



Australian Government

Department of Health
Office of the Gene Technology Regulator

MONITORING PROTOCOL

In accordance with the
Gene Technology Act 2000

February 2015

Monitoring 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 (OGTR) has been established within the Commonwealth Department of Health 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

The enactment of the *Gene Technology Act 2000* 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.

3. Overview of Monitoring

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 2001* (the Regulations). Other activities undertaken by monitoring personnel are:

- Providing advice to organisations on appropriate procedures to maintain compliance;
- 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;
- 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.

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. 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), or another OGTR staff member such as a scientific advisor.

7. 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, who have 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 field trial sites, a monitoring visit may involve:

- Interviews with the representatives of the licence holder or other personnel at the field trial site;
- Observation of the GM field trial site and activities being undertaken there 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 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.

For contained dealings/certified facilities, a monitoring visit may involve:

- Interviews with the representatives of the licence holder/certification holder or other personnel on the premises;
- Observation of activities within the certified facility;
- Inspection of records of training, waste disposal and maintenance of the facility;
- Recording of findings, by taking photographic images, video, audio recording, and sketches, obtaining copies of relevant records, or taking samples for testing.

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 providing prior notice and arranging 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.

8. 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. The OGTR's Risk Assessment Framework is followed when assessing any risks to human health and safety or the environment presented by the non-compliance and when determining what remedial action, if any, is required. The matter will also be referred to the Compliance and Investigation Section for a compliance assessment.

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.

9. 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 recommended (through co-operative compliance) or directed (by notice under section 146 of the Act) or otherwise requested by the Regulator. Failure by licence holders to comply with the Regulator's directions will result in the escalation of compliance strategies.

10. Referring issues for investigation

Issues arising from a monitoring inspection will 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.