GUIDELINES

FOR THE ENVIRONMENTAL RISK ASSESSMENT OF GENETICALLY MODIFIED (GM) PLANTS IN SRI LANKA

Ministry of Environment, Sri Lanka

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Guidelines for the environmental risk assessment of Genetically Modified (GM) plants in Sri Lanka

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CONTENTS

1. Introduction 1
2. Scope 1
3. Definitions 2
4. Regulatory authorities 3
5. Approach to environmental risk assessment 3
   - 5.1 Principles of risk assessment
   - 5.2 Risk assessment process
6. Information requirements in environmental risk assessment 6
   - 6.1 Description of GM event
   - 6.2 Description of non-modified parental plants
   - 6.3 Description on donor organisms
   - 6.4 Description of genetic modification
   - 6.5 Molecular characterization of genetic modification
   - 6.6 Phenotypic and agronomic characteristics of GM plants
   - 6.7 Cultivation practices of GM plants
   - 6.8 Potential impact on non-target organisms or effects on biodiversity and ecosystems
7. Post release environment monitoring 13
8. Instructions on Data Quality and Relevance 13
9. Detection and identification requirements 14

References and additional information 14

Annex 1: Format for application for environmental releases of a GM plant for the purpose of cultivation 15

1. Introduction

Genetically Modified (GM) plants produced using modern biotechnology[1] techniques have been developed for a variety of purposes in agriculture. These include enhancing agricultural productivity, reducing dependence on the use of agricultural chemicals, improving the agronomic qualities of plants, enhancing the nutritional value and increased tolerance to biotic and abiotic stresses and producing cost effective and sustainable industrial products, including biofuels. GM plants are also referred to as Genetically Engineered (GE), living modified or transgenic plants.

The National Biosafety Framework of Sri Lanka (NBF), 2005 aims to ensure that the risks likely to be caused by organisms and products produced using modern biotechnology are minimized and biodiversity, human health and environment are protected in a maximum way through formulation of relevant policies, regulations, technical guidelines and establishment of management bodies and supervisory mechanisms. Sri Lanka is also a Party to the Cartagena Protocol on Biosafety that requires Parties to make decisions on import and use of Living Modified Organisms (LMOs)[2] for intentional introduction into the environment in accordance with scientifically sound risk assessments. Annex III to the Protocol sets out principles and methodologies on how to conduct a risk assessment. These assessments aim at identifying and evaluating the potential adverse effects of LMOs prior to release. In line with the above, GM plants are subjected to safety assessments prior to release in Sri Lanka.

The *'Guidelines for Environmental Risk Assessment of GM plants'* have been prepared for planning and conducting an environmental risk assessment in support of a GM plant in Sri Lanka for the purpose of cultivation. These guidelines provide a comprehensive, transparent and science-based framework for Sri Lanka, by which regulators can identify and characterize the risks that might be caused by the cultivation of GM plants in a consistent manner in support of the release of a GM plant in Sri Lanka. These guidelines should be considered in conjunction with other national guidance documents i.e. *Guidelines for the safe use of GMOs/LMOs in the laboratory, Guidelines for the conduct of Confined Field Trials of GM Plants, Guidelines for the safety assessment of food derived from GM plants etc.* Also, careful attention should be paid to ensure that appropriate experimental studies are conducted to address all necessary information and data requirements.

2. Scope

These guidelines apply to imported and domestically developed GM plants that are:

i. Intended for cultivation in Sri Lanka or
ii. Propagable forms of GM plant material that may be imported for direct use in food, feed or processing, which may also get established and persist without human intervention, due to unintentional release into the environment.[3]

[1] Modern Biotechnology is defined as the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

[2] LMO is defined as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology; LMOs are considered to be synonymous with genetically modified organisms (GMOs).

[3] 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 GM plants.

These guidelines do not apply to:

i. The import of non-propagable products of GM plants for direct use in food, feed, or processing (e.g., flour, starch, crushed meal or oil derived from a GM plant);
ii. The environmental introduction of GMOs other than plants (e.g., recombinant micro-organisms); and
iii. Regulated GM plants in confined field trials[4]

3. Definitions

The definitions below apply to these guidelines for conduct of Environmental risk Assessment (ERA) of GM plants.

Event: A genotype produced by an independent act of transformation of a single plant species using a specific gene construct. For example, two lines of the same plant species transformed with the same gene construct but harbouring integrations of introduced DNA at different locations on the plant genome constitute two events.

Hazard: A biological, chemical or physical agent or condition of the GM plant, with the potential to cause an adverse environmental effect subject to exposure.

Risk: IIn relation to any GM plant, the probability that some valued environmental resource (including human and animal health) will be adversely affected by exposure to a hazard caused by the plant. Risk is commonly expressed as an equation: Risk = ∫ (Hazard • Exposure).

Risk assessment: Risk assessment is a scientific process of estimating the potential of a hazard to give rise to an adverse outcome. This estimation is based on a combination of the likelihood of the hazard occurring and the consequences if the hazard occurs.

Risk characterization: The determination of the seriousness of a harm and the chance that the harm will occur.

Risk management: Any actions or mechanisms used to control or mitigate risks.

[4] A confined field trial (CFT) is a field experiment of a GM plant under terms and conditions prescribed to mitigate the unregulated spread of the plant

4. Regulatory authorities

The Central Environment Authority under The Ministry of Environment (MoE) is the NCA for the implementation of biosafety regulations involving GMOs/LMOs in Sri Lanka. MoE has set up a National Coordinating Committee for Biosafety (NCCB) for overseeing activities involving GMOs/ LMOs. NCCB consists of members from concerned ministries, experts and epresentatives from relevant institutions of Sri Lanka. There are five government departments that serve as the Sectoral Competent Authorities (SCAs) viz., (i) Department of Animal Production and Health, (ii) Department of Fisheries and Aquatic Resources, (iii) Department of Agriculture, (iv) Department of Health Services, and (v) Department of Wildlife Conservation. The SCAs are considered as expert/technical bodies for risk assessment and risk management.

5. Approach to environmental risk assessment

Risk is defined as the probability or potential for harm from an activity. Environmental risk assessment (ERA) is a structured, reasoned, science-based approach for considering the chance of environmental harm from a particular activity, in this case, the widespread cultivation of a GM plant. The goal of the risk assessment is to identify, characterize and evaluate risks to the health and safety of the environment from the cultivation of the GM plant that resulted from the genetic engineering process. Risk assessments are performed in recognition of same fundamental principles, though the specific details of particular area will differ in details from another area. The approach to ERA of GM plants incorporates a case by case approach taking into account a variety of sources of information.

5.1 Principles of risk assessment

Regulatory decision making is informed by risk assessment in a wide range of products such as chemical pesticides, food additives etc Though the specific details of a particular risk assessment done in each area are different from the details of an assessment performed in another field, all modern risk assessments are performed in recognition of the same fundamental principles.

The fundamental principles for risk assessment are as outlined below:

i. Risk assessments must be carried out in a scientifically sound manner.

ii. Risk assessments should be comparative. For example, according to the Cartagena Protocol on Biosafety, “Risks associated with living modified organisms should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.”

iii. Risk assessments should be carried out on a case-by-case basis, taking into account the specific circumstances or context for each individual application.

iv. Risk assessments should be made available to the public to ensure transparency of the risk assessment process.

5.2 Risk assessment process

In addition to the same fundamental principles, risk assessments also follow the same basic organizational framework. That is extremely important, because if every risk assessment was performed in a unique way, there would be no basis for decision makers or the public to compare the results of one risk assessment with another. All risks are relative and the evaluation of a particular risk, e.g., the use of new pesticide, is meaningless unless it was performed using the same process as the assessments of existing pesticides already on the market. Similarly, risk assessments of GM plants should be performed using the same basic process each time, so that valid, robust comparisons can be made between multiple risk assessments. This should be true even if the assessments were performed at different times, by different risk assessors.

In line with generally accepted principles and framework, the assessment of environmental risks from GM plants, can be described as a four-step process to answer questions relating to:

i. Risk identification ("What could go wrong?") Regulators consider a broad range of scenarios in which the release of a GM plant, for purposes of cultivation, could possibly cause harm to people or the environment. In each scenario there must be a causal link between the cultivation of the GM plant and the harm.

ii. Risk characterization: Consequence assessment ("How serious could the harm be?") Once a risk has been identified, regulators assess the severity of the potential harm.

iii. Risk characterization: Likelihood assessment ("How likely is the harm to occur?") Regulators examine the causal link between the cultivation of the GM plant and a particular harm and determine how likely it is that the harm will occur.

iv. Risk evaluation ("What is the level of concern?") Once regulators have assessed the severity of the harm and the likelihood of its occurrence, they evaluate whether the risk is negligible, low, moderate, or high.

Risk assessment is based on the principle that GM plants can be compared with the non-GE version of the plant, typically, the host variety or a near isogenic parental line that have an established history of safe use. The concept of familiarity coupled with that of substantial equivalence is important for ERA of GM plants as it helps to determine if the GM plant presents any new or greater risks in comparison with its traditional counterpart, or whether it can be used interchangeably with its traditional counterpart without negatively affecting the environment in which it is grown. The reason for this is that assessments are not intended to identify all the risks associated with agriculture, but rather to identify any additional risk that will be conferred by the introduction of the GM plant under consideration. The goal is not to establish an absolute level of safety, but rather a relative level of safety, so that there is a reasonable certainty that no undue risk to the environment will result from the cultivation of the GM plant under anticipated conditions of production.

To conduct an assessment in a simplified, logical and transparen t way, a problem formulation approach may be followed for ERA of GM plants. A problem formulation approach enables regulators/risk assessors to include questions or risk hypothesis that the assessment will address and what data would be most relevant to be able to answer those questions. Additionally, it also helps risk assessors to determine whether data are relevant and sufficient to adequately test plausible and relevant risk hypotheses.

Figure 1: Risk Evaluation Matrix

		Risk Evaluation			
EXPOSURE	Highly Unlikely	Negligible	Negligible	Low	Moderate
	Unlikely	Negligible	Low	Moderate	High
	Likely	Negligible	Low	High	High
	Highly likely	Low	Moderate	High	High
		Marginal	Minor	Intermediate	Major
		HAZARD			

Risk being a function of hazard and exposure, risk assessment is completed by preparing a risk evaluation matrix showing likelihood and severity of a particular harm. Such a risk evaluation matrix is prepared for risk hypothesis on a case by case basis. During risk characterization, research plans are implemented to gather hazard and exposure data.

The risk assessment process is frequently iterative in nature: regulators may analyze the data they have collected relative to a particular risk hypothesis and determine that they need to return to problem formulation to collect more data or to restate the risk hypothesis. This iteration is common in all fields of risk assessment and generally results in a better outcome from the assessment process.

6. Information requirements in environmental risk assessment

In order to conduct an ERA for the release of a GM 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 identifying potential adverse effects to the environment that may result from the release of the GM 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. The following sections elaborate the necessary information to consider in the risk assessment of GM plants.

6.1 Description of GM plant

A description of the GM plant under consideration needs to be provided. This description should include the following information:

i. Name of the genetically engineered (GE) event that is the subject of the application (including any commercial or trade names)

ii. Unique event-specific identifier for the GM plants

iii. Scientific and common name of the parental plant that has not been genetically engineered

iv. Pedigree map of the GM plant, detailing the parental lines from which the GM plant was derived and, where applicable, showing the back crosses conducted following transformation[5]

v. Purpose of the genetic modification,
vi. Intended uses of the GM plant, and

vii. Geographical areas/agro-ecological zones within Sri Lanka where cultivation is intended

6.2 Description of non- modified parental plants

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 organizations/institutes. Consensus documents on biology of crop plants prepared by Organisation for Economic Co-operation and Development (OECD) Working Group on Harmonization of Regulatory Oversight in Biotechnology can also be consulted . 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). This information helps the regulators become familiar with the plant before it was genetically engineered and provides the basis of the comparative assessment.

5 Transformation is the uptake and integration of DNA in a cell, in which the introduced DNA is intended to change the phenotype of the recipient organism in a predictable manner.

6 May be accessed at http://www.oecd.org/env/ehs/biotrack/consensusdocumentsforthe-workonharmonisationofregulatoryoversightinbiotechnologybiologyofcrops.htm

The information requirements typically include the following:

I. Taxonomy, Geographic Origin and Domestication of the Plant:

- **a.** Taxonomy,
- **b.** Relatives of the species,
- **c.** Geographic origin (center of origin),
- **d.** Domestication,
- **e.** Germplasm diversity

II. Reproductive Biology:

- **a.** Growth and development,
- **b.** Floral biology,
- **c.** Pollination and fertilization,
- **d.** Sources/methods of dissemination of pollen
- **e.** Mating systems, including outcrossing rates,
- **f.** Dissemination of seed,
- **g.** Seed dormancy,
- **h.** Asexual reproduction

III. Naturally Occurring Crosses:

- **a.** Intra- and inter-specific crosses,
- **b.** Natural crossability,
- **c.** Inter-generic hybridization,
- **d.** Wild relatives in Sri Lanka and their distribution,

IV. Ecological Interactions:

- **a.** Volunteers and weediness,
- **b.** Potential for gene transfer to other plants (gene flow),
- **c.** Free-living populations

V. Cultivation in Sri Lanka:

- **a.** Climatic and soil types,
- **b.** Breeding objectives, milestones in breeding advances and challenges,
- **c.** Variety testing procedure,
- **d.** Major pests and pathogens of the plant species in Sri Lanka,
- **e.** Beneficial organisms associated with the plant species in Sri Lanka

6.3 Description of donor organisms

Information about the donor organism(s)[7] should include:

- **i.** Scientific and common name
- **ii.** Taxonomic classification, and
- **iii.** 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 GE events authorized for cultivation or use in food or feed in Sri Lanka sand/or other countries.

[7] Donor organism from which genetic material is obtained for transfer to the recipient organism

It is particularly important for the applicant to indicate if the donor of a genetic element used in the transformation is responsible for disease or injury to plants or other organisms, or if it encodes a known toxicant, allergen, pathogenicity factor or irritant.

6.4 Description of genetic modification

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:

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

(ii) 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;

(iii) 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);

(iv) A summary diagram of all genetic components, which comprise the vector[8] 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.

[8] Vector is a DNA molecule used as a vehicle to carry foreign genetic material into a cell

6.5 Molecular characterization of genetic modification

A comprehensive molecular and biochemical characterization of the genetic modification needs to be carried out. This should include information on DNA insertions into the plant genome and expressed substances, if any, as indicated below:

(a) The information regarding DNA insertions into the plant genome should include:

- **(i)** The characterization and description of the inserted genetic materials;
- **(ii)** The number of insertion sites;
- **(iii)** 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;
- **(iv)** Sequence data of the inserted material and of the flanking regions bordering the site of insertion;
- **(v)** Information on sequence homology with known allergen sequences;
- **(vi)** 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.

(b) The information regarding any expressed substances in the GM plant should include:

- **(i)** The gene product(s) (e.g., a protein or an untranslated RNA);
- **(ii)** The gene product(s)' function;
- **(iii)** The phenotypic description of the new trait(s);
- **(iv)** 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
- **(v)** 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.

(c) In addition, following information is also required:

- **(i)** To demonstrate whether deliberate modifications made to the amino acid sequence of the expressed protein result in changes in its posttranslational modifications or affect sites critical for its structure or function;
- **(ii)** 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;
- **(iii)** 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;
- **(iv)** 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
- **(v)** To confirm the identity and expression pattern of any new fusion proteins.

6.6 Phenotypic and agronomic characteristics of GM plant

Information must be provided on the intended phenotype of the GM plant, including any observation of unintended or unanticipated characteristics. The GM plant should be compared with a suitable conventional counterpart[9] (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. Normally such trials would be conducted over two, or more years in 4-6 different locations per year; however, case-by-case flexibility is permitted depending on the nature of the crop, the diversity of growing conditions and the introduced trait.

Phenotypic data should cover the following:

i. Breeding history: Describe the pedigree of the GM plant being evaluated starting at the point of trade introduction.
ii. Growth habit: Note any changes in basic morphology of the plant including any abnormalities or changes in overall growth habit.
iii. Life cycle: Describe if the annual, biennial or perennial and if this has changed from the non-transformed parental plant.
iv. Plant growth and reproductive characteristics: The growth, the morphology, output and other agronomic traits are normally used by the scientists to identify if any unusual or negative genetic changes occurred in the new varieties. Depending on the species, these may include parameters such as:

a. Plant height, biomass to be recorded at regular intervals during the growing season;
b. Number of days to onset of flowering; number of days of flowering;
c. Number of days until maturity e.g., time to the production of mature fruit or seed (suitable for harvesting);
d. Seed parameters e.g., seed production, length of time (days) of seed/fruit production, seed dormancy, seedling emergence;
e. Proportion surviving from seedling to reproduction;
f. 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).
g. 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;
h. 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;
i. Biotic stresses: Observations of susceptibility to pests and/or diseases commonly associated with the plant species.
j. Abiotic stresses: Observations of responses to water stress or nutrient deficiency or other stresses common to the plant species where applicable.

Based on the case-specific problem formulation, additional studies may be required, or some studies may not be warranted, based on the biology and phenotype of the GE event or where the applicant can justify the exclusion of a study using a scientific rationale.

[9] Conventional counterpart is the related plant variety or cultivar that has not been genetically engineered

6.7 Cultivation practices of GM plant

Information must be provided on any likely changes on existing agronomic practice that could arise as a consequence of cultivation of the GM 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:

i. Describe the regions where the conventional plant species is currently cultivated within Sri Lanka 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).

ii. 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-eco system 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).

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

iv. 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?

6.8 Potential impact on non-target organisms or effects on biodiversity and ecosystems

For those GM 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[10] should be evaluated. Typically, this follows a tiered approach. Plants that have traits which are not expected to alter their interactions with other organisms are not expected to be subjected 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 regulatory authorities.

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

Tier I (or early-tier) tests 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 present 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 GM 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 GM plants. It is not a list of required tests for releasing a GM plant in Sri Lanka. It should be noted that the abundance of arthropod test species is related to the use of insecticidal traits in GM plants, and may not be relevant for future applications.

Tier I studies conducted in support of ERA for GM plants with pesticidal traits have typically included the following non-target organisms:

- **i.** Mammalian
- **ii.** Avian
- **iii.** Freshwater fish
- **iv.** Aquatic vertibrates and invertebrate
- **v.** Arthropods:
    - **a.** Honey bees and other pollinators larvae and adults
    - **b.** Lady beetle
    - **c.** Green lacewing
    - **d.** Parasitic hymenopteran
    - **e.** Butterflies larvae and adults
- **vi.** Soil dwelling organisms:
    - **a.** Collembola
    - **b.** Earthworm
    - **c.** Soil dwelling insects and other spp
- **vii.** Pollinators
- **viii.** Natural enemies

Results from studies to assess the actual abundance of non-target species under field conditions (i.e.,Tier 2 studies) are only required if the results from Tier 1 studies indicate that there is a hazard 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 GM plant and its conventional counterpart with respect to the likely exposure to toxins, irritants, and allergens.

For GM plants engineered without an intentional adverse effect on target pest organisms, such as drought-tolerant plants or nutritionally enhanced plants, the risk assessment may include an evaluation of inadvertent impacts on biodiversity and on ecological functions, such as nutrient cycling.

Traditional agriculture is known to impact the environment and biodiversity in many significant ways, so the goal of the risk assessment is to identify biodiversity impacts that are unique to the GM plant or substantially different from the impacts caused by conventional plants. The problem formulation process should be used to help identify science-based risk hypotheses that address potential harms to biodiversity that are significantly different from the impacts caused by agriculture.

7. 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 hypothesis-driven and supported by scientific and statistically relevant data. For example, 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.

A general post-release monitoring plan for unintended or unexpected environmental effects of the GM plant should be included in the application and will be reviewed during the environmental safety assessment. The applicant should choose appropriate indicators to evaluate these effects based on the characteristics of the GM plant and the proposed use. A management plan addressing the responsible deployment of the GM plant into the environment may be considered acceptable for post-release monitoring purposes. The applicant must inform the NCA of any new information regarding risks to the environment that could result from the release of the GM plant.

8. Instructions on data quality and relevance

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 generating the 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 GM plant. The details of all confined field trial protocols, including experimental designs and sampling procedures, should be submitted.

9. Detection and identification requirements

Applicants are required to submit the following:

i. An event-specific detection method for the GM plant. The method must be complete and laid out in a step-wise fashion that may be easily followed by a person unfamiliar with the method. Detailed descriptions of sample size, replicates, extraction procedure, expected results (figures/sequences), interpretation and acceptance criteria must be included.

ii. Written agreement to provide, on request, the competent national authority with reference material suitable to support the detection methods.

References and additional information

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Annex-I

INFORMATION REQUIREMENTS TOWARDS APPLYING FOR ENVIRONMENTAL RELEASE OF A GENETICALLY MODIFIED ORGANISM FOR THE PURPOSE OF CULTIVATION

A. GENERAL INFORMATION ON THE GM PLANT

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

B. CHECKLIST OF INFORMATION TO BE 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.

B.1 Description of the GM Plant

INFORMATION PROVIDED	YES	NO
Name of the GM event		
Unique Identifier		
Name of the non-modified or parental plant		
Pedigree map of the GM plant		
Purpose of the genetic modification		
Intended uses of the GM plant		
Geographical areas within Sri Lanka to which distribution is intended		

B.2 Description of the host plant that has not been genetically engineered

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		
Intergeneric hybridization		
Wild relatives in Sri Lanka		
Gene flow		
Volunteers and weediness		
Potential for gene transfer to other plants		
Free-living populations		
Cultivation in Sri Lanka		
Climatic and soil types		
Breeding objectives, milestones in breeding advances and challenges		
Zonal varietal testing		
Major pests and pathogens of the plant species in India		
Significant beneficial organisms associated with the plant species in Sri Lanka		

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 GM plant, or what nformation is being provided in its place.

B.3 Description of the Donor Organisms

This information should be provided for the donor of each transgene present in the GM 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 GM plant, or what information is being provided in its place.

B.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 GM plant, or what information is being provided in its place.

B.5 Molecular Characterization of Transgene(s)

The following information should be provided for each transgene in the GM 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		
Phenotypic 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 GM plant, or what information is being provided in its place.

B.6 Phenotypic and Agronomic Characteristics of the GM 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.		
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 seedling 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 crossability		
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 GM plant, or what information is being provided in its place.

B.7 Cultivation Practices

INFORMATION PROVIDED	YES	NO
Regions of cultivation in India		
Cultivation practices for the GM plant		
Associated recommended management practices (e.g., insect resistance management)		
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 GM plant, or what information is being provided in its place.

B.8 Impacts 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?		

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 GM plant or what information is being provided in its place.

B.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?		

B.10 Detection and identification requirements

Detection methods will be required

	YES	NO
Has an event specific detection method provided along with the agreement to provide reference material?		

National Focal Point and Coordinating Agency for Biosafety in accordance with the Cartagena Protocol in Sri Lanka

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