



Australian Government

**Department of Health and Ageing
Office of the Gene Technology Regulator**

REVIEW PROTOCOL
In accordance with the
Gene Technology Act 2000

July 2007

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

Review Protocol

1. Introduction

The Office of the Gene Technology Regulator has been established within the Commonwealth Department of Health and Ageing to provide administrative support to the Gene Technology Regulator (the Regulator) in the performance of her 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 auditing dealings involving genetically modified organisms (GMOs). This legislative capacity is used in conjunction with experience gained under the voluntary system to achieve a comprehensive approach to monitoring and compliance strategies.

2. Background

Under the previous administrative arrangements for regulation of GMOs, licence holders releasing GMOs into the environment were advised by Genetic Manipulation Advisory Committee (GMAC) on the biosafety aspects (being risks to the environment and/or risks to human health and safety) associated with each particular release.

Compliance with these conditions was voluntary and initially the system relied largely on the proponents checking compliance and self-reporting of any breach of GMAC recommendations and, to a lesser extent, non-compliance reports made by third parties.

The enactment of the Act on 21 June 2001 provided the legislative basis for the regulation of GMOs in Australia and provided wide reaching powers to OGTR Inspectors. OGTR Inspectors are appointed by the Regulator and have powers relevant to monitoring, auditing and investigation of dealings with GMOs. To assist in these activities, a Review system has been developed to assess operational and compliance issues that arise.

3. Overview of Reviews

Reviews are focused examinations that are based on observations made by OGTR monitoring teams and/or information provided by organisations in their reporting to the OGTR. There are two types of Reviews:

1. *Incident Reviews*: These reviews are initiated when an organisation reports, or an OGTR monitoring team identifies, a particular incident that is suspected to be non-compliant with the Act and associated legislation. Incident Reviews are undertaken by both monitoring personnel and compliance and investigation personnel.
2. *Practice Reviews*: are reviews relating to monitoring to determine if licence conditions can be, and are being, effectively implemented in practice and the identification of the occurrence of adverse effects of a GMO that may not be appropriately managed. Practice Reviews are answering the question of whether the theoretical assumptions of a risk assessment and risk

management plan are happening in practice. Practice Reviews are overseen by monitoring personnel with appropriate scientific background.

Further detail is set out below.

4. Incident Reviews

If an incident is notified to the OGTR by an organisation, or if one is identified by a monitoring team, an Incident Review is initiated as soon as possible. An example of an incident may be a spill of microorganisms within a contained facility. The review involves an assessment to determine whether:

1. the incident has resulted in risk to public health or the environment; and
2. there has been a non-compliance with the Act and needs to be referred for investigation.

The primary focus of an Incident Review is to determine whether an incident has presented potential public health or environmental risks that require risk management actions to be implemented. Remedial action may be required to reduce potential risk or to bring a situation back into compliance with legislative requirements.

Risk analysis

In assessing the risks associated with a particular incident, the events that led to the incident and pathways where the GMO may be exposed to the environment in uncontrolled situations are identified. The hazards are then elucidated and the likelihood of the hazard occurring and consequences if it did, are determined. Risk management action may be proposed to:

- immediately remedy situations to prevent potential risks;
- prevent similar situations occurring in the future; and
- inform future OGTR monitoring activities.

Non-compliance

In assessing whether a non-compliance has occurred and whether referral for investigation is required, the following criteria is used:

1. Quality and reliability of information;
2. Strength of technical provisions in licences/guidelines;
3. Nature of the offence provisions within the Act; and
4. Types of compliance strategies available.

Non-compliance issues identified during an Incident Review may be referred to the OGTR Compliance team for investigation. Depending on the seriousness of the non-compliance, a decision may be made to terminate the review process before it is completed so that an investigation can be conducted. This is to ensure that the integrity of the investigation and the admissibility of evidence is protected. It is important to note that an Incident Review is not an investigation but an assessment of an incident or situation that has arisen.

Where matters of non-compliance are investigated as offences against the Act, a brief of evidence may be provided to the Commonwealth Director of Public Prosecutions (DPP). Prosecution decisions are under the direction of the Commonwealth DPP.

In all cases where non-compliance with the Act or with specific licence conditions is demonstrated, the OGTR will report the matter in the OGTR quarterly report. Incidents resulting in a serious risk to the health and safety of people and the environment will be notified through media channels immediately.

5. Practice Reviews

These are operational appraisals initiated on the basis of a potential need to check the theoretical risk assessments conducted by the OGTR or follow-up on indications that there are potential adverse effects associated with GMOs. A Practice Review assesses whether risk assessment and risk management plans are achieving the required aims in a practical sense.

This type of review is not about detecting non-compliances. It is about reviewing practices and providing advice, improving management processes and providing feedback on theoretical risk assessment processes. The reviews analyse perceived or real situations to expand on the body of information for certain GMOs.

Specific monitoring targets in relation to field trials include gene dispersal, via pollen or seed, and the establishment of GMO populations beyond trial sites. As part of a Practice Review, monitoring activities may include surveying whole farms where trials have been, or are being, conducted or along roadsides which represent transport routes for the movement of GMO seed. For example, specific studies may be:

- Efficacy of volunteer management in crops sown to a site after a trial is completed;
- Gene flow to related relatives surrounding certain trial sites; and
- Likelihood of seed dormancy at the completion of the post-harvest monitoring period for certain sites.

Methodologies for in-field monitoring activities relating to a Practice Review take into account appropriate statistical methods. In deciding on survey procedures and monitoring design, statistical power analysis can assist. The power analysis of a survey approach indicates the probability of obtaining a statistically significant result and takes into account the error of not detecting a problem when there is one.

Practice Reviews can also include a paper based analysis and examination of organisations' compliance reports to detect trends over time. An analysis of these trends can assist in the management of the GMO and provide an indication of the need to undertake a wider review or commence a comprehensive audit.

In cases where a potential non-compliance is found and may need to be referred for investigation, the Practice Review is aborted and either an Incident Review or an investigation is initiated.