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Biotechnology

Agricultural Biotechnology 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 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 moratoria on new plantings have been lifted in NSW and Victoria and the first commercial plantings of canola will take place this year. The moratoria remain in place in South Australia, Western Australia, Tasmania and the ACT.

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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 were more cautious about the introduction of the technology and most Australian states 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, but Western Australia and South Australia have decided to maintain their moratoria. In addition, 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, bread 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 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

would be most pronounced for feed grain, e.g. whole corn, and soybeans as these products have not yet received regulatory approval. However, Australia does not allow the importation of many grains and/or grain products for phytosanitary reasons.

Australia's regulatory framework for genetically modified food and feed has only a relatively limited impact on U.S. exports of these products. 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 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, this will be the first year that GM canola is grown commercially anywhere in the country. 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.

Biotech Cotton

Biotech cotton has been grown commercially in Australia since the approval and introduction of Bt, or Ingard, cotton in 1996. Roundup Ready cotton (herbicide tolerance) and Roundup Ready/Bt cotton (herbicide tolerance/insect resistance) were subsequently approved and grown commercially for the first time in 2001. In 2003, Australia's Gene Technology Regulator approved an additional cotton variety – 'Bollgard II' – for commercial release and the 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 varieties currently being developed (see Appendix II).

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

<u>Canola</u>

The commercial releases of two biotech canola varieties (InVigor[®] hybrid & Roundup Ready[®]) were approved by OGTR in 2003. The first commercial plantings of these varieties will take place in 2008 after the state governments in NSW and Victoria lifted their moratoria on commercial plantings of GM canola.

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 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 GMO into Australia. OGTR and the Australian Quarantine and Inspection Service (AQIS) work closely to regulate and enforce this situation. The AQIS application form for an 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 labeled if 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 III of this report.

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 Section III 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.

Section III: Biotechnology Policy

The GMO Regulatory System

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 Ministerial Council for Gene Technology, comprising ministers from the Commonwealth and each state and territory, oversees the regulatory framework and provides advice to the Gene Technology Regulator on policy principles to assist in decision-making. The individual states and territories have passed or are developing 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 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;
- Exempt dealing; or
- Included on the GMO Register.

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 GM Products that resides on the OGTR website: www.ogtr.gov.au.

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

Agency	What they Regulate	Scope	Relevant Legislation
OGTR – Office of the Gene Technology Regulatory (supporting the Gene Technology Regulator)	Dealings with GMOs	The Gene Technology Regulator administers a national scheme for the regulation of GMOs in Australia in order to protect health & 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 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 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 who provide scientific and technical advice on applications;
- The Gene Technology Ethics Committee (GTEC) a group of expert ethicists, which provides ethical advice, 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 representing the broad interests within the Australian community, including consumers,

researchers, and environmentalists. This group looks beyond the science of gene technology to matters of general concern to the community in relation to GMOs.

GMOs vs GM Product

The Gene Technology Act 2000 distinguishes between genetically modified organisms (GMOs) and genetically modified (GM) products. A genetically modified product - 'GM 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 GM products in Australia. However, the use of GM products is regulated by other regulatory agencies in a number of situations as 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 approving GM 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 <u>Standard 1.5.2</u> of the <u>Food Standards Code</u>. A list of currently approved biotech food products is contained in Appendix III of this report.

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%). 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.

Biotech Feed Products

Animal feeds containing GMOs (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 GMO 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.

The Australian Quarantine & Inspection Service (AQIS) 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 AQIS provides quarantine inspection

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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 AQIS.

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 80 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.

Coexistence between Biotech & Non-Biotech Crops

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.

In October 2005, national consensus was achieved in Australia regarding practical thresholds to deal with the issue of traces of GM 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 GM canola in conventional grain and seed.

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 Australian 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 reduced to 0.1 per cent thereafter. The Australian Seed Federation (ASF) established an AP threshold of 0.5 per cent GM seed in non-GM planting seed in 2003 following two years of research and consultation with the canola seed industry.

A number of projects on GMO supply chain management have been undertaken as part of the Department of 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 for consideration of accession to the Protocol. This is 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. Moreover, the 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.

Section IV: Marketing

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. Australia's biotechnology sector is small in global terms, but growing, with over 420 biotechnology companies (this includes all types of biotechnology, not just agricultural biotechnology).

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). The moratoria have recently been reviewed, and the states of NSW and Victoria have now lifted their bans on commercial plantings. Moratoria remain in place in the other four states mentioned above. Currently in Australia about 90 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.

A survey conducted on behalf of Biotechnology Australia in 2007 comparing changes in consumer attitudes towards biotechnology from 2005 to 2007 found significant increases in both awareness of and support for GM food crops since 2005. Attitudes towards biotechnology in food and agriculture were found to be, on balance, less positive than attitudes towards biotechnology in health and medicine. Many respondents tended to associate GM crops with commercial objectives – although when prompted (and sometimes spontaneously), people voiced strong support for 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 opposition to the release of unnaturally modified organisms into the ecosystem; health concerns about genetic modification in the food chain, and discomfort with science and new technology generally. Opposition to genetic modification is much stronger where animal products are involved – including among those not overly concerned about GM plants.

Stated willingness to eat foods commonly eaten – such as food with preservatives and food made with the use of pesticides – was equally as low as willingness to eat non-animal related GM products. Therefore it would seem that 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 is more in-principle support for non-food crops due to lower perceived risks to human health in the long term. Support is especially strong for GM biofuel crops, with people readily associating such crops with the looming fuel crisis and the need to combat global warming. However, some research participants expressed caution on this issue, arguing that 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 what such techniques would entail. Many assume that the techniques would be more 'natural' and therefore preferable to genetic modification.

The survey found that, broadly speaking, it appears that people became more familiar with biotechnology and gene 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 found that there was no great public appetite for detailed factual information about how things are done; rather, people were more interested in learning about the potential benefits of technology.

A full copy of the survey report is available at: <u>http://www.biotechnology.gov.au/assets/documents/bainternet/Eurekafoodandagriculture20</u> 0720070801082636.pdf

National Biotechnology Strategy

The Australian Federal Government launched the <u>National Biotechnology Strategy</u> (NBS) in July 2000 with A\$30.5 million over three years (FY 2001–04) for targeted initiatives to support the Government's vision for biotechnology. 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 through Science and Innovation, the Australian Government provided a further A\$20m to strengthen Australia's competitiveness in biotechnology, through continuing the National Biotechnology Strategy and Biotechnology Australia till 2008. 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 education portfolios. In addition to the Commonwealth Government's contribution to biotechnology development, Australia's 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 together to ensure that developments in biotechnology are captured for the benefit of the Australian community, industry and the environment, while safeguarding human health and ensuring environmental protection. The Strategy 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

<u>Biotechnology Australia</u> (BA) was established in 1999 as an agency comprising five Australian Government departments - the Department of Industry, Tourism and Resources, the Department of Agriculture, Fisheries and Forestry, Department of Health and Ageing, Department of Environment and Heritage, and Department of Education, Science and Training. Funding for BA ceased on June 30, 2008 and its functions devolved to these five departments. Publications and information are still available on the website.

National Farmers Federation

In September 2007, the National Farmers Federation released a <u>Gene Technology Policy</u> recognizing the potential of biotechnology as a valuable tool within agricultural production systems and urging that all potential benefits should 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 available on the <u>Agriculture & Food Biotechnology page</u>.

<u>Agrifood Awareness Australia</u> – This organization publishes a large number of bulletins and information guides.

<u>Rural Industries Research & Development Corporation</u> has published the following studies:

Impact of Genetic Engineering on Consumer Demand, February 2005 Global Response to GM Food Technology: Implications for Australia, February 2005

The <u>Australian Bureau of Agriculture & Resource Economics (ABARE)</u> has recently published the following studies:

<u>GM Crops in Emerging Economies: Impacts on the Australian Agriculture</u> <u>Economic Impacts of GM Crops in Australia</u>

Section V: 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

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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 applications are posted on the OGTR website when they are first received and again when public comment is sought. Full 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
Maize	Limited and controlled release of maize genetically modified to investigate gene function	CSIRO	Notification posted 16 June 2008
Cotton	Limited and controlled release of cotton genetically modified for altered fatty acid composition of the cottonseed oil	CSIRO	Notification posted 28 April 2008
Torenia	Limited and controlled release of torenia genetically modified for enhanced phosphate uptake	Florigene Pty Ltd	Notification posted 27 February 2008
Cotton	Limited and controlled release of cotton genetically modified for enhanced waterlogging tolerance	CSIRO	Notification posted 20 February 2008
Perennial Ryegrass & Tall Fescue	Limited and controlled release of perennial ryegrass and tall fescue genetically modified for improved forage qualities	Victorian Department of Primary Industries	Notification posted 1 February 2008
Cotton	Limited and controlled release of cotton genetically modified for enhanced water use efficiency	Monsanto Australia Ltd	Notification posted 29 January 2008
Sugarcane	Limited and controlled release of sugarcane genetically modified for altered sugar production	University of Queensland	Notification posted 18 March 2008

Appendix II: GMOs Already Licensed for Use in Australia

The table below provides summary information about all Dealings for Intentional Release (DIRs) currently on the GMO Record (i.e. granted licenses for various uses). Full details of all applications can be found on the OGTR website at:

http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dirclass-2

Сгор	Applicant	Modified Trait	License Purpose	Status
Bread Wheat (<i>Triticum aestivum</i>) L.	Victorian Department of Primary Industries	Drought tolerance	Limited and controlled release of wheat genetically modified for drought tolerance	Current
Banana (<i>Musa.</i> <i>acuminata</i> 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
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 (<i>Musa.</i> <i>acuminata</i> 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 hirsutum 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.)	Deltapine Australia Pty Ltd	Insect resistance and insect resistance/herbicide tolerance	Limited and controlled release of GM insect resistant and insect resistant/herbicide tolerant cotton	Current
Bread wheat (<i>Triticum aestivum</i> L.)	Department of Primary Industries - Victoria	Drought tolerance	Limited and Controlled Release of GM drought tolerant wheat	Current

Сгор	Applicant	Modified Trait	License Purpose	Status
Sugarcane (<i>Saccharum</i> 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 improved nitrogen use efficiency	Current
Canola & Indian Mustard (<i>Brassica napus</i> L. and <i>Brassica juncea</i> 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 colour	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.)	Deltapine Australia Pty Ltd	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

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Сгор	Applicant	Modified Trait	License Purpose	Status
Rose (<i>Rosa X hybrida</i> L.)	Florigene Limited	Altered flower colour, selectable marker	Limited and controlled release of GM rose lines	Current
Indian mustard (includes Brown and Oriental mustard) (<i>Brassica juncea</i> L. Czern and Coss.)	Bayer CropScience Pty Ltd	Herbicide tolerance and hybrid breeding system	Field trials of genetically modified herbicide tolerant, hybrid <i>Brassica</i> juncea	Current
Bread wheat (<i>Triticum aestivum</i> L.)	CSIRO	Altered grain starch and Antibiotic resistance	Field trial of genetically modified wheat with altered grain starch	Current
Cultivated rice (<i>Oryza sativa</i> 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 (<i>Oryza sativa</i> 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) (<i>Bovine herpesvirus</i> 1 subtype 1.2b strain V155)	Queensland Department of Primary Industries & Fisheries	 expression of green fluorescent protein (GFP) expression of envelope glycoprotein E2 expression of a truncated E0 glycoprotein fused to GFP or to the E2 glycoprotein localisation of introduced proteins on the surface of the GMOs or host cells deletion or disruption of endogenous BoHV- 1 genes 	Vaccination of cattle with recombinant bovine herpesvirus vaccines	Current

Сгор	Applicant	Modified Trait	License Purpose	Status
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 CFA44)	Imugene Limited	Immunomodulatory protein expression, Attenuation	Limited and controlled release of GM fowl adenovirus (FAV)	Current
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

Crop	Applicant	Modified Trait	License Purpose	Status
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 (<i>Brassica napus</i> L.)	Bayer CropScience Pty Ltd	Herbicide tolerance, Hybrid Breeding System	Commercial release of InVigor® hybrid canola (Brassica napus) for use in the Australian cropping system	Current
Canola (<i>Brassica napus</i> L.)	Monsanto Australia Limited	Herbicide tolerance	General release of Roundup Ready® canola (Brassica napus) in Australia	Current
Canola (<i>Brassica napus</i> L.)	Aventis CropScience Pty Ltd	Hybrid breeding system and herbicide tolerance	Small and large scale trialing of InVigor® canola (<i>Brassica napus</i>) 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 contained in <u>Standard 1.5.2</u> on the FSANZ web site.

Food produced using gene technology	Special conditions
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 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 40-3-2	
Food derived from glyphosate-tolerant	
sugarbeet line 77	
Food derived from high lysine corn line	Unless the protein content has been
LY038	removed as part of a refining process,
	the label on or attached to a package of
	a food derived from high lysine corn line 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	The label on or attached to a package of
lines G94-1, G94-19 and G168	a food derived from high oleic acid soy
	bean lines G94-1, 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	
glufosinate-ammonium tolerant corn line	
1507	
Food derived from insect-protected and	

glufosinate ammonium-tolerant DBT418	
corn	
Food derived from insect-protected and glyphosate-tolerant corn line MON88017	
Food derived from insect-protected Bt - 176	
corn.	
Food derived from insect-protected corn event MON863	
Food derived from insect-protected corn line MIR604	
Food derived from insect-protected corn line MON 810	
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 SPBT02-05	
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 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: <u>http://www.fas.usda.gov/scriptsw/AttacheRep/default.asp</u>.

Report Number	Title of Report	Date
AS8033	Grain and Feed Quarterly Update	07/08/08
AS8032	Wheat Reform Legislation Passes in Parliament	06/25/08
AS8031	Country Strategy Statement	06/20/08
AS8030	Grain and Feed Situation Update	06/13/08
AS8029	Response to the "Safeguards Inquiry Into The Imports of Pigmeat"	06/06/08
AS8028	New Wheat Marketing Legislation Progresses Through Parliament	06/05/08
AS8027	Biofuels Annual	06/04/08
AS8026	Aust Govt Expresses Disappointment Over Farm Bill	05/27/08
AS8024	US Farm Bill: Lost Opportunity – Minister for Trade	05/19/08
AS8023	Dairy Semi-Annual	05/19/08
AS8022	ABARE Report indicates GM crops will provide economic benefits to Australian regions	05/15/08
AS8020	Cotton Annual	05/01/08
AS8019	Draft IRA for Stone Fruit from the US Released for Comment	04/29/08
AS8017	Stone Fruit Annual	04/11/08
AS8016	Pork Safeguard: Productivity Commission Final Report	04/07/08
AS8015	Sugar Annual	04/08/08
AS8014	Grain & Feed Annual	03/28/08
AS8012	Livestock Semi-Annual	03/20/08
AS8011	Commencement of IRA for U.S. Apples Announced	03/19/08
AS8010	Wheat Industry Export Group Discussion Paper Released	03/18/08
AS8009	Call for Comments on Quarantine & Biosecurity Review	03/17/08
AS8008	Commencement of IRA for Stone Fruit Announced	03/14/08
AS8006	Draft Wheat Export Marketing Bill Released	03/06/08
AS8005	Wine Annual	02/26/08
AS8004	Government Announces Review of Australia's Quarantine & Biosecurity Processes	02/21/08
AS8002	Productivity Commission Invites Further Submissions to Pork Safeguards Inquiry	01/23/08
AS8001	Impact of Grain Prices on GOA Policy	01/11/08
AS7076	Productivity Commission Release Accelerated Report into Pigmeat Safeguards	12/21/07
AS7075	Bulk Wheat Export Applications	12/13/07
AS7074	Potato Report	12/11/07
AS7072	Ag Down Under Vol. 14	12/06/07
AS7071	GM Moratoria to be Lifted in Two States	11/29/07
AS7070	Cotton Quarterly Update	11/29/07
AS7069	Ag Down Under Vol. 13	11/26/07
AS7068	Fresh Deciduous Fruit Report	11/21/07
AS7067	Retail Sector Report	11/08/07
AS7066	Citrus Annual	11/07/07