



Australian Government

Department of Health

Office of the Gene Technology Regulator

**MONITORING AND COMPLIANCE
RISK ANALYSIS PROTOCOL**
In accordance with the
Gene Technology Act 2000

April 2016

Monitoring and compliance activities are under continual improvement and will evolve as systems are assessed and validated. This working document is intended as a guide only. Readers of this document should also familiarise themselves with the gene technology legislation.

Monitoring and Compliance Risk Analysis Protocol

1. Introduction

The Office of the Gene Technology Regulator (OGTR) has been established within the Commonwealth Department of Health to provide administrative support to the Gene Technology Regulator in the performance of the Regulator's functions under the *Gene Technology Act 2000* (the Act).

The Act, which came into force on 21 June 2001, introduces a national scheme for the regulation of genetically modified organisms in Australia, in order to protect the health and safety of Australians and the Australian environment.

The Act provides a legislative basis for monitoring and enforcing conditions that relate to dealings with genetically modified organisms (GMO).

In relation to issues of risk, analyses may be carried out for:

- Suspected non-compliances;
- Incidents; and
- Issues of concern, in addition to those assessed in licence evaluation processes.

This protocol is designed to provide a general guidance and does not attempt to classify the levels of risk in a risk analysis. Rather it outlines the broad framework employed by the Monitoring and Compliance Section to undertake the risk assessment and inform any necessary risk management plans.

2. Overview of risk analysis processes in the Monitoring and Compliance Section

The risk analysis processes employed by the Monitoring and Compliance Section take into account, and link to the Risk Analysis and Risk Management Plans (RARMP) developed for licence applications approved by the Regulator.

When a dealing with a GMO has not been conducted in accordance with the Act, or a condition of a licence it is necessary to conduct a risk analysis to estimate what risks may be present as a result of that non-compliance.

Such analysis processes are carried out to specify the level of risk posed where a hazard to human health and/or the environment may exist due to a dealing with a GMO and to determine an appropriate means to mitigate the risks posed by the hazard.

Risk analysis of a suspected non-compliance may arise as a result of findings from monitoring conducted by the Monitoring and Compliance Section, namely

- Routine monitoring visits which are based on risk profiling and sampling of a range of dealings; and
- Unannounced 'spot checks' which are undertaken as a subset of the routine monitoring activities or as part of follow-up checks, reviews, audits or investigations.

Suspected non-compliances which are self-reported by the licence holder will also be the subject of a risk analysis.

3. Objective of risk analyses in the OGTR

The purpose of performing risk analysis is to assess any issue that may present a hazard to the health and safety of people and/or the environment. Where hazards are identified, each hazard must be assessed through a scientifically rigorous process. In the assessment process, the level of risk is quantified, which leads to the development of risk management strategies commensurate with the level of risk.

4. Conducting risk analyses

The basis for performing risk analyses is the Regulator's [*Risk Analysis Framework*](#). The framework describes the principles of risk analysis used by the Regulator to protect human health and safety and the environment in accordance with the Act. However, it is worth noting the following points:

- Risk has two dimensions, probability (likelihood) of an event and consequence (the impact of the event when it happens). These need to be considered both separately and together; and
- The process of ensuring that relevant bodies and organisations are informed of risk analysis processes and to ensure an appropriate understanding is achieved is termed 'risk communication'. In the case of Monitoring and Compliance risk analysis processes, risk communication is essential so that where dealings with GMOs have led to potential risks, those carrying out the dealing are adequately informed about what risks exist and how they are to be managed.

The *Risk Analysis Framework* is a key document for informing applicants, stakeholders and the public about the Regulator's approach to applying risk analysis. It explains why and how the Regulator undertakes risk analysis by:

- describing the Australian legislative context for risk analysis;
- describing the Regulator's approach to risk analysis, which is based on national and international standards and guidance outlining the methodology the Regulator uses when preparing a risk assessment and risk management plan in response to a GMO licence discussing the Regulator's approach to risk communication.
- The term risk analysis is used to encompass all components of risk; namely, risk assessment, risk management and risk communication (FAO & WHO 2006).

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| risk analysis = risk assessment + risk management + risk communication |
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Risk assessment identifies risks from plausible sets of circumstances that may result in harm to people or to the environment and estimating the level of risk on the basis of the seriousness and chance of harm. **Risk management** evaluates, selects and implements plans or actions to ensure risks are appropriately managed. **Risk communication** is the exchange of information, ideas and views between the Regulator and stakeholders; it also conveys the rationale for decisions made by the Regulator.

The methodology used for risk analysis is based on the Australian New Zealand Standard 4360:2004, *Risk Management* (Standards Australia 2004) (see Chapter 2).

Risk matrix to estimate the level of risk from a combination of outcomes of likelihood and consequence assessments

| | | RISK ESTIMATE | | | |
|-----------------------|-----------------|------------------------|------------|--------------|----------|
| LIKELIHOOD ASSESSMENT | Highly likely | 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 | | | |

Consequence assessment scale for the health of people and the environment

| Consequences | Consequence assessment definitions relating to the health of people and the environment |
|--------------|---|
| Marginal | Minimal adverse health effects. Minimal or no damage to the environment or disruption to biological communities. |
| Minor | Adverse health effects that are reversible. Damage to the environment or disruption to biological communities that is reversible and limited in time and space or numbers affected. |
| Intermediate | Adverse health effects that are irreversible. Damage to the environment or disruption to biological communities that is widespread but reversible or of limited severity. |
| Major | Adverse health effects that are severe, widespread and irreversible. 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. |

4.1 The context of the OGTR risk analysis processes

The Act requires the Regulator to prepare a risk assessment and risk management plan for all licence applications. In performing this function the Regulator is assisted by the evaluation staff of the OGTR. The Regulator and the OGTR, supporting the functions of the Regulator, utilise the Regulator’s Risk Analysis Framework in assessing the risks posed by GMOs and in determining the measures necessary to manage any risks. Generally, such measures are outlined in licences as conditions. The national scheme for the regulation of gene technology itself reflects a risk-based approach to the regulation of GMOs. The legislation describes different levels of approval or authorisation commensurate with the level of risk posed by different types of dealings with GMOs.

4.2 The linkages between functional areas of the OGTR in risk analysis processes

Evaluation staff assists the Regulator by processing and evaluating applications to deal with GMOs and by providing advice to the Regulator on appropriate means of managing the risks associated with any dealings with GMOs. Dealings vary in their inherent risk and evaluations are performed to determine whether a dealing is able to proceed, depending on that risk. If a dealing is to proceed, a licence is issued which applies an appropriate strategy to manage the risks, which the applicant must demonstrate it can meet. It is the responsibility of the Monitoring and Compliance Section to perform monitoring activities of licence holders dealing with GMOs to determine whether there is compliance with relevant licence conditions and the Act. Each application for licence is considered on a case-by-case basis and is subject to a full risk analysis by the Regulator with assistance from evaluation staff. As each of the risks assessed in the process have a management strategy commensurate with that risk to mitigate its potential effect, any later contravention of licence conditions identified by the Monitoring and Compliance Section has at least been addressed, to a degree, within the evaluation process. Therefore, a risk analysis carried out by the Monitoring and Compliance Section on a suspected non-compliance with licence conditions, is informed by the prior risk analysis performed in the evaluation phase.

4.3 The Monitoring and Compliance risk analysis process

Risk analysis processes may take into account the findings from monitoring activities defined in the Act, including:

- Interviews with the representatives of the licence holder or other personnel on the licence holder's premises;
- Quantitative and qualitative observation of the GM trial site;
- Independent measurements, e.g. of buffer zones, calculation of isolation distances, identification of closely related weeds/species within GM trial sites and isolation zones, calibration of waste disposal mechanisms, readings of air pressure in contained facilities; and
- Records of findings, eg. photographic images, video, audio recording, and sketches, obtaining copies of relevant records, or samples taken for testing.

In identifying hazards relating to GMOs, the Monitoring and Compliance Section, will look specifically at:

- Hazards to human health and safety, taking into account effects on:
 - persons undertaking the dealings from an occupational health and safety aspect;
 - the general public, should the GMO be unintentionally, accidentally or deliberately released into the environment; and
 - the targeted group/s of population for which the GMO is intended; and
- Hazards to the environment, taking into account direct and indirect effects on the receiving environment including:
 - flora and fauna;
 - habitat;
 - biodiversity; and
 - soil, air and water.

Once the risk analysis has been completed, a risk management strategy commensurate with the level of risk posed by the GMO will be implemented. Where necessary, the Monitoring and Compliance Section will consult with and take advice from the Gene Technology Technical Advisory Committee on aspects of the assessment and management of risks.

5. Reporting outcomes of risk analyses to relevant parties

All risk analyses will be documented and reported to the Director, Monitoring and Compliance Section, the Director, Evaluation Section and, where relevant, the Regulator. Where an issue stems from the actions of a licence holder the Director, Monitoring and Compliance Section or the Regulator, will communicate to the licence holder the nature of the non-compliance or issue of risk. The licence holder will be informed of the risk management strategy to address the risk.

Where there is no preclusion to do so (such as limitations on release of information that may be subject to formal investigation), the findings of all risk analyses will be included, in summary, in the Regulator's Annual report. Where issues of risk are identified that lead to investigations, the summarised findings and outcomes of the investigation will be released upon the investigation's completion in the relevant annual report.