



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

**OGTR
COMPLIANCE AND ENFORCEMENT
POLICY**

July 2009

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.

Compliance and Enforcement Policy

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1. Introduction

This document sets out the policy framework the Office of the Gene Technology Regulator (OGTR) will use when dealing with possible contraventions of the legislation in accordance with criminal, civil and administrative provisions.

The purpose of this policy is to inform the public and regulated stakeholders of the factors that will be taken into account in determining appropriate responses to contraventions. This includes whether legal proceedings will be pursued pursuant to the *Gene Technology Act 2000* and related legislation under the national regulatory system for gene technology. The OGTR's approach and procedures for individual cases may vary where there are specific legislative requirements.

This policy sits within the broader Australian Government law enforcement policy context and should be read in conjunction with other relevant documents, including:

- *Prosecution Policy of the Commonwealth;*
- *Commonwealth Fraud Control Guidelines;*
- *Commonwealth Fraud Investigation Standards;* and
- Attorney-General's Department - Overarching Principles for Selecting Cases for Investigation and Administrative, Civil and Criminal Sanctions.

2. Objectives

The objectives of the OGTR's compliance and enforcement policy are that compliance and enforcement activities and arrangements:

- achieve the objectives of the national regulatory system for gene technology;
- detect, prevent and manage contraventions of the legislation and related risks to human health, safety and the environment; and
- maintain compliance with legislation:
 - through ongoing assessment of the compliance performance of regulated parties; and
 - where consistent with the above ongoing compliance assessment, apply a cooperative regulatory approach which builds effective compliance performance capacity by regulated parties.

3. The OGTR and the Public

In the course of implementing this policy, the OGTR will:

- administer and enforce its legislation in a coherent, consistent and objective manner;
- have relevant personnel available during normal office hours to assist with enquiries about legislation it administers;
- respond to requests for technical assistance and advice from applicants seeking information;
- provide the most accurate, up to date information available;

- respond in an appropriate manner and time in accordance with the OGTR's service charter;
- incorporate the Gene Technology Ethics and Community Consultative Committee *National Framework for the Development of Ethical Principles in Gene Technology* (available at www.ogtr.gov.au) as part of managing investigations, audits, practice reviews and monitoring;
 - handle all information in accordance with all relevant legislative obligations relating to security, including the Privacy Act 1988, the Freedom of Information Act 1982, the Commonwealth Fraud Control Guidelines, , and the Commonwealth Protective Security Manual; and
 - operate as efficiently, effectively and transparently as possible so as to be accountable to the Government and the community.

Final responsibility for compliance with the legislation, including ensuring the accuracy of all relevant information and advice, lies with the individual person or organisation.

4. Compliance and Enforcement Approach

To achieve its compliance and enforcement objectives, the OGTR uses a range of flexible and targeted measures to promote regulation.

Compliance measures such as a communication and education activities, timely provision of information and advice, persuasion, cooperative assistance and collaboration are designed to encourage stakeholders to abide by legislation.

Where non-compliances are detected, enforcement mechanisms may need to be used. The Office employs a range of responsive enforcement sanctions (Monitoring and Compliance Framework) that escalates in severity as the need arises. These sanctions rely on the deterrent effect such as suspension or cancellation of certifications, accreditation and or licence, injunctions, directives and criminal prosecution.

The OGTR recognises that both compliance and enforcement mechanisms are necessary to provide an effective and flexible regulatory system that enables the most appropriate response to be chosen for a given issue or incident.

Inspectors appointed under the legislation have powers to detect, prevent and manage contraventions of the legislation, related licences for dealings, and certification conditions for facilities. The following aspects of the findings by inspectors are taken into account as relevant to determining the compliance or otherwise of the activities of regulated stakeholders:

- the extent of risk to the health and safety of people and the environment;
- the severity of the issue or event involved in the finding;
- the culpability of the licence holder or other relevant persons in bringing about the issue or event e.g. whether there was a bona fide mistake involved;
- the types of mechanisms available to address the issue or event;
- the compliance history of the licence holder or other relevant persons;

- mitigating factors such as self-reporting or steps taken voluntarily by the licence holder to address the issue or event; and
- the need for deterrence.

After having regard to those matters, the OGTR has a range of options including additional investigation to determine if further action is warranted. This includes a recommendation of prosecution for an alleged breach of a licence condition or that a licence be suspended or cancelled.

The legislation also requires the Gene Technology Regulator to report each quarter to the Parliament of Australia on, amongst other things, contraventions under licences and the legislation.

The OGTR will regularly review its compliance and enforcement policy and procedures, and incorporate lessons learned back into the policy, procedures and the legislative process.

5. Detecting Contraventions

The OGTR assesses and manages compliance and detects contraventions of legislation through:

- regular and random *monitoring inspections*;
- a program of *practice reviews* and *audits* which apply investigation practices and performance audit techniques to identify and prevent contraventions of the legislation through cooperative capacity building of regulated stakeholders' compliance management arrangements;
- *assessment* of regulated-party annual reports and other information collected under the regulatory system;
- *third party reporting* (including a high degree of cooperative self-reporting of compliance issues by regulated parties);
- the contribution of *feedback towards continual improvement* of OGTR regulatory specifications and arrangements; and
- *investigations* which can draw on any of the above compliance management activities/data as information or as incorporated activity.

The OGTR recognises the importance of information provided to it by the general public and the importance of awareness and education campaigns. A facility to provide such information (including anonymously) is available on the OGTR website at www.ogtr.gov.au.

Where possible, strategic partnerships with other agencies are maintained to maximise cooperation where monitoring and compliance responsibilities overlap.

Further information about the Monitoring and Compliance Framework and Non-compliance protocols can be obtained from the Office's website at www.ogtr.gov.au, or by contacting the office on 1800 181 030.

6. Investigating Alleged or Suspected Contraventions

The OGTR investigates all reported or suspected contraventions of legislation it administers. This is undertaken by a preliminary examination and analysis of relevant facts and likely impacts in order to decide on the likelihood that a contravention has occurred or is about to occur, its seriousness and its likely consequences. Based on the outcome of this initial investigation and the relevant provisions of legislation, the OGTR determines the appropriate level, if any, of further investigation and response.

The OGTR investigations aim to:

- determine whether or not there has been a contravention of law;
- gather evidence which would be admissible in criminal prosecutions, or administrative or civil proceedings;
- satisfactorily prove or disprove allegations or achieve acceptable conclusions;
- deal appropriately with persons or organisations;
- improve controls for prevention of contraventions;
- deter others from further or similar action;
- maintain and improve public confidence in the integrity of the OGTR; and
- be completed within a reasonable time and at reasonable cost, in accordance with legislative requirements and the nature of the investigation.

The OGTR investigates serious contraventions to the point where enough information is available to determine whether a criminal prosecution should be pursued. Alternatively, options not involving criminal sanctions may also be considered depending on the facts and circumstances of the non-compliance.

In serious instances, the Regulator may refer the matter to and assist the Australian Federal Police or other enforcement agencies. During such investigations, the OGTR seeks to assist and conduct joint investigations with any investigating agencies on matters relating to administration of the Gene Technology Act and associated legislation.

7. Responding to Alleged or Suspected Contraventions

The OGTR employs a range of responses that escalate according to the severity of the contravention or if non-compliant activities continue. Generally, education and/or warnings are used in response to first and less serious contraventions; this ensures that relevant persons become aware of legislative requirements. For serious or continuing contraventions, deterrent sanctions are used that may include suspension or cancellation of certification, accreditation and or licence, injunctions, directives, and criminal prosecution.

7.1 Criteria for Determining Appropriate Responses

In determining appropriate responses to suspected contraventions of legislation the OGTR considers such factors as:

- objectives of the relevant legislation and the specific penalty provisions;

- seriousness of the harm caused by the alleged contravention, both to people and to the environment;
- the level of malice or culpability – was the contravention intentional, reckless, negligent, or a mistake;
- whether there is a history of prior contraventions;
- the cost to the Australian Government or general community of the contravention;
- the likelihood of the contravention continuing or being repeated;
- the prevalence of the type of contravention;
- the likely public perception of the breach and the manner with which it is dealt; and
- the most appropriate response to ensure an effective deterrent against continuing contravention or contravention by others.

Where legislation provides for both civil sanctions and criminal penalty provisions, the OGTR considers the most appropriate legal path based on the particular circumstances of the case. In determining the most appropriate course of action, consideration will be given to whether legal action is being pursued under other legislation or by another person or jurisdiction and whether there is any potential for multiple punishments for the same conduct.

7.2 Non-Criminal Sanctions

This option may be exercised with or without accompanying criminal sanctions but any decision in this regard will turn on matters such as the appropriateness of criminal proceedings having regard to matters such as the severity of the offence, the existence of prior breaches, and the necessity for deterrence. In some cases suspension of a licence may be seen as a sufficient sanction on its own.

In instances where neither criminal prosecution or suspension or cancellation of a licence is considered appropriate, the Regulator may request co-operative compliance by a licence holder to remedy a breach or, in certain circumstances, may direct compliance by written notice in accordance with directions powers within the Act. Failure to comply with such a direction is a criminal offence.

7.3 Criminal Action

Where the OGTR's investigations have produced sufficient evidence to prove a serious offence, criminal prosecution may be sought. A serious offence is one for which:

- there is a significant degree of criminality on the part of the offender; or
- previous administrative or civil responses to contraventions by the suspect have not resulted in compliance; and
- where the Australian Government or the community expects that a crime will be dealt with by prosecution conducted in public before a court and usually carries the risk of imprisonment in serious cases, and
- the crime produced significant real or potential harm to the Australian

Government or the community, including harm to people and the environment; or

- the crime is of such a nature or magnitude that is important to deter potential offenders and prosecution will act as a very effective deterrent.

The Commonwealth Director of Public Prosecutions (CDPP) has responsibility for the conduct of prosecutions for offences against Australian Government law. If the Regulator considers criminal prosecution to be the most appropriate course of action and sufficient evidence is gathered, a brief of evidence is prepared for submission to the CDPP. The OGTR also seeks assistance and advice from the CDPP about investigating serious offences, particularly in large and complex matters.

The final decision on whether or not a prosecution is to be instituted or continued rests with the CDPP. This decision is taken in accordance with the Prosecution Policy of the Commonwealth, the primary criterion being whether or not prosecution is in the public interest. In taking this decision, the CDPP takes into account the views expressed by the Regulator on the issue.

8. Media Inquiries into Matters under Investigation

All media inquiries will be dealt with in accordance with Departmental Media Guidelines and the Compliance and Investigations Procedures Manual.

In addition, staff will comply with the *Australian Government Investigations Standards* regarding information provided to the media concerning matters under investigation or that have been investigated. Procedural fairness and the presumption of innocence will be maintained.

Particularly, no comment will be made to the media that may:

- prejudice a person's right to a fair hearing or legal process;
- impinge upon the privacy or safety of others involved in the investigation (such as complainants, witnesses and suspects); or
- prejudice any past or future actions of the Office.

The Regulator may publicise a matter as part of the investigative or compliance process (for example, to seek information from potential witnesses). The details of an investigation remain confidential. The actual outcome of an investigation is publicly reported in the Gene Technology Regulator's quarterly report to the Parliament of Australia in accordance with Section 136A of the *Gene Technology Act 2000*.

9. Reports of Investigations

OGTR reports of investigations and reports from or to the Commonwealth Director of Public Prosecutions, the Australian Federal Police or any other enforcement agency remain strictly confidential and will be dealt with in accordance with broader Australian Government security provisions.

10. Australian Government Legislation

The Regulator administers the following Act and regulation:

- The *Gene Technology Act 2000*; and
- The Gene Technology Regulations 2001

Further information about the Monitoring and Compliance Framework and Non-compliance protocols can be obtained from the Office's website at www.ogtr.gov.au, or by contacting the office on 1800 181 030.

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