



**Australian Government**

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

**MONITORING AND  
COMPLIANCE FRAMEWORK**  
**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.**

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## **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 those actions in accordance with the 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 Act or the Gene Technology Regulations 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 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 Act.

### ***Monitoring***

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

### ***Monitoring visit***

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

### ***Non-compliance***

An inconsistency between an event or state of affairs and the requirements imposed by licence accreditation or certification conditions, or any of the requirements of the Act or Regulations.

### ***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

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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 identified hazard could lead to an adverse outcome 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).

### ***Spot checks***

Unannounced visits by the Monitoring and Compliance Section.

## **Overview**

This document presents an outline of the activities of the Monitoring and Compliance Sections within the Office of the Gene Technology Regulator (OGTR). The document sets the framework within which the Monitoring and Compliance Sections operate to meet obligations under the *Gene Technology Act 2000* (the Act).

The aim of OGTR monitoring and compliance activities is to ensure dealings with GMOs comply with legislative obligations and are consistent with the object of the 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, the Monitoring and Compliance Sections focus on management of dealings at field trial sites and within contained facilities certified by the Regulator to ensure:

- The dissemination of a GMO and its genetic material is minimised;
- The persistence of a GMO in the environment is managed;
- Effective management of the GMO is maintained; and
- OGTR monitoring and compliance activities comprise the functions of routine monitoring, reviews of risks, investigations and audits.

OGTR monitoring and compliance activities comprise the functions of routine monitoring, review of risks, investigations and audits and may result in remedial actions. OGTR monitoring activities comprise the functions of routine monitoring including spot checks, assessment of monitoring findings and, where necessary, recommending corrective action and follow-up activities. OGTR compliance activities comprise reviews of potential compliance risks, investigations, audits and related enforcement activities.

The Monitoring Section conducts routine monitoring visits of a minimum of 20 percent of field trial sites each year. To achieve this goal a minimum of five percent of current trial sites and five percent of trial sites subject to post-harvest monitoring are monitored each quarter.

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## **Monitoring and Compliance Strategy**

The purpose of routine monitoring of field trials is to ensure compliance with licence conditions and includes spot checks. The OGTR strategy for conducting field trial monitoring draws on accumulated operational experience of risk profiling in relation to compliance. For example, OGTR field trial monitoring coincides, where possible, with periods or circumstances when non-compliance with licence conditions designed to limit the spread and persistence of the GMOs is more likely to occur (for example, flowering and harvest of GM crops).

The monitoring program for contained dealings involves inspecting Dealings Not involving Intentional Release (DNIR's) 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.

Elements of interest to the Monitoring and Compliance Section include:

- 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 e.g. a recommendation of prosecution for an alleged breach of a licence condition or that a licence be suspended or cancelled. A proven breach of a licence condition will be reported in accordance with paragraph 136A(2)(b) of the Act.

### **'Mission' Statement for the Monitoring and Compliance Sections**

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 Sections**

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

## **Introduction to the Monitoring and Compliance Sections**

The Monitoring Section is made up of personnel with technical expertise in areas such as agriculture, ecology, environmental management and microbiology. Personnel from this team undertake monitoring, compliance 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,

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and gathering information on possible adverse effects of GMOs.

The Compliance and Investigations Section 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 Sections have assembled 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 a broad overview of OGTRs monitoring and compliance activities. The development of these Protocols is an evolving process whereby the documents are made public and are available 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 Sections 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 Sections utilises 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). A second database, called Australian Special Information Systems Case Manager is also used by the Monitoring Section to record and monitor breaches and undertake and track inspections.

### **Resources**

The Monitoring and Compliance Sections have 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 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 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 Act: *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 Sections undertake compliance 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 Act and associated legislation has been complied with. The compliance status of a monitoring or investigation activity is reported as either compliant or non-compliant.

In non-compliant situations, the level of risk is graded after completion of the compliance 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 and the relevant containment requirement.

<b>Non-compliant</b>	<b>High</b>	<b>Serious non-compliance</b>
	<b>Medium</b>	
	<b>Low</b>	
	<b>Negligible</b>	
<b>Compliant</b>	<b>Compliant</b>	

### 3. Compliance and Risk Factors – Frequency and Severity

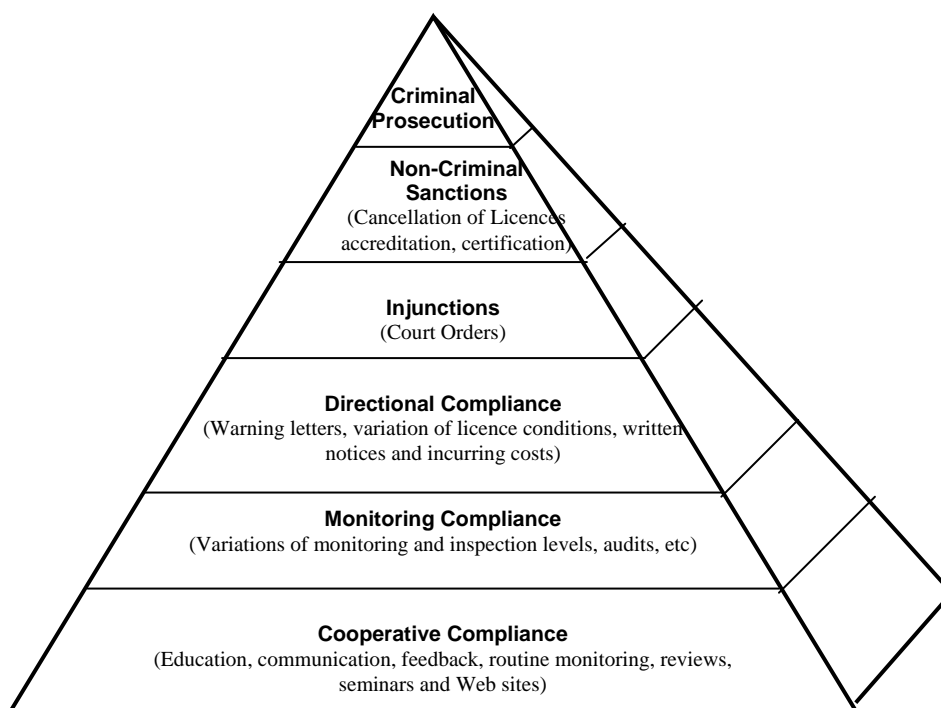
As with the level of risk, the frequency and severity of the risk to the health and safety of the Australian public and the environment impacts on the type of compliance response. A non-compliant activity by itself may represent negligible risk but in the context of an accredited organisation’s constant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

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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 Sections' 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.

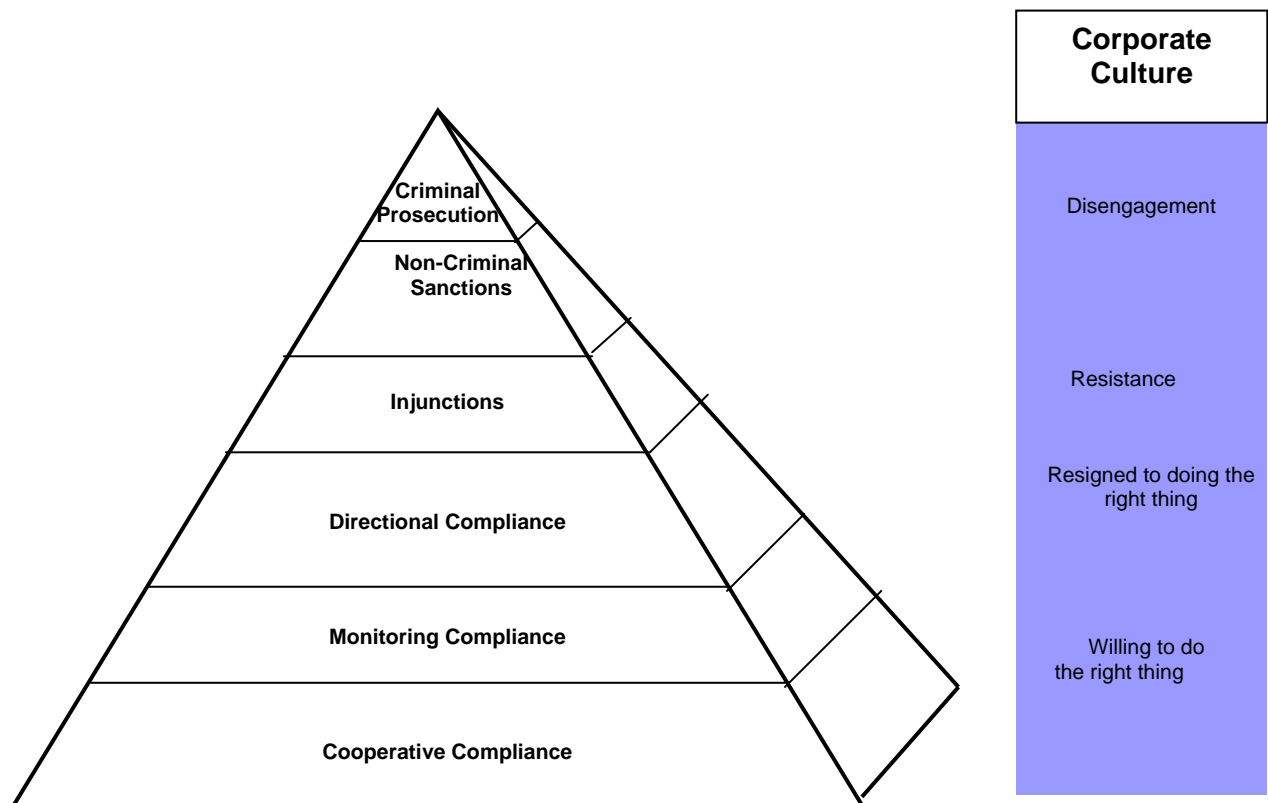
*Directional Compliance:* We continue up the hierarchy where we find accredited organisations not performing to a satisfactory level and are exhibiting non-compliant behaviour. The compliance strategies employed here include warning letters, variations to licence conditions to place tighter control on an accredited organisation's performance and/or Directions from the Regulator to comply with the 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 hierarchy 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.

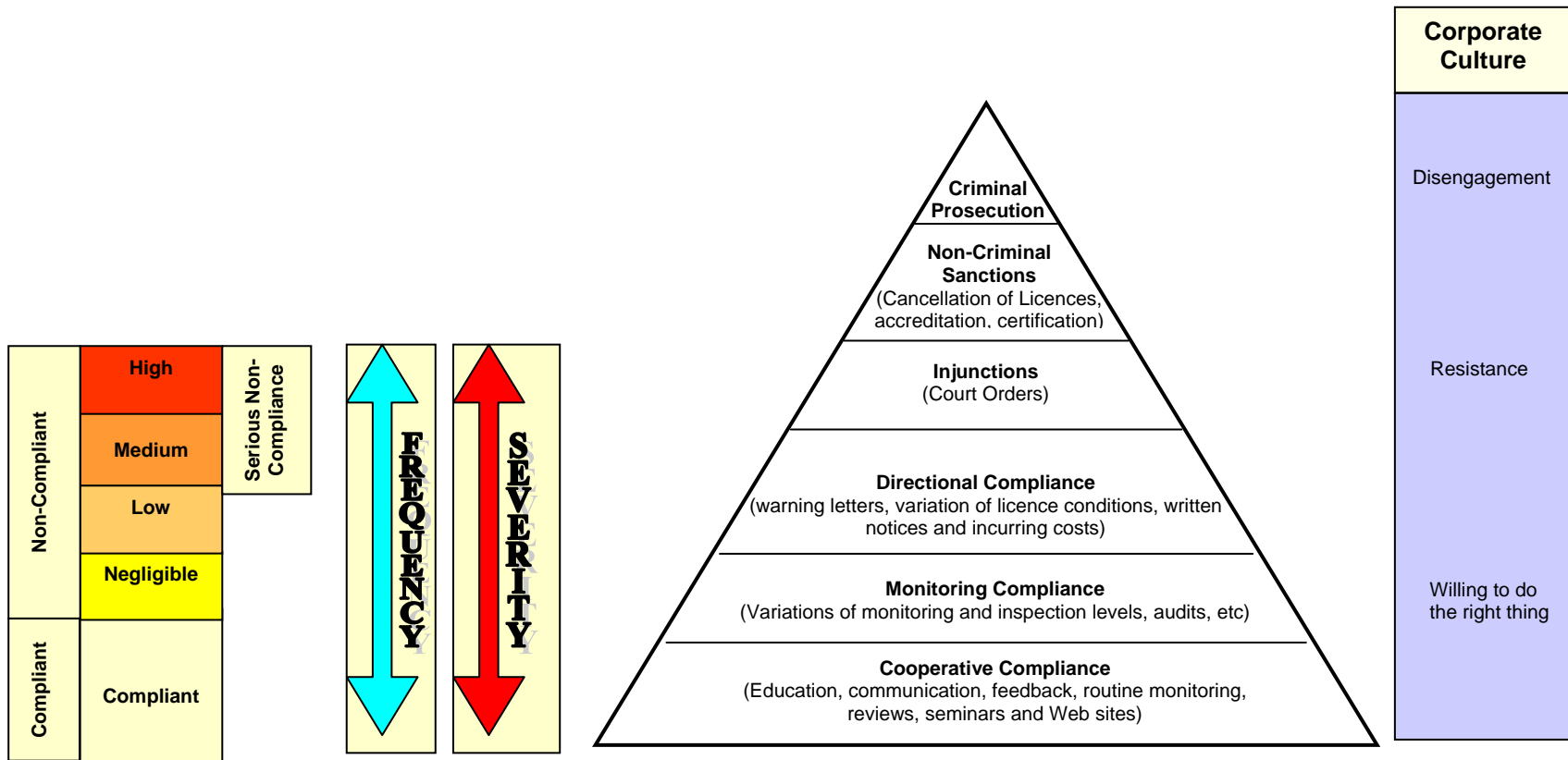
*Non-criminal and Criminal Sanctions:* At the top of the hierarchy are our severest strategies, used for the most non-compliant situations. Examples of action at this level are cancellation of licences, accreditation or certification instruments and finally criminal prosecution. Criminal prosecution 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



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