Australian Government
Department of Health
Office of the Gene Technology Regulator

Celebrating 20 Years of OGTR 2001 - 2021

Retrospective report 3

Public views, communication and regulation

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Contents

Public views, communication and regulation

Regulation of GMOs in Australia occurs within the National Gene Technology Scheme (the Scheme), which is a cooperative of state, territory and Commonwealth governments under the Intergovernmental Gene Technology Agreement (the Agreement). The scheme is made up of:

- the Agreement,
- the Gene Technology Act 2000 (the Act),
- the Gene technology Regulations 2001 (Cth) (the Regulations), and
- corresponding state and territory legislation.

One of the functions of the Regulator, as detailed in the Act, is to 'provide information and advice' to a number of stakeholders. This includes providing 'information and advice to the public about the regulation of genetically modified organisms (GMOs)'. However it must also be noted that the role of the OGTR is to provide objective information about GMOs, not to provide opinions on GMOs in general, or any class of GMO in particular. Understanding what the broader community knows and how this impacts on their attitudes to gene technology and its regulation, is key to identifying what information is important to the public and how it may best be provided.

Providing information to the public and other stakeholders is key to maintaining a robust regulatory system. Increased understanding amongst a range of stakeholders, including the public, is important when the Regulator is seeking and receiving informed input from them during the regulatory process. This chapter explores three areas including community (public) knowledge of and attitudes to GMOs, communication and interaction with regulated stakeholders, and ongoing focus on communication through monitoring and compliance activities in the OGTR.

Shifts in community attitudes over two decades

The OGTR provides information to the general public through the website, containing information such as fact sheets about GMOs and about regulation of GMOs; notification of all 'Dealings involving Intentional Release' (DIR) applications, invitations to comment during the assessment of these applications and notification of decisions on the applications; invitation to comment on activities such as reviews of the scheme. Requests for comment are also published in print media and the OGTR has a mailing list which receives all notifications directly by email.

Between 1999 and 2019, ten surveys have been conducted, examining public knowledge, understanding and attitudes to topics related to genetic modification and biotechnology. Although the specific questions asked have changed slightly over time, the surveys have aimed to:

- provide insight into public awareness of science and technology, particularly GM technologies;
- examine how public knowledge, attitudes and perceptions change;
- examine how these are influenced by factors such as age, gender, education, general interest in science and technology (and others);
- identify areas in which knowledge or understanding is limited.

Since the earliest survey in 1999, support for different uses of GMOs has varied over time (Figure 1).

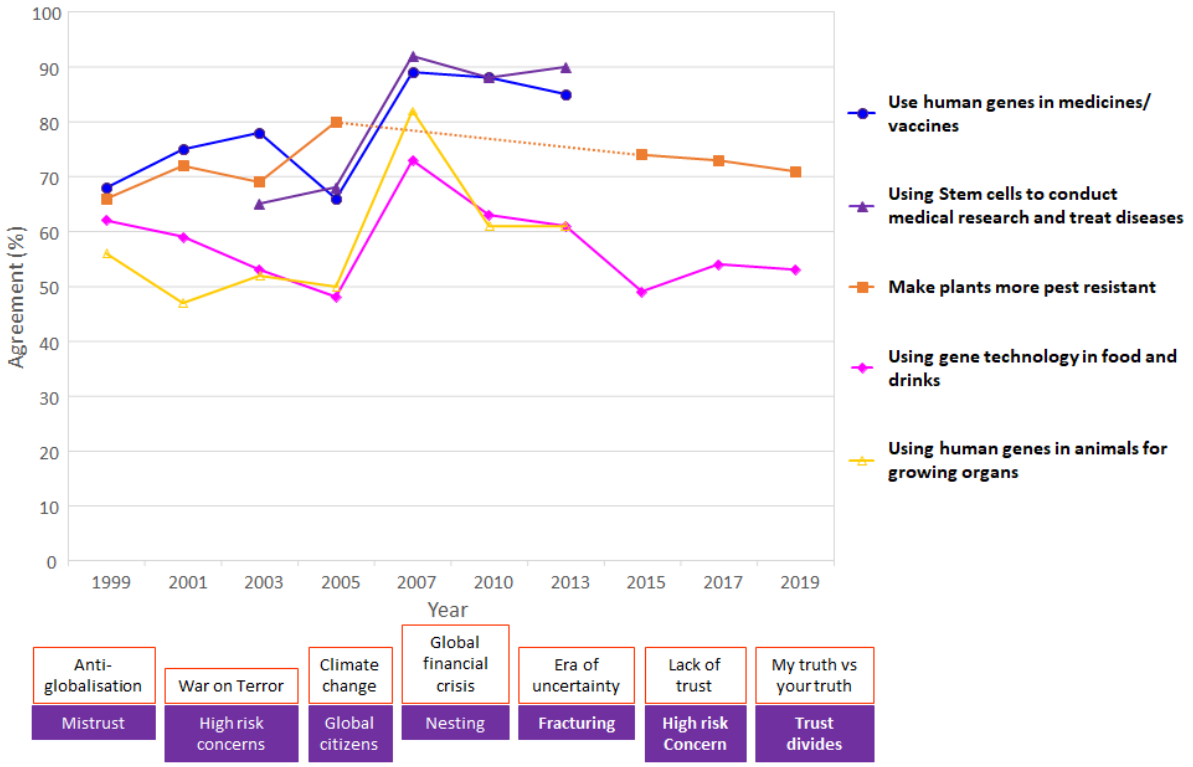


Figure 1: Support for specific uses of GMOs from 1999 to 2019. Note that not all specific uses were listed in all years. Dashed line indicates where data was not collected for intervening years. Adapted from Cormick and Mercer 2019.

In general, support for using GMOs for direct medical applications and research, and to making plants more resistant to disease, have had higher support than use for food and drink, or for growing organs. It should also be noted that world events and some general beliefs associated with such events – shown as an approximate timeline across the base of the graph – have an influence on community attitudes to GMOs.

Additionally, questions about the awareness of, and trust in, the gene technology regulatory system have been included in surveys since 1999 (Figure 2). Levels of awareness are low and have fluctuated across the years, however, awareness levels across the ten surveys has mainly been between 10 and 15%the level in 2019 (13%) was similar to that in 1999 (10%),. Once respondents were made aware of the OGTR, their level of trust in what the OGTR says about GMOs was relatively high. However, over the 20 years from 1999 to 2019, that level of trust has shown a decline from 70% to 60%. Again, it is likely that attitudes to the OGTR have been influenced by world events (shown as an approximate timeline across the base of Figure 2) and general levels of trust in governments.

It is also important to note that while the public are concerned about GMOs, the relative level of concern about GMOs is lower than about a range of other 'science and technology' issues. For example, in 2001, 73% of survey respondents indicated that use of gene technology was somewhat or definitely risky. However, when asked to rank levels of concern about a range of science and technology issues, concern about GM foods was ranked highest by only 11% of respondents, compared to pollution (29%), nuclear waste (24%), greenhouse (23%) and cloning, (13%). Additionally, 41% of respondents ranked GM foods as their lowest concern of those discussed (Millward Brown Australia, Biotechnology Australia 2001).

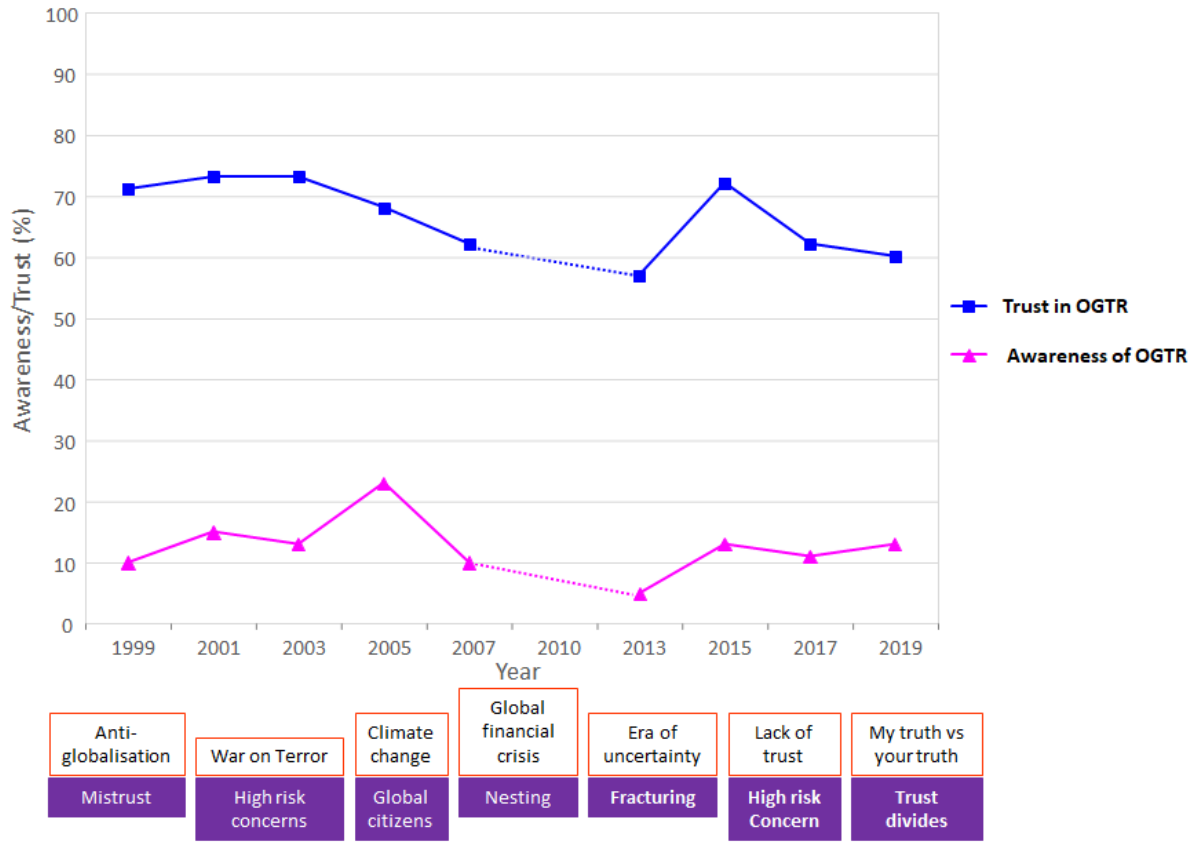


Figure 2: Awareness of and trust in the OGTR (and predecessor) from 1999 to 2019. Note that data is not available in all years. Dashed lines indicate where data was not available for intervening years. Adapted from Cormick and Mercer 2019.

The results of the most recent survey, conducted in 2019, provided some insights about differences in attitudes to GM plants within the broader public:

- a gradual decline in the proportion of respondents with strong concerns about GMOs in Australia, with an increase in the proportion who are undecided or don't know
- in general younger respondents were less concerned about different classes of modifications to plants, while older respondents were more likely to be concerned about most types of modifications in general and more concerned about specific types of modifications in particular;
- older respondents were more likely to answer 'don't know' when asked about their attitudes to specific types of plant modifications;
- male support for different types was higher than that for females and for most modifications male opposition was lower, females were also more likely to answer 'don't know'.

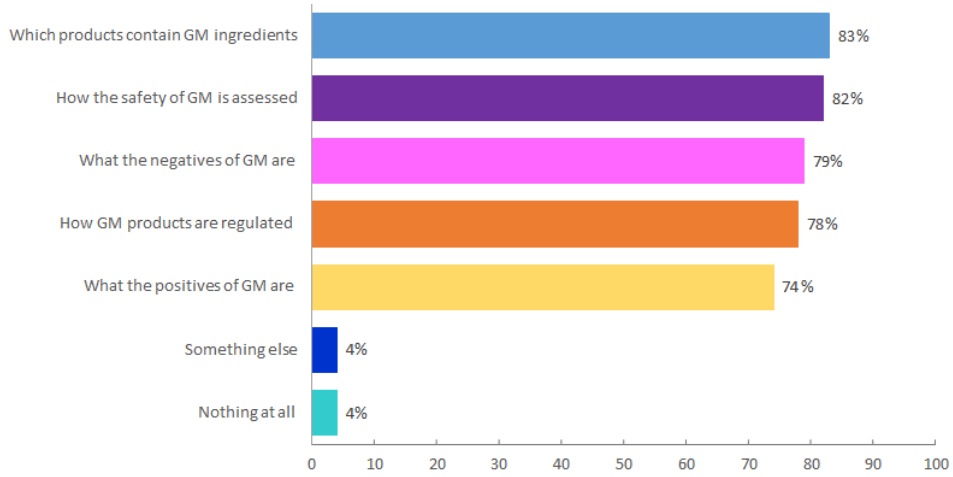
Additionally, four segments have been identified among the 'public':

1) strong support for gene technology
2) support for gene technology, but this is provisional support – 'yes, but…'
3) opposition to gene technology, but this is provisional opposition – 'no, however…'
4) strong opposition to gene technology

Among those with provisional support or provisional opposition to gene technology, there are key pieces of information that will help them to decide whether they support or oppose GM

technology. The key pieces of information will vary between people (or groups). For example, in terms of acceptance of GM foods, the two 'middle' groups could be described as supporting GM foods only if regulations are in place to make sure they're safe; and against GM foods until the science proves they are safe. Understanding what information is key to different groups and different individuals, is vital to providing it in a way that reaches those who are looking for it. This will enable them to make decisions based on objective information and to decide when and whether they want to provide input into the regulation of GMOs.

The most recent review of the Scheme outlined the types of information that were of interest to the public (Figure 3).



As mentioned in Chapter 2 of this report, community scientists are a section of the public that are using gene technology and as such are likely to be actively seeking technical information and information about the regulation of GMOs. They are likely to be seeking specific information that is different from that sought by other members of the public. The OGTR website provides information about regulation of community science activities, links to forms to apply to work with GMOs as necessary and guidance to assist with these.

Communicating about regulation

The OGTR's Science Strategy recognises the importance of keeping up to date with fast-evolving developments in the field. This enables regulatory science and the regulatory system to anticipate and respond to change. The strategy notes that new scientific information can reveal the possible risks associated with some work with GMOs.

Staying up to date with emerging technology is crucial. OGTR staff monitor relevant literature and interact with stakeholders involved in research, development and commercialisation activities. This helps them to identify scientific advances that can have an impact on regulatory science, current approvals and future risk assessments. In response to this new knowledge, the Regulator can recommend changes to the Regulations, for consideration by the Gene Technology Ministers in the first instance, and then for formal amendment of the legislation through the usual parliamentary processes.

The most recent review of the Scheme (2018) contains a number of recommendations under the theme of 'Social and Ethical Issues' that relate to communication with a range of audiences, including the public and those who are regulated as part of the Scheme (regulated stakeholders). The review report also noted that some stakeholders believe that public acceptance of gene technology is a limiting factor for its use in Australia. Many of these stakeholders indicated that this is 'best addressed through ongoing public communication and informed debate'.

The recommendations related to communication identified a need for:

- targeted communication from the appropriate channels to aid understanding of, and confidence in, the Scheme;

- the Regulator to maintain a high level of transparency and communication around risk assessment, risk identification and management of risks undertaken by the OGTR;
- science-based review of monitoring activities ensuring post release risks continue to be managed appropriately; and
- the Regulator continuing to provide information and maintain a high level of transparency.

Currently the OGTR provides information to people and organisations working with GMOs through the website, which contains guidance about how to apply to work with GMOs and the forms required to do so. It also provides links to the Act and the Regulations and information about Monitoring and Compliance activities. Every two years the OGTR runs a meeting for the Institutional Biosafety Committees (IBCs) from accredited organisations that work with GMOs.

Emerging technologies have been discussed in Chapter 2 of this report. Some of these techniques - for example CRIPSR - provide relatively simple methods to make increasingly precise changes to organisms. They may be used to insert genetic material into an organism, or to make changes that do not introduce genetic material. If only small changes are made to the organism's genetic material, the changes may be the same as those that could occur in nature, including with conventional breeding. If larger changes are made to an organism's genetic material, these are changes that would not arise in nature, including with conventional breeding. Understanding the nature of the differences between these outcomes is key to understanding how organisms are regulated. This presents challenges not only for regulation of such organisms, but also for communication of the regulatory process to a broad range of interested people, including the public and the scientific community. Understanding what information different sectors of the public and regulated stakeholders are seeking is key to ensuring that the Regulator can meet those needs where appropriate.

Around the world, governments and citizens are discussing appropriate regulatory approaches to manage future advances in gene technology, and biotechnology more broadly. The work of the OGTR reflects and contributes to development and international harmonisation of regulatory best practice.

Since the start of the scheme, Australian gene technology regulatory practices have been held in high regard, both locally and internationally. As a result, OGTR staff are often invited to contribute to capacity building, training and information exchange with other regulators. They engage regularly in multilateral fora to develop common approaches to risk assessment for GMOs. Locally, the OGTR interacts with other regulators both formally and informally. Participation in Regulatory Science Network which brings together staff from a range of regulators across Australia enables sharing of information about regulatory science, strengthening the knowledge across regulatory agencies.

The OGTR provides technical advice to support Australian engagement in international activities, such as those that the United Nations (UN) holds. These include the UN Convention on Biological Diversity and the UN Cartagena Protocol on Biosafety. The OGTR supports the Department of Agriculture, Water and the Environment at international conventions and protocol meetings (DoH 2019:11).

In addition, the OGTR remains engaged in international discussions about the regulation of new technologies, including synthetic biology and gene drives. The OGTR has contributed to work by the International Union for Conservation of Nature. It also supports New Zealand's work to educate and engage the public on gene editing. The OGTR has lead or contributed to a number of consensus documents published by the OECD. These provide technical information about the biology of organisms or introduced traits that can be used during regulatory assessment of products of biotechnology, including GMOs.

Monitoring and compliance

Another recommendation of the review relates to ensuring that the Scheme's current monitoring and enforcement activities remain adequate:

- undertaking regular reviews of these activities;
- communicating the regulatory requirements for working with gene technologies and ensuring that they are known widely
- monitoring the scope and associated risks of 'DIY biology' activity (DoH 2018a:10).

Encouraging compliance in order to prevent adverse outcomes is key to the OGTR's approach to monitoring and compliance. The strategy is based on cooperation, including early engagement and open dialogue with stakeholders. Effective communication increases the knowledge of the regulation of GMOs among regulated stakeholders and helps to build trust and confidence in the regulatory system. Information exchange and educational activities encourage people to adhere to the legislation. They become aware of the benefits of compliance as well as the risks of non-compliance.

The Monitoring and Compliance Framework contains information on how the OGTR meets both current and future regulatory needs. It sets out the key elements of:

- the legislative framework
- the regulatory framework
- the OGTR approach to monitoring.

The OGTR's monitoring program includes both environmental releases (DIRs) and dealings conducted in certified containment facilities or in clinical facilities under DNIR licences and NLRDs. Certified facilities are classified according to their physical containment (PC) level. PC4 and PC3 laboratories, and PC2 large-scale laboratories are intended to contain GMO dealings that need higher levels of containment. Inspections of facilities consider the integrity of a facility's physical structure, as well as the work practices used to manage GMOs.

To ensure that regulated entities comply with the legislation, OGTR inspectors undertake monitoring and compliance activities, together with general communication, education and outreach. Monitoring activities may be routine, responsive and strategic (OGTR 2018:9). Inspections of contained facilities (certified and clinical facilities), inspections of field trial or clinical trial sites, practice reviews and audits are all conducted regularly. Monitoring and compliance staff can follow up incident reports that may relate to non-compliance with licence conditions by accredited organisations.

OGTR's monitoring activities include practice reviews, which aim to facilitate co-operative compliance and to help stakeholders understand their regulatory requirements. Practice reviews have been used since the beginning of the Scheme, however the way they have been used has evolved with changes in the regulatory landscape. Practice reviews have been used for varied purposes such as developing an understanding of governance arrangements in organisations, understanding how risks can be managed in unique facility structures and developing lines of communication to assist with risk management. Practice reviews can also be initiated in response to observations made by OGTR staff during monitoring activities.

In the last 3 to 4 years, the OGTR has responded to the increase in clinical trials involving GMOs by initiating practice reviews for all new clinical trial licence holders. Practice reviews provide a chance for new licence holders to interact with the OGTR, to discuss the practical application of licence conditions and to ensure that they are fully prepared before they start working with GMOs. These practice reviews have been popular with stakeholders and OGTR has received many positive responses. Any licence holder can ask for a practice review to check that the practices their organisation uses ensure that they are conducting dealings in accordance with the Act. Practice reviews help to ensure that any risks to human health or the environmental are able to be managed.

During inspections OGTR staff can identify issues that could cause problems before they occur and to work with licence holders to promote best practices. The OGTR encourages cooperative compliance where people are well educated about any risks of working with GMOs and the compliance measures that mitigate those risks, and are confident to work with the OGTR to ensure compliance. This involves providing high quality, relevant information to regulated stakeholders as part of the monitoring and compliance processes.

The scheme has seen a high level of compliance by individuals and organisations. The OGTR recognises that compliance and enforcement mechanisms are 'necessary to provide a flexible, effective and efficient regulatory scheme' (OGTR 2018:11). However, the role of the Regulator is to 'effectively manage risk' rather than eliminate it completely (OGTR 2018:5).

The OGTR also carries out audits to verify that accredited organisations have relevant and effective management procedures and practices in place to ensure they meet their requirements under the Act. Documentary evidence, observations, and assessments of procedures and practices may be required as part of an audit. They may focus on a single dealing or issue, a range of dealings, the activity of an organisation across a range of dealings, or an activity common to a range of organisations. The OGTR can initiate audits or conduct them at the request of an accredited organisation.

Audits can help the OGTR to identify and resolve emerging risks, and where appropriate, suggest ways to improve procedures and practices. As such, audits provide another opportunity for education and sharing information.

The OGTR also conducts investigations when non-compliance with the Act and corresponding state laws is suspected. An investigation may be initiated after monitoring by the OGTR, through self-reporting by an accredited organisation, or third-party reporting. An investigation involves gathering relevant information to determine whether a non-compliance has occurred and if so, how it should be managed.

Community science – or 'biohacking' - covers a wide range of possible experiments and activities, which may involve the use of GMOs, with groups and individuals sharing their information with others. Engagement with community scientists through monitoring and compliance activities provides information about how to comply with the laws to work with GMOs to ensure that any risks are managed through education and compliance.

The OGTR is responsible for implementing a risk-based national strategy to manage potential unintended presence of unapproved GMOs in seeds imported for sowing in Australia - the National Strategy for Unintended Presence of Unapproved GMOs. A number of GM crops approved for commercial use overseas have not been approved for commercial planting in Australia, so it is possible that seed imports could contain GM seeds that could potentially establish in the Australian environment. The strategy was proposed and developed in 2005 under the Australian Government Biotechnology Ministerial Council. The strategy focusses on areas posing the highest likelihood of unintended presence of GMOs. The OGTR has worked with the Australian Seed Federation to develop a voluntary testing program of existing industry quality assurance measures (DoH 2017:53).

The OGTR issued licences for inadvertent dealings for the first time in 2016–17, for GM petunias that had not been approved for commercial release and were unknowingly imported into Australia. The OGTR published appropriate methods for disposal of the GM petunia seed and plant materials and worked with the Australian-based importers and suppliers to ensure that businesses understood that the GM petunias must not be propagated and sold, and that they had to be disposed of using the appropriate methods.

To ensure compliance with inadvertent dealing licences that were issued, OGTR inspectors visited the Australian-based importers and suppliers to ensure that nurseries were able to dispose of their seed stocks and plants in accordance with the licence conditions. Follow-up monitoring and communication with industry in 2017–18 was also part of the activities designed to ensure that the GM petunias were not sold or propagated by wholesalers and that their import and supply ceased.

Communication provided by the Regulator through the OGTR can ensure that the regulation of GMOs in Australia is robust, evidence-based and effective. For a wide range of people and organisations in Australia, whether they are working with GMOs, interested to know more about GMOs or concerned about the presence and regulation of GMOs in Australia, documents, notifications and other information available. Participation in local, national and international regulatory communities ensures that relevant information can be exchanged across a broad range of communities. Working with regulated communities to improve understanding and compliance promotes a system in which information can be exchanged freely and openly. All of these practices contribute to ensuring that the regulation of GMOs in Australia is robust and transparent.

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Shortened forms

DIR	dealing involving intentional release into the environment
DNIR	contained dealing with GMO not involving intentional release into the environment
EDD	emergency dealing determination
GM	genetically modified
GMAC	Genetic Manipulation Advisory Committee
GMO	genetically modified organism
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTMC	Gene Technology Ministerial Council
GTMM	Gene Technology Ministers' Meeting
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
IOGTR	Interim Office of the Gene Technology Regulator
LGFGT	Legislative and Governance Forum on Gene Technology
NLRD	notifiable low risk dealing
OGTR	Office of the Gene Technology Regulator
PC	physical containment
RAF	Risk Analysis Framework
RARMP	risk assessment and risk management plan
Regulator	Gene Technology Regulator