Required Report: Required - Public Distribution **Date:** December 04,2020

Report Number: AS2020-0036

Report Name: Agricultural Biotechnology Annual

Country: Australia

Post: Canberra

Report Category: Biotechnology and Other New Production Technologies

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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. Technical reviews of the Gene Technology Regulations 2001 and the relevant Standard of the Food Standards Code are currently being finalized to provide regulatory clarity involving new technologies. The South Australian government passed legislation in May 2020 to remove the moratorium in that state. GE crops can be grown in all areas of the state except Kangaroo Island.

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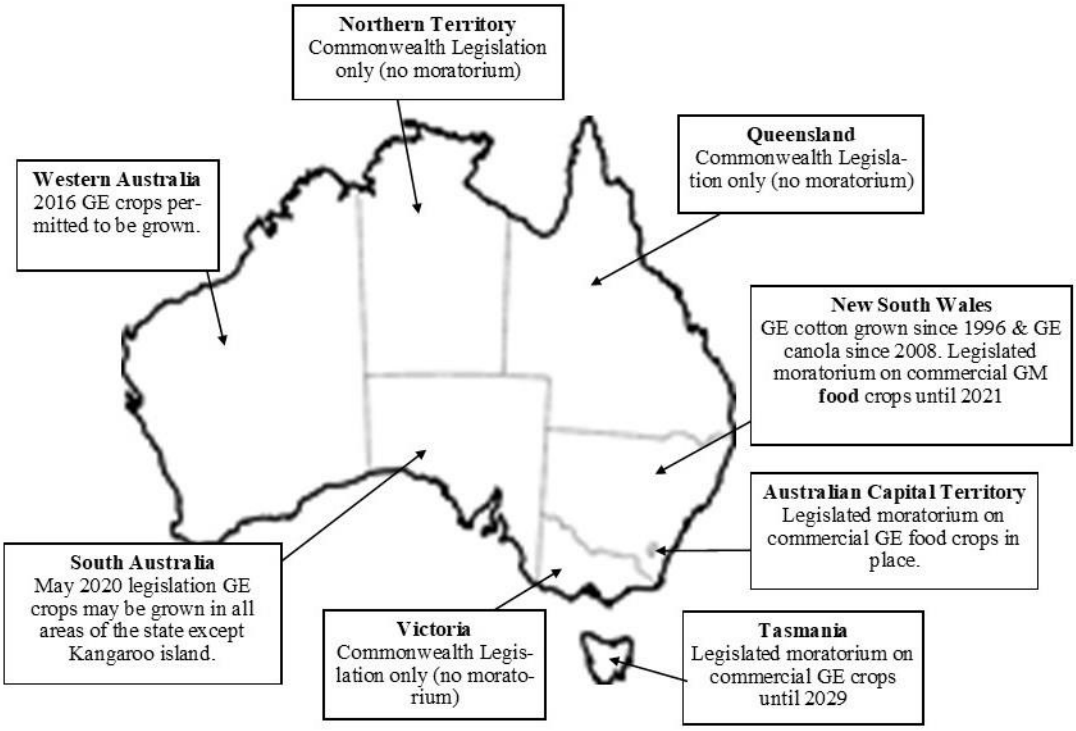
EXECUTIVE SUMMARY

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. However, the state's local council areas were given until the end of September 2020 to lodge applications to remain GE-free. Applications were received from 11 councils; however, all were subsequently rejected by the South Australian government, so the May 2020 legislation stands, and farmers are now free to grow GE crops. Moratoria remain in place in Tasmania (just extended to 2029) and the Australian Capital Territory. Queensland and the Northern Territory do not have moratoriums in place.

Australia
State Government GE Positions



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.

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 – Projects include mildew-resistance wine grapes and helping cattle breeders select for hornless cattle.
- GE – Projects include Bacillus thuringiensis (Bt) cotton, docosahexaenoic acid (DHA) canola, super high oleic (SHO) safflower, leaf oil, and Bt cowpeas.

See table in Annex A for a list of products approved for field trials.

b) COMMERCIAL PRODUCTION: GE cotton, canola, and carnations are the only crops approved for commercial release by the 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.

After a change of government in the 2018 elections, South Australia undertook an independent review of the GE moratorium . As a result, in August 2019, South Australia announced that it intended to lift the ban GE cultivation in all areas of the state except Kangaroo Island. Legislation was passed in May 2020, but local council areas in the state were given until the end of September 2020 to lodge an application to remain GE-free. Applications were received from 11 councils, but all were subsequently rejected by the South Australian government meaning that the May 2020 legislation stands. Further information on the process can be found at: https://www.pir.sa.gov.au/primary_industry/genetically_modified_gm_crops.

At the same time South Australia lifted its moratorium, 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 any GE cultivation; NSW maintains a moratorium on the growing of GE food crops. Major farm groups and the Commonwealth Government's science organizations oppose this position and have argued openly for acceptance of biotech 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. 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 cotton GE. Additionally, there are several new GE cotton varieties under development (see section on approvals in Part B).

Canola

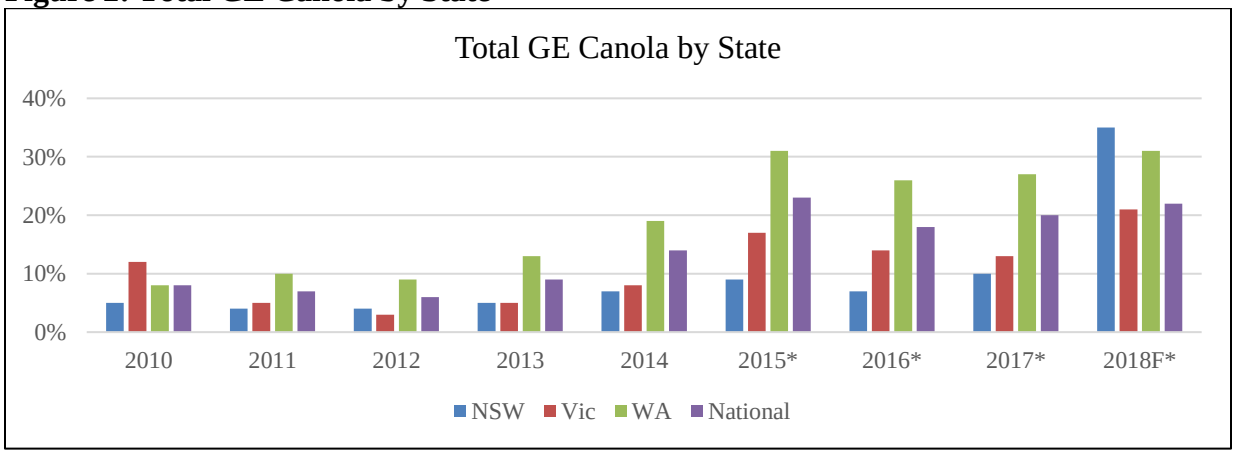
Since 2003, many GE canola varieties have been approved by OGTR. The first commercial plantings of these varieties took place in 2008 after the state governments in NSW and Victoria lifted their GE moratoria. In 2009, WA initiated trials with the first commercial plantings in 2010. Starting in 2020, South Australian farmers may grow GE canola. As of 2017, GE canola varieties made up approximately 20 percent of the total national canola crop.

Figure 1: Total GE Canola by Year (hectares)

	2010	2011	2012	2013	2014	2015†*	2016†*	2017†*	2018F*
NSW	23,286	28,530	40,324	31,573	52,000	51,870	54,970	68,163	66,045
Vic	39,405	22,272	19,012	21,232	37,000	47,137	47,069	56,900	63,825
WA	86,006	94,800	121,694	167,596	260,000	337,527	344,188	366,466	369,027
National	148,697	145,602	181,030	222,414	349,000	436,534	446,226	491,528	498,897
Total Area of Canola (GE and non-GE)	1,590,500	1,815,000	2,687,000	2,480,000	2,607,000	2,000,000*	2,125,000*	2,080,000*	2,220,000
% GE Canola	9%	7%	6%	9%	14%	23%	18%	20%	22%

† 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, Victoria, and NSW).
Source: Agricultural Biotechnology Council of Australia

Figure 2: Total GE Canola by State



* The 2015, 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

c) EXPORTS: Almost all of Australia's cotton is exports 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. 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 (see Part B) to be imported. There are, however, quarantine restrictions on some products. Unprocessed GE products imported as feed, such as whole grains, 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.

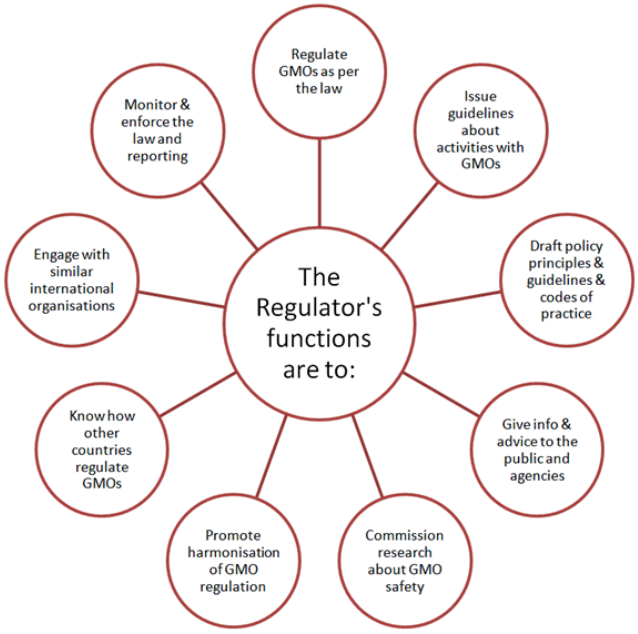
The objective of the Act is: "To protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms."

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.

Figure 3: Functions of the Gene Technology Regulator



Source: OGTR

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:

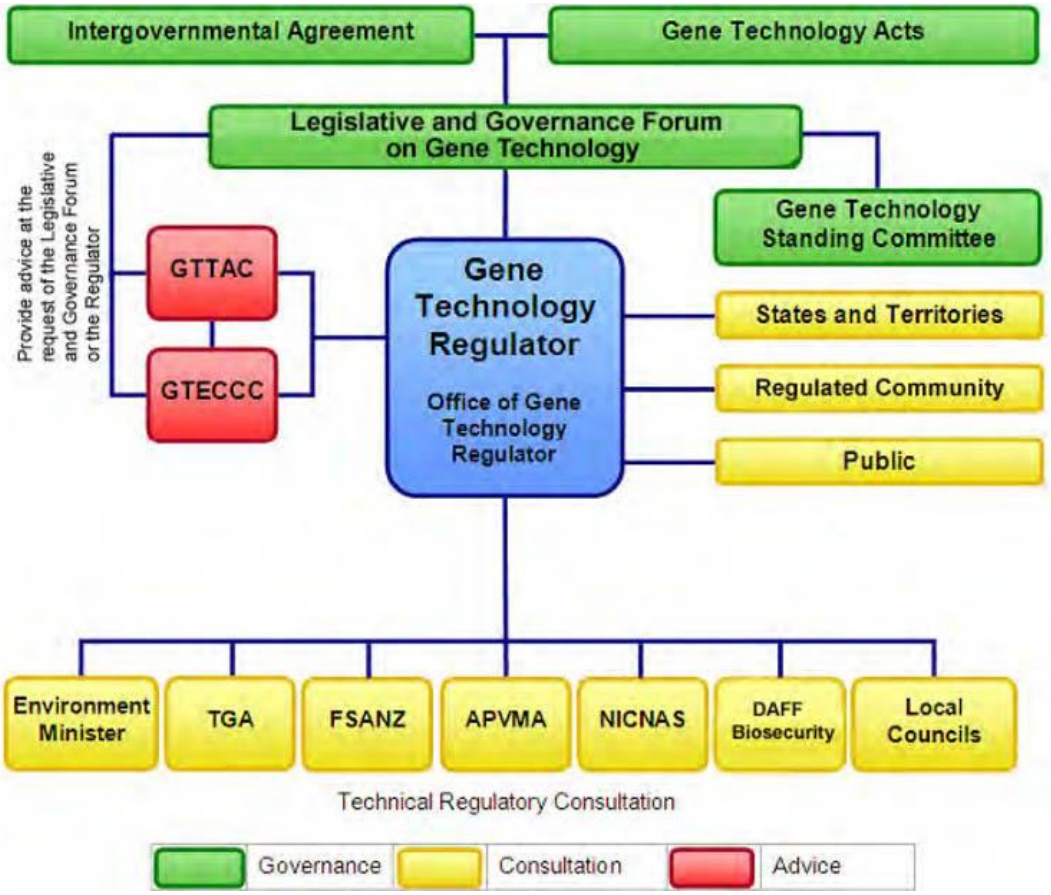
- The Gene Technology Technical Advisory Committee – a group of highly qualified experts who provide scientific and technical advice on applications.
- The Gene Technology Ethics and Community Consultative Committee – provides advice on ethical issues and on matters of general concern to the community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

Figure 4: 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.
APVMA – 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
AICIS – 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.
Department of Agriculture and Water Resources	Import and Export	The Department of Agriculture and Water Resources 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.

Figure 5: Gene Technology Regulatory System



Source: OGTR

The biotech debate remains important in Australia, and the federal government 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.

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 Gene Technology Amendment (2019 Measures No. 1) Regulations 2019, which went into effect in October 2019.

The scope of 2019 regulations was clarified as the following:

- 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 2019 Amendments to the Regulations website. An overview of the amendments can also be found in the Overview of amendments to the Gene Technology Regulations 2001 document.

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.

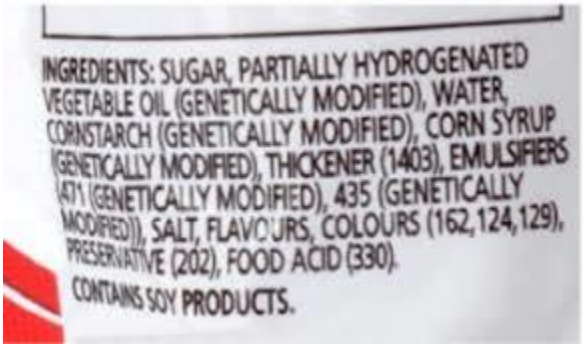
The review process began in February 2020, but public consultation has been delayed until late 2020 or 2021 due to the COVID-19 pandemic. Existing requirements continue to apply.

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.

A number of 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).

Figure 6: 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 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 (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.

In 2005, the Australian Government Biotechnology Ministerial Council endorsed a risk-based national strategy to manage LLP in imported seeds for sowing. The OGTR implements the strategy, which has six components (see Figure 6 below) and employs a risk management approach with resources dedicated to the areas posing the highest likelihood of unintended presence.

Figure 7: Components of National LLP Strategy

Component	Description
Risk profiling – identifying seed imports posing the highest likelihood of unintended presence	The OGTR has a memorandum of understanding with Department of Agriculture to access data on imports. Data on imported seeds for sowing, information on overseas commercial GE production, 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 greater LLP issue were subsequently identified.
Quality assurance/identity preservation	Industry uses quality assurance and identity preservation systems for seed quality purposes. The OGTR developed a program for auditing and testing industry's systems that has been adopted.
Laboratory testing	The OGTR's voluntary code of conduct refers to industry testing programs. Industry is required to manage 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 incident response documents for 12 GE crops identified for LLP in imports of seeds for sowing (canola, cotton, maize, potato, tomato, papaya, soybean, squash, alfalfa, grasses, rice and wheat) through risk profiling. These documents provide a basis for rapid risk assessment and management actions in the event of a LLP detection.
Post market detection	The OGTR recognizes the legislative limitations of LLP policies 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. The OGTR continues to work with the Australian Seed Federation to expand the quality assurance review program, supported by the standard OGTR practice of investigating LLP detections.
Enforcement action	In the event of a LLP detection, responses are determined on a case-by-case basis. The OGTR continues consultation with Australian Government agencies, relevant industry organizations, and states and territories on an incident response plan.

Source: Office of the Gene Technology Regulator

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 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 an 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 (2019) 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.

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.

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 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.

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. 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 and Water Resources
- 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
- The Centre for Law and Genetics
- The Australian Centre for Agriculture and Law
- The Australian Centre for Intellectual Property in Agriculture

ANNEX A: Dealings for Intentional Release – PLANTS

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) for **plant products**.

Crop	Applicant	Modified Trait	License Purpose
Banana (*Musa* spp.)	Queensland University of Technology	Disease resistance, Selectable marker – antibiotic	Limited and controlled release of banana genetically modified for disease resistance
Bread wheat (*Triticum aestivum*) and **durum wheat** (*Triticum turgidum subsp. durum*)	CSIRO	Disease resistance, Selectable markers	Limited and controlled release of bread wheat and durum wheat genetically modified for enhanced rust disease resistance
Buffalo grass (*Stenotaphrum secundatum* (Walter Kuntze)	Royal Melbourne Institute of Technology University	Herbicide tolerance, Plant development-altered plant architecture	Limited and controlled release of buffalo grass genetically modified for herbicide tolerance and dwarf phenotype
Canola (*Brassica napus* L.)	Monsanto Australia Limited	Herbicide tolerance	Limited and controlled release of canola genetically modified for herbicide tolerance
Canola (*Brassica napus* L.)	Nuseed Pty Ltd	Composition - food (human nutrition), Composition - animal nutrition, Selectable marker - herbicide, Selectable marker - antibiotic, Herbicide tolerance	Limited and controlled release of canola genetically modified for altered oil content and herbicide tolerance
Canola (*Brassica napus* L.)	Nuseed Pty Ltd	Composition - food (human nutrition), Composition - animal nutrition, Selectable marker - herbicide	Commercial release of canola genetically modified for omega-3 oil content (DHA canola)
Canola (*Brassica napus* L.)	Pioneer Hi-Bred Australia Pty Ltd	Herbicide tolerance	Commercial release of canola genetically modified for herbicide tolerance

Crop	Applicant	Modified Trait	License Purpose
Canola (*Brassica napus* L.)	BASF Australia Ltd	Herbicide tolerance, Hybrid breeding system	Commercial release of canola genetically modified for dual herbicide tolerance and a hybrid breeding system
Canola (*Brassica napus* L.)	Monsanto Australia Ltd	Herbicide tolerance	Commercial release of canola genetically modified for herbicide tolerance
Canola (*Brassica napus* L.)	BASF Australia Ltd	Herbicide tolerance/Hybrid breeding system	Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system
Canola (*Brassica napus* L.)	BASF Australia 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
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
Chickpea (*Cicer arietinum* L.)	Queensland University of Technology	Environmental stress tolerance – drought; Selectable marker – antibiotic	Limited and controlled release of chickpea genetically modified for drought and other environmental stress tolerance
Cotton (*Gossypium barbadense* L.)	Monsanto Australia Ltd	Herbicide tolerance	Commercial release of herbicide tolerant (Roundup Ready Flex®MON88913) pima cotton in Australia

Crop	Applicant	Modified Trait	License Purpose
Cotton (*Gossypium hirsutum* L.)	Syngenta Australia Pty Ltd	Insect resistance	Commercial release of cotton genetically modified for insect resistance (COT102)
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
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)
Cotton (*Gossypium hirsutum* L.)	BASF Australia 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))
Cotton (*Gossypium hirsutum* L.)	CSIRO	Product quality – non-food, Selectable marker – antibiotic	Limited and controlled release of cotton genetically modified for enhanced fiber quality
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(R)®III] and COT102 x MON-15985 x MON 88913 [Bollgard®III x Roundup Ready Flex®]) cotton

Crop	Applicant	Modified Trait	License Purpose
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.)	Dow AgroSciences Australia Pty Ltd	Insect resistance, Selectable marker - herbicide	Commercial release of cotton genetically modified for insect resistance (WideStrike™. Insect Protection Cotton)
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
Cotton (*Gossypium hirsutum* L.)	BASF Australia Ltd	Herbicide tolerance	Commercial release of herbicide tolerant Liberty Link® Cotton
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
Perennial ryegrass (*Lolium perenne* L.)	Department of Economic Development, Jobs, Transport and Resources	Composition – animal nutrition, Yield, Selectable marker – antibiotic resistance	Limited and controlled release of perennial ryegrass genetically modified for fructan biosynthesis
Safflower (*Carthamus tinctorius* L.)	Go Resources Pty Ltd	Composition – non-food (processing), Selectable marker – antibiotic	Commercial release of safflower genetically modified for high oleic acid composition
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

Crop	Applicant	Modified Trait	License Purpose
Sugarcane (Saccharum spp.)	Sugar Research Australia Ltd	Herbicide tolerance	Limited and controlled release of sugarcane genetically modified for herbicide tolerance
Wheat (*Triticum aestivum* L.)	The University of Melbourne	Composition – food (human nutrition), Selectable marker – antibiotic, Selectable marker – herbicide	Limited and controlled release of wheat genetically modified for altered iron uptake, transport and bioavailability
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
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 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

Source: Office of the Gene Technology Regulator

ANNEX B: Dealings of Intentional Release – ANIMALS

The table below provides summary information about current DIRs on the GMO Record (i.e. granted licenses for various uses including field trials) for **animals and viruses**.

Organism	Applicant	Modified Trait	License Purpose
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*
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
Infectious laryngotracheitis virus (*Gallid herpesvirus* 1).	Bioproperties Pty Ltd	Vaccine - attenuation	Limited and controlled release of a GM vaccine for chickens, Vaxsafe® ILT
Influenza virus	Clinical Network Services Pty Ltd	Vaccine - altered antigen expression; Vaccine – pathogenicity attenuation, replication incompetent	Clinical trial of genetically modified influenza vaccine (H3N2 M2SR)
Influenza virus	Clinical Network Services (CNS) Pty Ltd	Human therapeutic - attenuation	Clinical trial of live attenuated genetically modified influenza vaccines
Influenza virus	AstraZeneca Pty Ltd	Vaccine - attenuation	Commercial supply of attenuated GM influenza vaccines
Insect-specific flaviviruses	The University of Queensland	Vaccine – altered antigen expression	Limited and controlled release of genetically modified insect-specific viruses as vaccines against Kunjin virus infection in farmed crocodiles

Organism	Applicant	Modified Trait	License Purpose
Microalgae (Nannochloropsis oceanica Suda & Miyashita	The University of Queensland	Altered fatty acid composition; Inability to use nitrate as a nitrogen source (nutrient use)	Limited and controlled release of microalgae genetically modified for increased production of fatty acids
Respiratory syncytial virus	Clinical Network Services Pty Ltd	Human therapeutic - attenuation	A genetically modified respiratory syncytial virus (RSV) vaccine for use in clinical trials
Vaccinia virus	The University of Queensland	Vaccine - altered antigen expression; Vaccine - pathogenicity attenuation; Reporter gene expression	Trial of genetically modified vaccines against Ross River virus infection in horses
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, kidney and prostate cancer
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)™
Yellow fever virus (YF17D)	Sanofi-Aventis Australia Pty Ltd	Vaccine - altered antigen expression	Commercial supply of Dengvaxia, an attenuated GM dengue vaccine

Source: Office of the Gene Technology Regulator

Attachments:

No Attachments