AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

2011 Review of the *Gene Technology Act 2000 (the Act)*

Submission to the Department of Health and Ageing

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Executive Summary

AusBiotech Ltd (AusBiotech) welcomes the opportunity to contribute to the 2011 review of the *Gene Technology Act 2000* (the Act) that was announced on 26 May 2011 by the Gene Technology Ministerial Council (GTMC) Secretariat.

AusBiotech is Australia's biotechnology industry organisation, which represents over 3,000 members, covering the human health, agricultural, medical device, bioinformatics, environmental and industrial sectors in biotechnology.

AusBiotech represents its members by providing expertise as industry advocates and committee members on all biotech steering committees; as well as providing industry submissions to policy review panels at both government and corporate levels.

AusBiotech consulted with its agricultural, environmental and industrial biotechnology members from the public and private sectors, and we have presented in this submission the key issues our members believe should be considered by the Council.

AusBiotech shares the concerns raised by its members from the public and private sectors and others that:

1. The *Gene Technology Act 2000* remains relevant;

2. The Office of the Gene Technology Regulator (OGTR) is operating in an effective and efficient manner;

3. The OGTR continues to provide a transparent and consistent federal gene technology regulatory system;

4. Australia's science-based Federal regulatory system is rigorous and should remain focused on the assessment of human health, safety and the environment;

5. The OGTR continues to engage with stakeholders and communicates in both a transparent and timely manner to ensure the Australian community recognises of the existence and role of the OGTR in maintaining human health and environmental safety of Genetically Modified (GM) crops;

6. The Act was intended to establish a national, consistent and predictable gene technology regulatory system in Australia (which unfortunately has not been achieved);

7. Australia needs a nationally consistent gene technology scheme to provide a consistent path-to-market for approved GM traits and enabling technologies which can be applied to crops and pastures within Australia;

8. The Commonwealth and states, through the GTMC, needs to reconfirm its commitment and support for a nationally consistent scheme for gene technology regulation;

9. The Federal regulatory agencies responsible for gene technology (OGTR, Food Standards Australia and New Zealand (FSANZ) and the Australian Pesticides and Veterinary Medicines Authority (APVMA)) continue to focus on harmonising their operating procedures and assessment processes;

10. Improve efficiencies by rationalising the amalgamation of the Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC) as well as the councils.

Responses to Terms of Reference (TOR)

TOR 1

> **Examine and review 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;**

AusBiotech has consulted broadly and with members of the agricultural, environmental and industrial biotechnology industry from the public and private sectors and believes the Federal gene technology regulatory system administered by the OGTR is efficient and effective, thus meeting the needs of stakeholders within industry.

The current science-based approach by the OGTR is transparent and consistent - and the OGTR should be commended for its outstanding work and application of the principles of the Act.

The position of AusBiotech is that there should be a clear division between;

1. The role of government in regulating the human, health and safety and the possible environmental invasiveness of biotechnology; and

2. The role of the market in determining the acceptability of biotechnology to prevailing market conditions.

It is critical to the future inclusion of biotechnology into Australian agriculture that related regulation in Australia remains science-based, rigorous and transparent. As global food markets, driven by consumers' concerns on the issue of food safety and food security, seek ever greater information on the procurement of food products and the processes by which they are moved through the supply chain, the key fundamental oversight is by way of a combination of government and industry management of standards. The standards and processes must be science-based, rigorous and transparent, hence the need for the continuance of the current approach by the OGTR.

Providing a product is proven to be safe 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.

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.

It is critical to the future use and development of gene technology into Australian agriculture that gene technology regulation in Australia remains consistent with its current aims, but at the same 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 powers of the Act to ensure that they are sufficient to enforce compliance.**

- **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;**
c) **the stakeholders for various applications under the Act and the methodology used to engage them**.

The OGTR should be commended for its consultation and two-way communication with the agricultural, environmental and industrial biotechnology industries since the 2006 review of

the Act, which was achieved through proactive and reactive advertising, digital media, participation at events and face-to-face contact with stakeholders.

AusBiotech recommends that the OGTR continues to engage with stakeholders and communicates in both a transparent and timely manner with them to ensure the Australian community recognises the existence and role of the OGTR in maintaining human health and environmental safety of GM crops.

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, efficient, economic 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.

Although the advisory committee process in relation to GTEC and GTCCC has been established with sound intent, due to the 'vested interests' of some current participants and the issues with transparency, they have failed to deliver meaningful outcomes. The lack of transparency and outcomes has also contributed to the lack of confidence in the OGTR process.

AusBiotech 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.

As noted, the strength of the current applicant process is the breadth and depth of public and private sector 'expertise'-based consultation that is undertaken by the OGTR in relation to the various aspects of an applicant's submission via GTAC, GTEC and GTCCC. 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.

This aspect of consultation is flawed for a number of reasons:

1. The majority of councils do not know or understand that their council has an option to comment on applications due to a lack of knowledge of the Act;
2. Where applicant submissions are considered by councils, councillors are not active in the deliberation process;
3. In general the majority of councillors, particularly in regional areas are not from farming communities, rather they are representative of town/city interests and hence, do not understand many aspects of applicant submissions. Where previously offers were made to councils for the provision of information via field days, meetings or publications, there was an over whelming lack of response or acceptance of these offers;
4. In general, councillors' knowledge and understanding of the issues pertaining to agricultural biotechnology are limited. Despite the fact that a local farmer organisation (with greater knowledge) supports an applicant's submission, councils err of the side of caution and fail to support the same submission.

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.

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.

At present the cohesiveness between the Act and state-based legislation that regulates gene technology is absent. The ability of the states to impose bans on Genetically Modified Organisms (GMOs) approved by the OGTR act as a veto on the Federal body and means that there is no predictability for industry as to its ability to commercialise GMOs, even after undergoing the OGTR approval process. This is a significant disincentive for the investment and development of biotechnology in this country.

State legislation and moratoria in the Australian Capital, Territory, Tasmania and South Australia is hampering the innovation and growth of the agricultural, environmental and industrial biotechnology industries by restricting the path-to-market of OGTR-approved GM products.

Australia is a small market with respect to its size and population; however it retains a leading position within the global export market due to the quality and volume of its crop and animal-based exports. Thus it is a major generator of value by way of these exports for the Australian economy. While the current inconsistent regulatory approach remains in place between the Federal and state-based regulators, Australia will continue to fall behind in developments and adoption of biotechnology innovations in its export competitor countries. While the inconsistent regulatory system remains in place, it will continue to destabilise the entire industry affecting inward R&D investment to support innovation and international partnerships – despite Australia having a reputation for world-class plant science.

AusBiotech believes that Australia needs a nationally consistent gene technology scheme to provide a consistent path-to-market for approved GM traits and enabling technologies, which can be applied to crops and pastures within Australia.

AusBiotech recommends that the Commonwealth and States through the Gene Technology Ministry Council (GTMC) reconfirm its commitment and support to a nationally-consistent scheme for gene technology regulation as per Recommendation 9.1 of the 2006 Review of the Act.

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 current costs of the processes associated with a stakeholder operating within the Act are reasonable and beneficial based on the current classes of approval and the compliance approach undertaken by the OGTR within the Act. However, given the inconsistency between the Federal and state-based approaches to compliance (at a state level) the incremental compliance and associated costs are unrealistic and are detrimental to current and future investment in new technology for Australia.

Any GMO with pesticide function is required to be registered by APVMA. In all cases, the assessment of APVMA regarding safety to humans or the environment either relies on the assessment of the OGTR or duplicates it.

This duplication of regulation increases the regulatory costs without any associated benefit.

AusBiotech recommends that duplication with other Acts (e.g. *Agricultural and Veterinary Chemicals Act 1994*) should be reviewed to remove unnecessary duplication and achieve a consistent, unified regulatory system for GMOs.

TOR 2

> **Provision of recommendations for amendments to the Act and the Agreement (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**.

AusBiotech believes that the Act is relevant and provides for transparent, science-based regulation of GM crops in Australia. The Act was intended to establish a national, consistent and predictable gene technology regulatory scheme in Australia, and this was to be under-pinned by an Inter-Governmental Agreement (between the Federal, State and territory Governments). Although the Inter-Governmental Agreement refers to a national scheme, this has not been achieved.

Conclusion

It is apparent when reviewing the *Gene Technology Act 2000* that it was intended to establish a national, consistent and predictable gene technology regulatory scheme in Australia. Having consulted with AusBiotech's agricultural, environmental and industrial biotechnology members from the public and private sectors, this has not been achieved – due to state legislation and moratoria hampering innovation and growth of the agricultural biotechnology industry and, the path-to-market of OGTR-approved GM products.

AusBiotech recommends OGTR continues to provide a transparent and consistent federal gene technology regulatory system, which is science-based, and communicates with key stakeholders to ensure the Australian community is aware of its existence and role in maintaining human health and environmental safety of GM crops and pastures.

It is essential for the Commonwealth and states, through the GTMC, reconfirm its commitment and support to a national scheme for gene technology regulation – and enforce this as part of the Inter-Governmental Agreement underpinning the Act.