Strengthening Environmental Risk Assessment (ERA) in Indian Biosafety Regulations

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Indian Biosafety Regulatory Framework

- In India all GMOs and products thereof are regulated under Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/ Genetically Engineered Organisms or Cells, 1989 (Rules, 1989)” notified under the Environment (Protection) Act, 1986.

- Rules cover all types of GMOs and activities

- Rules implemented by the Ministry of Environment, Forest and Climate Change (MoEFCC) and the Department of Biotechnology (DBT) through six statutory committees;
  - The Recombinant DNA Advisory Committee (RDAC).
  - Institutional Biosafety Committee (IBSC)
  - Review Committee on Genetic Manipulation (RCGM)
  - Genetic Engineering Approval Committee (GEAC)
  - State Biotechnology Coordination Committee (SBCC)
  - District Level Committee (DLC)
Indian Biosafety Regulatory Framework

Rules are supported by guidelines issued by RCGM and GEAC from time to time

<table>
<thead>
<tr>
<th>Guidelines</th>
<th>Year</th>
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<tbody>
<tr>
<td>Recombinant DNA Safety Guidelines (focus on contained research)</td>
<td>1990</td>
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<tr>
<td>Research with transgenic plants</td>
<td>1998</td>
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<tr>
<td>Conduct of confined field trials</td>
<td>2008</td>
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<td>Food safety assessment</td>
<td>2008</td>
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<tr>
<td>Institutional Biosafety Committees (IBSC)</td>
<td>2011</td>
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<tr>
<td>Biosimilars</td>
<td>2012</td>
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<td></td>
<td>(Updated in 2016)</td>
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Background

- Environmental Risk Assessment (ERA) is a key step prior to commercial release of genetically engineered (GE) plants
- India is a signatory to the Cartagena Protocol on Biosafety (CPB) and Annex-3 provides guidance on Risk Assessment and Risk Management (RARM) of living modified organisms (LMOs)
- Guidance available so far in India further elaborated and structured to be at par with international practices through initiatives by MoEFCC under the Phase-II Capacity Building Project on Biosafety.
Process

- An Expert Committee under the Chairmanship of Prof. C.R. Babu and Prof. K. Veluthambi as the Co-Chair was constituted for preparation of ERA guidelines. The committee has members from relevant disciplines viz. agronomy, breeding, entomology, ecology etc.
- Process consisted of Problem Formulation Workshops, review of commitments under CPB and study on international practices.
- Eight meetings of the Expert Committee held over a period of two years.
- Draft guidance circulated to more than 100 experts and members of regulatory committees.
- Consultative workshop organized with regulators and scientists from public and private sector.
- The guidance finalized in May 2016 and adopted by GEAC in August 2016.
ERA guidance: Three documents

- Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016
- Environmental Risk Assessment of Genetically Engineered Plants: A Guide for Stakeholders
- Risk Analysis Framework, 2016

The three documents put together provides a practical elaboration of risk assessment framework included in the Indian regulations in conjunction with Annex-III of the Cartagena Protocol on Biosafety, to which India is a Party.
Objective: To ensure the safe development and use of plants resulting from modern biotechnology through the assessment of potentially adverse effects that these plants may have on humans, the environment and biological diversity.
SCOPE

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

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

These guidelines do not apply to

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

- Risk assessments should be carried out in a scientifically sound and transparent manner
- Risk assessment should be comparative
- Risk assessments should be carried out on a case-by-case basis, taking into account the specific circumstances or context for each individual application.
- The guidelines are based on problem formulation approach
Problem Formulation for ERA

- Problem formulation is a multi-step framework that provides the means to organize an environmental risk assessment so that the assessment is done in a logical and transparent way.

- It helps risk assessors decide what questions the assessment will address and what data are most relevant to those questions.

- In the end, problem formulation both facilitates the decision-making processes in risk assessment and clarifies for stakeholders how the decisions are made.
Problem Formulation is a 5 step process as below:

- **Identify the Protection Goal**: The purpose of an ERA for the commercial release of a GE plant is to determine whether the plant can be released while protecting valued environmental resources.

- **Derive the Operational Goal**: Broad Protection Goals can encompass a range of specific issues, but an environmental risk assessment must focus on more context-specific questions.

- **Determine the Assessment Endpoint**: Next, the risk assessors must determine one or more assessment endpoints appropriate to the Operational Goal.

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

- **Determine the Measurement Endpoints**: Once the Risk Hypothesis has been formulated, the assessors determine the types of data, whether qualitative or quantitative, that will enable them to test the Risk Hypothesis.
Data requirements for ERA

- Description of GE event
- Description of non-transgenic parental plants
- Description of donor organisms
- Description of methods and DNA sequences used in the genetic modification(s)
- Characterization of genetic modification(s)
- Phenotypic and agronomic characteristics of GE event(s)
- Cultivation practices of GE plants
- Potential adverse non-target effects or effects on biodiversity and ecosystems
Source of Data

Useful data will come from a variety of sources:

- Published scientific literature
- Applications submitted for confined field trial permits
- Past environmental risk assessments of GE plants with the same phenotype, including risk assessments from other countries; and
- Professional experience of the risk assessors
# Completing the Risk Assessment: Risk Evaluation Matrix

<table>
<thead>
<tr>
<th>EXPOSURE</th>
<th>Marginal</th>
<th>Minor</th>
<th>Intermediate</th>
<th>Major</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highly Unlikely</td>
<td>Negligible</td>
<td>Negligible</td>
<td>Low</td>
<td>Moderate</td>
</tr>
<tr>
<td>Unlikely</td>
<td>Negligible</td>
<td>Low</td>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td>Likely</td>
<td>Negligible</td>
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</tr>
</tbody>
</table>

**Risk Evaluation**

- Negligible
- Low
- Moderate
- High
Risk Assessment Process for GE Plants

1. Problem Formulation
   - Protection Goals
   - Risk Hypotheses
   - Relevant Data

2. Likelihood Assessment
3. Consequence Assessment

4. Is Risk Evaluation Complete?
   - NO
   - YES

5. Risk Evaluation
   - Negligible, Low, Medium, High
A post-release monitoring plan for the genetically engineered plant should be included in the application.

The objectives of post-release monitoring are to confirm the conclusions made in the risk assessment and to identify the occurrence of any unanticipated adverse effects.
ERA of GE Plants: A Guide for Stakeholders

- The Users’ Guide prepared to provide a better understanding on what risk assessment is about and how it is performed in the context of GE Plants
- Provides additional explanatory material, illustrative examples, and references to scientific literature.
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.
Risk Management and Risk Communication

- Risk management identifies and implements measures to ensure that risks are maintained within acceptable levels.
- Risk communication is the exchange of information, ideas and views between regulators and stakeholders and it conveys the rationale for regulatory decisions.
Summary and way forward

- ERA guidance provides a comprehensive, transparent, and science-based framework by which regulators can identify potential harms and collect relevant scientific data pertaining to level of risk posed by GE plants.
- The guidelines developed for planning and conducting an environmental risk assessment in support of the release of a GE plant in India for the purpose of cultivation.
- The guidelines supplement the CFT guidance and food safety guidance to ensure comprehensive safety assessment of new GE plants.
- Extensive training and capacity building required amongst scientists and regulators for effective implementation of principles outlined in the guidance.
Thank You !!!