রেজিস্টার্ড নং ডি এ-১

বাংলাদেশ গেজেট

অতিরিক্ত সংখ্যা
কর্তৃপক্ষ কর্তৃক প্রকাশিত

শুক্রবার, ডিসেম্বর ৯, ২০১৬

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার

পরিবেশ ও বন মন্ত্রণালয়

পরিবেশ অধিশাখা-২

প্রজ্ঞাপন

তারিখ: ২২ নভেম্বর ২০১৬

নং ২২.০০.০০০০.০৭৩.৪১.০০১.২০১৪-২২৮—জেনেটিক্যালি ইঞ্জিনিয়ারড বা মডিফাইড উদ্ভিদের পরিবেশগত ঝুঁকি নিরূপণের ক্ষেত্রে সংশ্লিষ্ট বিজ্ঞানী/গবেষক এবং জীবনিরাপত্তা সংশ্লিষ্ট নিয়ন্ত্রক কর্মকর্তাবৃন্দ কর্তৃক অনুসৃতব্য কারিগরি বা বৈজ্ঞানিক **Terms and Terminologies** সমৃদ্ধ **Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants** শীর্ষক চূড়ান্ত গাইডলাইন্সটি এতদ্বারা সংশ্লিষ্ট সকলের জ্ঞাতার্থে প্রকাশ করা হইল।

1. INTRODUCTION

Modern biotechnology, involving the use of recombinant DNA (rDNA) technologies, also known as genetic engineering, has emerged as a powerful tool with many potential applications in healthcare and agriculture. New plant varieties developed using rDNA techniques, commonly referred to as genetically engineered (GF), genetically modified (GM) or transgenic plants, have been and are being developed with the aim of enhancing productivity; decreasing dependence on the use of agricultural chemicals; modifying the inherent properties of crops; improving the nutritional value of foods and feeds; and mitigating the adverse biotic and abiotic impacts of climate variability.

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In Bangladesh, the regulation of GE plants is encoded in the Biosafety Rules, promulgated under the Environment Conservation Act, 1995 and elaborated in the Bangladesh Biosafety Guidelines. A National Committee on Biosafety (NCB) which is responsible for making decisions regarding the use of GE plants, as well as a Biosafety Core Committee (BCC) which is responsible for providing the NCB with technical advice and analysis, including environmental risk assessment are functional in this regard.

2. PURPOSE OF THE ERA GUIDELINES IN THE CONTEXT OF THE BIOSAFETY FRAMEWORK OF BANGLADESH

The Biosafety Guidelines of Bangladesh have been made part of the regulations under the Biosafety Rules 2012. These provide a framework and principles for conducting environmental risk assessments (Section 3.1), as well as a detailed description of the decision-making process for conducting and managing field trials for GE plants (Annex 5). However, there is no elaboration of the elements necessary to conduct an environmental risk assessment for an open release (*e.g.* for commercial cultivation) of a GE plant. In order to fill this gap, this document has been developed for planning and conducting an environmental risk assessment in support of an open release of a GE plant in Bangladesh. It provides a practical elaboration to the risk assessment framework included in the Biosafety Guidelines of Bangladesh by detailing the types of information that will be informative for environmental risk assessment of GE plants in Bangladesh. Where appropriate, these guidelines will refer back to the ERA framework and the principles of ERA that are contained in the Biosafety Guidelines of Bangladesh.

Environmental Risk Assessments conducted in accordance with these guidelines should be in compliance with pertinent national and international guidelines, protocols and standards such as but not limited to:

- The Bangladesh Guidelines for the Safety Assessment of Foods Derived From Genetically Engineered Plant.
- Annex III of the Cartagena Protocol.
- Consensus documents published by the Organization for Economic Cooperation and Development's (OECD's) Working Group on Harmonization of Regulatory Oversight in Biotechnology.

3. SCOPE

These guidelines are intended to apply to both imported and domestically developed GE plants that are:

1. Intended for cultivation; or
2. Propagable forms of GE plant material that may be imported for direct use in food, feed, or processing, which could become established and persist without human intervention due to unintentional release into the environment[1].

These guidelines are not intended to apply to:

1. The importation of non-propagable products of GE plants for direct use in food, feed or processing (*e.g.*, flour, starch, crushed meal, oil derived from a GE plant);
2. The environmental introduction of non-plant genetically engineered organisms (*e.g.*, recombinant micro-organisms);
3. Experimental GE plants in confined field trials.

4. DEFINITIONS

Confined field trial is a field experiment of growing a regulated, GE plant in the environment under specified terms and conditions that are intended to mitigate the establishment and spread of the plant.

Conventional counterpart means the related, non-genetically engineered plant variety.

Donor organism means the organism from which genetic material is obtained for transfer to the recipient organism.

Event is a genotype produced from the transformation of a single plant using a specific genetic construct. For example, two lines of the same plant species transformed with the same of different constructs constitute two events.

Host organism means the plant species that was transformed to produce the genetically engineered plant.

Genetically engineered plant (GE plant) means a plant in which the genetic material has been changed through *in vitro* nucleic acid techniques, including

[1]Depending on the host plant species and the expressed trait(s) of the subject GE event, the environmental risk/safety assessment may be limited to a subset of the requirements described in these guidelines due to the reduced environmental exposure associated with this category of GE plants.

recombinant deoxyribonucleic acid (rDNA) and direct injection of nucleic acid into cells or organelles.

Also referred to as a genetically modified (GM) or transgenic plant.

Hazard means a biological, chemical or physical agent in, or condition of the GE plant with the potential to cause an adverse environmental effect subject to exposure.

Modern biotechnology means the application of:

I. *In vitro* nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles of plants/crops OR.

II. Fusion of cells beyond the taxonomic family, that overcome natural and physiological reproductive or recombinant barriers, and that are not the techniques used in traditional breeding and selection of plants/crops.

Non-target organism means an organism that is not targeted for intended action.

Risk, in relation to any plant, means the probability of an adverse effect on the environment and the severity of that effect, consequential to an environmental hazard.

Risk analysis, in relation to any plant, means a process consisting of three components, *i.e.,* risk assessment, risk management and risk communication.

Risk assessment means a scientifically-based process consisting of the following steps: (i) hazard identification; (ii) hazard characterization; (iii) exposure assessment; (iv) risk characterization.

Risk management is any actions or mechanisms used to control or mitigate risks.

Risk communication includes the processes, mechanisms or structures used to communicate with stakeholders, including the public, policy and decision makers, and others regarding risks and the results of a risk assessment.

Transgene means transfer of gene from and organism of one species to an organism of another species by genetic engineering.

Transgenic plant means a plant in which a transgene has been integrated into its genome.

Transformation means the unique DNA recombination event that took place through the integration of a transgenic(s) in one plant cell for genetic modification, which was then used to generate entire transgenic plants.

5. GENERAL CONSIDERATIONS IN ERA

In order to conduct an environmental risk assessment for the release of a GE plant, it is first necessary to have a thorough understanding of what plant is being assessed. This includes basic information about the plant species, the introduced trait, how the trait was introduced and the origins of the trait, as well as the basic characteristics of the resulting transformed plant. While only some of this information will ultimately be informative for indentifying potential adverse effects to the environment that may result from the release of the GE plant, it is necessary for a risk assessor to review the information in order to establish what characteristics of the plant are novel, and what characteristics are familiar, as described in Section 3.1.4 of the Biosafety Guidelines. The following sections elaborate the necessary information identified in the points to consider for risk assessment contained in Section 3.1.5 of the Biosafety Guidelines.

5.1 DESCRIPTION OF GE PLANT

A description of the GE plant being presented for risk/safety assessment needs to be provided. This description should identify:

1. Name of the GE event that is the subject of this application (including any commercial or trade names);
2. Unique event-specific identifier for the GE Plant[2];
3. Name of the non-transgenic host plant or non-modified counterpart or parental plant;
4. Pedigree map of the GE Plant, detailing the parental lines from which the GE Plant was derived and showing the back crosses conducted following transformation;
5. Purpose of the genetic modification;
6. Intended uses of the GE Plant;
7. Geographical areas within Bangladesh to which distribution of the product is intended.

[2]Please refer to the document "OECD guidance for the designation of a unique identifier for transgenic plants" at http:/www.olis.oecd.org/oild/2002doc.nsf/LinkTo/NT00000C6E/SFILE/JT00172125.PDF.

5.2 DESCRIPTION OF THE NON-TRANSGENIC HOST PLANT OR NON-MODIFIED COUNTERPART OR PARENTAL PLANT

Information requirements under this section may be fulfilled by referencing the appropriate biology document for the subject plant species, where this has been published by relevant organization/institutes or MoEF, and/or by the OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology. In all other cases, the applicant must submit detailed information for each of the subject areas below including all relevant sources of this information (*e.g.*, literature citations).

1. Taxonomy, geographic origin and domestication of the plant
    a. Taxonomy
    b. Relatives of the species
    c. Geographic origin (centre of origin)
    d. Domestication
    e. Status of Germplasm diversity
2. Reproductive biology
    a. Growth and development
    b. Floral biology
    c. Pollination and fertilization
    d. Asexual reproduction
    e. Dissemination of seed
    f. Seed dormancy
    g. Mating systems
3. Naturally occuring crosses
    a. Intra-and inter-specific crosses
    b. Natural crossability
    c. Intra-generic hybridization
    d. Wild relatives in Bangladesh
    e. Gene flow
    f. Volunteers and weediness
    g. Potential for gene transfer to other plants
    h. Free-living populations

4. Cultivation in Bangladesh
    a. Climatic and soil types.
    b. Breeding objectives, milestones in breeding advances and challenges.
    c. Zonalization of varietal testing or Zonal Varietal Testing.
    d. Major pests and pathogens of the plant species in Bangladesh.
    e. Beneficial organisms associated with the plant species in Bangladesh.

5.3 DESCRIPTION OF THE DONOR ORGANISMS

Information has to be provided on the donor organism(s) and, when appropriate, on other species related to the donor. It is particularly important to indicate if the genetic component is responsible for disease or injury to plants or other organisms, or if it encodes a known toxicant, allergen, pathogenicity factor, or irritant. The description of the donor organism(s) should include:

1. Common name (Both Bengali and English);
2. Scientific name;
3. Taxonomic classification;
4. Information on the history of safe use of the donor organism, or components thereof, including whether the introduced genetic element is present in any other genetically engineered plants authorized for general release in Bangladesh and/or other countries.

5.4 DESCRIPTION OF THE GENETIC MODIFICATION(S)

Consistent with the Bangladesh Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants—2013, detailed information is required on the genetic modification to allow for the identification of all genetic material potentially delivered to the host plant and to provide all relevant information required for the analysis of the data supporting the characterization of the DNA inserted in the plant:

The description of the genetic modification needs to include:

1. Information on the specific method used for the modification (*e.g. Agrobacterium* mediated transformation or direct transformation by methods such as particle bombardment or eleetroporation, etc.);

2. Description and characterization of all genetic material used to modify the plant, including the source (*e.g.* plant, microbial, viral, synthetic), identity and expected function in the plant;
3. Details of modifications to be introduced, intermediate and recipient genetic material (*e.g.,* changes in amino acid sequence that may affect expression of the expressed protein);
4. A summary diagram of all genetic components, which comprise the vector including coding regions, and non-coding sequences of known function, needs to be provided. For each genetic component a citation where these functional sequences are characterized (publicly available database citations are acceptable) is required and also indicate:
    a. The portion and size of the sequence inserted.
    b. The location, order, and orientation in the vector.
    c. The function in the plant.
    d. The source (common and scientific and/or trade name, of the donor organism).
    e. If the genetic component is responsible for disease or injury to plants or other organisms, and is a known toxicant, allergen, pathogenicity factor, or irritant, if any.
    f. If the donor organism responsible for any disease or injury to plants or other organisms, produces toxicants, allergens or irritants or whether closely related to organisms that do.
    g. History of safe use of the donor organism or components thereof, if available.

5.5 MOLECULAR CHARACTRIZATION OF TRNSGENE (S)

A comprehensive molecular and biochemical characterization of the genetic modification needs to be carried out. The requirements below are consistent with the Bangladesh Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants—2013: Information is required on the DNA insertions into the plant genome and should include:

1. The characterization and description of the inserted genetic materials;
2. The number of insertion sites;
3. The organization of the inserted genetic material at each insertion site including copy number and data to demonstrate if complete or partial

copies were inserted, and if the arrangement of the genetic material was conserved or if significant rearrangements have occurred upon integration;

4. Sequence data of the inserted material and of the flanking regions bordering the site of insertion;
5. Information on sequence homology with known allergen sequences;
6. Identification of any open reading frames within the inserted DNA or created by the insertion with contiguous plant genomic DNA including those that could result in fusion proteins.

Information needs to be provided on any expressed substances in the GE plant including:

1. The gene product(s) (*e.g*., a protein or an untranslated RNA);
2. The gene product(s)' function;
3. The phenotypic description of the new trait(s);
4. The level and site of expression of the expressed gene product(s) in the plant, and the levels of its metabolites in the edible portions; and
5. The amount of the target gene product(s), where possible if the function of the expressed sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein.

In addition, information is also required:

1. To demonstrate whether deliberate modifications made to the amino acid sequence of the expressed protein result in changes in its post-translational modifications or affect sites critical for its structure or function;
2. To demonstrate whether the intended effect of the modification has been achieved and that all expected traits are expressed and inherited in a manner that is stable through several generations consistent with laws of inheritance. It may be necessary to examine the inheritance of the DNA insert itself or the expression of the corresponding RNA if the phenotypic characteristics cannot be measured directly;
3. To demonstrate whether the newly expressed trait(s) are expressed as expected in the appropriate tissues in a manner and at levels that are consistent with the associated regulatory sequences driving the expression of the corresponding gene;

4. To indicate whether there is any evidence to suggest that one or several genes in the host plant has been affected by the transformation process; and

5. To confirm the identity and expression pattern of any new fusion proteins.

5.6 PHENOTYPIC AND AGRONOMIC CHARACTERISTICS OF THE GE PLANT

Information must be provided on the phenotype of the GE plant, including any observation of unintended or unanticipated characteristics. The GE plant should be compared with a suitable conventional counterpart (*e.g.,* near-isogenic line or parental line and related cultivated varieties. Data should be collected from confined field trials conducted in a range of environmental conditions representative of the intended area of commercial cultivation.

Phenotypic data should address the following consideration[3] :

1. Growth habit : note any changes in basic morphology of the plant including any abnormalities or changes in overall growth habit.

2. Life cycle: describe if the annual, biennial or perennial and if this has changed from the non-transformed parental plant.

3. Plant growth and reproductive characteristics, including:

   a. Vegetative vigor *e.g.,* plant height, crop biomass, etc.;

   b. Ability to overwinter (or over season);

   c. Number of days to onset of flowering; number of days ofr flowering;

   d. Number of days until maturity *e.g*., time to the production of mature fruit or seed (suitable for harvesting);

   e. Seed parameters *e.g.,* seed production, length of time (days) of seed/fruit production, seed dormancy, seedling emergence;

   f. Proportion surviving from seedling to reproduction;

   g. Out crossing frequency (generally an inferred conclusion based on other empirical observations related to reproductive biology and not on experimental measurements of gene flow for the engineered plant).

[3] Applicants may provide valid scientific rationale why certain information is unnecessary or inappropriate.

h. Impact on beneficial species *e.g.*, changes in pollinator species visiting flowers and data on changes in flower morphology, color, fragrance, etc. that may affect interactions with pollinators;

i. Pollen parameters *e.g.*, amount of pollen produced, proportion of viable pollen; the longevity of pollen under varying environmental conditions; physical parameters such as stickiness, shape, and weight;

j. Fertility *e.g.*, fertility acquired or lost;

k. Self-compatibility;

l. Asexual reproduction *e.g.*, vegetative reproduction; ability of the plant material to set roots; parthenocarpy;

m. Seed dispersal factors *e.g.*, characteristics such as seed shattering or dispersal by animals;

n. Stress adaptations to biotic and/or a biotic stresses, including changes in disease susceptibility.

6 CULTIVATION PRACTICES

Information must be provided on any predictable impacts on existing agronomic practice that could arise as a consequence of cultivation of the GE plant and that would have a potential effect on the biodiversity of the receiving environment (in most cases this refers to the agro-ecosystem where the genetically engineered plant will be cultivated). The following considerations should be taken into account:

1. Describe the regions where the conventional plant species is currently cultivated within Bangladesh and if the genetic modification is anticipated to change the area of current cultivation for the plant species. Describe any new ecosystems where the genetically engineered plant may be cultivated (*e.g.*, salt tolerance that allows cultivation in degraded soils).

2. Describe cultivation practices for the genetically engineered plant, including land preparation, fertilizer usage, weed and pest control, harvest, post-harvest protocols, and any other applicable cultivation practices. Discuss any differences with practices traditionally used for

the plant species, particularly how these could affect agro-ecosystem sustainability, crop rotations, pesticide use, frequency of tillage, soil erosion, or the management of volunteers for succeeding crops (*e.g.*, any changes in tillage practices associated with herbicide tolerance traits).

3. Describe any specific deployment strategies recommended for the genetically engineered plant (*e.g.*, insect resistance management in the case of insect-resistant GE plants).

4. Discuss the environmental impact of any potential gene flow if the genetically engineered plant will be cultivated in areas where other sexually compatible plants exist (*e.g.*, unmodified varieties of the same plant species, other sexually compatible species or wild relatives). The following questions should be addressed:

    a. Is the introduced trait similar to a trait currently present in natural populations of the compatible wild species (e.g., drought tolerance as a phenotypic trait may already be known in the host plant species but enhanced in the GE event)?

    b. If so, does it have the potential to increase the reproductive fitness or confer a selective advantage in the recipients of gene flow?

    c. Would this be expected to significantly affect the establishment and spread of populations where gene flow has occurred?

    d. Would those alterations lead to an identifiable harm to the environment or to biodiversity?

7 IMPACT ON NON-TARGET ORGANISMS

For those GE plants that have a target organism, including insect resistant or nematode resistant plants expressing a pesticidal protein or molecule, or in cases where the introduced trait is known to have toxic activity, the potential for adverse environmental impacts on non-target organisms should be evaluated. Typically, this follows a tiered approach. Plans that have traits which are not expected to alter their interactions with other organisms are not expected to undertake the types of testing described below. These tests are not necessary for plants developed for altered stress tolerance and nutritional characteristics. Final decisions on the adequacy of information developed in support of a risk assessment will be made on a case by case basis by the National Committee on Biosafety.

Tier I (or early-tier) teste are laboratory experiments conducted under highly conservative exposure conditions. Test species are exposed to concentrations of the transgene product (*e.g.,* insecticidal protein) in excess of exposure levels in the field to increase the likelihood of detecting adverse effects on non-target organisms. Applicants should consider the range of non-target organisms that are appropriate for Tier I tests when selecting the test species. These should be representative of functional groups persent in the receiving environment and that are likely to be exposed to the active compound *i.e.,* through direct feeding or other exposure to the plant or plant part, dispersed plant parts, secretion, degradation, or leaching of the introduced gene product(s), or to organisms that feed on the plant.

Applicants should provide the results of Tier I studies using test diets incorporating concentrations of the transgene product at, or above, the maximum estimated environmental exposure for representative non-target organisms. Actual organisms to be tested may be determined on a case by case basis depending on the nature of the GE plant being assessed and its intended use. The following list provides examples of test organisms which have been routinely used for Tier I testing associated with GE plants. It is not a list of required tests for releasing a GE plant in Bangladesh. It should be noted that the abundance of arthropod test species is related to the use of insecticidal traits in GE plants, and may not be relevant for future applications.

Tire I studies conducting in support of ERA for GE plants with pesticidal traits have typically included:

1. Mammalian (*e.g*. mouse)
2. Aquatic invertebrate, (*e.g*. *Daphnia magna*)
3. Non-target arthropods:
    a. Honey bee larvae and adults (*e.g*. *Apis mellifera*)
    b. Lady beetle (*e.g*. *Hippodamia convergent*)
    c. Green lacewing, (*e.g*. *Chrysopa carnea*)
    d. Parasitic hymenopteran (*e.g*. *Brachymeria intermedia*)
4. Soil dwelling organisms:
    a. Collembola
    b. Earthworm, (*e.g*. *Lumbricus terrestris*)

Results from studies to assess the actual abundance of non-target species under field conditions (*i.e*., Tire 2 studies) are only required if the results from Tier 1 studies indicate that hazrad characterization and exposure assessment need to be further refined (*i.e*., the results of Tier 1 tests indicate there is a hazrad to the test organisms and harm may be realized under environmentally relevant conditions).

In addition, the applicant should characterize any potential adverse effects on the health of humans that may arise through physical contact with the genetically engineered plant. This may include a comparison of the GE plant and its conventional counterpart with respect to the likely exposure to toxins, irritants, and allergens.

8 POST-RELEASE ENVIRONMENTAL MONITORING

The need for post-release environmental monitoring will be determined on a case-by-case basis, taking into account familiarity with the plant species and trait. In all cases, monitoring shall be hypotheseis-driven and supported by scientific and statistically relevant data, For exemple, plants expressing insecticidal proteins may be approved for cultivation with a requirement for implementation of an insect resistance management plan that includes monitoring for the development of resistance in the target insect population.

9 INSTRUCTIONS ON DATA QUALITY

The quality of data submitted with the application should be equivalent to that submitted for peer-reviewed scientific publications. Applicants should clearly describe experimental procedures followed in developing data, including methods, reference materials, quality control and quality assurance procedures, statistical analyses, together with bibliographic references as appropriate. Statistically valid experimental designs and protocols should be employed in the generation of all field trial data, and trials should be conducted in a manner consistent with the proposed agricultural practices for the GE plant. The details of all confined field trial protocols, including experimental designs and sampling procedures, should be submitted.

Annex 1: Proforma for Submission of Data Supporting Environmental Risk Assessment of GE Plants

1 APPLICANT INFORMATION

The applicant should identify the point of contact related to the submission as well as the identity of the legally responsible party in Bangladesh.

Name of Applicant Organization	
Legally Responsible Representative/Individul (must be resident in Bangladesh)	
Contact Person (if different than above) or	
Address	
Telephone Number	
Cell No	
Fax	
email	

2 GENERAL INFORMATION ON THE GE PLANT

Name of the GE plant or event	
Common name of the plant	
Scientific name of the plant	
Description of the introduced trait (*e.g.* drought tolerance; insect resistance, etc.)	
Origin or source of the introduced genes	
Unique Identifier (if applicable)	
Intended Use (*e.g.* Food, Feed, Cultivation)	

3 CHECKLIST OF INFORMATION SUBMITTED IN SUPPORT OF ENVIRONMENTAL RISK ASSESSMENT

The below checklists are intended to provide useful reference to both applicants and risk assessors. Decisions about what information is required for any particular risk assessment will be made on a case by case basis. Information listed here may not be required in all cases, and information not listed here may be required for a particular case if additional information needs are identified.

3.1 DESCRIPTION OF THE GE PLANT

Information Provided	YES	NO
Name of the GE event		
Unique Identifier		
Name of the non-modified or parental plant		
Pedigree map of the GE plant		
Purpose of the genetic modification		
Intended uses of the GE plant		
Geographical areas within Bangladesh to which distribution is intended		

3.2 DESCRIPTION OF THE NON-TRANSGENIC HOST PLANT OR NON-MODIFIED PLANTS

Information Provided	YES	NO
Taxonomy, geographic origin and domestication of the plant		
Taxonomy		
Relatives of the species		
Geographic origin (centre of origin)		
Domestication		
Germplasm diversity		
Reproductive biology		

Growth and Development		
Floral Biology		
Pollination and fertilization		
Asexual reproduction		
Dissemination of seed		
Seed dormancy		
Mating systems		
Naturally occurring crosses		
Intra-and inter-specific crosses		
Natural crossability		
Inter-generic hybridization		
Wild relatives in Bangladesh		
Gene flow		
Volunteers and weediness		
Potential for gene transfer to other plants		
Free-living populations		
Cultivation in Bangladesh		
Climatic and soil types		
Breeding objectives, milestones in breeding advances and challenges		
Zonal varietal testing		
Major pests and pathogens of the plant species in Bangladesh		
Significant beneficial organisms associated with the plant species in Bangladesh		

For any information not included, please provide a rationale as to why the information is not relevant or necessary for environmental risk assessment of the GE plant, or what information is being provided in its place.

3.3 DESCRIPTION OF THE DONOR ORGANISMS

This Information should be provided for the donor of each transgene present in the GE plant

Information Provided	YES	NO
Common name		
Scientific name		
Taxonomic classification		
History of use		

For any information not included, please provide a rationale as to why the information is not relevant or necessary for environmental risk assessment of the GE plant, or what information is being provided in its place.

3.4 DESCRIPTION OF THE GENETIC MODIFICATIONS

Information Provided	YES	NO
Modification method		
Characterisation of the genetic material		
Description of any modifications to be introduced		
Summary diagram of the genetic components		

For any information not included, please provide a rationale as to why the information is not relevant or necessary for environmental risk assessment of the GE plant, or what information is being provided in its place.

3.5 MOLECULAR CHARACTERIZATION OF TRANSGENE(S)

The following information should be provided for each transgene in the GE plant

Information Provided	YES	NO
The genetic modification		
Characterization and description of the inserted genetic material		
Number of insertion sites		
Description of the organization of the genetic material at each insertion site		

Sequence data of the inserted material and flanking regions			
Homology with known allergen sequences			
Identification of open reading frames within the inserted DNA or contiguous plant genome			
Expressed substances			
Gene product (e.g. protein or RNA)			
Function of the gene product			
Pheonotypic description of the new trait			
The level and site of expression of the gene product in the plant			
Confirmation of intended effects			
Evidence supported the function of any modifications to the amino acid sequence or post translational modification			
Evidence of stable inheritance			

For any information not included, please provide a rationale as to why the information is not relevant or necessary for environmental risk assessment of the GE plant, or what information is being provided in its place.

3.6 PHENOTYPIC AND AGRONOMIC CHARACTERISTICS OF THE GE PLANT

Information Provided	YES	NO
Growth Habit		
Life Cycle of the plant		
Plant growth and reproductive characteristics		
Vegetative vigour *e.g.,* plant height, crop biomass, etc		
Ability to overwinter (or over season)		
Number of days to onset of flowering number of days for flowering		
Number of days until maturity *e.g.,* time to the production of mature fruit or seed (suitable for harvesting)		
Seed parameters *e.g.,* seed production, length of time (days) of seed/fruit production, seed dormancy, seedling emergence		
Proportion surviving from seeding to reproduction		
Outcrossing frequency (generally an inferred conclusion based on other empirical observations related to reproductive biology and not on experimental measurements of gene flow for the engineered plant)		
Impact on beneficial species *e.g.,* changes in pollinator species visiting flowers and data on changes in flower morphology, colour, fragrance, etc. that may affect interactions with pollinators.		

Pollen parameters *e.g.,* amount of pollen produced, proportion of viable pollen; the longevity of pollen under varying environmental conditions; physical parameters such as stickiness, shape, and weight.		
Fertility *e.g.,* fertility acquired or lost.		
Self-compatibility		
Cross-pollination or corssability		
Asexual reproduction *e.g.,* vegetative reproduction; ability of the plant material to set roots; parthenocarpy.		
Seed dispersal factors *e.g.,* characteristics such as seed shattering or dispersal by animals.		
Stress adaptations to biotic and/or abiotic stresses, including changes in disease susceptibility.		

For any information not included, please provide a rationale as to why the information is not relevant or necessary for environmental risk assessment of the GE plant, or what information is being provided in its place.

3.7 **CULTIVATION PRACTICES**

Information Provided	YES	NO
Regions of cultivation in Bangladesh		
Cultivation practices for the GE plant		
Associated recommended management practices (e.g. insect resistance manage−ment)		
Environmental impact of gene flow		

For any information not included, please provide a rationale as to why the information is not relevant or necessary for environmental risk assessment of the GE plant, or what information is being provided in its place.

3.8 IMPATS ON NON-TARGET ORGANISMS

If the genetic modification is expected to have impacts to other organisms, then information addressing potential impacts on non-target organisms will be required.

Information Provided	YES	NO
Tier I Testing Results		
Mammalian		
Aquatic organisms		
Non-target arthropod		

Soil dwelling organisms		
Tier II or higher Tier testing results		
Have higher tier NTO Studies been reported?		

3.9 POST RELEASE ENVIRONMENTAL MONITORING

Post release environmental monitoring may be required on a case by case basis.

	YES	NO
Has information been submitted detailing plans for post release environmental monitoring?		

রাষ্ট্রপতির আদেশক্রমে

খোরশেদা ইয়াসমীন
উপসচিব।

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