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Agricultural Biotechnology Annual

2017 Agricultural Biotechnology Report

Approved By:
Rey Santella, Agricultural Counselor
Prepared By:
Lindy Crothers, Agricultural Marketing Specialist

Report Highlights:
The Australian federal government is very supportive of biotechnology and has committed considerable long-term funding to research and development. The Australian Productivity Commission recently completed an inquiry into the regulatory burden on farm businesses focusing on regulations that have a material impact on the competitiveness and productivity of Australian agriculture, including the impact of GE regulations. Technical reviews of the Gene Technology Regulations 2001 and the relevant Standard of the Food Standards Code are currently underway to provide clarity regarding regulatory capture of new technologies.

REPORT OUTLINE

EXECUTIVE SUMMARY

The United States has substantial interest in Australia's policies and regulatory framework regarding agricultural biotechnology and products derived thereof because of the impact this has on the ability of the United States to export to Australia. Unprocessed (whole) biotech corn and soybeans have not received regulatory approval in Australia and cannot be imported without further processing. Foods with biotech content of over one percent must receive prior approval and be labeled. This requirement can restrict sales of U.S. intermediate and processed products. Australia's policies and views on this technology influence other which may potentially lead them to developing a similar regulatory system of their own.

The biotech debate remains important in Australia. The federal government is very supportive of the technology, has committed considerable long-term funding to research and development, and approved GE cotton, carnations and canola varieties for general release. The state governments have also committed funds for research and development. Initially most states were cautious about the introduction of the technology and initially put in place moratoria on new plantings of biotechnology crops. After a number of state-level reviews in New South Wales (NSW), Victoria, and Western Australia have lifted their moratoria on GE canola.

South Australia, Tasmania, and the Australian Capital Territory (ACT) have maintained their moratoria and NSW maintains a moratorium on the growing of GE food crops. The South Australian government is currently (November 2017) in the process of passing legislation to continue their ban until at least 2025. Major farm groups and the Commonwealth government's science organizations do not support this position and have argued openly for acceptance of biotech crops.

The Australian Productivity Commission has recently undertaken a public inquiry into the regulatory burden on farm businesses. The inquiry focused on regulations that have a material impact on the competitiveness and productivity of Australian agriculture, with the aim of defining priority areas for removing or reducing unnecessary regulatory burdens on farm businesses, and, identifying unnecessary restrictions on competition. Two of the recommendations are of relevance to agricultural biotechnology (see Part B Policy).

To date, biotech cotton, canola and carnation varieties are the only agricultural crops approved for commercial release in Australia. The lifting of the moratoria in New South Wales, Victoria and Western Australia has seen plantings of GE canola increase rapidly. Research is being conducted on other biotech crops, with field trials controlled by The Office of the Gene Technology Regulator (OGTR), including crops such as banana, barley, carnation, cotton, cotton, Indian mustard, potato, safflower, sorghum, sugarcane, wheat, and white clover. Approval has already been granted for food products derived from biotech alfalfa, canola, corn, cotton, potatoes, rice, soybean, and sugar beet. A list of currently approved biotech food products is contained in Schedule 26 of the Australia New Zealand Food Standards Code.

For "GMOs" that have not received regulatory approval in Australia, U.S. export opportunities are obviously restricted. For the United States, the commercial impact of this constraint is most pronounced for feed grains, e.g. whole corn and soybeans as these products have not yet received regulatory approval. In addition to this market access restriction, Australia does not allow the importation of many grains and/or grain products for phytosanitary reasons, citing the need to limit exotic weed seeds.

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: See table under the "Regulatory Framework" section for a list of products approved for field trials. A map of trial sites is available on the OGTR website at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/map.

The Commonwealth Scientific and Industrial Research Organization (CSIRO) is currently undertaking research on a range of other techniques in the areas of agriculture, biosecurity and environmental sciences. Examples include:

- RNAi (gene silencing) technology for developing wheat varieties with beneficial traits; increasing aquaculture productivity; virus-resistant plants; healthier cottonseed oil; and better biofuels.
- Marker-assisted breeding – a conventional technique allowing breeders to track genes without using transgenic approaches. Projects include identifying resistance genes providing growers the ability to protect wine grapes from mildew and helping cattle breeders select for hornless cattle.

b) COMMERCIAL PRODUCTION: Biotech cotton, canola and carnations are the only crops approved for commercial release by Australia's Gene Technology Regulator (the Regulator). It is estimated that biotech cotton varieties are grown on almost all of Australia's cotton area. The Regulator approved the commercial releases of two biotech canola varieties in 2003. In 2008 GE canola was grown commercially for the first time in Australia following the lifting of the moratoria in New South Wales and Victoria. In November 2008, Western Australia lifted its ban to allow biotech cotton to be grown in the Ord River region, and in April 2009 WA announced that trials of GE canola would be allowed at 20 sites in that state. In October 2016 WA repealed the 2003 *GM Free Areas Bill* thus allowing approved GE crops to be grown freely in that State.

In 2006, biotech carnations became the first biotech product to be assessed by the Regulator to "pose minimal risks to people or the environment, and are sufficiently safe to be used by anyone without the need for a license." They have accordingly been placed on the "GMO" Register.

A full list of GE crops authorized for commercial release can be found at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/cr-1.

Cotton

Biotech cotton has been grown commercially in Australia since the approval and introduction of the first GE variety in 1996. Almost 100 percent of the Australian cotton crop is made up of GE varieties. In addition, there are a number of new biotech cotton varieties currently being developed (see section on approvals in the Part B of this report).

Canola

Since 2003 a number of biotech canola varieties have been approved by OGTR. The first commercial plantings of these varieties took place in 2008 after the state governments in NSW and Victoria lifted their moratoria on commercial plantings of GE canola. In 2009 Western Australia allowed trials to begin and the first commercial plantings began in 2010.

According to industry sources, 491,528 hectares of GE canola have been planted in 2017, up from 446,226 hectares in 2016. GE canola varieties now make up approximately 24 percent of the total national canola crop.

Total GM Canola by Year (hectares)

	2009	2010	2011	2012	2013	2014	2015†	2016†	2017†
NSW	13,930	23,286	28,530	40,324	31,573	52,000	51,870	54,970	68,163
Vic	31,186	39,405	22,272	19,012	21,232	37,000	47,137	47,069	56,900
WA		86,006	94,800	121,694	167,596	260,000	337,527	344,188	366,466
National	45,116	148,697	145,602	181,030	222,414	349,000	436,534	446,226	491,528
Total Area of Canola (GM and non GM)	1,390,000	1,590,500	1,815,000	2,687,000	2,480,000	2,607,000	2,000,000*	2,125,000*	2,080,000*
% GM Canola	3%	9%	8%	7%	9%	13%	22%*	21%*	24%*

† The seeding rate is 2.5 Kg/Ha from 2009 to 2014 and 2.0 Kg/Ha from 2015 onwards. Improved crop genetics, vigor and establishment help contribute towards a lower seeding rate over time.
* The 2015, 2016 and 2017 total area figure represents those states that grow GM canola only (WA, VIC and NSW).
Source: Australian Biotechnology Council of Australia

Total GM Canola by State (%)

	2009	2010	2011	2012	2013	2014	2015	2016	2017
NSW	6%	8%	7%	5%	5%	9%	11%	10%	11%
Vic	13%	16%	6%	3%	5%	9%	13%	13%	14%
WA	0%	10%	12%	13%	14%	21%	30%	28%	34%
National	3%	9%	8%	10%	9%	13%	22%*	21%*	24%*

* The 2015, 2016 and 2017 total area/national figure represents those states that grow GM canola only (WA, VIC and NSW)

c) EXPORTS: GE crops grown in Australia have been developed in Australia. Given that almost 100 percent of Australia's cotton products come from GE varieties, it is more than likely that all exports of cotton and cotton products are GE varieties. Australia does not export cotton to the United States. In 2016 Australia exported 43,539 MT of cotton seed (for industrial use) to the U.S. (tariff code 1207.29). It is likely that this seed was from GE cotton varieties.

The Australian Department of Agriculture and Water Resources (DAWR) maintains an online Manual of Importing Country Requirements (MICoR) for meat, dairy, fish, live animals, plants and eggs and

non-prescribed goods (honey, processed foods). These databases list whether importing countries require a declaration of the presence or absence of biotech.

d) IMPORTS: Under the Gene Technology Act 2000, approval or authorization must be obtained to manage "GMOs." This means that the importation of live, viable "GMOs," is regulated under the Act. Importers need to apply to OGTR for a license or authorization to import any GE materials into Australia. OGTR and the DAWR work closely to regulate and enforce this situation. The application form for an import permit (for any product) contains a section relating to the GE status of the product. When importing GE seed/grain or seed/grain that is known to be mixed with any amount of a GE material, the importer is required to notify DAWR by marking 'yes' at the appropriate question in the Application for Permit to Import Quarantine Material. The permit application form also requires importers to provide details of the relevant authorization under the Act (e.g. OGTR license number of Notifiable Low Risk Dealings (NLRD), identifier number and name of assessing Institutional Biosafety Committee (IBC)). To verify authorizations, DAWR and the OGTR may exchange information that importers have provided to either agency.

Foods containing biotech materials must be approved by Food Standards Australia New Zealand and be labeled if the biotech content is greater than one percent before they can be sold in Australia. This applies to all domestically produced and imported food. A list of currently approved biotech food products is contained in Standard 1.5.2.

Processed animal feeds such as soy meal are not covered by biotech legislation in Australia. These products, therefore, do not require prior approval or a license (see Part B of this report) to be imported. There are, however, quarantine restrictions on some products. Unprocessed biotech products imported as feed (i.e. whole grain, etc.), would require a license from OGTR, as there is a possibility that seed could be released into the environment.

e) FOOD AID: Australia does not provide any direct food aid. The Australian Department of Foreign Affairs and Trade provides immediate humanitarian food assistance through agencies such as the World Food Program and the FAO.

f) TRADE BARRIERS: See Part B, paragraph g) below on labeling requirements.

PART B: POLICY

a) REGULATORY FRAMEWORK: The *Gene Technology Act 2000* (the Act) came into force on June 21, 2001 as the Commonwealth component of a national regulatory scheme. The Act and the associated Gene Technology Regulations 2001, provide a comprehensive process for the Gene Technology Regulator to assess proposed dealings with live and viable "GMOs" ranging from contained work in certified laboratories to general releases of GE organisms into the environment, and extensive powers to monitor and enforce license conditions. An Inter-Governmental Agreement, between the Commonwealth and the states and territories, underpins the system for regulating GE organisms in Australia. The Legislative and Governance Forum on Gene Technology (LGFGT) (previously the Ministerial Council for Gene Technology), comprising ministers from the Commonwealth and each state and territory, provides broad oversight of the regulatory framework and guidance on matters of policy that underpin the legislation. High level support is provided to the LGFGT by the Gene Technology Standing Committee, which comprises senior officials from all jurisdictions.

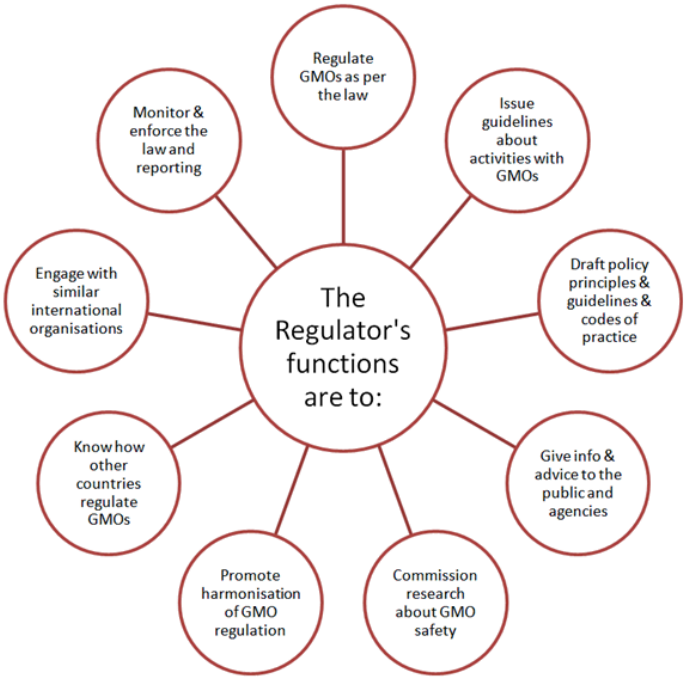
The object of the Gene Technology Act is: "To protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms."

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

- A licensed dealing;
- A notifiable low risk dealing;
- Included on the "GMO" Register;
- Specified in an Emergency Dealing Determination.

Key features of the Act are the appointment of an independent Gene Technology Regulator and a requirement for transparent and accountable implementation. The Regulator administers the regulation of all dealings with "GMOs" in Australia, in accordance with the Act and ensures compliance with the conditions of any approvals. The Regulator consults extensively with the community, research institutions and private enterprise.

Functions of the Gene Technology Regulator



The Gene Technology Regulator liaises with other regulatory agencies to coordinate the approval of biotech products for use and sale (see table below). The Act creates a Public Record of "GMO" Dealings and GE Products that resides on the OGTR website: www.ogtr.gov.au.

Regulatory Agencies in Australia with a Role in Regulation of Gene Technology

Agency	What They Regulate	Scope	Relevant Legislation
OGTR – Office of the Gene Technology Regulatory (supporting the Gene Technology Regulator)	Dealings with "GMOs"	The Gene Technology Regulator administers a national scheme for the regulation of "GMOs" in Australia in order to protect 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".	Gene Technology Act 2000

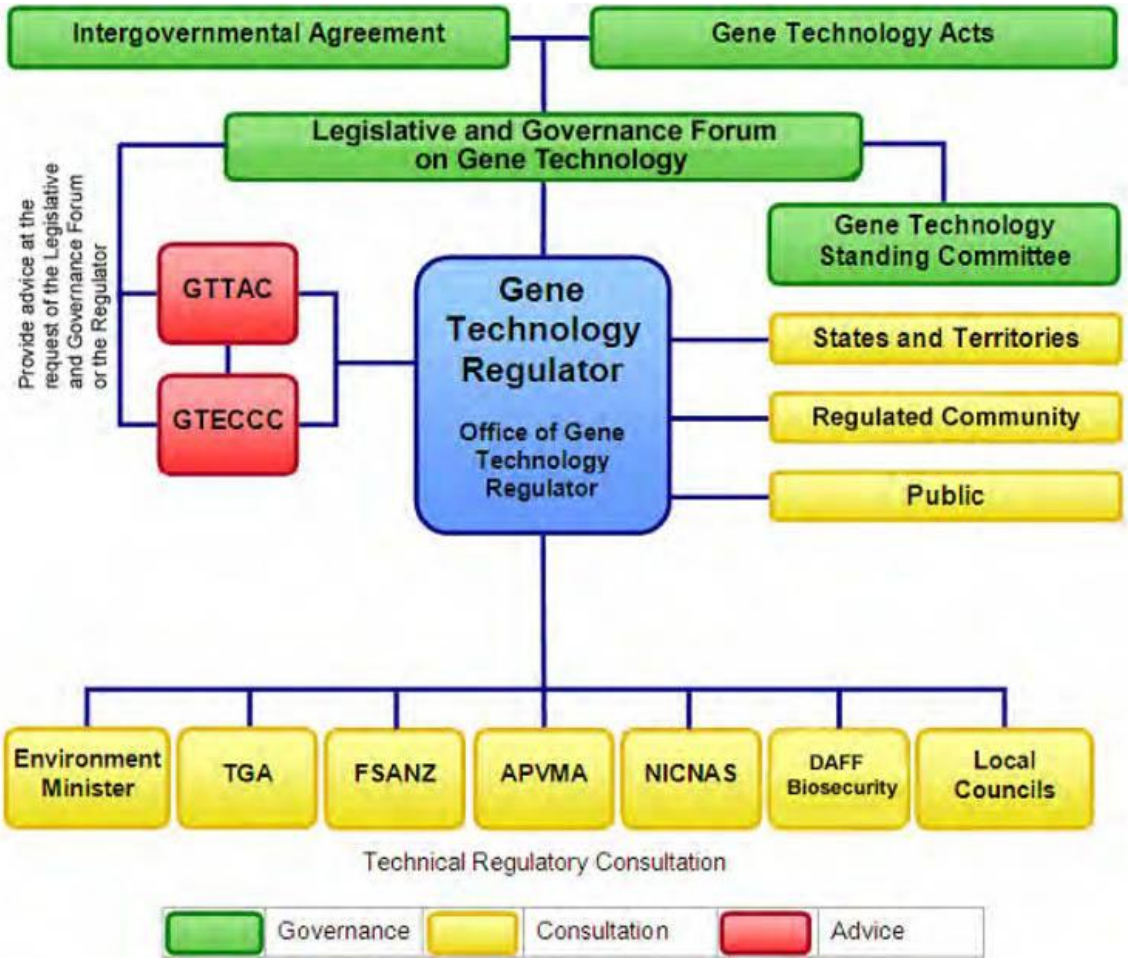
TGA – Therapeutic Goods Administration	Medicines, medical devices, blood and tissues	TGA administers legislation that provides a national framework for the regulation of medicines, medical devices, blood and tissues in Australia, including GE and GM-derived therapeutic products, and ensures their quality, safety and efficacy.	Therapeutic Goods Act 1989
FSANZ – Food Standards Australia New Zealand	Food	FSANZ is responsible for setting standards for the safety, content and labeling of food. FSANZ conducts mandatory pre-market safety assessments for food produced using gene technology.	Food Standards Australia New Zealand Act 1991
APVMA – Australian Pesticides and Veterinary Medicines Authority	Agricultural and Veterinary Chemicals	APVMA operates the national system that regulates all agricultural chemicals (including those produced or used on GE 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	Agricultural and Veterinary Chemicals (Code) Act 1994 Agricultural and Veterinary Chemicals Administration Act 1994
NICNAS – National Industrial Chemicals Notification and Assessment Scheme	Industrial Chemicals	NICNAS provides a national notification and assessment scheme to protect the health of the public, workers and the environment from the harmful effects of industrial chemicals.	Industrial Chemicals (Notification and Assessment) Act 1989
Department of Agriculture and Water Resources	Quarantine	The Department of Agriculture and Water Resources regulates the importation into Australia of all animal, plant and biological products that may pose a quarantine pest and/or disease risk. Import permit applications must indicate the presence of "GMOs" or GE material and the relevant authorization under the Gene Technology Act 2000.	Biosecurity Act 2015

The Act also establishes two advisory committees to advise the Gene Technology Regulator and the Legislative and Governance Forum on Gene Technology (LGFGT):

- The Gene Technology Technical Advisory Committee (GTTAC) – a group of highly qualified experts who provide scientific and technical advice on applications;

- The Gene Technology Ethics and Community Consultative Committee (GTECCC) – provides advice on ethical issues and on matters of general concern to the community in relation to GE materials and products.

Gene Technology Regulatory System



The Gene Technology Act 2000 distinguishes between "GMOs" and GM products. A genetically modified product - 'GM product' (referred to as GE product throughout this report) - means a thing derived or produced from a "GMO" (Section 10 of the Gene Technology Act).

OGTR does not directly regulate the use of GE products in Australia. However, the use of GE products is regulated by other regulatory agencies in a number of situations as set out in the table above.

The potential of agricultural biotechnologies to improve agricultural competitiveness was included in the Issues Paper (Issue 6: Improving the Competitiveness of Inputs to the Supply Chain) of the 2015 Agricultural Competitiveness White Paper. That issues paper states:

> "Agricultural biotechnologies, such as genetically modified crops, have the potential to transform agricultural productivity by delivering increased yields and lowering input costs. They

> can also improve environmental outcomes by reducing the need for inputs such as herbicides and water. Looking to the future, GE crops could better equip cropping systems to withstand drought, frost and other climate challenges. Biotechnology may also enable agricultural systems to be adapted to produce pharmaceuticals and products with industrial applications, potentially expanding the markets in which farmers can operate. Given the potential benefits of biotechnology to the agriculture sector, a regulatory regime in which consumers have confidence will be part of ensuring the benefits of biotechnology to the agriculture sector are fully realized. Australia has a strong regulatory framework to manage any risks to human health and safety and the environment from GE organisms and GE foods, but there continue to be limitations imposed by some states and territories on growing GE crops within their jurisdictions. These limitations have the potential to constrain the ability of farmers to adopt the latest available technologies to improve their productivity."

In the Green Paper (consultation paper), which was issued in October 2014, it was noted that:

> "Many stakeholders commented on the regulation of genetically modified (GM) organisms, with some advocating for GM technologies to facilitate higher productivity of Australian farms. Others pointed to the marketing advantage of GM-free status. Australia has a strong regulatory framework to manage any risks to human health and safety or the environment from GM technology. There continue to be limitations imposed by some States and Territories on growing GM crops for marketing reasons. Stakeholders noted the importance of national consistency. The Government believes that farmers should have the choice to adopt the approaches that best suit their business needs, including through the use of GM technologies."

The Australian Productivity Commission undertook a public inquiry into the regulatory burden on farm businesses in 2016 and the final report was publicly released in March 2017. The inquiry focused on regulations that have a material impact on the competitiveness and productivity of Australian agriculture, with the aim of defining priority areas for removing or reducing unnecessary regulatory burdens on farm businesses, and identifying unnecessary restrictions on competition. Two of the recommendations are of relevance to agricultural biotechnology:

- Regulation of technologies
  RECOMMENDATION 6.1: The New South Wales, South Australian, Tasmanian and Australian Capital Territory Governments should remove their moratoria (prohibitions) on genetically modified crops. All state and territory governments should also repeal the legislation that imposes or gives them powers to impose moratoria on genetically modified organisms by 2018.

  The removal of the moratoria and repeal of the relevant legislation should be accompanied by coordinated communication strategies designed to increase public knowledge about the benefits and risks to the Australian community from genetic modification technologies. The Australian, state and territory governments, the Office of the Gene Technology Regulator and Food Standards Australia New Zealand should actively coordinate their communication strategies.

- Food regulation
  RECOMMENDATION 10.1: The Australia and New Zealand Ministerial Forum on Food Regulation should amend its policy guidelines to make labelling of genetically modified foods

voluntary, and Food Standards Australia New Zealand should remove the requirement in the Food Standards Code to label genetically modified foods.

The biotech debate remains important in Australia. The federal government is very supportive of the technology, has committed considerable long-term funding to research and development, and approved GE cotton, carnations and canola varieties for general release. The state governments have also committed funds for research and development, but most were more cautious about the introduction of the technology and most Australian states initially put in place moratoria on new plantings of biotechnology crops. After state-level reviews in November 2007, New South Wales (NSW) and Victoria lifted the moratoria on GE canola. In November 2008, Western Australia (WA) lifted its ban to allow biotech cotton to be grown in the Ord River region and in April 2009 announced that trials of GE canola would be allowed. In early 2010, WA passed legislation allowing the commercial production of GE canola. The outcome of a 2014 court case (see details further down in this report) and considerable pressure from key farm lobby groups saw the WA Government repeal the 2003 *GM Free Areas Bill* in October 2016. This means that GE crops can be legally grown in WA without the need for annual exemptions – i.e. the growing of GE canola in WA since 2010 has required the WA government to pass an exemption to the Bill each year.

South Australia, Tasmania and the Australian Capital Territory (ACT) have maintained their moratoria and NSW maintains a moratorium on the growing of GE food crops. The South Australian government is currently (November 2017) in the process of passing legislation that will extend their moratorium until at least 2025. Major farm groups and the Commonwealth government's science organizations do not support this position and have argued openly for acceptance of biotech crops. Currently in Australia, almost 100 percent of the cotton planted is from biotech varieties, which were approved for release prior to the state moratoria. Although GE cotton varieties dominate the cotton industry in Australia, the state moratoria has slowed the commercialization and adoption of the technology for food crops.

The potential of agricultural biotechnologies to improve agricultural competitiveness was included in the Australian Government's 2015 Agricultural Competitiveness White Paper. The government indicated that "agricultural biotechnologies, such as genetically modified crops, have the potential to transform agricultural productivity by delivering increased yields and lowering input costs. They can also improve environmental outcomes by reducing the need for inputs such as herbicides and water."

As indications of the GE argument continuing to move forward in Australia, in August 2015 the Australian Senate passed a motion supporting GE crops for being "an environmentally friendly farming technology supported by scientific rigor;" and in January 2016, the leader of the Australian Greens party questioned the party's longstanding policy that calls for a moratorium on growing any GE crops and organisms – a move welcomed by Australian farm groups (but which has not led to the party changing their position on GE).

b) APPROVALS: The table below provides summary information about current Dealings for Intentional Release (DIRs) on the "GMO" Record (i.e. granted licenses for various uses including field trials). Full details of all applications (including those withdrawn and surrendered and those released for commercial use) can be found on the OGTR website at:
http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1

Crop	Applicant	Modified Trait	License Purpose
Sorghum (*Sorghum bicolor*)	University of Queensland	Composition - animal nutrition, Yield, Selectable marker - antibiotic	Limited and controlled release of sorghum genetically modified for grain quality traits
Wheat (*Triticum aestivum* L.) and **Barley** (*Hordeum vulgare* L.)	The University of Adelaide	Abiotic stress tolerance; enhanced yield; selectable marker	Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance and yield improvement
Wheat (*Triticum aestivum* L.)	CSIRO	Disease resistance, drought tolerance, Composition - food (processing), Composition - food (human nutrition)	Limited and controlled release of wheat genetically modified for disease resistance, drought tolerance, altered oil content and altered grain composition
Potato (*Solanum tuberosum* L.)	Queensland University of Technology	Disease resistance	Limited and controlled release of potato genetically modified for disease resistance
Indian mustard (*Brassica juncea*(L.) Czern. & Coss.)	Nuseed Pty Ltd	Composition - food (human nutrition), Composition - animal nutrition, Selectable marker	Limited and controlled release of Indian mustard (Juncea canola) genetically modified for altered oil content
Cotton (*Gossypium hirsutum* L.)	Monsanto Australia Limited	Insect resistance and herbicide tolerance	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance
Banana (*Musa*spp.)	Queensland University of Technology	Disease resistance, Selectable marker – antibiotic	Limited and controlled release of banana genetically modified for disease resistance
Cotton (*Gossypium hirsutum* L.)	Monsanto Australia Limited	Insect resistance and herbicide tolerance	Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (Bollgard® 3 XtendFlex™and XtendFlex™ cotton)

Crop	Applicant	Modified Trait	License Purpose
Cotton (*Gossypium hirsutum* L.)	Bayer CropScience Pty Ltd	Insect resistance and herbicide tolerance	Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (GlyTol® (BCS-GH002-5) and GlyTol TwinLink Plus® (BCS-GH002-5 x BCS-GH004-7 x BCS-GH005-8 x SYN-IR102-7))
Wheat (*Triticum aestivum* L.)	Victorian Department of Economic Development, Jobs, Transport and Resources (DEDJTR)	Yield and Abiotic stress tolerance Selectable marker – herbicide	Limited and controlled release of wheat genetically modified for enhanced nitrogen use efficiency and water use efficiency - Victorian Department of Economic Development, Jobs, Transport and Resources (DEDJTR)
Canola (*Brassica napus* L.)	Pioneer Hi-Bred Australia Pty Ltd	Herbicide tolerance	Commercial release of canola genetically modified for herbicide tolerance
Canola (*Brassica napus* L.)	Bayer CropScience Pty Ltd	Herbicide tolerance, Hybrid breeding system	Commercial release of canola genetically modified for dual herbicide tolerance and a hybrid breeding system
Cotton (*Gossypium hirsutum* L.)	CSIRO	Product quality – non-food, Selectable marker – antibiotic	Limited and controlled release of cotton genetically modified for enhanced fiber quality
Sugarcane (*Saccharum* spp.)	The University of Queensland	Yield, Selectable marker – antibiotic	Limited and controlled release of sugarcane genetically modified for enhanced sugar content – The University of Queensland
Carnation (*Dianthus caryophyllus* L.)	International Flower Developments Pty Ltd	Modified color , Selectable marker – herbicide	Commercial import and distribution of genetically modified carnation cut-flowers with altered flower color

Crop	Applicant	Modified Trait	License Purpose
Cotton (*Gossypium hirsutum* L.)	Bayer CropScience Pty Ltd	Herbicide tolerance, insect resistance	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance
Safflower (Carthamus tinctorius L.)	Go Resources Pty Ltd	Composition – non-food (processing), Selectable marker – antibiotic, Reporter gene expression	Limited and controlled release of safflower genetically modified for high oleic acid composition
Wheat (*Triticum aestivum* L. em Thell.)	Murdoch University	Composition – food (processing), Selectable marker – herbicide	Limited and controlled release of wheat genetically modified for improved grain quality
Sugarcane (Saccharum spp.)	Sugar Research Australia Ltd	Herbicide tolerance	Limited and controlled release of sugarcane genetically modified for herbicide tolerance
Wheat and barley (*Triticum aestivum*L. and *Hordeum vulgare* L.)	The University of Adelaide	Abiotic stress tolerance, Yield, Composition – food (human nutrition), Selectable marker – antibiotic	Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance or micronutrient uptake
Canola (*Brassica napus* L.)	Monsanto Australia Ltd	Herbicide tolerance	Commercial release of canola genetically modified for herbicide tolerance
Cotton (*Gossypium hirsutum* L.)	Monsanto Australia Ltd	Herbicide tolerance, Insect resistance, Selectable marker - antibiotic, Reporter gene expression	Commercial release of GM insect resistant and herbicide tolerant (COT102 x MON-15985 [Bollgard®III] and COT102 x MON-15985 x MON 88913 [Bollgard®III x Roundup Ready Flex®]) cotton
Canola (*Brassica napus* L.)	Nuseed Pty Ltd	Composition - food (human nutrition), Composition - animal nutrition, Selectable marker	Limited and controlled release of canola genetically modified for altered oil content

Crop	Applicant	Modified Trait	License Purpose
Wheat (*Triticum aestivum* L.)	Victorian Government Department of Environment and Primary Industries	Abiotic stress tolerance, Yield, Selectable marker – herbicide	Limited and controlled release of wheat genetically modified for enhanced yield stability
Safflower (*Carthamus tinctorius* L.)	CSIRO	Composition – non-food (processing), Selectable marker – antibiotic, reporter gene expression	Limited and controlled release of safflower genetically modified for increased levels of oleic acid (CSIRO)
Cotton (*Gossypium hirsutum* L.)	Monsanto Australia Ltd	Insect resistance and Herbicide tolerance	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance (Monsanto Australia Ltd)
Cotton (*Gossypium barbadense* L.)	Monsanto Australia Ltd	Herbicide tolerance	Commercial release of herbicide tolerant (Roundup Ready Flex®MON88913) pima cotton in Australia
Cotton (*Gossypium hirsutum* L.)	CSIRO	Yield, Selectable marker – antibiotic	Limited and controlled release of cotton genetically modified for enhanced fiber yield
Cotton (*Gossypium hirsutum* L.)	Bayer CropScience Pty Ltd	Insect resistance, Herbicide tolerance, Selectable marker - antibiotic	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance
Wheat and barley (*Triticum aestivum*L. and *Hordeum vulgare* L.)	CSIRO	Composition - food (human nutrition), Yield, Disease resistance, Abiotic stress tolerance, Selectable marker - antibiotic, Selectable marker - herbicide	Limited and controlled release of wheat and barley genetically modified for altered grain composition, nutrient utilization efficiency, disease resistance or stress tolerance
Banana (*Musa*spp.)	Queensland University of Technology	Composition - food (human nutrition), Selectable marker - antibiotic, Reporter gene expression	Limited and controlled release of banana genetically modified for enhanced nutrition

Crop	Applicant	Modified Trait	License Purpose
Canola (*Brassica napus* L.)	Bayer CropScience Pty Ltd	Herbicide tolerance/Hybrid breeding system	Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system
Canola (*Brassica napus* L.) **and Indian mustard** (*Brassica juncea* L.) Czern	Bayer CropScience Pty Ltd	Herbicide tolerance, Hybrid breeding system,	Limited and controlled release of canola and Indian mustard genetically modified for herbicide tolerance and/or a hybrid breeding system
Canola (*Brassica napus* L.)	Victorian Department of Primary Industries	Yield, Plant development, Selectable marker - antibiotic	Limited and controlled release of canola genetically modified for enhanced yield and delayed leaf senescence
Wheat and Barley (*Triticum aestivum*L. and *Hordeum vulgare* L.)	The University of Adelaide	Abiotic stress tolerance, Yield, Composition - food (human nutrition), Selectable marker - antiobiotic	Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance
Cotton (*Gossypium hirsutum* L.)	Dow AgroSciences Australia Pty Ltd	Insect resistance, Selectable marker - herbicide	Commercial release of cotton genetically modified for insect resistance (WideStrike™ Insect Protection Cotton)
White Clover (*Trifolium repens* L.)	Victorian Department of Economic Development, Jobs, Transport and Resources (DEDJTR)	Disease resistance, Selectable marker - antibiotic	Limited and controlled release of white clover genetically modified to resist infection by Alfalfa mosaic virus
Cotton (*Gossypium hirsutum* L.)	CSIRO	Composition - food (processing), Selectable marker - antibiotic	Limited and controlled release of cotton genetically modified for altered fatty acid composition of the cottonseed oil
Cotton (*Gossypium hirsutum* L.)	Monsanto Australia Ltd	Herbicide tolerance, Insect resistance, Selectable marker - antibiotic, Reporter gene expression	Commercial release of GM herbicide tolerant and/or insect resistant cotton lines north of latitude 22° South

Crop	Applicant	Modified Trait	License Purpose
Cotton (*Gossypium hirsutum* L.)	Bayer CropScience Pty Ltd	Herbicide tolerance	Commercial release of herbicide tolerant Liberty Link®Cotton
White Clover (*Trifolium repens* L.)	Victorian Department of Primary Industries	Disease resistance, Selectable marker - antibiotic	Field Evaluation of Genetically Modified White Clover Resistant to Infection by Alfalfa Mosaic Virus
Canola (*Brassica napus* L.)	Bayer CropScience Pty Ltd	Herbicide tolerance, Hybrid breeding system	Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system for use in the Australian cropping system
Canola (*Brassica napus* L.)	Monsanto Australia Ltd	Herbicide tolerance	General release of Roundup Ready® canola (Brassica napus) in Australia

Source: OGTR

c) STACKED EVENT APPROVALS: Stacked events must be licensed by the OGTR. For commercial release, this requirement can be met by either explicit listing of a particular stacked "GMO" in a license (through the license application process or license variation); or, inclusion of the specific conditions in the licenses for the parent "GMOs" to encompass stacking between genetic modifications listed in separate licenses.

Full details of the Office of the Gene Technology Regulator policy on GE stacking can be found at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmstacking08-htm.

d) FIELD TESTING: See above table for a list of products approved for field trials. A map of trial sites is available on the OGTR website at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/map.

e) INNOVATIVE BIOTECHNOLOGIES: The *Gene Technology Act 2000* (section 10) contains a broad definition of 'gene technology' and thus also a broad definition of 'genetically modified organism' (GMO). The Gene Technology Regulations 2001 (the Regulations) provide some exclusions to the definitions, some of which have not been changed since 2001. Under the current legislation there are challenges in applying the current definitions to some new technologies, however, the Regulator must apply the legislation as it stands.

A technical review of the Regulations is currently underway to ensure the level of regulation of activities with "GMOs" remains commensurate with risk according to current science. The review aims to provide clarity regarding regulatory capture of new technologies. It is anticipated that OGTR will open consultation on draft amendments in November 2017 until January 2018. Potential amendments could include such things as: exclusion of specific techniques or organisms from regulation by listing in the Regulations if they were not given clear treatment at the beginning of the scheme; or alter current exclusions if scientific understanding of the risk of particular techniques or organisms has changed since the Regulations were introduced in 2001.

Food Standards Australia New Zealand (FSANZ) is also reviewing how the Food Standards Code applies to food derived from new breeding techniques (NBTs) that were not in use when Standard 1.5.2 – Food produced using gene technology – was first developed nearly 20 years ago.

The review will consider the extent to which food derived from various NBTs should be captured for pre-market approval under Standard 1.5.2 and whether the definitions for 'food produced using gene technology' and 'gene technology' in Standard 1.1.2─2 should be changed to improve clarity about which foods require pre-market approval.

The review is expected to be completed by mid-2018, at which time FSANZ will consider whether to prepare a proposal to amend the Code.

f) COEXISTENCE: Coexistence of biotech, conventional, and organic crops has occurred in Australia since biotech cotton varieties were commercially grown in 1996. As part of any license to grow a biotech crop, OGTR stipulates the conditions under which the crop can be grown to ensure no cross-contamination with conventional or organic crops in the vicinity on a case-by -case basis. For license applications for environmental release of "GMOs," the Regulator must consult on the risk assessment and risk management plan with States and Territories, other Australian Government agencies, relevant local councils and the public.

Segregation and coexistence, along with other marketing and economic considerations, are managed through state specific regulations and industry protocols.

A survey in March 2014 of growers of GE canola found that co-existence had not been a major factor influencing grower behavior in terms of farmers living amicably with their neighbors or within the broader farming community. Nor had the issue of co-existence influenced farmer's choice in opting to grow, or not to grow, GE canola or whether to increase GE canola area.

A 2014 court case in Australia, where an organic farmer sued his neighbor for contamination of his fields with GE canola and lost (see GAIN report), brought the issue of coexistence with organic crops into the spotlight. The final judgment indicated that the National Association for Sustainable Agriculture Australia's (NASAA) organic standards were unclear and their zero-tolerance policy was unrealistic. This zero-tolerance threshold varies widely from those of other countries such as the EU and Japan, which have percentage thresholds, and the United States which has a process based system dealing with violations on a case-by-case basis. Note: The Australian organic standard is an organic industry standard only – i.e. there is no Australian government standard for organic production in Australia.

A number of publications on coexistence are available on the DAWR website at: http://www.agriculture.gov.au/ag-farm-food/biotechnology/reports. The Agricultural Biotechnology Council of Australia also maintains a mini-website focused on providing information on coexistence - http://coexistence.abca.com.au/.

g) LABELING:

Labeling of Biotech Food

Food Standards Australia New Zealand (FSANZ) is the Australian Government agency responsible for approving GE food products for the Australian market. Mandatory labeling of GE foods, where introduced deoxyribonucleic acid (DNA) or protein is present in the final food, came into force in Australia on December 7, 2001. Regulations for labeling are contained in Standard 1.5.2 of the Food Standards Code.

Under the Standard, food or ingredients labeled genetically modified contain new genetic material or protein as a result of the genetic modification or have altered characteristics, e.g. changed nutritional values, compared to the conventional food. Some flavorings may also be derived from GE organisms, but labeling is only required if they are in a concentration of more than one percent. Food additives and processing aids do not need to be labeled unless the introduced genetic material is present in the final food.

Under the labeling standard, if the one percent threshold of GE ingredients is present, packaged foods must use the words 'genetically modified' in conjunction with the name of the food, or in association with the specific ingredient within the ingredient list. For unpackaged foods for retail sale (such as unpackaged fruit and vegetables, or unpackaged processed or semi-processed foods) the words 'genetically modified' must be displayed in association with the food, or in association with the particular ingredient within that food.

Refined oil from biotech cottonseed does not require a label because the oil contains no genetic material and the cottonseed oil is identical to conventional cottonseed oil.

Labeling of Biotech Feed Products

GE animal feed does not require special labeling in Australia. These products do, however, need to be approved by the OGTR for use in Australia and must also meet biosecurity import conditions.

The DAWR and the OGTR must approve GE whole grain commodities (including oilseeds) imported into Australia for animal feed (such as whole soybeans and corn). The DAWR provides quarantine inspection and certification for the arrival of imports of the products to ensure the product is free of pest and disease and specific license conditions are enforced to ensure the product meets requirements. The OGTR also assesses the product, issues a license to the organization importing the product, and may apply further conditions above those stipulated by the DAWR.

Animal feed containing GE materials (e.g. whole grains or oilseeds) are regulated by the OGTR. The OGTR considers any biosafety risks associated with the product and, if necessary, will apply special conditions, or may prohibit the use of the product as animal feed. As an example, after a GE product has undergone field trials, the organization conducting the trials may wish to use the unviable by-product (such as seed) as animal feed. Before the product is used in any way, the Gene Technology Regulator will consider any risks and, if necessary, will apply conditions or disallow the product to be used. See: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmstockfeed-htm

Large amounts of biotech feed products are used in Australia's intensive livestock sector. A large proportion of Australia's soybean meal is imported, including from the United States. All cottonseed meal used in Australia is considered to be biotech as almost 100 percent of the cotton crop is planted to biotech varieties. Biotech and non-biotech cotton varieties are not typically segregated in Australia.

h) MONITORING AND TESTING: To ensure that GE products comply with regulatory requirements, the Regulatory Compliance area of the OGTR undertakes monitoring, audits, inspections and investigations under the auspices of the Gene Technology Act 2000. Monitoring and compliance activities also comprise risk assessment and management, reviews of an organization's activities and reporting.

i) LOW LEVEL PRESENCE POLICY: Australia has endorsed the International Statement on Low Level Presence of GE.

In October 2005, national consensus was achieved in Australia regarding practical thresholds to deal with the issue of traces of GE canola in conventional canola consignments and variety trials. The Primary Industries Ministerial Council (PIMC), which is comprised of Ministers from the Australian Government and each state and territory, agreed upon adventitious presence (AP) thresholds for the presence of GE canola in conventional grain and seed.

The PIMC meeting agreed on two thresholds:

- An AP threshold of 0.9 percent GE canola in canola grain. This is the threshold supported by the Australian Oilseeds Federation (AOF).

- A second threshold for AP of GE canola in seed was set at 0.5 percent for 2006 and 2007, to be reduced to 0.1 per cent thereafter. The Australian Seed Federation (ASF) established an AP threshold of 0.5 per cent GE seed in non-GE planting seed in 2003 following two years of research and consultation with the canola seed industry.

In 2005 the Australian Government Biotechnology Ministerial Council endorsed a risk-based national strategy to manage the unintended presence of unapproved GE in imported seeds for sowing. The OGTR is responsible for implementing the strategy which has six components (see table below) and employs a risk management approach with resources dedicated to the areas posing the highest likelihood of unintended presence.

Components of National Strategy for Unintended Presence of Unapproved "GMOs"

Component	Description
Risk profiling – identifying seed imports posing the highest likelihood of unintended presence	The OGTR has established a memorandum of understanding with AQIS to access data on imports. Data on imported seeds for sowing, together with information on overseas commercial production of GMOs and input from the Department of Environment, Water, Heritage and the Arts, and other relevant agencies was used to identify eight priority crops. Four additional crops that may pose a higher likelihood of unintended presence were subsequently identified.
Quality assurance/identity preservation	Industry uses quality assurance and identity preservation systems for seed quality purposes. The OGTR has developed a program for auditing and testing industry quality assurance systems that industry has agreed and adopted.
Laboratory testing	The OGTR's voluntary code of conduct refers to industry testing programs. Industry needs to be able to assure itself that it is managing the risk of importing unapproved seeds. Discussions between the OGTR and the National Measurement Institute about appropriate testing methodologies are ongoing.
Approvals/advance risk assessments for Australia's regulatory agencies	The OGTR has prepared GMO incident response documents for 12 crops identified through risk profiling as having the highest likelihood of unintended presence in imports of seeds for sowing (canola, cotton, maize, potato, tomato, papaya, soybean, squash, alfalfa, grasses, rice and wheat). These documents will provide a basis for rapid risk assessment and management actions should an unintended presence of an unapproved GMO be detected.

Component	Description
Post market detection	The OGTR recognizes the legislative limitations of preventing unintended imports of unapproved GMOs and has worked cooperatively with industry to develop a voluntary code. The code aims to isolate risks as early as possible in the commercial seed supply chain. In 2007 the OGTR inspected a number of the larger seed breeding operations. This allowed the OGTR to build its knowledge base of the industry and the QA systems used by the major players. These inspections focused on canola as the ASF had already developed GM testing protocols for this crop. In 2008 the OGTR and the Australian Seed Federation assessed the effectiveness of the first stage of reviews completed in 2007, noting that no issues of concern were identified for the five companies participating in the quality assurance reviews. The OGTR is continuing work with the Australian Seed Federation to expand the quality assurance review program as needed. These activities are supported by the standard OGTR practice of investigating information about potential and possible incidents.
Enforcement action	In the event of detection of unapproved GMOs, appropriate responses would be determined on a case-by-case risk management basis. The OGTR continues consultation with Australian Government agencies, relevant industry organizations and states and territories to develop an incident response plan.

Source: OGTR

j) ADDITIONAL REGULATORY REQUIREMENTS: Not applicable.

k) INTELLECTUAL PROPERTY RIGHTS (IPR): Intellectual property rights for plants are administered by IP Australia under the *Plant Breeder's Rights Act 1994*.

l) CARTAGENA PROTOCOL RATIFICATION: Australia has not signed or ratified the Biosafety Protocol and the Australian Government has no timetable for consideration of accession to the Protocol. This was due to concerns about how the Protocol will operate in practice (documentation requirements, and the liability and compliance arrangements are yet to be agreed), uncertainty about how parties will implement the Protocol and whether they will do so in a way which respects all of their international obligations, and uncertainty about any individual country's capacity to influence decision-making. The Australian government considers that the Protocol is not needed for Australia to manage biotech imports as Australia already has a robust regulatory framework through the OGTR.

m) INTERNATIONAL TREATIES/FORUMS: Under section 27 of the *Gene Technology Act 2000* the Gene Technology Regulator's functions include: monitoring international practice in relation to regulation of "GMOs"; maintaining links with international organizations that regulate "GMOs" in countries outside Australia; and, promoting harmonization of risk assessments relating to "GMOs" and GE products by regulatory agencies. The OGTR have established a significant international presence.

Australia participates in multilateral efforts to promote the application of science–based, transparent and

predictable regulatory approaches that foster innovation and ensure a safe and reliable global food supply, including the cultivation and use of agricultural products derived from innovative technologies. Since the Australian regulatory scheme began in 2001, the OGTR has been involved in multilateral forums and collaborations with counterpart agencies in other countries.

Australia is one of the supporting governments (along with Brazil, Canada, Argentina, Paraguay and the United States) of the "Joint Statement on Innovative Agricultural Production Technologies, particularly Plant Biotechnologies"; is a contracting party to the International Plant Protection Convention; has been a member of Codex since 1963; and participates in the OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology.

n) RELATED ISSUES: The Australian Centre for International Agricultural Research (ACIAR) has a policy for funding collaborative research projects involving "GMOs". Their policy statement on biotechnology includes the following points:

- ACIAR endorses the use of biotechnology as a valid tool in the quest for improved global food security and for reducing the environmental footprint of terrestrial food production.
- ACIAR recognizes that crop genetic engineering is one of a set of approaches in the development of improved crop varieties.
- ACIAR will initiate collaborative projects at the specific request of partner countries.
- Technologies will be developed and tested only in countries where effective biosafety, regulatory and enforcement systems for the use of "GMOs" are in force.
- ACIAR will collaborate with partners to link with extension systems to ensure improved varieties and technologies are disseminated.

ACIAR is an Australian Government statutory authority within the Foreign Affairs portfolio. ACIAR is Australia's specialist international agricultural research for development agency. Their core business is brokering and funding research partnerships between Australian scientists and their counterparts in developing countries as an element of the Australian Government's aid policy. They work primarily in four regions: Papua New Guinea and Pacific Island countries; East Asia; South and West Asia; and Eastern and Southern Africa.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS: A survey conducted by the Australian National University in August 2017 on Australian beliefs and attitudes towards science found that Australians would prefer eating GM foods (47 percent) to foods grown with pesticides (32 percent).

In late 2012, the Department of Industry commissioned research on community attitudes to biotechnology the results of which were published in March 2013. Previous surveys have been conducted every few years from 1999, to determine public attitudes towards biotechnology and biotechnology applications in Australia. This survey has not been carried out since 2012.

Key findings of the report were:

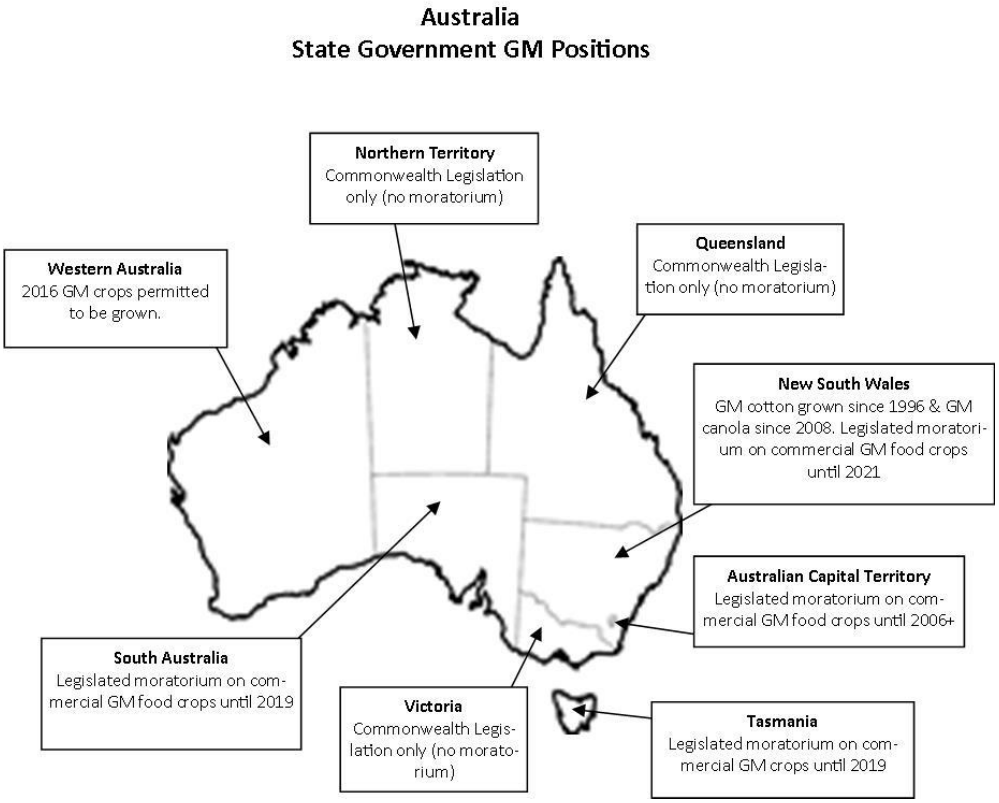
- Males, younger people and those who live in capital cities are more likely to support GE foods.
- Australian concerns about GE foods are comparable to concerns about pesticides and preservatives in foods.
- People are more supportive of GE foods that have health outcomes or are cheaper, and find lasting longer or tasting better only of minor benefit.
- Support for GE foods and crops has remained fairly consistent over the past few years, with about 60 per cent of the population willing to eat most GE foods, and about 25 percent not willing. However this figure changes depending on the type of food being modified, whether there are benefits to the consumer and perception of effective regulation.
- There are differences in attitudes to GE foods by gender, age and attitude to science and technology, with males scoring an average of 5.2 on a ten point scale of support for various GE foods and females scoring 4.0; people under 30 consistently rated a full point higher than those over 30; and those with a high support for science scored 6.6, while those who generally mistrusted science scored 4.0.
- The study also found that almost nine in ten Australians had heard of modifying genes in plants to produce food, and half felt the benefits of doing this outweighed the risks while one in six felt the risks outweighed the benefits.
- Just over half (52 percent) of the population were in favor of growing GE crops in their state and a third (32 percent) were opposed – but about six in ten of those opposed would change their mind if the crops could demonstrate positive outcomes for the environment, provide benefits to health, or pass stringent regulations.
- Conversely, many of those who supported growing GE crops in their state would change their position if benefits were not proven or it diminished farmers' competitiveness.

Full details of this report and those from previous years and other information are available on the Department of Industry website at:
http://www.industry.gov.au/industry/IndustrySectors/nanotechnology/Publications/Pages/Public-Attitude-Research.aspx.

b) MARKET ACCEPTANCE: Australia has a substantial, risk assessment based regulatory framework for dealings with gene technology and GE organisms and the Government is supportive of the technology for its agricultural producers and has been an ally of the United States with regard to the Cartagena Protocol on Biosafety (CPB). This comes despite anti-biotechnology activism in Australia

that promoted stringent labeling requirements and encouraged moratoria on biotechnology plantings.

Major Australian commodity groups originally voiced concerns about introducing biotech canola and advocated for a 'go-slow' approach largely because of the potential impact biotech canola, which OGTR approved for commercial release in 2003, could have on their domestic and export businesses. In 2003 and 2004, several state governments (Victoria, NSW, South Australia, Western Australia, Tasmania and the ACT), using their powers over commodity 'marketing', imposed moratoria on the commercial release of products of biotechnology (with the exception of the previously approved cotton and carnations). Most of the moratoria were reviewed in 2007, and the states of NSW and Victoria lifted their bans on commercial plantings of GE canola and the first commercial crops were grown in these two states in 2008. In November 2008, the Western Australian government lifted their moratoria to allow GE cotton to be grown in the Ord River area and in April 2009 they also announced that trials of GE canola would be allowed at 20 sites in that state. In October 2016 WA repealed the *2003 GM Free Areas Bill*, allowing approved GE crops to be grown freely in that state without the need for annual exemptions. Moratoria remain in place in South Australia, Tasmania and the ACT.



Currently in Australia almost 100 percent of the cotton planted is from biotech varieties, and there has been little controversy concerning its cultivation. Indeed, environmental benefits and the significant decline in pesticide and herbicide use for this crop have been widely reported. Biotech cottonseed does appear in the domestic market through the oil and meal, and this has not met with any major opposition.

MARKETING STUDIES

- Department of Agriculture and Water Resources
- Agricultural Biotechnology Council of Australia
- AusBiotech
- Australian Bureau of Agriculture and Resource Economics and Sciences (ABARES)
- National Farmers Federation
- Grains Research and Development Corporation (search for GM)
    - GM Canola Impact Survey

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: Researchers are using gene technology to improve the efficiency of animal production in Australia. This research, carried out by universities, Cooperative Research Centers (CRCs) and CSIRO, uses the natural genetic variation in livestock populations to selectively breed animals that produce more meat, milk and fiber. Genetic technologies are also used to develop new vaccines and treatments for preventing and diagnosing livestock diseases. Research which involves the genetic modification of animals to benefit animal and human health using new innovative biotechnologies, such as CRISPR/Cas9 genome editing techniques to produce such organisms as AI-resistant chickens and modify allergens in chicken eggs, is also being conducted.

The CSIRO are currently undertaking research on a range of other innovative biotechnologies in the areas of agriculture, biosecurity and environmental sciences. Examples include:

- RNAi (gene silencing) technology for developing novel vaccines to improve the immunity of chickens and silencing molecules against specific diseases such as avian influenza.
- Marker-assisted breeding – a conventional technique allowing breeders to track genes without using transgenic approaches. Projects include the Australian Poll Gene Marker test to help breeders select the best breeding cattle and help the industry end the need for dehorning cattle.
- Sex determination techniques for the egg and poultry industries to differentiate between male and female chicks pre-hatch which could improve animal production, reduce costs and eliminate ethical dilemmas.

In Australia, cloning of livestock is currently limited to small numbers of breeding cattle, predicted to be less than 100 beef and dairy cattle and a few sheep within a confined research environment. The work is being carried out by public and private research institutions and universities.

A full list of NLRDs, including the institutions carrying out the research, is available on the OGTR website at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/nlrdrec-1.

Organism	Applicant	Modified Trait	License Purpose
Infectious laryngotracheitis virus (*Gallid herpesvirus* 1).	Bioproperties Pty Ltd	Vaccine - attenuation	Limited and controlled release of a GM vaccine for chickens, Vaxsafe® ILT
Yellow fever virus (YF17D)	Sanofi-Aventis Australia Pty Ltd	Vaccine - altered antigen expression	Commercial supply of Dengvaxia, an attenuated GM dengue vaccine
Influenza virus	Clinical Network Services (CNS) Pty Ltd	Human therapeutic - attenuation	Clinical trial of live attenuated genetically modified influenza vaccines

Organism	Applicant	Modified Trait	License Purpose
Vaccinia virus	Clinical Network Services (CNS) Pty Ltd	Human therapeutic-attenuation, enhanced immune response. Reporter gene expression.	Clinical trial of a genetically modified virus for treatment of liver cancer - Clinical Network Services (CNS) Pty Ltd
Influenza virus	AstraZeneca Pty Ltd	Vaccine - attenuation	Commercial supply of attenuated GM influenza vaccines
Herpes simplex virus-1	Amgen Australia Pty Ltd	Therapeutic – attenuation, therapeutic – enhanced immune response	Commercial supply of a tumor-selective genetically modified virus for cancer therapy
Cholera bacterium (Vibrio cholerae)	PaxVax Australia Pty Ltd	Vaccine – attenuation, Selectable marker – other	Clinical trial of a genetically modified vaccine against Cholera
Escherichia coli	Zoetis Australia Research & Manufacturing Pty Ltd	Vaccine - attenuation	Commercial release of genetically modified vaccine to protect chickens against pathogenic *Escherichia coli*
Yellow fever virus (YF 17D)	Sanofi-Aventis Australia Pty Ltd	Vaccine - attenuation, Vaccine - antigen expression	Commercial release of a genetically modified live viral vaccine to protect against Japanese encephalitis (IMOJEV)™

Australian research involving gene technology and animals is regulated by the Office of the Gene Technology Regulator. In addition, GE and cloned animals are subject to state and territory government animal welfare legislation applicable to animals used for scientific purposes, in addition to the Australian code of practice for the care and use of animals for scientific purposes.

b) COMMERCIAL PRODUCTION: None for commercial use.

c) EXPORTS: None for commercial use.

d) IMPORTS: None for commercial use.

e) TRADE BARRIERS: Quarantine requirements are the main trade barrier to animal products entering Australia. These requirements would equally apply to any GE animal products. There are no additional biosecurity requirements for cloned animals or animal products.

PART E: POLICY

a) REGULATORY FRAMEWORK: Australian research involving gene technology and animals is regulated by the Office of the Gene Technology Regulator. GE and cloned animals are also subject to state and territory government animal welfare legislation applicable to animals used for scientific purposes, as well as the Australian code of practice for the care and use of animals for scientific purposes. GE animals are considered 'Notifiable Low Risk Dealings' (NLRDs) by the OGTR – i.e. "dealings with "GMOs" that have been assessed as posing low risk to the health and safety of people and the environment provided certain risk management conditions are met." A full list of NLRDs, including the institutions carrying out the research, is available on the OGTR website at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/nlrdrec-1.

The DAWR covers animal health (biosecurity) issues in their import risk assessments (IRAs). Cloned animals or products from cloned animals are not considered to be an animal health or biosecurity risk and have not been assessed as a hazard in the IRAs. There are no biosecurity restrictions in relation to the import of embryos derived from cattle, sheep or goats. The same applies for the import of products derived from cloned animals. They are subject to the same quarantine regulations as non-cloned products.

Food from cloned animals is not regulated in the same way as food from "GMOs". FSANZ considers that food products from cloned animals and their offspring are as safe as food products from conventionally bred animals and does not require any additional regulation such as they have for food derived from GE crops.

b) INNOVATIVE BIOTECHNOLOGIES: See Section II, Part B(e) above.

c) LABELING AND TRACEABILITY: There are currently a small number (30-40) cloned cattle in Australia being used for breeding purposes. Food from cloned animals is not currently entering the food chain but food from their offspring probably is. There is a voluntary agreement in place by Australian researchers and industry on the placing of food from cloned animals into the food chain. Food from cloned animals or their offspring does not require pre-market approval in Australia and there are no special labeling requirements. See FSANZ website for details.

d) INTELLECTUAL PROPERTY RIGHTS (IPR): Intellectual Property Rights in Australia are administered by IP Australia.

e) INTERNATIONAL TREATIES/FORUMS: See Part B, paragraph m) above.

f) RELATED ISSUES: N/A

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS: No products from GE or cloned animals are currently in the Australian food chain. Probably because of this, there does not seem to be any opinion pieces appearing in the media in Australia either for or against. The information contained in Part C above indicates that public attitudes towards biotechnology in general are favorable but those attitudes have changed over a number of years to become more accepting. It is likely that, initially, public opinion towards GE or cloned animal food products would be less accepting. Scientists from CSIRO and other research institutions have collaborated through the OECD on the barriers to the uptake of GM animals and how to determine a pathway to removing those barriers.

b) MARKET ACCEPTANCE: No specific market acceptance research has been conducted on the acceptance of food from cloned animals.

REFERENCE MATERIAL

Below are links to various organizations involved in the agricultural biotechnology sector in Australia.

AUSTRALIAN GOVERNMENT

- Office of the Gene Technology Regulator
- Food Standards Australia New Zealand
- Australian Pesticides and Veterinary Medicines Authority
- Department of Agriculture and Water Resources
- Department of Industry and Science
- Commonwealth Scientific and Industrial Research Organization (CSIRO)
- Grains Research and Development Corporation
- IP Australia
- Australian Centre for International Agricultural Research (ACIAR)

OTHER ORGANIZATIONS

- Agricultural Biotechnology Council of Australia
- AusBiotech
- National Farmers Federation
- The Centre for Law and Genetics
- The Australian Centre for Agriculture and Law
- The Australian Centre for Intellectual Property in Agriculture
- CropLife Australia
- Australian Farm Institute

RECENT MEDIA ARTICLES

- Farmer Fury at GM Moratorium Extension
- State GM ban could continue into 2025
- GM hypocrisy: Australia's best technologies shunned here, snapped up overseas
- Industry has its say on GM regulations
- ANU poll finds majority of Australians think science has made life easier
- Twenty years on, the GM debate continues
- Bayer backs Hybrid wheat over GM, despite looming Monsanto merger
- Unfair GM laws a "catastrophe" for Australian agriculture
- SA GM ban nothing to do with health or science - all about politics
- Barnaby Joyce pleads case for GM crops at UN
- New report reignites calls to drop GM crop bans
- Grains research hub to examine crop pathology, GM