



Australian Government  
Grains Research and Development Corporation

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GTMC Secretariat  
Department of Health and Ageing  
MDP 138  
GPO Box 9848  
CANBERRA ACT 2609  
Email: [GTMC.Secretariat@health.gov.au](mailto:GTMC.Secretariat@health.gov.au)

## 2011 REVIEW OF THE GENE TECHNOLOGY ACT 2000

Dear Council Members,

The Grains Research and Development Corporation (GRDC) is pleased to provide input to the 2011 Review of the *Gene Technology Act 2000* (the Act).

In this submission, the GRDC maintains that:

- (a) The OGTR has continued to be effective in regulating GMOs since the last review was completed in 2006, but opportunities exist to improve the efficiency of the overall approval process.
- (b) It is pleasing to see that growers in NSW, VIC and WA now have the choice to grow OGTR-approved GM canola.
- (c) It is disappointing that growers in SA and TAS are still denied the choice to grow OGTR-approved GM canola because of GM moratoria.
- (d) Section 21 of the Act and Clause 6(d)(i) of the Intergovernmental Agreement continue to generate uncertainty for investors because State Governments can block the commercial release of OGTR-approved GM food crops based on matters other than protecting human health and safety or the environment.
- (e) A new class of application for multiple dealings involving intentional release (DIR) in dedicated GM facilities should be allowed under the Act. This new class of application would allow for multiple events to be trialled at a dedicated site and would be a much simpler process than a full application, as all management practices for containing the GMO would be covered under a facilities licence. Obviously assessment of human and environmental risks of the events would continue to be an important part of this process. However, it is envisaged that the facility would be designed to allow monitoring of the most stringent conditions likely to be applied to an event or organism.

### **About GRDC**

The GRDC is a statutory authority established to plan and invest in research, development and extension (RD&E) activities for the Australian grains industry. Its primary objective is to support effective competition by Australian grain growers in global grain markets, through enhanced profitability and environmental sustainability. In this endeavour the GRDC is a major supporter of plant breeding and agronomic research programs that are carried out by both public sector and private sector research organisations across Australia. Some of this research includes the development and evaluation of new technologies, including in the field of biotechnology and genetic modification (GM) of crops. These technologies can greatly improve the speed, efficiency and precision of plant breeding. The GM technologies in particular may offer novel approaches to frost, salinity and drought, enable efficient weed management, and help reduce fertiliser input by increasing

the plant's nitrogen use efficiency. In the case of plant diseases, GM technologies may provide genetic solutions against recalcitrant fungal pathogens for which resistance is yet elusive despite many years of research, such as sclerotinia disease (canola), powdery mildew (barley), spot form net blotch (barley), take-all (wheat and barley), *Septoria nodorum* (wheat), and rhizoctonia/bare-patch (wheat and barley) to name just a few.

On a global scale, there is growing recognition that global food production will need to double by 2050 on the same area of arable land to meet the growing food demand of a rising global population. This will require a major lift in productivity, which in turn will require continued public and private sector investment in grains R&D. Gene technology and the development of GM crops are viewed as an important tool to help achieve the productivity gains required to boost global food production. As explained in more detail below under emerging trends, the area of GM crops being planted in other parts of the world is increasing rapidly and for Australian growers to remain competitive in international markets, the industry needs to keep up with these developments. The GM technologies providing advantages in any of the areas mentioned above will assist with keeping Australian growers competitive in international markets in the future.

### ***GRDC's position on gene technology***

The GRDC's position on gene technology is as follows:

*"The GRDC will invest in the development and use of gene technologies and genetically modified crops in line with the Australian Government and State Government regulations where this has the potential to provide substantial and long-term agronomic, environmental or economic benefits to its stakeholders.*

*The GRDC will also contribute to industry efforts to maintain the coexistence of different production systems and supply chains and facilitate informed decision-making regarding the use of gene technologies and genetically modified crops in Australian research programs and farming systems.*

*The GRDC is committed to working with industry and Government stakeholders to develop a path to market for GM food crops in Australia and a national approach to their regulation that is supported by Australian, State and Territory Governments."*

The GRDC aims to ensure that any technologies or activities in which it invests are beneficial to Australian growers and are delivered to them as quickly as possible. In this way, the outputs of many projects GRDC is involved in are placed in the public domain and made freely available to growers. In other cases, the most efficient mechanism for research outputs to be converted to grower benefits is through public-private partnerships with private investment in grains R&D becoming increasingly important in Australia.

In some cases, barriers exist which make the path to market for research outputs more difficult. One such barrier over the past decade since the introduction of the *Gene Technology Act* has been the moratoria imposed by State and Territory Governments on the commercial release of OGTR-approved GM food crops. Section 21 of the Act and Clause 6(d)(i) of the Intergovernmental Agreement "provide for the Ministerial Council to issue policy principles in relation to ethical issues, recognising areas (if any) designated under State law for the purpose of preserving the identity of GM crops or non-GM crops for marketing purposes, and other matters prescribed by regulation (which may relate to matters other than human health and safety or the environment)".

The GRDC is pleased that this barrier has been removed for GM canola in NSW, VIC and WA, but disappointed that the barrier still exists in SA and TAS. Despite the eventual commercial release of GM canola in Australia, the ability of State Governments to place moratoria on OGTR-approved events continues to be a source of considerable uncertainty for investors wishing to establish gene technology releases in Australia.

### ***National consistency***

It is imperative to have a nationally consistent approach to the regulation of GM crops in Australia that is science-based, rigorous and transparent, predictable for users, trusted by the community and provides a clear path to market. A national framework already exists for the assessment of risks to human health and safety and the environment, but in practice, national consistency has not been achieved. The State Governments of NSW, WA, SA, TAS and ACT still have moratoria on GM crops based on concerns around market access

and trade impacts—each with its own timeframe and conditions (e.g. exemptions granted to OGTR-approved GM crops that are also approved by the relevant State Minister on a case-by-case basis)—that provide no clear path to market for GM crops in future.

In GRDC's view, the objective of the Act to protect human health and safety and the environment, and the activities of the OGTR clearly demonstrate that Australia (at the national level) possesses one of the most rigorous processes for the release of GM technologies that continue to meet this mandate.

### ***TOR 1: Emerging trends and international developments in biotechnology and its regulation***

The GRDC has monitored the steady global uptake of GM crops since they were first commercialised 15 years ago in 1996. According to the latest report by the International Service for the Acquisition of Agri-biotech Applications (ISAAA Brief 42: February 2011), the global area planted to GM crops reached 148 million hectares (MHa) in 2010. This represents a 10 percent increase from 134 MHa in 2009, an 83 percent increase from 81 million hectares in 2004, and an 87-fold increase over the 1.7 MHa planted globally in 1996. The number of countries growing GM crops has also increased steadily from 6 in 1996, to 18 in 2003, 25 in 2008 and 29 in 2010. The ten biggest GM crop producing countries by planting area all planted more than 1 million hectares to GM crops in 2010. In rank order of planting area (MHa), they were: USA (66.8), Brazil (25.4), Argentina (22.9), India (9.4), Canada (8.8), China (3.5), Paraguay (2.6), Pakistan (2.4), South Africa (2.2) and Uruguay (1.1). In comparison, Australia ranked 12<sup>th</sup> and planted 0.7MHa of GM cotton and canola.

The four dominant commercialised GM crops continue to be soybean, maize, cotton and canola in that order. Currently, herbicide tolerance remains the dominant trait introduced into genetically modified (GM) crops, followed by insect resistance or a combination of these (referred to as 'stacked traits'). However in the next five to seven years we are likely to see GM crops under research and development with traits for herbicide tolerance, insect resistance, nitrogen utilisation and nitrogen use efficiency, higher yield, stress tolerance (e.g. drought and frost), improved feed quality, nematode resistance, disease and fungal resistance, increased oil quality/profiles, virus resistance, and modified starch composition.

The 2011 ISAAA report also provides an example of how GM crops might contribute to increased global food security. Productivity increases attributed to GM crops have enabled Brazil to double its annual grain production since 1990 while increasing cropland by only 27 percent. This and other benefits from GM crops are reported to be spurring strong political will and substantial new R&D investments in GM crops in that country. With an ability to bring up to 100 million more hectares of cropland into production, Brazil is expected to remain a driving force in the global adoption of GM crops and is reported to be investing in infrastructure to support that growth (ISAAA, 2011).

The GRDC believes the weight of evidence suggests that gene technology and the science surrounding it are here to stay, are extremely useful, and will remain important for the future of Agriculture—both in terms of its ability to deliver specific traits to meet market requirements and to address food security issues as the global population rises. GM is already providing benefits to growers, communities and the environment in Australia and around the world. In Australia, GM herbicide tolerant canola is the first example of a GM food crop being approved for commercial release by the Gene Technology Regulator. Canola is an important crop in Australian crop-livestock rotations. Apart from its direct financial return, the use of canola helps to break crop disease cycles through a process called 'biofumigation'. As a result, wheat and barley yields are significantly higher after a canola crop. Similarly, GM herbicide tolerant lupins may be the answer to a declining lupin industry in Australia, which struggles without effective weed management systems. Lupins are an important rotation crop in wheat and barley in Western Australia which produces a large share of Australia's wheat crop, so improving the viability of lupin cultivation would have positive follow-on benefits for Australia's cereal grain production and exportable supplies. The bulk of Australia's cotton crop is a GM variety providing a range of benefits to growers, such as better insect resistance and weed control or a combination of these. The result is a big reduction in pesticide use per hectare and a reduction in the use of stronger chemicals as glyphosate replaces them as a means of weed control.

***TOR 2: The efficiency and effectiveness of the operation of the Act consistently across the national scheme for gene technology regulation in Australia***

***Effectiveness***

The GRDC understands that those conducting gene technology R&D in Australia within the agriculture and science communities agree that both the *Gene Technology Act* and the OGTR are operating in an effective manner. Most interactions are positive and the OGTR is very open to consultation before and during the application process. In fact, the OGTR has been very forthcoming in interacting with GRDC and our research partners in GM projects and have actively sought regular updates on the stage of the regulatory applications.

***Efficiency***

In terms of efficiency, whilst OGTR approvals are mostly given in the specified time frame, the process takes so long that researchers must start preparing an application up to 18 months before they intend planting GM trials. One of GRDC's research partners is working on an application now (June 2011) and in order to be able to plant a GM trial in May 2012 they will need to get the application to the OGTR by the middle of July this year. Applications can be up to 100 pages long and require significant resources both in personnel and time for preparation.

Some researchers believe the legislation is very restrictive in prescribing what the OGTR can and can't do. During the assessment phase the OGTR develops a risk assessment and risk management plan (RARMP) for the trial in which they identify and review risks. The licence is then issued or declined based upon the information in this document. If the researcher subsequently wishes to apply for a variation it can only be considered if the risks were assessed during the original application process. If any new risks identified are outside those in the RARMP, then it is necessary to start with a new application.

This process was acceptable when the trials involved were small and had a limited number of lines, but as researchers move to trialling on a larger scale and dedicated facilities are being built this becomes very restrictive. CSIRO now has two dedicated facilities and the Department of Agriculture and Food, Western Australia (DAFWA) has built two 5 Ha facilities in WA. For these to be utilised properly a new class of application for multiple dealings involving intentional release (DIR) in dedicated GM facilities should be allowed under the Act. This new class of application would allow for multiple events to be trialled at a dedicated site and would be a much simpler process than a full application, as all management practices for containing the GMO would be covered under a facilities licence. Obviously assessment of human and environmental risks of the events would continue to be an important part of this process. However, it is envisaged that the facility would be designed to allow monitoring of the most stringent conditions likely to be applied to an event or organism.

At the moment the only way to use a facility such as those now being developed is to either try and anticipate all needs 5 years in advance, which is not realistic given the nature of research, or only apply to the OGTR for a one-year licence and submit a new full application each year. The second option would substantially increase the workload and cost for both the organisation applying for the licence and the OGTR.

In related efforts to improve efficiency, CSIRO, the Australian Centre for Plant Functional Genomics (ACPG) and others have been interacting with the OGTR to change some regulations regarding the use of single-use sites for GM trials. At present GM trial sites used only once may need to be monitored for many years afterwards. To address this issue in WA, DAFWA, in deliberation with the OGTR, recently made a major investment to establish the dedicated GM trial sites mentioned above.

***TOR 3: The interface between the Act and other Acts and schemes in Australia***

***Interface between gene technology and quarantine regulations***

Australia is a net importer of the base genetic material, or germplasm, that underpins development of improved crop varieties, since it possesses very few indigenous plant species related to Australia's primary grain crops (cereals, pulses and oilseeds). This means that Australia is very dependent on continued access to

new germplasm held in international germplasm collections at international agricultural research centres such as the International Maize and Wheat Improvement Centre (CIMMYT) in Mexico and the International Centre for Agricultural Research in the Dry Areas (ICARDA) in Syria—both of which have very large genetic resource banks. Australia will soon be importing pulse germplasm from the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) in India.

A smooth path of entry for introducing international germplasm and traits (both GM and non-GM) into Australian plant breeding programs is facilitated by Australia having efficient and effective regulatory processes. In the case of GM material, Australia's quarantine regulations and gene technology regulations work together to protect Australia from exotic diseases and pests, and to protect the health and safety of people and the environment from risks posed by, or as a result of, gene technology. In Australia, all 'dealings' with live and viable genetically modified organisms (GMOs), including import, are illegal unless authorised under the Act. To ensure the necessary approvals or authorisations are obtained prior to importation, the OGTR works closely with AQIS, especially in relation to GM seeds/grains. When importing GM seed/grain, or seed/grain that is known to be mixed with any amount of a GM material, the importer is required to notify AQIS by marking 'yes' at the appropriate question in the Application for Permit to Import Quarantine Material. The AQIS permit application form also requires importers to provide details of the relevant authorisation under the Act (e.g. OGTR licence number and other details). To verify authorisations, AQIS and the OGTR may exchange information that importers have provided to either agency. Importers are advised that an authorisation may take time and should therefore be sought well in advance of importing.

At the other end of the research spectrum, when GM crops are successfully developed and approved by the OGTR and State and Territory Governments for commercial release in Australia, the necessary approvals to import and use GM grain will need to be in place in the importing country before trade with Australia is possible. The absence of such approvals in Australia's export markets could become a technical barrier to trade in GM crops that are approved for commercial production in Australia.

### ***Recommendations for amendments to the Act and the Agreement***

The GRDC believes the review presents a further opportunity for the State and Territory Governments to reconsider their position and shift their support behind a nationally consistent approach to gene technology regulation and the activities and decisions of the Gene Technology Regulator. State moratoria prohibiting the commercial cultivation of GM crops make redundant any risk assessment process undertaken and licence issued by the OGTR for GM food crops and should be removed.

The lifting of the moratoria on GM canola allowed commercial production to commence in NSW and VIC in 2008 and in WA in 2010. This saw a limited area of Roundup Ready® canola grown, harvested and marketed in those three states through a segregated system which meant the crop was grown by a small number of accredited farmers, delivered to dedicated delivery sites and sold only to domestic processors. The commercial production occurred under strict processes and protocols developed by the Australian grains industry to manage the co-existence process to effectively segregate GM and non-GM canola through the Australian grains supply chain—including production, transport, storage and marketing. The protocols were developed as part of a grains industry project supported by GRDC and undertaken by Single Vision Grains Australia (SVGA). They outline the grains industry's capacity to deliver and manage the commercial introduction of GM canola and the principles for process management of GM and non-GM grain within the Australian grains supply chain. Together, the documents provided the basis on which the Australian grains industry and the Governments of NSW, VIC and WA were confident to move forward and allow commercial production of OGTR-approved GM canola.

A new class of application for multiple dealings involving intentional release (DIR) in dedicated GM facilities should be allowed under the Act. This new class of application would allow for multiple events to be trialled at a dedicated site and would be a much simpler process than a full application, as all management practices for containing the GMO would be covered under a facilities licence. Obviously assessment of human and environmental risks of the events would continue to be an important part of this process. However, it is envisaged that the facility would be designed to allow monitoring of the most stringent conditions likely to be applied to an event or organism.

The GRDC would be pleased to hold further discussions with the Council on the issues raised in this submission or any other matter relating to gene technology regulation and its impact on grains research activities in Australia. If you would like to hold further discussions with the GRDC, please contact Ms Leecia Angus, Executive Manager, Corporate Strategy and Impact Assessment, on (02) 6166 4500 or email [L.Angus@grdc.com.au](mailto:L.Angus@grdc.com.au).

Yours sincerely



**JOHN HARVEY**

Managing Director