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Environmental Risk Assessment of Genetically Engineered Plants: A Guide for Stakeholders

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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सत्यमेव जयते

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ENVIRONMENT, FOREST & CLIMATE CHANGE
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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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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
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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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Environmental Risk Assessment of Genetically Engineered Plants

1 PREAMBLE

The **"Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016"** (the Guidelines) have been prepared by the Ministry of Environment, Forest & Climate Change with an objective to describe the approach followed by the Government of India to assess any potentially adverse environmental effects resulting from the environmental release of genetically engineered (GE) plants, i.e., plants that have resulted from the use of modern biotechnology. The goal is to ensure that these plants may be safely developed, cultivated and used without causing unacceptable adverse impacts on humans, the environment and biological diversity. The Guidelines describe a comprehensive, transparent and science-based framework by which regulators can identify potential harms that might be caused by the cultivation of GE plants and applicants can plan and conduct an environmental risk assessment in support of the release of a GE plant in India.

2 INTRODUCTION

Plant breeding techniques have been used for generations to both improve existing crops, like rice and to produce entirely new crops, like modern maize. Over time, plant breeders have adopted new tools and technologies to accelerate the development of crops with greater yields, better nutritional value and the ability to withstand diseases, pests and other environmental stresses. For example, plant breeders have artificially changed plants' chromosome numbers, induced mutations using chemicals and radiation and used tissue culture and embryo rescue to recover the offspring of crosses between distantly related species (Carpenter *et al*. 2002; Lemaux 2008).

In the effort to make crop improvements faster and more precise, plant breeders and other scientists have adopted tools of modern biotechnology, involving the use of recombinant DNA (rDNA) techniques and crops resulting from these techniques have been adopted by farmers worldwide (James 2014). To assure the public, as well as the international trading community, that these crops are safe, many countries, including India, have signed the Cartagena Protocol on Biosafety (CPB). Among other provisions, CPB signatories agree to assess environmental risks of GE plants before they are placed on the global market.

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; and 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 research as well as large-scale applications of GE organisms and products made from them 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)
- State Biotechnology Coordination Committees (SBCC)
- District Level Committees (DLC)

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

- Revised Guidelines for Research in Transgenic Plants, 1998[2]
- Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants (2008)[3]
- Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered (GE) Plants (2008)[4]

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 present an overview of the risk assessment process used in India.

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[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/

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

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

3 SCOPE

The Guidelines apply to GE plants, whether they were developed in India or developed by another country and proposed to be imported into India for domestic use. The Guidelines do not apply to GE organisms other than plants (e.g., GE microorganisms). Because non-living, non-propagable GE plant material cannot persist in the environment, the Guidelines do not apply to these plant materials, such as leaves, cut flowers, crushed seed meal or extracted oil. The Guidelines also do not cover research conducted with GE plants in contained facilities, such as laboratories and greenhouses, nor the experimental growth of GE plants in confined field trials. Separate guidance exists for these situations[5].

4 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 Indian approach to environmental risk assessment is described in the Guidelines. 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.

For any given activity posing some hazard or harm, risk of harm can never be zero. Safeguards against the harm can be put in place, but the risk can never be completely eliminated (Kaplan and Garrick 1981). The only way to completely avoid a particular risk associated with an activity is to not undertake that activity. But that may cause new risks. For example, a person may refuse to be vaccinated, to avoid any risk of an allergic reaction to the vaccine, but the person is then at risk of getting a serious disease.

Principles of 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 GE 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 GE plant that resulted from

[5] See Revised Guidelines for Research in Transgenic Plants & Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, 1998 (http://dbtbiosafety.nic.in/Files/CD_IBSC/Files/transgenic.PDF) and Guidelines for the Conduct of Confined Field Trials of Regulated, GE Plants (http://dbtbiosafety.nic.in/Files/Guidelines%20for%20the%20conduct%20of%20confined%20field%20trials.pdf)

the genetic engineering process. The risk assessment identifies risks by considering a wide range of potential pathways through which harm might occur. Risks are then characterized by considering how serious the harm could be (consequences) and how likely it is that a particular harm could occur. The risk is then evaluated by integrating the consequences and the likelihood (OGTR 2013).

It is important to remember that all agricultural practices, including traditional and organic agriculture, pose the risk of adverse environmental impacts. Therefore, ERA for the cultivation of GE plants takes a comparative approach: the assessment evaluates any risks posed by the GE plant in comparison to the risks posed by the non-GE plant (Hill and Sendashonga 2003). For example, several species of the genus Brassica are grown worldwide as valuable crops, such as mustard and canola, however many of these species can become weeds (OECD 2012). Therefore, in the assessment of environmental risks posed by a GE variety of mustard (*Brassica juncea*), the risk assessment process must evaluate the weediness potential of the GE variety in comparison to the known weediness of the species. A comparative analysis can help risk assessors identify unintended environmental effects resulting from the genetic engineering process. If there are no biologically significant differences, the GE plant is considered to be "substantially equivalent" to the non-GE variety (Cellini *et al*. 2004; FAO/WHO 1991; OECD 1993). If there are significant differences between the GE and non-GE varieties, the analysis focuses on the impact of these differences. A difference does not automatically indicate the potential for harm; many differences will have no adverse environmental effects or even beneficial effects. However, if the risk assessors determine that the difference poses environmental harm, either because an existing risk has increased or because a new risk has been identified, the impact of these differences on the environment should be further assessed (Craig and Tepfer 2007; Keese *et al*. 2013).

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 (Hill 2005; Kaplan and Garrick 1981; Keese *et al*. 2013; NRC 2008).

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 (Hayes *et al*. 2004; Keese *et al*. 2013). In each scenario there must be a causal link between the cultivation of the GE plant and the harm. Risk identification should be comprehensive and rigorous, however, care should be taken to avoid over-emphasizing insubstantial risk scenarios. Risks that warrant detailed consequence and likelihood assessments to determine the level of risk they pose to human health and safety or to the environment are generally identified by considering the following questions.
   - **Is the potential harm attributable to the genetic engineering process?** Any harm not posed by or resulting from the use of gene technology should not be considered.
   - **Is there a plausible and observable pathway linking the proposed cultivation of the GE plant to the potential harm?** In cases where no plausible or observable pathways link the proposed cultivation to the potential harm, the risk scenario should not be considered further.
   - **Is the risk substantive?** After an initial consideration of the chance and seriousness of harm, does the risk scenario warrant more detailed consideration?

Figure 4.1: Severity of harm

Consequence Assessment	Degree of potential harm
Marginal	Minimal or no increase in illness/injury to people Minimal or no increase in harm to desirable components of the environment
Minor	Minor increase in illness/injury to people that is readily treatable Minor increase in damage to desirable components of the environment that is reversible and limited in time and space or numbers effected
Intermediate	Significant increase in illness/injury to people that requires specialized treatment. Significant increase in damage to desirable components of the environment that is widespread but reversible or of limited severity
Major	Significant increase in severity of illness/injury to people or large numbers of people affected and generally not treatable Major increase in damage to desirable components of the environment, with extensive biological or physical disruption to whole ecosystems, communities or an entire species, which persists over time

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 (Fig 4.1). The seriousness of harm is dependent on the scale at which impacts are considered. Harm to humans may be considered significant at the level of an individual, whereas harm to the environment is usually considered significant at

the level of species, communities or ecosystems. Assessing the seriousness of harm to people or to the environment may include consideration of the following questions.

- What is the **magnitude** of each potential adverse impact: does it cause a large change over baseline conditions?
- What is the **spatial extent or scale** of the potential adverse impact?
- What is the **temporal component** of the impact, namely, the duration and frequency? Does it cause a rapid rate of change? Is it likely to occur in the short or long term? What is the duration (day, year, decade) over which an impact may be discernible? Will the nature of the impact change over time? Is it intermittent or repetitive? Will the impact disappear at some point?

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. (Fig 4.2) In the chance of harm is close to zero, then risk is considered minimal and needs no further analysis. However, care needs to be exercised when considering the remote possibility of risks that may have extreme adverse impacts. The process of analyzing any causal links between the GE plant and an environmental harm will be covered in greater detail in the next chapter.

Figure 4.2: Likelihood of harm

Likelihood Assessment	Nature of likelihood
Highly unlikely	Harm may occur only in very rare circumstances
Unlikely	Harm could occur in some limited circumstances
Likely	Harm could occur in many circumstances
Highly likely	Harm is expected to occur in most circumstances

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. Risk is evaluated against the objective of protecting the health and safety of people and the environment to determine the level of concern and subsequently, the need for controls to

Figure 4.3: 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			

mitigate or reduce risk. Risk evaluation may also aid consideration of whether the proposed cultivation should be authorized, whether further assessment is necessary or whether additional data must be collected.

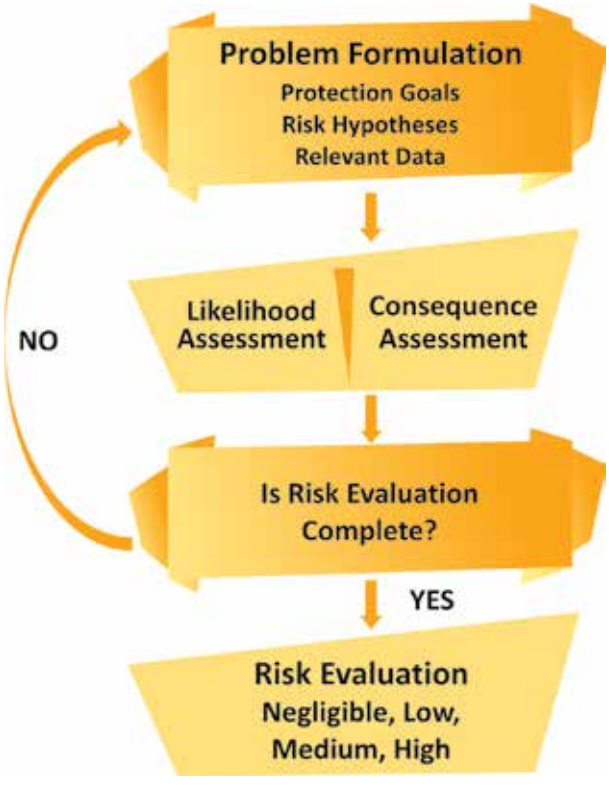
Risk evaluation combines the findings from the consequence (hazard) and likelihood (exposure) assessments, using a matrix (Fig 4.3) to determine the level of risk and whether risk mitigation is needed to reduce the level of risk. To help inform the regulatory decision making process and make the process more transparent, it is useful to define discrete levels of risk (Fig 4.4).

Figure 4.4: Risk level definitions

Level of risk	Risk level definition
Negligible	Risk is of no discernible concern and there is no present need to invoke actions for mitigation
Low	Risk is of minimal concern, but may invoke actions for mitigation beyond standard practices.
Moderate	Risk is of marked concern and will necessitate actions for mitigation that need to be demonstrated as effective
High	Risk is of considerable concern that is unacceptable unless actions for mitigation are highly feasible and effective.

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 Fig 4.5 for a summary of this iterative process.

Figure 4.5: 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 plants are 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.

5 PROBLEM FORMULATION FOR ENVIRONMENTAL RISK ASSESSMENT

Problem formulation is a multi-step framework that provides the means to organize an environmental risk assessment so that the assessment is done in a logical and transparent way (Wolt et al. 2010). Typically the problem formulation process is represented as a series of five steps:

1. Identify the Protection Goal
2. Derive the Operational Goal
3. Determine the Assessment Endpoint
4. Formulate the Risk Hypothesis
5. Determine the Measurement Endpoints

This stepwise process helps risk assessors decide what questions the assessment will address and what data are most relevant to those questions. In the end, problem formulation facilitates both the decision-making processes in risk assessment and clarifies to stakeholders on how the decisions are made. It is a five-step process, presented below. In this example, the risk assessors are assessing the potential risks of growing an insect-resistant GE cotton variety; the cotton plant produces a protein ("Bt protein") that is toxic to certain insects.

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. The purpose of a risk assessment for the commercial release of a GM plant is to determine whether the plant can be released while protecting these valued environmental resources.

   Example: "Protect biodiversity"

   In other words, the assessment addresses the question of whether the commercial release of insect-resistant cotton will impair India's ability to meet one of its protection goals, in this example, the protection of biodiversity.

2. **Derive the Operational Goal:** Generally, protection goals are articulated using very broad language, sometimes including legal or technical terms; however, the risk assessment process is case-specific, grounded in science and based on testable hypotheses (Herman et al. 2013). 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. For example, from a broad protection goal, such as "protect biodiversity," the risk assessors could derive a more specific operational goal that relates to the context of crop production.

Example: "Protect agriculturally important pollinators."

This goal suggests the types of questions the risk assessors must address and it begins to narrow the scope of the data the assessors must consider to assess potential risks from the commercial release of a GM crop plant. In this case, it is data regarding risks to 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 nature of the protection given to the environmental resource, i.e., what specifically will be protected, how much protection will be given and for how long.

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

   For example, this assessment endpoint identifies honeybees as a valued environmental resource that India intends to protect; it defines sustainable bee populations as the nature of the protection; and it states that protection will be provided to bees for a long period of time.

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

   Example: "Cultivation of insect-resistant cotton will adversely affect honeybee populations, compared to cultivation of non-GE cotton."

In this example, the risk hypothesis has been phrased as a positive statement, but it is also acceptable to phrase the hypothesis as a negative statement, i.e., "Cultivation of the GE plant will not adversely affect…." In either case, the job of the risk assessors is the same: to determine, using scientific data, whether the hypothesis is true or false.

Once the risk hypothesis has been formulated, the assessors return to the original causal pathway they developed during the Risk Identification step (Section 4). The assessors may have hypothesized a causal link between Bt cotton and honeybees in which the bees could be adversely affected, simply because bees are known to pollinate cotton. However, this type of preliminary causal relationship is insufficient for the purposes of risk assessment. Identifying all the intervening steps in a causal pathway leading to harm is crucial to determining the likelihood that a particular harm may occur. A causal pathway leading to increased harm may involve many steps, all of which must occur. If some of the steps have only a small chance of occurring, then the overall pathway has an extremely limited chance of occurring due to the combination of several steps with low probablility. Alternatively, one step may have almost no chance of occurring, resulting in a very low overall probability even if all other steps have a reasonable chance of occurring. Some pathways can be complex, but identifying each of the steps makes the analysis simpler to do and easier for stakeholders to understand.

Using the example of a GE cotton variety that has been genetically engineered to produce bacterial toxins that kill insect pests that feed on cotton, regulators may be concerned that the commercial cultivation of this GE cotton variety may cause harm to honeybees. To assess the risk, they develop a detailed causal pathway (also called a "pathway to harm") to help evaluate the probability that bees will be harmed. This pathway starts with the risk hypothesis and breaks it into discrete steps, all of which must happen for the harm to occur.

Risk Hypothesis: Cultivation of insect-resistant cotton will adversely affect honeybee populations, compared to cultivation of non-GE cotton.

IF: Insect-resistant cotton is grown commercially in India

AND: Honeybees visit cotton flowers in large numbers

AND: Honeybees collect pollen and nector from cotton flowers

AND: The bacterial toxin is produced in pollen or nectar

AND: The bacterial toxin is toxic to honeybees

AND: The level of protein produced in the pollen and nectar is sufficiently high to kill honeybees in large numbers

THEN: Cultivation of insect-resistant cotton will adversely affect honeybee populations, compared to cultivation of non-GE cotton.

The steps can be thought of as questions and the regulators must identify data that answer each question. For example, they need to find data regarding the frequency that honeybees visit cotton plants. If they determine that honeybees do not visit cotton plants in measurable numbers, the causal link between the cotton plants and harm to the honeybees is broken. If the data indicate that honeybees do in fact visit cotton plants in large numbers, that particular causal link is not broken and they must move on the next step and so on through the entire pathway.

5. **Determine the Measurement Endpoints:** Once the Risk Hypothesis has been formulated and the detailed pathway to harm has been prepared, it is straightforward for the assessors to determine the specific 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 cotton plants

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 long-term sustainability of honeybee populations.

The Risk Hypothesis is based on a comparison between the GE plant and the non-GE version of the plant and so the data collection process must first collect sufficient information to fully characterize the biology of the non-GE version (Häggman et al.

2013). Then data must be collected that might identify and characterize significant differences between the GE and non-GE versions of the plant that might adversely impact honeybees. The "pathway to harm" method helps with the determination of Measurement Endpoints in two important ways. First, each step suggests the specific data that the risk assessors will need to collect and analyze. This data will probably be provided by the applicant or it may be available in the published scientific literature. Second, this method helps developers of new GE crops identify and understand which data they will need to collect for the risk assessment process. A third advantage to this technique is that it describes a very logical process that is easily understood by stakeholders.

For example, given the hypothesis regarding impacts to honeybee populations, the risk assessors must fully understand how the non-GM version of the plant interacts directly or indirectly with honeybees and evaluate the repercussions of those interactions, in terms of negative impacts on the bees. Then the potential adverse impacts of the GE plants on bees are compared with those posed by the non-GE version of the plant. Ultimately, the risk assessors will determine whether the differences between the GM and non-GM plants are likely to result in significantly different impacts on bees (Häggman et al. 2013; OECD 1993; OGTR 2013; SCBD 2000).

Returning to the pathway to harm provided above, it is obvious that one step is crucial: whether the bacterial toxin produced by the cotton plant is toxic to honeybees. If there is data in the application relevant to this question, possibly supplemented with data from the scientific literature, the risk assessors should be able to answer this key question. For example, it is well known that the commonly used bacterial toxins used in insect-resistant crops are not toxic to honeybees (Hendriksma et al. 2013; Mendelsohn et al. 2003). Returning to the causal pathway, it is clear that if honeybees are not affected by the toxin, then it is not possible for honeybees to be harmed from the commercial cultivation of insect-resistant cotton in a manner that is different from non-GE cotton.

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 their 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.

6 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* [6], developed pursuant to the Cartagena Protocol on Biosafety, provides criteria for data:

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

Data used in the risk assessment will be generated by two sources: the applicant and the risk assessor. 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 for developing the event, collecting 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. The trials should be conducted in a manner consistent with the proposed agricultural practices for the GE event/s. The details of all confined field trial protocols, including experimental designs and sampling procedures, should be submitted. Each piece of information

[6] 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

may be ranked differently against these criteria and, where contradictory information exists, the Regulator must judge the relative strength of each piece. Some information may be redundant or not of high enough value to be used as evidence.

The risk assessor has an obligation to search beyond the application to identify additional data and other information that will help in the completion of the risk assessment. Useful data will come from a variety of sources:

- **Published scientific literature –** Scientific papers published in peer-reviewed journals generally provide some assurance of quality, but it is important to check that the conclusions of the authors are supported by data presented in the paper and corroborated by other data reported by different authors. The reputation and research experience of the authors should also be considered when judging the quality of the data.
- **Consensus documents –** International bodies, such as the Organization for Economic Co-Operation and Development[7], as well as the governments of many countries, have published documents providing detailed information regarding the biology of several commonly planted crop plants. Many of these documents have been prepared specifically to inform the environmental risk assessment process for GE versions of the plant (Bergmans 2007). These documents are typically developed using a process that ensures scientific consensus.
- **Confined field trial permit applications –** Applications submitted for confined field trial permits concerning the same or similar GE plants can provide additional background information as well as specific data regarding the genetic changes that have been implemented.
- **Past environmental risk assessments –** Risk assessors should review past assessments regarding GE plants with the same or a similar phenotype, including risk assessments prepared in other countries. These documents can provide valuable data and they will also help the risk assessors identify risk hypotheses and measurement endpoints that other regulators found useful in their assessments.
- **Professional experience of the risk assessors –** Risk assessors may and should draw on their own personal expertise and research experience, when appropriate. However, it is always important to hold such information to the same high standards for objectivity and scientific support, so that personal biases do not enter into the assessment.

The data used in a risk assessment must be relevant and appropriate, given the risk hypotheses identified in the problem formulation process. The Draft *Roadmap for Risk Assessment of Living Modified Organisms*, also provides criteria for determining the relevance of data:

[7] http://www.oecd.org/env/ehs/biotrack/consensus documents for the work on harmonisation of regulatory over sight in biotechnology biology of crops.htm

Relevance of the information for 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
- 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.

Figure 6.1 Illustrates how the risk assessor may view the value of some different types of information. Information may be ranked low in one criterion but high in others.

Reliability	Increasing Value	Relevance/Appropriateness
Validated studies conducted according to international protocols meeting defined standards		Experimental data on the GE plant in the Indian environment
Peer reviewed literature – strongly supported reports, models, theories		Experimental data on the non-GE plant in the Indian environment
Opinion of an expert familiar with the GMO, parent organism, modified traits, ecology		Experimental data on the GE plant from countries outside India
Technical reports, government reports		Experimental data on the non-GE plant from countries outside India
Unsubstantiated statements		Experimental data on the same GE trait in other plants

The combined weight of evidence may also influence the risk assessment: a single strong piece of information (as judged by the above criteria) may stand on its own or a number of weaker pieces of evidence may support each other, enabling the risk assessor to have sufficient confidence in the information. In addition, judgment is needed to determine the sufficiency of the data to achieve a reliable and robust evaluation of risk. On the other hand, the collection and consideration of unnecessary or irrelevant data is an inefficient use of resources for applicants and the risk assessor (Raybould 2006).

7 INFORMATION REQUIREMENTS FOR ENVIRONMENTAL RISK ASSESSMENT

As stated in the Guidelines, when a developer desires to release a GE plant into the environment for commercial use, an environmental risk assessment must be performed. Each assessment is done on a case-by-case basis and so each assessment requires specific data and other information about the GE plant in question. Some of this data will be available in the published literature and other sources, but typically the majority of the data is supplied by the applicant in the application for environmental release.

Both in the Guidelines and in this Users' Guide, it has been emphasized that the Indian government supports a comparative approach to the environmental risk assessment of GE plants. A comparative approach means the risk assessment of the GE plant is not performed in isolation. Instead the GE plant is compared to the non-GE comparator, in the same context of the agro-environment in which the plants are grown. To perform this type of comparative assessment, the risk assessor must be fully familiar with the non-GE plant, its cultivation and its interactions with the environment. The assessor must then also become familiar with the GE plant, how it is similar to the non-GE counterpart, how it is different and how these differences may change the plant's cultivation and interactions with the environment. Only with this level of familiarity can the assessor be ready to determine whether any of these differences might result in significant harm.

Familiarity comes from data as well as from experience with crops in general and with genetically engineered plants specifically. This data and experience may be in regard to a number of different subject matter areas (OECD 1993):

- The crop plant, its flowering and reproductive characteristics, including its sexually compatible relatives, agronomic requirements and environmental interactions
- The trait or traits that have been conferred on the GE plant, which genetic components were used, what is known about their safety and how they function in the plant

- The range of characteristics exhibited by traditionally bred varieties of the crop.
- The characteristics of the GE plant while grown in a research environment, e.g., in a greenhouse or in a confined field trial, when compared to a non-GE counterpart grown in the same circumstances

It is important to remember that becoming fully familiar with the GE plant and its non-GE comparator is not the risk assessment itself, but it is a key early step in performing the risk assessment. Familiarity enables the risk assessor to determine the extent to which the GE and non-GE plants are similar: their biological characteristics, their agronomic properties and their interactions with the environment. Aspects of the two plants that are substantially similar do not need further assessment. Instead the assessment focuses on those aspects that are substantially different, remembering that a mere difference is not necessarily a hazard. For example, there are hundreds of different varieties of roses, with different growth habits and flower colors, but none of these substantial differences pose a hazard to the environment.

The Guidelines recognize that risk assessors must be fully familiar with the GE plant that is proposed for environmental release before that release can be authorized and so the Indian government has identified data and other information that must be collected and considered by the assessors before the risk assessment can be completed. These data are described in Chapter 9 of the Guidelines. This data, which is supplied by the applicant, provides the majority of the information that the assessors will need to become familiar with the plant, both GE and non-GE: plant biology, agronomic properties and interactions with the environment. The data may be supplemented by information drawn from the published scientific literature, international consensus documents, such as those published by the OECD[8], and by published regulatory decisions from other countries. This additional information is seldom collected all at once: it is more typical that the regulators will collect more data throughout the risk assessment process as needed to answer specific questions that may arise. It is also common for the regulators to return to the applicant for more data.

Chapter 9 of the **Guidelines** lists the following types of data:

- **Description of the GE Event (Section 9.1) –** This data is needed largely to distinguish the GE plant in questions from other GE plants the regulators may be evaluating.
- **Description of the Non-Transgenic Parental Plant (Section 9.2) –** This data helps the regulators become familiar with the plant before it was genetically engineered and this information provides the basis of the comparative

[8] http://www.oecd.org/science/biotrack/documentsonharmonisationofregulatoryoversightinbiotechnologyandthesafetyofnovelfoodsandfeeds.htm

assessment. The data includes botanical, biochemical, agronomic, genetic and ecological information, as well as other data, usually determined on a case-by-case basis.

- **Description of the Donor Organisms (Section 9.3) –** "Donor" organisms are the ones from which genetic material, typically DNA, was used in the genetic engineering process. The donors may be microorganisms, plants or rarely, animals. Regulators need to know if any of the donors have a history of safe use in agriculture or in food and whether any of the donors are pathogenic or allergenic. Regulators need this information to verify that no potential pathogenic characteristics or allergens could be conferred to the GE plant through the use of the donor's DNA.
- **Description of the Method and DNA sequences Used in the Genetic Modification (Section 9.4) –** This information helps the regulators understand exactly what genetic changes were made to the plant and how those changes were made. Information regarding the history of safe use of individual genetic components is also useful.
- **Characterization of the Genetic Modification (Section 9.5) –** This data describes what new properties the GE plant has that the non-GE version lacks and those differences may be biochemical, morphological or agronomic in nature. Together, these data as well as the data in Section 9.2, help the regulators understand the ways in which the GE and non-GE plant are substantially similar and the ways in which they are substantially different. As discussed previously, substantial differences are not necessarily hazards; the regulators must continue the risk assessment process to determine which of the differences, if any, pose environmental hazards.
- **Phenotypic and Agronomic Characteristics of GE Event(s) (Section 9.6) –** This data describes the phenotype and agronomic characteristics of the GE and non-GE plant, in essence how the plant grows, how it performs as a crop and how it interacts with the agro-environment. This information enables the regulators to determine ways in which the non-GE and GE plants perform similarly in the field and ways in which their performance is substantially different. Again, differences are not necessarily hazards; the regulators must determine if any of the differences could have significant environmental impacts.
- **Cultivation Practices of GE Plants (Section 9.7) –** This data describes whether the GE plant would be cultivated differently as a crop or grown in areas where the non-GE crop is not traditionally grown. This data helps the regulators determine whether the GE plant could have different impacts in these new locations or whether the GE plant would be more likely, in the new locations, to come into contact with sexually compatible relatives. Again, the regulators would need to determine whether any differences would result in environmental harm.

- **Potential Adverse Non-Target Effect or Effects on Biodiversity and Ecosystems (Section 9.8) –** This data helps determine the potential for the GE plants to have impacts on biodiversity and ecosystems. This kind of data is especially relevant for insect-resistant GE plants, because these plants have an intentional, adverse effect on certain insect pests of the plant. Traditional agriculture typically includes control measures for insect pests, so the insect-resistant, GE plant may not be substantially different in the regard. However, the GE plant may have inadvertent, adverse impacts on non-pest insects or other organisms, so called "non-target organisms." Data, typically the results of toxicological studies, are included in the application to help the regulators evaluate the potential for harm to non-target organisms. For GE plants that are not insect resistant, regulators will evaluate the phenotypic and agronomic characteristics of the GE plant to determine whether they are substantially different from those of the non-GE plant and whether any of those differences could have significant adverse environmental impacts.

8 POST-RELEASE ENVIRONMENTAL MONITORING

Regulatory agencies support the appropriate use of post-release monitoring (PRM) in the context of regulatory approvals of GE crops for cultivation in India. The need for PRM is determined on a case-specific basis during the environmental risk assessment. If PRM is determined as a condition of approval for a specific GE event, it will be stated clearly written authorization by regulatory agency. For most GE plants with a history of safe use in India and/or other countries, PRM is considered a duty of care, which means the authorized party must proactively provide regulatory agencies with any information related to unexpected phenotypes or environmental impacts. Regulatory agencies will then review this information and determine if the risk assessment of the subject GE event should to be reconsidered and/or if the conditions of the GE event's approval should be modified.

The need for PRM,and the details of a monitoring plan, must be consistent with the goals of the original environmental risk assessment. This means that PRM should only be required when a clearly identified risk hypothesis has been formulated regarding potential harms to recognized protection goals. A post-release monitoring plan should then be drafted that specifies the goal(s) of the monitoring program, the appropriate measurement end points and the data that should be collected and reported. Monitoring efforts can be phased out after a reasonable number of years, if no unexpected effects are noted.

The nature of a PRM plan is not described in detail here because each plan will be tailored to the nature of the crop/trait combination, the crop production methods that may be used, as well as other factors. To assist in drafting an appropriate PRM plan, a series of questions should be asked and answered as below:

Why is the monitoring being proposed?

The most critical step in conducting a monitoring study is a clear definition of need and purpose. The purpose of the monitoring plan should be specific, with the goal of the plan being to collect data that will be used to test one or more specific risk hypotheses. Vaguely articulated purposes such as "to investigate potential effects on the ecosystem" or "to reduce uncertainties associated with the risk assessment" are not testable risk hypotheses and will inhibit the collection of data that will be useful in a risk assessment. On the other hand, a testable risk hypothesis such as "a change from conventional to Bt cotton will have less of an effect on populations of pollinators than the effects of commonly practiced insect-control techniques" clearly indicates the data that needs to be collected and will facilitate the risk assessment process.

Once a risk hypothesis is formulated, the next step is to characterize the severity of the hazard and likelihood of the hazard occurring. This is a critical step because risks with an insignificant probability of occurring do not justify the time and resources that may be expended in the PRM process.

What data need to be collected?

To ensure that PRM is carried out in a resource-efficient way, the specific data needed to test the risk hypothesis i.e., the "measurement endpoints," should be identified as part of the problem formulation and PRM plan design phase. The PRM plan should identify the statistical methods that will be used for data analysis. In PRM studies where large amounts of data are collected, it is usual to find "statistically significant" differences simply due to the high natural variability of the agricultural systems being studied. These should be expected and are not necessarily indicators of biological significance or adverse environmental impacts.

When and where should PRM studies be undertaken?

PRM studies, when required, should be located and designed to best answer the study purpose. Usually, in order to obtain the greatest use of study data, such studies should be conducted at locations that are representative of regions where the GE crop is grown commercially. Studies should contain the appropriate replicates and controls at each location. In most cases, results from well-designed studies conducted in one area are applicable to other areas with similar agriculture practices, soil characteristics and climate.

How should the data be collected?

In most cases, monitoring methods can easily be adapted from related agricultural or agro-ecological studies e.g., the use of pitfall and sticky traps, visual observations and various soil or plant debris sampling methods are available. In all cases, the methods chosen should be validated and ideally described in the published literature.

Untested or novel data collection methods should be avoided as they may give rise to data that cannot be easily compared to existing baseline data and will not lend themselves to standard statistical analysis.

Other considerations

Concurrent with the identification of data collection methods, the PRM plan should also consider the need for training of field personnel. Data quality can be compromised if workers are not fully trained in the collection methods, including the correct handling of samples (labeling, storage and transport).

The outcomes from PRM studies should be recorded in a monitoring report that provides detailed information about risk hypotheses, methods, results and conclusions and in a format that can be used by regulators and risk assessors to inform risk assessment and regulatory decision making.

ANNEXURE I: REFERENCES

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

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	

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, ultivation)	

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.

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		

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.

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.

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.

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.

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.

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.

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?		

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		

Important Contacts

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