



How are genetically modified organisms (GMOs) regulated in Australia?



The import and use of genetically modified organisms (GMOs) in Australia is regulated through a nationally consistent legal scheme, including the Commonwealth *Gene Technology Act 2000* (the Act), the Gene Technology Regulations 2001 and corresponding state laws.

The Gene Technology Regulator (the Regulator) regulates the use of GMOs in Australia to:

- protect Australians' health and safety
- protect the environment
- identify and manage risks.

Governance

- The Regulator is appointed by the Governor General of Australia.
- The Regulator is supported by the Office of the Gene Technology Regulator (OGTR).
- The gene technology regulatory scheme guides the work of the Regulator and of the other relevant agencies.
- Commonwealth, State, and Territory Ministers oversee the gene technology regulatory scheme through the [Gene Technology Ministers' Meeting \(GTMM\)](#).
- The [Gene Technology Standing Committee](#), a committee of senior officials from all jurisdictions, provides high-level support to the LGFGT.

The Regulator has specific responsibility 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 genetically modified organisms (GMOs).

The Regulator's roles and functions

The Act sets out the functions of the Regulator to:

- perform functions in relation to GMO licences as set out in the Act
- develop draft policy principles and policy guidelines, as requested by the LGFGT
- develop codes of practice
- provide information and advice to:
 - other regulatory agencies, about GMOs and GM products
 - the public, about the regulation of GMOs
 - the Legislative and Governance Forum on Gene Technology about the
 - operations of the Regulator and GTTAC
 - effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation
- issue technical and procedural guidelines in relation to GMOs

- undertake or commission research in relation to risk assessment and the biosafety of GMOs
- promote the harmonisation by regulatory agencies of risk assessments relating to GMOs and GM products
- monitor international practice in relation to the regulation of GMOs
- maintain links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia
- conduct other functions conferred by the Act, the Regulations or any other law, such as monitoring and enforcing the legislation

Open community communication

The OGTR maintains open communication with the wider community:

- via the [OGTR news](#) register where anyone can subscribe to receive news and notifications from the OGTR
- by seeking comment before making a decision on any application to release a GMO into the environment (eg a new GM crop);
- by maintaining the [GMO Record](#), a public register of the status of all applications and approvals to release a GMO into the environment
- via the [OGTR website](#) and [annual reports to Parliament](#).





The advisory committees

The two advisory committees are established under the *Gene Technology Act 2000* to provide the Gene Technology Regulator with expert advice on scientific, community and ethical issues.

These are:

- [Gene Technology Technical Advisory Committee](#) (GTTAC), providing expert scientific and technical advice, and
- [Gene Technology Ethics and Community Consultative Committee](#) (GTECCC), providing advice on ethical issues and on matters of general concern to the community.

GTTAC must include a person who is a member of GTECCC, and a layperson. GTTAC also provides advice to the Regulator for the risk assessment and risk management plans prepared for all applications to work with GMOs in the environment, all applications for clinical trials involving GMOs, and for some applications to work with GMOs which don't involve environmental release.

GTECCC must include a person who is a member of GTTAC and a person who is a member of the [Australian Health Ethics Committee](#).

The recommendations of the committees are published in communiqués after each meeting.

More information on the work of the committees including communiqués and other publications can be found on the [GTTAC](#) and [GTECCC](#) web pages.

The national framework

The gene technology regulatory scheme is overseen by the [Gene Technology Ministers' Meeting](#) (GTMM), which is made up of Ministers from the Commonwealth and each state and territory.

A number of other Australian government regulators also oversee work with GMOs, depending on the use of the GMO. The *Gene Technology Act 2000* was set up to avoid overlapping with their responsibilities. These regulators include:

- [Australian Pesticides and Veterinary Medicines Authority](#) (APVMA) handle veterinary products and agricultural chemicals produced in, or used on, crops.
- [Department of Agriculture, Water and the Environment](#) handle quarantine; all animal, plant and biological products that could pose a risk if they were imported; import permit applications. Formerly the Australian Quarantine & Inspection Service (AQIS) and DAFF Biosecurity
- [Food Standards Australia New Zealand](#) (FSANZ) handle food issues, including labelling and mandatory pre-market safety assessments for GM foods.
- [Australian Industrial Chemicals Introduction Scheme](#) (AICIS) assesses the risk of industrial chemicals and provides information to promote their safe use.
- [Therapeutic Goods Administration](#) (TGA) handle medical issues (including GM and GM-derived therapeutic products)

[Related factsheets](#)

[Genetically modified organisms in Australia](#)

[Genetically modified \(GM\) crops in Australia](#)

Version 2

November 2021

