USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Required Report - public distribution

Date: 8/7/2015
GAIN Report Number: AS1517

Australia

Agricultural Biotechnology Annual

Agricultural Biotechnology Annual - 2015

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Report Highlights:
The Australian federal government is very supportive of biotechnology and has committed considerable long-term funding to research and development. To date, biotech cotton, canola and carnation varieties are the only agricultural crops approved for commercial release into the environment in Australia. Australia requires that food products derived from genetically engineered crops, if they contain more than one percent of biotech product, must not be sold or used as an ingredient or component of any food unless it is approved in the Food Standards Code. Such products must also be labeled to indicate that they contain biotech products.

REPORT OUTLINE

SECTION I: EXECUTIVE SUMMARY

The United States has substantial interest in Australia's policies and regulatory framework regarding agricultural biotechnology and products derived thereof because of the impact this has on the ability of the U.S. to export to Australia. Food produced using gene technology, other than a substance regulated as a food additive or processing aid, must not be sold or used as an ingredient of component of any food unless it is listed and complies with conditions set out in the Food Standards Code. This requirement can restrict sales of U.S. intermediate and processed products. Australia's policies and views on this technology influence other countries in the region, and elsewhere, which may follow Australia's lead in developing a regulatory system of their own.

The biotech debate is very important in Australia. The federal government is very supportive of the technology, has committed considerable long-term funding to research and development, and has approved GM cotton, carnations and canola varieties for general release. The State governments have also committed funds for research and development, but most were more cautious about the introduction of the technology and most Australian states initially put in place moratoria on new plantings of biotechnology crops. After state-level reviews in November 2007, New South Wales (NSW) and Victoria lifted the moratoria on genetically engineered canola. In November 2008, Western Australia lifted its ban to allow biotech cotton to be grown in the Ord River region and in April 2009 announced that trials of GE canola would be allowed. In early 2010, WA passed legislation allowing the commercial production of GE canola in that state. South Australia, Tasmania and the Australian Capital Territory (ACT) have maintained their moratoria. Major farm groups and the Commonwealth government's science organizations do not support this position and have argued openly for acceptance of biotech crops. Currently in Australia, almost 100 percent of the cotton planted is from biotech varieties, which were approved for release prior to the state moratoria. Although GE cotton varieties dominate the cotton industry in Australia, the state moratoria slowed the commercialization and adoption of the technology for food crops.

The potential of agricultural biotechnologies to improve agricultural competitiveness was included in the Issues Paper (Issue 6: Improving the competitiveness of inputs to the supply chain) of the draft Agricultural Competitiveness White Paper. That paper states:

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

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

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

The final Agricultural Competitiveness White Paper was released in July 2015. Funding of over A$240 million a year is included for research and development of new and improved technologies, including genetic modification.

Australia has a substantial risk assessment based regulatory framework for dealings with gene technology and genetically modified organisms, as well as a process for assessment and approval of genetically modified foods. The Gene Technology Act of 2000 established Australia's regulatory scheme for dealings with gene technology and genetically modified organisms ("GMOs"). The Commonwealth's Gene Technology Regulator serves the key role in assessing, regulating and licensing "GMOs" and enforcing license conditions. Genetically modified foods must also be assessed, determined to be safe, and be approved before being sold for human consumption. The standards for such foods are developed by Food Standards Australia New Zealand (FSANZ) and are contained in the Food Standards Code. There are labeling requirements for genetically modified foods containing modified genetic material and/or novel protein, and for foods with altered characteristics. Imports of food products containing GE ingredients need to meet these same regulations.

To date, biotech cotton, canola and carnation varieties are the only agricultural crops approved for commercial release into the environment in Australia. The lifting of the moratoria in New South Wales, Victoria and Western Australia, has seen plantings of GE canola increase rapidly. Research is being conducted on other biotech crops, with field trials controlled by The Office of the Gene Technology Regulator (OGTR) being conducted on some, e.g. bananas, barley, canola, cotton, grapevines, Indian mustard, maize, papaya, perennial ryegrass, pineapple, safflower, sugarcane, tall fescue, torenia, wheat, and white clover. Approval has already been granted for food products derived from biotech canola, corn, cotton, soybean, sugar beet, potatoes, alfalfa and rice. A list of currently approved biotech food products is contained in Standard 1.5.2 of the Australia New Zealand Food Standards Code.

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

Australia requires that if food products derived from GE contain more than one percent of biotech product, there must be prior approval from Food Standards Australia New Zealand before they can be sold. Such products must also be labeled to indicate that they contain biotech products.

SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

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

b) COMMERCIAL PRODUCTION: Biotech cotton, canola and carnations are the only crops approved for commercial release by Australia's Gene Technology Regulator. It is estimated that biotech cotton varieties are grown on almost 100 percent of Australia's cotton area. The Regulator approved the commercial releases of two biotech canola varieties in 2003. With the lifting of the moratoria in New South Wales and Victoria in early 2008, that was the first year that GE canola was grown commercially anywhere in the country. In November 2008, Western Australia lifted its ban to allow biotech cotton to be grown in the Ord River region and in April 2009 announced that trials of GE canola would be allowed at 20 sites in that state.

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

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

Biotech Cotton

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

Canola

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

According to Monsanto, more than 436,000 hectares of GE canola will be planted this year, up from nearly 350,000 hectares last year. GE canola varieties now make up 22% of the canola planted in the states that allow GE canola to be grown – Western Australia, Victoria and New South Wales. Almost 1,200 farmers will grow GM canola this year, a 20% increase over last year.

c) EXPORTS: GE crops grown in Australia have been developed in Australia. Given that almost 100 percent of Australia's cotton products come from GE varieties, it is more than likely that any exports of cotton & cotton products would contain these varieties.

Australia does not export cotton to the U.S. In 2014 Australia exported 135,253 MT of cotton seed to the U.S. (tariff code 1207.29). It is likely that this seed was from GE cotton varieties.

The Australian Department of Agriculture maintains an online Manual of Importing Country Requirement (MICoR) for meat, dairy, fish, live animals, plants and eggs and non-prescribed goods (honey, processed foods). These databases list whether importing countries require a declaration of the presence or absence of GM.

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

Foods containing biotech materials must be approved by Food Standards Australia New Zealand and be labeled if the biotech content is greater than 1 percent before they can be sold in Australia. This applies to all domestically produced and imported food. A list of currently approved biotech food products is contained in Standard 1.5.2.

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

e) FOOD AID: Not applicable.

PART B: POLICY

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

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

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

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

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

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

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

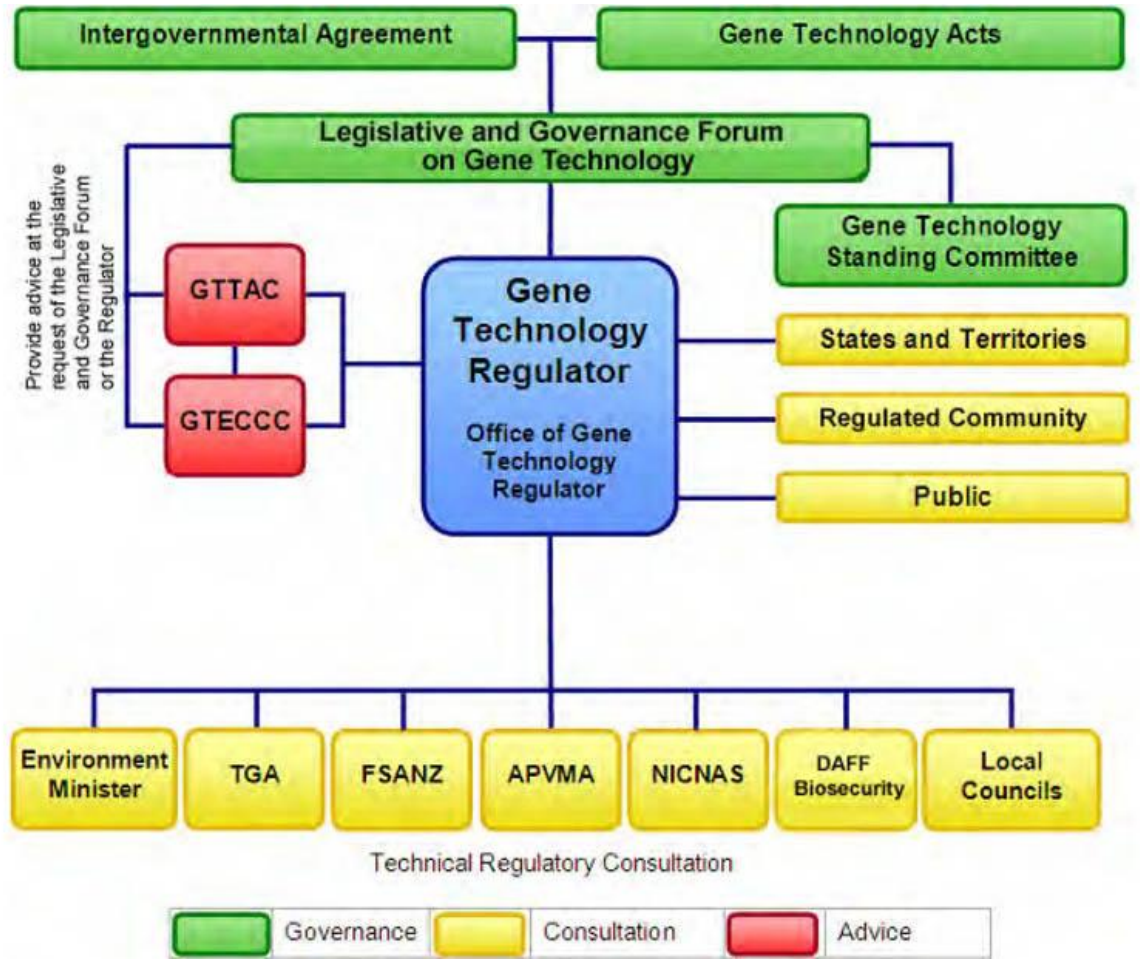
Agency	What They Regulate	Scope	Relevant Legislation
OGTR – Office of the Gene Technology Regulator (supporting the Gene Technology Regulator)	Dealings with GMOs	The Gene Technology Regulator administers a national scheme for the regulation of GMOs in Australia in order to protect health & safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.	Gene Technology Act 2000
TGA – Therapeutic Goods Administration	Medicines, medical devices, blood & tissues	TGA administers legislation that provides a national framework for the regulation of medicines, medical devices, blood and tissues in Australia, including GE & GM-derived therapeutic products, & ensures their quality, safety & efficacy.	Therapeutic Goods Act 1989
FSANZ – Food Standards Australia & New Zealand	Food	FSANZ is responsible for setting standards for the safety, content and labeling of food. FSANZ conducts mandatory pre-market safety assessments for food produced using gene technology.	Food Standards Australia New Zealand Act 1991
APVMA – Australian Pesticides & Veterinary Medicines Authority	Agricultural & Veterinary Chemicals	APVMA operates the national system that regulates all agricultural chemicals (including those produced or used on GE crops) and veterinary therapeutic products. Assessments consider human and environmental safety, product efficacy (including insecticide and herbicide resistance management), and trade issues relating to residues	Agricultural & Veterinary Chemicals (Code) Act 1994 Agricultural & Veterinary Chemicals Administration Act 1994
NICNAS – National Industrial Chemicals Notification & Assessment Scheme	Industrial Chemicals	NICNAS provides a national notification & assessment scheme to protect the health of the public, workers & the environment from the harmful effects of industrial chemicals.	Industrial Chemicals (Notification & Assessment) Act 1989

Department of Agriculture	Quarantine	The Department of Agriculture regulates the importation into Australia of all animal, plant & biological products that may pose a quarantine pest &/or disease risk. Import permit applications must indicate the presence of GMOs or GE material and the relevant authorization under the Gene Technology Act 2000.	Quarantine Act 1908 Imported Food Control Act 1992

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

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

Gene Technology Regulatory System



The Gene Technology Act 2000 distinguishes between genetically modified organisms (GMOs) and genetically modified (GM) products. A genetically modified product - 'GE product' - means a thing (other than a "GMO") derived or produced from a "GMO" (Section 10 of the GT Act).

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

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

Crop	Applicant	Modified Trait	License Purpose
Cotton (Gossypium hirsutum L.)	Bayer CropScience Pty Ltd	Herbicide tolerance, insect resistance	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance
Safflower (Carthamus tinctorius L.)	CSIRO	Altered oil profile	Limited and controlled release of safflower genetically modified for high oleic acid composition
Wheat (Triticum aestivum L. em Thell.)	Murdoch University	Improved grain quality	Limited and controlled release of wheat genetically modified for improved grain quality
Sugarcane (Saccharum spp.)	Sugar Research Australia Ltd	Herbicide tolerance	Limited and controlled release of sugarcane genetically modified for herbicide tolerance
Wheat and barley (Triticum aestivum L. and Hordeum vulgare L.)	The University of Adelaide	Abiotic stress tolerance or micronutrient uptake	Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance or micronutrient uptake
Canola (Brassica napus L.)	Monsanto Australia Ltd	Herbicide tolerance	Commercial release of canola genetically modified for herbicide tolerance
Cholera bacterium (Vibrio cholerae)	PaxVax Australia Pty Ltd	Loss of toxin expression (vaccine attenuation) and Selectable marker (mercury resistance)	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
Cotton (Gossypium hirsutum L.)	Monsanto Australia Ltd	Herbicide tolerance, Insect resistance, Selectable marker - herbicide, Selectable marker - antibiotic, Reporter gene expression	Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (Bollgard®III and Bollgard®III x Roundup Ready Flex®)

Crop	Applicant	Modified Trait	License Purpose
Canola (Brassica napus L.)	Nuseed Pty Ltd	Composition - food (human nutrition), Composition - animal nutrition, Selectable marker	Limited and controlled release of canola genetically modified for altered oil content
Wheat (Triticum aestivum L.)	Victorian Government Department of Environment and Primary Industries	Abiotic stress tolerance, Yield	Limited and controlled release of wheat genetically modified for enhanced yield stability
Safflower (Carthamus tinctorius L.)	CSIRO	Altered oil profile	Limited and controlled release of safflower genetically modified for increased levels of oleic acid (CSIRO)
Cotton (Gossypium hirsutum L.)	Monsanto Australia Ltd	Insect resistance and Herbicide tolerance	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance (Monsanto Australia Ltd)
Narrow-leafed lupin (Lupinus angustifolius L.)	The University of Western Australia	Herbicide tolerance	Limited and controlled release of narrow-leafed lupin genetically modified for herbicide tolerance (University of Western Australia)
Cotton (Gossypium barbadense L.)	Monsanto Australia Ltd	Herbicide tolerance	Commercial release of herbicide tolerant (Roundup Ready Flex®MON88913) pima cotton in Australia
Wheat and Barley (Triticum aestivum L. and Hordeum vulgare L.)	CSIRO	Composition - food (human nutrition), Yield, Selectable marker - antibiotic	Limited and controlled release of wheat and barley genetically modified for altered grain composition or nutrient utilization efficiency (CSIRO)
Vaccinia Virus, Fowlpox virus	PPD Australia Pty Ltd	Vaccine - attenuation, Vaccine - antigen expression	Limited and Controlled Release Of Genetically Modified Live Viral Vaccines Against Prostate Cancer

Crop	Applicant	Modified Trait	License Purpose
Cotton (Gossypium hirsutum L.)	CSIRO	Enhanced fiber yield	Limited and controlled release of cotton genetically modified for enhanced fiber yield
Canola (Brassica napus L.)	Pioneer Hi-Bred Australia Pty Ltd	Herbicide tolerance	Limited and controlled release of canola genetically modified for herbicide tolerance
Cotton (Gossypium hirsutum L.)	Bayer CropScience Pty Ltd	Insect resistance, Herbicide tolerance, Selectable marker - antibiotic	Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance
Wheat and barley (Triticum aestivum L. and Hordeum vulgare L.)	CSIRO	Composition - food (human nutrition), Yield, Selectable marker - antibiotic	Limited and controlled release of wheat and barley genetically modified for altered grain composition and nutrient utilization efficiency
Wheat and barley (Triticum aestivumL. and Hordeum vulgare L.)	CSIRO	Composition - food (human nutrition), Yield, Disease resistance, Abiotic stress tolerance, Selectable marker - antibiotic, Selectable marker - herbicide	Limited and controlled release of wheat and barley genetically modified for altered grain composition, nutrient utilization efficiency, disease resistance or stress tolerance
Banana (Musa spp.)	Queensland University of Technology	Composition - food (human nutrition), Selectable marker - antibiotic, Reporter gene expression	Limited and controlled release of banana genetically modified for enhanced nutrition
Canola (Brassica napus L.)	Bayer CropScience Pty Ltd	Herbicide tolerance/Hybrid breeding system	Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system (GM InVigor® x Roundup Ready® canola)
Banana (Musa spp.)	Queensland University of Technology	Disease resistance, Selectable marker - antibiotic, Reporter gene expression	Limited and controlled release of banana genetically modified for disease resistance

Crop	Applicant	Modified Trait	License Purpose
Canola (Brassica napus L.) and **Indian mustard** (Brassica juncea L.) Czern	Bayer CropScience Pty Ltd	Herbicide tolerance, Plant development, Selectable marker - herbicide	Limited and controlled release of canola and Indian mustard genetically modified for herbicide tolerance and/or a hybrid breeding system
Canola (Brassica napus L.)	Victorian Department of Primary Industries	Yield, Plant development, Selectable marker - antibiotic	Limited and controlled release of canola genetically modified for enhanced yield and delayed leaf senescence
Wheat and Barley (Triticum aestivum L. and Hordeum vulgare L.)	The University of Adelaide	Abiotic stress tolerance, Yield, Composition - food (human nutrition), Selectable marker - antiobiotic	Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance
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)™
Sugarcane (Saccharum spp.)	Sugar Research Australia Ltd (formerly BSES Limited)	Herbicide tolerance, Selectable marker - herbicide, Selectable marker - antibiotic, Reporter gene expression	Limited and controlled release of sugarcane genetically modified for herbicide tolerance
Sugarcane (Saccharum spp.)	Sugar Research Australia Ltd (formerly BSES Limited)	Plant development, Abiotic stress tolerance, Yield, Composition - non-food (processing), Selectable marker - antibiotic, Reporter gene expression	Limited and controlled release of sugarcane genetically modified for altered plant growth, enhanced drought tolerance, enhanced nitrogen use efficiency, altered sucrose accumulation, and improved cellulosic ethanol production from sugarcane biomass
Cotton (Gossypium hirsutum L.)	Dow AgroSciences Australia Pty Ltd	Insect resistance, Herbicide tolerance, Selectable marker - herbicide	Commercial release of cotton genetically modified for insect resistance (WideStrike™ Insect Protection Cotton)

Crop	Applicant	Modified Trait	License Purpose
White Clover (Trifolium repens L.)	Victorian Department of Primary Industries	Disease resistance, Selectable marker - antibiotic	Limited and controlled release of white clover genetically modified to resist infection by Alfalfa mosaic virus
Cotton (Gossypium hirsutum L.)	CSIRO	Composition - food (processing), Selectable marker - antibiotic	Limited and controlled release of cotton genetically modified for altered fatty acid composition of the cottonseed oil
Perennial ryegrass and tall fescue (Lolium perenne L.) and (Lolium arundinaceum) (Schreb.) Darbysh	Victorian Department of Primary Industries	Composition - animal nutrition, Selectable marker - antibiotic	Limited and controlled release of perennial ryegrass and tall fescue genetically modified for improved forage qualities
Wheat (Triticum aestivum L.)	Victorian Department of Primary Industries	Abiotic stress tolerance, Selectable marker - herbicide	Limited and controlled release of wheat genetically modified for drought tolerance
Banana (Musa. acuminata cv. Grande Naine)	Queensland University of Technology	Disease resistance, Selectable marker - antibiotic, Reporter gene expression	Limited and controlled release of banana genetically modified for disease resistance
Wheat and barley (Triticum aestivum) and (Hordeum vulgare)	The University of Adelaide	Abiotic stress tolerance, Composition - food (human nutrition), Selectable marker - antibiotic	Limited and controlled release of wheat and barley genetically modified for enhanced tolerance to abiotic stresses or increased beta glucan
Banana (Musa. acuminata cv. Williams)	Queensland University of Technology	Composition - food (human nutrition), Selectable marker - antibiotic, Reporter gene expression	Limited and controlled release of banana genetically modified for enhanced nutrition
Wheat (Triticum aestivum L.)	Victorian Department of Primary Industries	Abiotic stress tolerance, Selectable marker - herbicide	Limited and Controlled Release of GM drought tolerant wheat

Crop	Applicant	Modified Trait	License Purpose
Canola and Indian Mustard (Brassica napus L. and Brassica juncea L.)	Bayer CropScience Pty Ltd	Herbicide tolerance, Hybrid breeding system, Selectable marker - herbicide	Limited and controlled release of GM herbicide tolerant hybrid Brassica napus and hybrid Brassica juncea
Cotton (Gossypium hirsutum L.)	Monsanto Australia Ltd	Herbicide tolerance, Insect resistance, Selectable marker - herbicide, 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.)	Bayer CropScience Pty Ltd	Herbicide tolerance, Selectable marker - herbicide	Commercial release of herbicide tolerant Liberty Link® Cotton
White Clover (Trifolium repens L.)	Victorian Department of Primary Industries	Disease resistance, Selectable marker - antibiotic	Field Evaluation of Genetically Modified White Clover Resistant to Infection by Alfalfa Mosaic Virus
Cotton (Gossypium hirsutum L.)	Dow AgroSciences Australia Pty Ltd	Insect resistance, Selectable marker - herbicide	Agronomic assessment and seed increase of transgenic cottons expressing insecticidal genes (cry1Ac and cry1Fa) from Bacillus thuringiensis
Canola (Brassica napus L.)	Bayer CropScience Pty Ltd	Herbicide tolerance, Plant development, Selectable marker - herbicide	Commercial release of InVigor® hybrid canola (Brassica napus) 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

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

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

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

e) ADDITIONAL REQUIREMENTS: Not applicable.

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

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

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

On the other hand, a recent court case in Australia, where an organic farmer sued his neighbor for contamination of his fields and lost (see GAIN report), has brought the issue of coexistence with organic crops into the spotlight and is likely to lead examination of the current system by industry and governments.

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

g) LABELING:

Labeling of Biotech Food

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

Under the Standard, food or ingredients labeled genetically modified contain new genetic material or protein as a result of the genetic modification or have altered characteristics, e.g. changed nutritional values, compared to the conventional food. Some flavorings may also be derived from genetically modified organisms, but labeling is only required if they are in a concentration of more than 1 gram per kilogram (0.1 percent). Food additives and processing aids do not need to be labeled unless the introduced genetic material is present in the final food.

Under the labeling standard, for packaged foods the words 'genetically modified' must be used in conjunction with the name of the food, or in association with the specific ingredient within the ingredient list; and for unpackaged foods for retail sale (such as unpackaged fruit and vegetables, or unpackaged processed or semi-processed foods) the words 'genetically modified' must be displayed in association with the food, or in association with the particular ingredient within that food.

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

Labeling of Biotech Feed Products

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

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

Large amounts of biotech feed products are used in Australia's intensive livestock sector. A large proportion of Australia's soybean meal is imported, including from the United States. All cottonseed

meal used in Australia is considered to be biotech as over 90 percent of the cotton crop is planted to biotech varieties. Biotech and non-biotech cotton varieties are not typically segregated in Australia.

Genetically modified animal feed does not require special labeling in Australia.

h) TRADE BARRIERS: See part g) above on labeling requirements.

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

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

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

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

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

l) RELATED ISSUES: None.

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

n) LOW LEVEL PRESENCE POLICY: Australia has endorsed an international statement on low level presence of GE.

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

The PIMC meeting agreed on two thresholds:

- An AP threshold of 0.9 per cent GE canola in canola grain. This is the threshold supported by the Australian Oilseeds Federation (AOF).
- A second threshold for AP of GE canola in seed was set at 0.5 per cent for 2006 and 2007, to be reduced to 0.1 per cent thereafter. The Australian Seed Federation (ASF) established an AP threshold of 0.5 per cent GE seed in non-GE planting seed in 2003 following two years of research and consultation with the canola seed industry.

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

Components of National Strategy for Unintended Presence of Unapproved GMOs

Component	Description
Risk profiling – identifying seed imports posing the highest likelihood of unintended presence	The OGTR has established a memorandum of understanding with the Department of Agriculture to access data on imports. Data on imported seeds for sowing, together with information on overseas commercial production of GMOs and input from the Department of Environment and other relevant agencies, was used to identify 12 priority crops.
Quality assurance/identity preservation	Industry uses quality assurance and identity preservation systems for seed quality purposes. The OGTR has developed a program for auditing and testing industry quality assurance systems that industry has agreed and adopted.
Laboratory testing	The voluntary code of conduct refers to testing programs. Industry needs to be able to assure itself that it is managing the risk of importing unapproved seeds.
Approvals/advance risk assessments for Australia's regulatory agencies	The OGTR has prepared GMO incident response documents for 12 crops identified through risk profiling as having the highest likelihood of unintended presence in imports of seeds for sowing (canola, cotton, maize, potato, tomato, papaya, soybean, squash, alfalfa, grasses, rice and wheat). These documents will provide a basis for rapid risk assessment and management actions should an unintended presence of an unapproved GMO be detected.
Post market detection	The OGTR recognizes the legislative limitations of preventing unintended imports of unapproved GMOs and has worked cooperatively with industry to develop a voluntary code. The code aims to isolate risks as early as possible in the commercial seed supply chain. This is supported by the standard OGTR practice of investigating information about potential and possible incidents.
Enforcement action	In the event of detection of unapproved GMOs, appropriate responses would be determined on a case-by-case risk management basis. The OGTR continues engagement with Australian Government agencies, relevant industry organizations and states and territories on this issue.

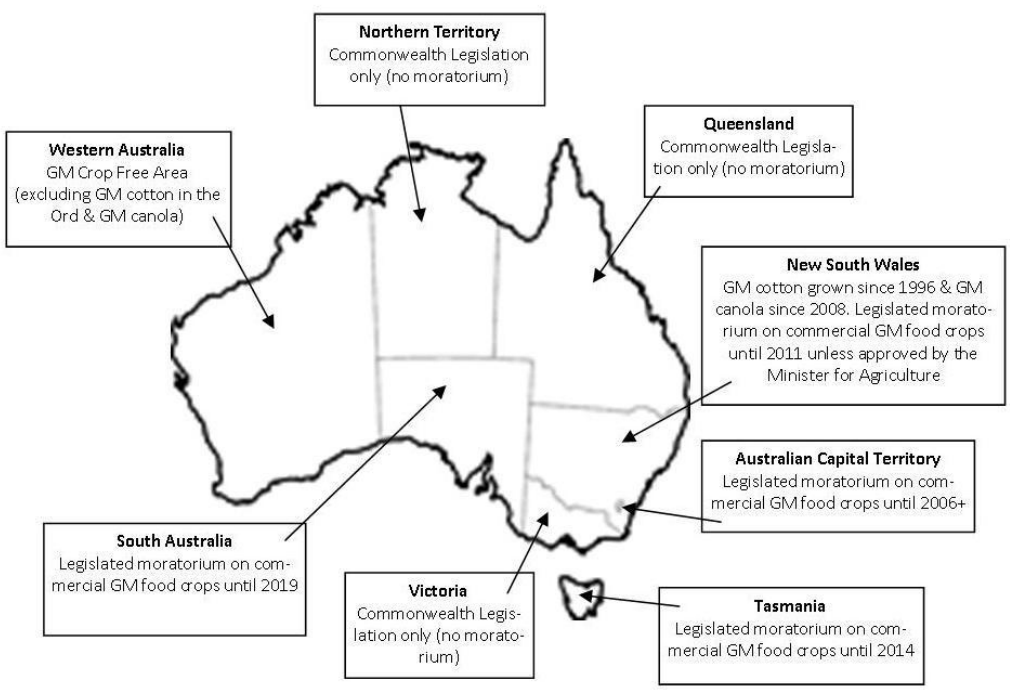
Source: OGTR

PART C: MARKETING

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

Major Australian commodity groups originally voiced concerns about introducing biotech canola and advocated for a 'go-slow' approach largely because of the potential impact biotech canola, which OGTR approved for commercial release in 2003, could have on their domestic and export businesses. In 2003 and 2004, several state governments (Victoria, NSW, South Australia, Western Australia, Tasmania and the ACT), using their powers over commodity 'marketing', imposed moratoria on the commercial release of products of biotechnology (with the exception of the previously approved cotton and carnations). Most of the moratoria were reviewed in 2007, and the states of NSW and Victoria lifted their bans on commercial plantings of GE canola and the first commercial crops were grown in these two states in 2008. In November 2008, the Western Australian government lifted their moratoria to allow GE cotton to be grown in the Ord River area and in April 2009 they also announced that trials of GE canola would be allowed at 20 sites in that state. Moratoria remain in place in South Australia, Tasmania and the ACT.

Australia
State Government GM Positions



Currently in Australia about 95 percent of the cotton planted is from biotech varieties, and there has been little controversy concerning its cultivation. Indeed, environmental benefits and the significant decline in pesticide and herbicide use for this crop have been widely reported. Biotech cottonseed does appear in the domestic market through the oil and meal, and this has not met with any major opposition.

b) PUBLIC/PRIVATE OPINIONS: In late 2012, the Department of Industry commissioned research on community attitudes to biotechnology the results of which were published in March 2013. Previous surveys have been conducted every few years from 1999, to determine public attitudes towards biotechnology and biotechnology applications in Australia.

Key findings of the report were:

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

Full details of this report and those from previous years and other information are available on the Department of Industry website at:
http://www.industry.gov.au/industry/nanotechnology/PublicAwarenessandEngagement/Pages/ResearchandReports.aspx.

c) MARKETING STUDIES: See links below.

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

PART D: CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES:

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

In 2013–14 the OGTR actively engaged in international forums focusing on harmonizing the risk assessment and regulation of GMOs. This included contributing to development of guidance documents by groups under the OECD and the United Nations Cartagena Protocol on Biosafety. In the OECD, Australia is represented on the Working Group on the Harmonization of Regulatory Oversight in Biotechnology by a staff member from the OGTR. The OGTR coordinated Australia's input to current projects, including the guidance document on low-level presence in seeds and commodities, the guidance document on environmental considerations, and the sub-working group on microorganisms. The OGTR also represented Australia as the lead for consensus biology documents on sugarcane, eucalyptus and cowpea. The sugarcane document was finalized in November 2013. In February 2014, the OGTR also represented Australia at an OECD workshop on risk assessment of crops developed using new plant breeding technologies, and presented on working group activities on biotechnology to the 51st session of Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology.

As part of the OGTR's engagement with the UN Cartagena Protocol on Biosafety, a staff member participated in an open-ended online forum on risk assessment and risk management and on the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management.

In August 2013, the Regulator signed a Memorandum of Understanding with the International Centre for Genetic Engineering and Biotechnology for establishing collaborative activities on risk assessment and regulation of GMOs with a number of African GMO regulators to promote harmonization, monitor international practice and maintain links with international organizations that regulate GMOs.

In November 2013 the OGTR held a workshop with representatives from international regulatory agencies in Australia with four international speakers to discuss international regulatory challenges in

gene technology. The workshop was attended by staff from the OGTR and other Australian government agencies with an interest in gene technology regulation.

The OGTR also participated in Australian Government and international discussions around strategies for preventing and managing possible low-level presence of GM crops and attended a Food and Agriculture Organization of the United States' meeting on LLP. The OGTR continued to liaise with other Australian Government agencies in responding to the detection of unauthorized GM wheat in the U.S.

The OGTR interacted with key regulatory counterparts in other countries through bilateral discussions and participation in international forums in 2013–14. These activities included presentations, consultation and/or involvement at:

- Workshop on Biotechnology Commercialization and Trade in APEC Economies – Biosafety regulatory Perspective, September 2013, Kuala Lumpur, Malaysia
- International Life Sciences Institute South Asia Biosafety Conference and Workshop, September 2013, Delhi, India
- Biosafety Inspections Workshop, Kula Lumpur, Malaysia, October 2013
- 3rd Annual Conference of the Association for Biological Safety of Australia and New Zealand, Auckland, New Zealand, November 2013
- Workshop on International Regulatory Challenges in Gene Technology, Canberra, Australia, November 2013
- Workshop on Genetic Basis of Unintended Effects in Modified Plants, Canadian Food Inspection Agency, January 2014, Ottawa, Canada
- OECD Workshop on Environmental Risk Assessment of Products Derived from Novel Plant Breeding Techniques, February 2014, Paris, France
- OECD Focus Session on Biotechnology during 51st Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, February 2014, Paris, France
- 28th meeting of the OECD Working Group on the Harmonization of Regulatory Oversight in Biotechnology, February 2014, Paris, France
- Technical Consultation on Low Levels of Genetically Modified Crops in International Food and Feed Trade, UN Food and Agriculture Organization, March 2014, Rome, Italy
- European Commission workshop, The Global Pipeline of GM Crops: An Outlook for 2020, Seville, Spain, June 2014

Other examples of scientific collaboration include:

- Australia-India Strategic Research Fund
- CSIRO international collaboration
- Australian Department of Industry & Science Collaboration with the Asia-Pacific and Africa Regions.

Australia will host the Agricultural Bioscience International Conference in September 7-9, 2015.

b) STRATEGIES AND NEEDS: None.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART E: PRODUCTION AND TRADE

a) BIOTECHNOLOGY PRODUCT DEVELOPMENT: Researchers are using gene technology to improve the efficiency of animal production in Australia. This research, carried out by universities, Cooperative Research Centers (CRCs) and CSIRO, uses the natural genetic variation in livestock populations to selectively breed animals that produce more meat, milk and fiber. Genetic technologies are also used to develop new vaccines and treatments for preventing and diagnosing livestock diseases. Research which involves the genetic modification of animals to benefit animal and human health is also being conducted.

In Australia, the cloning of livestock is currently restricted to small numbers of elite breeding stock, predicted to be less than 100 beef and dairy cattle and a few sheep within a confined research environment. The work is being carried out by public and private research institutions and universities. A full list of NLRDs, including the institutions carrying out the research, is available on the OGTR website at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/nlrdrec-1.

Parent Organism	Applicant	Modified Trait	License Purpose
Cholera bacterium (Vibrio cholerae)	PaxVax Australia Pty Ltd	Loss of toxin expression (vaccine attenuation) and Selectable marker (mercury resistance)	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
Vaccinia Virus, Fowlpox virus	PPD Australia Pty Ltd	Vaccine - attenuation, Vaccine - antigen expression	Limited and Controlled Release Of Genetically Modified Live Viral Vaccines Against 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)™

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

b) COMMERCIAL PRODUCTION: One company in Australia advertises livestock cloning services to breeders.

c) BIOTECHNOLOGY EXPORTS: None for commercial use.

d) BIOTECHNOLOGY IMPORTS: None for commercial use.

PART F: POLICY

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

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

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

b) LABELING AND TRACEABILITY: All cloned animals are currently confined to the research environment and do not enter the food chain. There is a voluntary agreement in place by Australian researchers and industry on the placing of food from cloned animals or their offspring into the food chain.

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

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

e) INTERNATIONAL TREATIES/FORA: 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 multilateral forums and collaborations with counterpart agencies in other countries. In 2012-13 the OGTR assisted regulatory capacity building activities in countries such as Vietnam, Bhutan and Ghana; presented to a review of the United Kingdom regulatory scheme; participated in an Asia-Pacific Economic Cooperation (APEC) Workshop on Regulatory Issues for Emerging Technologies; delivered presentations to a session on GMO regulation at the World Congress on Risk; participated in an international working group on environmental risk assessment of

genetically modified trees; and provided two plenary addresses and chair discussion panels at the 12th International Symposium on Biosafety of GMOs (ISBGMO 12).

PART G: MARKETING

a) MARKET ACCEPTANCE: No specific market acceptance research has been conducted on the acceptance of food from cloned animals. The information in Part C above on the acceptance of plant GE technology would likely apply to animal biotechnology as well, although the acceptance level would initially be less for GE animals.

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

c) MARKET STUDIES: None.

PART H: CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES: The Office of the Gene Technology Regulator and Australian research institutions carry out much collaborative research with overseas partners (see Part D above).

b) STRATEGIES AND NEEDS: None.

CHAPTER 3: REFERENCE MATERIAL

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

Australian Government

- Office of the Gene Technology Regulator
- Food Standards Australia New Zealand
- Australian Pesticides & Veterinary Medicines Authority
- Department of Agriculture
- Department of Industry & Science
- Commonwealth Scientific & Industrial Research Organization (CSIRO)
- Grains Research & Development Corporation

Other Organizations

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