

## Submission to the Review of the Gene Technology Act 2000+

July 15, 2005

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### Background

The Grains Council of Australia (GCA) is the peak representative organisation for Australian grain producers. Grains Council membership is made up of state farming organisations from six states.

Our current state farming organisation members are:

- Western Australian Farmers' Federation
- South Australian Farmers' Federation
- Victorian Farmers' Federation
- New South Wales Farmers' Association
- AgForce Grains
- Tasmanian Farmers and Graziers Association (Associate Member)

Members of Grains Council determine the policies of the Council, which the Council then seeks to enact at a national level. This submission to the review of the *Gene Technology Act 2000* (the Act) is made on behalf of the Grains Council member organisations.

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### Introduction

In June 2005, the Grains Council adopted a new agricultural biotechnology policy.

*Agricultural biotechnology is critical to the future of Australian plant industries, as it will allow greater freedom for the development of more efficient, environmentally and socially sustainable food, fibre and industrial product value chains that will;*

- *Facilitate the offer of a wider range of consumer benefits through the development of innovative food and health solutions,*
- *Allow producers to access new options for managing the interface between farming and the natural resource base,*
- *Provide a range of alternatives to meet the challenges of global climate change and*
- *Allow the Australian plant industries to diversify into the production of a range of new industrial and renewable energy products.*

The new GCA policy takes account of several key factors;

1. The release in March 2004 of the Australian Grains Industry Strategy 2005 – 2025. That report identified the major role agricultural biotechnology will play in the future of the Australian grains industry.
2. The potential of biotechnology to deliver new consumer foods and health solutions, and new industrial products.
3. The ability of biotechnology to deliver tools that will aid natural resource management.
4. An awareness that agri-biotechnology is much broader than modification of plant varieties to confer chemical resistance, the latter accounting for only about 10% of the technology.
5. The adoption by competitors of agri-biotechnology that is providing them with a productivity advantage over Australian producers.

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## Types of Biotechnology

Of particular concern to the members of Grains Council at a national level, is the manner in which the regulation of agri-biotechnology is slanted to what is often referred to as 'first wave'<sup>1</sup> or GMO technologies that focus primarily on input or agronomic factors.

This technology is generally referred to in the wider community as 'GMO' and accounts for approximately 5% of the total scope of agri- biotechnology; a field that covers a range of processes, products and applications that are quite different from the pioneer processes represented by 'first wave' products.

The 'first wave' of GMO's are based on *relatively* old science<sup>2</sup> that has been surpassed by a range of innovations, many of which are focused on product outputs<sup>3</sup> and the integration of technology into sophisticated farming systems.

The 'second wave' of plant biotechnologies will be technically more sophisticated than the first wave, as they will be focused on;

- Allowing scientists to tailor plants to specific agri-ecological conditions (tolerance to drought, salinity, cold) and farmers to modify cropping systems to suit the environment rather than the reverse
- Producing a range of product or market specific traits that will allow more value to be added to crops at the farm end of the value chain.

Third and subsequent waves of plant biotechnology will see the production of molecules in plants replacing industrial production, the growth of medicines in plants (pharma-crops) and a range of new technologies and applications that have not yet been developed.

The production of second and third wave products has either already commenced or is due to commence within the next few years in countries that Australia competes with. Further delays in the introduction of first wave biotechnologies further set Australia back against its competitors and detract from any consideration of the advancement of second and third wave of technologies in Australia.

Australians technology development capabilities are becoming severely compromised if there is not domestic demand for biotechnologies. There is a strong likelihood that any technologies developed in Australia, paid for by Australian producers via levies, will be exported to competitors rather than being commercialised domestically,

## Risks and Perception

In Australia as in many western countries, with the notable exception of the United States, the debate on GMO's has been primarily motivated by socio-political drivers, in particular objections to 'dominance' of the seed / agri-input / biotechnology sectors by trans-national corporations such as Monsanto, Bayer, Du-Pont and Syngenta.

Objections to plant varieties such as herbicide tolerant maize, canola, potatoes, soy, etc, have not been due to 'provable' risks to human or animal health, but to suspicion of trans-national corporations and to the public's reaction to a 'new' area of science.

Excepting advances in public health, most new technologies meet some degree of initial public resistance based on the fear of novelty, where perceived risk is heightened well beyond the levels of actual risk<sup>4</sup>.

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<sup>1</sup> The definition GCA uses for GMO's includes plant varieties that have been genetically modified through the insertion of genetic material to confer resistance to patented agricultural chemicals, or have been genetically modified to express chemical substances that confer protection from insects.

<sup>2</sup> It is generally accepted that the first 'GMO' to reach the attention of the public, industry and activists, was the Calgene Flavr Savr tomato, originally developed in the USA in the late 1980's, early 1990's.

<sup>3</sup> The 'outputs' in this context refer to technology applications aimed less agronomic inputs and more at producing a specific product that has a defined end use and include 'functional foods' – modified starches, oils and a range of other consumer focused products - the use of crops to produce molecules for the Pharma industries, crops developed for specific industrial purposes including the manufacture of bio-fuels and bio-plastics, specific feed crops such as high lysine maize.

<sup>4</sup> Palfreman J. *Sending Messages Nobody Wants to Hear: A Primer in Risk Communication*. AgBioforum – Volume 4, Number 3&4 – 2001 Pages 173 – 178.

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It is a common human reaction to assimilate high risk activities that are familiar (such as driving a car) to a point where the high risk activity is an accepted part of daily living<sup>5</sup>.

The obverse of this is the case with many statistically insignificant risks, such as the risk of chemical residues in food causing cancer or the risk to health posed by food developed from biotechnologies. These 'fears' are raised to a conscious level that is quite irrational, based on the statistical threat to ones health.

In Australia, food borne illness caused by poor food hygiene in the home hospitalises between 5 000 and 10000 people PA, causing hundreds of man hours of productivity to be lost and multiple deaths.

The 'safety' of foods from biotech plants has yet to be disproved and there have been no reported hospitalisations or deaths in Australia or anywhere else in the world from the consumption of food made from GM plants.

### **Regulation**

The current agri-biotechnology regulatory regime requires an overhaul because it is stifling real economic growth, not only in the agricultural sector, but also in the areas of related science, education and technology development.

Regulatory provisions must be significantly reduced and/or streamlined, to allow industry freer access to biotechnologies and to allow the Australian community to benefit from the additional economic activity related to the technology sector that will develop.

Without a major shake up in the way in which agri-biotechnology is regulated, the Australian grains industry runs the risk of becoming a technological, marketing and natural resource management backwater.

It is vital that our industry rapidly progress from a 'non adopter' of the second and third wave of agri-biotechnologies, to being an 'early adopter', if we are to grow the value of our grains industry, create sustainable prosperity in regional Australia and increase the profitability of Australian grain producers.

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<sup>5</sup> Marks. L. *Communicating About Agri-biotechnology*. AgBioforum – Volume 4, Number 3&4 – 2001 Pages 152 – 154.

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## Response to Act Review Terms of Reference

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### Scope of Act

1. *Review the scope of the Act to determine whether the policy objectives remain valid; and consider other issues, technologies or organisms that may be included in the scope of the Act, including:*
  - a. *consideration of economic, marketing and trade, cultural and social impacts, and re-examine how ethical issues are considered*
  - b. *the definitions in the Act, including of the environment, and the need for the definition of other terms, including health*
  - c. *consideration of the technologies and organisms covered by the Act*
  - d. *consideration of a trait based or novel organism based regulatory scope*

The basic policy position of the GCA is that there should be a clear division between;

1. The role of government in regulating the human and animal health and safety
2. The possible environmental invasiveness of a technology and
3. The role of the market in determining the acceptability of technology to prevailing market conditions.

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### TOR 1a

*consideration of economic, marketing and trade, cultural and social impacts, and re-examine how ethical issues are considered*

Governments are notoriously poor at intervening in markets and the world is littered with examples of government having got 'market' intervention wrong.

There is no role for the Gene Technology Act or the Regulator (The Office of the Gene Technology Regulator or OGTR) to consider or intervene in economic or market related matters. These matters should be left to industry to determine, based on the prevailing market conditions at the time.

It is the role of industry organisations such as Grains Council, to bring relevant industry groups together to find market based solutions to technology release and uptake.

While there is a role for researchers in industry deliberations, researchers and research funding organisations should not be primary drivers in this context.

There is a clear role for the Regulator to make determinations on the human and animal health and safety related to agri-biotechnology and on postulating environmental impacts. Cultural and social matters should not be within the scope of the Regulator.

With regard to ethical considerations, there is a clear role for the Regulator when considering biotechnology in an animal context (i.e. cloning and related activities) but not in relation to plant biotechnology.

### **Recommendation 1**

*The Regulator should not become involved in economic or market related matters that are the province of industry and the 'market', nor should the Regulator include cultural or social matters within its purview.*

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### TOR 1 b

*the definitions in the Act, including of the environment, and the need for the definition of other terms, including health*

Good regulation is based on clear and agreed definitions of key matters. In the case of this Act, 'health' and 'environment' are central to the role of the Regulator.

**Health** - The definition of human and animal health should be limited to a scientific assessment of the statistical risk of a technology causing disease or abnormality, using principals and methodologies to define risk that have been established for the assessment of the safety of agricultural chemicals.

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Existing risk assessment processes are based on well established health and medical principals. They have provided a reliable and well accepted method of ensuring that the interests of chemical users, the community and the environment are balanced.

### **Recommendation 1b 1**

*A definition of human and animal health should be adopted that focuses on the risk of a technology causing disease or abnormality, where established statistical analysis and evaluation processes are used to determine if direct health risks from plant bio-technologies are apparent.*

**Environment** - The definition of 'environment' and 'environmental impact' are potentially less clear-cut and more contentious than the definition of health.

#### *Mans' Impact on the Environment*

The production of raw food and fibre is a function of the complex interactions between the environment and mans' ability to manage the interface (the farming system). In a farming system, the environment is represented by available natural resources such as soil and water and other factors such as temperature, evaporation rates, etc.

Agricultural production has, over the last 5000 years, significantly modified the environment on a local, regional and global scale. Modification of the environment by man has accelerated since the industrial revolution and gained considerable pace since the 'green revolution' of the 1950's.

Since the development of 'modern' plant breeding by Gregor Mendel in the 1840's<sup>6</sup> agriculturalists have been introducing new varieties of plants for agricultural production with overwhelming success.

When compared to the introduction of ornamental plants to the environment, where there is a litany of domesticated plants becoming invasive, very few, if any agricultural plants, survive outside their intended production systems.<sup>7</sup>

The modifications carried out to GM varieties currently in production are genetically minor. For example, a 'conventionally bred' canola (*Brassica napus*) variety has between 80 000 and 120 000 genes<sup>8</sup>.

If 80 000 genes is used as a base line for calculation and a GM variety is developed to tolerate the application of a herbicide that would otherwise kill or retard its growth via the insertion, masking or mutation of one gene, this modification represents 0.00124998% of the genes in the plant. The GM and conventional varieties thus share 99.99875002% of their genes.

Genetic modification is more predictable than conventional breeding as it is building on a set of known characteristics from the parent variety. There is precise control over gene insertion, masking or mutation leading to new varieties that share more than 99.99% of genes with the parent plant.

Thus it is not statistically or scientifically sound to maintain that a modified plant, regardless of the technology used to develop it, will cause an 'environmental impact' that is more or less significant than a parent plant, due to the minor nature of the modification.

#### *Farming Systems and Value Chain Context*

The production of plants for food and fibre is essentially an energy transformation process<sup>9</sup>. A broader or more pragmatic definition of 'environmental impacts' should place consideration of a plant technology within a farming system or value chain context.

A calculation of the potential of a biotechnology to contribute to energy use and production efficiency within farming systems or value chains should be used as a primary indicator of potential positive and negative environmental impacts.

In the context of a farming system, this will include plant varieties that allow for lower input usage for comparative energy outputs<sup>10</sup> or similar input levels to deliver yield increases, or preferably both.

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<sup>6</sup> Raven, Evert & Eichorn, *Biology of Plants Sixth Edition*. ISBN: 1 57259 041 6

<sup>7</sup> Carpenter J, Felsot A, Goode T, Hammig M, Onstad D & Sankula S. Comparative Environmental Impacts of Bioechnology derived and Traditional Soybean, Corn and Cotton Crops, Council for Agricultural Science and Technology, June 2002 ISBN 1 887383 21 2, pp.33

<sup>8</sup> Council for Biotechnology Information. <http://whybiotech.ca/canada-english.asp?id=4736>

<sup>9</sup> This perspective refers to the transformation of fossil fuel, sunlight and other energy inputs to produce grains, oilseeds or fibre that is in effect a concentration of the energy used in the production process. This energy is transferred to humans and animals for consumption as food (energy) or to other industrial processes for, in some instances, the replacement of fossil fuels.

<sup>10</sup> Such as replacing cultivation with chemical use.

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In the context of a whole value chain, greater energy efficiency at farm level will translate to energy savings across the value chain, particularly if plant technologies can be used to directly replace fossil fuels (production of bio-fuels and bio-plastics) or if plants can replace industrial process (production of molecules).

Biotechnology will offer the agricultural sector a range of responses to managing the production of greenhouse gas emissions and managing climate change. Any decisions made by the Regulator should take into account these externalities.

Any definition of 'environment' or 'environmental impact' in the Act, has to take account of the fact that there is no 'natural environment', the environment we have today is the product of thousands of years of human (and other animal) intervention and that agri-biotechnologies will play an important role in lessening the impacts of food and fibre production on the environment.

**Recommendation 1b 2**

*The analysis of environmental impacts of agri-biotechnology should encompass whole of value chain benefits, particularly with regard to energy use efficiency and realistically evaluate the potential for invasiveness of new varieties based on the behaviour of non-modified, genetically related varieties.*

**Recommendation 1b 3**

*Industry should be consulted on the definitions of health, safety and the environment (and associated definitions), where industry agreed positions determine the definitions used by the Regulator.*

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**TOR 1 c**

*consideration of the technologies and organisms covered by the Act*

The first wave of modified plants, colloquially known as 'GMO's', represent approximately 5% of the scope of agri-biotechnology.

The current regulations were developed to address concerns raised over the potential release of these technologies into agricultural production systems.

The Regulator should not take into consideration issues other than the evaluation of human and animal health matters and the abovementioned environmental evaluation when considering the appropriateness of agri-biotechnologies.

**Recommendation 1c**

*If a technology is proven to be 'safe', the decision for adoption should be left to the market, regardless of the type of biotechnology under consideration.*

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**TOR 1 d**

*consideration of a trait based or novel organism based regulatory scope*

Similar comments apply to trait based or novel organisms as those made for 1c.

The role of the Regulator should be to evaluate the 'health' of a particular agri-biotechnology that is submitted to it for examination. The Regulator should determine, on the basis of data supplied or on the development of its own data, that a technology poses no statistically significant risk to humans or animals or poses no additional risk to the environment, other than those already posed by normal human activity.

Once the Regulator has made this judgement, the adoption of a technology should be left to market forces to balance the opportunity and threat equation.

**Recommendation 1d**

*There should not be any additional regulation of trait based or novel organisms within the scope of the current Act or activities of the Regulator.*

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## **Act achieving objects**

2. *Investigate whether the object of the Act is being achieved and whether the regulatory framework stipulated in section 4 of the Act is still appropriate.*

Opinions submitted by Grains Council members suggests that the Regulator is undertaking its role to "...protect the health and safety of Australians and the Australian environment..." in a manner that is satisfactory.

However, there is great concern over the manner in which the development of a national framework for the evaluation of agri-biotechnology has broken down, with the intervention of State governments seeking to ban trials, experimentation and the commercial release of agri-biotechnologies.

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## **Operation of the Act**

3. *Examine the structure and effectiveness of the OGTR.*

As previously mentioned, advice provided to the Grains Council by its members is that there is a degree of satisfaction with the 'science based' approach to the evaluation of the 'safety' of agri-biotechnologies by the Regulator.

However, it is important to emphasise that the Regulator should confine its activities to matters that relate directly to health and safety and not become involved in matter that should be left to the market to sort out. Refer to Appendix 1.

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4. *Review the consultation provisions of the Act including:*

- a. *their effectiveness with respect to their costs and benefits, including the value of advice received, and the transparency and accountability they provide*
- b. *the functions and roles of the statutory advisory committees*

While there is a degree of satisfaction with the operations of the Regulator and its advisory committees, the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Ministerial Council (GTMC), the Grains Council has to ask a fundamental question; Why is the regulatory framework so complex?

While the GTTAC provides valuable advice to the Regulator as it carries out its role of evaluating the safety of submitted technology, much of the rest of the framework has been developed to satisfy political, rather than scientific or economic development ends.

Over-regulation places a cost burden technology developers, the grains industry and the wider community. These costs include direct compliance costs, indirect losses from foregone efficiency gains and through reduction in domestic and international competitiveness, where Australian grain producers are 'locked out' of technology their competitors use.

Where political, rather than scientific and economic considerations are made, transparency and accountability suffers. As such committees should be limited to providing advice based on sound methodologies and science, and should not be involved in providing commentary on individual applications to the Regulator.

## **Recommendation**

*The administration of agri-biotechnology should be simplified and focused on evaluating relevant safety and environmental risk factors, leaving marketing, economic and other non safety / environment factors to industry and markets.*

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## **TOR 4 c**

- c *the statutory timeframes for applications under the Act*

The world of agri-biotechnology is a rapidly evolving and developing one. Unfortunately, due to the regulatory regime, Australia is increasingly finding itself becoming a 'technological backwater'.

This is a dangerous position to be in, as we are not only finding that Australian producers are competing with producers in other countries who have a greater range of technologies at their disposal, but we are missing a range of opportunities to better manage our natural resource base.

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As well as these direct impacts, the Australian community at large is missing out from the economic activity that will be generated from the allied industries associated with the development and application of agri-biotechnologies.

Australian Federal and State governments should be encouraging the adoption and development of technology in Australia, not hindering and retarding it.

**Recommendation**

*Australia should aim to have the most efficient agri-biotechnology approval regime in the world that has at its foundation*

- *the provision of health assurances to the broader community and*
- *freedom for industry and markets to determine the applicability of technologies once their safety has been evaluated by the Regulator.*

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**TOR 4 d**

*d the stakeholders included in consultations for various applications under the Act*

It is unfortunate that the current Federal and State regulatory regime has become captive to populist politics and is open to minority or extremist lobbying, using media scare mongering to sensationalise pseudo-science.

Rather than having a system that is based on the sober evaluation of empirical data and specialist advice, there is a tendency in the current system toward political interference in the evaluation of agri-biotechnology.

This has culminated in the State moratoria that have stymied the research, development, growth and uptake of agri-biotechnology in Australia and in bans being placed on the deployment of biotechnology at regional (Local Council) level.

Grains Council contends that neither State nor Local government should have the right to over-rule federal determinations such as those relating to the commercial release of agri-biotechnology.

The regulatory system has to be overhauled and evaluations must be carried out in a manner that is cognisant of short, medium and long term opportunities presented by agri-biotechnology.

Stakeholders involved in the consultation and evaluation processes must be compelled to validate their representation or stakeholder credentials.

**Recommendation 4d**

*As part of the reform process, there should be a clear definition of a 'stakeholder' to ensure that extremist or alarmist groups are not able to mendaciously obstruct the development of technologies that will serve the interests of the majority in the community.*

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**TOR 5**

*Determine whether the powers of the Act allow enforcement of compliance which is effective and appropriate to the circumstances including instances where GMO's may be detected that are present unintentionally.*

The focus of the Regulator should be on providing health assurances to the community and ensuring that, where a proposed technology does pose a higher than acceptable threat to human and animal health or a higher than acceptable risk of environmental invasiveness, a technology will be either;

- a. banned and prevented from being released to the market for commercialisation if there are extreme risks to health or the environment or
- b. have a set of restrictions imposed upon it that has been evaluated by the Regulator to minimise any statistically significant risk to the community.

The current regulatory system encourages a degree of 'self regulation'. Technology suppliers and potential users are encouraged to cooperate to develop management and stewardship regimes and this is a base of self regulation that should be built upon.

When a technology becomes more sophisticated, management regimes must become equally sophisticated. Many of the measures to 'protect' technology and to decrease any possible impact on existing production systems can be incorporated into user licence agreements that prescribe technology management methodologies.

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In many instances, stewardship programs<sup>11</sup> will have to be voluntarily applied, if technology users are to protect the technology from degradation. An example of this successfully occurring is the management of Bt cotton where modelling indicates that "...rapid resistance build-up in pest populations appears to be unlikely is minimum non-Bt refuge areas are maintained".<sup>12</sup>

In instances where the Regulator has determined that a technology is worthy of commercial release and where there is a high probability of a disturbance being created to another party, guidelines can be established to control the application of the technology.

Using agricultural biotechnology should be no different from using any other technology on farm. Where the possibility exists for the user of a technology (a plant variety, a chemical application, a cultivation technique, etc) to cause impacts on a neighbour, systems can be put in place to ensure that any real risk is minimised to statistical insignificance.

It is important to emphasise the responsibility any user of any technology has to ensure that their actions do not cause material damage to others. With regard to the matter of liability for unintended consequences or material damage, Grains Council members believe that common law provisions provide adequate protection for all parties.

#### **Recommendation 5**

*The Regulator should take into account the presence or availability of stewardship programs when assessing the safety of any technology and the capability of such programs to minimise risks. No legal powers should rest with the Regulation with regard to the use of a technology once it has been released to the market.*

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#### **Regulatory burden**

6. *Examine whether compliance and administrative costs, including information requirements, for organisations working in gene technology are reasonable and justified compared to benefits achieved and possible alternatives to legislation.*

In discussions with CSIRO Plant Industry, GCA representatives compared the regulatory regime in Australia with that of the USA, in terms of ease with which technology can be developed.

The complexity and thus cost of the regulatory burden in Australia is providing a disincentive to domestic technology development, at a time when we should be encouraging it. The CSIRO informed GCA that if it were to take the development of its modified starch wheat variety to the USA for trials and evaluation, it could develop a market ready variety 2 to 3 years faster than in Australia.

A 2 to 3 year 'head start' on the development of a product with real human and consumer application<sup>13</sup> such as the one referred to above, would provide the Australian grains industry with a real international competitive advantage and boost the prospects for the development of more second and third wave agri-biotechnologies in Australia.

#### **Recommendation 6**

*A reduction in compliance and administration costs is essential to increase the speed of approvals and to remove the regulatory barriers to the development / release of agri-biotechnologies. Where appropriate, alternatives to legislation should be employed, particularly in the areas of evaluating market and economic factors, which should be determined by the industry / market place – See Appendix 1.*

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<sup>11</sup> Program of this type will include Quality Assurance, Environmental Management Systems, Best Practice Models and similar initiatives.

<sup>12</sup> Qaim M, Cao E & de Janvry A, Agronomics and Sustainability of transgenic Cotton in Argentina. AgBioforum, 6(1&2): 41/47.

<sup>13</sup> High amylose or 'protected starch' will be useful in the treatment of Type 2 diabetes and combating bowel cancer, saving up to 1500 lives per annum in Australia.

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7. *Review the system of approvals and the application of regulatory requirements commensurate to the level of risk.*

The basis premise of the Act is that plants developed using gene insertion, deletion, masking or mutation, are inherently unsafe. In effect, plant biotechnology is presumed to be 'unsafe' and potentially 'hazardous' until proven otherwise. This is not a scientifically defensible presumption.

Grains Council believes that plants produced by insertion, deletion, masking or mutation of a gene or genes, are not inherently less safe than non-modified plants and that the 'risk' or 'threat' has to be proven, not assumed.

Under a revised regulatory regime, such as that referred to in Appendix 1, the Regulator would focus on human, animal and environmental health, providing a risk analysis using accepted processes and principals.

**Recommendation 7**

*The risk assessment process carried out by the Regulator should be reversed to start from the position that a product of agri-biotechnology has to be proven to be harmful or unsafe and that this status should not be assumed. Any assessment of risk should be carried out in a manner that weighs benefits and risks in a transparent and methodologically sound manner.*

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**Interface with other systems**

8. *Examine the nationally consistent scheme for gene technology regulation in Australia and identify any need for, and ways to achieve, improvements in its consistency, efficiency and coordination.*

Unfortunately there is no real nationally consistent approach to the evaluation of gene technology in Australia. The imposition by States of moratoria on the conduct of commercial scale trials and the commercial release of plant biotechnologies is a major stumbling block to industry development.

It is interesting to note that Australia is a 'third party' to a World Trade Organisation (WTO) action being taken by the United States against the European Union over the EU imposition of moratoria similar to those that have been imposed by State governments in Australia. This is a politically inconsistent position and invites the possibility of the United States taking similar action against Australia for the moratoria in place in this country.

The Regulator must ensure that its activities synchronise with other relevant agencies such as Environment Australia, APVMA and ANZFA. The Regulatory process, evaluation of health and environment related matters, should be carried out within a guaranteed maximum time, to ensure that costs to industry are kept to a minimum.

**Recommendation 8**

*The Federal government should examine the powers at its disposal to over rule or invalidate the moratoria placed by State governments on agri-biotechnology.*

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9. *Examine the interface between the Act and other Acts and schemes (either Australian Government or State and Territory) that regulate gene technology and gene technology products. Identify any discrepancies, including regulatory gaps and areas needing consistency and harmonisation of provisions.*

Cooperation and coordination between relevant regulatory agencies should be both an internal and external key performance indicator for all regulatory activities.

In the case of the Act and the Regulator, it is important that a close relationship is maintained with other similar regulatory authorities, such as the Australian Pesticides and Veterinary Medicines Authority (APVMA) and Food Standards Australia New Zealand (FSANZ).

Regardless of the efficiency of Federal regulations, if the matter of State moratoria is not rectified, the matter of Federal regulation will become a moot point.

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### **Changing circumstances**

10. *Examine emerging trends and international developments in biotechnology and its regulation and whether the regulatory system stipulated by the Act is flexible enough to accommodate changing circumstances.*

A major weakness of the Act is that it focuses on 'first wave' GMO's and is not flexible enough to take into account the rapid pace of technological development and market change.

Under the approach outlined in Appendix 1, regulation of agri-biotechnology would become more transparent, flexible and less complex, and compliance costs would be reduced.

The most effective way for the regulations to become more flexible, is to make them less onerous and prescriptive and to incorporate greater freedom for industry and the market to make appropriate technology adoption determinations.

At an operational level, the Regulator appears to be out of step with a range of international regulatory systems. Grains Council is of the opinion that the Regulator should develop a set of mutual recognition protocols, to avoid duplication of regulatory examination, as a means of reducing the cost of regulation in Australia.

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### **Changes to the legislation**

11. *Recommend amendments to the Act (including consideration of those recommendations made by State or Territory Parliamentary Committees), or alternatives to legislation, which improve the effectiveness, efficiency, fairness, timeliness and accessibility of the regulatory system.*

Appendix 1 proposes a more flexible and responsive regulatory system based on two principals.

1. That regulation should be confined to risk analysis and assessment of human and animal health and relevant environmental matters,
2. That all matters relating to marketing and economics be left to industry to evaluate, using market principals as the basic decisions making criteria.

### **Recommendation 11**

*The Act should be significantly revised, with the focus on changing regulation to reflect greater emphasis on and allowance of, the development of industry and market based decision making.*

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### **IGA achieving its aims**

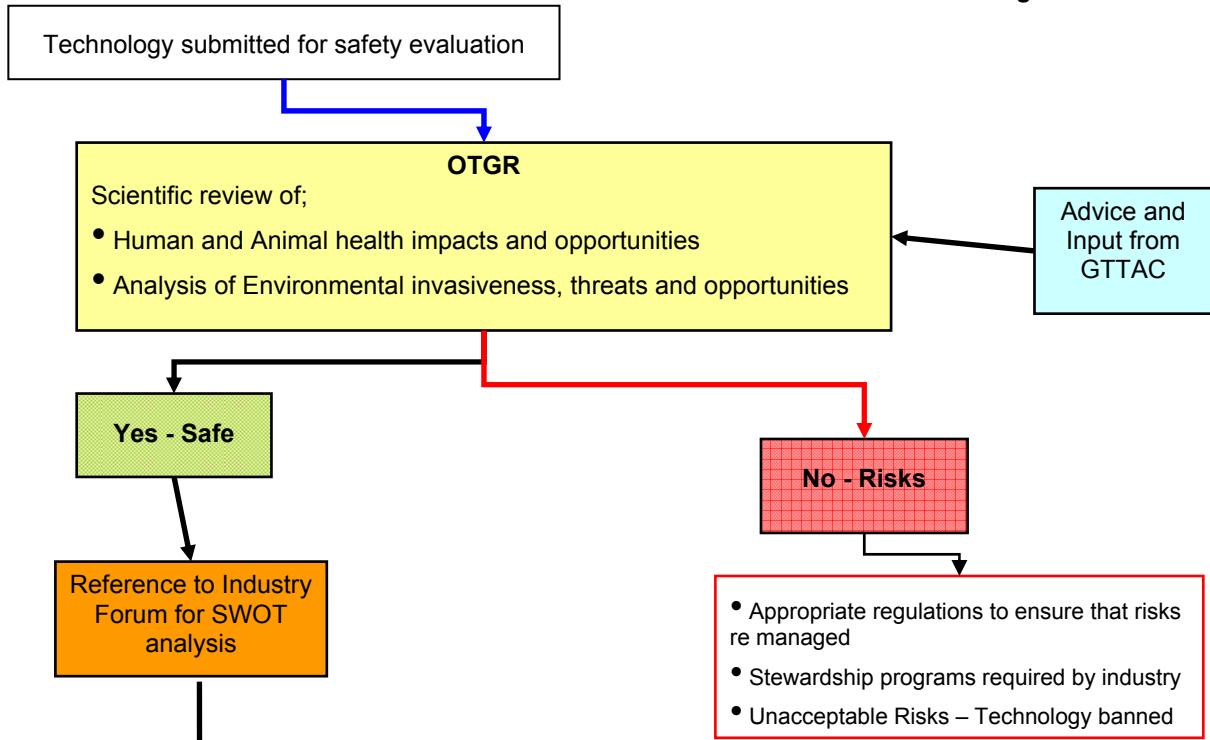
12. *Investigate whether the Intergovernmental Agreement on Gene Technology is achieving the aims listed in its Recitals.*

Clearly the Intergovernmental Agreement is not operating with any degree of satisfaction while State governments impose moratoria.

Until State governments change their positions, or the Federal government moves to over rule or invalidate the moratoria, the IGA is not facilitating consistency of policy making and implementation, or allowing the benefits of agri-biotechnology to flow through to the community.

**Appendix 1 -Regulatory Model for Evaluation of Agri-biotechnology**

**Regulation of Agri-biotechnology – A market based solution  
Commonwealth Regulation Phase**



**REGULATION**

**MARKET**

**Regulation of Agri-biotechnology – A market based solution  
Industry / Market Evaluation Phase**

