

Updating Gene Technology Regulation in Australia Regulation Impact Statement for Consultation

***Submission from the WA State Agricultural Biotechnology Centre, Murdoch University,
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Introduction

The WA State Agricultural Biotechnology Centre (SABC) at Murdoch University is the major centre in Western Australia undertaking applied R&D in agricultural biotechnology. Murdoch is the only university in Australia with top Excellence in Research in Australia (ERA) scores of 5 in both the ERA 2012 and ERA 2015 assessments.

We welcome the opportunity to add to our earlier submission on the Technical Review of the Gene Technology Regulations.

Updating the Gene Technology (GT) Regulations to reflect advances in science, technology and experience of safe use of GT crops is now important and necessary to support future improvements in crop production, defence against pests and diseases, improved quality of produce for human health, and benefits delivered to the environment.

In addition, the exclusion of some new technologies from regulation as GMOs will have a revolutionary effect on the ability of small Australian companies to apply them and treat them as any other product of 'conventional' plant breeding. The current GT definitions and regulations have strangled investment in trait development in Australia, and ensured that only major international companies have had sufficient resources to meet required regulatory approvals. The current definition of GMOs has essentially prevented commercial innovation by SMEs in this area in Australia.

The GT regulations have also spawned a small but vocal anti-GM 'industry' in Australia, with members who appear free to disseminate misinformation on GMOs. There is now a 20-year history of safe use of GM crops worldwide. All the many scientific studies which have been undertaken in developed countries, including many in the EU, and assessments by government regulators (e.g. OGTR, FSANZ) show that GM food is safe – indeed safer than conventionally produced foods, with organic marginally the least safe.

The GT Act 2000 defines all forms of crop improvement in which there are new combinations of genetic material as Genetically Modified Organisms (GMOs). This definition includes all forms of conventional plant breeding – crossing, transfer of chromosome segments between species, double haploids, mutagenesis, cell fusion and genetic changes using recombinant DNA technology. It then excludes the technologies that do not involve recombinant DNA from the legislation. Thus forms of breeding that can transfer very large blocks of genes, such as cytogenetics are excluded – for example, all wheat grown in Australia has about 125 million bases of DNA transferred from the rye genome, but since this did not use precise recombinant DNA technology it is excluded from legislation. Similarly, triticale is a completely artificial hybrid of wheat and rye, obtained using colchicine to double up chromosome numbers, and mutants generated by harsh chemical or irradiation treatments, are not regulated.

Expanding this aspect, wheat grown in Australia, which contains about 125 million bases of DNA from rye, is not regulated, but if one single base is added using recombinant DNA technology to the 15 billion bases that constitute the wheat genome, it is regulated as GM! Such issues highlight the scientific paradox, that if we

know little about what genetic changes have occurred in developing a new variety by conventional means it is not regulated as a GMO, but if we use the best science and technology to make small, precise, knowledge-based changes the product is highly regulated. Logic would tell us it should be the other way round!

Such issues highlight the need to make decisions based on understanding the science and relative risks of all forms of plant breeding, and not on the basis of unsubstantiated claims in websites, letters to newspapers or for political gain.

Consultation RIS

Please note the “**Submission to the Review of the National Gene Technology Scheme 2017**
On behalf of the WA State Agricultural Biotechnology Centre, Murdoch University, Perth WA 6150 and Murdoch University Institutional Biosafety Committee.”

Many of the aspects covered in the Consultation RIS are addressed in detail in that submission. In that submission support was argued for Option 4.

It is noted that the structure of the RIS is as follows:

- *a statement of the problem (section 1)*
 - **ambiguity in the GT Regulations due to technological developments** – new technologies for modifying genetic sequence and gene expression have developed rapidly and so in some cases it is not clear whether organisms modified by certain techniques are ‘GMOs’ or not.

Comment – this is clearly the case. At present, in relation to some new breeding technologies, the level of regulation is not commensurate with the risk: over-regulation is inhibiting commercial innovations using these technologies. This means that there are delays in bringing new products to market developed in Australia, and that the benefits do mainly go overseas.

- **the need to keep the categorisation of contained dealings with GMOs up to date** – the techniques and organisms used in gene technology research have changed since the GT Regulations were last reviewed, as has understanding of risk.

Comment – agreed. Some classifications do now set a greater level of oversight than is warranted.

- **the need for improved clarity** regarding the regulatory status of organisms that are not themselves categorised as GMOs but have been derived from GMOs. There is no problem with the current regulatory status of these organisms; rather, improved clarity would assist user understanding and compliance.

Comment – agreed. It is difficult to justify regulation of ‘null segregants’ or SDN-1 gene-edited plants, which do not contain any external DNA, as GMOs. Especially when ‘sledgehammer’ techniques like chemical or irradiation mutations, cytogenetic transfer of chromosome arms between species and the many DNA inversions, deletions, mutations and rearrangements that occur in conventionally bred crops, are not classified as GMOs.

- *a statement of the objectives and intended outcomes (section 2)*

Comment – OK

- *a statement of the possible options to address the problem (section 3)*
 - **Option 1 – retain the current GT Regulations**

Comment – Not supported – out-of-date, no longer meet requirements

- **Option 2 – amend the GT Regulations by introducing all elements of the draft amendments at Appendix C**

Comment – supported in general, but Option 3 preferred.

- **Option 3 - amend the GT Regulations by introducing some, but not all, of the amendment elements from Option 2.**

Comment – supported, with some changes. Regulations should take into account that the same end results can be achieved by different methods, some of which are regulated whilst others are not.

The proposed changes do not take into account potential future methods, so that additional revisions are likely to be required. There are other forms of modifications, eg epigenetic changes which modify DNA bases without changing the actual base. More clarity is needed in relation to null segregants and that products of SDN-1 are excluded from being included as a GMO. It should be made clearer that Spray-Induced Gene Silencing (SIGS) is exempt from being defined as a GM technology.

The overall discussion does not adequately consider the nature of the end product rather than the method used to produce it. A Scheme for how such a history of safe use can be included in the regulatory process has been provided in the **Submission to the Review of the National Gene Technology Scheme 2017 On behalf of the WA State Agricultural Biotechnology Centre, Murdoch University, Perth WA 6150 and Murdoch University Institutional Biosafety Committee.**