Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016

UNEP/GEF supported Phase II
Capacity Building Project on Biosafety

Ministry of Environment Forest and Climate Change | Department of Biotechnology Ministry of Science and Technology

Government of India

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MESSAGE

India is a signatory to the Cartagena Protocol on Biosafety and is committed to comply with the obligations. Ministry of Environment, Forest and Climate Change (MoEF&CC) is the nodal agency for implementing the Cartagena Protocol on Biosafety and is also responsible for implementation of Indian biosafety regulatory framework under the Environment (Protection) Act, 1986.

I am happy to learn that the MoEF&CC as part of the initiative under the UNEP-GEF supported "Phase II Capacity Building Project on Biosafety" has prepared guidance documents for strengthening the environmental risk assessment of genetically engineered (GE) plants. These documents aim to provide a holistic guidance to researchers, developers and regulators.

India is at the forefront of research and development in the area of GE plants and the present set of Environmental Risk Assessment documents would provide strong scientific basis for safety assessment of GE plants to deal with challenges of agriculture and to ensure benefits to farmers and consumers.

I am happy to note that these documents have been prepared through the involvement of an expert committee with members drawn from multiple disciplines to ensure that all key concerns are suitably addressed.

I would like to appreciate all those who were involved in preparing these guidance documents and steering this initiative.

(Prakash Javadekar)

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सत्यमेव जयते

FOREWORD

Risk analysis is a fundamental part of any effective safety management strategy and comprises of three main elements namely risk assessment, risk management and risk communication. Safety assessment of modern biotechnology in agriculture is no exception and therefore risk assessment form an integral part of the national regulatory framework as well as obligations under Cartagena Protocol on Biosafety as specifically elaborated in Annex Ill of the Protocol.

In view of the scientific advances taking place globally in the area of genetically engineered plants, several GM crops with a variety of traits are at various stages of development in the product pipeline in India from both Public and Private Institutions. The Ministry of Environment, Forest and Climate Change (MoEF&CC) as the nodal agency for regulating products from genetic engineering along with the Department of Biotechnology, Ministry of Science & Technology have been bringing out a series of guidelines from time to time to deal with various aspects of safety assessment.

I am pleased to inform that this Ministry as part of the UNEP-GEF supported Phase-11 Capacity Building Project on Biosafety has taken a lead in the formulation of ERA guidelines for Genetically Engineered plants (GE). In this context, MoEF&CC constituted an Expert Committee comprising of members from multi-disciplinary areas under the Chairmanship of Prof. C. R. Babu, Emeritus Professor CEMDE, Delhi University & Member, Genetic Engineering Appraisal Committee (GEAC) and Prof. K. Veluthambi, School of Biotechnology, Madurai Kamaraj University & Co Chair, GEAC. The Committee through a series of meetings and consultations with relevant stakeholders has prepared three sets of documents namely a Risk Analysis Framework, ERA Guidelines for GE Plants and Users' Guide.

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The Risk Analysis Framework (RAF) describes the principles of risk analysis used by the Regulatory Agencies to protect human health and safety, and the environment. RAF also includes concepts related to, risk management, and risk communication in addition to risk assessment. The ERA Guidelines for GE Plants provides a comprehensive, transparent, and science-based framework by which regulators can identify potential harms, collect relevant scientific data pertaining to the nature and severity of any harms, and consistently characterize the level of risk posed by Genetically Engineered plants. The Users' Guide aims to provide additional explanatory material, illustrative examples, and references to scientific literature to provide a better understanding on what risk assessment is about and how it is performed in the context of GE Plants. The three documents put together provides a practical elaboration of risk assessment framework included in the Indian regulations in conjunction with Annex-Ill of the Cartagena Protocol on Biosafety, to which India is a Party.

I congratulate the Chairs and Members of the Expert Committee for the excellent work done in the preparation of ERA documents to facilitate the work of the regulatory committees. I express my deep appreciation for the sincere and dedicated efforts put in by Dr. Ranjini Warrier, Adviser, MoEF&CC in effectively steering this initiative in a timely manner.

The set of three ERA documents aims to serve as a resource tool for all those involved in the research, development and regulation of GE plants. I hope this initiative would further strengthen our efforts to ensure safe use and deployment of GE plants.

(Ajay Narayan Jha)

के. विजयराघवन
K. VijayRaghavan

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PREFACE

India is one of the earliest countries to put in place the regulatory process for risk assessment and management under Rules 1989 of Environmental Protection Act (EPA), 1986. Due to evolving nature of science of safety assessment and GM technology developments, the regulatory system has also been dynamic and flexible to adopt global best practices from time to time. Several guidelines and standard operating practices have been published. Some important guidance documents related to genetically engineered crops have been: Revised Guidelines for Research in Transgenic Plants, 1998; Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants (2008); and Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered (GE) Plants (2008). For review or revision or updating of protocols, guidelines of safety assessment of GE crops, the approach followed is to critically examine the best International practices along with other available peer reviewed research publications and documented experiences. The revised or updated documents are subjected to wide ranging consultations at multiple levels of stakeholders to arrive at consensus documents for wider adoption and harmonization of practices at global level.

Following such the elaborate process described above and in continuation of the existing "Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016" presented here to provide a separate emphasis for assessment of environmental effects. For the convenience this guidance document is also supported with two more documents namely "Environmental Risk Assessment of Genetically Engineered Plants: A Guide for Stakeholders" and "Risk Analysis Framework, 2016" for understanding the concepts and data generation by the

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developers and biosafety assessment by the regulatory bodies and their experts.In implementing these guidelines it is important to note that all the theory and practice described in these documents is to guide case-by-case risk analysis, risk assessment and management including related communication requirements and accordingly the data requirements vary from trait to trait and biology of crops.

In concluding this intricate task, I appreciate the efforts of the Expert Committee Members and contributions of stakeholders from industry, academia and civil society. My special appreciation is to Dr. Ranjini Warrier, Adviser, MoEF&CC and Dr. S. R. Rao, Adviser, MoS&T for their continued interest, passion and joint venture in reforming regulatory process and updating various guidelines.

(K. VijayRaghavan)

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PROLOGUE

The Ministry of Environment, Forest and Climate Change (MoEF&CC), is the nodal agency for permitting environmental release of genetically engineered (GE)plants in India,as per the Rules for Manufacture, Use/Import/ Export & Storage of Hazardous Micro-organisms/GE organisms or cells, 1989 (commonly called Rules, 1989). The Environmental Risk Assessment (ERA) of GE plant is an important component of the safety assessment process of GE plants.

MoEF&CC is also the nodal agency for implementation of obligations under the Cartagena Protocol on Biosafety (CPB) and is accordingly implementing the UNEP/GEF supported Phase II Capacity Building Project on Biosafety with an objective to strengthen the biosafety management systems in India. A series of activities under the project, contributed towards providing inputs to the Multi-disciplinary Expert Committee that was set up for preparing guidance documents on ERA of GE plants. A study on the Multi Country comparison of information and data requirements for ERA of GE plants, Review of conformity of India's regulatory system for GE plants with CPB and also the interactions with regulatory agencies during study tour toOffice of the Gene Technology Regulator (OGTR), Australia providedsignificant inputs to the work of the Expert Committee. The activities also helped ensure streamlining of existing environmental safety assessment process in India to be in line with the international best practices.

Following intensive deliberations over eight meetings of the Expert Committee and through consultations with regulators and scientists, three guidance documents have been prepared viz., Guidelines for the ERA of GE Plants, 2016; A Guide for Stakeholders, 2016 and the Risk Analysis Framework, 2016. Thethree documents have been adopted by Genetic Engineering and Appraisal Committee (GEAC) in its 130th meeting held on August 11, 2016.

I am confident that thethree documents would be extremely useful in planning and reviewing ERA of GE plants through a step wise science based approach.

(Dr. Amita Prasad)
Chairperson, GEAC

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Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016

1 PREAMBLE

In accordance with the laws, regulations, and policies of India and the Cartagena Protocol on Biosafety, the objective of **"Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016"** (the Guidelines) is to ensure the safe development and use of plants resulting from modern biotechnology through the assessment of potentially adverse effects that these plants may have on humans, the environment and biological diversity. These Guidelines describe a comprehensive, transparent and science-based framework by which regulators can identify potential harms that might be caused by genetically engineered (GE) plants, collect relevant scientific data pertaining to the nature and severity of any harms, and consistently characterize the level of risk posed by the use of genetically engineered plants.
This framework uses a conventional approach to risk assessment similar to ones used in many other areas of risk assessment and it incorporates a case-by-case approach that takes into account a variety of sources of information.

The guidance provided herein has been developed for planning and conducting an environmental risk assessment in support of the release of a GE plant in India for the purpose of cultivation. The topics of risk assessments performed prior to the testing of regulated GE plants in confined field trials and safety assessments of food and feed produced from GE plants are covered in separate guidance. This guidance provides a practical elaboration of the risk assessment framework included in the Indian regulations and in Annex III of the Cartagena Protocol on Biosafety, to which India is a Party and it is also consistent with the consensus documents published by the Organization for Economic Cooperation and Development's (OECD's) Working Group on Harmonization of Regulatory Oversight in Biotechnology.

2 INTRODUCTION

Modern biotechnology, involving the use of recombinant DNA (rDNA) techniques, 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 GE, genetically modified (GM) or transgenic plants, are being developed for a variety of purposes:

- enhancing agricultural productivity,
- reducing dependence on the use of agricultural chemicals,
- improving the agronomic qualities of plants,
- enhancing the nutritional value of foods and feeds,
- increasing tolerance to biotic and abiotic stresses, and
- providing cost effective and sustainable industrial products, including biofuels.

GE plants developed for cultivation and use in food and livestock feed in India are regulated at all steps along the development pathway. This includes research that takes place in contained facilities, such as laboratories, growth chambers, greenhouses and screen houses; evaluation of experimental plant material in confined field trials (CFTs). It also includes the mandatory pre-market safety assessment of the GE plant and its derived food and feed products by regulatory authorities as a prerequisite to obtaining approval for commercial release. In India, the manufacture, import, use, research and release of GE organisms as well as products made by the use of such organisms are governed by the rules notified by Ministry of Environment and Forests (MoEF; now the Ministry of Environment, Forests and Climate Change or MoEF&CC), Government of India, on December 5, 1989 under the Environment (Protection) Act 1986 (EPA). These rules and regulations, commonly referred to as "Rules 1989,"[1] cover the areas of research as well as large-scale applications of GE organisms and products made therefrom throughout India. The regulatory agencies responsible for implementation of the Rules 1989 are MoEF&CC and the Department of Biotechnology (DBT), Ministry of Science and Technology through six competent authorities:

- Recombinant DNA Advisory Committee (RDAC),
- Institutional Biosafety Committees (IBSC),
- Review Committee on Genetic Manipulation (RCGM),
- Genetic Engineering Appraisal Committee (GEAC, formerly known as the Genetic Engineering Approval Committee),
- State Biotechnology Coordination Committees (SBCC) and
- District Level Committees (DLC).

The Rules 1989 are supported by a series of guidelines including three guidance documents that are specific to GE plants:

- Revised Guidelines for Research in Transgenic Plants, 1998
- Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants (2008)[2]

[1] The Rules 1989 are available at the MoEF&CC website, http://envfor.nic.in/legis/hsm/hsm3.html.

[2] Available at http://dbtbiosafety.nic.in/files%5CCoverpage.pdf.

- Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered (GE) Plants (2008)[3] .

India requires that, prior to their commercial release, GE plants undergo a case-by-case risk assessment to evaluate any potential adverse environmental impacts. The *Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants* should be considered in conjunction with the other guidance documents identified above and careful attention should be paid to ensure that appropriate experimental studies are conducted to address all necessary information and data requirements.

3 SCOPE

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

1. Intended for cultivation in India or
2. Propagable forms of GE 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.[4]

These guidelines do not apply to

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

4 DEFINITIONS

Application: An application is an informative data package (regulatory dossier) in prescribed format submitted for each regulated GE event intended for environmental release for the purpose of cultivation. Many independent events of a single plant species may be included in a single application, provided each event was transformed with the same construct. Applicants must follow the format attached in Annexure 1.

[3] Available at http://dbtbiosafety.nic.in/field_trials_guidelines/combined_sops.pdf

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

Confined field trial: A confined field trial (CFT) is a field experiment of a regulated GE plant under terms and conditions prescribed to mitigate the unregulated spread of the plant. Please see *Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered (GE) Plants (2008).*

Contained use: Any operation undertaken within a facility, installation or other physical structure that involves GE organisms controlled by specific measures to effectively limit their contact with and their impact on the external environment.

Construct: An engineered DNA fragment containing but not limited to the DNA sequences to be integrated into the genome of the target plant.

Conventional counterpart: The related, non-genetically engineered plant variety, cultivar or line.

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

Environment: Water, air and land and the inter-relationship which exists among and between water, air and land and human beings, other living creatures, plants, microorganisms and property.

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.

Genetically engineered plant: A plant in which the genetic material has been changed through *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells, organelles, or tissues. Also referred to as a genetically modified (GM) or transgenic plant.

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

Hazard identification: In the context of Environmental Risk Assessment (ERA) of GE plants, it is the identification of potential harms that could occur as a result of the unconfined environmental release of a specific GE plant.

Living modified organism (LMO): 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)

Modern biotechnology: The application of:

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

Protection goal: A goal or an objective of a country's environmental policies, typically defined in laws and regulations.

Risk: In relation to any GE 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: A case-by-case, science-based process consisting of the following steps: 1) risk identification; 2) risk characterization: consequence assessment; 3) risk characterization: likelihood assessment and 4) risk evaluation.

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

Risk hypothesis: A declarative sentence that describes a specific valued environmental resource (as determined by the country's protection goals) and how it could be harmed by the environmental release of a specific GE plant.

Seed: Any type of embryo or propagule capable of regeneration and giving rise to a plant that is true to type.

Transformation: The process of incorporating DNA into an organism's genome. There are several methods to do this in plants. The most commonly used methods for plant transformation are Agrobacterium-mediated transformation and biolistic transformation.

Vector: A DNA molecule used as a vehicle to carry foreign genetic material into a cell.

5 APPLICANT INFORMATION

The Applicant must be a permanent resident of India or must designate an Authorized Signatory (AS) who is a permanent resident of India. Where an AS is used, there must be a formal, legal agreement indicating the AS is acting on behalf of the Applicant and that both act under the jurisdiction of any Court of Law of India. A copy of this agreement must be submitted to the Regulatory Authorities along with the application for environmental release. The Applicant need not be the breeder/developer or owner of the subject GE event, in which case a signed statement is required from the breeder/developer or owner authorizing representation by the Applicant or the designated AS. All correspondence with

respect to the application for environmental release, including the notification of authorization, will be addressed to the Applicant or when appropriate, the AS.

6 APPROACH TO ENVIRONMENTAL RISK ASSESSMENT

Indian law and the Cartagena Protocol on Biosafety, to which India is a signatory, require that a risk assessment be performed prior to the commercial release of a GE plant in India. The purpose of the risk assessment is to identify risks to the health and safety of people and the environment from the cultivation of the GE plant, when compared with the cultivation of the non-GE version of the plant and to characterize the risks on the basis of severity and likelihood.

Principles of Risk Assessment

Modern methods of risk assessment have been in use for decades to inform regulatory decision making in a wide range of disciplines, from chemical pesticides to insurance. Necessarily, the specific details of a particular risk assessment done in one arena, such as highway safety, will differ from the details of an assessment performed in another field, such as biological pest control. However, all modern risk assessments are performed in recognition of the same fundamental principles.

Risk assessment is part of the **risk analysis** process, which also includes **risk management** and **risk communication.** Risk management identifies and implements measures to ensure that risks are maintained within acceptable levels. Risk communication is the exchange of information, ideas and views between regulators and stakeholders and it conveys the rationale for regulatory decisions.

- Risk assessments must be carried out in a scientifically sound manner.
- 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.”
- Risk assessments should be carried out on a case-by-case basis, taking into account the specific circumstances or context for each individual application.
- Risk assessments should be made available to the public to ensure transparency of the risk assessment process.

Risk Assessment Process

Just as risk assessments tend to reflect the same fundamental principles, they tend

to share the same basic organizational framework. That is not surprising, 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 GE 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.

Risk assessment, including the assessment of risks from GE plants, can be described as a four-step process, the goal of which is to answer questions relating to

1. **Risk identification** ("What could go wrong?") Regulators consider a broad range of scenarios in which the release of a GE 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 GE plant and the harm.
2. **Risk characterization: consequence assessment** ("How serious could the harm be?") Once a risk has been identified, regulators assess the severity of the potential harm.
3. **Risk characterization: likelihood assessment** ("How likely is the harm to occur?") Regulators examine the causal link between the cultivation of the GE plant and a particular harm and determine how likely it is that the harm will occur.
4. **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.

Problem formulation is a framework that provides the means to organize an environmental risk assessment so that the assessment is done in a logical and transparent way. It helps risk assessors decide what questions the assessment will address and what data are most relevant to those questions.

7 PROBLEM FORMULATION FOR ENVIRONMENTAL RISK ASSESSMENT

Problem formulation can help simplify the assessment of risks involved when GE plants are introduced into the environment process and make the process more transparent. In the end, problem formulation facilitates both the decision-making processes in risk assessment and clarifies to stakeholders how the decisions are made. It is a five-step process, presented below. In this example, the risk assessors are assessing potential risks of growing an insect-resistant GE plant.

1. **Identify the Protection Goal:** The purpose of an environmental risk assessment for the commercial release of a GE plant is to determine whether the plant can be released while protecting valued environmental resources. A Protection Goal is a broad statement of national policy focused on the protection of a key environmental resource of recognized value, such as water quality, human health or agricultural productivity.

   Example: "Protect biodiversity"

2. **Derive the Operational Goal:** Broad Protection Goals can encompass a range of specific issues, but an environmental risk assessment must focus on more context-specific questions. So before the risk assessment process can begin, assessors must derive one or more specific **Operational Goals** from the Protection Goal, which suggests the types of questions the assessors must address and the data they must consider.

   Example: "Protect agriculturally important pollinators"

3. **Determine the Assessment Endpoint:** Next, the risk assessors must determine one or more **Assessment Endpoints** appropriate to the Operational Goal. An Assessment Endpoint specifies the environmental resource to be protected and the nature of the protection given to the environmental resource.

   Example: "Cultivation of the GE plant will not threaten long-term sustainability of honeybee populations, compared to cultivation of the non-GE plant."

4. **Formulate the Risk Hypothesis:** The Assessment Endpoint is then formulated into a **Risk Hypothesis**, which can be tested and found to be either true or false, using specific scientific data.

   Example: "Cultivation of the GE plant will adversely affect honeybee populations, compared to cultivation of the non-GE plant."

5. **Determine the Measurement Endpoints:** Once the Risk Hypothesis has been formulated, the assessors determine the types of data, whether qualitative or quantitative, that will enable them to test the Risk Hypothesis. These data are called **Measurement Endpoints.**

   Example: Data regarding honeybee mortality when exposed to GE and non-GE plants.

The Risk Hypothesis is based on a comparison between the GE plant and the non-GE version of the plant, typically, the host variety or a near isogenic parental line and so the data collection process must first collect sufficient information to fully characterize the biology of the non-GE version of the plant. This information establishes a background of long-standing familiarity with the crop and with the breeding of novel varieties using traditional methods. It is also important to collect data about aspects of the plant's biology that may alter the potential of the plant to cause harm. Relevant data should focus on characteristics that could likely have environmental implications, such as the plant's reproductive biology, whether the plant is known to have weedy or invasive properties, and whether the plant is known to produce toxic or allergenic substances. The goal is to identify specific ways, including both intentional changes and unintended ones, in which the GE

plant is significantly different from the non-GE version and how those differences could impact the environmental resource in question. Useful data will come from a variety of sources:

- published scientific literature,
- applications submitted for confined field trial permits,
- past environmental risk assessments of GE plants with the same phenotype, including risk assessments from other countries, and
- professional experience of the risk assessors.

The data are evaluated to determine their relevance and validity, and throughout the data collection process, the risk assessors should continue to question the sufficiency of the data to adequately test the hypothesis.

The process outlined above demonstrates how problem formulation should be used to correctly frame each environmental risk assessment in a structured, transparent and efficient way. Problem formulation focuses attention on key questions, the answers to which determine whether a particular course of action, i.e., the commercial release of a GE plant, will adversely affect India's capacity to meet its designated Protection Goals. Problem formulation also helps risk assessors determine the data needs to answer these questions and provides them with tools to determine whether data are relevant and sufficient to adequately test plausible and relevant risk hypotheses. When performed properly, problem formulation helps reduce the collection of irrelevant data and focus the assessment process on questions that directly impact India's environmental protection goals. Problem formulation creates a logical framework for the risk assessment that is easy for regulators to explain to stakeholders and creates an avenue for stakeholders to provide questions and data to regulators that is relevant to the risk assessment process.

8 INSTRUCTIONS ON DATA QUALITY AND RELEVANCE

The adequacy of a risk assessment and the validity of any regulatory decisions based on that assessment are directly dependent on the quality and relevance of the data used in the assessment. Regulators should use accepted criteria for determining whether data submitted by the applicant, as well as data collected directly by risk assessors are of sufficient quality to be used in the risk assessment. The Draft

Roadmap for Risk Assessment of Living Modified Organisms,[5] developed pursuant to the Cartagena Protocol on Biosafety provides criteria for data quality and relevance:

Criteria for the Quality of Scientific Information:

- Information, including raw data, of acceptable scientific quality should be used in the risk assessment. Data quality should be consistent with the accepted practices of scientific evidence-gathering and reporting and may include independent review of the methods and designs of studies.
- Appropriate statistical methods should be used where appropriate, to strengthen the scientific conclusions of a risk assessment and be described in the risk assessment report. Risk assessments frequently use data generated from multiple scientific fields.
- Reporting of data and methods should be sufficiently detailed and transparent to allow independent verification and reproduction. This would include ensuring the accessibility of data used by the risk assessors (e.g., the availability of relevant data or information and, if requested and as appropriate, sample material), taking into account the provisions of Article 21 of the Protocol on the confidentiality of information.

Relevance of Information for the Risk Assessment:

- Information, including data, may be considered relevant if they are linked to protection goals or assessment endpoints, contribute to the identification and evaluation of potential adverse effects of the LMO, or if they can affect the outcome of the risk assessment or the decision.
- Relevant information may be derived from a variety of sources such as new experimental data, data from relevant peer reviewed scientific literature, as well as data, experience and outcomes from previous risk assessments if regarded as of acceptable scientific quality, in particular for the same or similar LMOs introduced in similar receiving environments.
- Information from national and international standards and guidelines may be used in the risk assessment, as well as knowledge and experience of, for example, farmers, growers, scientists, regulatory officials, and indigenous and local communities depending on the type of LMO, its intended use and the likely potential receiving environment.

[5] The Draft document is available at https://bch.cbd.int/onlineconferences/guidance_ra_roadmap.shtml. Also see: World Health Organization (2008) Uncertainty and data quality in exposure assessment: Part 2, Hallmarks of data quality in chemical exposure assessment. International Programme on Chemical Safety Harmonization Project Document No. 6. World Health Organisation, Geneva, http://www.inchem.org/documents/harmproj/harmproj/harmproj6.pdf

- The information that is relevant to perform a risk assessment will vary from case to case depending on the nature of the modification of the LMO, on its intended use, and on the scale and duration of the environmental introduction. In cases of environmental releases whose objective is to generate information for further risk assessments and where exposure of the environment to the LMO is limited, such as for some early-stage experimental releases and trials, less information may be available or required when performing the risk assessment. The uncertainty resulting from the limited information available in such cases may be addressed by risk management and monitoring measures.

9 INFORMATION REQUIREMENTS FOR ENVIRONMENTAL RISK ASSESSMENT

To characterize the risk that a specific harm will impact a valued environmental resource, each risk hypothesis must be tested using scientific data. A well-formulated risk hypothesis will help the assessors focus on the information they need to characterize potential risks. The risk hypothesis is based on a comparison between the GE plant and its non-GE counterpart (e.g., non-transformed parental line, variety or hybrid), therefore the data collection process must collect sufficient information to fully characterize the biology of both the non-GE and the GE versions of the plant.

9.1 DESCRIPTION OF GE EVENT

A description of the subject GE event should be provided. This description should identify:

1. Name of the GE event that is the subject of the application (including any commercial or trade names)
2. Unique event-specific identifier for the GE event[6]
3. Scientific and common name of the non-transgenic parental plant
4. Pedigree map of the GE event, detailing the parental lines from which the GE event was derived and, where applicable, showing the back crosses conducted following transformation
5. In addition, information is also required on:
    a. Purpose of the genetic modification,

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

b. Intended uses of the GE event, and

c. Geographical areas/agro-ecological zones within India where cultivation is intended

9.2 DESCRIPTION OF NON-TRANSGENIC PARENTAL PLANTS

Information requirements under this section may be fulfilled by referencing an appropriate biology document for the subject plant species, preferably one that has been published by MoEF&CC/DBT[7], or other organization that publishes biology documents specifically developed as resources for environmental risk assessment, such as the OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology[8]. Where no such biology document is available, the applicant must submit detailed information for each of the subject areas listed below including all relevant sources of this information (e.g., literature citations). It is recommended that applicants may consult with DBT/MoEF&CC on the format and content.

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. Germplasm diversity
2. **Reproductive Biology:**
   a. Growth and development,
   b. Floral biology,
   c. Pollination and fertilization,
   d. Mating systems, including outcrossing rates,
   e. Shattering and seed dispersal,
   f. Seed dormancy,
   g. Asexual reproduction
3. **Naturally Occurring Crosses:**
   a. Natural crossability,
   b. Wild relatives in India and their distribution,
   c. Intra- and inter-specific crosses and Inter-generic hybridization,
   d. Ploidy of the cultivated crop and any closely related species present in India

[7] Several biology documents have been prepared by the DBT, and they are available at http://www.envfor.nic.in/divisions/csurv/geac/information.html.

[8] OECD plant biology documents are available at http://www.oecd.org/env/ehs/biotrack/consensusdocumentsfortheworkonharmonisationofregulatoryoversightinbiotechnologybiologyofcrops.htm.

4. **Ecological Interactions:**
    a. Volunteers and weediness,
    b. Potential for gene transfer to other plants (gene flow),
    c. Free-living populations
5. **Human Health Considerations:**
    a. Any known endogenous toxins, allergens or anti-nutrients
6. **Cultivation in India:**
    a. Climatic and soil types,
    b. Breeding objectives, milestones in breeding advances and challenges,
    c. Zonalization of varietal testing,
    d. Significant pests of the plant species in India,
    e. Significant beneficial organisms associated with the plant species in India

9.3 DESCRIPTION OF DONOR ORGANISMS

Information must be provided regarding the donor organism(s). 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. The description of the donor organism(s) should include:

1. Scientific and common name,
2. Taxonomic classification, and
3. 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 India and/or other countries.

9.4 DESCRIPTION OF METHODS AND DNA SEQUENCES USED IN THE GENETIC MODIFICATION(S)

Detailed information is required on the method and DNA sequences used in 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.

A. The description of the method and DNA sequences used in the genetic modification should 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 electroporation, etc.).
    2. Description and characterization of all genetic material used to modify the

plant, including the source (e.g., plant, microbial, viral or synthetic) and its expected function in the plant.

3. Details of any modifications made to the inserted DNA sequences and their consequences (e.g., changes in amino acid sequence that may affect the properties of the expressed protein).

B. A summary diagram of all genetic components within 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. The applicant should provide information regarding the following:

1. Source (common and scientific and/or trade name, of the donor organism),
2. Portion and size of the sequence inserted,
3. Location, order and orientation in the vector,
4. Function in the plant
5. Whether the genetic component is responsible for disease or injury to plants or other organisms,
6. Whether the genetic component results in the production of a known human toxin, allergen, pathogenicity factor or irritant,
7. History of safe use of the donor organism or components thereof, if available

9.5 CHARACTERIZATION OF GENETIC MODIFICATION(S)

A. Information is required regarding the DNA insertions into the plant genome and it should include:

1. The characterization and description of the inserted genetic materials, including whether portions of the vector backbone sequences, such as antibiotic resistance genes with bacterial promoters and bacterial origins of replication are present,
2. The number of insertion sites and the method used to make the determination,
3. The organization of the inserted genetic material at each insertion site, including orientation as well as 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. DNA sequence of the inserted material and of the flanking regions bordering the site of insertion,
5. Identification of any open reading frames within the inserted DNA or created by the insertions with contiguous plant genomic DNA, including those that could result in fusion proteins

B. Information needs to be provided on any expressed substances in the GE event including:

1. Gene product(s) (e.g., a protein or an untranslated RNA),
2. Function of each gene product,
3. Phenotypic description of the new trait(s),
4. Expression sites and level of each novel expressed gene product in the plant, if the function of the expressed sequence/gene is to alter the accumulation of a specific endogenous mRNA or protein

C. In addition, information is also required on the following:

1. To demonstrate whether deliberate modifications made to the amino acid sequence of the expressed protein result in changes to 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.[9]
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.
5. To confirm the identity and expression pattern of any new fusion proteins.

9.6 PHENOTYPIC AND AGRONOMIC CHARACTERISTICS OF GE EVENT(S)

Data should be collected from test plants grown in replicated confined field trials over at least two years, from a minimum of three trial site locations representative of the range of agro-ecosystems where the GE event may be cultivated. Multiple field trial sites may be required to ensure that the normal range of agro-ecosystems where that plant species will be cultivated is adequately represented. Each field trial should include at least two negative controls: the non-transformed parental line and at least one other non-transformed control variety/hybrid representative of varieties/hybrids of that plant species typically cultivated in the area where the trial is planted.

Phenotypic data should address the following considerations: [10]

[9] It may be necessary to examine the inheritance of the DNA insert itself or the expression of the corresponding RNA or expressed protein, if the phenotypic characteristics cannot be measured directly.

[10] 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 scientific rationale.

1. Growth habit: observations regarding observed changes in basic morphology of the plant, including any abnormalities or indications of aggressive or invasive growth.
2. Life cycle: observations regarding the length and nature of the plant's life cycle, for example, whether the plant remains categorized as annual, biennial or perennial.
3. Plant height and biomass: observations to be recorded at regular intervals during the growing season.
4. Impact on pollinator species: observations regarding whether there have been changes in the number or species of visiting pollinators (requires previous information on pollinators of the non-GE plant species).
5. Indicators of changes in weediness potential: observations regarding introduced plant characteristics that are likely to affect dissemination of seed. Measurements include the following:
    a. Seed germination and dormancy,
    b. Number of flowers produced per plant,
    c. Number of fruits produced per plant (or grain yield as appropriate),
    d. Pollen production, morphology and viability,
    e. Time to maturity,
    f. Number of flowering days,
    g. Number of viable seeds produced per fruit, and
    h. Percentage of germinated seeds surviving to maturation
6. Biotic stresses: Observations of susceptibility to pests and/or diseases commonly associated with the plant species.
7. Abiotic stresses: Observations of responses to water stress or nutrient deficiency or other stresses common to the plant species where applicable.

9.7 CULTIVATION PRACTICES OF GE PLANTS

Information should be provided on any likely changes to existing agronomic practices that may arise as a consequence of cultivation of the GE event. This refers specifically to changes in cultivation practices that could have a potential adverse effect on the biodiversity of the receiving environment (usually the agro-ecosystem where the GE event will be cultivated) when compared to the cultivation practices used for the non-transformed parental line. The following considerations should be taken into account:

1. Describe the regions in India where the conventional plant species is currently cultivated, and indicate if the phenotype of the subject GE event is anticipated to permit cultivation in regions other than these. Describe any new ecosystems where the GE event may be cultivated (e.g., salt tolerance that allows cultivation in degraded soils).
2. Describe cultivation practices for the GE event, 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 rotation, 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 GE event (e.g., insect resistance management in the case of insect-resistant GE events).
4. Discuss the environmental impact of any potential gene flow if the GE event will be cultivated in areas where other sexually compatible plants exist (i.e., unmodified varieties of the same plant species or 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 to progeny resulting from out-crossing and trait introgression?
   c. Would this be expected to significantly affect the establishment and spread of natural populations where gene flow has occurred?
   d. Would those alterations lead to an identifiable harm to the receiving environment or to biodiversity?

9.8 POTENTIAL ADVERSE NON-TARGET EFFECTS OR EFFECTS ON BIODIVERSITY AND ECOSYSTEMS

A risk may exist if a GE plant possesses an introduced trait having the potential to adversely impact individual species, ecosystems or biodiversity and these potential risks must be evaluated before the GE plant may be authorized for widespread planting. Risk assessors use scientific data regarding potential hazards and exposure to assess the likelihood of adverse impacts on populations of organisms as well as on communities of organisms and their diversity.

I. For specific GE plants, e.g., insect-resistant plants having an intentional adverse effect on pest organisms, it may be necessary to evaluate the potential impact of the GE event on non-target organisms. In such cases, applicants should undertake the following:

A. Tier I: These tier 1 studies are laboratory experiments conducted under worst-case exposure conditions. Species representative of non-target organisms that are both present in the receiving environment and are likely to be exposed to the target protein are evaluated using test diets incorporating concentrations of the target protein at, or above, the maximum estimated environmental exposure. This increases the likelihood of detecting adverse effects on non-target organisms. Representative non-target organisms typically used in Tier 1 testing are:

1. Mammalian e.g., mouse (*Mus musculus*)
2. Avian e.g., northern bobwhite quail (*Colinus virginianus*)
3. Freshwater fish e.g., channel catfish (*Ictalurus punctatus*)
4. Aquatic invertebrate e.g., *Daphnia magna*
5. Honey bee larvae and adults e.g., (*Apis mellifera*)
6. Lady beetle e.g., (*Hippodamia convergent*)
7. Green lacewing e.g., (*Chrysoperla carnea*)
8. Parasitic hymenopteran e.g., (*Brachymeria intermedia*)
9. Collembola
10. Earthworm e.g., (*Lumbricus terrestris*)

B. Tier II or Higher Tier Studies: Higher tier studies (e.g., semi-field or field studies) may be required if effects are seen under laboratory conditions at high test substance exposure concentrations. Higher tier studies are used to further characterize potential adverse impacts on non-targets organisms using more realistic environmental exposure scenarios. Higher tier, field based studies that require the assessment of the actual abundance of non-target species under test and control conditions should be designed to consider:

1. Threatened and endangered species in the area where the plant is to be grown;
2. Beneficial organisms known to be directly or indirectly associated with the plant, including:
   a. Primary pollinators
   b. Predators
   c. Parasites
   d. Biological control organisms
   e. Soil microbes
   f. Other appropriate non-target organisms (when identified as relevant assessment endpoints)

II. For GE 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 GE 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.

10 COMPLETING THE RISK ASSESSMENT

The risk assessment process for GE plants described in these Guidelines is based on a comprehensive, transparent and science-based framework by which regulators can identify potential harms that might be caused by GE plants, collect relevant scientific data pertaining to the likelihood and severity of any harms, and consistently evaluate the level of risk posed by the use of GE plants. This framework uses a conventional approach to risk assessment similar to ones used in many other areas of risk assessment and it incorporates a case-by-case approach that takes into account a variety of sources of information.

Using Problem Formulation, regulators will identify protection goals, formulate risk hypotheses that explore causal relationships between the cultivation of GE plants and the identified goals, and then determine which relevant data are needed to test the hypotheses. Using these data, regulators will assess the severity and likelihood of harms and ultimately evaluate the level of risk that would result from cultivating the GE plant. This process is performed for each risk hypothesis generated through Problem Formulation. For example, if the risk assessors identify three risk hypotheses: one regarding impacts on non-target organisms, one regarding impacts on agricultural productivity, and one regarding weediness of the GE plant, they will produce three risk evaluations. See Figure 1 for a matrix showing the relationship between the likelihood and the severity of a particular harm when evaluating the risk.

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			

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. See Figure 2 for a summary of this iterative process.

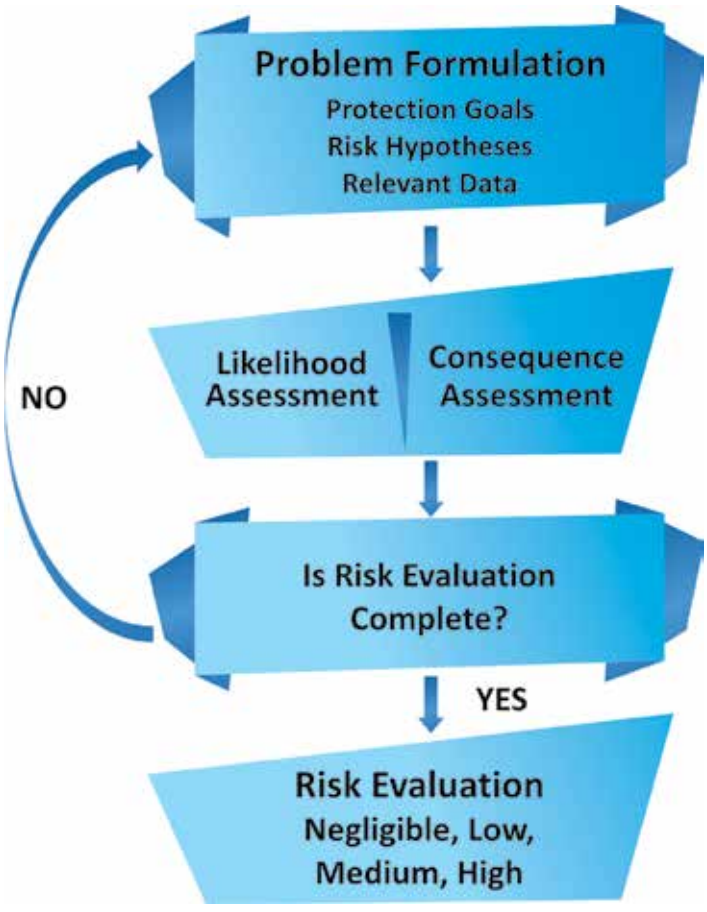

Figure 2: Risk Assessment Process for GE Plants

After testing all the risk hypotheses that were identified during Problem Formulation, the risk assessors will make an overall risk evaluation to determine whether the GE plant likely to pose significantly different risks of adverse environmental impacts than a non-GE comparator. Once all the identified risks have been evaluated, the risk assessors will issue a risk assessment report.

11 POST-RELEASE ENVIRONMENTAL MONITORING

Post-release monitoring (PRM) of GE crop plants in the context of biosafety regulatory approvals may be required when conditional management or other practices are considered necessary for risk mitigation purposes. This is typically determined on a case-by-case basis as an outcome of the risk assessment, although there may be GE crop/trait combinations where this is generally required e.g., monitoring for effective implementation of insect resistant management plans for crops expressing specific *Cry* proteins. In the event that PRM reveals unanticipated adverse effects to the environment or to human health from the general release of the GE plant, the applicant must promptly inform GEAC.

PRM should be tailored to the specific characteristics of the GE plant and it should follow the problem formulation framework:

- It should address relevant protection goals;
- It should focus on specific hazards posed by the GE plant;
- It should be based on specific risk hypotheses that can be tested with data;
- It should include specific measurement endpoints to determine when an effect has been detected;
- It should include a termination date for monitoring, if the risk hypotheses are confirmed or rejected;

In drafting an appropriate PRM plan, a series of questions in four basic areas provided in Table below should be considered:

General Question	**Specific Questions**
Why is the monitoring being proposed?	• Is there a science-based risk hypothesis that can be tested using data collected during PRM? • Has existing hazard and exposure data been evaluated to determine whether there is a need for PRM? • Is the potential risk significant enough to justify the resources needed for PRM?
What data needs to be collected?	• Are appropriate positive and negative controls available for comparison? • Is baseline data available? • What types of data are needed to test the risk hypothesis? • Which statistical methods and significance levels will be used?
What data needs to be collected?	• Are appropriate positive and negative controls available for comparison? • Is baseline data available? • What types of data are needed to test the risk hypothesis? • Which statistical methods and significance levels will be used?
When and where should the monitoring data be collected?	• Is there an appropriate number of study locations? • Should sampling occur only once or at multiple times during the growing season?

How should the data be collected?	• Under what conditions should samples be taken? • Are validated methods available for analyzing the samples? • What training will be needed for field workers? • How will samples be preserved, stored, and transported? • How will the data be processed and communicated in a monitoring report?

Product developers may seek to implement PRM plans for other purposes, such as ensuring that products continue to meet the needs of farmers or to monitor if farmers are changing crop management practices after adoption of a particular GE event. Such stewardship programs may provide interesting or useful information for environmental risk assessments, and consequently stewardship plans addressing the responsible deployment of the GE plant into the environment may be considered acceptable for post-release monitoring purposes.

ANNEXURE I: FORMAT FOR APPLICATION FOR ENVIRONMENTAL RELEASE OF A GE PLANT FOR THE PURPOSE OF CULTIVATION

A. 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 India.

Name of Applicant Organization	
Legally Responsible Representative/ Individual (must be resident of India)	
Contact Person (if different than above)	
Address	
Telephone Number	
Fax:	
Email	

B. 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)	
Origin or source of the introduced genes	
Unique Identifier (if applicable)	
Intended Use (e.g., Food, Feed, Cultivation)	

C. 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.

C.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 India to which distribution is intended		

C.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 India		
Gene flow		
Volunteers and weediness		
Potential for gene transfer to other plants		
Free-living populations		
Cultivation in India		
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 India		

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.

C.3 Description of the Donor Organisms

The following 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.

C.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.

C.5 Molecular Characterization of Transgene(s)

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

Information Provided	YES	NO
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 GE plant, or what information is being provided in its place.

C.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 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 GE plant, or what information is being provided in its place.

C.7 Cultivation Practices

Information Provided	YES	NO
Regions of cultivation in India		
Cultivation practices for the GE 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 GE plant, or what information is being provided in its place.

C.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		
Avian		
Aquatic organisms		
Non-target arthropod		
Soil dwelling organisms		
Tier II or Higher Tier testing results		
Have higher tier NTO studies been reported?		

D. Post-Release Environmental Monitoring

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

Information Provided	YES	NO
Detailed monitoring plans for post release environmental monitoring		

Notes

Notes

Important Contacts

Dr. Ranjini Warrier
Adviser, Ministry of Environment, Forest and Climate Change

Dr. S R Rao
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