (BR), 2012 (see Gain Report BG4005), a GE product needs to be approved by the MOEF before it can be imported and commercially sold or cultivated within Bangladesh (see Regulatory Framework section below). On July 15, 2015, the Cotton Development Board (CDB) of Bangladesh initiated contained field trials for Bt cotton seed at BARI greenhouses. The Supreme Seed Company Ltd. of Bangladesh and the Hubei Provincial Seed Group Co. formed a joint venture, which resulted in the partnership submitting one kilogram of Bt cotton seed to the GOB for GE approval. 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.

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 such as the National Biotechnology Policy, 2012, Action Plan of the National Biotechnology Policy 2012, 2014, National Biosafety Framework (NBF), 2007 (See Gain Report BG4007), Biosafety Guidelines of Bangladesh (BG), 2007 (See Gain Report BG4006), and Bangladesh Biosafety Rules, 2012 (See Gain Report BG4005). The MOEF is also crafting a Bangladesh Biosafety Policy, which may be published in the next year, but it is unclear what the draft may contain at this time.

The Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants was published in the last few years and allegedly 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." Sources state 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 Development (NTFBD), 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 NTFBD approved the National Biotechnology Policy, 2006 and other ministry level policies, such as the BG, 2007. 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 BR, 2012 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]." Because Bangladesh is a signatory of the Cartagena Protocol on Biosafety (CP), the BG, 2007 closely follows the GE application approval processes contained in the CP.

The MOEF is the lead ministry in charge of implementing the CP, 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: 1) Biosafety Core Committee (BCC), which provides the NCB with technical comments and recommendations on GE applications, and advises on other GE issues; 2) Institutional Biosafety Committee (IBC), which evaluates and monitors research and development activities in research institutions; and 3) 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 BG, 2007, 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 BG, 2007 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 as long as 360 days, if not more.

Although the BG, 2007 does 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 NCB. Afterward, in most cases, the NCB will send the dossier to the BCC for further review and to recommend a 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 BG, 2007).

According to Post contacts, 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 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.
After obtaining approval from the NCB, according to an informal translation of BR, 2012, "[the] application may be filed to the Ministry of Commerce or other concerned authorities to commercially 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: Import Policy Order 2012-15, Export Policy Order 2012-15, Plant Quarantine Rules, 1966 (amended up to 1989), and the Animal Quarantine Act, 2005.

Table 1. Bangladesh: Ministry Responsible in Biotechnology

Ministry	Responsibility/Role
Ministry of Environment and Forests	Leads the National Committee on Biosafety (NCB). The Secretary of MOEF is the Chairman of the NCB Leads the National Technical Committee on Biodiversity Houses the Biosafety Core Committee (BCC). Competent national authority and focal point to implement the Cartagena Protocol of Biosafety. Lead Ministry for implementing the Bangladesh Biosafety Rules, 2012
Ministry of Agriculture (MOA)	Leads the National Technical Committee on Crop Biotechnology (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	Leads the National Technical Committee on Medical Biotechnology

(MOH)	(NTCMB), which evaluates and recommends a decision on GE medical applications. The Secretary of MOH is the chairman of the NTCMB.

b. Approval:

Four varieties of Bt eggplant seed were developed by BARI and have been approved for limited scale commercial production. The varieties include: 1) Bt eggplant 1 (Bt Uttara); 2) Bt eggplant 2 (Bt Kajla); 3) Bt eggplant 3 (Bt Nayantara); and 4) Bt eggplant 4 (Bt ISD 006). According to contacts, BARI plans to apply to release another three Bt eggplant varieties (Shingnath, Dohazari, and Khatkhatia).

c. Field Testing:

The National Technical Committee on Agriculture Biotechnology (NTCAB), National Technical Committee on Fisheries Biotechnology (NTCFB), or National Technical Committee on Animal Biotechnology (NTCAB) 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.

d. Stacked Events:

No regulations exist at this time.

e. Additional Requirements:

Variety registration is required for approved GE seeds. According to the Seed Policy of Bangladesh, 1992, 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 BG, 2007, 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.''

f. Coexistence:

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

g. Labelling:

An informal translation of BR, 2012 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." Additional requirements are specified in section 3.2.2.4 of the BG, 2007 and the Product Labeling Policy, 2006.

h. Trade Barriers:

BG, 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 additional confusion. Labeling requirements and other certifications (see Additional Requirements) may also create challenges.

i. Intellectual Property Rights:

Bangladesh lacks effective legislation or enforcement mechanisms to protect intellectual property rights.

j. Cartagena Protocol Ratification

Bangladesh is a signatory to the Cartagena Protocol on Biosafety (CP). It ratified the protocol in 2004. The BR, 2012 and BG, 2007 create a framework to implement the CP.

k. International Treaties/Fora

Bangladesh is a member of International Plant Protection Convention (IPPC) and Codex Alimentarius (Codex). Activity in these two international bodies has been limited.

l. Related Issues:

None.

m. Monitoring and testing:

On behalf of the NCB, the Field Level Biosafety Committee monitors approved GE crops and animals for performance and impact on biodiversity or the environment.

n. Low Level Presence:

Currently, there are no regulations or policies that address low level presence.

PART C: MARKETING

a. Market Acceptance:

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.

b. 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, according to the media, some of these groups legally challenged the GOB on whether it could release Bt eggplant.

c. Marketing Studies:

None.

PART D: CAPACITY BUILDING AND OUTREACH

a. Activities:

Since 2004, USAID has funded the Agricultural Biotechnology Support Project (ABSP II), which has provided technical assistance to BARI in developing new GE products (see Product Development section). Bangladesh has also received biotechnology research funding through the U.S. National Academy of Science (NAS) administrative program entitled, "Partnership for Enhanced Engagement in Research (PEER)."

The ISAAA (International Service for the Acquisition of Agro-biotech Applications) and South Asia Biosafety Program (SABP) have a limited presence in Bangladesh. Bangladesh is a member of the International Centre for Genetic Engineering and Biotechnology (ICGEB), and receives funding for young scientist training as well as research collaboration and development.

b. Strategies and Need:

Due to the information gap on agricultural biotechnology, disseminating information based on sound science will be critical to educate the public on agricultural biotechnology as new technologies are developed and commercialized. In this regard, further education on risk communication may also be helpful.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART E: PRODUCTION AND TRADE

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 Action Plan of the National Biotechnology Policy 2012, 2014, 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.

PART F: POLICY

BR, 2012 and BG, 2007 also apply for approving GE animal research, commercialization, and trade (see previous sections on Regulatory Framework, Field Testing, and Monitoring and Testing). The National Guidelines for Fish and Animal Biotechnology, 2006 establish objectives to promote: (i) acquisition of knowledge of 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.

PART G: MARKETING

Most Bangladeshis have little or no knowledge about GE animals. For Muslim majority conservative societies, public perception of animal biotechnology and cloning is likely to be sensitive.

PART H: CAPACITY BUILDING AND OUTREACH

There has been no U.S. Government financial support for animal biotechnology in Bangladesh.