



**AusBiotech submission
to the 'Third Review of the National
Gene Technology Scheme'**

To: The Department of Health and Ageing:
<https://consultations.health.gov.au/health-systems-policy-division/genetechreview2017/>

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Executive Summary

AusBiotech Ltd (AusBiotech) welcomes the opportunity to contribute to the 2017 *Review of the Gene Technology Scheme* that was announced by the Gene Technology Ministerial Council Secretariat in July 2017.

This submission represents a collation of comments and submissions from AusBiotech members engaged in delivering economic benefits to Australia through the commercialisation of biotechnology.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology, food technology, industrial and agricultural biotechnology sectors. The industry consists of an estimated 900 biotechnology companies and employs in excess of 45,000 Australians.

Within AusBiotech the agriculture, food and industrial biotechnology sectors are represented by the AusAg & Foodtech Committee, a special interest industry group dedicated to support AusBiotech with its mission to:

“...foster a growing, strong and profitable biotechnology and life science industry in Australia through representation, advocacy and the provision of services and benefits to its members to help the industry realise its nationally important economic potential.”

AusBiotech consulted with AusAg & Foodtech Committee members from the public and private sectors, and have presented in this submission the key issues our members believe should be considered by the Australian Government.

AusBiotech shares the genuine 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. Australia’s science-based federal regulatory system is rigorous and should remain focused on the assessment of human health, safety and the environment;
4. The OGTR continues to engage with stakeholders and communicates in both a transparent and timely manner, to ensure the Australian community recognises the role of the OGTR in maintaining human health and environmental safety of GM crops;

5. 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;
6. The Commonwealth and States through the Gene Technology Ministry Council (GTMC) need to reconfirm its commitment and support for a nationally consistent scheme for gene technology regulation.
7. The Federal regulatory agencies responsible for Gene Technology (OGTR, FSANZ, APVMA) continue to focus on harmonizing their operating procedures and assessment processes.

Background

The ability of Australian agriculture to meet the potential for growth in demand for food, feed, fibre and energy, for a growing global population will depend on the industry's capacity to embrace innovation, engage investment and bring new technology to market.

The success of Australian agriculture has been built on innovation that has come from both the development of Australia's own technology and the rapid adoption of world best practices, including the freedom to evaluate and adopt new technology.

The need for Australian agriculture to continue to innovate and have the freedom to evaluate and adopt new technology was reinforced in the findings of the *Creating Our Future — Agriculture and food policy for the next generation* report (DAFF, February 2006)¹, which identified the foundations of long-term success for Australian agriculture and food.

“Biotechnology is transforming agriculture and food production. Its benefits — agronomic, environmental, nutritional, human health and economic — can strengthen the Australian agriculture and food sector’s competitive position in world markets. Other farmers around the world are rapidly adopting crop varieties that are genetically modified for traits such as insect resistance and herbicide tolerance. Many other traits are in the pipeline for a wide range of crops and livestock. If Australia falls behind in this rapidly developing area of innovation, it will lose ground to competitors whose investment in, and adoption of, biotechnology is racing ahead...As Australian agriculture and food businesses strive to remain competitive, GM and other biotechnologies offer ways to reduce costs, drive innovation and maintain sustainable industries.”

As outlined in this seminal report, biotechnology offers a set of innovative tools that will create new and improved food and fibre products, more efficient and resilient farming systems with far-reaching agronomic, environmental, nutritional, human health and economic benefits. Such benefits will strengthen Australia's competitive position in global food and fibre markets and provide increased surety of supply for domestic consumers. To

¹ Corish, P. et al. 2006 Agriculture and Food Policy Reference Group 2006, *Creating Our Future: Agriculture and Food Policy for the Next Generation*, Report to the Minister for Agriculture, Fisheries and Forestry, Canberra, February.

achieve these benefits, innovators need to be able to bring new products to the market supported by a workable and predictable regulatory system.

Applying biotechnology in agriculture will allow Australia to capture potentially significant human health, environmental and economic benefits. With this in mind the authors of the *Creating Our Future — Agriculture and food policy for the next generation* report put forward the following recommendations:

- *“Governments must give higher priority to communicating the benefits of current and emerging agrifood biotechnology, and to publicising the robustness of the regulatory regime for the safety of research and the resulting products.*
- *Agriculture and food businesses should work with governments to facilitate the rapid uptake of agrifood biotechnologies that will contribute to better health, a cleaner environment and more globally competitive industries.*
- *State governments should lift their moratoriums on the commercial use of GM crops immediately, and work with the Australian Government, industry and researchers to achieve nationally consistent traceability and tolerance protocols, and to clarify legal liability surrounding the use of GM organisms in agriculture and food products.”*

Agricultural biotechnology has been the source of some of the greatest innovations in agriculture and if appropriately regulated, will contribute some of the most exciting future innovations. Agricultural production systems are being reworked to take advantage of newly developed Ag biotech processes and products and the pipeline of future products is truly exciting.

Inconsistent and unpredictable legislation and regulation, is the single most influential factor impacting the decision of major research providers to invest in Australia. This uncertainty is being exacerbated with the development and introduction of new technologies at a time when policy and regulation has not kept pace with these developments.

AusBiotech responses to the terms of reference (TOR)

TOR 1) Current developments and techniques, as well as extensions and advancements in gene technology to ensure the Scheme can accommodate continued technological development

Scientific progress and the rapid development of new technologies in the plant breeding sector, referred to as New Breeding Techniques (NBTs), have led to the discussion whether these techniques lead to products which are subject to the legislation as described in the Act (2000) and the Gene Technology Regulations 2001.

Groundbreaking plant breeding technologies are creating an exciting time for Australian agricultural researchers, promising benefits for both local farmers and consumers. If

Australia is to maintain its competitive strength in the sector, policy and regulation must keep pace with the latest innovations.

New breeding technologies (NBTs) are a game-changer in agricultural plant breeding and potentially livestock genetics. They offer the means to improve productivity, generate differentiated products and build sustainable production systems. NBTs help plant breeders precisely and efficiently develop desirable characteristics in their crops such as tolerance to drought, disease or insects; improved nutrition; reduced allergens; and extended shelf-life. NBTs have the potential to enhance food-chain sustainability by reducing food waste, tailoring foods to meet the needs of specific markets and decreasing the need for pesticides. The result is a higher-quality and efficiently produced crop tailored to suit producers' requirements and market demand.

Earlier genetic modification (GM) techniques, including transgenes, inserted new genes into target plants (e.g. herbicide/insect tolerance) where these pests were a major limitation to production. NBTs, on the other hand, work with genes already present in the plant's own DNA to enhance the desirable characteristics of the plant. NBTs are a vital platform for improving crop yield and the quality products from these crops. NBTs have the potential to make a significant contribution to addressing the issues of feeding a continuously growing global population, expected to exceed nine billion by 2050. To remain globally competitive, the Australian agricultural industry must embrace innovation, including the adoption of new crop varieties derived from NBTs.

It is now well recognised and acknowledged by the biotechnology industry, researchers and regulators such as the OGTR and FSANZ, that Australia's regulatory framework has not kept pace with innovation and there is a lack of clarity surrounding the requirement for regulation of NBTs.

If the current legislative and regulatory framework is left unchanged, the regulatory burden unnecessarily imposed on these technologies will impact the benefits and broad adoption of NBTs in Australia. Therefore it is a matter of priority that the Australian policy and regulatory scheme through the current review of the Act be updated to accommodate these new techniques. Only then can Australian agriculture confidently adopt these innovations and move forward to enhance plant production and product quality for domestic and overseas markets.

AusBiotech members recognise that a robust gene technology regulatory framework, based on global best practice, is critical to build confidence and certainty; it underpins public investment and ensures Australia's global competitiveness.

AusBiotech is strongly aligned with other science-based organisations such as the Australian Academy of Science (AAS) and the Australian Academy of Technological Sciences (ATSE). AusBiotech contends that a robust legislative and regulatory framework for NBT's should be developed with the understanding that:

- Extensive variations in breeding techniques have existed prior to now, and have historically been accepted without a need for regulation.

- Plants and animals developed through new technologies should not be differentially regulated if they are similar to, or indistinguishable from, those that could have been produced through earlier breeding methods (i.e. those exempted from regulation under Schedule 1A).
- The risks to the health and safety of people and the environment posed by the products developed using most new technologies are comparable to those of earlier breeding methods.
- New technologies are more targeted and precise than earlier, non-regulated breeding methods.
- Products developed using new technologies have significant socio-economic, environmental and health benefits that may be inhibited by regulation that is not commensurate with risk.
- Generally applicable environmental, health and food safety regulations should continue to apply.
- Beyond the generally applicable regulations, any additional regulatory oversight should be based on the risks inherent in the end-product, not the process used to develop that product as far as possible; and
- Regulatory oversight should be science- and evidence-based, transparent, predictable, proportional to risk, time- and cost-effective, non- redundant, enforceable, globally harmonised and politically independent.

AusBiotech makes the following recommendations in relation to NBTs, which are consistent with the principles of the robust legislative and regulatory framework described above:

1. Adopt Option 4 of the recent OGTR Review of Regulations which excludes certain new technologies from regulation on the basis of the product and/or outcomes they produce.
2. Redefine Schedule 1, Item 1 of the regulations which currently states:

“Mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species).”

This definition is inconsistent with other definitions within the ‘Act’, such as:

- a. **gene technology**: any technique for the modification of genes or other genetic material
- b. **genetically modified organism**: an organism that has been modified by gene technology

There is a need to provide more definitions around mutagenesis as well as providing consistency in the definitions with other government agencies (e.g. FSANZ). AusBiotech recommends that this be changed to a definition that states:

“A mutant organism in which the mutational event did not involve the introduction of any non-homologous DNA sequences from a non-sexually compatible species.”

3. Exclude ODM, SDN-1 and SDN-2 from regulation under the GT Act 2000 by including these new technologies in Schedule 1A.
4. Exclude cisgenesis from regulation under the GT Act 2000, by including cisgenesis in Schedule 1A.

AusBiotech supports the ATSE and ASS recommendation that the OGTR adopt an exemption model for those modifications that are indistinguishable from those made using conventional breeding, natural mutations or mutagenic techniques where:

- a) Extensive genetic variations have been introduced by a range of previously available breeding techniques that have historically been accepted without a need for regulation.
- b) Plants and animals modified using new technologies should not be differentially regulated if they are similar to, or indistinguishable from, those that could have been produced through earlier breeding methods (i.e. those exempted from regulation under Schedule 1A).

TOR 2) existing and potential mechanisms to facilitate an agile and effective Scheme, which will ensure continued protection of health and safety of people and the environment

AusBiotech has consulted with its AusAg & Foodtech Committee members from the public and private sectors and believes the Federal gene technology regulatory system administered by the OGTR needs to be efficient and effective, thus meeting the needs of stakeholders within industry and the broader community.

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.

However, 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 introduction of biotechnology into Australian agriculture that related regulation in Australia remains science-based, rigorous and transparent. Consumers are seeking ever greater information on the food supply chain. The best way to provide confidence in the supply chain is through a combination of government and industry management of standards.

Provided that a product is considered to be safe and its origins can be independently traced to support that claim, then the market should remain free to choose the product or not.

Within the context of reviewing the operations of the current Scheme a number of opportunities have been identified by AusBiotech for the OGTR to improve its processes and responsiveness to stakeholders, while at the same time maintaining continuity and consistency within the legislative and regulatory framework within which it operates. Examples of these changes include the adoption of:

- a) A tiered structure for approval of licensed dealings where it has been established and/or demonstrated that proposed licenced dealings are low risk and therefore the requirements and timeframes for assessment could be substantially reduced. Since the inception of the Scheme there have been a number of advancements such as the use of species biology documents and extensive documentation of the characterisation of various technologies (e.g. RNAi) which have reduced the need for substantial provision of supporting data within an application. These advancements should be reflected in the ability of the GTR to provide approvals where the opportunity exists, for licensed dealings earlier than the minimum statutory time-frames within the Scheme. This would be of significant benefit to researchers and the broader industry in the time-frame for development and commercialisation of innovation products derived from biotechnology.
- b) A review of the current regulations so that there is clear delineation between the requirements for sexually produced plants and those that are developed through vegetative propagation.
- c) A reduction in the regulatory data requirements associated with the deregulation of vegetatively propagated crops (e.g. potato, sugar cane) where the same construct is transformed into different varieties of the same crop. This would remove the need to provide a new deregulation dossier for each new event generated in a different variety with the same construct
- d) A tiered approach to the evaluation and assessment of protein safety based on an applicant's demonstration of the product's history of safe use. This is important for proteins which are produced at extremely low levels in plants (less than 500 ppb) and cannot be purified in sufficient amounts for biochemical assessments (Bushey et

al., 2014). Use a weight-of-evidence approach to evaluate and demonstrate the safety of the protein of interest.

- e) The adoption of definitions of 'Gene Technology' and 'Genetically Modified Organism' that are consistent between the OGTR and FSANZ.

TOR 3) the appropriate legislative arrangements to meet the needs of the Scheme, now and into the future, including the Gene Technology Agreement.

AusBiotech recognises that a robust gene technology legislative and regulatory framework, based on global best practice, is critical to building confidence and certainty, which underpins public investment and ensures Australia's global competitiveness.

a) Legislative arrangements for the future operation of the Act

i. Central Policy Setting of the Act

AusBiotech recognises that under Australia's current gene technology legislative and regulatory Scheme the central policy setting for the enactment of regulation is the process by which a product derived from gene technology has been developed. To better recognise the more recent developments in technology and the future needs of the Scheme, AusBiotech recommends a change to a central policy setting where the trigger for regulation within the Scheme is based on outcomes or products rather than the process by which the product has been derived.

ii. Role of the Gene Technology Regulator

Since the previous review of the Act in 2011, recent advances in gene technology, together with the diverse range of emerging enabling technologies have demonstrated that the current framework (i.e. Gene technology Act (2000) and the Gene technology Regulations (2001)) within which the Gene Technology Regulator (GTR) operates lacks the flexibility to respond to the rapidly changing environment within which the GTR operates.

The GTR is increasingly being asked to provide an assessment as to whether an increasing array of these innovative technologies require regulation within the context of the current framework, which did not contemplate these advancements at the time of drafting, legislation and subsequent review (2006 & 2011). As a result the public and private sector have become increasingly frustrated at the inability of the GTR to respond to these advancements due to the limitations placed by the historic framework within which the GTR operates.

To address this current situation AusBiotech recommends the development and adoption via the current review of the Act of a more responsive framework. This framework should recognise the pace of change in the sector by proactively allowing the GTR through consultation and if required through regulation, the ability to address changes in gene technology in a more timely and efficient manner than what the current framework allows.

In essence, AusBiotech is seeking the implementation of a flexible mechanism that allows the GTR the capability and capacity to rapidly adapt the regulatory system to these changes while at the same time continuing to be based on scientific evidence and best-practice regulatory principles. The proposed mechanism would be supported by changes to the timeframes for modifications to the Act and/or the Regulations (i.e. reduced to 3 years), both of which currently require significant and unacceptable lead and implementation time frames.

AusBiotech supports the proposed approach of The Australian Academy of Technology and Engineering (ATSE) and the Australian Academy of Science (AAS) to increase the powers and responsibilities of advisory bodies to the GTR. For example, GTTAC could have a more defined role in advising and making recommendations to the GTR on advancements in gene technology and associated enabling technologies within the context of the current and future legislative and regulatory framework (i.e. do they require regulation or not and if so, do they fall within the current framework or are changes required in regulation and/or legislation).

Similarly, IBCs could be provided with greater powers in the management of containment facility certification. The OGTR relies heavily on IBCs to provide information and confirmation that physical containment facilities meet the guidelines and requirements of certification. However, the timeframes for new certifications (i.e. 90 working days) are not reasonable and often lead to unnecessary time delays that have direct costs to organisations. To circumvent this, many institutions are submitting partial applications to start the clock to ensure that the certification process does not prevent teaching or research activity. Also, organisations consult extensively with the OGTR during the review period in order to seek expeditious certification. This puts OGTR personnel in awkward situations and under unnecessary pressure.

b) Continuity and consistency between the Federal Act and the Gene Technology Agreement.

AusBiotech believes that the Act continues to be 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 Gene technology Agreement refers to a national scheme, this has not been achieved.

At present, the cohesiveness between the Act and the State-base legislation that regulates gene technology is absent. The ability of the States to impose bans on GMOs approved by the OGTR act as a veto on the Federal body. This means that there is no predictability for the public and private sector to invest in research, development and commercialise technologies derived from biotechnology even after undergoing the OGTR approval process. This continues to be a significant disincentive for public and private sectors to investment in the research and development of biotechnology in Australia.

State legislation that has allowed the imposition of moratoria in the Australian Capital, Territory, Tasmania and South Australia has significantly hampered the innovation and growth of the agricultural, environmental and industrial biotechnology industries in

Australia by restricting the path-to-market of OGTR-approved technologies across a range of uses.

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 for the Australian economy. While the current inconsistent regulatory approach remains in place between the Federal and State based legislation, Australia will continue to fall behind in the development and adoption of biotechnology innovations, in relation to its export competitor countries. While the inconsistent regulatory system remains in place, it will continue to destabilise the entire industry affecting inward research and development investment to support innovation and international partnerships – despite Australia having a reputation for world-class plant and animal science.

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.

AusBiotech recommends that the Commonwealth and States through the Legislative and Governance Forum on Gene Technology reconfirm its commitment and support for a nationally consistent scheme for gene technology regulation in accordance with the Inter-Governmental Agreement.

TOR 4) funding arrangements to ensure sustainable funding levels and mechanisms are aligned with the level and depth of activity to support the Scheme.

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.

Any proposed changes to the current activity that is required by the OGTR to support the scheme will generate unrealistic incremental compliance and associated costs and will be detrimental to current and future investment in introducing new technology to Australia.

AusBiotech is of the view that the OGTR has the opportunity to generate improved operating efficiencies and hence economic efficiency by way of adopting improvements to the current regulatory and compliance model under which it operates. (Refer TOR 2)

AusBiotech is of the view that due to the hurdles imposed by State governments, such as the imposition of moratoria, the growth of the biotechnology industry in Australia, especially in agriculture has been severely impacted and has not reached the level of investment and development in the public and private sectors to support an industry based funding arrangement as exists currently with FSANZ.

Therefore, in the near term, the imposition of any cost recovery arrangements by the OGTR would be detrimental to both the public and private sectors as it would act as a disincentive

for investment in building capacity and capability in the research, development and commercialisation of biotechnology within Australia.

Conclusion

In summary, biotechnology offers a set of innovative tools for Australia's agricultural industries that will create new and improved food, feed, fibre and energy based products and result in more efficient and resilient farming systems and supply chains. The benefits and value from the adoption of agricultural biotechnology will underpin future food security by delivering far-reaching agronomic, environmental, nutritional, human health and economic benefits to Australian agriculture and its domestic and export consumers. Such benefits will strengthen Australia's competitive position in global food and fibre markets and provide increased surety of supply for domestic consumers.

While not all farmers will want access to these technologies, those that see a commercial benefit should be afforded the choice to use these technologies and be able to compete on a level playing field with their global competitors.

AusBiotech cannot emphasise strongly enough the imperative that legislation and regulation pertaining to gene technology must keep pace with innovation, to enable the economic, efficiency and environmental benefits from new technologies to be realised. 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 role in maintaining human health and environmental safety of GM crops.

AusBiotech recommends that the Act be updated to reflect developments in gene technology since the initial drafting and adoption of the Act in 2000 and the more recent review in 2011.

AusBiotech implores the Australia Government to adopt these recommendations expeditiously to ensure that the legislative policy settings that underpin the current gene technology regulatory scheme will remain relevant in the future. This will provide the necessary confidence to the Australian biotechnology public and private sectors to continue to invest in building the capability and capacity required to support research, development and commercialisation of products that will benefit Australian farmers and the community.