INTRODUCTION TO ENVIRONMENTAL RISK ASSESSMENT

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Office of the Gene Technology Regulator

Environmental risk assessment of Transgenic Plants,
Brasilia, Brazil
16-17 August 2010
How dangerous are GMOs?
ENVIRONMENTAL RISK ASSESSMENT – Background

What is risk?

“Probability of occurrence of an adverse effect”

“Probabilidade de ocorrência de efeito adverso”

Normative Resolution #5 Article 6, VIII
ENVIRONMENTAL RISK ASSESSMENT – Background

What is a risk assessment?

“A combination of procedures or methods, by means of which it is assessed, case by case, the potential effects of the commercial release of the GMO and derivates on the environment and the human and animal health”

“combinação de procedimentos ou métodos, por meio dos quais se avaliam, caso a caso, os potenciais efeitos da liberação comercial do OGM e seus derivados sobre o ambiente e a saúde humana e animal”

Normative Resolution #5 Article 6, 1
ENVIRONMENTAL RISK ASSESSMENT – Background

Frameworks

INTERNATIONAL STANDARDS AND GUIDANCE DOCUMENTS

RISK ANALYSIS FRAMEWORK
www.ogtr.gov.au
ENVIRONMENTAL RISK ASSESSMENT – Framework

What is the problem?
Defining the problem / Planning

What could go wrong?
Risk identification

EVIDENCE

How serious could the harm be?
Consequence assessment

How likely is harm to occur?
Likelihood assessment

What is the level of risk?
Risk estimation

UNCERTAINTY

Should the risk be reduced?

Problem formulation
Risk characterisation
Risk evaluation
PROBLEM FORMULATION – Planning

General considerations

- LEGISLATIVE REQUIREMENTS – Scope and boundaries
- RISK CRITERIA
- RISK ASSESSMENT METHODOLOGY
PROBLEM FORMULATION – Planning

Specific considerations

PROPOSED DEALINGS
- Proposed activities with the GMO
- Proposed limits of the release
- Proposed control measures

GMO
- Introduced genes (genotype)
- Novel traits (phenotype)

PARENT ORGANISM
- Origin and taxonomy
- Cultivation and use
- Biological characterisation
- Ecology

RECEIVING ENVIRONMENT
- Environmental conditions
- Agronomic practices
- Sexually compatible relatives
- Presence of similar genes

PREVIOUS RELEASES
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Problem formulation
Risk characterisation
Risk evaluation
PROBLEM FORMULATION – Risk identification

- How might harm to the environment occur from activities with GMOs?
- Which risks need more detailed consideration?
RISK IDENTIFICATION – postulating risk pathways

Plausible risk pathway

Activity with GMO → Harm to the environment
EXAMPLE OF A RISK PATHWAY

Plausible risk pathway

Growing GM cotton containing Bt gene

Loss of GM seed during transport

Establishment of GM cotton near native cotton

Gene flow from GM to native cotton

Increased spread of native cotton

Harm: reduced establishment of desirable vegetation
RISK IDENTIFICATION – risks to consider further

- Is the risk pathway reasonable and observable?
- Is the potential harm attributable to GM?
- Is the possible level of risk greater than negligible?
- Is additional analysis likely to be useful?
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Risk characterisation

UNCERTAINTY

Risk evaluation
RISK CHARACTERISATION

- What are the **consequences** (severity of harm) ?
- What is the **likelihood** of harm ?
- What is the **level of risk** ?
EXAMPLE OF A RISK PATHWAY

Plausible risk pathway

Growing GM cotton containing Bt gene → Loss of GM seed during transport → Establishment of GM cotton near native cotton → Gene flow from GM to native cotton → Increased spread of native cotton → Harm: reduced establishment of desirable vegetation
## RISK CHARACTERISATION – Consequences assessment

| Provide details of the major components in the GMO(s) that may cause ill-health (eg toxicity, allergenicity, disease). |
| Provide details of the GMO(s) properties that may cause adverse effects for the occupational health and safety of people conducting the proposed dealing(s). |
| Provide details of the major components in the GMO(s) that may cause ill-health (eg toxicity, disease) in desirable organisms. |
| Provide details of the reduction in major desirable components in the GMO(s). |
| Could the GMO(s) reduce the establishment of desirable organisms? |
| Could the GMO(s) reduce the yield or quantity of desirable organisms? |
| Could the GMO(s) increase the establishment or quantity of undesirable organisms (ie weeds, pests, pathogens)? |
| Could the GMO(s) reduce the quality of services or products obtained from the receiving environment? |
| Could the GMO(s) reduce the quality of the abiotic environment? |
## RISK CHARACTERISATION – Consequences assessment

<table>
<thead>
<tr>
<th>Consequences</th>
<th>Consequence assessment definitions relating to the health of people and the environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marginal</td>
<td>Minimal adverse health effects.</td>
</tr>
<tr>
<td></td>
<td>Minimal or no damage to the environment or disruption to biological communities.</td>
</tr>
<tr>
<td>Minor</td>
<td>Adverse health effects that are reversible.</td>
</tr>
<tr>
<td></td>
<td>Damage to the environment or disruption to biological communities that is reversible and limited in time and space or numbers affected.</td>
</tr>
<tr>
<td>Intermediate</td>
<td>Adverse health effects that are irreversible.</td>
</tr>
<tr>
<td></td>
<td>Damage to the environment or disruption to biological communities that is widespread but reversible or of limited severity.</td>
</tr>
<tr>
<td>Major</td>
<td>Adverse health effects that are severe, widespread and irreversible.</td>
</tr>
<tr>
<td></td>
<td>Extensive damage to the environment or extensive biological and physical disruption of whole ecosystems, communities or an entire species that persists over time or is not readily reversible.</td>
</tr>
</tbody>
</table>
# RISK CHARACTERISATION – Likelihood assessment

## SPREAD AND PERSISTENCE OF THE GMO(S)

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the GMO(s) ability to establish existing organisms?</td>
<td></td>
</tr>
<tr>
<td>What is the reproductive ability of the GMO(s) in the potential receiving environment?</td>
<td></td>
</tr>
<tr>
<td>How likely is long distance spread by natural means?</td>
<td></td>
</tr>
<tr>
<td>How likely is long distance spread by people?</td>
<td></td>
</tr>
<tr>
<td>If the GMO(s) lives on other organisms how likely is spread between host organisms?</td>
<td></td>
</tr>
<tr>
<td>How effective are average measures to control the spread and persistence of the GMO(s)?</td>
<td></td>
</tr>
</tbody>
</table>

## SEXUAL GENE TRANSFER

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>How likely is gene transfer and introgression of the introduced genetic material to other organisms of the same species as the parental organism(s) by sexual reproduction?</td>
<td></td>
</tr>
<tr>
<td>How likely is gene transfer and introgression of the introduced genetic material to other organisms of other compatible species by sexual reproduction?</td>
<td></td>
</tr>
</tbody>
</table>
## RISK CHARACTERISATION

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Likelihood assessment definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highly unlikely</td>
<td>May occur only in very rare circumstances</td>
</tr>
<tr>
<td>Unlikely</td>
<td>Could occur in some circumstances</td>
</tr>
<tr>
<td>Likely</td>
<td>Could occur in many circumstances</td>
</tr>
<tr>
<td>Highly likely</td>
<td>Is expected to occur in most circumstances</td>
</tr>
</tbody>
</table>
RISK CHARACTERISATION – Estimating the level of risk

- Combining the likelihood and consequences from risk characterization into an overall description of risk
- Qualitative assessments may make use of a “risk matrix”

<table>
<thead>
<tr>
<th>LIKELIHOOD ASSESSMENT</th>
<th>HIGHLY LIKELY</th>
<th>LIKELY</th>
<th>UNLIKELY</th>
<th>HIGHLY UNLIKELY</th>
</tr>
</thead>
<tbody>
<tr>
<td>RISK ESTIMATE</td>
<td>LOW</td>
<td>MODERATE</td>
<td>HIGH</td>
<td>HIGH</td>
</tr>
<tr>
<td></td>
<td>LOW</td>
<td>LOW</td>
<td>MODERATE</td>
<td>HIGH</td>
</tr>
<tr>
<td></td>
<td>NEGREGIBLE</td>
<td>LOW</td>
<td>MODERATE</td>
<td>MODERATE</td>
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<table>
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<tr>
<th>CONSEQUENCE ASSESSMENT</th>
<th>MARGINAL</th>
<th>MINOR</th>
<th>INTERMEDIATE</th>
<th>MAJOR</th>
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ENVIRONMENTAL RISK ASSESSMENT – Framework

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RISK EVALUATION – Do risks require management?

CONSIDERATIONS

- Level of risk
- Feasibility of management
- Uncertainty
## RISK ESTIMATION

<table>
<thead>
<tr>
<th>Risk estimate</th>
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</thead>
<tbody>
<tr>
<td>Negligible</td>
<td>Risk is insubstantial and there is no present need to invoke actions for mitigation.</td>
</tr>
<tr>
<td>Low</td>
<td>Risk is minimal, but may invoke actions for mitigation beyond normal practices.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Risk is of marked concern that will necessitate actions for mitigation that need to be demonstrated as effective.</td>
</tr>
<tr>
<td>High</td>
<td>Risk is unacceptable unless actions for mitigation are highly feasible and effective.</td>
</tr>
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</table>
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Risk evaluation
EVIDENCE – Data quality

- Is it useful (do we need it)?
- Is it credible?
- Is it enough?
EVIDENCE

IS THE DATA RELEVANT?

2-D protein gel
EVIDENCE

Validated studies according to international protocols
Peer reviewed experimental data on parent organism, modified traits or ecology
Peer reviewed literature - strongly supported reports, models, theory
Commissioned research data
General biological principles
Other scientific reports, specialist literature, government reports
Unsubstantiated statements

IS THE DATA CREDIBLE?

INCREASING CREDIBILITY
Uncertainty is an intrinsic part of risk

- Present in all parts of a risk assessment
- There are several distinct types of uncertainty
UNCERTAINTY - risk

Risk – some definitions

- The effect of uncertainty on objectives – ISO 31000
- Probabilistic summary of unknowable future events - Finkel
- A concept to help understand and cope with the dangers and uncertainties of life - Slovic
UNCERTAINTY – Types of uncertainty

- Knowledge
- Variability
- Description
- Cognition

“When I use a word, ....it means just what I choose it to mean – neither more or less.”

Lewis Carroll
UNCERTAINTY – Traditional solutions

- Do more analysis
- Apply worst case scenarios
- Get more data
- Put in more controls

“We took safety precautions until we knew where the problem was.”  Bob Noble
UNCERTAINTY – Data gaps

‘Knowledge Paradox’

“Beware of what you wish for” Trad
UNCERTAINTY – Data gaps

RESOURCES TO REDUCE DATA GAPS

Large

Effort to reduce uncertainty

Small

Large

Small
UNCERTAINTY – Practical solutions

- Do a structured risk assessment
- Keep it simple

If your experiment needs statistics, then you ought to have done a better experiment.  
Ernest Rutherford
The level of risk: the really simple

Number of Google citations (millions)

- No risk
- Very low
- Extremely low
- Minimal
- Trivial
- Negligible
- Low
- Intermediate
- High
- Very high
- Extremely high
- Extreme
- Severe
- Catastrophic
ERA - Remaining considerations

- Communication and consultation
- Monitor and review
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