



Australian Government

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

**ACCREDITED ORGANISATIONS'
COMPLIANCE MANAGEMENT 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.

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 in the performance of her functions under the *Gene Technology Act 2000* (the Act).

The Act, which came into force on 21 June 2001, introduced 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 (GMOs). This legislative capacity is used in conjunction with experience gained under the interim compliance monitoring system to achieve a comprehensive approach to monitoring and compliance strategies.

In meeting these requirements accredited organisations increasingly rely on systematic approaches to managing licensed operational activities.

This information is designed to provide a general guidance on available systematic approaches to risk management and monitoring and reporting practices.

2. Background

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

Under those arrangements, there was no legislative capacity to enforce compliance with risk management plans, although the IOGTR worked cooperatively with licence holders of GM field trials to secure appropriate outcomes. The regulatory system for gene technology calls for strong compliance performance on the part of accredited organisations making the benchmarking of the best available approaches for risk management and monitoring and reporting an increasing priority.

The OGTR acknowledges that accredited organisations:

- Face significant confounding factors in achieving compliance; and
- Are adopting some of the elements of these best practice arrangements where they have seen a need for a preventative approach to risk management and monitoring.

Guidelines for Accreditation of Organisations Version 2 (OGTR June 2005) provide details for accredited organisations to understand and comply with the requirements of the regulatory system for gene technology. Organisations should familiarise themselves with these guidelines.

It should also be noted that the Act, and other Commonwealth legislation such as law on trade practices, corporations, tax and environment protection need to be read in conjunction with the Commonwealth Criminal Code.

3. Purpose of this Protocol

To provide guidance for accredited organisations on methods to achieve best practice, continual improvement and meeting compliance obligations in relation to risk management, monitoring and reporting.

4. Management elements

These arrangements are underpinned by the following contemporary management elements:

- *Effective compliance* – Recognising that minimum cost and minimum compliance approaches are risk-laden;
- *Best practice* – Being an industry leader in techniques for compliance and risk management and monitoring;
- *Continual improvement* – Reviewing and revising management and monitoring techniques to handle emerging confounding factors which exacerbate risk;
- *Appropriately timed/precautionary approach to procedures* – Approaches to risk management that allow margins for response to emerging risks or compounding factors in the risk management and monitoring arrangements; and
- *Scientific credibility of risk management and monitoring and reporting arrangements* – Application of the best available techniques/knowledge of how to manage risks and compounding factors.

5. Procedures

The following procedures can be applied to risk management and monitoring arrangements to assist accredited organisations to meet compliance requirements under the Act:

5.1 Management Arrangements

Management commitment to:

- Develop, and communicate throughout the organisation, an overarching risk management and monitoring policy binding all relevant management, staff and contractors;
- Identified responsibilities;
- Providing the resources;
- The applicability of the arrangements to all relevant managers, staff and contractors;
- New procedures that will emerge under the arrangements; and
- Implementation in the context of continual improvement and best practice; and
- An initial review on which to base the development and implementation of the arrangements.

5.2 Assessing needs and the scope of the arrangements

Identification of:

- Legal responsibilities under the Act and conditions of licence/accreditation/certification as they stand and as they are likely to evolve;
- Risks to human health and safety and to the environment from the dealing;
- Secondary risks arising from confounding factors including:

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- attitudes, commitment and understanding of staff or contractors (and the scope of the ‘change-management’ and awareness training to be included in the new arrangements);
 - environmental variables (i.e. built or natural environment) to be managed with appropriately precautionary arrangements;
 - risk-management resources; and
 - any lack of certainty in the efficacy of available risk management actions; about elements of the dealing; and requiring appropriately precautionary and prudently timed procedures and further research.

5.3 Development and implementation

- Identification, development and executive approval and implementation of organisational control mechanisms and procedures such as:
 - management plans;
 - provision of resources;
 - operational procedures;
 - emergency preparedness and response plans;
 - control documentation;
 - monitoring reports; and
 - procedures for the review of the arrangements.
- The setting of performance indicators and operational targets and assigning responsibilities and reporting mechanisms through the organisation structure;
- Identification, development and provision of training and change-management/awareness programs and manuals;
- Identification and development of competencies and responsibilities for inclusion in management, staff and contractor’s contracts;
- Retention and appropriate provision of records; and
- Internal procedures to address non-conformance to the arrangements and to specify and initiate corrective, educational and preventative actions.

5.4 Report, Review, Revise and Reward

- The routine review and revision of the approach, resources, state of knowledge and systems, including:
 - risk assessment(s);
 - organisation performance;
 - performance indicators and operational targets;
 - management plans;
 - adequacy of resources;
 - operational procedures;
 - emergency preparedness and response plans;
 - control documentation and monitoring reports;
 - training and awareness programs; and
 - efficacy of staff and contractor competencies and awareness, etc.
- Dissemination of principles, internal sharing of experiences, and performance outcomes through formal reports, new training and organisational newsletters etc;
- Awards for best practice outcomes or new solutions to problems; and
- Promotion of achievements, external sharing of knowledge and participation in industry awareness raising activities/forums, and marketing of expertise.

6. Key procedural principles

The following principles should underpin any management arrangements for meeting licence obligations under the Act.

6.1 Risk management principles

Actions to address confounding factors taken by the licence holder need to comprise timely, sufficient and effective monitoring and risk management arrangements that would cautiously deal with such factors through:

- Appropriately resourced and timed monitoring to identify hazards/risk;
- Immediate treatment of hazards/risks under prepared and scientifically credible contingency arrangements;
- Appropriately timed and effectively implemented follow-up assessments to identify the persistence of, or any new existence of hazards/risk; and
- Where necessary, implement any needed revised treatments and/or emergency contingency plans and reporting arrangements, to ensure that, every reasonable step to meet the object of the Act as expressed through the licence/accreditation/certification conditions is taken.

6.2 Monitoring and reporting principles

Detailed arrangements to prevent the dissemination of the GMO should include:

- Periodic monitoring and reporting on the state of containment and control of the GMO;
- Where possible, appropriately timed monitoring arrangements to account for the nature of the GMO and the environment/facilities in which it must be contained, so that emerging risks of dissemination or loss of control of the GMO are identified and managed before dissemination occurs;
- Monitoring information to be recorded and provided to the OGTR (where required or as part of adopted best practice) and to licence holder management and IBCs in a consistent manner so that periodic review can provide for prevention of emerging risks and improvements to long-term management practices or improvements to the state of knowledge of the GMO and/or the risks;
- Sufficient preparations for the management of an occurrence of a imminent risk or an actual dissemination or a loss of control of the GMO, by ensuring that such preventative treatments, emergency contingency arrangements and incident reporting procedures:
 - are scientifically credible;
 - are already in place;
 - are applied immediately;
 - are effective;
 - are periodically scientifically reviewed and then assessed by management to keep pace with the changing state of knowledge and the best practice; and
 - where judged necessary by the accredited organisation, ensure that the treatments of hazards err in favour of full control of the GMO as opposed to a concern for costs of the action.

6.3 Incident reporting principles

Where the monitoring and prevention steps fail and dissemination has occurred, immediate steps to control and contain the GMO should be taken. An incident report should be immediately forwarded to the Monitoring and Compliance Section of the OGTR. The incident report should outline:

- Immediate steps taken to remove the risk of dissemination of the GMO;

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- Changes in procedure to ensure the risk is not repeated;
 - A proposed implementation plan for any further follow-up actions; and
 - The name and 24-hour contact details of a representative who can respond to further requested actions from the OGTR.

Accredited organisations should use their own routine monitoring reports as a tool to evaluate and revise risk management effectiveness. The effectiveness of some risk management strategies and the basis for revising timing of prudent follow-up visits can be very evident in the inspection/monitoring records.

7. Conceptual origin

These arrangements can be developed using the ISO 9000 (Quality Assurance Systems) and ISO 14000 (Environment Management Systems) standards as a model. You may even apply for accreditation under these arrangements. For more information on these systems or accreditation, see the ISO Internet site:

<http://www.iso.ch/iso/en/ISOOnline.frontpage>

8. Costs

It is recognised that in some instances taking such approaches may mean increased up-front costs, but that they often yield cost-effectiveness benefits over time. The cost-effectiveness benefit of these arrangements is canvassed below under *Benefits*.

Costs can bear directly on the issue of the capacity of a licence holder to meet licence conditions and/or whether the required risk management is logistically or cost prohibitive for any entity to undertake. It might be necessary for the Gene Technology Regulator to reconsider whether a licenced dealing is beyond the capacity of a/any licence holder to undertake the dealing within the required risk management arrangements. Such considerations are provided for under the Act.

Organisations that consider that meeting responsibilities under the Act (and conditions of licence or accreditation or certification) has become cost prohibitive or logistically unfeasible should inform the OGTR immediately. It is expected that such organisations would do so before any risks of the GMO being disseminated could take effect, where they know or ought to know that this could be the case.

9. Benefits

A factor in any assessment by the Gene Technology Regulator of the capacity and effectiveness of organisations to comply with the Act, Regulations and licence/accreditation conditions would be the existence and effectiveness of the organisation's monitoring, reporting and management system.

What we are looking for is a systematic approach to performing, monitoring and documenting compliance practices consistent with Quality Assurance (QA) and Environment Management Systems (EMS). These approaches must be consistent with the objective of the Act.

A systematic approach for compliance, which is underpinned by continual improvement, allows for identification of the most efficient and effective available actions accredited organisations can take in terms of meeting responsibilities. A well-informed systematic approach can save time and money with its:

- Inherent efficiency and cost-effectiveness;
- The avoidance of penalties and costs associated with damage to environment and human safety;
- A structure for effective decision making; and
- Increases in social and market acceptability.