



Office of the
Gene Technology Regulator

**MONITORING AND
COMPLIANCE FRAMEWORK**
In accordance with the
Gene Technology Act 2000 (Cth)

**A working document
26 July 2002**

Monitoring and compliance activities are under continual improvement and will evolve as systems are assessed and validated. This working document is intended as a guide only. Readers of this document should also familiarise themselves with the gene technology legislation.

Overview

This document presents an outline of the activities of the Monitoring and Compliance Section that is located within the Office of the Gene Technology Regulator (OGTR). The document sets the framework within which the Monitoring and Compliance Section operates to meet obligations under the *Gene Technology Act 2000 (Cth)* (the GT Act).

The Monitoring and Compliance Section supports the Gene Technology Regulator by undertaking monitoring, audits, inspections and investigations under the auspices of the GT Act. Monitoring and compliance activities also comprise risk assessment and management, reviews of an accredited organisation's activities and reporting.

Elements of interest to the Monitoring and Compliance Section include an assessment of:

- whether a non-compliance with the regulatory requirements has occurred; and
- the public health and environmental risk associated with an incident.

The aim of the OGTR monitoring and compliance activities is to ensure that dealings with Genetically Modified Organisms (GMOs) comply with regulatory requirements. These requirements are designed to meet the object of the GT Act:

To protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

In particular, monitoring and compliance focus on the management of dealings for field trial sites and within contained facilities to ensure the:

- minimisation of the risk of dissemination of a GMO and its genetic material;
- minimisation of the risk of persistence of a GMO in the environment; and
- effective management of a GMO is maintained.

'Mission' Statement for the Monitoring and Compliance Section

To protect the health and safety of people and the environment by providing effective, efficient and thorough monitoring and compliance oversight of accredited organisations dealing with genetically modified organisms.

'Vision' for the Monitoring and Compliance Section

To set world's best practice in monitoring and compliance oversight of an accredited organisation's dealing with genetically modified organisms.

Definitions of terms

Auditing

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

Compliance

Means actions taken to determine if organisations/individuals are acting in accordance with legislative requirements and/or sanctions applied to encourage accredited organisations/individuals to act in accordance with legislative requirements.

Enforcement

Means actions taken when a licence holder or person is not complying with legislative requirements and the Gene Technology Regulator believes it is necessary to undertake the GT Act in order to protect the health and safety of people and the environment.

Evidential material

- (a) a thing with respect to which an offence against the GT Act or the Gene Technology Regulations 2001 has been committed or is suspected, on reasonable grounds, to have been committed;
- (b) a thing that there are reasonable grounds for suspecting will afford evidence as to the commission of any such offence;
- (c) a thing that there are reasonable grounds for suspecting is intended to be used for the purpose of committing any such offence.

Intelligence

Means the collection of information that may inform an investigation.

Investigation

Means an inquiry into a suspected breach of the GT Act and corresponding state laws with the aim of gathering evidence. Such investigations are not restricted to purely criminal aspects – in the wider context they may include advice on detected flaws and vulnerabilities in policies, practices and procedures. An investigation may be initiated as a consequence of monitoring by the OGTR, by self-reporting or by third party reporting.

Licence holder

Means a holder of a GMO licence under the GT Act.

Monitoring

Means to make observations and to check that legislative requirements are being complied with.

Monitoring Visit

Means an examination of a premises to find out whether legislative requirements are being complied with.

Non-compliance

Means a failure to comply with legislative requirements including licence, accreditation or certification conditions

Review

Means a focused examination and analysis of observations made by monitoring teams and information provided by accredited organisations in their reporting to the OGTR. A review is to follow-up on issues that have arisen to determine both possible risks and / or suggest remedial action and possible non-compliance for referral to investigation.

Risk Analysis

Includes the probability that, in a certain timeframe, an adverse outcome will occur in a person, group of people, plants, animals and/or the ecology of a specified area that is exposed to a particular GMO. Typically, risk depends on both the level of hazard of the agent and the level of exposure of the receptor (human, animal, plant, etc). Risk analysis has two dimensions, probability (likelihood) of an event and consequence (the impact of the event when it happens).

Introduction to the Monitoring and Compliance Section

For administrative purposes, the Monitoring and Compliance Section is split into two teams: the '*Monitoring team*' and the '*Compliance and Investigations team*'.

The '*Monitoring team*' is made up of personnel with technical expertise in agriculture, ecology, environmental management and microbiology. Personnel from this team undertake monitoring, risk assessment, reviews and auditing activities. The primary focus of monitoring activities is to determine whether the legislation is being complied with. Other roles include advice on the application of the theoretical risk assessments in operational situations, and gathering information on possible adverse effects of GMOs.

The '*Compliance and Investigations team*' is made up of personnel with extensive law enforcement and compliance backgrounds. This team undertakes investigations into matters either referred to it by the *Monitoring team*, matters that are self reported or allegations raised by third parties. The team conducts criminal investigations and prepares briefs of evidence for the Director of Public Prosecutions. The team may also undertake inquiries to detect flaws and vulnerabilities in policies, practices and procedures.

Protocols

The Monitoring and Compliance Section is assembling Protocols for specific areas of its operation as an information source for accredited organisations and for the general public. The information contained in the Protocols provides accredited organisations and members of the public with a broad overview of OGTR's monitoring and compliance activities. The development of these Protocols is an evolving process whereby the documents are being made available to the public for comment and feedback.

By releasing Protocols, the OGTR can assist accredited organisations in maintaining compliant behaviour. Openness and transparency augers well for frank discussions with accredited organisations and facilitates cooperation in relation to the prevention of non-compliance activity.

Standard Operating Procedures

The teams within the Monitoring and Compliance Section operate to detailed Standard Operating Procedures set out in either the '*Monitoring Manual*' or the '*Compliance and Investigation Manual*'. Under the Fraud Control Policy of the Commonwealth, the

operating procedures set out in the Compliance and Investigation Manual are subject to quality assurance review by the Australian Federal Police. The Standard Operating Procedures are confidential and are not for public release.

Database

The Monitoring and Compliance Section will utilise an electronic database that is used by the OGTR to record and manage all dealings with GMOs in Australia. The database is called the Gene Technology Information Management System (GTIMS). It provides a facility for the Monitoring and Compliance Section to record and monitor breaches and undertake and track inspections

Resources

The Monitoring and Compliance Section has available to it the scientific and technical expertise within the OGTR and the expertise of the Gene Technology Technical Advisory Committee (GTTAC) for risk assessment purposes.

Monitoring and Compliance Model

The OGTR has developed a Monitoring and Compliance model that depicts a pro-active strategy for monitoring and compliance activities under the new regulatory framework. The Monitoring and Compliance Model is a way in which the OGTR can adopt a systematic approach to monitoring and compliance. The model consists of five parts:

1. Health and safety of people and the Environment;
2. Compliance Status and Risk Levels;
3. Compliance and Risk Factors;
4. Compliance Strategies; and
5. Corporate Culture

The model allows for the assessment and management of two aspects of concern:

- Risks to public health and safety of people and the environment; and
- Non-compliance with the legislation.

The model applies to all dealings with GMOs regulated under the GT Act and can be used at both strategic and operational levels. A description of each part is set out below.

1. Australian Public Health and the Environment

The principal role of the OGTR is to support the Gene Technology Regulator to fulfil the objective of the Gene Technology Act 2000: to protect the health and safety of people and the environment by identifying risks posed by, or as a result of gene technology, and by managing those risks through regulating certain dealings with Genetically Modified Organisms (GMOs).

Under this component of the model, the Monitoring and Compliance Section undertakes risk assessments in relation to potential non-compliant activity. The focus of the risk assessment is risks to public health and the environment.



2. Compliance Status and Risk Levels

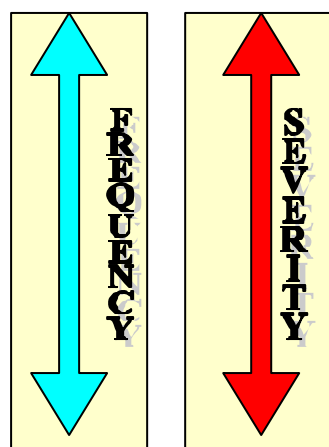
The result of monitoring or investigative work is findings as to whether the GT Act and associated legislation has been complied with. The compliance status of a monitoring or investigation activity is reported as either compliant, borderline compliant or non-compliant.

In non-compliant situations, the level of risk is graded after completion of the risk assessment described under '1. Australian Public Health and the Environment' above. By categorising the risk the type of management response, or the type of compliance strategy, can be determined. This ensures the level of response is commensurate with the level of risk.

Non-compliance	High	Serious non-compliance
	Medium	
	Low	
Compliant	Negligible	
	Conceded Compliant	
	Compliant	

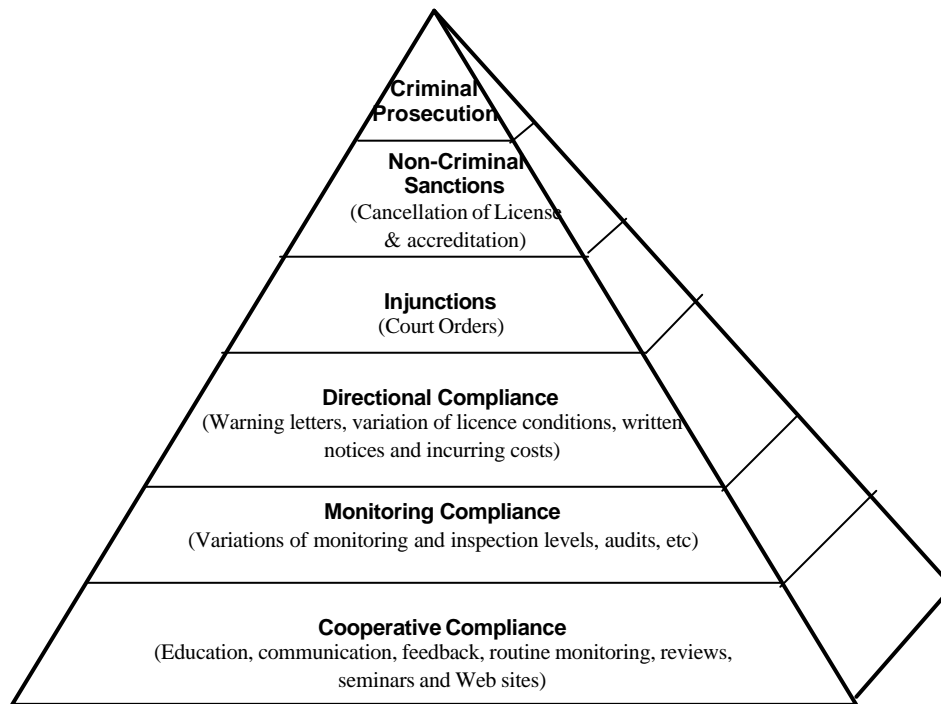
3. Compliance and Risk Factors – Frequency and Severity

As with the level of risk, the frequency and severity of the risk to the health and safety of the Australian public and the environment impacts on the type of compliance response. A non-compliant activity by itself may represent negligible risk but in the context of an accredited organisation's constant derogation from the legislative requirements, or high frequency of non-compliant behaviour, a different type of compliance strategy may need to be employed. Additionally, the severity or the triviality of the non-compliance also elicits varying compliance strategies.



4. Compliance Strategies

The fourth part of the model is a pyramid featuring a hierarchy of compliance enforcement strategies, escalating in severity. The model gives accredited organisations every opportunity to comply. The divisions between the levels are not mutually exclusive. For example, it may be the case that directions to stop certain acts are given at the same time as a person is prosecuted for the non-compliant activity.



Cooperative Compliance: The OGTR aims to keep accredited organisations at the bottom of the hierarchy, so we start action with compliance strategies like education, routine monitoring and inspections, review feedback, seminars and web-site information. This area represents the bulk of the Monitoring and Compliance Section's work. The strategy seeks to put into place preventative measures to minimise non-compliant behaviour by accredited organisations.

Monitoring Compliance: As we move up the model our strategies become more about keeping accredited organisations on track with compliance such as variations of inspection levels to include spot checks and re-visits. Comprehensive audits of an accredited organisation's procedures may also be instigated to determine whether improvements can be made to operations or if non-compliant activity is prevalent throughout an accredited organisation.

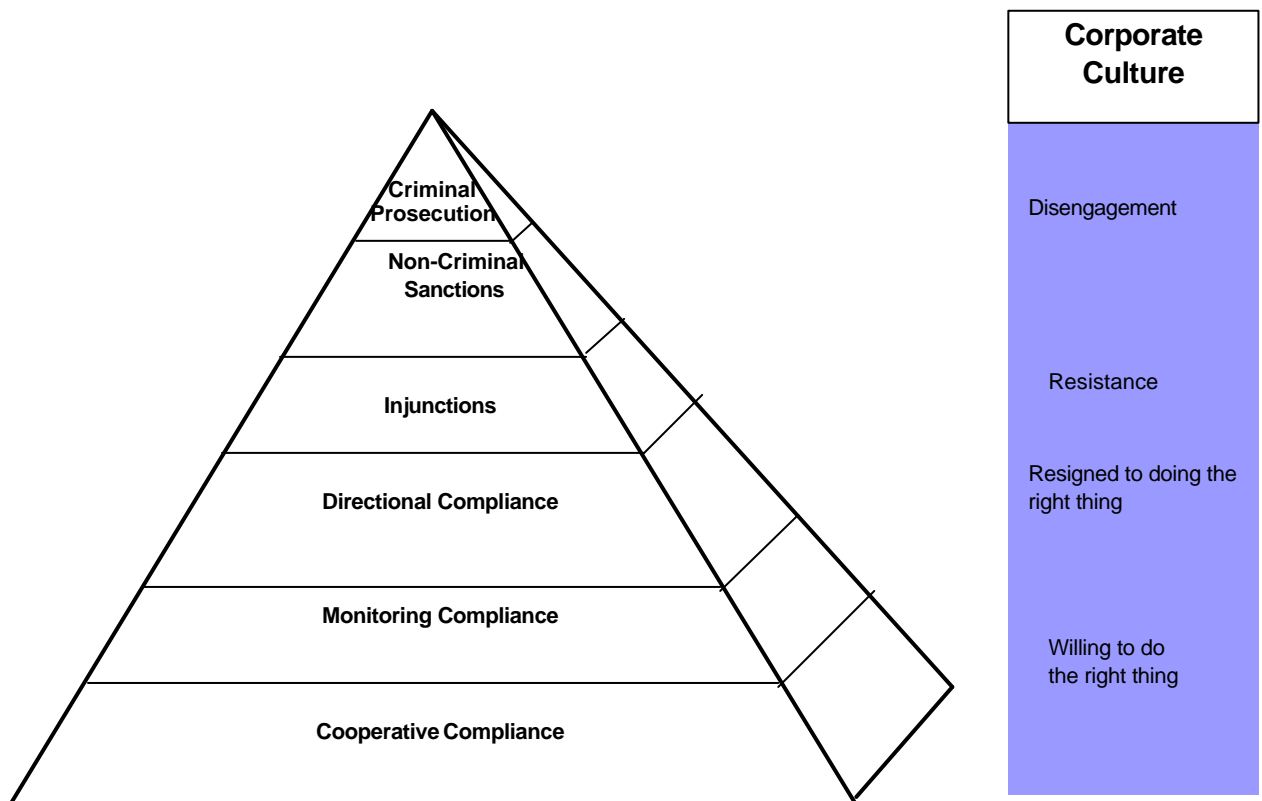
Directional Compliance: We continue up the hierarchy where we find accredited organisations not performing to a satisfactory level and are exhibiting non-compliant behaviour. The compliance strategies employed here include warning letters, variations to licence conditions to place tighter control on an accredited organisation's performance and/or Directions from the Regulator to comply with the GT Act. Where a Direction is issued by the Regulator, costs incurred by the Regulator in undertaking remedial action can be recouped from the non-compliant accredited organisation.

Injunctions: We continue up the hierarch when accredited organisations choose to be non-compliant after having been given reasonable opportunity to comply. At this level our actions increase in severity and intervention. This level applies to particular situations where a person is engaging, or is about to engage in any conduct that is or would be an offence against the legislation and immediate action is required to prevent that non-compliant activity from commencing or continuing.

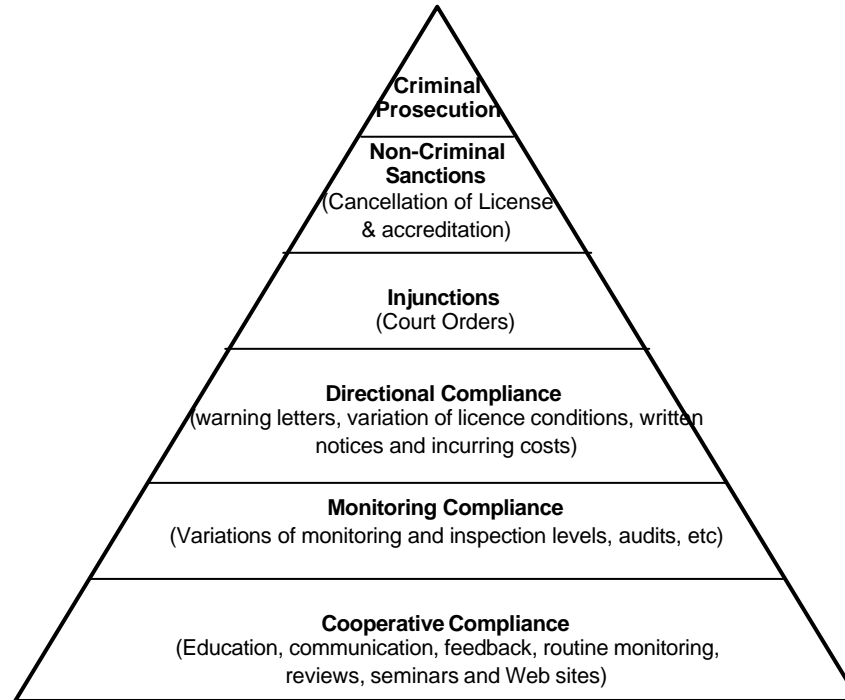
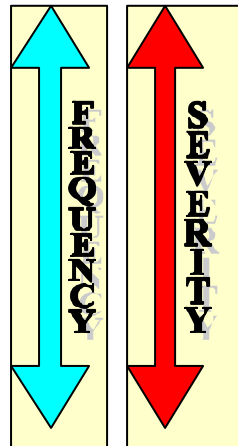
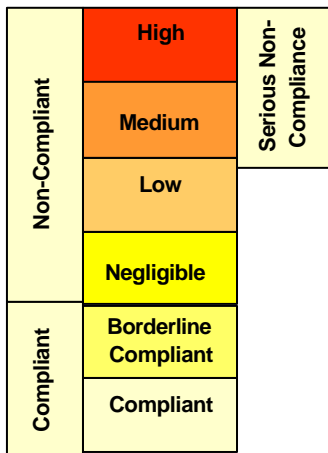
Non-criminal and Criminal Sanctions: At the top of the hierarchy are our severest strategies, used for the most non-compliant situations. Examples of action at this level are cancellation of licences, accreditation or certification and finally criminal prosecution. Criminal prosecution involves referral to the Director of Public Prosecutions for a decision on whether the case will be pursued in the courts.

5. Corporate Culture

The Compliance Model also includes corporate commitment to and documentation on effective risk management and compliance practices together with a corporate culture (underpinned by training and informed awareness) which enables personnel and the organisation as a whole to comply.



SUMMARY OF THE OGTR MONITORING AND COMPLIANCE MODEL



1. HEALTH AND SAFETY OF PEOPLE AND THE ENVIRONMENT

2. COMPLIANCE STATUS & RISK LEVELS

3. COMPLIANCE & RISK FACTORS

4. COMPLIANCE STRATEGIES

5. CORPORATE CULTURE

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