



Australian Government

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

AUDIT 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.

OGTR Audit 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 *Gene Technology Act 2000*, 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 to achieve a comprehensive approach to auditing 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 proponents checking compliance and self-reporting 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 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 audit dealings with GMOs.

3. Overview of the Auditing System

The auditing system used by the OGTR under the legislative system is 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 or premises for auditing purposes.

An Audit is a wide ranging examination of an organisation's procedures, records and other relevant information to find out whether improvements can be made to an organisation's compliance systems and/or to determine whether legislative requirements can be met.

An Audit may involve two aspects:

- A systematic paper based examination of relevant information, records and standard operating procedures; and/or
- Comprehensive on-site monitoring activities to inform the audit and to verify information, records and standard operating procedures.

The auditing activities involve:

- Defining the purpose and scope of an audit. Part 4 of this Protocol refers;
- Identifying when an audit will be undertaken. Part 5 refers;
- Identifying the relevant criteria to audit against. Part 6 refers;
- Establishing an audit team. Part 7 refers;
- Relationship between the audit team and the organisation. Part 8 refers;
- Conducting the audit. Part 9 refers;
- Conducting follow up visits. Part 10 refers; and
- Referring non-compliance issues for investigation. Part 11 refers.

4. Defining the purpose and scope of an audit

The purpose of an audit is to determine whether there are deficiencies in an organisations ability to meet legislative requirements and to suggest improvements to the organisation's system of operation. An audit is conducted to make recommendations on how future activities of an organisation can ensure improvements for controlling a GMO.

The scope of audit is defined on a case-by-case basis. The scope sets the extent and boundaries of the audit activity.

5. Identifying when an audit will be undertaken

In identifying when an audit will be undertaken, organisations are selected on the basis of a risk profile. In assembling a risk profile of an organisation, the following matters are taken into account:

- History of compliance of the organisation;
- Quality of reporting to the OGTR;
- System or management faults that the OGTR has been made aware of;
- Culture or attitude of the organisation; and
- Types of dealings being undertaken by the organisation.

An audit may be initiated as a result of an investigation into breaches of the Act. If, for example, a non-compliance is unsubstantiated in an investigation, an audit may be recommended to look at how future dealings by the organisation can ensure improvements in the control of a GMO.

6. Identifying relevant criteria to audit against

When undertaking an audit, various factors or criteria may be examined to meet the purpose of the audit. The criteria for an audit will be specified on a case-by-case basis as it varies with the type of dealing. However, in general, the criteria that will be audited against will include the following factors:

- Suitable Standard Operating Procedures (SOPs) designed to meet regulatory requirements;

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- Appropriately qualified and trained staff including the provision of training programs with a focus on regulatory requirements;
 - Appropriate allocation of resources dedicated to meeting regulatory obligations (personnel and equipment); and
 - Quality management systems to track and record activities relating to the regulatory requirements.

7. Establishing an audit team

In undertaking an audit, a team of appropriately qualified people will be assembled to ensure that the OGTR has access to a range of advice and views. The audit team will comprise a lead auditor who will, in nearly all cases, be an OGTR staff member. Other team members will be drawn from either within the OGTR or an external agency depending on the type of knowledge, skills and expertise needed to make up the auditing team.

Members of the audit team will be in a position to provide objective advice on improvements to an organisation's mode of operation in a way that is free from bias and conflict of interest.

All members of the audit team will be required to disclose any potential conflicts of interest. Where a potential conflict of interest is disclosed, the Regulator will weigh up whether the disclosed interest is likely to conflict with the proposed auditing activity, and a decision will be made as to whether or not the person should still be involved in the proposed auditing activity. All audit team members will sign a confidentiality agreement preventing disclosure of information, used or obtained in the auditing process, beyond its intended use.

8. Relationship between the audit team and the organisation

For the purposes of an audit, the OGTR will attempt to work cooperatively with organisations to facilitate the auditing process. A cordial approach to an audit ensures a high level of communication and permits the objectives of an audit to be more readily achieved. An organisation will be requested to provide information, records and SOPs to the audit team for the purposes of auditing the organisation.

An organisation may refuse to consent to an audit. Those organisations that are licence holders and refuse to consent to the entry into premises where dealings are being undertaken (under section 64 of the Act), entry being by authorised persons for the purposes of monitoring or auditing, may be in breach of their licence conditions.

9. Conducting the audit

9.1 Collection of background information

The audit team, under direction of the lead auditor, will review background documentation of an organisation in the lead up to commencing an audit. The background information will assist the audit team in preparing an audit plan including defining the scope and setting criteria to audit against.

At this stage, the organisation will be informed of the OGTR's intentions to audit the organisation. Various documents may be requested from the organisation to ensure appropriate background knowledge is obtained.

9.2 Development of audit plan

The audit team will prepare an audit plan. The plan will include the following elements:

- Objective and scope of the audit;
- Audit criteria;
- Major audit activities and timelines;
- Identification of audit team members and/or audit team members backgrounds;
- Confidentially requirements; and
- Information such as content and release of a final audit report.

The audit plan will be flexible so that the direction of the audit can be changed based on the information being gathered.

The audit plan will be provided to the organisation for comment and agreement. If there is any disagreement to the audit plan, the lead auditor will attempt to resolve any issues. The audit plan should be agreed with the organisation to ensure a cooperative approach is taken to the audit process. Where agreement can not be obtained the OGTR has an option of looking at other compliance strategies to address the possible issues.

9.3 Opening meeting with organisation

A meeting between the audit team and relevant staff from the organisation will be convened. The purpose of the meeting is to:

- Introduce the audit team;
- Confirm the agreed scope, audit plan and timetable for activities;
- Provide a summary of the methods and procedures used to conduct an audit (paper based review of records and/or on-site visits including interviews with workers);
- Confirm that the organisation is prepared to commit resources to facilitate the auditing activity;
- Establish lines of communication between the audit team and the organisation (the organisation should appoint an audit manager); and
- Promote the involvement of the organisation in the audit and the importance of cooperation in meeting the audit objectives.

9.4 Collection, examination and analysis of information, records and procedures for the audit

The audit team will collect information, records and procedural documents for the purposes of the audit from the organisation. The audit team members may also conduct interviews with workers and/or conduct site visits to view the operation of procedures and verify records. The information collected will be examined and analysed against the audit criteria.

9.5 Preliminary audit findings

After analysis of the information, preliminary findings will be documented along with supporting information that the findings are based on. The preliminary audit findings will be reviewed with the organisation to confirm factual information.

9.6 Closing meeting with organisation

At the completion of the audit, but before the audit report is prepared, a closing meeting between the audit team and the relevant organisation's representatives will be held. This meeting is to confirm the basis of the audit findings and to seek the organisation's agreement with the audit team's findings.

Disagreements are to be either resolved by the lead auditor or taken into account in the preparation of the final audit report. Final decisions on the findings of an audit rest with the lead auditor. The organisation may not necessarily agree with all findings of the audit team.

9.7 Preparation of the audit report

The audit report is prepared by the audit team under the supervision of the lead auditor. The content of the audit report includes the following:

- The name of the organisation, the objectives and the scope of the audit;
- Criteria for the audit and documents and materials used in the audit;
- Relevant dates covering the period of the audit;
- Identification of the audit team members;
- Findings and supporting evidence;
- Any obstacles or disagreements and reasons; and
- Audit conclusions and recommendations.

The draft audit report is provided to the organisation for comment on factual matters within the report. The organisation is also asked to specify elements of the report they believe to be confidential and not for public release. Reasons for the confidentiality will need to be specified by the organisation.

9.8 Finalisation of the audit report

The final report is prepared by the audit team. The lead auditor is responsible for the accuracy of the report. The report is signed and dated by the lead auditor.

The final report is provided to the organisation and to the Regulator. The Regulator determines whether, based on the supporting evidence, to accept the audit team's recommendations. The Regulator also makes a decision on whether information considered to be confidential by the organisation should be withheld in any report that is publicly released.

9.9 Preparation of implementation plan

The OGTR prepares an implementation plan for the accepted recommendations. The organisation is consulted and a timeline of activities to fulfil each recommendation is developed. The implementation plan is provided to the organisation for agreement and a commitment is sought from the organisation to undertake the specified action in the timelines indicated.

9.10 Distribution of the audit report and implementation plan

The final audit report and implementation plan will be publicly released via the OGTR website.

10. Conducting follow-up visits

Follow-up monitoring visits by the OGTR may occur on the premises of where dealings occur to check that any action recommended by the Regulator has been implemented as agreed in the implementation plan.

Failure by an organisation to not adequately justify or account for any non-action on their part may lead to an escalation of compliance strategies by the OGTR.

11. Referring non-compliance issues for investigation

Non-compliance issues identified by an audit team are referred to the OGTR Compliance and Investigations team for assessment and, if warranted, an investigation may be launched. Depending on the seriousness of the non-compliance, a decision may be made to abort the audit process so that an investigation can be conducted. It is important to note that an audit is not an investigation. The purpose of an audit is to find deficiencies in an organisation's system of operation and suggest improvements.

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. Non-compliance resulting in a serious risk to the health and safety of people and the environment will be notified through media channels immediately.