

AUSTRALIA GOVERNMENT

REVIEW OF THE

Gene Technology Act 2000 (the Act)

Submission to the
Department of Health and Ageing

Pioneer Hi-Bred Australia Pty Ltd

June 2011

GTMC Secretariat
Department of Health and Ageing
MDP 138
GPO Box 9848
CANBERRA ACT 2609

**RE: SUBMISSION TO THE AUSTRALIA GOVERNMENT'S, DEPARTMENT OF HEALTH & AGEING,
2011 REVIEW OF THE GENE TECHNOLOGY ACT 2000**

Thank you for the opportunity to provide comment on the Australian Government's Gene Technology Act (2000) Review-. Pioneer Hi-Bred is a world leader in plant biotechnology and in Australia we are a seed genetics and crop planting seed provider.

Pioneer Hi-Bred International, Inc., a [DuPont](#) company, is the world's leading developer and supplier of advanced plant genetics to farmers worldwide. With headquarters in Des Moines, Iowa, Pioneer develops, produces and markets a full line of top-quality seeds and forage and grain additives and provides services to customers in nearly 70 countries. Each year Pioneer invests more than US \$150 million in just corn biotechnology (Pioneer's global research budget is around \$US 400 million).

The company's three key research and development objectives are:

1. To improve harvestable yield
2. To reduce crop losses, grower input costs and risks
3. To create value in grain

Examples of agricultural biotechnology innovations to be developed by Pioneer include drought and salinity tolerance, improved nitrogen use efficiency, bio-based clothes and plastics from corn, higher levels of starch in corn for better biofuel efficiency, further improvements to yields and quality.

Pioneer Hi-Bred Australia Pty Ltd was founded in 1975. The company works closely with Australian farmers to develop seed products for the diverse agro-ecological environment in Australia. Pioneer Hi-Bred has invested significantly in providing infrastructure that supports an Australia wide network of field staff and agronomists, each of whom provide in-field support to seed distributors and growers. We have an on-going commitment to expand this investment within Australia to service the supply chain involved in canola growing within the state.

In 2008 Pioneer was the first canola breeding company to release new varieties of GM canola into the Victorian and New South Wales canola markets. In 2009 Pioneer continued to be the market leader with the release of its GM canola varieties in Western Australia following the decision by the Western Australian Government to allow commercial cultivation of GM canola.

In Australia, Pioneer Hi-Bred sells seed of proprietary Pioneer® brand corn, grain sorghum, forage sorghum as well as GM and non-GM varieties of canola. In addition, Pioneer Hi-Bred International has a number of research and development collaborations and investments with a number of Australia's leading private and public sector research institutions.

Yours sincerely



Mr. Keith Glasson
General Manager
Pioneer Hi-Bred Australia Pty Ltd

Pioneer Hi-Bred Australia Response to the Terms of Reference (TOR)

TOR 1: The effectiveness and efficiency of the way that the regulatory scheme operates, taking account of developments since 2005-06 including:

TOR 1 a) *the national scheme for gene technology regulation in Australia to identify any need for, and opportunities to achieve, improvement in its national consistency, efficiency and effectiveness and coordination; and investigate if the aims of the Agreement to determine these are being achieved;*

Following considerable consultation with State and Territory governments together with industry and community stakeholders The Gene Technology Act (2000) was established by the Federal Government with the objective of establishing a nationally consistent gene technology regulatory scheme in Australia. This was established with the intent of providing a “one-stop shop” for stakeholders wishing to introduce, develop and gain approval for the use of gene technology across its many and varied applications within Australia.

To ensure continuity and consistency by the Federal, States and Territory governments in working within the Act, the Inter-Governmental Agreement (between the Federal, State and Territory governments) was established. The Inter-Governmental Agreement makes several references to a national scheme however this has not been achieved.

Under the Gene Technology Act, the Ministerial Council may issue policy principles in relation to the following:

- Ethical issues relating to dealings with GMOs
- Recognising areas, if any, designated under State law for the purpose of preserving the identity of one or both of the following for marketing purposes:
 - GM crops
 - Non-GM crops.

Based on this platform the position of Pioneer Hi-Bred is that there should be a clear division between;

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

As the global food markets, driven by consumers concerns relating to the issues of food security, food safety and food production sustainability and their desire to seek ever greater information on the procurement of food products and the processes by which they are moved through the supply chain, the key to meeting this demand is by way of a combination of of government legislation dealing with human health, safety and the environment and industry/supply chain standards and processes for addressing market related matters.

The legislation for which governments are responsible must remain to be science-based, rigorous and transparent. Hence the need for the continuance of the current approach by the OGTR under the Act, for which Pioneer Hi-Bred would commend the OGTR for its effective and efficient management and engagement with stakeholders.

It is critical to the future introduction of gene technology into Australian agriculture that gene technology regulation in Australia remains science-based, rigorous and transparent and

remains independent of Federal, State or Territory government intervention other than for matters related to market failure.

Pioneer Hi-Bred would strongly encourage the Federal Government to initiate a proactive engagement process with its counter parts in State and Territory governments via the Gene Technology Ministry Council (GTMC) to re-establish continuity and consistency in the application of the principles expressed in the Act and reflected in the Inter-Government Agreement.

TOR 1 b) *emerging trends and international developments in biotechnology and its regulation and whether the regulatory system stipulated by the Act, including definitions within the Act, is flexible enough to accommodate changing circumstances; and*

The field of plant biotechnology encompasses diverse fields with technologies and outputs far broader than just GM crop outputs. Non-GM applications of plant biotechnology can be used to improve variety selection and screening strategies in conventional breeding programs, to identify and source new variations in land races and wild relatives and to better understand the genes and proteins controlling plant responses. The use of markers to track genes or groups of genes responsible for complex traits can increase the success and greatly reduce the time required for conventional breeding programs, giving greater flexibility, more precision and better varieties sooner.

Continuing challenges face the Australian agriculture and food sector; namely, the declining terms of trade, protectionist international trading policies and in some areas significant land and water degradation. New challenges are emerging that will also have impacts on Australian agriculture. Some issues of importance include:

- The increasing importance of consumer demand for markets
- Maintaining the competitiveness of Australian products in the international marketplace
- Increasing importance of efficient and well-linked supply chains
- Appropriate infrastructure, for example transport, communication, water and energy availability
- Higher demands on management skills and access to suitable skilled labour
- Sustainable resource management
- Encouragement of research and development in the agriculture and food sectors
- Impacts of climate variability and change

Amongst the plethora of technologies that will be developed and applied to resolving these issues, the pre-eminent technological development will come from plant biotechnology. The field of plant biotechnology encompasses diverse fields with technologies and outputs far broader than just GM crop outputs. Non-GM applications of plant biotechnology can be used to improve variety selection and screening strategies in conventional breeding programs, to identify and source new variations in land races and wild relatives and to better understand the genes and proteins controlling plant responses. The use of markers to track genes or groups of genes responsible for complex traits can increase the success and greatly reduce the time required for conventional breeding programs, giving greater flexibility, more precision and better varieties sooner.

It is critical to the future use of these technologies in Australian agriculture that gene technology regulation in Australia remains consistent with its current aims, but at the same time reflects developments in the field of biotechnology, including the use of enabling technologies.

Currently, private and public sector organisations within Australia are engaged in a range of international research and development collaborations with outcomes that will have direct application in crops and pastures grown in Australia. Examples of key areas of research and development include applications of traits for biotic and abiotic stress, improvements in nutrient use efficiency, genetic marker technology for selection of elite plants for breeding, yield enhancement, product quality improvement and novel protein production for the industrial and medical research markets:

The most effective way for the regulations and the operations of the OGTR to reflect emerging trends and international developments, is to focus on the implementation of a nationally consistent system that is science-based, rigorous and transparent. The process should not unduly interfere with industry and provides a clear and predictable path-to market.

The Act currently captures a wide range of related technologies, including processes that do not include the incorporation of novel DNA or that mimic natural processes. With the advent of such new technologies the definition of GMOs captured within the Act should be reviewed and at the same time harmonised with agencies such as Food Standards Australia and New Zealand (FSANZ) and the Australian Pesticides and Veterinary Medicines Authority (APVMA).

TOR 1 c) *definitions and provisions within the Act to identify possible areas for enhancement in light of experience with the operation of the regulatory system.*

Whether the object of the Act is being achieved and whether the regulatory framework stipulated in section 4 of the Act is operating effectively.

The object of the Act is to “protect the health and safety of Australians and the Australian environment from risks posed by, or as a result of, gene technology by identifying those risks and managing them by regulating certain dealings with genetically modified organisms (GMOs)”.

Within the definition of the current Act, the OGTR is achieving the Acts objectives via the framework it has adopted for the assessment of risk which is based on a rigorous science-based regulatory.

Where the “spirit” of the Act has not been achieved is where State and Territory government legislation relating to “Market Choice” (i.e. economics, markets and trade) has been allowed (directly or indirectly) to influence the ability of technology proponents to commercialize traits in crops (e.g. GM canola) which have been approved by the OGTR as being safe to human health and the environment.

The only acceptable role of the Federal, State and Territory governments for becoming engaged in market related matters is where there has been clear market failure.

In the case of GM canola, the grains industry supply chain addressed concerns raised by State and Territory governments in relation to market issues by issuing a statement entitled “Delivering Market Choice with GM canola”.

(http://www.afa.com.au/pdf/Delivering_Market_Choice_with_GM_canola.pdf).

In endorsing this statement, the industry agreed that it could deliver the three key elements of market choice which are:

- the ability of any supply chain participant to source product that meets a predetermined set of specifications
- the ability of any supply chain participant to supply product that meets a predetermined set of specifications
- the ability of any supply chain participant to manage their area of the production, processing, manufacturing and delivery of product to a pre-determined set of specifications.

Despite this commitment from the grains industry in addressing the issue's raised, various State and Territory governments proceeded to impose moratorium under their respective legislation. The lack of consistency in dealing with GM canola between the Federal and State/Territory governments was further emphasised by the lack of consistency and continuity between the States and Territories in nominating criteria and process for the approval for growing of GM canola commercially.

Providing a product is proven to be safe under The Act and its origins can be independently traced to support that claim, then it is the role of the market within a 'free trade' economy to determine if the benefits the product offers to consumers and/or the supply chain are acceptable or not, when compared to current alternative options. The market remains free to choose the product or not. If the product provides these benefits then it will be adopted, if not then the product will not remain in the market.

Pioneer Hi-Bred would strongly encourage the Federal Government to initiate a proactive engagement process with its counter parts in State and Territory governments via the Gene Technology Ministry Council (GTMC) to re-establish continuity and consistency in the application of the principles expressed in the Act and reflected in the Inter-Government Agreement.

The powers of the Act to ensure that they are sufficient to enforce compliance.

The OGTR has to be commended on its approach to the manner in which it monitors and enforces compliance within the powers of The Act. From being a key point of conflict between the regulator and stakeholders, the manner in which OGTR currently engages with stakeholders has evolved to a position where this is no longer seen as point of contention. Rather, the compliance process between the OGTR and stakeholders is now a proactive process in which a collaborative prevention approach has been adopted rather than the original enforcement- punitive approach.

However, due to the introduction of various State and Territory legislation relating to the growing and management of GM crops and pastures, a significant level of inconsistency now exists between the Federal and State/Territory based approaches to compliance.

This inconsistency in relation to compliance at a State and Territory level has resulted in the imposition of unrealistic restrictions (e.g. banning the transport of GM canola seed in SA), compliance practices and management costs, even when the GM crop has been approved as being safe to human, health, safety and the environment by the OGTR.

Due to the lack of consistency between the OGTR and its governance of compliance and the approach taken by respective State and Territory governments, there is a lack of confidence in there being a predictable and clear path to market for new gene technologies. If this

inconsistency is allowed to persist it will continue to be detrimental to introducing innovative gene technology to Australia.

Pioneer Hi-Bred would strongly encourage the Federal Government to initiate a proactive engagement process with its counter parts in State and Territory governments to re-establish continuity and consistency in the application of the principles expressed in the Act and reflected in the Inter-Government Agreement.

The consultation provisions of the Act to determine:

- a) *their effectiveness with respect to changes in communication modes, such as various social media tools; the costs and benefits, including the value of advice received; and the transparency and accountability that they provide;*
- b) *the functions and roles of the statutory advisory committees; and*
- c) *the stakeholders for various applications under the Act and the methodology used to engage them.*

As a member of the Australian Seed Federation (ASF) and a company which markets GM canola seed, Pioneer would like to commend the OGTR for its consultation and communication process within the Australian seed industry. This has been achieved through the OGTR demonstrating a positive approach to engagement with participants and their preparedness to proactively offer assistance and advice when dealing with a range of matters associated with the dealings within The Act.

Pioneer recommends that the OGTR continues to engage with stakeholders in this same manner and where possible enhance its communication so as to ensure that the Australian community (including the seed industry) recognises the existence and strategic role of the OGTR in independently assessing and adjudicating on the human, health and environmental safety of GM crops and pastures.

Pioneer supports the following position of the ASF and other industry stakeholders on the following matters:

- a) The role of GTAC, GTEC and GTCCC:

Of the three advisory committees to the OGTR, the Gene Technology Advisory Committee (GTAC), the Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC), only GTAC provides an effective and efficient and transparent process for the evaluation and provision of feedback to the OGTR.

The GTAC approach of assessment for agricultural, environmental and industrial biotechnology research applications and multi-disciplinary focus is critical to maintaining a rigorous, science-based regulatory framework.

Pioneer Hi-Bred agrees to the current amalgamation of GTEC and GTCCC. The purpose of the amalgamated committee should be advisory - to provide guidance to the OGTR without placing any statutory obligation on the decisions of the OGTR.

b) The role of city and shire councils:

One aspect of the consultation process which lacks credibility and relevance is in relation to the role of the 'city and/or shire' councils in providing submissions in the application process.

Going forward, councils should either take a more proactive educated approach to their role in the application process or be replaced by that of farmer-based organisations (e.g. VFF, SAFF, NSWFF, PGA, and WAFF) that represent the majority of the stakeholders in these rural environments.

TOR 1 d) The interface between the Act and other Acts and schemes in Australia (include all States and Territories) that regulate gene technology and its products; and identify any discrepancies, including regulatory gaps and areas needing consistency and harmonisation of provisions.

The major problem with the current regulation of gene technology in Australia at the Federal Government level is the level of undue duplication between regulatory agencies such as the OGTR and the APVMA, when dealing with insect, fungal and/or herbicide tolerant crops.

Unnecessary duplication of regulation is undesirable because it increases regulatory costs with no associated benefit. For example there are provisions under the Act which requires both the approval of the OGTR and APVMA for GM crops. Over time it has become increasingly clear that the roles of the OGTR and APVMA overlap.

Pioneer Hi-Bred supports the CropLife proposal that the APVMA develop specific guidelines for registering GM crops and that the Ministerial Council directs the Intergovernmental Regulators Forum to consider this regulatory streamlining, and any other regulatory duplications that can be identified.

TOR 1 e) The regulatory burden and whether compliance costs for organisations working in gene technology are reasonable and justified compared to benefits achieved and if the regulatory requirements for classes of approval under the Act are commensurate with the level of risk.

The obligation of the regulatory system is to serve both the public and private sectors of research and development, as such the basic dilemma for the OGTR is to establish a cost structure which is equitable to all participants and that does not differentiate between each sector.

Currently, the administrative compliance cost structure, implemented by the OGTR for regulatory requirements for classes of approval under the Act is commensurate with the level of risk and the expectations of stakeholders.

However in relation to the imposition of administrative costs relating to compliance there is a distinct "gap" between what is realistic and equitable as administered by the OGTR versus State and Territory compliance systems which have fundamental flaws on which it is undertaken. Hence, for there to be equity between the Federal and State/Territory compliance cost structure, there needs to be a fundamental realignment of the operating principles of the OGTR and that of State and Territory governments, in relation to compliance.

Where appropriate, alternatives to compliance based legislation should be employed, particularly in the areas of evaluating market and economic factors, which should be determined by the industry / market place.

Pioneer Hi-Bred would strongly encourage the Federal Government to initiate a proactive engagement process with its counter parts in State and Territory governments via the Gene Technology Ministry Council (GTMC) to re-establish continuity and consistency in the application of the principles expressed in the Act and reflected in the Inter-Government Agreement.