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# Australia

# AGRICULTURAL BIOTECHNOLOGY ANNUAL

# New Agricultural Technologies Annual Report

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**Report Highlights:**
The United States has substantial interest in Australia's policies and regulatory framework regarding agricultural biotechnology and products derived thereof. Unprocessed (whole) biotech corn and soybeans have not received regulatory approval in Australia and, thus, cannot be imported without further processing. Foods with biotech content of over one percent must receive prior approval and be labeled. This requirement can restrict sales of U.S. intermediate and processed products. Australia's policies and views on this technology influence other countries in the region, and elsewhere, which may follow Australia's lead in developing a regulatory system of their own. The moratoria on new plantings have been lifted in NSW and Victoria and the first commercial plantings of canola took place in 2008. Western Australia lifted it's moratoria in November 2008 to allow GM cotton to be grown in the Ord River region and in April 2009 announced that trials of GM canola would be allowed at 20 sites in that state. The moratoria remain in place in South Australia, Tasmania and the ACT.

## Section I. Executive Summary:

The United States has substantial interest in Australia's policies and regulatory framework regarding agricultural biotechnology and products derived thereof. Unprocessed (whole) biotech corn and soybeans have not received regulatory approval in Australia and, thus, cannot

be imported without further processing. Foods with biotech content of over 1 percent must receive prior approval and be labeled. This requirement can restrict sales of U.S. intermediate and processed products. Australia's policies and views on this technology influence other 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 genetically modified (GM) canola varieties for general release. The State governments have also committed funds for research and development, but most have been 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 and Victoria lifted the moratoria on genetically engineered canola. In November 2008, Western Australia lifted it's ban to allow biotech cotton to be grown in the Ord River region and in April 2009 announced that trials of GM canola would be allowed at 20 sites in that state. South Australia has maintained its moratoria, and moratoria remain in place in Tasmania and the Australian Capital Territory (ACT). 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, about 90 percent of the cotton planted is from biotech varieties, which were approved for release prior to the state moratoria. Although genetically engineered cotton remains popular and planting of this product now dominates the cotton industry in Australia, the moratoria slowed the commercialization and adoption of the technology.

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 viable GMOs and food products containing genetically modified ingredients need to meet these same regulations.

To date, biotech cotton, carnations and canola varieties are the only agricultural crops approved for commercial release into the environment in Australia, while biotech cotton is the only crop grown widely in the country. With the lifting of the moratoria in New South Wales and Victoria, plantings of GM canola are expected to 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. Indian mustard, wheat, rice, sugarcane, white clover, grapevines, pineapple, papaya, canola and cotton. Approval has already been granted for food products derived from biotech corn, soybean, sugarbeet, potatoes, alfalfa, rice and oils from biotech cotton and canola (see Appendices II & III).

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 food products derived from GMOs, if they contain more than one percent of biotech product, get 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. Biotechnology Trade and Production:
## Commercial Crops

Biotech cotton, color modified carnations and canola are the only crops approved for commercial release by Australia's Gene Technology Regulator. It is estimated that biotech cotton varieties are grown on about 90 of Australia's cotton area. The Regulator approved the commercial releases of two biotech canola varieties With the lifting of the moratoria in New South Wales and Victoria in early 2008, that was the first year that canola was grown commercially anywhere in the country. Biotech carnations became the first biotech prod be assessed by the Gene Technology Regulator to "pose minimal risks to people or the environment, and a sufficiently safe to be used by anyone without the need for a license" and they have accordingly been place GMO Register.

Biotech Cotton

Biotech cotton has been grown commercially in Australia since the approval and introduction of Bt, or Inga in 1996. Roundup Ready cotton (herbicide tolerance) and Roundup Ready/Bt cotton (herbicide tolerance/in resistance) were subsequently approved and grown commercially for the first time in 2001. In 2003, Austr Gene Technology Regulator approved an additional cotton variety – 'Bollgard II' – for commercial release a first major commercial plantings were made during the 2003/04 season. Currently, over 90 percent of the Australian cotton crop is made up of GM varieties. In addition, there are a number of new biotech cotton v currently being developed (see Appendix II at the end of this report).

Australian food standards require approval and labeling of food or food ingredients that contain new geneti or protein or have altered characteristics as a result of gene modification. Refined oil from biotech cottons however, does not require a label because the oil contains no genetic material and the cottonseed oil is ide conventional cottonseed oil.

Canola

The commercial releases of two biotech canola varieties (InVigor® hybrid & Roundup Ready®) were approv OGTR in 2003. The first commercial plantings of these varieties took place in 2008 after the state governm NSW and Victoria lifted their moratoria on commercial plantings of GM canola. Approximately 9,600 hectar canola was planted by 108 growers. It is expected that area planted to GM canola varieties will expand in possibly by as much as a multiple of 4, bringing the total to nearly 40,000 ha.

### Applications Under Evaluation

A list of GMO applications currently under evaluation by OGTR is contained in Appendix I of this report.

### Imported Products

Under the Gene Technology Act 2000, approval or authorization must be obtained to deal with genetically m organisms. This means that the importation of live, viable GMOs, are regulated under the Act. Importers apply to OGTR for a license or authorization to import any GMO into Australia. OGTR and the Australian Qu

and Inspection Service (AQIS) work closely to regulate and enforce this situation. The AQIS application for import permit contains a section relating to the genetically modified status of the product.

Foods containing biotech materials must be approved by Food Standards Australia New Zealand and be lab the biotech content is greater than 1% 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 Appendix II report.

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

**Products Developed Outside U.S.**

GM crops grown in Australia have been developed in Australia (see Appendices I & II for list of crops & thei developers). Given that most of Australia's cotton products comes from GM varieties, it is likely that any e cotton & cotton products would contain these varieties. Australia does not export cotton to the U.S. No co was exported to the U.S. in 2008 although small amounts have been exported in the past.

## Section III. New Technologies:

There is a small amount of work currently being conducted in Australia on genetically engineered agricultur relevant animals – mainly chicken & sheep. The work is in the very early stages and is being carried out b and private research institutions and universities. GE animals are considered 'Notifiable Low Risk Dealings' by the OGTR – i.e. "dealings with GMOs that have been assessed as posing low risk to the health and safet people and the environment provided certain risk management conditions are met." A full list of NLRDs, in the institutions carrying out the research, is available on the OGTR website at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/nlrdclass-2.

No GE animals are currently anywhere near the commercial production stage. Should they become comme viable and be intended for the food chain, they would be subject to the same regulations as plant-derived G products are - see 'Biotech Food' section below.

## Section IV. Biotechnology Policy:

**The GMO Regulatory System**

The Gene Technology Act 2000 (the Act) came into force on June 21, 2001 as the Commonwealth compon 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 viabl ranging from contained work in certified laboratories to general releases of GMOs into the environment, an extensive powers to monitor and enforce license conditions. An Inter-Governmental Agreement, between Commonwealth and the states and territories, underpins the system for regulating genetically modified org in Australia. The Ministerial Council for Gene Technology, comprising ministers from the Commonwealth a

state and territory, oversees the regulatory framework and provides advice to the Gene Technology Regula policy principles to assist in decision-making. The individual states and territories have passed or are deve complimentary legislation to the Gene Technology Act in their 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 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;
- Exempt dealing; or
- Included on the GMO Register.

Key features of the Act are the appointment of an independent Gene Technology Regulator and a requirem transparent and accountable implementation. The Regulator administers the regulation of all dealings with 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 GM Pro that resides on the OGTR website: www.ogtr.gov.au.

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

| Agency | What They Regulate | Scope | Relevant Legislation |
|---|---|---|---|
| **OGTR** – Office of the Gene Technology Regulatory (supporting the Gene Technology Regulator) | Dealings with GMOs | The Gene Technology Regulator administers a national scheme for the regulation of GMOs in Australia in order to protect health & 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 GM & 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 GM 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<br><br>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 |
| **AQIS** – Australian Quarantine & Inspection Service | Quarantine | AQIS 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 GM material and the relevant authorization under the Gene Technology Act 2000. | Quarantine Act 1908<br><br>Imported Food Control Act 1992 |

The Act also establishes three committees to advise the Regulator and the Ministerial Council:

- The Gene Technology Technical Advisory Committee (GTTAC) – a group of highly qualified experts w provide scientific and technical advice on applications;
- The Gene Technology Ethics Committee (GTEC) – a group of expert ethicists, which provides ethical particularly in the areas of law, religious practices, animal welfare and population health; and
- The Gene Technology Community Consultative Committee (GTCCC) – a group of people representin broad interests within the Australian community, including consumers, researchers, and environme This group looks beyond the science of gene technology to matters of general concern to the comm relation to GMOs.

**GMOs vs GM Product**

The Gene Technology Act 2000 distinguishes between genetically modified organisms (GMOs) and genetica modified (GM) products. A genetically modified product - 'GM product' - means a thing (other than a GMO 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 GM products in Australia. However, the use of GM products is regulated by other regulatory agencies in a number of situa set out in the table above.

**GMOs Already Licensed by OGTR**

A list of GMOs already licensed by OGTR is contained in Appendix II of this report.

**Biotech Food**

Food Standards Australia New Zealand (FSANZ) is the Australian Government agency responsible for appr food products for the Australian market. Mandatory labeling of genetically modified foods, where introduc or protein is present in the final food, came into force in Australia on December 7, 2001. Regulations for l are contained in Standard 1.5.2 of the Food Standards Code. A list of currently approved biotech food pro contained in Appendix III of this report.

Under the Standard, food or ingredients labeled genetically modified contain new genetic material or prote result of the genetic modification or have altered characteristics, e.g. changed nutritional values, compare conventional food. Some flavorings may also be derived from genetically modified organisms, but labeling required if they are in a concentration of more than 1 gram per kilogram (0.1%). Food additives and proce 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 conjuncti the name of the food, or in association with the specific ingredient within the ingredient list; and for unpac foods for retail sale (such as unpackaged fruit and vegetables, or unpackaged processed or semi-processe the words 'genetically modified' must be displayed in association with the food, or in association with the p ingredient within that food.

**Biotech Feed Products**

Animal feeds containing GMOs (e.g. whole grains or oilseeds) are regulated by the OGTR. The OGTR consi biosafety risks associated with the product and, if necessary, will apply special conditions, or may prohibit of the product as animal feed. As an example, after a GMO has undergone field trials, the organization co the trials may wish to use the unviable by-product (such as seed) as animal feed. Before the product is us any way, the Gene Technology Regulator will consider any risks and, if necessary, will apply conditions or the product to be used.

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

Large amounts of biotech feed products are used in Australia's intensive livestock sector. A large proporti Australia's soybean meal is imported, including from the United States. All cottonseed meal used in Austra considered to be biotech as over 90 percent of the cotton crop is planted to biotech varieties. Biotech and

biotech cotton varieties are not typically segregated in Australia.

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

**Coexistence between Biotech & Non-Biotech Crops**

Coexistence of biotech, conventional, and organic crops has occurred in Australia since biotech cotton varie were commercially grown in 1996. As part of any license to grow a biotech crop, OGTR stipulates the cond under which the crop can be grown to ensure no cross-contamination with conventional or organic crops in vicinity.

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

The PIMC meeting agreed on two thresholds:

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

A number of projects on GMO supply chain management have been undertaken as part of the Department Agriculture, Fisheries & Forestry's Biotechnology Strategy for Agriculture, Food and Fibre (BSAFF). These publications are available at: http://www.daff.gov.au/agriculture-food/biotechnology.

**Biosafety Protocol**

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

## Section V. Marketing:
**Market Acceptance**

Australia has a substantial, risk assessment based regulatory framework for dealings with gene technology genetically modified organisms and the Government is supportive of the technology for its agricultural prod and has been an ally of the United States with regard to the Cartagena Protocol on Biosafety (CPB). This c despite anti-biotechnology activism in Australia that promoted stringent labeling requirements and encoura moratoria on biotechnology plantings. Australia's biotechnology sector is small in global terms, but growin over 440 biotechnology companies (this includes all types of biotechnology, not just agricultural biotechnol

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

Currently in Australia about 90 percent of the cotton planted is from biotech varieties, and there has been l controversy concerning its cultivation. Indeed, environmental benefits and the significant decline in pestici herbicide use for this crop have been widely reported. Biotech cottonseed does appear in the domestic ma through the oil and meal, and this has not met with any major opposition.

A survey conducted on behalf of Biotechnology Australia in 2007 comparing changes in consumer attitudes biotechnology from 2005 to 2007 found significant increases in both awareness of and support for GM food since 2005. Attitudes towards biotechnology in food and agriculture were found to be, on balance, less pos attitudes towards biotechnology in health and medicine. Many respondents tended to associate GM crops w commercial objectives – although when prompted (and sometimes spontaneously), people voiced strong su the development of GM crops that could contribute to humanitarian or environmental objectives (the most prominent example being drought resistant crops). Most participants in the survey regarded environmental objectives as very valuable in the development of gene technology and GM plants.

A minority of survey participants remain strongly opposed to GM food crops in particular. This resistance is associated with a number of attitudes and beliefs, including a belief in natural (non-industrialized) farming practices; opposition to big business and the globalization of commercial agriculture; environmental opposi the release of unnaturally modified organisms into the ecosystem; health concerns about genetic modificat food chain, and discomfort with science and new technology generally. Opposition to genetic modification is stronger where animal products are involved – including among those not overly concerned about GM plant

Stated willingness to eat foods commonly eaten – such as food with preservatives and food made with the pesticides – was equally as low as willingness to eat non-animal related GM products. Therefore it would se stated concerns are somewhat inflated and that actual behavior will not necessarily follow claimed intent.

Compared to food crops, awareness of understanding of GM non-food crops is much lower, although there in-principle support for non-food crops due to lower perceived risks to human health in the long term. Supp especially strong for GM biofuel crops, with people readily associating such crops with the looming fuel crisi need to combat global warming. However, some research participants expressed caution on this issue, argu care (and perhaps GM) would be needed to avoid displacing food crops from prime land.

There was a low understanding of the use of non-GM techniques in agriculture, with the majority unsure wh techniques would entail. Many assume that the techniques would be more 'natural' and therefore preferabl

genetic modification.

The survey found that, broadly speaking, it appears that people became more familiar with biotechnology a technology between 2005 and 2007 and that there is no reason to suppose that the trend towards greater acceptance will not continue, as these technologies become a more normal part of everyday life. They foun there was no great public appetite for detailed factual information about how things are done; rather, peop more interested in learning about the potential benefits of technology.

A full copy of the survey report is available at:
http://www.biotechnology.gov.au/assets/documents/bainternet/Eurekafoodandagriculture20072007080108

A number of reports on market acceptance are also available on the DAFF website at:
http://www.daff.gov.au/agriculture-food/biotechnology/reports/marketing_and_trade.

National Biotechnology Strategy

The Australian Federal Government launched the National Biotechnology Strategy (NBS) in July 2000 with million over three years (FY 2001–04) for targeted initiatives to support the Government's vision for biotec The Strategy was boosted in January 2001 by a further A$66.5m from the Innovation Statement, Backing Australia's Ability, with funding for the Biotechnology Center of Excellence and additional funding for the Biotechnology Innovation Fund. In July 2004, under Backing Australia's Ability- Building Our Future throug and Innovation, the Australian Government provided a further A$20m to strengthen Australia's competitive biotechnology, through continuing the National Biotechnology Strategy and Biotechnology Australia till 200 Further funding was also provided to extend support for the Australian Stem Cell Centre until 2010-11.

Biotechnology also receives funding through other programs in the health, agriculture, environment and ed portfolios. In addition to the Commonwealth Government's contribution to biotechnology development, Au State and Territory governments also commit resources to the development of biotechnology.

The key objective of the Strategy is to provide a framework for Government and key stakeholders to work to ensure that developments in biotechnology are captured for the benefit of the Australian community, inc and the environment, while safeguarding human health and ensuring environmental protection. The Strate addresses six key themes with specific objectives and strategies to achieve them:

- Biotechnology in the community
- Ensuring effective regulation
- Biotechnology in the economy
- Australian biotechnology in the global market
- Resources for biotechnology; and
- Maintaining momentum and coordination.

Biotechnology Australia

Biotechnology Australia (BA) was established in 1999 as an agency comprising five Australian Government departments - Department of Agriculture, Fisheries and Forestry; Department of Education, Employment a Workplace Relations; Department of Health and Ageing; Department of Innovation, Industry, Science and and, Department of Environment, Heritage and the Arts. Funding for BA ceased on June 30, 2008 and its f devolved to these five departments.

National Farmers Federation

In September 2007, the National Farmers Federation released a Gene Technology Policy recognizing the po

biotechnology as a valuable tool within agricultural production systems and urging that all potential benefit be available to farmers to make informed choice in their farming decisions.

**Country Specific Studies Relevant to U.S. Exporters**

The **Department of Agriculture, Fisheries & Forestry** has a number of publications, studies and fact sh available on the Agriculture & Food Biotechnology page.

**Agrifood Awareness Australia** – This organization publishes a large number of bulletins and information

The **Australian Bureau of Agriculture & Resource Economics (ABARE)** has released a large number o & papers on GM industries. Conduct a search for GM on the ABARE website.

## Section VII. Author Defined:

**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

Therapeutic Goods Administration

Department of Agriculture, Fisheries & Forestry

Department of Health & Ageing

Department of Innovation, Industry, Science & Research

Commonwealth Scientific & Industrial Research Organization (CSIRO)

**Other Organizations**

Agrifood Awareness Australia

National Farmers Federation

**Appendix I: GMO Applications Under Evaluation**

The Office of the Gene Technology Register has received the following applications for evaluation. All appl
are posted on the OGTR website when they are first received and again when public comment is sought. F
details of all applications can be found at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-
evaluation-1

| Product | Trait Category | Applicant | Status |
|---|---|---|---|
| **Sugarcane** | Limited and controlled release of sugarcane genetically modified for herbicide tolerance | BSES Limited | Notification posted 1 2009 |
| **Sugarcane** | Limited and controlled release of sugarcane genetically modified for improved drought tolerance and nitrogen use efficiency, enhanced sucrose and fermentable sugars accumulation, and altered plant growth | BSES Limited | Notification posted 1 February 2009 |
| **Wheat & Barley** | Limited and controlled release of wheat and barley genetically modified for enhanced nutrient utilization efficiency | CSIRO | Notification posted 1 February 2009 |
| **Cotton** | Commercial release of cotton genetically modified for insect resistance (Widestrike Insect Protection cotton) | Dow AgroSciences Australia Ltd. | Notification posted 3 October 2008 |

**Appendix II: GMOs Already Licensed for Use in Australia**

The table below provides summary information about all Dealings for Intentional Release (DIRs) currently
GMO Record (i.e. granted licenses for various uses). Full details of all applications can be found on the OG
website at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dirclass-2

| Crop | Applicant | Modified Trait | License Purpose | Status |
|---|---|---|---|---|
| **Wheat & Barley** (*Triticum aestivum* L. and *Hordeum vulgare* L. ) | CSIRO | Altered grain starch composition | Limited and controlled release of wheat and barley genetically modified for altered grain starch composition | Current |
| **Wheat** (*Triticum aestivum* L.) | CSIRO | Altered grain composition | Limited and controlled release of wheat genetically modified for altered grain composition | Current |
| **Rose** (*Rosa X hybrida*) | Florigene Pty Ltd | Altered flower color | Commercial release of rose genetically modified for altered flower color | Current |
| **White Clover** (*Trifolium repens* L.) | Victorian Department of | Viral disease resistance, Antibiotic | Limited and controlled release of | Current |

| | | | | |
|---|---|---|---|---|
| | Primary Industries | resistance | white clover genetically modified to resist infection by Alfalfa mosaic virus | |
| **Cotton** (*Gossypium hirsutum* L.) | Bayer CropScience Pty Ltd | Insect resistance, herbicide tolerance | Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance | Current |
| **Maize** (corn) (Zea mays L.) | CSIRO | The genetic modification helps to identify maize genes that may alter plant characteristics. Antibiotic resistance, herbicide tolerance and reporter gene activity | Limited and controlled release of maize genetically modified to investigate gene function | Current |
| **Cotton** (*Gossypium hirsutum* L.) | CSIRO | Fatty acid composition of the cottonseed oil | Limited and controlled release of cotton genetically modified for altered fatty acid composition of the cottonseed oil | Current |
| **Torenia** (*Torenia x hybrida*) | Florigene Pty Ltd | Phosphate uptake | Limited and controlled release of torenia genetically modified for enhanced phosphate uptake | Current |
| **Cotton** (*Gossypium hirsutum* L.) | CSIRO | Waterlogging tolerance | Limited and controlled release of cotton genetically modified for enhanced waterlogging tolerance | Current |
| **Perennial ryegrass & tall fescue** (*Lolium perenne* L.) and (*Lolium arundinaceum*) (Schreb.) Darbysh | Victorian Department of Primary Industries | Altered lignin and fructan metabolism | Limited and controlled release of perennial ryegrass and tall fescue genetically modified for improved forage qualities | Current |
| **Cotton** (*Gossypium hirsutum* L.) | Monsanto Australia Limited | Water use efficiency | Limited and controlled release of cotton genetically modified for enhanced water use efficiency | Current |

| | | | | |
|---|---|---|---|---|
| **Bread Wheat** (*Triticum aestivum* L.) | Victorian Department of Primary Industries | Drought tolerance | Limited and controlled release of wheat genetically modified for drought tolerance | Current |
| **Banana** (*Musa. acuminata* cv. Grande Naine) | Queensland University of Technology | Enhanced disease resistance, reporter gene expression | Limited and controlled release of banana genetically modified for disease resistance | Current |
| **Sugarcane** (*Saccharum spp.*) | The University of Queensland | Altered sugar production | Limited and controlled release of sugarcane genetically modified for altered sugar production | Current |
| **Wheat & barley** (*Triticum aestivum*)and (*Hordeum vulgare*) | The University of Adelaide | Enhanced tolerance to abiotic stressors, including soil boron and drought, and increased beta glucan levels | Limited and controlled release of wheat and barley genetically modified for enhanced tolerance to abiotic stresses or increased beta glucan | Current |
| **Banana** (*Musa. acuminata* cv. Williams) | Queensland University of Technology | Increased levels of pro-vitamin A, vitamin E or iron | Limited and controlled release of banana genetically modified for enhanced nutrition | Current |
| **Cotton** (*Gossypium barbadense* L.) | Monsanto Australia Limited | Insect resistance and/or herbicide tolerance | Limited and controlled release of GM insect resistant and/or herbicide tolerant *Gossypium barbadense* cotton | Current |
| **Cotton** (*Gossypium hirsutum* L.) | Monsanto Australia Limited | Insect resistance and insect resistance/herbicide tolerance | Limited and controlled release of GM insect resistant and insect resistant/herbicide tolerant cotton | Current |
| **Bread wheat** (*Triticum aestivum* L.) | Department of Primary Industries - Victoria | Drought tolerance | Limited and Controlled Release of GM drought tolerant wheat | Current |
| **Sugarcane** (*Saccharum* spp.) | BSES Limited | Altered plant architecture, enhanced water or improved nitrogen use efficiency | Limited and Controlled Release of GM Sugarcane with altered plant architecture, enhanced water or | Current |

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| | | | improved nitrogen use efficiency | |
| **Canola & Indian Mustard** (*Brassica napus* L. and *Brassica juncea* L.) | Bayer CropScience Pty Ltd | Herbicide tolerance and hybrid breeding system | Limited and controlled release of GM herbicide tolerant hybrid *Brassica napus* and hybrid *Brassica juncea* | Current |
| **Torenia cv. "Summerwave®"** (*Torenia X hybrida*) | Florigene Pty Ltd | Altered flower colour (flavonoid biosynthesis) | Limited and Controlled Release of Genetically Modified (GM) Torenia with altered flower color | Current |
| **Cotton** (*Gossypium hirsutum* L.) | CSIRO | Waterlogging tolerance | Limited and Controlled Release of Waterlogging Tolerant (GM) Cotton | Current |
| **Cotton** (*Gossypium hirsutum* L.) | Monsanto Australia Limited | Herbicide tolerant and/or insect resistant | Commercial Release of GM herbicide tolerant and/or insect resistant cotton lines north of latitude 22° South | Current |
| **Cotton** (*Gossypium hirsutum* L.) | Monsanto Australia Limited | Insect resistance | Limited and Controlled Release of Insect Resistant Genetically Modified Cotton | Current |
| **Cotton** (*Gossypium hirsutum* L.) | Monsanto Australia Limited | Water-use efficiency | Limited and Controlled Release of Water-Efficient Genetically Modified Cotton | Current |
| **Cotton** (*Gossypium hirsutum* L.) | Hexima Ltd | Fungal resistance | Field trial of GM cotton expressing natural plant genes for fungal control | Current |
| **Cotton** (*Gossypium hirsutum* L.) | Bayer CropScience Pty Ltd | Herbicide tolerance | Commercial release of herbicide tolerant Liberty Link® Cotton | Current |
| **Indian mustard** (includes Brown and Oriental mustard) (*Brassica juncea* L. Czern and Coss.) | Bayer CropScience Pty Ltd | Herbicide tolerance and hybrid breeding system | Field trials of genetically modified herbicide tolerant, hybrid *Brassica juncea* | Current |
| **Bread wheat** (*Triticum aestivum* L.) | CSIRO | Altered grain starch and Antibiotic resistance | Field trial of genetically modified wheat with altered | Current |

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| | | | grain starch | |
| **Cultivated rice** (*Oryza sativa* L. cv Nipponbare) | CSIRO | Herbicide tolerance, antibiotic resistance and reporter genes have been randomly inserted into rice plants. Some plant growth traits may be modified by gene knockouts. | Field trial of genetically modified rice (*Oryza sativa* L.) functional characterisation of the rice genome | Current |
| **Sugarcane** (*Saccharum officinarum* L. x S. spontaneum L.) | The University of Queensland | Altered sugar production and antibiotic resistance | Field trial of genetically modified (GM) sugarcane expressing sucrose isomerase | Current |
| **Bovine herpesvirus 1 (BoHV-1)** (*Bovine herpesvirus* 1 subtype 1.2b strain V155) | Queensland Department of Primary Industries & Fisheries | • expression of green fluorescent protein (GFP)<br>• expression of envelope glycoprotein E2<br>• expression of a truncated E0 glycoprotein fused to GFP or to the E2 glycoprotein<br>• localization of introduced proteins on the surface of the GMOs or host cells<br>• deletion or disruption of endogenous BoHV-1 genes | Vaccination of cattle with recombinant bovine herpesvirus vaccines | Current |
| **Cotton** (*Gossypium hirsutum* L.) | Hexima Limited | Insecticidal action, antibiotic resistance | Field trial to assess transgenic cotton expressing natural plant genes for insect control | Current |
| **White Clover** (*Trifolium repens* L.) | Department of Primary Industries (Victoria) | Viral Disease Resistance, Antibiotic resistance | Field Evaluation of Genetically Modified White Clover Resistant to Infection by Alfalfa Mosaic Virus | Current |
| **Fowl adenovirus** (Fowl adenovirus, serotype 8, isolate | Imugene Limited | Immunomodulatory protein expression, Attenuation | Limited and controlled release of GM fowl adenovirus | Current |

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| CFA44) | | | (FAV) | |
| **Cotton** (*Gossypium hirsutum* L.) | Dow AgroSciences Australia Pty Ltd | Insecticidal and herbicide tolerance | Agronomic assessment and seed increase of transgenic cottons expressing insecticidal genes (cry1Ac and cry1Fa) from Bacillus thuringiensis | Current |
| **Cotton** (*Gossypium hirsutum* L.) | CSIRO | Modified fatty acid content in cottonseed oil | Field Evaluation of Genetically Modified High Oleic (HO) Cotton | Current |
| **Cotton** (*Gossypium hirsutum* L.) | Syngenta Seeds Pty Ltd | Insect resistance, antibiotic resistance | The Evaluation of Transgenic Cotton Plants Expressing the VIP Gene | Current |
| **Cholera vaccine** (*Vibrio cholerae*) | CSL Ltd | Attenuation by removal of cholera toxin subunit A and inclusion of a mercury resistance marker | Commercial release of recombinant live oral cholera vaccine (Orochol® vaccine) | Current |
| **Canola** (*Brassica napus* L.) | Bayer CropScience Pty Ltd | herbicide tolerant hybrid canola | Field Trial - Seed increase and field evaluation of herbicide tolerant hybrid canola | Current |
| **Grapevines** (*Vitis vinifera* L.) | CSIRO | Expression of modified colour, sugar composition, flowering and fruit development, expression of green fluorescence protein, antibiotic resistance | Field trial of GM grapevines - Evaluation of berry colour, sugar composition, flower and fruit development and gene flow study | Current |
| **Pineapple** (*Ananas comosus*) | Department of Primary Industries | Reduction of blackheart, delayed flowering, reporter gene expression, antibiotic resistance | Field trial of pineapple plants modified for blackheart reduction and to delay flowering | Current |
| **Papaya** (*Carica papaya*) | The University of Queensland | Delayed fruit ripening, reporter gene expression and antibiotic resistance | Field trial for evaluation of GM papaya to delay fruit ripening and to test the expression of the introduced genes | Current |
| **Canola** (*Brassica napus* L.) | Bayer CropScience Pty Ltd | Herbicide tolerance, Hybrid Breeding System | Commercial release of InVigor® hybrid canola (Brassica | Current |

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| | | | napus) for use in the Australian cropping system | |
| **Canola** (*Brassica napus* L.) | Monsanto Australia Limited | Herbicide tolerance | General release of Roundup Ready® canola (Brassica napus) in Australia | Current |
| **Canola** (*Brassica napus* L.) | Aventis CropScience Pty Ltd | Hybrid breeding system and herbicide tolerance | Small and large scale trialing of InVigor® canola (*Brassica napus*) for development for the Australian cropping system | Current |

**Appendix III: Approved GM Food Products**

The following table contains a current list of approved biotech food products. Detailed information is conta
Standard 1.5.2 on the FSANZ web site.

| Food Produced Using Gene Technology | Special Conditions |
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| Food derived from amylase-modified corn line 3272 | |
| Food derived from glufosinate ammonium-tolerant corn line T25 | |
| Food derived from glufosinate ammonium tolerant cotton line LL25 | |
| Food derived from glufosinate ammonium-tolerant rice line LLRICE62 | |
| Food derived from glufosinate ammonium tolerant soybean lines A2704-12 and A5547-127 | |
| Food derived from glyphosate-tolerant corn line GA21 | |
| Food derived from glyphosate-tolerant corn line NK603 | |
| Food derived from glyphosate-tolerant cotton line MON 88913 | |
| Food derived from glyphosate-tolerant lucerne J101 and J163 | |
| Food derived from glyphosate-tolerant soybean line 403-2 | |
| Food derived from glyphosate-tolerant soybean line MON 89788 | |
| Food derived from glyphosate-tolerant sugarbeet line 77 | |
| Food derived from high lysine corn line LY038 | Unless the protein content has been removed as part of a refining process, the label on or attached to a package of a food derived from high lysine corn line |

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| | LY038 must include a statement to the effect that the food has been genetically modified to contain increased levels of lysine. |
| Food derived from high oleic acid soybean lines G94-1, G94-19 and G168 | The label on or attached to a package of a food derived from high oleic acid soy bean lines G941, G94-19 and G168 must include a statement to the effect that the food has been genetically modified to contain high levels of oleic acid |
| Food derived from insect- and potato leafroll virus-protected potato lines RBMT21-129, RBMT21-350, and RBMT22-82. | |
| Food derived from insect- and potato virus Y-protected potato lines RBMT15-101, SEM15-02 and SEM15-15. | |
| Food derived from insect-protected and glufosinateammonium tolerant corn line 1507 | |
| Food derived from insect-protected and glufosinate ammonium-tolerant DBT418 corn | |
| Food derived from insect-protected and glyphosatetolerant corn line MON88017 | |
| Food derived from insect-protected Bt-176 corn. | |
| Food derived from insect-protected corn line MIR162 | |
| Food derived from insect-protected corn line MIR604 | |
| Food derived from insect-protected corn line MON 810 | |
| Food derived from insect-protected corn event MON863 | |
| Food derived from insect-protected corn line MON 89034 | |
| Food derived from insect-protected, glufosinate ammonium-tolerant Bt-11 corn. | |
| Food derived from insect-protected, glufosinate ammonium-tolerant corn line DAS-59122-7 | |
| Food derived from insect-protected potato lines BT-06, ATBT04-06, ATBT04-31, ATBT04-36, and SPBT0205 | |
| Food derived from sugar beet line H7-1 | |
| Oil and linters derived from bromoxynil-tolerant cotton containing transformation events 10211 and 10222 | |
| Oil and linters derived from glyphosate-tolerant cotton line 1445 | |
| Oil and linters derived from insect-protected cotton line COT102 | |
| Oil and linters derived from insect-protected cotton lines containing event 15985 | |
| Oil and linters derived from insect-protected cotton | |

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| lines 531, 757 and 1076 | |
| Oil and linters derived from insect-protected, glufosinate ammonium-tolerant cotton line MXB-13 | |
| Oil derived from bromoxynil-tolerant canola line Westar-Oxy-235 | |
| Oil derived from glufosinate-ammonium tolerant canola lines Topas 19/2 and T45 and glufosinate-ammonium tolerant and pollination controlled canola lines Ms1, Ms8, Rf1, Rf2 and Rf3 | |
| Oil derived from glyphosate-tolerant canola line GT73 | |

**Recent Reports from FAS/Canberra**

The reports listed below can all be downloaded from the FAS website at: http://www.fas.usda.gov/scriptsw/AttacheRep/default.asp.

| Report Number | Title of Report | Date |
|---|---|---|
| AS9025 | Australia Gains Improved Access for Citrus & Mangos to China | 06/17/09 |
| AS9024 | Global Biosecurity Conference to be held in Australia: Call for Abstracts | 06/11/09 |
| AS9020 | Dairy & Products Semi-Annual | 05/15/09 |
| AS9018 | Cotton Annual | 04/28/09 |
| AS9016 | Sugar Annual | 04/02/09 |
| AS9015 | Grain and Feed Annual 2009 | 03/20/09 |
| AS9014 | Stone Fruit Annual 2009 | 03/13/09 |
| AS9012 | Agricultural Economy and Policy Report | 03/12/09 |
| AS9010 | Livestock Semi-Annual | 03/06/09 |
| AS9009 | Government Announces A$32m Research into Soil Carbon & Emissions | 03/06/09 |
| AS9008 | Wine Annual 2009 | 03/05/09 |
| AS9007 | New Import Conditions for Chicken Meat Finalized | 03/05/09 |
| AS9006 | Cotton Quarterly Update – March | 02/20/09 |
| AS9005 | Agricultural situation 2009 | 02/11/09 |
| AS9004 | Govt. announces A$9 million boost to wood export industries | 01/29/09 |
| AS9003 | February Grain Lockup | 01/29/09 |
| AS9002 | New Support for Wheat Exporters to Develop Markets Announced | 01/27/09 |
| AS9001 | Australian Government Announces Food Production Grants Programs | 01/23/09 |