AusBiotech submission in response to the *Regulation Impact Statement for Consultation: Updating Gene Technology Regulation in Australia* and the draft amendments to the Gene Technology Regulations (GT Regulations)

To: The Regulations Review
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1. Introduction

AusBiotech is pleased to submit feedback on the *Regulation Impact Statement for Consultation: Updating Gene Technology Regulation in Australia* and the draft amendments to the Gene Technology Regulations (GT Regulations) as released for public comment in November 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 69,000 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 supports the objectives of the Technical Review of the Gene Technology Regulations 2001, in particular exploring options for regulating new technologies. In the previous consultation round, AusBiotech supported Option 4, to exclude certain new technologies from regulation on the basis of the outcomes they produce. This current submission is specifically in response to the Exposure Draft Regulations on the understanding that the Regulator has limited scope to amend the GT Regulations within the current policy framework.

AusBiotech largely supports the amendments that have been put forward but view the proposed changes as an interim measure until an updated policy framework is implemented, following completion of the 2017 Review of the National Gene Technology Scheme.

AusBiotech Response to Consultation Questions

1. **What is your preferred Option? Please explain why.**

AusBiotech supports **Option 3** that proposes to amend the Gene Technology Regulations (GT Regulations) with some but not all draft amendment proposals, as detailed in Section 3 of the Consultation Regulation Impact Statement.

It is the view of AusBiotech that most of the amendments proposed in the Exposure Draft Regulations are supported, but some changes need further consideration to ensure that Australia has a system that is flexible, agile and able to keep pace with rapid changes in technology. This must be done in line with the principle that the Gene Technology Scheme is science based and that GT Regulations are commensurate to risk.

2. Do the draft amendments clearly implement the measures described in Section 3 of the Consultation RIS? If not, which areas of the draft amendments do you think require additional clarification, and what clarification is needed?

AusBiotech believes that the proposed amendments largely implement the measures described in Section 3 of the Regulation Impact Statement for Consultation. The following are the elements that AusBiotech suggest requires further consideration.

1. Schedule 1 – New Schedule 1B (Item 31).
2. Schedule 1 – New Item (Item 32) Organisms modified using SDN-1 are not GMOs.
3. Schedule 1 – two new Items (Item 33) Organisms derived from GMOs.
4. Schedule 2 – Repeal Schedule 1 (Item 1).

Each of these is considered separately.

Schedule 1 – New Schedule 1B (Item 31)

AusBiotech **does not support** the proposed regulation of SDN-2 and ODM as GMOs as offered in the new Schedule 1B. As discussed in our previous submission, AusBiotech supports the exclusion of certain new technologies from regulation on the basis of the outcomes they produce.

The GT Regulations should also allow techniques that use SDN-2 and ODM not to be regulated as GMOs. The regulation of these techniques imposes unnecessary regulation on techniques that are functionally equivalent to other mutagenesis techniques, including the proposed changes that allow for SDN-1 to be considered a technique that is not gene technology.

The use of a template as part of the genome editing technique should not be a trigger for deciding if a product is a GMO or not. The decision should relate to the final outcome of the change(s) that have been made and whether the change(s) are likely to present a new or increased risk to human health and the environment.

AusBiotech reiterates that the genome editing techniques should be defined as mutagenesis techniques under Schedule 1A. We contend that any molecule, albeit significantly sized molecules utilised in the new techniques of genome editing, could be described as a chemical and the definition should not restrict the definition of 'chemicals' to molecules that are artificially synthesised, but rather accept a broader definition that includes the product of a biological process.

Further, these techniques do not involve the introduction of non-homologous DNA sequences from a non-sexually compatible species, nor do they involve the introduction of whole gene sequences. The products that could be generated from these techniques could be derived from other techniques that are excluded from regulation (e.g. radiation-induced mutagenesis, chemical-induced mutagenesis).

Schedule 1 – New Item (Item 32) Organisms modified using SDN-1 are not GMOs

AusBiotech **supports the classification** of organisms derived from SDN-1 as non-GMOs. However, AusBiotech notes that the term SDN-1 is not defined in the proposed GT Regulations as a technique that is not gene technology (Schedule 1A). Given there are various techniques currently available and new emerging techniques that don't specifically rely on Site Directed Nucleases (e.g. other enzymes and 'chemicals'), there is perhaps a need for a definition of what is not considered gene technology. AusBiotech suggests that for the avoidance of doubt, a definition be included in the

revised Schedule 1A to more broadly define products that are derived from a double-stranded break to their DNA and repair of that break using the non-homologous end-joining process as products that are not products of gene technology.

Schedule 1 – two new Items (Item 33) Organisms derived from GMOs

AusBiotech **supports the need for clarification** on the regulatory status of organisms descended from a GMO. However, the proposed amendments may still lead to some uncertainty. The intent proposed in the amendments is clear with respect to traditional GMOs and gene cassettes designed to confer a specific trait (e.g. disease resistance). The proposed Schedule 1, Item 8 clarifies this whereby an organism that has '....not inherited any traits that occurred in the initial organism because of gene technology...' would not be considered a GMO.

How would this proposed change relate to products derived from genome editing? The term trait is often associated with a gene and a gene product. AusBiotech notes that some genome edits may involve changes to non-coding regions and not directly confer a 'trait' *per se*.

AusBiotech notes that in Schedule 1, reference is given to NoGall and Vaxsafe PM. Both of these are trade names associated with commercial products and as such AusBiotech does believes they are not appropriate to be specifically listed in the GT Regulations. The identification of the specific strains as listed should be sufficient.

Schedule 2 – Repeal Schedule 1 (Item 1)

AusBiotech **prefers that the Regulator maintain Schedule 1 Item 1**. This item specifically addresses mutagenic techniques that have a long history of safe use. The removal of this item may lead to greater confusion across the industry than currently exists. The proposed addition of Item 4 provides some context around the definition contained in Item 1.

As put forward in our previous submission, AusBiotech recommends that the term chemical mutagenesis should be defined under Schedule 1A and the language of the definition modified to clearly capture techniques such as those associated with genome editing.

3. **If your preferred option is Option 3, please indicate which amendments (or parts thereof) you support being progressed and why.**

AusBiotech supports the proposed amendments to the GT Regulations, except for those outlined above in Section 2.

4. **What are the costs and benefits to you or your organisation from the proposed amendments? Please describe these compared to current arrangements, for each area of amendment.**

The costs and benefits associated with each of the proposed amendments to the GT Regulations will vary for each of the AusBiotech members. In most cases, members will be required to review their current product portfolios and pipeline strategies to identify likely impacts. Importantly, the proposed regulation of SDN-2 and ODM techniques will likely prevent the further development and ultimately commercialisation of many products beneficial to both human health and to agriculture and allowing Australian businesses remain globally competitive.

5. **Are the proposals to change the classification of certain NLRDs and exempt dealings (identified in Appendix B of the Consultation RIS) commensurate with any risks to the health and safety of people and the environment posed by the dealings?**

AusBiotech **supports the proposed change** to the classification of certain NLRDs and exempt dealings identified in Appendix B. However, AusBiotech is of the view that organisms modified by SDN-2 and ODM should not be classified as GMOs.

6. **Are there any features in the options presented that you have concerns with? Or, are there any particular features that you believe should be included? Please explain why and give substantiating evidence where possible.**

AusBiotech emphasises the need for regulation to keep pace with innovation, to enable the benefits from new technologies to be realised. AusBiotech strongly encourages a change in the policy framework that provides a platform to ensure that Australia has a system that is flexible, agile and able to keep pace with rapid changes in technology. This must be done in line with the principle that the Gene Technology Policy is science based and that GT Regulations are commensurate to risk.