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# Bangladesh

# Agricultural Biotechnology Annual

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**Report Highlights:**
The modern biotech sector in Bangladesh is advancing moderately through research on several crops with support from policymakers, regulators, and development partners. The target is to ensure food security and safe food availability through production of biotic and abiotic stress tolerant crops with lower production costs. This target is encouraging scientists to research new varieties through biotech methods. The regulatory system is making changes to keep pace with biotech research advancement and to accelerate the approval process.

## *EXECUTIVE SUMMARY*

Biotechnology research and development is cautiously advancing genetically engineered (GE) crop variety development and is drawing on both national and international collaborations. Greenhouse trials have signaled growing interest in biotech. To ensure food security, the Government of Bangladesh (GOB) is accelerating research, approval, and marketing of GE crop varieties. Since approval of biotech (Bt) brinjal (eggplant) in 2013, brinjal seeds have been widely distributed to farmers, and more Bt brinjal varieties are in the pipeline for release to commercial cultivation. Ensuring food security and adapting with climate change includes development of new GE varieties of rice, potatoes, peanuts and cotton. Currently, import of research samples and contained field trials are approved for late blight resistant (LBR) potatoes, high zinc and iron enriched rice, and Bt cotton.

Biosafety rules and guidelines are followed for research purposes on all GE products developed domestically or abroad. However, currently no protocol exists for importing GE commodities and no application has been submitted for approval to import GE product. Regulations and dissemination of information based on sound science is necessary to educate the public policymakers and regulators as new technologies are developed and commercialized. Activities on outreach and risk communication are necessary to prepare science-based regulations and raise acceptance and awareness of GE commodity consumption.

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***PLANT AND ANIMAL BIOTECHOLOGY***

## *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 of Bangladesh. Some public universities also do limited GE biotech research.

   BARI was the first public institute to release four GE eggplant varieties in Bangladesh in the year 2013. At present, another three Bt eggplant varieties are undergoing government approval process for release to commercial cultivation. The proposed varieties are BARI Bt *Begun*-5 (Local variety Dohazari); BARI Bt *Begun*-6 (Khatkhatia) and BARI Bt *Begun*-7 (Singnath).

After confined field trials of another two Bt brinjal lines, *Bt Chega* and *Bt Islampuri*, scientists found *Bt Chega* was uniform and homozygous. Scientists' have proposed that *Bt Chega* variety be released into commercial production.

The biotech division of BARI tested the presence of Cry1Ac gene in the released varieties through ELISA and the lateral flow strip method. A positive result was found among 99.55% of four Bt brinjal varieties and showed a greater than +1.0 mean absorbance, which indicates the presence of protein in the crop. Gene flow was tested among the transgenic and non-transgenic varieties and found that 5.42% of the transgenic plants showed out crossed (cross pollination) with non-transgenic varieties; the cross ratio reduces with increasing distance.

The biotech division of BARI is also developing an LBR potato variety using single RB gene technology. In 2016 BARI submitted an application to the National Technical Committee of Crop Biotechnology (NTCCB) of the Ministry of Agriculture (MoA) to deregulate this selected Phythopthora-resistant SP 951 clone as a BARI biotech *alu*-1. The regulatory authority is assessing the varietal trait performance.

The biotech division of BARI is also doing research on a leaf-curl-resistant (LCR) transgenic tomato variety. Scientists completed characterization of the gemini virus strain in different crops, especially tomatoes, which is a prerequisite for developing appropriate diagnostic methods and for formulating transgenic approaches to develop resistant varieties.

Another project involving the LBR-resistant GE potato variety uses 3R-gene technology and is being done at Tuber Crop Research Center (TCRC) of BARI. By June 2018, the center is expecting to start contained field trials of 3R-gene inserted plantlets of BARI *alu*-7 variety (Alu is the Bengali name of potato).

The biotechnology division of Bangladesh Rice Research Institute (BRRI) is collaborating with Arcadia Bioscience to develop a salt-tolerant transgenic rice variety. The National Committee on Biosafety (NCB) of GOB has approved the importing of salt tolerant transgenic IR64 rice lines from Arcadia Bioscience. Scientists expect that within 2-3 months, the import process will be completed and contained trials will begin.

The plant breeding division of BRRI is conducting multiple trials of Golden rice BRRI *dhan* 29 in different locations of the country. The plant breeding division is also working with the International Rice Research Institute (IRRI) to develop zinc (Zn) and iron (Fe) enriched transgenic rice variety, for which the National Committee for Biosafety (NCB) already has approved the importation of seed for trials.

With green house support of the biotech division of BRRI, the department of biochemistry and molecular biology of University of Dhaka has been screening some of the salt tolerant transgenic rice lines. BRRI's Annual Report 2016-17 reported seedling tests for 14 transgenic lines of rice variety BRRI *dhan* 28, 29, 36 and 2 BRRI *dhan* 47 containing Pea DNA Helicase 45 (PDH45). Of those, five lines were found to be saline tolerant at the seedling stage and were selected for reproductive stage characterization at 10 $dSm^{-1}$ and for assessing yield potential under stress.

The biotech division of BRRI is also researching development of non-transgenic low glycemic index (GI) rice variety, a salt-tolerant rice variety, and an antioxidant-enriched black rice variety.

The plant breeding and biotechnology laboratory of the Department of Botany, University of Dhaka, has been working since 2009 to develop a peanut resistant to fungal disease (*Arachis hypogaea* L.) Transformation experiments in two varieties of peanut, namely, Dhaka-1 and BINA Chinabadam-4, were performed using *Agrobacterium* strains LBA4404 containing antifungal protein gene (AFP) and marker gene Neomycin phosphotransferase II (NPTII). Transformation frequency was 0.85% and 0.69% in Dhaka-1 and BINA Chinabadam-4 variety, respectively. The integration of a fungal-disease-resistant gene within the genomic DNA was confirmed through PCR analysis followed by Southern blot. T2 seeds were collected and further molecular analysis will be carried out with these transgenic plants.

To develop a GE cotton variety for commercial release, the Cotton Development Board (CDB) has initiated collaborative research with foreign cotton seed producing companies. This year CDB applied for approval to import seed and conduct research jointly with JK Agri-Genetics Ltd. (JKAL), India. An approval for Material Transfer Agreement (MTA) and contained trial were given to test productivity and stability of four hybrid Bt cotton varieties having X-GENE, Cry1Ac Truncated (Event- 1). The goal is development of an efficient GE cotton variety which is resistant to Bollworm and Spodoptera/Army worm.

b) COMMERCIAL PRODUCTION: In October 2013, four Bt brinjal varieties were approved for seed production and cultivation by the National Committee on Biosafety (NCB), which is located in the Ministry of Environment and Forests (MOEF). In FY 2016-17, biotechnology division and seed technology division of Bangladesh Agricultural Research Institute (BARI) continued its breeder seed production program and produced 1,537 kg breeder seed of four Bt brinjal varieties. The biotech division alone produced 1,068 kg of seed against the target 800 kg; the seed technology division produced 469 kg seed. The seed will be distributed to various interested government and non-government organizations and farmers.

   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 Bangladesh Agricultural Development Corporation (BADC). In FY 2017-18, BADC is planning to sell commercially 140 kg of Bt *Begun* 2 and 144.5 kg of Bt *Begun* 4. Also of note, Bt brinjal that is currently being produced now can be sold in local markets.

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

d) IMPORT: According to the 2012 Bangladesh Biosafety Rules (BR) (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). Post 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.

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; the 2014 Action Plan of the National Biotechnology Policy 2012; the 2007 National Biosafety Framework (NBF) (See Gain Report BG4007); the 2007 Biosafety Guidelines of Bangladesh (BG) (See Gain Report BG4006); the 2012 Bangladesh Biosafety Rules (See Gain Report BG4005); the 2013 Bangladesh Standard for Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants; the 2016 Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants; and the 2017 User's Guide to Biosafety Regulatory Process for Genetically Engineered Plants in Bangladesh. The MoEF is also crafting a Bangladesh Biosafety Policy, which is subject to GOB approval.

The User's Guide to Biosafety Regulatory Process on Genetically Engineered Plants in Bangladesh, published in 2017, guides the user through the process of submitting an application to the biosafety regulatory system. The Guideline for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants, published in 2016, is used for planning and conducting an environmental risk assessment in support of an open release of a GE plant 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, 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 was published in 2013 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 2006

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]." Because Bangladesh is a signatory of the Cartagena Protocol on Biosafety (CP), the 2007 BG, 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 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 as long as 360 days, if not more.

Although the 2007 BG 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 2007 BG).

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 the 2012 BR, "[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, 1996 Plant Quarantine Rules, (amended up to 1989), and the 2005 Animal Quarantine Act.

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<br><br>Leads the National Technical Committee on Biodiversity<br>Houses the Biosafety Core Committee (BCC).<br><br>Competent national authority and focal point to implement the Cartagena Protocol of Biosafety.<br><br>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.<br><br>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.<br><br>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.<br><br>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 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). Late blight resistant potato variety 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 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.

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 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." 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 as there is 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.

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.

l) 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.

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 is available.

c) EXPORT: No information is available.

d) IMPORT: No information is available.

e) TRADE BARRIERS: No information is 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: (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.

b) INNOVATIVE BIOTECHNOLOGYIES: The country has not decided whether to regulate innovative biotechnology like genome editing in animals.

c) LABELING AND TRACEABILITY: No information is available.

d) INTELLECTUAL PROPERTY RIGHTS (IPR): No information is available

e) INTERNATIONAL TREATIES and FORUMS: Bangladesh is member of the World Organization for Animal Health (OIE) and the Codex Alimentarius (Codex). Activity in these two international bodies has been limited.

f) RELATED ISSUES: No information is 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 is available.