Australian Government

Department of Health

Office of the Gene Technology Regulator

Office of the Gene Technology Regulator

Monitoring and Compliance Framework

July 2018

Disclaimer

This document is intended as a guide only and should be read in conjunction with the gene technology legislation.

Version control

Version	Date	Author	Description
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1. Introduction

1.1 The Office of the Gene Technology Regulator

The Office of the Gene Technology Regulator (OGTR) is located within the Australian Government Department of Health and provides administrative support to the Gene Technology Regulator (***the Regulator***) in the performance of functions under the *Gene Technology Act 2000* (the Act).

The Regulator is an independent statutory office holder who administers the Act and has powers under the Act to monitor for ***compliance***, and to take ***enforcement*** action when required.

1.2 The purpose of this document

This document informs the public and regulated stakeholders of the legislative and regulatory framework the OGTR may use to meet current and future regulatory needs and protect people and the environment from risks posed by ***gene technology***.

This document sets out the key elements of the legislative framework, the regulatory framework, and the OGTR approach to monitoring.

2. The legislative framework

2.1 The national legislative scheme

There is a nationally consistent legislative scheme (the national scheme) for *gene technology* which is comprised of the Act and the *Gene Technology Regulations 2001* (the Regulations), and corresponding State and Territory legislation.

The legislation was developed in consultation with all Australian jurisdictions and the national scheme is supported by the inter-governmental Gene Technology Agreement between the Australian Government and each State and Territory.

The implementation of the national scheme is overseen by the Legislative and Governance Forum on Gene Technology, which comprises ministerial representation from all Australian jurisdictions.

The Australian Government *gene technology* legislation took effect on 21 June 2001 and consists of the:

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

The Australian Government and States and Territories *gene technology* legislation provides a legislative basis for ***monitoring*** and enforcing ***compliance***, including in respect to licence conditions relating to ***dealings with Genetically Modified Organisms*** (GMOs).

2.2 The Objective of the *Gene Technology Act 2000*

> *"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"*

3. The Regulatory Framework

3.1 The expectations and requirements for Australian Government regulatory agencies

The Australian Government documents listed below outline expectations and requirements for Australian Government agencies that undertake regulatory activities:

- The *Australian National Audit Office Better Practice Guide – Administering Regulation: Achieving the right balance* (ANAO, 2014) contains Australian Government standards for best practice regulation,
    - A key component of the ANAO Guide is that it asks regulatory agencies to take a risk-based approach in order to target their regulatory activities.
- The *Regulator Audit Framework* (RAF) (PC, 2014) specifies that regulators be clear about how they perform and undertake the four key areas of regulator interaction,
    - The four key areas are: *Advice and Guidance*, ***Licensing and Approvals***, *Monitoring and Compliance*, and *Enforcement*.
- The *Regulator Performance Framework* (PM&C, 2014) establishes Key Performance Indicators (KPIs) for regulatory agencies to be aware of as they approach regulatory delivery in their operating context,
    - The KPIs relate to the effective and efficient delivery of regulation.

The OGTR delivers its regulatory obligations in a way that is consistent with the above documented expectations and requirements.

3.2 A focus on risk

Managing regulatory risk is considered an integral component of good regulatory administration and should underpin almost all regulatory activity (ANAO 2014, p.14). However, it is important to highlight that a regulator's role is not to completely eliminate risk but to effectively manage risk.

The OGTR considers and focusses on understanding risks, managing risk through *Licensing and Approvals*, and managing risks arising from potential or apparent non-compliant activity (through *Monitoring and Compliance*, and *Enforcement*). The OGTR also works to educate stakeholders on risks and risk management (through *Advice and Guidance*).

OGTR risk considerations for licence applications

The OGTR has developed a *Risk Analysis Framework* (2013) the purpose of which is to:

- provide a guide to the current rationale and approach to risk analysis,
- enable a consistent and rigorous risk analysis approach to evaluate *licence* applications, and
- provide transparency on the use of risk analysis for decision making (p. vii).

The OGTR conducts risk analysis according to the *Risk Analysis Framework* in relation to certain dealings with GMOs in order to provide advice to the Regulator on appropriate *licence* conditions.

OGTR broader risk considerations

The OGTR uses risk analysis to:

- guide the development of management systems, processes and structures to support regulatory administration,
- focus *monitoring* and management of regulatory *compliance*, and
- enable the efficient allocation of available resources (ANAO 2014, p. 14).

Further information regarding the assessment of risk and risk management processes surrounding *monitoring* activities is included in the *Monitoring and Compliance Risk Analysis Protocol* (April 2016).

While the *Risk Analysis Framework* is primarily focussed on consideration of GMO licence applications, it is also applicable to GMO risk analysis in other contexts. The OGTR's development and use of its *Risk Analysis Framework* and broader application of risk analysis, across the four key areas of regulator interaction, demonstrates its commitment to taking a risk-based approach to regulation.

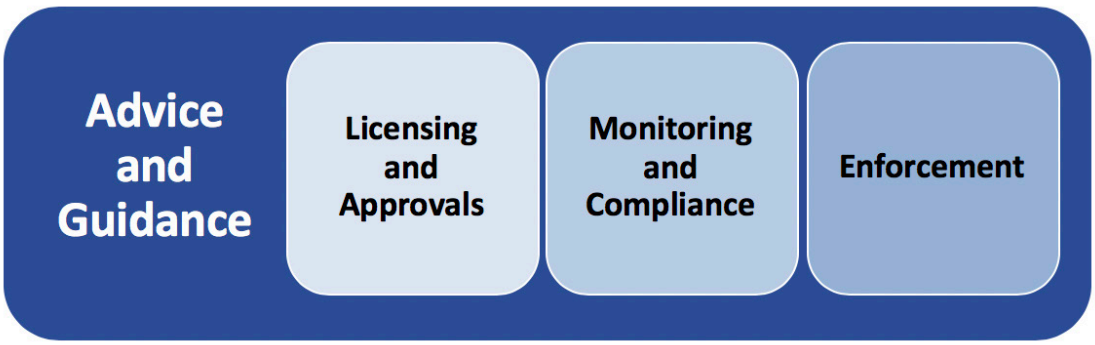
3.3 A focus on prevention

The OGTR maintains capacity of staff and systems to perform all of the four key areas of regulator interaction, investing heavily in providing *Advice and Guidance* and information gathering to best prevent harm to people and the environment from dealings with the GMOs.

The OGTR's deliberative and ongoing commitment to an open dialogue provides it with a deep understanding of *gene technology* and associated risks. This cooperative approach, with an emphasis on education and engagement, has helped to create an environment whereby the OGTR is able to set and adjust its regulatory posture and allocation of resources across the other areas of regulator interaction to best effect.

Diagram 1 depicts OGTR's focus on harm prevention through a commitment to *Advice and Guidance*, irrespective of the particular regulator interaction at play.

Diagram 1: The OGTR commitment to ongoing Advice and Guidance



3.4 A focus on effectiveness

The OGTR engages in an open dialogue and actively seeks feedback from regulated entities, co-regulators, key stakeholders, and the wider community to ensure the effectiveness of the regulatory scheme. Specifically, the regulatory activities of the OGTR are:

- undertaken so as to not unnecessarily impede scientific research and innovation;
- communicated to regulated entities in ways that are clear, targeted and effective;
- undertaken proportionate to the regulatory risk being managed;
- streamlined and coordinated with regards to monitoring and compliance;
- open and transparent; and
- actively contributing to the continuous improvement of regulatory processes.

The activities of the OGTR are reported annually in accordance with the requirements in the Act and Regulations, and more frequently in other public forums such as conferences and industry events. The Regulator is accountable to the Australian Parliament, Commonwealth Ministers and the Forum (State and Territory Ministers).

4. The OGTR approach to monitoring

4.1 Why we monitor use of GMOs

The primary purpose of OGTR's *monitoring* effort is to confirm the effectiveness of the risk management requirements, to proactively identify and prevent harm to people and the environment from dealing with GMOs, by ensuring the:

- dissemination of a GMO and its genetic material is managed or prevented;
- persistence of a GMO in the environment is managed;
- effective management of the GMO is maintained; and
- opportunities to undertake preventive action are identified and acted upon.

Consistent with its harm prevention approach to regulation, the OGTR monitors for *compliance* with the legislation, and collects and collates information which is required for regulatory decision making.

The Australian Government *gene technology* legislation prohibits persons from dealing with a GMO unless the dealing is authorised via:

- an ***exempt dealing***;
- a ***notifiable low risk dealing***;
- an ***emergency dealing determination***;
- the ***GMO Register***; or
- a licence issued by the Regulator.

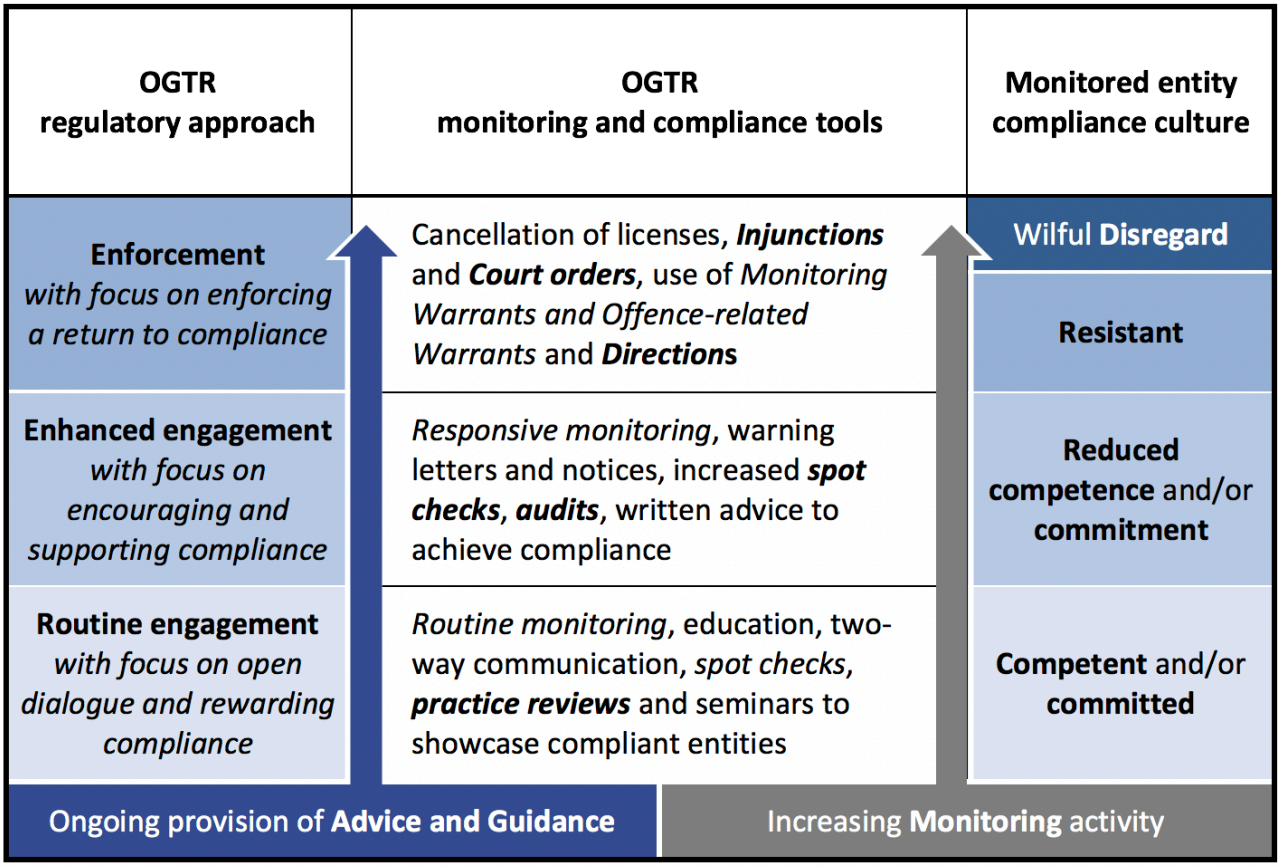
4.2 A focus on collaboration

The OGTR undertakes regulatory activity in order to encourage high levels of voluntary compliance.

Through its monitoring activities, the OGTR establishes an open dialogue and collaborative approach with regulated entities operating within an environment of earned autonomy. This collaboration-focused approach, shown in more detail in Diagram 2, seeks to ensure that monitoring activity is proportionate, and appropriately adapted to what is required to achieve the outcome sought.

The OGTR takes this cooperative approach, with a strong emphasis on education and engagement, and when necessary enforcement, in order to ensure that regulated entities remain in compliance or are assisted in a timely manner to return to compliance.

Diagram 2: The OGTR responsive approach to monitoring



OGTR's open dialogue with stakeholders and co-regulators

The development and use of GMOs in Australia is regulated through an integrated legislative framework which includes the Regulator and a number of other regulatory authorities with complementary responsibilities and expertise. The integrated legislative framework is supported by the appropriate sharing of information between partner and relevant agencies.

Additionally, the OGTR's collaborative approach extends to an open dialogue with regulated entities, stakeholders, and the wider community. For example, through public and industry meetings, transparent reporting, and the *Allegations by Third parties Protocol*, to assist stakeholders to report direct to OGTR.

5. Types of monitoring activity

5.1 The three types of monitoring activity

The OGTR undertakes three types of monitoring activity: routine; responsive; and strategic.

Each type of monitoring activity, further described below, is generally deployed in a manner proportionate to the risk associated with the GMO and the potential for harm to people and the environment.

The compliance culture of the entity being monitored may also be taken into account, and responded to accordingly, as explained on the previous page in Diagram 2.

5.2 Routine monitoring

Routine monitoring, typically relates to the Regulator providing general deterrence and assisting organisational compliance. Routine monitoring may include:

- assessing compliance at field trial sites, clinical trials, and within contained facilities that are certified (i.e. premises licenced/approved) by the Regulator.

Routine monitoring usually involves the following characteristics:

- the monitoring activity is planned and pre-arranged, often to coincide with an agreed milestone (such as harvest of a field trial or commencement of dealings in a containment ***facility***),
- the monitoring activity may be unannounced (i.e. as part of ***spot checks*** of a licenced *facility* or a field trial), and
- the monitoring activity generally involves physical attendance by OGTR staff but can also be conducted remotely, based on provision of data or information by the regulated entity (by desktop) ,
    - *routine monitoring* occurs with the voluntary or consensual involvement of the regulated entity.

5.3 Responsive monitoring

Responsive monitoring, typically relates to the regulator responding to some form of trigger. Responsive monitoring may include:

- responding to allegations of non-compliance received; or concerns identified in reports or during previous *routine monitoring*, or as a result of repeated and/or aggravated instances of non-compliance.

Responsive monitoring usually involves the following characteristics:

- the monitoring activity is planned and pre-arranged, especially in response to a natural or man-made trigger such as adverse weather events or fire or spills etc, and
- the monitoring may be unannounced, especially in response to allegations of non-compliance received; or concerns identified in reports or during previous *routine monitoring*, or as a result of repeated and/or aggravated instances of non-compliance, and in these circumstances may involve use of coercive (non-voluntary) powers including monitoring warrants and offence-related warrants issued by a Court.
    - *responsive monitoring* typically occurs with either limited or no prior knowledge of the regulated entity.

5.4 Strategic monitoring

Strategic monitoring, typically relates to ensuring compliance in a preventative context. Strategic monitoring may include:

- proactively engaging with a broad group of stakeholders in order to maintain a presence and awareness of the risks associated with the evolving use of GMOs in emerging sectors, and/or where GMOs have entered Australia through unintentional means.

Strategic monitoring usually involves the following characteristics:

- the monitoring activity is planned and pre-arranged, and occurs with the prior knowledge of relevant stakeholders, (i.e. as part of ***practice review*** of a *facility*), and
- the monitoring activity generally involves physical attendance by OGTR staff but can also be conducted remotely, based on provision of data or information by the regulated entity (by desktop) ,
    - *strategic monitoring* occurs with the voluntary or consensual involvement of relevant stakeholders.

5.5 Transparency and accountability

The OGTR is committed to maintaining transparency and accountability in terms of its regulatory activities. This commitment is evidenced through the OGTR clearly articulating its monitoring approaches and activities as documented above.

All auditing and monitoring of dealings with GMOs will be reported in the Regulator's Annual Report in accordance with paragraph 136(1A)(e) of the Act.

Furthermore, additional detail regarding the regulatory practice of OGTR is documented in protocols, practice notes and other guidance material provided on the OGTR website.

5.6 Monitoring capability

The OGTR has staff with specific monitoring expertise, and other expertise which support monitoring activities.

OGTR, through its staff and managers, has diverse professional and technical expertise in areas including but not limited to law, administration, risk analysis and science (for example agriculture, ecology, plant science, medical science, environmental management and microbiology). Additionally, staff also have wide range of experience in audits, fraud control and compliance investigations.

The OGTR is committed to continual professional development of all personnel in order to stay current with the legal and technical requirements to carry out its role.

6. Responding to non-compliance

The *OGTR Compliance and Enforcement Policy* (April 2016) (the C&E Policy) outlines the approach to responding to non-compliance and enforcement action.

The C&E Policy lists the aspects mentioned below as being considerations which may be taken into account by *the Regulator* in determining the appropriate compliance or enforcement response by OGTR, including the:

- extent of risk to the health and safety of people and the environment;
- severity of the issue or event involved in the finding;
- culpability of the licence holder or other relevant persons in bringing about the issue or event;
- types of mechanisms available to address the issue or event;
- 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
- need for deterrence.

The OGTR recognises that both compliance and enforcement mechanisms are necessary to provide a flexible, effective and efficient regulatory scheme.

6.1 Reporting non-compliance

All proven breaches of conditions of a GMO licence that have come to the Regulator's attention during the financial year will be reported in the Regulator's Annual Report in accordance with paragraph 136(1A)(b) of the Act.

7. Glossary

Advice and Guidance	One of the four key areas of regulator interaction as defined by the Regulator Audit Framework (PC 2014).
Audit	Generally, a planned examination of an organisations practices, procedures and performance against regulatory requirements. Specifically, under the Act: *(1) It is a condition of a licence that if:* *(a) a person is authorised by the licence to deal with a GMO; and* *(b) a particular condition of the licence applies to the dealing by the person;* *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.*
Compliance	The action or fact of complying with regulatory requirements.
Dealings with GMOs (deal with)	*In relation to a GMO, means the following:* *(a) conduct experiments with the GMO;* *(b) make, develop, produce or manufacture the GMO;* *(c) breed the GMO;* *(d) propagate the GMO;* *(e) use the GMO in the course of manufacture of a thing that is not the GMO;* *(f) grow, raise or culture the GMO;* *(g) import the GMO;* *(h) transport the GMO;* *(i) dispose of the GMO;* *and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i).*
Emergency dealing determination	A determination in force under section 72B of the Act.
Enforcement	One of the four key areas of regulator interaction as defined by the Regulator Audit Framework (PC 2014).
Exempt dealing	A category of dealings with GMOs, specified in the Gene Technology Regulations 2001, that have been assessed over time as posing a very low risk (i.e. contained research involving very well understood organisms and processes for creating and studying GMOs) and which don't require a licence but must not involve the intentional release of GMOs into the environment.
Facility	*Includes, but is not limited to, the following:* *(a) a building or part of a building;* *(b) a laboratory;* *(c) an aviary;* *(d) a glasshouse;* *(e) an insectary;* *(f) an animal house;* *(g) an aquarium or tank.*

Gene technology	*Any technique for the modification of genes or other genetic material, but does not include:* *(a) sexual reproduction; or* *(b) homologous recombination; or* *(c) any other technique specified in the regulations for the purposes of this paragraph.*
GMO	A genetically modified organism as defined in s 10 of the Act.
GMO Register	The GMO Register established by section 76 of the Act.
Licensing and Approvals	One of the four key areas of regulator interaction as defined by the Regulator Audit Framework (PC 2014).
GMO licence	A licence issued under section 55 of the Act.
Licence holder	*The holder of a GMO licence.* May also be referred to as a regulated entity.
Monitoring	Generally, observing and checking the progress or quality of (something) over a period of time; keeping under systematic review, especially in terms of an organisations practices, procedures and performance against regulatory requirements. See also *Audit*.
Monitoring and Compliance	One of the four key areas of regulator interaction as defined by the Regulator Audit Framework (PC 2014).
Monitoring warrant	An instrument providing access to premises for the purposes of finding out whether the Act or the regulations have been complied with.
Notifiable Low Risk Dealings	Are dealings with GMOs, specified in the Gene Technology Regulations 2001, which don't require a licence but must be conducted in appropriate physical containment facilities.
Responsive monitoring	One of the three types of monitoring activity used by the OGTR, and typically relates to the regulator responding to some form of trigger.
Review	A focused examination and analysis of observations made through monitoring and information provided in reporting to OGTR.
Risk analysis	As defined in the OGTR's Risk analysis framework, the *overall process of risk assessment, risk management and risk communication*.
Routine monitoring	One of the three types of monitoring activity used by the OGTR, and typically relates to the regulator providing a general deterrence.
Offence-related warrant	An instrument providing access to premises where there are reasonable grounds for suspecting that there is, or there may be within the next 72 hours, evidential material in or on the premises.
Spot checks	Section 136 of the Act states that 'Auditing and monitoring may include spot checks'.
Strategic monitoring	One of the three types of monitoring activity used by the OGTR, and typically relates to ensuring compliance in a preventative context.
The Act	*Gene Technology Act 2000* or where applicable the corresponding State Law.
The Regulator	The Gene Technology Regulator appointed under section 118 of the Act.

8. References and relevant reading

ANAO 2014, *Australian National Audit Office Better Practice Guide - Administering Regulation: Achieving the right balance*, Australian National Audit Office, Canberra

OGTR 2016, *Allegation by third parties Protocol*, *in accordance with the Gene Technology Act 2000*, Office of the Gene Technology Regulator, Canberra

OGTR 2016, *Audit Protocol*, *in accordance with the Gene Technology Act 2000*, Office of the Gene Technology Regulator, Canberra

OGTR 2016, *Compliance and Enforcement Policy, in accordance with the Gene Technology Act 2000*, Office of the Gene Technology Regulator, Canberra

OGTR 2016, *OGTR Monitoring and Compliance Risk Analysis Protocol*, *in accordance with the Gene Technology Act 2000*, Office of the Gene Technology Regulator, Canberra

OGTR 2016, *Review Protocol*, *in accordance with the Gene Technology Act 2000*, Office of the Gene Technology Regulator, Canberra

OGTR 2015, *Practice Note: Field Monitoring Patterns*, *in accordance with the Gene Technology Act 2000*, Office of the Gene Technology Regulator, Canberra

OGTR 2015, *Practice Note: Unannounced spot checks*, *in accordance with the Gene Technology Act 2000*, Office of the Gene Technology Regulator, Canberra

OGTR 2013, *OGTR Science Strategy 2013-2018*, Office of the Gene Technology Regulator, Canberra

OGTR 2013, *Risk Analysis Framework 2013*, Office of the Gene Technology Regulator, Canberra

OGTR 2007, *Accredited Organisations' Compliance Management Protocol*, *in accordance with the Gene Technology Act 2000*, Office of the Gene Technology Regulator, Canberra

PC 2014, *The Regulator Audit Framework,* Productivity Commission, Canberra

PM&C 2014, *Regulator Performance Framework*, Prime Minister and Cabinet, Canberra