Australian Government

Department of Health and Ageing
Office of the Gene Technology Regulator

MONITORING 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.

Monitoring Protocol

1. Introduction

The Office of the Gene Technology Regulator (OGTR) 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 people and the Australian environment.

The Act provides a legislative basis for monitoring and enforcing conditions relating 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.

2. Background

Under the previous voluntary oversight for GMOs, approvals to undertake dealings with GMOs were issued by the Genetic Manipulation Advisory Committee (GMAC) based on an evaluation of biosafety issues (being risks to the environment and/or risks to human health and safety) associated with each particular GMO dealing.

As compliance with any conditions GMAC suggested was voluntary, the system relied largely on the organisation conducting the dealings to check compliance and self-report any breach of GMAC recommendations and, to a lesser extent, non-compliance reports made by third parties.

In the lead up to the introduction of the *Gene Technology Bill 2000,* the Interim Office of the Gene Technology Regulator (IOGTR) developed a monitoring system. However there was still no legislative capacity to enforce compliance with GMAC recommendations or to enforce compliance with risk management plans. The IOGTR therefore continued to work cooperatively with organisations conducting dealings with GMOs.

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, appointed by the Gene Technology Regulator, to monitor premises where dealings with GMOs are undertaken.

The Gene Technology Amendment Regulations 2006 commenced on 31 March 2007, which amend the Gene Technology Regulations 2001.

These amendments are the outcome of a review initiated by the Gene Technology Regulator in response to suggestions from regulated organisations, as well as the operational experience of the OGTR, regarding a number of provisions that might be improved. These changes reduce the regulatory burden of the regulations and streamline their operation, while maintaining the policy objectives of the regulatory system.

An independent review of the Act was completed in 2006 which introduced the Gene Technology Amendment Bill 2007 (the Bill) which commenced on 1 July 2007. Further amendments to the Gene Technology Amendment Regulations 2007 were required to facilitate these changes.

3. Overview of Monitoring

The Monitoring Protocols used by the OGTR under the legislative system are an enhanced version of the system developed under the previous voluntary system. The new system has been strengthened by legislation that allows the OGTR inspectors greater access to documents and premises to investigate issues arising from inspection activities. The OGTR also has the legislative capacity to enforce compliance with licence conditions or to enforce compliance with risk management strategies.

There are various types of monitoring activities undertaken by the OGTR. Monitoring inspections are primarily undertaken to determine whether there is compliance with the Act or the *Gene Technology Regulations*. Other activities undertaken by the monitoring personnel are:

- Provision of advice on the application of theoretical risk assessments in operational situations; and
- Gathering of information on possible adverse effects from the release of GMOs.

The various types of monitoring are:

- Routine monitoring inspections – these are based on risk profiling and sampling of a range of dealings, locations where dealings are undertaken, and organisations who are conducting dealings;
- Follow-up visits – these are undertaken to follow-up on issues or to check the implementation of remedial action;
- Review visits – monitoring of premises may be focused on a specific issue that is being reviewed by the Monitoring and Compliance Sections and visits selected on that basis;
- Audit visits – a comprehensive examination of an organisations activities that includes specific visits to inform the audit process;
- Investigation visits – these visits are based on inquiries into allegations of a breach of the Gene Technology Act 2000; and
- Unannounced ‘spot checks’ – these are undertaken as a subset of the routine monitoring activities or as part of follow-up checks, incident reviews, or investigations.

This Monitoring Protocol focuses on routine monitoring visits designed to determine whether the Act and the Regulations have been complied with.

Routine monitoring occurs at premises where dealings with a GMO are being undertaken. These premises are primarily:

- Field trial sites – located on government research stations, commercial or private properties; and
- Certified Facilities – physical containment (PC) facilities located at both government and private institutions, including hospitals and universities.

The routine monitoring activities under the legislative arrangements involve:

- Understanding the purpose of monitoring visits. Part 4 of this Protocol refers;
- Identifying when routine monitoring will occur. Part 5 refers;
- Identifying the number of premises to be monitored. Part 6 refers;
- Specifying the people to undertake the monitoring visits. Part 7 refers;

- Conducting the monitoring visits. Part 8 refers;
- Reporting on visits and implementing any necessary action. Part 9 refers;
- Conducting follow up visits when non-compliance is found. Part 10 refers; and
- Referring non-compliance issues for investigation. Part 11 refers.

4. Purpose of routine monitoring visits

The purpose of routine monitoring visits is primarily to find out whether the Act and the Regulations have been complied with. Secondary objectives of routine monitoring are to educate organisations and encourage compliant behaviour in a cooperative manner.

5. Identifying when routine monitoring will occur

In identifying when to undertake routine monitoring visits, premises are selected on the basis of a risk profile. In assembling a risk profile of premises, risks relating to the following are taken into account:

- The type of GMOs and their biology;
- The facilities and procedures of the organisations conducting work with GMOs; and
- Seasonal / geographical / ecological risk factors for both current and post-harvest field trial sites.

For example, the critical period for monitoring to occur in respect to GM field trials is when the field trial is at its 'higher risk' points (i.e. when there is an inherently higher risk to the health and safety of people and the environment). A licence condition in relation to a trial of GM Indian Mustard (*Brassica juncea*) may be the monitoring and removal of sexually-compatible plants in the month prior to flowering of the trial crop. Therefore, one crucial period for monitoring would be immediately before flowering occurred to allow a monitoring visit to ascertain whether sexually compatible plants had been removed from the trial site.

Key stages for genetically modified crop trials include planting, flowering, fruiting/seed production and harvesting. Post harvest monitoring occurs when the trial itself is complete but follow-up monitoring is required by the organisation to 'clean up' residual GMO material. Post harvest monitoring will also have crucial monitoring periods and these depend on the seasonal conditions and the biology of the organism.

6. Identifying the number of premises to be monitored

6.1 How many GM field trial sites will be monitored?

The OGTR will monitor a minimum of 20% of approved GM trial sites per year. As monitoring and reporting is structured on a quarterly basis, at least 5% of approved trial sites are monitored per quarter (3-month period). This involves monitoring 5% of all trial sites current at that time and 5% of trial sites subject to post-trial monitoring. This percentage may change over time, depending on the total numbers of field trial sites; however, as a minimum, 5% per quarter will be monitored.

6.2 How many contained facilities will be monitored?

The monitoring program for contained dealings involves inspecting Dealings Not involving Intentional Release (DNIRs) and the facilities that those dealings are conducted in, as well as monitoring a minimum of 20 percent of physical containment (PC) PC4, PC3 and PC2 large-scale facilities per year. These inspections focus on the integrity of the physical structure of the facility and on the general laboratory practices followed in that facility, including those practices followed for DNIRs and NLRDs. In addition, PC2 certified facilities will be monitored on a random basis.

7. Appropriately qualified people to undertake routine monitoring visits

Each routine monitoring visit will be undertaken by a minimum of two OGTR representatives. An OGTR inspector will lead the team and may be accompanied by another inspector, an OGTR authorised person (under section 64 of the Act).

8. Conducting monitoring visits

Under the legislative framework the OGTR has wide reaching monitoring powers that include the power to enter premises for the purpose of monitoring compliance of licence holders.

The Act allows the Gene Technology Regulator to appoint inspectors with a range of powers for monitoring compliance with the Act, the Regulations and licence conditions.

Under section 64 of the Act, where a person is authorised by a licence to deal with a GMO, it is a condition of the licence that the person must allow the Regulator or a person authorised by the Regulator to enter premises where the dealing is being undertaken for the purposes of auditing or monitoring the dealing.

Section 152 (1) of the Act allows inspectors to enter premises for the purpose of finding out whether the Act or the regulations have been complied with and to exercise the monitoring powers set out in section 153 of the Act.

Section 152 (2) of the Act states an inspector is not authorised to enter premises under subsection (1) unless:

- The occupier of the premises has consented to the entry; or
- The entry is made under a warrant under section 172 of the Act; or
- The occupier of the premises is a licence holder, or a person covered by a licence, and the entry is at a reasonable time.

8.1 The monitoring visit

Monitoring visits will be tailored to the licence conditions of the work being undertaken. The conduct of a routine monitoring visit will be within the bounds of the provisions of section 153 of the Act. For trial sites, a monitoring visit may involve:

- Interviews with the representatives of the licence holder or other personnel on the premise;
- Observation of activities, and the GM field trial site, for objective evidence of compliance;

- Independent measurement of buffer zones, calculation of isolation distances, identification of closely related weeds/species within a GM field trial site and isolation zones, and monitoring of waste disposal methods; and
- Recording of findings, by either taking photographic images, video, audio recording, and sketches, obtaining copies of relevant records, or taking samples for testing.

If an inspector identifies a non-compliance issue on site, the inspector may request the representative of the licence holder to immediately take any corrective action considered appropriate to ensure the site is brought back into compliance with the licence conditions and/or to ensure the safety of persons and the environment.

8.2 Consent of the licence holder or persons covered by a licence

Under the legislative system, the OGTR inspector does not need to contact the licence holder or persons covered by a licence prior to conducting a monitoring visit. However, in most cases, the OGTR will work cooperatively with licence holders to facilitate routine monitoring visits. This includes prior notice and arrangement of a mutually acceptable time to conduct the routine monitoring visit. In practical terms, the OGTR will give licence holders the opportunity to give consent for monitoring access. However, the licence holder may contravene a condition of their licence if consent is not given.

9. Reporting on the monitoring visits and implementing any necessary action

Where non-compliance with specific licence conditions is identified a risk assessment and compliance assessment will be conducted. This report will assess any risks to human health and safety or the environment presented by the non-compliance and determine what remedial action, if any, is required. The report will also determine what if any compliance action is required. The report may also recommend that investigation action be considered.

A separate report summarising the findings will be provided to the licence holder conducting the GMO dealing for comment on matters of fact.

The findings of all monitoring visits will be included in the Regulator's Quarterly Reports.

10. Conducting follow-up visits when non-compliance is found

Follow-up monitoring visits by the OGTR may occur to the premises of licence holders when non-compliance issues have been identified and appropriate corrective action has been directed (by notice under section 146 of the Act) or requested by the Regulator. Failure by licence holders to comply with the Regulator's directions will result in the escalation of compliance strategies that may include the imposition of penalties.

11. Referring issues for investigation

Issues arising from a monitoring inspection may be referred to the OGTR Compliance and Investigation's team for assessment and, if warranted, an investigation may be launched.

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, the regulations or with specific licence conditions is demonstrated, the OGTR will report the matter in the Regulator's Quarterly Report. Non-compliance resulting in a serious risk to the health and safety of people and / or the environment will be notified to local authorities and the public through media channels.