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Nature Protects if She is Protected

UNEP

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Risk Analysis Framework, 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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भारत सरकार / GOVERNMENT OF INDIA

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
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)

EXECUTIVE SUMMARY

The *Risk Analysis Framework* describes the principles of risk analysis used by the Regulatory Agencies to protect human health and safety and the environment, in accordance with the Environment (Protection) Act, 1986.

The *Risk Analysis Framework* provides guidance on how the Government of India, through its Regulatory Agencies, implements the risk analysis of genetically engineered (GE) plants in accordance with its laws and regulations.

The purpose of this *Risk Analysis Framework* is to:

- provide a guide to the current rationale and approach to risk analysis
- enable a consistent and rigorous risk analysis approach to evaluating applications for the environmental release of GE plants
- provide transparency on the use of risk analysis for decision making.

The *Risk Analysis Framework* incorporates recent advances in risk analysis, increased scientific knowledge and regulatory experience gained with GE plants both in India and other countries.

Risk analysis integrates the assessment, management and communication of risks posed by GE plants.

Risk analysis includes **risk assessment,** risk management and risk communication. Risk assessment identifies risks from plausible sets of circumstances that may result in harm to people or to the environment from GE plants, characterises the risks on the basis of seriousness and chance of harm and evaluates the need for controls. **Risk management** selects and implements plans or actions to appropriately mitigate identified risks. **Risk communication** is the exchange of information, ideas and views between the government and stakeholders and conveys the rationale for decisions made by the government

The risk context defines the parameters within which risk is assessed, managed and communicated.

Establishing the **risk context** is the preparatory step that defines the scope and boundaries of the risk analysis, sets the criteria against which risk will be evaluated and describes the process for the analysis. This includes setting criteria for what is considered as harm to people or the environment.

Decisions on applications require case-by-case assessment, including preparation of a risk assessment and a risk management plan. Details of the GE plant and the proposed activities, including any proposed controls, form the specific context for the risk assessment and risk management plan. Details of the parent organism, the GE plant and the environment where the GE plant will be grown form the baselines by which the parent and the GE plant will be compared.

Risk assessment is a structured, reasoned approach for determining the chance of harm from the environmental release of a GE plant, based on scientific evidence and taking into account any information received from

Risk assessment **identifies substantive risks and evaluates the level of risk based on a combination of the consequences and likelihood of potential harm.**

consultation with experts and other stakeholders. The aim is to identify, characterize and evaluate risks to the health and safety of people or to the environment from the use of GE plants, when compared with risks posed by conventional plant varieties. The risk assessment begins by determining what could go wrong and how harm might occur if a particular GE plant was intentionally released into the environment. Risks are then characterized by considering how serious the harm could be (consequences) and how likely it is that harm could occur. The level of risk is then evaluated by integrating consequences and likelihood.

The risk assessment initially considers a wide range of potential pathways whereby harm might occur. Those pathways that describe substantive risks are considered in more detail and the level of risk evaluated.

Risk management protects the health and safety of people and the environment by implementing various measures to control or mitigate risk. Risk management typically includes preparation of a risk management plan that describes the mitigation measures and how each will be implemented. The plan may also establish a monitoring process to ensure that the proposed risk management measures are being implemented consistently and effectively.

Risk management **determines appropriate mitigation measures to manage risk and applies these through proposed authorization conditions.**

The risk assessment and risk management plan forms the basis upon which the Regulatory Agencies decide whether to issue an authorization for environmental release and what conditions to impose. To issue an authorization the Regulators must be satisfied either that the identified risks are acceptable or that they can be managed to protect human health and safety and the environment.

Risk communication is integral to the processes of risk analysis and involves an interactive dialogue between the Regulatory Agencies and stakeholders to exchange information of mutual interest and to build trust in the Regulatory system by discussing issues and addressing concerns relating to protecting the health and safety of people and the environment.

Risk communication **establishes an interactive dialogue between the Regulatory Agencies and stakeholders to provide open, transparent and consultative risk-based regulation of GE plants.**

Different stakeholders may perceive risks in a variety of ways, so the Regulatory Agencies undertake extensive consultation with a diverse range of expert groups and authorities and key stakeholders, including the public, before deciding whether to authorize the release of a GE plant into the environment. Regulators provide information to interested parties on risk assessment and risk management plans, GE plants and monitoring and compliance activities. The *Risk Analysis Framework* is part of the Regulator's commitment to clarity, transparency and accountability of decision-making processes.

ABBREVIATIONS

FAO	Food and Agriculture Organization
GE	Genetically Engineered
GEAC	Genetic Engineering Appraisal Committee
IBSC	Institutional Biosafety Committee
IPPC	International Plant Protection Convention
OECD	Organisation for Economic Co-operation and Development
OIE	World Organisation for Animal Health
RCGM	Review Committee on Genetic Manipulation
WHO	World Health Organization

GLOSSARY

Consequence	Harm to protection goals from an activity. A consequence assessment determines the degree of seriousness of harm ranging from marginal to major
Environment	Includes: water, air and land and the interrelationship which exists among and between water, air and land and human beings, other living creatures, plants, micro-organisms and property
Modern biotechnology	The application of: 1) In vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles; or 2) 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
Harm	Adverse outcome or impact
Likelihood	A general description of the probability, frequency or possibility of causal links in a postulated pathway to harm. A likelihood assessment determines the chance that harm may occur, ranging from highly unlikely to highly likely
Monitoring	Ongoing checking, supervising, critically observing or determining the status in order to identify change from the performance level required or expected. A primary role is monitoring for compliance with authorization conditions to ensure that the risk management plan is adhered to
Post-release review	Ongoing oversight of general/commercial releases, focused on verifying the findings of the risk assessment and risk management conditions
Risk	Potential for harm from an activity

Risk analysis	Overall process of risk assessment, risk management and risk communication
Risk assessment	Process of risk identification, risk characterisation and risk evaluation
Risk characterisation	Process to comprehend the nature of risk in terms of consequences and likelihood.
Risk communication	Continual and iterative process to provide, share or obtain information and to engage in dialogue with stakeholders regarding the analysis of risk
Risk context	Parameters to be taken into account when analyzing risk, including the scope and risk criteria
Risk identification	Process of finding, recognizing and describing risks
Risk management	Processes to control and mitigate risk
Risk management plan	Scheme for managing risk posed by the environmental release of a GE plant
Risk scenario	A set of conditions or circumstances that may occur and result in harm from a risk source. A risk scenario describes a credible causal pathway through which activities with a GE plant could lead to harm due to exposure to a changed attribute of the GE plant or of its products or to the introduced genetic material
Risk source	Element which alone or in combination has the intrinsic potential to give rise to risk. The risk source relates to changed attributes of the GE plant or of its products that are due to modern biotechnology
Stakeholders	Those people and organisations that may affect, be affected by or perceive themselves to be affected by a decision, activity or risk
States	Includes all State Governments within India

CONTENTS

Chapter 1

INTRODUCTION

1.1 Background

The Government of India has recognised the potential for modern biotechnology to contribute to society and has acknowledged the concerns of stakeholders over development and deployment of this technology. In India, the manufacture, import, research and release of genetically modified organisms (GMOs), as well as products made by the use of such organisms are governed by rules notified by the Ministry of Environment, Forest and Climate Change (MoEF&CC), on December 5, 1989, under the Environment (Protection) Act 1986[1]. The Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms, Genetically Engineered Organisms or Cells, commonly referred to as "Rules 1989,"[2] cover the areas of research, including confined field trials (CFTs) as well as large-scale applications of genetically engineered organisms (GEOs) and products made from GEOs, throughout India. The regulatory agencies responsible for implementation of the Rules 1989 are MoEF&CC, the Department of Biotechnology (DBT) and State Governments, through six competent authorities:

- Recombinant DNA Advisory Committee (RDAC)
- Institutional Biosafety Committees (IBSC)
- Review Committee on Genetic Manipulation (RCGM)
- Genetic Engineering Approval Committee (GEAC)
- State Biotechnology Coordination Committees (SBCCs)
- District Level Committees (DLCs)

This *Risk Analysis Framework* provides guidance about the approach used by these Regulatory Agencies in applying risk analysis. It is the primary risk analysis reference for regulatory staff and may also be useful to a range of stakeholders including:

- developers of genetically engineered GE plants
- government agencies involved in regulating GE plants
- experts who provide advice to the Regulatory Agencies regarding GE plants
- regulators of GE plants from other international jurisdictions
- individuals and groups interested in the regulation of GE plants in India

[1] The Environment (Protection) Act 1986 is available at http://envfor.nic.in/legis/env/env1.html.

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

The Government of India will review this document from time to time as experience, scientific consensus and regulatory practice evolve.

1.2 Purpose of the Risk Analysis Framework

Within the context of the laws, regulations and policies of India, the purpose of this *Risk Analysis Framework* is to:

- provide guidance on the current rationale and approach to risk analysis
- enable a consistent and rigorous risk analysis approach to evaluating applications for environmental releases of GE plants
- provide transparency on the use of risk analysis to support decision making

The *Risk Analysis Framework* seeks to:

- describe the Indian legislative context for risk analysis (this Chapter)
- describe the Regulatory Agencies' approach to risk analysis, which is based on national and international standards and guidance, including the Cartagena Protocol on Biosafety (Chapter 2)
- outline the approach the Regulatory Agencies use when preparing risk assessments and risk management plans in response to an application to authorize the environmental release of a GE plant (Chapters 3 to 5)
- discuss the Regulatory Agencies approach to risk communication (Chapter 6)

1.3 Identifying and Managing Risks

Risk assessment is a science-driven process that includes identifying hazards, assessing their magnitude and duration and estimating their likelihood of occurrence. In the context of GE plants, environmental risk can be defined as the probability that some valued environmental resource (including human and animal health) will be adversely affected by exposure to a hazard caused by a GE plant. As it is commonly expressed, risk is a function of the nature and severity of the hazard as well as the extent to which the environmental resource will be exposed to the hazard:

$$\text{Risk} = (\text{hazard} \bullet \text{exposure})$$

Processes other than modern biotechnology may give rise to organisms with the same or similar novel trait. For instance, wheat with improved water use efficiency (that is, increased drought tolerance) could also be generated by chemical or radiation mutagenesis, wide crosses or by conventional breeding practices.

Similarly alterations in virulence or pathogenicity of a microorganism can occur by chemical or radiation mutagenesis or natural recombination. Experience with organisms that have similar traits generated without use of modern biotechnology provides useful information for considering potential risks from a GE plant.

Where possible, risks are identified using a comparative risk assessment, such that risk from a GE plant is evaluated relative to the risk posed by the non-GE variety of the plant[3]. The focus of the assessment is whether traits modified by modern biotechnology increase the level of risk or give rise to additional risks. For instance, a parent organism may already have weedy or pathogenic characteristics; these characteristics form part of the baseline against which risk is identified.

Risk can be managed by imposing conditions that place controls and limits on certain activities with the GE plant. For example, conditions might be imposed to restrict (1) spread and persistence of the GE plant, its progeny or the introduced genes or (2) exposure of people and the environment to the GE plant or its products.

1.4 Protection Goals – The Health and Safety of People and the Environment

The objective of India's approach to the regulation of GE plants is to protect the health and safety of people and the environment. Therefore, risks are identified in relation to the potential for harm to the health and safety of people or to the environment. Assessment of risk to the health and safety of people includes consideration of the occupational health and safety of people working with a GE plant, as well as the general public who may come into contact with the GE plant or material derived from the GE plant. Assessment of risk to the environment includes consideration of effects on both the biotic and abiotic components of the environment and their interactions leading to ecological services such as soil development and nutrient cycling. The risk depends on the effects of the genetic modification and the exposure of people and the environment to the GE plant. In particular, the potential for increased toxicity, allergenicity, disease or injury as a result of the possible production of a novel product or by altered production of an endogenous product is evaluated.

[3] Comparators may also be called "parental organisms" or "near-isogenic varieties."

Chapter 2

RISK ANALYSIS APPROACH USED IN INDIA

This chapter describes the risk analysis approach used in India and the national and international sources that informed the development of this approach.

2.1 Models of Risk Analysis

A number of international organisations and treaties provide standards and guidance for risk analysis in the specific areas of animal, plant and human health risks. The first comprehensive guidance on risk analysis of GE plants was published by the Organisation for Economic Co-operation and Development (OECD 1986; Bergmans 2006), based on the approach presented in a 1983 report from the US Academy of Sciences National Research Council (Jardine *et al.* 2003; National Research Council 1983; National Research Council 2008). The World Organisation for Animal Health (OIE 2004), the Food and Agriculture Organization of the United Nations (FAO/WHO 2005) and the Codex Alimentarius Commission (Codex Alimentarius Commission 2003) have also published risk analysis guidelines. Annex III of the United Nations Cartagena Protocol on Biosafety (Secretariat of the Convention on Biological Diversity 2000), to which India is a signatory, also provides guidance for risk assessments of GE plants.

2.2 India's Risk Analysis Method

The risk analysis method used for the environmental release of a GE plant is outlined in Figure 2.1. As illustrated, the process is not necessarily linear as there are steps where information flows in both directions, such as between risk assessment and risk management and between risk communication and stakeholders.

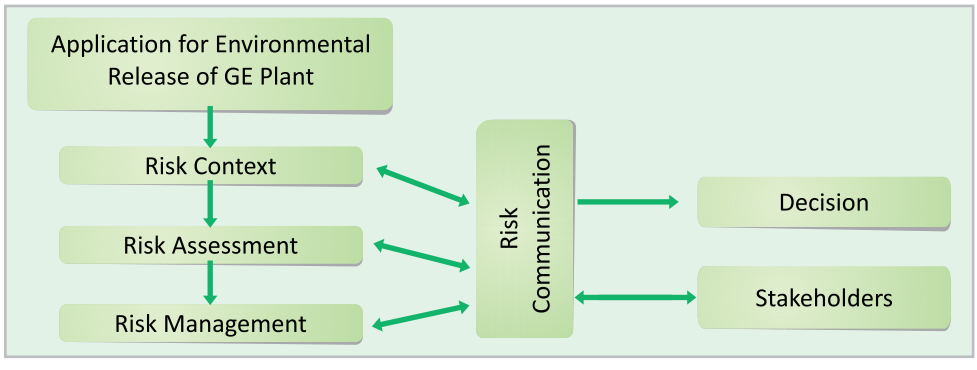


Figure 2.1: Risk analysis method for the environmental release of a GE plant

2.3 Components of Risk Analysis

2.3.1 Risk Context

Establishing the risk context (see Chapter 3) is the preparatory step that defines the scope and boundaries, sets the criteria against which risk will be evaluated and describes the structures and processes for the analysis. This includes setting criteria for what is considered to be damage or injury to people or the environment.

Decisions on applications for the environmental release of a GE plant require case-by-case assessment and details of the GE plant and the proposed activities, including any proposed controls, limits or containment measures, form the specific risk context. Details of the parent organism and the environment where activities with the GE plant will occur form the comparative baselines.

2.3.2 Risk Assessment

Risk assessment (see Chapter 4) is a structured, reasoned approach to consider the potential for harm from certain activities with a GE plant, based on scientific/technical evidence. Identifying and characterising risk relies on scientific/technical evidence, involving consultation with experts and other stakeholders. The aim is to identify, characterize and evaluate risks to the health and safety of people or to the environment from GE plants. The risk assessment initially considers a wide range of potential pathways whereby harm might occur. Those pathways that identify substantive risks are considered in more detail by characterising how serious the harm could be (consequences) and how likely it is that harm could occur. The level of risk is then evaluated to determine whether the risk is acceptable or not.

2.3.3 Risk Management

Risk management (see Chapter 5) may be described as answering the following question: what can be done to mitigate any unacceptable risks identified during the risk assessment? Risk management measures are elaborated in a risk management plan that includes any conditions the regulators have imposed to control or reduce risk. Monitoring may be included to validate the original decisions based on plausible hypothesis and to adjust risk management measures to account for changes in circumstances or new information. The risk management plan helps the Regulatory Agencies decide whether to authorize an environmental release and what conditions to impose, if any. If the Regulatory Agencies conclude that risks cannot be sufficiently mitigated to protect human health and safety and the environment, the environmental release of the GE plant should not be authorized.

2.3.4 Risk Communication

Risk communication (see Chapter 6) engages in dialogue about the risks to human health and the environment posed by GE plants. Risk communication is integral to the processes of risk assessment and risk management. It involves an interactive dialogue between the Regulatory Agencies and stakeholders to build trust in the Regulatory system by discussing issues and addressing concerns. The Regulatory Agencies undertake extensive consultation with a diverse range of expert groups and authorities and key stakeholders, including the public, before deciding whether to authorize the release of a GE plant into the environment. The Risk Analysis Framework is part of the Indian government's commitment to clarity, transparency and accountability for decision-making processes.

2.4 Guiding Principles of Risk Analysis

For risk analysis to be effective, a number of principles are followed to ensure the goals of the regulatory processes for GE plants are achieved. These are:

a) Risk analysis helps achieve the objectives of protecting the health and safety of people and the environment.

b) Risk analysis is not a stand-alone activity but integral to the whole regulatory process.

c) Risk analysis helps the regulator make informed choices, prioritize actions and distinguish among alternative courses of action.

d) Risk analysis is systematic, structured and timely, contributing to better efficiency and to consistent, comparable and reliable results.

e) Risk analysis is based on the best available information: scientific evidence, historical data, experience, stakeholder feedback, observation, forecasts and expert judgment.

f) Risk analysis is transparent, inclusive and up-to-date, allowing stakeholders to be properly represented and to have their views taken into account.

g) Risk analysis is dynamic, iterative and responsive to change.

h) Risk analysis facilitates continual improvement.

Chapter 3

RISK CONTEXT

This chapter describes the role of the context in risk analysis and how it is applied for the proposed environmental release of a GE plant.

Important parameters for establishing the risk context include the scope and boundaries; the criteria for determining harm, including its seriousness and likelihood; and the method for assessing, managing and communicating risk. Defining these parameters are key to identifying relevant risks, accurately assessing the level of risk and implementing suitable measures to manage risk in an efficient, efficacious and transparent manner.

3.1 Scope and Boundaries

The scope and boundaries for risk analysis of proposed environmental releases of GE plants are determined, in part, by the requirements of the laws of India as they relate to health and safety of people and/or to the environment. Certain issues, such as impacts on trade, social and cultural effects or food labelling, as well as benefits that may be derived from modern biotechnology, are outside the scope of the analysis.

3.2 Establishing Risk Criteria

The ERA Guidelines specify matters that the Regulatory Agencies must consider in preparing the risk assessment, including consideration of both the short- and long-term effects from the proposed environmental release of a GE plant in comparison to its non-GE counterpart. These matters include:

- properties of the parent organism
- effect of the genetic modification on the parent organism
- previous assessments
- potential of the GE plant to be harmful to humans and other organisms
- potential of the GE plant to adversely affect any ecosystem
- potential of the GE plant to transfer genetic material to another organism
- potential of the GE plant to spread or persist in the environment
- whether the GE plant may have a selective advantage in the environment
- whether the GE plant is toxic, allergenic or pathogenic to other organisms
- extent of scale of the proposed environmental release

- likely impacts of the proposed environmental release on the health and safety of people

These matters provide the basis for establishing risk criteria as part of the risk context, including:

- nature and types of consequences that may occur and how they will be measured
- how consequence is defined in the consequence assessment
- how likelihood is defined in the likelihood assessment
- how the level of risk is evaluated

3.3 Establishing Risk Consequence Criteria

Defining the nature of harm and the level of harm is the central element in establishing the risk consequence criteria. Consequence criteria are derived from the protection goals. International standards and national health and environmental legislation, can provide guidance on the values to be protected from harm. In risk assessment, the consequences are expressed in terms of potential harm to human health and safety and the environment.

Harm to the health and safety of people includes:

- toxicity or allergenicity
- disease
- illness or injury

Harm to the environment includes:

- toxicity to desirable (valued) organisms that should be protected
- loss of biodiversity including loss of species diversity or genetic diversity within a species
- adverse impacts of a new or more serious weed, pest or pathogen
- disruption of biotic communities
- degradation of the abiotic environment

Harm reflects an undesirable condition involving damage or injury. This includes change in the morphology, physiology, growth, development, reproduction or life span of an organism or group of organisms that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences.

The perception of harm can vary between people. It can also change over time and differ according to other factors such as variations in the vulnerability of individuals or type of land use. For example, a fast-growing plant would be considered desirable in the context of producing forage for livestock or biomass for biofuels

production, whereas the same plant may be considered harmful (weedy) in a nature conservation area, because it may displace a native species. In addition, one harmful outcome can sometimes give rise to further downstream harms. For example, increased harms from weeds, pests or pathogens can lead to loss of biodiversity.

The criteria for harm are used to establish the baseline for assessing risk for the parent organism, that is, the non-GE version of the plant (Table 3.1). The criteria also specify the types of changes due to genetic engineering that would be considered significant in terms of potential harm from the GE plant. Potential harm from genetic engineering may be associated with characteristics of the GE plants associated with the traits intentionally introduced into the GE plant or with unintended changes.

Table 3.1: Generic consequence assessment criteria for the degree of harm to the health and safety of people or the environment

Level of Harm	Health	Environment
Marginal	Ailment not requiring medical treatment	Minimal disruption to a biotic community that is reversible and limited in time and space
Minor	Minor illness/injury requiring medical treatment	Limited damage that is reversible and limited in time and space or in the numbers affected
Intermediate	Serious illness/injuries usually requiring hospitalisation; treatment is usually available; prevention may be available	Damage that is widespread but reversible or of minor severity
Major	Deaths or life-threatening illness/injuries; treatment or prevention is not usually available	Extensive damage to whole ecosystems, communities or entire species that persists over time

Notes: The criteria listed in this table are illustrative and will depend on the circumstances of the specific case. These may be used to establish baselines for parent organisms as well as to assess the potential harm (degree of change) due to modern biotechnology.

3.4 Risk Assessment Context

Establishing the risk assessment context includes consideration of the following:

- The parent organism – details of the comparator (e.g. origin and taxonomy, production and uses, biological characterisation, ecology)
- The GE plant – details of the genetic modification and resulting phenotype

- The receiving environment – baseline information (e.g., environmental conditions, production or work practices, presence of organisms that the GE plant can exchange DNA with through sexual reproduction, presence of similar genes)
- Previous releases – previous risk assessments or experience gained with a particular GE plant in the course of prior regulatory decisions in India or overseas

Information on the GE plant, including the nature of the genetic modification and any novel or altered phenotypic properties (intended or unintended), forms an essential part of the risk assessment context. This includes information on the following three components, when compared with the parent organisms, a near isogenic variety or another appropriate comparator:

1. Invasiveness : This is the ability of the GE plant to spread and persist in the environment. This includes properties that affect the ability to survive, establish, colonize, infect or parasitize, reproduce and disperse over long distances or between hosts.
2. Capacity for harm : This includes properties of the GE plant that may cause damage, toxicity, disease or injury to people or desirable components of the environment.
3. Capacity for gene transfer : This includes potential transfer of the introduced/ modified genetic material to sexually compatible relatives of a plant or animal.[4]

Selecting the appropriate comparator is generally straightforward. However, there may be rare exceptions.

The environment into which the GE plant is released is also relevant. For example, for a GE crop plant, the development of a baseline for the risk assessment would include consideration of information on current crop management practices applied to the non-GE plant; presence of related, sexually compatible species and the presence of relevant pests and diseases.

However, receiving environments are not static and change over time due to factors such as the dynamic nature of ecosystems, climate change or changes in agricultural practices and changes in land use. For example, normal agricultural practice for cotton prior to release of GE insecticidal cotton included intensive pesticide use with multiple applications per growing season. Subsequently, there has been a significant reduction in the amount of insecticides applied globally to the cotton crop after the introduction of insect-resistant cotton (Fitt 2008, Krishna and Qaim, 2012). Reduced chemical application has also led to reports of changes in

[4] Antibiotic resistance marker genes commonly used in the selection process for generating GE plants are derived from soil bacteria abundant in the environment. Therefore, exposure to an antibiotic resistance gene or to the protein encoded by such a gene, derived from a GE plant, may not be significant against the naturally occurring background.

the abundance of non-target insects in cotton-growing areas (Cattaneo *et al*. 2006; Romeis *et al*. 2008; Whitehouse *et al*. 2005). Such changes form part of the baseline considerations when developing the risk context for analysis of a specific application for environmental release.

3.5 Risk Management Context

Establishing the risk management context for consideration of an application for environmental release includes consideration of:

- Protection goals against which measures to manage risk are evaluated, including proposed controls or containment measures
- Decision-making processes to decide whether to issue an authorization for environmental release
- The types and nature of conditions, if any, that may be prescribed or imposed on the environmental release and monitoring those conditions

These factors are described in more detail in Chapter 5.

All organisms have intrinsic potential to cause harm to a varying degree. Management of risks inherent to the parent species provides an important context for managing risks of GE plant. The management requirements that typically apply to the parent species provide an important context for managing risk from the GE plant.

3.6 Risk Communication Context

The risk communication context provides details of who is consulted, when, in what capacity, on what matters and in what manner. Regulators can seek advice from appropriate people or organisations on a case by case basis.

Chapter 4

RISK ASSESSMENT

This chapter explains the risk assessment method that the Regulatory Agencies use to consider applications for the environmental release of GE plants. The purpose of the risk assessment is to identify and characterize risks to the health and safety of people or to the environment from the release of GE plants.

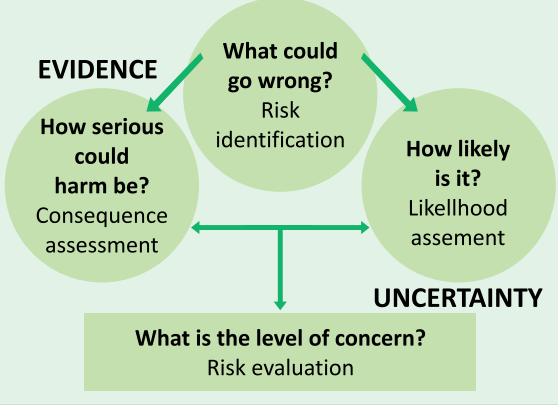
4.1 Methodology

Risk assessment can be viewed as a narrative that answers a set of key questions, namely:

- What could go wrong? (Risk identification) Initially, a broad range of circumstances is considered, whereby the proposed activities with a GE plant are postulated to give rise to harm to people or the environment (risk scenarios). Each risk scenario describes a plausible causal linkage between the GE plant and harm.
- How serious could the harm be? (Risk characterisation – consequence assessment) An identified risk is subjected to an assessment of the seriousness of potential harm via the particular risk scenario.
- How likely is the harm to occur? (Risk characterisation – likelihood assessment) An identified risk is also assessed with regard to the chance of the occurrence of a series of individual steps in a risk scenario that may lead to harm. The assessment will derive the chance of harm from the overall series of individual steps.
- What is the level of concern? (Risk evaluation) The level of risk is evaluated as negligible, low, moderate or high by considering a combination of the seriousness of harm and the likelihood of it occurring. Risk evaluation determines whether or not mitigation measures to reduce risk are required.

Scientific and technical information is used to answer the first three questions.

Figure 4.1: Considerations for risk assessment



In practice, the risk assessment process tends to be iterative and the steps depicted in Figure 4.1 can be viewed as part of a repeated cycle. The risk assessment steps may be repeated under the following situations:

- as a result of ongoing accumulation of information (such as data requested from the applicant, expert advice, consultation or literature searches)
- as a result of the development of more specific consequence criteria when substantive risks are identified and considered in more detail
- as a result of consideration of potential interactions between postulated risk scenarios or
- in response to the monitoring and review process (see Chapter 5).

For instance, consultation with stakeholders (see Chapter 6) on a risk assessment may identify additional risks or provide further information relevant to risk characterisation or evaluation of the level of an identified risk.

The degree of consideration given to each cycle of the process should correlate with the degree of risk; greater consideration should be given to risks that are potentially more substantial.

4.2 Risk Identification

Risk identification considers what could go wrong from activities with a GE plant. It is the 'process of finding, recognising and describing risk.' Risks are identified within the context established for the risk assessment (see Chapter 3), taking into account the proposed environmental releases of the GE plant, relevant baseline information on the non-GE comparator and the receiving environment.

4.2.1 Postulating Risk Scenarios

Initially, risk identification considers a wide range of circumstances where potential harm to people or the environment could be credibly linked to exposure to the GE plant.

A risk scenario can be viewed as a 'what if' statement that describes a possible set of circumstances that might give rise to harm in the future. It is a hypothesis constructed from three essential components (Figure 4.2).

1. A risk source. A new or altered property/trait of the GE plant
2. A potential harm to people or the environment
3. A plausible causal linkage between components 1 and 2

Figure 4.2: Components of risk scenario

However, the relevance or importance of a risk scenario will depend on the context. The effects of a novel GE trait need to be considered in the context of the whole organism. Also, the plausibility of a causal linkage to harm will depend on a broad range of external factors such as the availability of sexually compatible relatives, likely environmental conditions or the nature of nearby land use.

Many possible risk scenarios can be formulated, for instance, a risk scenario involving the transfer of a stress tolerance gene from a GE plant to a sexually compatible species resulting in an increase of the weediness of the recipient species. But only those risks that may be greater than negligible are considered in detail in the risk assessment and in the end, only a small fraction of the original risk scenarios will be considered substantive.

In addition, interactions between risk scenarios may give rise to synergistic, additive or antagonistic effects. For instance:

- synergism arises when the combined effects are greater than the sum of the individual effects
- additive effects may occur when different scenarios lead to the same adverse outcome, which could increase the negative impact
- antagonistic effects may occur when the introduced trait alters the characteristics of the organism in opposing ways.

The techniques available for developing a comprehensive set of risk scenarios range from checklists and brainstorming to targeted analysis, including previous agency experience, reported international experience, consultation, scenario analysis and inductive reasoning.

The type of information used to establish the risk assessment context includes the genotype and phenotype of the GE plant, the parent organism, the receiving environment and any relevant previous releases. Information on other factors might also be applicable to postulating risk scenarios, but not all will be relevant to all risk assessments or require the same degree of consideration. The factors include:

- altered biochemistry
- altered physiology
- unintended change in gene expression
- production of a substance that is toxic or allergenic to humans

- production of a substance that is toxic to other organisms
- survival and persistence at the release site
- survival and persistence outside the release site
- gene flow by sexual gene transfer
- expression of an introduced gene that may alter the infectivity or pathogenicity, host range, transmissibility, pathogen load or vector specificity of a disease agent
- interaction of introduced genes or products related to pathogenicity with other pathogens
- secondary effects (such as development of herbicide resistance in related species as a result of gene flow)
- altered production (such as farming) practices

4.2.2 Identifying Risks that require further characterisation

Risk identification should be comprehensive and rigorous; however, care should be taken to avoid over-emphasising 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 questions:

- Is the potential harm attributable to the use of modern biotechnology? Any harm not posed by or resulting from the use of modern biotechnology should not be considered.
- Is there a plausible and observable pathway linking the environmental release to the potential harm? In cases where no plausible or observable pathways link the proposed activities 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?

Risk identification aims to include all risks that may require risk mitigation or reduction. However, in the absence of extensive experience with impacts from a particular GE plant, identifying all substantive risks having a level of risk that is greater than negligible is based on predicting the chance and seriousness of harmful scenarios.

It is important to avoid underestimating or missing substantive risks. Therefore, the Regulatory Agencies take a cautious approach, postulating and considering an extensive list of potential risk scenarios. As a result, some identified potential risks can subsequently be classified as negligible risks after more detailed consequence and likelihood assessments.

4.3 Risk Characterisation

Risk characterisation determines the seriousness of harm (consequence assessment) and the chance of harm (likelihood assessment) from a GE plant. The likelihood and consequence assessments are based on inferences from the available scientific and technical information.

4.3.1 Quantitative and Qualitative Assessment

Likelihood and consequence assessments can be either quantitative (reporting risks numerically) or qualitative (reporting risks descriptively). For instance, likelihood can be expressed as a relative measure of either probability (from zero to one, where zero is an impossible outcome and one is a certain outcome) or as a frequency (the number of occurrences per unit of time). For qualitative assessments, likelihood is expressed in terms of highly likely, likely, unlikely and highly unlikely.

Quantitative risk assessment determines the conditional probabilities of risk and the associated statistical error (uncertainty). This type of analysis can be used where there is a history of accumulated information, such as with chemical and industrial manufacturing. Quantitative risk assessments are most useful for addressing narrowly defined risks with relatively simple pathways, leading to well-specified adverse outcomes.

Quantitative assessments use numerical values, which may be derived from:

- experimental data
- extrapolation from experimental studies on related systems
- historical data or
- inference from models used to describe the system and its interactions

By contrast, risk assessments of biological systems are often qualitative because the complex, dynamic and variable nature of such systems limits the degree of certainty that can be ascribed to our knowledge of them. There is often a degree of uncertainty about the mechanisms that may lead to an adverse outcome, making it difficult to quantify the probability of the adverse outcome occurring (van der Sluijs *et al.* 2005).

Qualitative assessments use relative descriptions of likelihood and consequences and can combine data derived from various sources, including quantitative data, if available. By using qualitative assessments, the maximum amount of information can be used in describing likelihood and consequence.

Use of qualitative or quantitative approaches depends on the amount, type and quality of available data; the complexity of the risk scenario under consideration; and the level of detail needed to make a decision. Some of the relative merits that distinguish the two approaches are listed in Table 4.1 (Hart 2001).

Table 4.1: Relative merits of qualitative and quantitative risk assessments

	Type of assessment	
	Qualitative	**Quantitative**
Strengths	• Flexible – can be applied when there are data gaps, properties of risk are unable to be analysed numerically, high complexity, limited resources or ethical constraints in obtaining the experimental data • Integrates a diverse range of analytical techniques • Allows assessors to make judgments that aid decision making despite data gaps and uncertainty • Useful where there is a lack of experience in observing adverse effects • Accessible to a wide range of stakeholders	• High objectivity • Typically repeatable and testable • Greater consistency between assessors • Compatible with statistical analysis
Weaknesses	• Subject to greater ambiguity, vagueness and under-specificity • Estimates are more subject to variation between assessors • More prone to heuristics and biases of inputs such as expert opinion • Validation is difficult	• Use of numbers can lead to overconfidence • More complex • No established criteria for interpreting the outputs • Difficult to communicate to stakeholders • Accuracy may be illusionary if effects are serious, but there is little direct evidence • Can give misleading results due to poor data, over-simplification or complexity • Some methods require more data

For GE plants, qualitative risk assessments are, in most instances, the most appropriate form because:

- there may be limited long-term experience with particular organisms and/or introduced genes/traits

- there is an absence of demonstrated harm
- potential harm relating to human health and safety and the environment is highly varied
- environmental effects manifest within highly complex systems that have many incompletely understood variables
- harm may occur in the long term through indirect routes, for example through interaction with impacts from climate change and is therefore difficult to quantify

Qualitative risk assessment for GE plants provides the most feasible mechanism to assess risk for the majority of cases, as there is insufficient data to apply quantitative methods. Models can be used to inform the process but are unable to approach the complexity of the systems involved or contribute definitive answers. The use of common language rather than numbers makes qualitative assessments more accessible for risk communication.

The weaknesses of qualitative assessments described in Table 4.1 can be controlled and minimized in several ways, including the use of different terms for the various levels of likelihood, consequences and risk to reduce ambiguity. Potential variations between assessors can be reduced through quality control measures such as internal and external review and sourcing of expert advice. Differing viewpoints, perspectives and biases can be reduced through stakeholder input via effective consultation. Validation of findings can be supported by the monitoring and review processes.

Nevertheless, there may be a need for testable and repeatable scientific evidence to support qualitative estimates of likelihood and consequences according to measurable, observable criteria of harm to human health and safety or to the environment. Depending on case by case, qualitative or quantitative or a mix of both types of data may be used.

4.3.2 Consequence assessment

Consequence is 'harm to protection goals from an activity' in particular, harm to people or to the environment. A consequence assessment determines the potential degree of seriousness of harm (see Table 4.2). The seriousness of harm is dependent on the scale at which impacts are considered. Harm to humans is usually 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.

The presence of vulnerable, including rare or endangered, individuals, populations, species, communities or ecosystems is also considered.

Assessing the seriousness of potential harm to people or to the environment may include consideration of:

- 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 occurrence 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) for which an impact may be discernible and the nature of that impact over time? Is it intermittent and/or repetitive, if so, how often? Will it disappear?

- Can the adverse impact be reversed and, if so, how long will this take?
- Is the exposed species rare or endangered?

Table 4.2 provides a descriptive scale for the seriousness of harm in relation to the health of people and in relation to the environment. The explanations are relatively simple so as to be applicable to the wide range of potential risks. The variety of potential risks may be affected by different factors (magnitude, scale, time, reversibility) that may contribute to the significance of adverse outcomes. For specific risks, these descriptors may be defined in more detail.

Table 4.2: Consequence assessment scale

Consequence assessment	**Degree of potential harm to the health of people and the environment due to modern biotechnology relative to the parent organism**
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 affected.
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.

In some cases, these qualitative descriptors may be supported by quantitative descriptors for certain harms. For example, the adverse impact of a GE plant to reduce the establishment of desirable vegetation would be considered marginal, if the GE plant does not affect the germination and seedling survival of desired plants (e.g., regenerating pasture, sown crops, planted trees, regenerating native vegetation); minor, if the GE plant stops the establishment of less than 10% of desired plants; intermediate, if the GE plant stops the establishment of between

10% and 50% of desired plants and major, if the GE plant stops the establishment of more than 50% of desired plants.

Desirable organisms or components of the environment that should be protected (or undesirable counterparts that should be controlled) may be determined by legislation, government policies, national and international guidance material or by widely accepted community norms.

4.3.3 Likelihood Assessment

The likelihood assessment determines the chance that harm will occur and is expressed as highly likely, likely, unlikely or highly unlikely (see Table 4.3). If 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.

Table 4.3: Likelihood assessment scale

	Likelihood of harm from modern biotechnology
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

Factors that are important in considering the likelihood of harm occurring are those related to plausible linkages between an activity with a GE plant and potential harm to people or susceptible entities in the environment from exposure to the GE plant, the introduced gene(s) or products of the introduced gene(s).

Identifying major steps in a causal pathway leading to harm is important for deriving an overall assessment of the chance that harm may occur. For example, a causal pathway leading to increased harm (e.g., weediness or pathogenicity) may involve many steps, including transfer of the introduced genetic material from the GE plant into a sexually compatible relative; survival and increased fitness of the recipient species; followed by spread and persistence of the recipient species, which then results in harm (e.g., reduced establishment of native plants in a protected area). If several 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 low probability steps. Alternatively, one step may have almost no chance of occurring (e.g., the co-occurrence of a sexually compatible relative is not expected due to incompatible climate requirements between the GE plant and its relative), resulting in a very low overall probability even if all other steps have a reasonable chance of occurring.

Assessing likelihood is more difficult for complex pathways. For instance, successful gene transfer from a GE plant to a sexually compatible relative through hybridization requires a large number of events to occur in sequence. However, occurrence of the gene transfer does not necessarily result in harm. Further steps are necessary,

including the ability of the hybrid plant to survive, replicate, display a selective advantage over the parent organism and give rise to some identifiable harm such as increased weediness. In such cases, the overall likelihood of an adverse outcome occurring will be substantially lower than the likelihood of any individual step.

In contrast, scenarios that outline a simpler route to a potentially adverse outcome, such as a gene product that is toxic to non-target organisms, usually allow more robust estimates of likelihood, particularly as there is often a direct correlation between the dose of toxin and the severity of the adverse outcome and the mechanism of action may have been experimentally verified.

4.3.4 Quality of Evidence

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:

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 is generated by the applicant. The risk assessors also use other sources of information such as peer-reviewed publications, research papers and other relevant documents on risk assessment of GE plants. The quality of data submitted with the application should be also equivalent to

[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

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 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,[6] 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.

[6] http://www.oecd.org/env/ehs/biotrack/consensusdocumentsfortheworkonharmonisationofregulatoryoversightinbiotechnologybiologyofcrops.htm

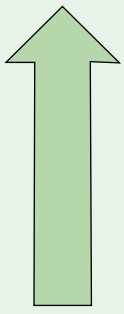
- **Professional experience of the risk assessors** – Risk assessors may and should draw on their own personal expertise and research experience, when appropriate. However, it is always important to hold such information to the same high standards for objectivity and scientific support, so that personal 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:

The 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
- 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.

Table 4.4: Reliability and relevance of various types of data used in risk assessments

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). Talbe 4.4 illustrates how the risk assessor may view the value of some different types of information in terms of reliability and relevance. Information may be ranked low in one criterion but high in the other. The overall value of the data for the risk assessment is open to the Regulator's judgment.

4.4 Risk Evaluation

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 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 (Table 4.5) 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. Risk matrices should generally keep the number of risk categories within the matrix to a minimum and the inherent sources of uncertainty associated with formulation of the risk matrix should be reduced (Cox 2008).

Table 4.5: Risk matrix used to estimate the level of risk

		LEVEL OF RISK			
LIKELIHOOD ASSESSMENT	Highly Unlikely	Low	Moderate	High	High
	Likely	Low	Low	Moderate	High
	Unlikely	Negligible	Low	Moderate	Moderate
	Highly unlikely	Negligible	Negligible	Low	Moderate
		Marginal	**Minor**	**Intermediate**	**Major**
		CONSEQUENCE ASSESSMENT			

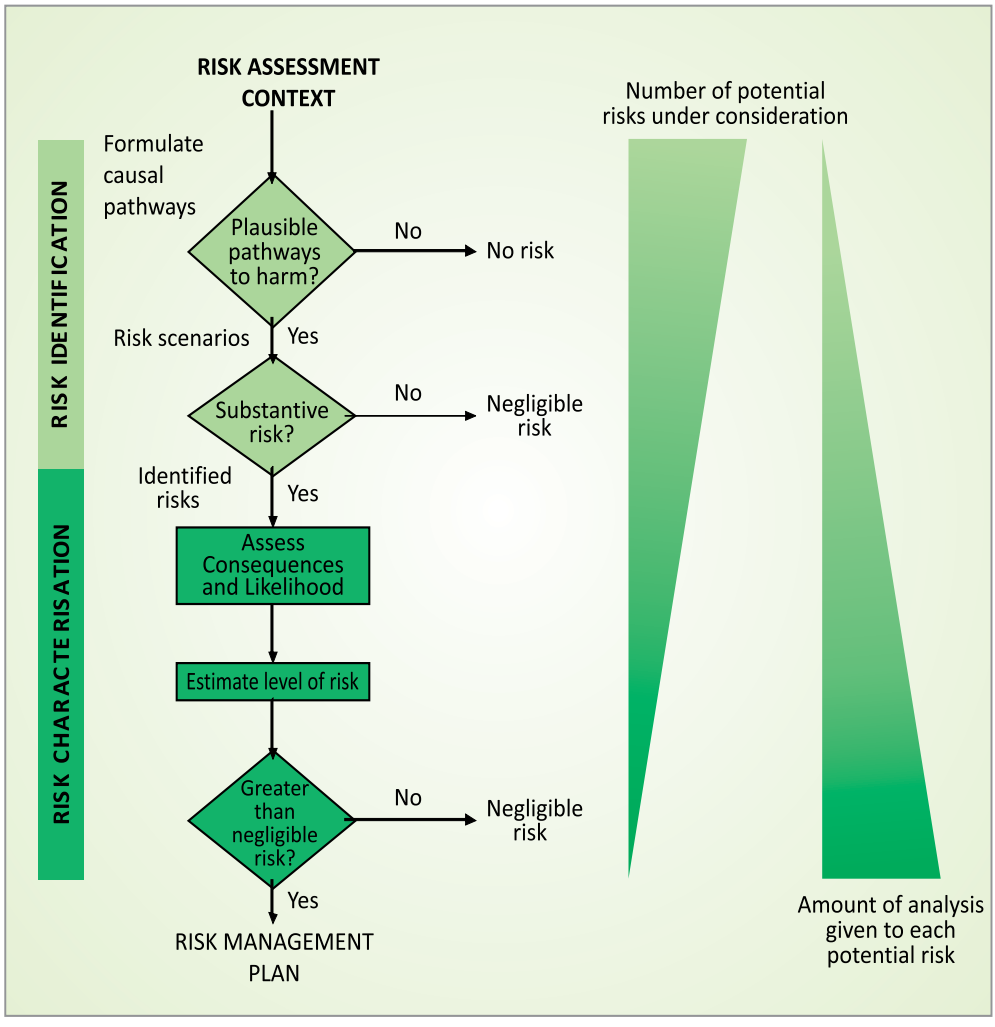
The regulator applies a set of distinct descriptors to the consequence assessment (Table 4.2), likelihood assessment (Table 4.3) and level of risk (Table 4.6) to reduce ambiguity of terminology used in qualitative risk assessments. Application of these descriptors to identified risks must be considered in the context of the proposed environmental release, including the introduced trait, the parent organism and the receiving environment.

Table 4.6: Risk levels scale

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.

Typically, the method used for preparing a risk assessment for an environmental release is an iterative process that places increasing focus on risks that are more substantive and usually require more information, more detailed characterisation and a closer examination of uncertainty (see Figure 4.3). Many potential risks are considered initially but most of these will be insubstantial. Therefore as the assessment process progresses, fewer risks will remain that require a more detailed assessment and even fewer risks that will warrant consideration for risk management.

Figure 4.3: Approach used for preparing a risk assessment for environmental releases



4.5 Significant Risk

After preparing the risk assessment the Regulatory Agencies consider whether the environmental release may pose a significant risk to the health and safety of people or to the environment. Although determination of significant risk is made on a case-by-case basis, it is expected that in most cases risk would be considered significant if the risk requires mitigation measures. These risks correspond to a level of risk that the regulator has estimated as either moderate or high. In some cases, risks that are estimated to be low, but evaluated as requiring risk management, may also be determined as significant. In contrast, risks that do not need mitigation (that is, negligible risks) would not be expected to be significant.

Chapter 5

RISK MANAGEMENT

The purpose of risk management is to protect the health and safety of people and to protect the environment by mitigating risk.

Risk management encompasses:

- preparing a risk management plan – includes general risk management measures and draft release conditions, if any
- monitoring and reviewing measures, if any, to assess the effectiveness of all steps in risk analysis, including post-release review of general/commercial releases of GE plants.

The risk assessment (see Chapter 4) and risk management plan inform the decision regarding whether to authorize an environmental release and what conditions, if any, are included.

5.1 Risk Management Plan

The risk management plan provides an answer to the question: "How any risks posed by an environmental release might be managed in such a way as to protect the health and safety of people and the environment?"

Preparation of a risk management plan may be informed by considering a number of general questions, including:

- What are the outcomes of the risk evaluation?
- What measures are available for managing risk?
- How effective have risk management measures been in the past?
- How feasible, practical or compatible are the risk management measures?
- Which treatment measure(s) provide the optimum and/or desired level of management for the proposed activity?

Consistent with the overarching objective of protection, the Regulatory Agencies prioritize preventative risk treatment measures over ameliorative or curative ones; that is, the risk treatment measures would be focused on preventing the risk being realized rather than on reducing or repairing the resultant harm.

The risk assessment includes consideration of the causal pathway(s) necessary for any given risk to be realized. This understanding of how the environmental release of a GE plant might result in harm and the nature of the harm provides valuable information for identifying risk treatment options. For example, knowledge of the causal pathway enables identification of points in the chain where treatment may be most easily and/or effectively applied.

In considering possible management conditions to mitigate moderate or high-risk estimates, it is important to establish if the harm or damage that might result could be reversed and to identify curative or ameliorative actions as well as preventative measures. For example, if a GE plant produced a protein toxic to humans it would be important to establish if a medical treatment existed to treat the toxicity. Such remedial measures should be included in contingency or emergency plans.

Redundancy in risk treatment options, for example by establishing measures that 'break' more than one link in a causal pathway, increase the effectiveness of risk management. In such cases, failure of a single risk treatment measure would not necessarily result in realisation of an adverse outcome. For example, a standard preventative condition in transporting GE seeds is double containment, often related to managing a risk of potential weediness. However, even if the double containment were breached and seed spilled, it would be unlikely that the weediness risk would be realized because clean-up measures would be invoked.

5.1.1 Selecting Risk Management Measures

When a risk is evaluated as requiring mitigation, options to reduce or avoid the risk are identified and assessed and selected management measures are implemented through release conditions. This includes consideration of options to reduce exposure to the GE plant or its products and to restrict opportunities for the spread and persistence of the GE plant, its progeny or the introduced genes.

The range of suitable controls and limits will depend on the nature of the:

- nature and properties of the organism
- trait (the characteristics of the GE plant conferred by modern biotechnology)
- properties, number and location of the introduced genes
- location of the release
- normal production and management practices
- controls and limits proposed by the applicant, if any

Once measures have been identified, they must be evaluated to ensure they will be effective and sufficient over time and space. Specifically, they must:

- be feasible to implement and able to operate effectively in practice
- meet currently accepted requirements for best practice (e.g., good agricultural practice, good laboratory practice, good clinical practice, good manufacturing practice)
- manage the risks to the level required for the duration of the activities and period of the release
- be able to be monitored.

The selection of risk management measures is made according to their efficacy, efficiency and practicality, commensurate with the level of risk. If risk treatment measures are selected for an identified risk, they should reduce risk sufficiently such that any residual risk does not compromise protection of the health and safety of people and the environment.

The most appropriate options available to manage the risk are then selected. It is possible to identify a number of options that may provide different levels of management of a specific risk. Equally, one management strategy may control a number of risks. The Regulatory Agencies must be satisfied that the risks will be managed by the draft options before the authorization can be issued.

Any identified uncertainty in aspects of the risk assessment or risk treatment measures must be addressed in determining the appropriate risk management. Uncertainty in risk estimates may be due to insufficient or conflicting data about the pathways to harm (e.g., due to climate change) or the likelihood or severity of potential adverse outcomes.

5.1.2 General Risk Management Measures

The risk management plan considers the adequacy and appropriateness of proposed measures to restrict the spread and persistence of the GE plant such that risks can be managed. Therefore, the risk management plan considers whether these measures will be sufficient to contain or restrict the spread and persistence of the GE plant. However, these measures are also considered in terms of suitability, necessity and the possibility of introducing additional risks.

The authorization should contain reporting provisions in case of unexpected events occurring or new information becoming available relating to the GE plant and the activities. The authorized party may be required to provide regular reports to the Regulatory Agencies and to report any relevant changes in circumstances, unintended effects, new risks or contravention of conditions. If new or increased risks associated with the environmental release are identified, the Regulatory Agencies may vary release conditions or if necessary, suspend or cancel the release authorization. Another important factor the Regulatory Agencies must consider

before authorizing an environmental release is whether the applicant will be able to effectively implement the conditions, if any, considered necessary to manage the risks associated with the environmental release.

In cases of non-compliance with conditions, the Regulatory Agencies may initiate an investigation to determine the nature and extent of non-compliance. If proven, a range of remedies are available under the Environment (Protection) Act, 1986 that include provisions for criminal sanctions or large fines and/or imprisonment for failing to abide by the legislation, conditions or directions, especially where significant damage to health and safety of people or the environment could result.

5.2 Monitor and Review

The purpose of monitoring and reviewing all steps in risk analysis is to ensure that each step is done correctly and the outcomes remain valid in the light of changes in the circumstances or new information. A number of both internal and external feedback mechanisms can be used to maintain the effectiveness and efficiency of risk assessment and risk management, while considering the concerns of all interested and affected stakeholders.

Monitoring and reviewing contribute to identifying situations where treatment measures are not adequately managing the risks, either as a result of control measures not maintaining the effectiveness of the limits imposed or non-compliance or because of changed circumstances and/or unexpected or unintended effects. Monitoring also facilitates ongoing review of the conclusions of risk assessment and of the risk treatment options. Identifying changed circumstances enables a reassessment of the risks posed by the activities and the treatment measures in the light of experience and for risk management to be modified where necessary. Such review activities may also provide important information for the risk assessment of subsequent release applications for the same or related GE plants.

5.3 Decision Making

The risk assessment (Chapter 4) and the risk management plan are essential components of decision making in relation to applications for the environmental release of GE plants.

The Regulatory Agencies are authorized to make decisions on activities with GE plants, which includes imposition of release conditions, if any. The Regulatory Agencies also have the power to suspend, cancel or modify the terms of release authorization. Each of these decisions is based on whether the Regulatory Agencies are satisfied that any risks posed by the release can be managed in such a way as to protect the health and safety of people and the environment.

Although the risk analysis framework described applies to the consideration of all applications for environmental release of GE plants, there is no one-size-fits-all solution. The Regulatory Agencies adopt a case-by-case approach, considering all relevant information and the availability of management measures, to arrive at a prudent judgment.

5.4 Monitoring for Compliance

The Regulatory Agencies possess extensive powers for monitoring compliance with the laws and regulations concerning GE plants. Where risks requiring management have been identified and treatment measures imposed through conditions or in guidelines, monitoring is necessary in order to verify that those treatment measures or obligations are being applied and that risks are being appropriately managed.

The laws and regulations stipulate, as a condition of every authorization, that the authorized party must allow persons authorized by the Regulatory Agencies to enter premises where a release is occurring for the purpose of monitoring or auditing.

Chapter 6

RISK COMMUNICATION

This chapter presents the main objectives of risk communication and the approach that the Regulatory Agencies take to fulfil these objectives. It also includes a discussion of some theoretical elements of risk communication and risk perception.

In practice, the Regulatory Agencies aim to:

- raise awareness of India's regulatory system for GE plants nationally and internationally
- undertake rigorous, scientifically based risk assessment and risk management of environmental releases of GE plants in an open and transparent manner
- communicate the reasoning behind regulatory decisions in an open and objective manner in clear language
- listen and respond, in a timely manner, to relevant concerns of stakeholders
- periodically review communication strategies and practices to ensure effective, appropriately targeted and efficient communication with stakeholders.

6.1 What is Risk Communication?

Risk communication is a continual and iterative process to provide, share or obtain information and to engage in dialogue with stakeholders regarding the analysis of risk.

Risk communication is a two-way process. The Regulatory Agencies recognize and accept that the community holds a wide range of views on modern biotechnology and considers all issues and concerns raised that are within the scope of their authorities.

The Regulatory Agencies exchange information and views with stakeholders and the general community about potential risks from modern biotechnology. Risk communication provides the Regulatory Agencies with access to the relevant factual information and analyses, as well as awareness of the needs, values and concerns of stakeholders. The Regulatory Agencies also communicate the reasons underpinning decisions based on risk assessment.

6.2 What are the Goals of Risk Communication?

Effective risk communication is central to effective risk analysis. The goals of risk communication relevant to regulation can be categorized as follows:

- **Engagement** – to involve internal and external stakeholders in the risk analysis

process through dialogue. Release of GE plants into the Indian environment is of interest to a wide spectrum of the community, including Central ,and State governments, local bodies, non-government organisations, community groups, scientists industry and individuals.

- **Informing** – to foster understanding of the risks amongst different constituencies (e.g., authorized parties and others from the regulated community, as well as researchers, farmers, health workers, industry, consumers, interest groups and the general community). The information can relate to the existence, nature, form, likelihood, significance, evaluation, control measures and monitoring of the risks, including the quality of the evidence, inherent uncertainty and compliance with environmental release conditions.
- **Building trust** – to promote trust and credibility in the ability of the Regulatory Agencies and the Indian government to effectively regulate modern biotechnology.

6.3 Risk Communication Processes

Risk communication processes consider the following questions.

- What are the objectives of the specific communication?
- Who will be involved?
- What is to be communicated?
- How will the information be communicated?
- How will consultation, if any, be conducted?

6.4 The Role of Risk Communication in the Risk Analysis Process

Risk communication is integral to all other steps in risk analysis (Figure 2.1), including the risk context, to ensure that the scope and boundaries are clearly elaborated, the criteria used to make decisions about risk are clearly defined, stakeholder interests are considered and feedback is provided.

When establishing the risk context, risk communication requires:

- identifying key stakeholders
- specifying the purpose of the process, information requirements and the means of meeting them
- specifying who is to be consulted and when and how the process will occur, including feedback and evaluation
- identifying information that may have restricted access for commercial or security reasons

Risk communication also supports the risk assessment and risk management processes. Risk assessment is supported by broad communication and consultation with stakeholders to avoid overlooking important risks. In addition, risk assessment includes the use of the risk matrix (Figure 4.5) to communicate the level of risk. Another important aspect is acknowledgement and analysis of uncertainty. This is particularly relevant for qualitative risk assessments conducted by the Regulatory Agencies, where clarity of the language can help to reduce the overall uncertainty.

The risk management plan provides the analysis and rationale for proposed controls or restrictions, which are communicated to the applicant and others through the release conditions. Release conditions should explicitly and clearly describe the obligations to the authorized party to ensure risk is managed effectively and consistently. In addition, consultation may be required during monitoring and review, including post-release review.

6.4.1 Engagement

Effective risk communication involves presenting the facts, communicating and explaining the facts, demonstrating that similar risks have been accepted in the past and bringing stakeholders on board as partners. Therefore, provision of information is not sufficient. Stakeholders views should be sought as they provide a valid input into risk assessment and risk management (Fiorino 1990).

Successful engagement depends upon providing suitable platforms and procedures for dialogue (Renn 2009). Processes for engagement range from simple surveys to forms of deliberative democracy, which provide the highest level of public involvement (McComas *et al*. 2009). Three broad categories of engagement are described in Table 6.1.

Table 6.1: Different levels of engagement

Mode of engagement	Basis for dialogue	Examples	Strengths	Weaknesses
Passive	Knowledge and expertise	• Notification of decisions • Surveys	• Efficient when non-controversial	• Processes tend to be opaque • Ineffective where there is controversy or significant uncertainty

Consultative	Experience and competence that is reliant on evidence	• Written comments on draft material • Workshops and meetings • Advisory bodies • Public hearings	• Allows input from a broad range of individuals and interest groups • Supports transparency of decision making • Supports more informed decisions where moderate conflict is present	• May favour formality and elitism • May poorly resolve high-intensity conflict
Participatory	World views and values	• Public discussion events • Deliberative democracy	• Useful for high-intensity conflict • Supports shared decision making	• Costly in time and resources • Difficult to achieve true represen-tativeness • Can be influenced by better organized interest groups • Does not necessarily lead to better decisions than simpler modes of communication

The Regulatory Agencies can establish dialogue with stakeholders and the community through:

- consultation with stakeholders and the community on risk assessments and risk management plans prepared for the proposed environmental releases of a GE plant

- communication with applicants on data requirements and with authorized parties on implementation of any release conditions
- requests for advice or submissions from experts and interested parties on specific guidance documents
- communication with other regulatory bodies, academics, industry representatives, risk analysts and interest groups at public meetings, workshops and conferences on risk assessment and regulation of GE plants
- communication with government policy groups
- involvement in specific focus group meetings, workshops and collaborations (e.g., IBSCs, consensus documents produced by the OECD Working Group on Harmonisation of Regulatory Oversight of Biotechnology)
- exchange of information with regulatory agencies and experts from other countries on approaches to risk analysis and regulation of GE plants

6.4.2 Informing

One of the functions of the Regulatory Agencies is to provide information to the public about the regulation of GE plants.

Informing serves several purposes, including:

- increasing community awareness of the technology and of the regulatory scheme
- clarifying obligations and requirements of stakeholders such as applicants, authorized parties and Institutional Biosafety Committees (IBSCs)
- assisting coordination of different government agencies with a role in the regulation of GE plants or GE products
- informing the Regulatory Agencies of stakeholder perceptions of risks relating to GE plants
- informing the community of decisions and the reasons for those decisions
- maintaining links with international organisations and agencies associated with the regulation of GE plants

However, many factors influence the effectiveness of information transmission. Some of these include:

- the degree of concern or conflict present
- the social and cultural background of the transmitter and receiver
- demographic variation such as gender, age, education, income and personal circumstances
- uncertainty of the meaning of words, models and other descriptive forms
- psychological biases

- the complexity of the language and concepts in the message
- the timeliness in sending the message
- the appropriateness of the communication channel and its impact on the clarity of the message
- knowledge or understanding of the receiver
- the motivation, readiness and interest of the receiver to process the message

Many of these factors are characteristics of individual receivers. The Regulatory Agencies seek to maximize effective transmission of information by taking a structured, consistent approach to risk analysis and using consistent language when communicating about risk.

6.4.3 Building trust

Another important goal of risk communication is building trust, because effective regulation relies on trust. Regulation should be seen in both words and actions as even-handed and independent of any particular interest group. The Regulatory Agencies are neither proponents for, nor opponents of, modern biotechnology and GE plants, but impartial decision makers who are required to communicate to the Indian government and people on matters relating to the risk assessment and risk management of GE plants.

Trust is considered to involve the confident expectation of certain behaviours. These include (based on Covello 2009):

- **Competence** – having appropriate expertise, knowledge and experience and applying sound judgment
- **Integrity** – operating in a manner that is objective, fair, consistent and honest and with goodwill
- **Respect** – recognising and valuing individuality and differences and demonstrating listening, compassion, empathy and caring, particularly in a crisis.

Important factors intended to address trust in the regulation of GE plants include:

- **Governance** – primarily achieved by establishing a mandatory regulatory system.
- **Openness** – being accessible and available; encouraging listening, debate and deliberation of concerns; acknowledging errors and uncertainty; and showing capacity to learn.
- **Transparency** – providing insight and clarity into how regulation works in practice, including:

Loss of trust in the Regulatory Agencies and the Indian government diminishes the effectiveness of regulation. It may result in loss of confidence by the community,

reduced compliance with legislation or release conditions, reduced numbers of applications for environmental release and unnecessary delays in the adoption of useful agricultural technologies.

6.5 Risk Perception

The effectiveness of risk communication can be affected by how people understand or perceive risk. However, many different factors influence perception of risk (Slovic 1987). For example, perception of risk varies considerably between individuals, depending on each person's unique proximity and susceptibility to any given risk (Finkel 2008). Perception and understanding of risk can also be influenced by personal experiences, knowledge, beliefs, values and attitudes.

Understanding how risks may be perceived can be important in ensuring effective transmission and receipt of risk communication messages. It is not the goal of risk communication to change people's perceptions of risks, but it is possible that a transparent exchange of information may provide alternative perspectives for stakeholders to consider.

6.5.1 Risk Communication in Practice

The application process for the environmental release of a GE plant provides an opportunity for stakeholders and the public to have direct input into the decision making process. As mentioned above, the goals of risk communication are to **engage** stakeholders and the public, **inform** them as to what the risk assessment process is and how it will be done and to **build trust** by making the risk assessment process transparent. Effective risk communication is a multi-step process and it is both more effective and more likely to inspire trust in the regulatory process if the communication extends from the time the application is received to the issuance of the final decision.

Public consultations is not mandatory as per the Indian regulations under Rules, 1989. However , the regulatory agencies seek views from various stakeholders. The steps followed in this consultation process include the following:

- Information about submission of applications for environmental release of GE plants to the regulatory agencies is communicated through the minutes of the meetings
- A risk assessment and risk management plan (RARMP) for each application would be prepared by the regulatory agencies , The purpose of RARMP is to inform how the assessment was conducted; which risk hypotheses were identified and what data was collected to test the hypotheses; how significant risks were characterized; and which mitigation measures, if any,

were selected to manage identified risks.

- This document would be uploaded on the official website for receiving comments for a period of 30 days. Information about RARMP may also be published in the range of newspapers to facilitate the consultation process.
- After due consideration of the responses received, decision document summarizing how the data was considered by the regulators to support the decision will be placed on the official website

In addition to the submission of data relevant to the risk assessment, the public comment process will likely result in the submission of many questions and information (related to issues such as economics, food labelling, trade and personal preference) that are outside the scope of the risk assessment and the authority of the Regulatory Agencies. It is important not to ignore this information, even when it is not useful. The decision document should briefly summarize this information, so that the public feels its voice has been heard and indicate why this information was not relevant. By clearly articulating how the risk assessment was performed and how the risk hypotheses were tested using relevant data, the Regulatory Agencies can help educate the public regarding their role in the risk communication process.

6.5.2 Adapting Risk Communication to Changing Conditions

In an environment of rapidly changing forms of communication, the Indian government seeks to continually improve its risk communication processes. This involves monitoring submissions on consultation documents, reviewing the type and form of information made available to stakeholders and interested parties and improving collaboration and coordination with other government agencies on risk communication. Initiatives to adapt risk communication to changing circumstances include:

- using a variety of graphical tools and new electronic forms of transmitting information to communicate risk-based decisions and consultation processes (including making better use of existing tools, i.e. the government website)
- using modern web-based tools to enhance engagement with a broader range of people in the community
- increasing the use of clear language, including minimising scientific/technical jargon and complex bureaucratic language.

6.6 Conclusions

The Regulatory Agencies have committed to undertake a wide range of risk communication activities, exchanging information with stakeholders and the general community about modern biotechnology and the potential risks it may pose. To summarize:

- Risk communication is crucial to all aspects of risk analysis.
- Risk communication seeks to engage, inform and build trust with stakeholders and the community.
- Consultation with stakeholders, interest groups and the community is an important component for establishing engagement.
- The community varies considerably in their attitudes, interests, beliefs and risk biases, which requires matching with different types, amounts and channels of communication.

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