
**THIRD REVIEW
OF THE
GENE TECHNOLOGY
SCHEME**

**Submission to
Phase 3 Consultation Findings**

May 2018





ABOUT US

Agribusiness Australia is the peak national body for the 'whole of supply' chain agribusiness sector. We represent businesses involved in all stages of farming and agriculture-related commercial activities required to send an agricultural good to market, including research, production, processing, and distribution. Our membership also includes supporting service industries, such as finance and business advisors.

A competitive and productive agribusiness sector will contribute to the security and profitability of Australia's food and fibre supply chain and contribute to wider economic growth. It will also provide ongoing economic opportunities across rural and regional Australia including employment, infrastructure and community wellbeing.

The long-term growth and profitability of Australian agribusiness is linked closely to its status as a globally competitive producer that can develop and retain market positions. A solid domestic economic framework will help the global competitiveness of Australian agriculture for agriculture and participants in the supply chain.

Agribusiness Australia is the peak national representative body for the 'whole of supply' chain agribusiness sector.

Our purpose is to promote an efficient, profitable and dynamic Australian agribusiness industry through influential advocacy, strong and credible leadership, and information sharing and debate.

OUR POSITION ON REGULATION OF GM TECHNOLOGY

Agribusiness Australia welcomes the opportunity to provide comments to Phase 3 of the Third Review of the National Gene Technology Scheme.

As noted in our previous submissions, Agribusiness Australia supports gene technology research and development (R&D) and believes the outcomes of R&D can contribute to meeting Australia's future challenges

Our members remain concerned at the prospect of differential regulation of products developed using plant breeding innovations, based simply on the technique employed during the development of specific traits and not on the characteristics of the final product.

Genetic modification (GM) is simply a tool. Like all tools, the application is what matters. All new technologies require review and testing, but concerns should be based on science and evidence, not on myths and misunderstandings. A discriminatory application of regulation which is not tied to risk would be untenable. It would result in a situation where certain methods of gene technology are excluded from the scope of regulation based on their history of safe use, while at the same time regulation would be applied to methods that result in even more precise and more predictable outcomes than ever achievable with earlier excluded methods.

Realisation of the potential benefits of gene technology within Australian farming systems is dependent upon a regulatory environment which promotes R&D investment and is sufficiently flexible to accommodate advances in breeding techniques.



The ultimate aim of government should be to create an operating environment that encourages public and privately funded research; and also supports the development of Australian innovation, including in the field of gene technology.

This requires a robust system of science-based and risk-aligned regulation that protects human and environmental health and provides a clear and predictable path to market.

The original mandate of the OGTR was to ensure the continued protection of human health and safety. Yet, since its establishment, the Office of the Gene Technology Regulator (OGTR) has presided over the development of onerous and expensive regulations which have denied farmers access to new and existing GM crop varieties, reduced farm profitability, and stifled the industry's capacity to innovate.

This has stifled agricultural innovation and placed Australian farmers at a significant and increasing competitive disadvantage when compared with farmers in other countries who have access to GM varieties.

In effect, the OGTR process actively discriminates against the Australian agricultural industry. For these reasons, we have welcomed this review and the opportunity to provide further comment.

COMMENTS ON THE CONSULTATION FINDINGS

It is not our intent to address each of the 33 findings in detail. Rather, we have provided general comment on the findings related to each of the 4 overarching themes.

Review theme one: Technical findings (Findings 1 - 7)

In the main, Agribusiness Australia agrees with the findings related to this theme.

In particular, we believe that the establishment of a *Nationally Consistent Scheme* for the regulation of gene technology should be a priority outcome of the Review. This was envisaged by the inter-governmental Agreement in 2001 but has not eventuated due to inconsistent state government interventions and duplication of risk assessment tasks with other regulatory agencies and schemes.

We also support the need for a review of the definitions in the Act and Regulations, as these have clearly not kept pace with advances in gene technology.

However, we do not support the recommendation related to Finding 6. In our view, this finding could result in additional, scientifically unjustified regulatory burden on the environmental release of GMO's.

There should not be a presumption that where an organism is "new" it presents unprecedented challenges. The current Scheme includes adequate and appropriate risk assessment requirements for organisms to be used in biological control, and these are examined on a case-by-case basis depending on the GMO and its intended use.

Review theme two: Regulatory findings (Findings 8 - 15)

In the main, Agribusiness Australia agrees with the findings related to this theme.

However, Agribusiness Australia does not support the recommendation in Finding 8 that a process-based trigger remains an effective entry for the Scheme. The current Scheme is a hybrid of process and product based regulation.



Given the diversity of the regulated community covered by the Scheme, it is unlikely that a solely process-based or product-based system will best serve the needs of every situation.

Agribusiness Australia agrees that there are opportunities for additional risk tiering to be applied within the Scheme. We encourage the Review Secretariat and the Expert Advisory Panel to consider the proposals in this respect put forward by CropLife Australia.

We recognise that principles-based regulation would allow a greater degree of future-proofing and enable the Scheme to respond to new gene technologies as they arise without having to create new rules each time. This approach would potentially overcome the comparative rigidity of rules-based regulation.

Having said that, regulatory clarity and certainty is of the greatest importance to our members. Prescriptive rules can provide greater clarity, as it is easier for a regulated entity to determine what rules it must comply with and the minimum standards of compliance expected. We would therefore encourage consideration of a hybrid model that delivers the best outcomes from both system approaches.

Review theme three: Governance findings (Findings 16 - 28)

Agribusiness Australia has serious concerns about many of the findings related to this theme.

We support the view that the operation of the Scheme is credible, and that the Scheme operates with integrity and legitimacy; and we recognise the need for regular and focussed reviews in ensuring this remains the case. However, reviews such as this must be directed at ensuring a transparent, consistently applied and credible science-based Scheme, rather than at responding to public concerns that are outside the scope of the legislation and the OGTR's terms of reference.

We also support the need for national consistency and international harmonisation of regulation to ensure a level playing field by all involved in the gene technology sector.

However, Agribusiness Australia is surprised and disappointed that Finding 18 appears to have taken no account of the overwhelming, clear and unambiguous evidence of the lack of any trade and market advantage gained from the state and territory GMO's moratoriums. Research undertaken in Tasmania and South Australia could not identify any substantive benefit from the moratoriums in place in those states.

The Productivity Commission's *Review of Regulation of Australian Agriculture* came to the same conclusion in 2016 and recommended that all states and territories should also repeal the legislation that imposes or gives them powers to impose moratoria on GMOs by 2018. The 2015 Harper *Competition Policy Review* also cited GMO moratoriums as a significant example of a regulatory restriction on competition

We are strongly opposed to the proposal to introduce 'benefit' considerations as outlined in Finding 20. There are no accepted methodologies for determining ex-ante benefits and we believe that the Scheme should remain focussed on identifying and managing risks posed by gene technology to human health and safety, and to the environment.

Agribusiness Australia does not support the proposal for the Legislative and Governance Forum on Gene Technology to lead a forward work program. Furthermore, we are adamantly opposed to any suggestion that further consideration being given to create new policy principles, unless they are limited to a purely scientific issues.



Agribusiness Australia would only support the development of a dedicated gene technology regulation web portal if there are iron-clad guarantees that funding for such an initiative would not be taken out of existing OGTR appropriation funding, nor cost-recovered from applicants.

In our view, full cost recovery would inhibit future growth in what is essentially a new and emerging industry sector. Australian farmers are already at a serious cost-disadvantage in comparison with overseas producers and increasing the regulatory cost burden will simply make them uncompetitive.

In fact, it could be argued that even existing funding for OGTR is insufficient to support the regulatory activities necessary in this sector. On that basis, we believe that any additional funding that may be made available should be directed to addressing current and future regulatory activities rather than looking to expand the operational scope of the regulator.

Review theme four: Social and ethical findings (Findings 29 - 33)

Agribusiness Australia agrees with the finding that public understanding and confidence in the Scheme may be aided by additional communication mechanisms. We also recognise OGTR's work in leading communication activities directly related to risk assessment and risk management of live and viable GMO's, and we would support improved public communication of the regulatory scheme, on the basis this was not funded from the Regulator's existing funding appropriation. We would further argue that there is a clear role for governments and other regulatory agencies to provide more information and to clarify misinformation about GMO technologies.

However, we strongly oppose the suggestion in Finding 31 that the current science-based approach be broadened, given that no risks to human health and safety or the environment have been identified that warrant the need to make any changes.

The OGTR has no role in addressing perceived public misunderstandings of gene technology regulation and the safety of approved GMOs. This is a communications challenge, not a human health or environmental safety issue, and is so outside the scope of both the regulations and the regulator's remit.

The suggestion in Finding 33 that a high level of transparency can be achieved through the OGTR continuing to make relevant information publicly available is a reasonable one. However, it would be important to ensure a clear balance between regulatory transparency and protection of applicant's intellectual property rights.

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