



## **FACT SHEET**

### **Overview of the Gene Technology Regulatory System**

The development and use of genetically modified organisms (GMOs) in Australia is regulated through an integrated legislative framework which includes the Gene Technology Regulator (the Regulator) and a number of other regulatory authorities with complementary responsibilities and expertise (see table). This arrangement both enhances coordinated decision making and avoids duplication.

The *Gene Technology Act 2000* (C'wth) (the Act) and the *Gene Technology Regulations 2001*, in conjunction with corresponding State and Territory legislation, underpin the national scheme for the regulation of live and viable GMOs in Australia. The implementation of the scheme is overseen by the Gene Technology Ministerial Council, which comprises representation from all Australian jurisdictions.

The object of the Act is “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”.

Marketing and trade impacts are outside the scope of assessments required by the Act, which preserves the right of the States and Territories to enact their own laws to address these issues.

The Act prohibits all dealings with GMOs unless the dealing is:

- a licensed dealing;
- a Notifiable Low Risk Dealing (NLRD);
- an Exempt dealing;
- included on the GMO Register; or
- specified in an Emergency Dealing Determination (EDD).

Information about each of these types of dealings is provided in the fact sheet *Types of GMO Dealings*.

The Regulator is an independent statutory office holder who administers the Act and has extensive powers to monitor and enforce the legislation. The Regulator must not issue a licence to deal with a GMO unless satisfied that any risks posed by the dealing are able to be managed in such a way as to protect the health and safety of people and protect the environment.

Openness and transparency are built into the regulatory system through requirements in the gene technology legislation for the Regulator to: maintain a publicly accessible record of GMO and GM product dealings; provide quarterly and annual reports to the Australian Parliament; and conduct extensive consultation with the public and a wide range of experts, agencies and authorities on applications for dealings involving the intentional release (DIR) of GMOs into the environment.

## Regulatory Agencies in Australia with a role in regulation of gene technology

Agency	What they regulated	Scope	Relevant Legislation
<b>OGTR</b> Office of the Gene Technology Regulator (supporting the Gene Technology Regulator)	<b>Dealings with GMOs</b>	The Gene Technology Regulator administers a national scheme for the regulation of GMOs in Australia, in order to protect health & 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.	<i>Gene Technology Act 2000</i>
<b>TGA</b> Therapeutic Goods Administration	<b>Medicines, medical devices, blood &amp; tissues</b>	TGA administers legislation that provides a national framework for the regulation of medicines, medical devices, blood and tissues in Australia, including GM and GM-derived therapeutic products, & ensures their quality, safety & efficacy.	<i>Therapeutic Goods Act 1989</i>
<b>FSANZ</b> Food Standards Australia & New Zealand	<b>Food</b>	FSANZ is responsible for setting standards for the safety, content and labelling of food. FSANZ conducts mandatory pre-market safety assessments for food produced using gene technology.	<i>Food Standards Australia New Zealand Act 1991</i>
<b>APVMA</b> Australian Pesticides & Veterinary Medicines Authority	<b>Agricultural &amp; Veterinary Chemicals</b>	APVMA operates the national system that regulates all agricultural chemicals (including those produced in or used on GM crops) and veterinary therapeutic products. Assessments consider human and environmental safety, product efficacy (including insecticide and herbicide resistance management), and trade issues relating to residues.	<i>Agricultural &amp; Veterinary Chemicals (Code) Act 1994;</i>  <i>Agricultural &amp; Veterinary Chemicals Administration Act 1994</i>
<b>NICNAS</b> National Industrial Chemicals Notification & Assessment Scheme	<b>Industrial Chemicals</b>	NICNAS provides a national notification & assessment scheme to protect the health of the public, workers & the environment from the harmful effects of industrial chemicals.	<i>Industrial Chemicals (Notification &amp; Assessment) Act 1989</i>
<b>AQIS</b> Australian Quarantine & Inspection Service	<b>Quarantine</b>	AQIS regulates the importation into Australia of all animal, plant & biological products that may pose a quarantine pest &/or disease risk. Import permit applications must indicate the presence of GMOs or GM material and the relevant authorisation under the <i>Gene Technology Act 2000</i> .	<i>Quarantine Act 1908;</i>  <i>Imported Food Control Act 1992</i>