Australian Seed Federation

Submission to the
Statutory Review of the
Gene Technology Act 2000

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Executive Summary

Australian Seed Federation (ASF) welcomes the opportunity to contribute to the 2011 Review of the *Gene Technology Act 2000* that was announced by the Gene Technology Ministerial Council Secretariat on May 26.

The Australian Seed Federation (ASF) is the peak industry body for the Australian seed industry at the local, state, and national level. ASF membership is from all sectors of the seed supply chain and covers a diversity of geography, climate, crops and cultivars.

ASF shares the genuine concerns raised by its members that:

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

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

3. Australia's science-based federal regulatory system is rigorous and critical;

4. 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;

5. The Commonwealth, States and Territory governments through the Gene Technology Ministry Council (GTMC) reconfirm their commitment and support to a nationally consistent scheme for gene technology regulation as per Recommendation 9.1 of the 2006 Review of the Act.

6. ASF 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.

7. With the advent of new technologies the definition of GMOs captured within the Act should be reviewed and harmonized with its counter parts in affiliated regulatory agencies.

8. There is no clear path to market for ASF stakeholders engaged in the development and marketing of GM crops and pastures even when they have satisfied the requirements of the Gene Technology Act.

9. 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.

10. Australian governments (Federal, State and Territory) need to recommit to supporting and maintaining a nationally consistent gene technology scheme which will provide a consistent path-to-market for stakeholders wishing to seek OGTR approval under the Act for approved GM traits and enabling technologies.

Background

The Australian Seed Federation (ASF) is the peak industry body for the Australian seed industry at the local, state, and national level.

The ASF membership is commercial, diverse and includes stakeholders from all sectors of the total seed supply chain. The ASF membership also covers a diversity of geography, climate, crops and cultivars.

The ASF also represents its members internationally, as a member of the International Seed Federation (ISF) and the Asia Pacific Seed Association (APSA).

For more information on the ASF and its membership please visit www.asf.asn.au

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 1a

> **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 consultation with ASF members that are stakeholders in the introduction and use of gene technology the ASF is pleased to report that the overwhelming consensus of the membership is that the Federal gene technology regulatory system administered by the Office of Gene Technology Regulator (OGTR) is operating in a efficient and effective manner which is acceptable to its members and stakeholders within the seed industry.

The ASF would like to commend the OGTR for the transparent scientific based approach which it takes to dealings with the industry participants whether that be in general consultation or via the formal application process. An outcome of this approach is that the OGTR delivers a consistent approach to the application of the principles of the Act for all stakeholders and the broader Australian community.

It is critical to the current and future introduction of gene technology into Australian agriculture that regulation in Australia remains science-based, rigorous and transparent. However to meet global demand for the use of gene technology for food, feed and fibre production from Australia and to provide a clear pathway to market for these products, ASF believes that Australia needs a nationally (i.e. Federal, State and Territories) 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.

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

TOR 1b

> **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 introduction 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 and which is predictable and provides a clear 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 harmonized with its counter parts in affiliated regulatory agencies such as the APVMA, FSANZ and AQIS.

TOR 1c

> **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 is commended for its consultation and communication process with the broader agricultural industry, and more specifically with 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. ASF 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 assessing and adjudicating on the human, health and environmental safety of GM crops and pastures.
The ASF supports the position of 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, 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, advice to the OGTR is often biased and poor. As a direct result, there is a lack of confidence in the OGTR process.

   The ASF 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. The ASF believes that to be successful, the amalgamated advisory committee must comprise of members that cover the broad scope of community interests.

   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.

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.

   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.

In order to retain the effectiveness of the OGTR in dealing with industry and community stakeholders while at the same time remaining consistent with the principles of the Act, the position of ASF (as with similar industry organisations) is that there should continue to be a clear division between;

1. The role of government in regulating human, health and safety and the environment; and

2. The role of the market in determining the acceptability of products derived from biotechnology to prevailing market conditions (i.e. market choice).

Following extensive consultation with stakeholders prior to the introduction of the Gene Technology Act (2000) it was agreed by stakeholders that the Act, would be underpinned by an underlying principle that the Act would provide to industry and the community a nationally consistent gene technology regulatory scheme in Australia. Despite the commitment from Federal, State and territory governments to support this approach by way of the Inter-Governmental Agreement this has not been achieved.

The principle underpinning the Act has been undermined by way of the majority of States and Territories having introduced subsequent legislation to address "marketing concerns". The resulting legislation established by the various State and Territory governments being neither consistent between States and Territories nor transparent to stakeholders in its application and interpretation. The outcome is that there is no clear path to market for ASF stakeholders engaged in the development and marketing of GM crops and pastures even when they have satisfied the requirements of the Gene Technology Act.

This scenario is reflected in the situation regarding the continued lack of continuity in the regulatory approach between the Federal government and State and Territory governments to the growing and transport of GM canola. The continued ban on the growing of GM canola in South Australia and Tasmania for "marketing reasons" has had a direct impact on the ASF canola seed producer members who supply the Australian market with canola sowing seed.

Canola seed varieties are developed by seed companies to supply all State markets with a range of varieties to meet the particular climatic and environmental conditions, in general many varieties can be grown across all States, as time goes on it will become more difficult to produce varieties for the non-GM States due to the increased cost of developing additional varieties for these small canola growing States thus depriving growers in South Australia and Tasmania of access to new canola varieties that are technologically advance and high yielding. If these discrepancies are allowed to remain in place the viability of canola seed and grain industries within these states will be placed in jeopardy.

The movement on GM canola sowing seed through SA is banned

The South Australian Government currently has a moratorium in place which prevents the growing of GM canola commercially in the Sate unless under a restrictive permit system, the ban extends until 2019.

One of the unfortunate consequences of the moratorium on the growing of GM crops in South Australia is the inability for the canola seed industry to transport canola sowing seed of GM varieties through South Australia. The moratorium prevents the movement of such canola sowing seed from Queensland/Victoria/NSW to Western Australia and from Western Australia to the Eastern States. Canola seed companies/producers in the Eastern states and Western Australia are now forced to ship GM canola seed by sea or move by road transport through Darwin, avoiding the natural transport route through South Australia. The consequences of rerouting canola planting seed due to this current scenario are:

- an increase in transportation costs,
- greater complexity in logistics,
- additional time to transport the seed to customers in the east or west, and
- increased risk of farmers losing yield potential due to having to delay planting as a result of delays in planting seed supply. (e.g. floods in 2011)

ASF has developed a protocol for the movement of seed from Queensland/Victoria/NSW to Western Australia through South Australia and vice versa. The purpose of these protocols is to describe good practice that seed companies can adopt to manage the risk of inadvertent loss or spillage of GM seed when transporting seed within South Australia. To date the protocols have not been accepted by the South Australia Government.

The protocols, in conjunction with the following documents have been developed and adopted by the Australian Seed Federation (ASF) to enhance the ability of the Australian seed industry to demonstrate that procedures have been put in place by ASF Members to manage co – existence and the movement of seed.

- Code of Practice for the Labelling and Marketing of Sowing Seed
- Best Practice Guidelines for the Management of Adventitious Presence in Canola Varieties,
- Management of Adventitious Presence in Seed

Difficulties of canola seed entering Tasmania

As GM canola sowing seed is prohibited from being grown in Tasmania addition testing costs are encountered by canola seed companies when importing non-GM canola seed into Tasmania.

The testing of all canola sowing seed is mandated by the Tasmanian Quarantine Act to provide evidence that the canola seed does not contain GM events. The testing procedures are expensive and restrictive for the small size of the Tasmanian market, Tasmanian farmers are penalised due to the higher cost of seed and that they are unable to obtain technologically advanced high yielding canola varieties.

The outcome is that it has created an unnecessary perception, domestically and internationally, that Australia does not have a clear path to market for gene technology and by implication the regulatory process has contributed to this perception due to the lack of continuity between the Federal government and its counter parts at a State and Territory government level.

In summary it is critical to the future viability of Australian agriculture and its ability to compete on global markets with its exports that the regulation governing the introduction of gene technology into Australian agriculture remains science-based, rigorous and transparent. ASF believes that all Australian governments (Federal, State and Territory) need to recommit to supporting and maintaining a nationally consistent gene technology scheme which will provide a consistent path-to-market for stakeholders wishing to seek OGTR approval under the Act for approved GM traits and enabling technologies.

ASF 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 based on the current classes of approval and the compliance approach undertaken by the OGTR within the Act.

However, as previously noted, due to the introduction of various State and Territory legislation relating to the growing and management of GM crops and pastures, there is inconsistency between the Federal and State based approaches to compliance.

This inconsistency in relation to compliance at a State and Territory level has resulted in the imposition of incremental and unrealistic compliance and management costs, even when the GM crop has been approved as being safe to human, health, safety and the environment by the OGTR.

The lack of consistency between the OGTR and its governance of compliance under the Act and the approach taken by respective State and Territory governments will continue to be detrimental to current and future investment in introducing new technology to Australia.

ASF 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.

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**.

ASF believes that the Act within itself continues to remain relevant and provides for transparent, science-based regulation of GM crops and pastures 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.

ASF recommends that the Commonwealth and States through the Gene Technology Ministry Council (GTMC) reconfirm its commitment and support for a nationally consistent scheme for gene technology regulation in accordance with the Inter-Governmental Agreement.

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 ASF biotechnology members, 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.

ASF 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.

It is essential for the Commonwealth and States through the Gene Technology Ministry Council (GTMC) to reconfirm its commitment and support to national scheme for gene technology regulation – and enforce this as part of the Inter-Governmental Agreement underpinning the Act.

ASF Submission Ends