

4.1 Australia



4.1.1 Gene Technology Act 2000 (2001)

The GT Act provides the framework for the Australian system of regulation for GMOs (including plants, animals and microorganisms). It is the Australian Government's component of the nationally consistent regulatory scheme for gene technology.

The objective of the gene technology legislation 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.

The Act establishes the position of the Gene Technology Regulator (the GT Regulator), an independent statutory officer, to administer the legislation. It prohibits anyone dealing with a GMO (e.g. for research, manufacture, production, breeding, propagation, commercial release or import) unless the dealing is an exempt dealing or a Notifiable Low Risk Dealing (classes of contained GMO work demonstrated to pose minimal risk to people and the environment, specified in the Regulations); or on the GMO Register; or licensed by the GT Regulator.

The use of GM products is regulated by other regulatory agencies. The GT Regulator does not directly regulate the use of GM products that are not live and viable. The GT Regulator provides advice on the genetic modification aspects of such products to other regulatory authorities for food, therapeutic goods, industrial chemicals, and agricultural and veterinary chemicals.

The GT Regulator is required to maintain a publicly available record of GMO and GM product dealings, including information on licensed dealings, Notifiable low risk dealings, dealings on the GMO Register, and GM products approved by other regulatory authorities.

4.1.2 Gene Technology (Consequential Amendments) Act 2000

The Act requires that the existing regulators of GM products, which operate under the existing schemes for the regulation of food, therapeutic goods, industrial chemicals, and agricultural and veterinary chemicals must consult the GT Regulator in relation to any application for approval of a GM product.

4.1.3 Gene Technology Regulations 2001 (Amended in 2007 by the Gene Technology Amendment Regulations 2006)

4.1.4 Guidelines issued by the GT Regulator

The Regulations supports the implementation of the GT Act by providing technical details, such as the categorization of different dealings with GMOs, as well as specifying administrative processes and procedures.

The Amendment Regulations 2006 commenced on 31 March 2007, amending the 2001 Regulations.

Various technical and procedural Guidelines, issued by the GT Regulator under the GT Act, describe additional requirements in relation to dealings with GMOs.

Source:

1. *The office of the Gene Technology Regulator (2004) Handbook on the Regulations of Gene Technology in Australia- A users guide to the Gene Technology Act 2000 and related legislation (pdf)*. (Available at www.ogtr.gov.au; accessed on 26 November 2007.)
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