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Report Highlights:

The Australian federal government is 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 regulations for genetically engineered (GE) products. On July 1, 2021, New South Wales lifted its ban on GE food crops after an 18-year moratorium. This means that federally approved GE crops can now be grown in every Australian state except Tasmania.

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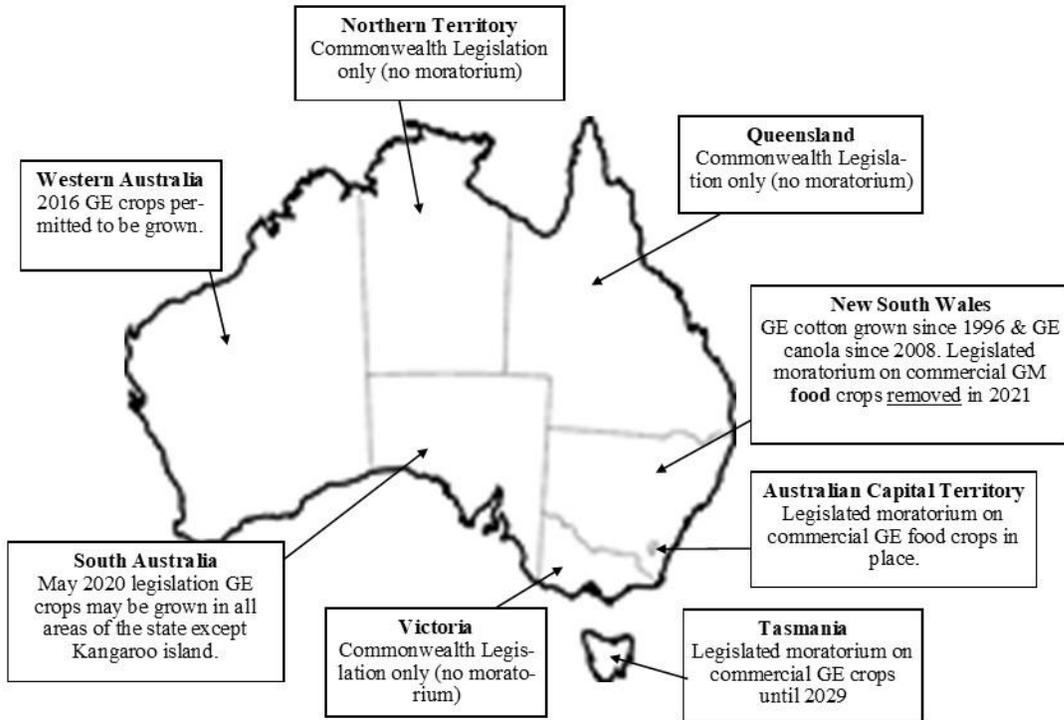
EXECUTIVE SUMMARY

The United States has substantial interest in Australia's policies and regulatory framework regarding agricultural biotechnology and products derived thereof because of their potential impact on U.S. exports. Two Australian policies are disruptive to trade with the US. First, unprocessed (whole) GE corn and soybeans have not received regulatory approval in Australia and cannot be imported without further processing. Second, foods with GE content of over one percent must receive prior approval and be labeled, which has the potential of restricting sales of U.S. intermediate and processed products. Australia's policies and views on this technology influence other countries, which may potentially lead them to developing a similar regulatory system.

The biotech debate remains important in Australia. The federal government is very supportive of biotech; has committed considerable long-term funding to research and development; and approved biotech products like genetically engineered (GE) cotton, carnation, and canola varieties for general release. State governments have also committed funds for research and development. Initially, most states were cautious about the introduction of the technology and put moratoria in place that prevented cultivation of GE crops. However, after several state-level reviews, New South Wales, Victoria, and Western Australia lifted their moratoria on producing GE canola. South Australia signaled its intention to lift its moratorium in August 2019 and legislation was passed in May 2020 that allows GE crops to be cultivated all areas of South Australia except Kangaroo Island. On July 1, 2021, New South Wales (NSW) lifted its ban on the growing of GE food crops after an 18-year moratorium. This means that federally approved GE crops can now be grown in every mainland state in Australia. Moratoria remain in place in Tasmania (until the next review in 2029) and the Australian Capital Territory (ACT) which does not grow commercial crops but does allow the field trials.

U.S. export opportunities to Australia are restricted by a lack of government approval for certain GE products. The commercial impact to the United States of this constraint is most pronounced for feed grains, e.g. whole corn and soybeans. In addition to this market access restriction, Australia blocks the importation of many grains and grain products for phytosanitary reasons, citing the need to limit exotic weed seeds and diseases.

Australia State Government GE Positions



CHAPTER 1: PLANT BIOTECHNOLOGY

The Gene Technology Act 2000 distinguishes between “genetically modified organisms” (“GMOs”) and “genetically modified” (“GM”) products. A genetically modified product – GM product (referred to as GE product throughout this report) is a product derived or produced from a GMO ([Section 10 of the Gene Technology Act](#)).

PART A: PRODUCTION AND TRADE

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

- Ribonucleic acid interference ([RNAi](#)) or gene silencing – Projects include breeding wheat varieties with value-added traits, enhancing aquaculture productivity, virus-resistant plants, non-browning potatoes, animal feed with increased digestibility, and enhanced biofuels.
- [Marker-assisted breeding](#) – Plant projects include [mildew-resistance wine grapes](#).

See table in [Annex A](#) for a list of products approved for field trials.

b) COMMERCIAL PRODUCTION: GE cotton, canola, safflower, Indian mustard, and carnations are the only crops approved for commercial release by the Office of Gene Technology Regulator (OGTR). It is estimated that GE cotton varieties are grown on almost all of Australia’s cotton area. The OGTR approved the commercial releases of two GE canola varieties in 2003. In 2008, the state-level moratoria in New South Wales (NSW), Victoria, and Western Australia (WA) were lifted, allowing for cultivation of GE canola and cotton in select areas. In 2016, WA repealed the 2003 *GM Free Areas Bill*, allowing approved GE crops to be cultivated. In 2020, South Australia lifted its moratorium on GE crops to allow them to be grown in all parts of the state except Kangaroo Island. In July 2021, New South Wales lifted its moratorium on GE food crops paving the way for future developments. GE cotton and canola have been allowed to be grown in NSW for many years.

In 2020, the Tasmanian government approved an extension of its GE moratorium until 2029. Tasmania and the Australian Capital Territory (ACT) are now the only states that have moratoria on GE cultivation. It should be noted that no commercial crops are grown in the ACT, but they do permit research institutions such as the CSIRO and universities to carry out field trials of GE crops.

In 2006, GE carnations became the first GE product to be assessed by the OGTR 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. In October 2022, the first GE Indian mustard was approved for commercial release. A full list of GE crops authorized for commercial release can be found on the [OGTR website](#).

Cotton

[GE cotton](#) has been grown commercially in Australia since the approval and introduction of the first GE variety in 1996. Almost all Australian grown cotton (over 99 percent) is GE. Additionally, there are several new GE cotton varieties under development (see section on approvals in Part B).

Canola

Since 2003, many [GE 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 GE moratoria. In 2009, WA initiated trials with the first commercial plantings in 2010. South Australian farmers have been able to grow GE canola since 2020 and the first crop was harvested in 2021.

Total GE Canola by Stated (hectares)

State	2016*	2017*	2018	2019	2020	2021
NSW	54,970	68,163	66,045	50,030	54,970	104,250
VIC	47,069	56,900	63,825	66,793	47,069	118,390
WA	344,188	366,466	369,027	433,833	344,188	580,115
SA						23,550
National (GM)	446,227	491,529	498,897	550,656	539,643	826,305
Total Area of Canola (GM and non-GM)	2,461,524	2,476,400	2,220,000	5,674,448	2,611,186	3,210,000
% GM Canola	18%	20%	22%	10%	21%	26%

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

Source: Agricultural Biotechnology Council of Australia

Safflower

Safflower is a minor crop in Australia mainly grown for the edible and industrial oil markets with the meal used as stockfeed. Whole seeds are also used for birdseed. Commercial safflower production occurs mainly in NSW, Victoria, and South Australia. The first commercial GE safflower was released in 2018. Two GE safflower lines have been approved for release and have been modified to increase the level of oleic acid in the seeds. A [fact sheet](#) is available on the OGTR website.

c) EXPORTS: Almost all of Australia's cotton are GE, but Australia does not export cotton to the United States. Australia is a major exporter of canola, some of which is GE. The Australian Department of Agriculture 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). This database lists importing countries that require a biotech declaration.

d) IMPORTS: Under the [Gene Technology Act 2000](#) (the Act), approval or authorization must be obtained. Importers must apply to the OGTR for a license or authorization to import any GE materials (except food) into Australia. The Regulator and the Department of Agriculture work closely to regulate

and enforce this requirement. The application form for an import permit (for any product) contains a section relating to the GE status of the product. When importing GE product or product that is known to be mixed with GE material, the importer is required to notify the Department of Agriculture through 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. the OGTR license number of Notifiable Low Risk Dealings, NLRD, identifier number, and name of the assessing Institutional Biosafety Committee, IBC).

Foods containing GE materials must be approved by Food Standards Australia New Zealand (FSANZ) and labeled if the GE content is greater than one percent. This applies to all domestically produced and imported food. A list of currently approved GE food products is contained in [Standard 1.5.2](#). A significant proportion of Australia's soybean meal is imported, including from the United States. 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 to be imported (see Part B). There are, however, quarantine restrictions on some products such as whole grain for feed. Unprocessed GE products imported as feed would require a license from the OGTR, due to possible environmental release. See the OGTR Fact Sheet: [“Stockfeed and genetically modified crops.”](#)

e) FOOD AID: Australia does not provide or receive 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 Food and Agricultural Organization of the United Nations.

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

PART B: POLICY

a) REGULATORY FRAMEWORK: The Act came into force on June 21, 2001, as the Commonwealth component of a national regulatory scheme. The Act and associated Gene Technology Regulations 2001 provide a comprehensive process for the OGTR to assess viable GE products ranging from contained work in certified laboratories to environmental release. The Gene Technology Regulator has extensive powers to monitor and enforce license conditions. An intergovernmental agreement between the Commonwealth, states, and territories underpins the system for regulating GE organisms in Australia. The Legislative and Governance Forum on Gene Technology (LGFGT) comprises ministers from the Commonwealth and each state and territory. It 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.

Legal Term	Laws and Regulations where term is used	Legal Definition
Genetically modified organism (GMO)	<ul style="list-style-type: none"> • Gene Technology Act 2000 • Gene Technology Regulations 2001 	(a) an organism that has been modified by gene technology; or (b) an organism that has inherited particular traits from an organism (the <i>initial organism</i>), being traits that occurred in the initial organism because of gene technology; or (c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms.
Genetically modified (GM) product	<ul style="list-style-type: none"> • Gene Technology Act 2000 • Gene Technology Regulations 2001 • Standard 1.5.2 of the Food Standards Code 	A thing (other than a GMO) derived or produced from a GMO
Food produced using gene technology	<ul style="list-style-type: none"> • Standard 1.5.2 of the Food Standards Code 	A food which has been derived or developed from an organism which has been modified by gene technology
Gene technology	<ul style="list-style-type: none"> • Gene Technology Act 2000 • Standard 1.5.2 of the Food Standards Code 	Any technique for the modification of genes or other genetic material Recombinant DNA techniques that alter the heritable genetic material of living cells or organisms

The objective 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 genetically modified organisms.”

The Act prohibits all dealings with biotech products unless the dealing is:

- A licensed dealing,
- A notifiable low risk dealing,
- Included on the GMO Register, and
- 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 consults extensively with

the community, research institutions, and private enterprise to administer and ensures compliance with the Act.

The OGTR 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, managing those risks through regulating certain dealings with genetically modified organisms (GMOs).

The Regulator (through OGTR) also:

- provides information and advice to the public about the regulation of GE organisms.
- provides advice to the Gene Technology Minister’s Meeting (GTMM) about the effectiveness of the legislative framework for regulating GE organisms, including possible amendments of relevant legislation.
- promotes the harmonization of risk assessments of GE organisms and genetically modified products by regulatory agencies.
- monitors international practice in the regulation of GE organisms.
- maintains links with international organizations that regulate gene technology and with agencies that regulate GE organisms in countries outside Australia.

The OGTR liaises with other regulatory agencies to coordinate biotech product approval for use and sale (see Figure 4 below). The Act creates a public Record of GMO Dealings and GE Products that resides on the [OGTR website](#). The Act also establishes two [advisory committees](#) to advise the OGTR and the LGFGT, including:

- [The Gene Technology Technical Advisory Committee](#) – a group of highly qualified experts who provide scientific and technical advice on applications.
- [The Gene Technology Ethics and Community Consultative Committee](#) – provides advice on ethical issues and on matters of general concern to the community in relation to GE materials and products.

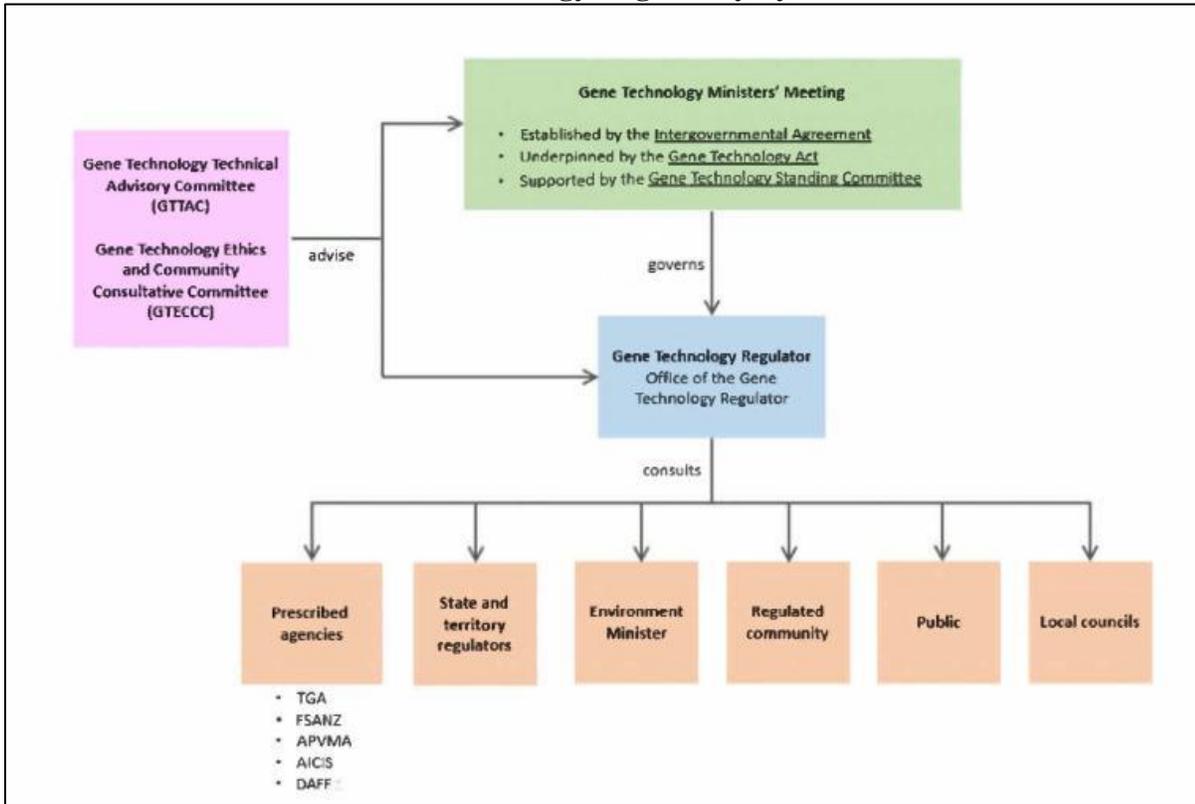
Regulatory Agencies in Australia with a Role in Regulation of Gene Technology

Agency	What They Regulate	Scope
OGTR (supporting the Regulator)	Dealings with “GMOs”	The Regulator administers a national scheme for the regulation of biotech products in Australia. Their directive is to protect health and safety and environmental protection by identifying and managing risks posed by or as a result of gene technology.
TGA – Therapeutic Goods Administration	Human Therapeutics	TGA administers legislation that provides a national framework for the regulation of medicines, medical devices, blood, and tissues in Australia, including GE-derived therapeutic products, and ensures their quality, safety and efficacy.
FSANZ – Food Standards Australia New Zealand	Human 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 biotechnology.

Agency	What They Regulate	Scope
<u>APVMA</u> – Australian Pesticides and Veterinary Medicines Authority	Agricultural Chemicals and Veterinary Medicines	APVMA operates the national regulatory system for agricultural chemicals, including those produced by 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
<u>AICIS</u> – Australian Industrial Chemicals Introduction Scheme	Industrial Chemicals	AICIS 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.
<u>Department of Agriculture, Fisheries and Forestry</u>	Import and Export	The Department of Agriculture, Fisheries and Forestry regulates the importation 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 GE products or material and the relevant authorization under the Act.

The Department of Agriculture and the OGTR must approve whole grain GE products, principally corn and soybeans imported into Australia for animal feed. Large amounts of GE feed products are used in Australia’s intensive livestock sector. The Department of Agriculture also provides quarantine inspection and certification for imports to ensure that they are free of pests and disease and meet specific license conditions. The Regulator also assesses the product, issues a license to the organization importing the product, and may apply further conditions beyond those stipulated by the Department of Agriculture. The Regulator considers possible biosafety risks, if necessary, will apply special conditions prohibit the use of products. Figure 5 below outlines the Australian regulatory framework.

Gene Technology Regulatory System



Source: OGTR

The biotech debate remains important in Australia, and the federal government who is very supportive of biotech, 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 precautionary with initial moratoria on GE cultivation.

b) APPROVALS: Along with GE cotton, canola, and carnation varieties, the OGTR approved cultivation of GE safflower modified for high oleic acid composition used in industrial applications in June 2018. GE safflower cultivation occurs mainly in NSW, Victoria, and South Australia. In October 2022, the first GE Indian mustard was approved for commercial release.

The table in [Annex A](#) provides information about current Dealings for Intentional Release (DIRs) on the GMO Record (i.e. granting licenses for uses, including field trials). Full details of all applications, including applications that have been withdrawn or approved, can be found on [the OGTR website](#).

c) STACKED EVENT APPROVALS: Stacked events must be licensed by the OGTR. For commercial release, this requirement can be met by explicit listing of a particular stacked GE product in a license or inclusion of the specific conditions in the licenses for the parent cultivars. Full details of the OGTR policy on GE stacking can be found [here](#).

d) FIELD TESTING: See the table in [Annex A](#) for a list of products approved for field trials. A map

of trial sites is available on the [OGTR website](#).

e) INNOVATIVE BIOTECHNOLOGIES: The Act contains a broad definition of “gene technology” and a broad definition of “GMO.” The [Gene Technology Regulations 2001](#) provided some exclusions to the definitions but remained unchanged from 2001, which presented challenges for integrating innovative biotechnologies. In June 2019, a technical review of the Gene Technology Regulations 2001 resulted in the following findings:

- Organisms modified using SDN-1 **are not** GE,
- Organisms modified using template guided SDN techniques and ODM **are** GE,
- Some RNA interference (RNAi) techniques **are not** GE, and
- GE-derived products without transgenes **are not** GE.

Further information can be found on the OGTR [Legislative documents website](#). An overview of the amendments can also be found on the [Third Review of the National Gene Technology Scheme](#) page.

As a result of the above changes, field trials of genome edited products have begun. In Victoria, [DairyBio](#) is carrying out the world’s largest field trial of genome edited high-energy ryegrass. This product, aimed at boosting digestibility, has been developed in collaboration with the dairy industry, along with other tropical grasses. There is also genome edited sorghum varieties being developed in Queensland intended to boost protein levels and increase digestibility in livestock and poultry to lower production costs.

FSANZ is [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. FSANZ is considering which food derived from various NBTs should require 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 more clearly state which foods require pre-market approval.

In December 2019, the [final report](#) was released and contained the following three recommendations:

1. FSANZ will prepare a proposal to revise and modernize the definitions in the Food Standards Code for food derived from NBTs.
2. FSANZ will consider process and non-process-based definitions and to ensure that foods derived from NBTs are regulated in a risk proportionate manner.
3. FSANZ will ensure open communication and active engagement with stakeholders and explore ways to raise awareness about foods derived from NBTs.

The review process began in February 2020 via [Proposal P1055](#). The first round of public consultation took place in late 2021. A second round of public consultation is due to be undertaken in 2022 but no announcement has yet been made. Existing requirements continue to apply.

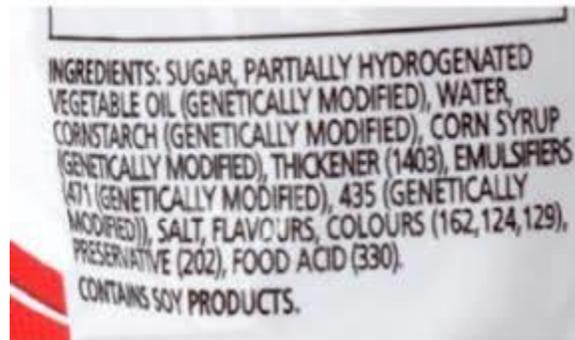
f) COEXISTENCE: Coexistence of biotech, conventional, and organic crops have occurred in Australia since GE cotton varieties were first commercially grown in 1996. As part of any license for a biotech crop, the OGTR stipulates that conditions of cultivation will not lead to unintended comingling with conventional or organic crops. For environmental release applications, the OGTR must consult on the risk assessment and risk management plans with states and territories, other Australian Government

agencies, relevant local councils, and the public. Segregation and coexistence are managed through state specific regulations and industry protocols.

Several publications on coexistence are available on the Department of Agriculture [website](#). The Agricultural Biotechnology Council of Australia also maintains a mini website focused on providing information on [coexistence](#).

g) LABELING: FSANZ is responsible for approving GE food products for the Australian market. Since 2001, Australia has required mandatory labeling of GE foods where introduced DNA or protein is present in the final food. Under the Standard, food or ingredients containing GE material or with altered characteristics (e.g. changed nutritional values compared to the conventional food) must be [labeled](#) with the words “genetically modified” (example below).

Example of mandatory labeling of GE foods



For unpackaged foods for retail sale (such as unpackaged fruit, vegetables, processed, or semi-processed foods), the words “genetically modified” must be displayed in association with the food or in association with the GE ingredient within that food. Refined oil from GE products (such as cottonseed or canola) does not require a label because the oil contains no genetic material and is identical to conventional cottonseed oil. Labeling regulations can be found in [Standard 1.5.2](#) of the [Food Standards Code](#). GE animal feed does not require labeling. These products do, however, need to be approved by the OGTR for use in Australia and must also meet biosecurity import conditions.

h) MONITORING AND TESTING: The [Regulatory Compliance](#) area of the OGTR undertakes monitoring, audits, inspections, and investigations under the requirements 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](#) (LLP) of GE products. In 2005, Australia reached national consensus on thresholds for traces of GE canola in conventional canola consignments and variety trials. The Primary Industries Ministerial Council comprises ministers from the Australian Government and each state and territory agreed on two adventitious presence (AP) thresholds for LLP, which were:

- An AP threshold of 0.9 percent GE canola in canola grain, which is supported by the Australian Oilseeds Federation.

- A second threshold for AP of GE canola in seed was set at 0.5 percent for 2006 and 2007, reduced to 0.1 per cent thereafter.

Details of the OGTR's ongoing regulatory compliance, including routine monitoring, can be found on their [website](#).

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 is due to concerns about practical implementation of the Protocol, uncertainty about other Parties' implementation, and uncertainty about Parties' capacity to influence decision-making. The Australian Government maintains that the Protocol is not necessary, 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 for biotech regulation; maintaining links with relevant international organizations; and promoting harmonization of biotech risk assessments. 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 many 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 International Plant Protection Convention's "[Joint Statement on Innovative Agricultural Production Technologies, particularly Plant Biotechnologies](#)" and a member of Codex since 1963 and the Organization of Economic Co-operation and Development (OECD) Working Group on Harmonization of Regulatory Oversight in Biotechnology.

n) RELATED ISSUES: The [Australian Centre for International Agricultural Research](#) (ACIAR) is a government development agency that oversees international agricultural research projects, including on biotech, derived from statutory authority within the Foreign Affairs portfolio within the Department of Foreign Affairs and Trade. Their core purpose is brokering and funding research partnerships between Australia and developing countries as part 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: The OGTR commissions a report into community attitudes toward biotech. The most recent survey (2021) and final report can be downloaded on the [OGTR](#)

[website](#). The overall finding was that Australian attitudes to biotech have trended towards neutral positions on biotech with those less supportive declining.

b) MARKET ACCEPTANCE: The government is supportive of agricultural biotech and has been an ally to the United States regarding the Cartagena Protocol on Biosafety, despite anti-biotech activism in Australia that promoted stringent labeling requirements and encouraged moratoria on cultivation. There is widespread domestic cultivation of GE cotton with little controversy, like due to wide reports of environmental benefits and significant decline in pesticide and herbicide use. Biotech cottonseed appears in the domestic market in oil and meal also without major opposition.

In broad terms, the above survey found that the Australian community attitudes and beliefs about genetic modification have changed little since the previous survey in 2019. Similarly, understanding of genetic modification is unchanged. Since 2019, however, more people say that genetically modified organisms will improve our way of life (up 9% since 2019), while support for genetic modification in general is up (by 6%), including for: medical uses (up 8%), animal cloning (up 5%), using genetic modification to assist growing food (up 9%), and its use in modification of plant genes (up 8%).

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: Australian researchers are using biotech to improve animal production efficiency. Cooperative Research Centers (CRCs) and the CSIRO support research that develops new vaccines and treatments for livestock disease prevention and diagnosis. Genome editing research to produce Avian Influenza-resistant chickens and modify allergens in chicken eggs is also being conducted. CSIRO is undertaking research on other [techniques](#) in the areas of agriculture, biosecurity and environmental sciences, including:

- [Marker-assisted breeding](#) – helping cattle breeders select for hornless cattle and
- [Chicken sex determination](#) – a new biotechnology to differentiate between male and female chicks pre-hatch.
- [Unlocking genetic diversity in fishes](#) – combining genetic techniques and traditional taxonomic methods.

Australian livestock cloning by public and private research institutions and universities is limited to select breeding cattle, approximately fewer than a hundred beef and dairy cattle and fewer sheep in a confined research environment.

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 equally apply to GE animal products. There are no additional biosecurity requirements for cloned animals or animal products.

PART E: POLICY

a) REGULATORY FRAMEWORK: Australian biotech animal research is regulated by the OGTR with GE and cloned animals also subject to state and territorial government animal welfare legislation and the [Australian code for the care and use of animals for scientific purposes](#). GE animals are considered “Notifiable Low Risk Dealings” (NLRDs) by the OGTR, meaning that, “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](#).

The Department of Agriculture covers animal health (biosecurity) issues in their biosecurity import risk assessments. 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. There are no additional biosecurity restrictions in relation to the import of embryos derived from cloned cattle, sheep, or goats. The same applies for the import of products derived from cloned animals, which are subject to the same quarantine regulations as non-cloned products. Food from cloned animals is not regulated in the same way as GE food. FSANZ considers food products from [cloned animals](#) and their offspring as equivalent to products from conventionally bred animals, requiring no additional regulation.

b) APPROVALS

The table in [Annex B](#) provides summary information on current 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](#).

c) INNOVATIVE BIOTECHNOLOGIES: See Chapter 2, Part B (e) above.

d) LABELING AND TRACEABILITY: Food from cloned animals or their offspring does not require special labeling requirements; see [FSANZ website](#) for details.

e) INTELLECTUAL PROPERTY RIGHTS (IPR): Intellectual Property Rights in Australia are administered by [IP Australia](#).

f) INTERNATIONAL TREATIES/FORUMS: Australia is an active member of the World Organization for Animal Health (OIE). Australia’s Chief Veterinary Officer is the current elected President of the OIE World Assembly of Delegates, and their office coordinates Australia’s OIE work, drawing on expertise of other Australian Government departments and agencies, industry bodies and other experts.

f) RELATED ISSUES: N/A

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS: There are currently a small number of Australian cloned cattle used for breeding purposes. While food from cloned animals does not enter the food chain, it is likely that food from their offspring does. Australian researchers and industry have voluntarily agreed to not allow food from cloned animals into the food chain. No opinion pieces in the Australian media have been identified. The information contained in Chapter 1; Part C indicates that consumers have increasingly accepting attitudes towards biotechnology. CSIRO and other scientists have collaborated through the OECD to identify barriers to GE animals and work toward removing those barriers.

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

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

Note: Regulation of GE products in Australia is applicable to the final product and not the process used to produce the product. Products produced using microbial biotech will only be subject to regulation if the final product contains novel DNA (i.e., DNA which is different than that produced using ‘traditional’ methods).

PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION: Companies in Australia are believed to be producing food ingredients using microbial biotech, but it is difficult to identify specific information.

b) EXPORTS: There are neither official statistics nor estimates on exports of microbial biotech products available. However, Australia exports alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients.

c) IMPORTS: All enzymes, including those derived from microbial biotech, require an import permit to enter Australia. Full details of the requirements can be found via a search on the [Australian Biosecurity Import Conditions](#) (BICON) database. A checklist for importing biological materials, which could be used for food ingredients derived from GE microorganisms, is also required as part of the import permit application for enzymes. Checklist details can be found on the Australian Department of Agriculture, Water, and the Environment [website](#).

There are neither official statistics nor estimates on imports of microbial biotech products. Australia imports microbial biotech-derived food ingredients, such as enzymes that are traditionally used in alcoholic beverages, dairy products, and processed products. Likewise, Australia imports alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients.

d) TRADE BARRIERS: Requirements for prior approval and labeling of GE food products are the main trade barrier for products coming to Australia. Given most products produced using microbial biotech methods do not contain GE proteins in the final product, these issues do not apply.

PART H: POLICY

a) REGULATORY POLICY: The same policy regulations that cover other forms of biotech apply to microbial biotech. If there is no novel DNA in the final product, there is no regulation (except for the need for an import permit); if there is novel DNA, it is subject to regulation by FSANZ.

b) APPROVALS: Prior approval and labeling is only required if the final product contains novel DNA. [Schedule 26](#) of the Food Standards Code lists approvals of food produced using gene technology of microbial origin.

c) LABELING AND TRACEABILITY: Food that includes microbial biotech-derived ingredients is **not** required to be labeled as “genetically modified” in conjunction with the name of the specific ingredient within the ingredient list if:

- both of the following are satisfied:
 - the food or ingredient is a substance used as a processing aid or used as a food additive in accordance with the [Food Standards Code](#) or
 - no novel DNA or novel protein from the substance remains present in the food.
- the food or ingredient is a flavouring substance that is present in the food in a concentration of no more than 1g of flavouring/kg of food (i.e. no more than 0.1 percent); or
- the food or ingredient is:
 - unintentionally present in the food; and
 - present in an amount of no more than 10g in a kilogram of each ingredient.

The sections of the Australia New Zealand Food Standards Code that apply to food ingredients produced using microbial biotech include:

- [Standard 1.3.1](#) – Food Additives
- [Schedule 16](#) – Types of substances that may be used as food additives
- [Standard 1.3.3](#) – Processing Aids
- [Schedule 18](#) – Processing aids
- [Standard 1.5.2](#) – Foods produced using gene technology
- [Schedule 26](#) – Food produced using gene technology.

d) MONITORING AND TESTING: Food products are not routinely tested for the presence of GE.

e) ADDITIONAL REGULATORY REQUIREMENTS: Not applicable.

f) INTELLECTUAL PROPERTY RIGHTS: Intellectual Property Rights are administered by [IP Australia](#).

g) RELATED ISSUES: Not applicable.

PART I: MARKETING

a) PUBLIC PRIVATE OPINIONS: Please see Chapter 1, Part C and Chapter 1, Part F of this report. To date, no specific questions regarding microbial biotech have been included in the market research so it is not possible to provide information on opinions.

b) MARKET ACCEPTANCE: As above.

REFERENCE MATERIAL

Below are links to various organizations involved in the agricultural biotech 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, Fisheries and Forestry](#)
- [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](#)
- [CropLife Australia](#)
- [Australian Farm Institute](#)

ANNEX A: Dealings for Intentional Release – PLANTS

The table below provides summary information on **current** [Dealings Involving Intentional Release](#) (DIRs) on the “GMO Record” (i.e. granted licenses for various uses including field trials) for **plant products**.

Crop	Applicant	License Purpose and Modified Trait
Banana	Queensland University of Technology	Limited and controlled release of banana genetically modified for disease resistance
Buffalo Grass	Royal Melbourne Institute of Technology University	Limited and controlled release of buffalo grass genetically modified for herbicide tolerance and dwarf phenotype
Canola	BASF Australia Ltd	Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system (MS11× RF3 and MS11 × RF3 × MON 88302)
Canola	BASF Australia Ltd	Commercial release of canola (<i>Brassica napus</i>) genetically modified for herbicide tolerance and a hybrid breeding system (MS11)
Canola	Monsanto Australia Limited	Limited and controlled release of canola genetically modified for herbicide tolerance
Canola	Nuseed Pty Ltd	Limited and controlled release of canola genetically modified for altered oil content and herbicide tolerance
Canola	Nuseed Pty Ltd	Commercial release of canola genetically modified for omega-3 oil content (DHA canola)
Canola	Pioneer Hi-Bred Australia Pty Ltd	Commercial release of canola genetically modified for herbicide tolerance
Canola	BASF Australia Ltd	Commercial release of canola genetically modified for dual herbicide tolerance and a hybrid breeding system
Canola	Monsanto Australia Ltd	Commercial release of canola genetically modified for herbicide tolerance
Canola	BASF Australia Ltd	Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system
Canola	BASF Australia Ltd	Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system for use in the Australian cropping system
Canola	Monsanto Australia Ltd	General release of Roundup Ready® canola (<i>Brassica napus</i>) in Australia

Crop	Applicant	License Purpose and Modified Trait
Canola and Indian Mustard	Nuseed Pty Ltd	Limited and controlled release of canola and Indian mustard genetically modified for altered oil content and herbicide tolerance
Chickpea	Queensland University of Technology	Limited and controlled release of chickpea genetically modified for drought and other environmental stress tolerance
Cotton	Monsanto Australia Pty Ltd	Commercial release of cotton genetically modified for herbicide tolerance (MON 88701)
Cotton	Syngenta Australia Pty Ltd	Commercial release of cotton genetically modified for insect resistance (COT102)
Cotton	Monsanto Australia Limited	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance
Cotton	Monsanto Australia Limited	Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (Bollgard® 3 XtendFlex™ and XtendFlex™ cotton)
Cotton	BASF Australia Ltd	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)
Cotton	Monsanto Australia Ltd	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
Cotton	Monsanto Australia Ltd	Commercial release of herbicide tolerant (Roundup Ready Flex®MON88913) pima cotton in Australia
Cotton	Corteva Agriscience Australia Pty Ltd	Commercial release of cotton genetically modified for insect resistance (WideStrike™ Insect Protection Cotton)
Cotton	Monsanto Australia Ltd	Commercial release of GM herbicide tolerant and/or insect resistant cotton lines north of latitude 22° South
Cotton	BASF Australia Ltd	Commercial release of herbicide tolerant Liberty Link® Cotton
Indian Mustard	Nuseed Pty Ltd	Limited and controlled release of Indian mustard (Juncea canola) genetically modified for altered oil content
Indian Mustard	BASF Australia Ltd	Commercial release of Indian mustard genetically modified for herbicide tolerance (RF3)
Safflower	Go Resources Pty Ltd	Commercial release of safflower genetically modified for high oleic acid composition

Crop	Applicant	License Purpose and Modified Trait
Sorghum	University of Queensland	Limited and controlled release of sorghum genetically modified for grain quality traits
Sorghum and Indian Mustard	The University of Queensland	Limited and controlled release of sorghum genetically modified for asexual seed formation
Wheat	The University of Melbourne	Limited and controlled release of wheat genetically modified for altered iron uptake, transport and bioavailability
Wheat	CSIRO	Limited and controlled release of wheat genetically modified for disease resistance, drought tolerance, altered oil content and altered grain composition
Wheat - Bread and Durum	CSIRO	Limited and controlled release of bread wheat and durum wheat genetically modified for enhanced rust disease resistance
Wheat and Barley	The University of Adelaide	Limited and controlled release of wheat and barley genetically modified for yield enhancement and improved abiotic stress tolerance
Wheat and Barley	The University of Adelaide	Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance and yield improvement
White Clover	Grasslanz Technology Australia Pty Limited	Limited and controlled release of white clover genetically modified for increased condensed tannins

Source: Office of the Gene Technology Regulator

ANNEX B: Dealings of Intentional Release – ANIMALS

The table below provides summary information about **current** [Dealings Involving Intentional Release](#) (DIRs) on the GMO Record (i.e. granted licenses for various uses including trials) for **animals and viruses**.

Product Use	Applicant	License Purpose and Modified Trait
Vaccine – farmed crocodiles	The University of Queensland	Limited and controlled release of genetically modified insect-specific viruses as vaccines against Kunjin virus infection in farmed crocodiles
Vaccine – chickens	Bioproperties Pty Ltd	Limited and controlled release of a GM vaccine for chickens, Vaxsafe® ILT
Vaccine – chickens	Zoetis Australia Research & Manufacturing Pty Ltd	Commercial release of genetically modified vaccine to protect chickens against pathogenic <i>Escherichia coli</i>

Source: Office of the Gene Technology Regulator

Attachments:

No Attachments