Australian Government
Department of Health
Office of the Gene Technology Regulator

Updating Gene Technology Regulation in Australia

Consultation quick guide

Introduction

Since the Gene Technology Regulator (the Regulator) last conducted a technical review of the Gene Technology Regulations 2001 (the GT Regulations), technological and scientific developments have occurred. As a result, Australia's current gene technology legislation is not as effective as it could be in providing clear and unambiguous regulatory requirements for working with GMOs.

While the GT Regulations as a whole are working well, with no major changes to their overall operation proposed, feedback received from stakeholders as part of the *2016-17 Technical Review of the Gene Technology Regulations 2001* (the Technical Review) as well as operational experience from within the OGTR have demonstrated a need to address specific technical issues within the legislation.

The objective of the Technical Review is to keep the GT Regulations up to date with advances in technology and increased scientific understanding. The Technical Review is limited to the existing policy settings of the gene technology regulatory scheme, and cannot extend to topics outside of the current scope of the GT regulations, for example, the safety assessment and labelling of genetically modified food.

Following consultation on a discussion paper in late 2016, the Regulator has developed draft amendments to the GT Regulations which are the focus of this consultation. The need for, and intended effect, of the amendment proposals is **detailed in full in the Consultation Regulation Impact Statement (RIS) available on the OGTR website**. This Consultation Quick Guide is intended for those who wish to contribute to this consultation and are already familiar with the issues canvassed in the Discussion Paper.

Discussion Paper consultation

The 2016-17 Technical Review of the GT Regulations was initiated to provide clarity about whether organisms developed using several new technologies are subject to regulation as genetically modified organisms (GMOs) and to ensure that new technologies are regulated in a manner commensurate with the risks they pose.

From 17 October to 16 December 2016, the Regulator sought submissions on a discussion paper detailing four options for how several new technologies could be regulated. The Discussion Paper also sought information about RNA interference (RNAi) techniques and gene drives, and invited proposals for amendments to technical and scientific aspects of the GT Regulations. A summary of the 741 submissions received, and the submissions, is available on the OGTR website.

Development of draft amendment proposals

The issues raised in submissions were considered by the Regulator and contributed to the development of the draft amendment proposals. The Regulator has also considered OGTR's experience, current scientific understanding, potential risks, the regulatory burden implications for stakeholders, whether regulatory burden would be commensurate with risks, and the policy intent of the GT Act.

The Regulator is now consulting to ensure the draft amendment proposals achieve their intended effects, and to seek information on the potential impacts of these proposals (see Consultation RIS sections 3 and 4, respectively).

The amendments would maintain the existing policy settings and bring the GT Regulations up to date with current science, ensure the level of regulation is commensurate with risk, and make it easier to determine which regulatory requirements apply for activities with GMOs.

Key amendment topics

The full draft amendments are available on the OGTR website, including as a future law compilation of the GT Regulations to aid understanding. The rationale for and intended effect of each proposal is discussed in detail in section 3 of the Consultation RIS. The summary below highlights the key amendment topics.

Amendments responding to technological developments

There are ambiguities in the GT Regulations because new technologies for altering genetic sequence and gene expression are not specifically addressed in the legislation. Under existing provisions, it is not clear whether or not organisms that have undergone several site-directed nuclease techniques[1], oligo-directed mutagenesis (ODM) and some RNAi techniques are within or excluded from the scope of regulation under the GT Act. Additional information on these techniques is provided at Appendix E of the Consultation RIS. The proposed amendments would clarify the regulatory status of organisms that have undergone these techniques.

[1] Site-directed nuclease (SDN) techniques without and with a template to guide small changes to the genome, referred to as SDN-1 and SDN-2, respectively.

Site-directed nuclease techniques and oligo-directed mutagenesis

The draft amendments would implement option 3 from the Discussion Paper under which organisms modified using site-directed nucleases without templates to guide genome repair (i.e. **SDN-1**) would **not be regulated as GMOs**. Organisms modified using the template-guided techniques **SDN-2** and **ODM** would continue to be **regulated as GMOs**.

This proposal is on the basis of risk, compliance enforceability and consideration of the policy settings of the regulatory scheme. For SDN-1, the targeted genomic break created by a site directed nuclease is repaired through the same mechanisms that repair naturally occurring DNA breaks, and the same range of changes to the DNA nucleotide sequence can occur as for natural mutations. The possible changes to the characteristics of the organism are therefore the same, and pose the same risk. As the outcomes of SDN-1 pose no different risk to natural mutations, which are not regulated, they should not be regulated as GMOs.

RNA interference techniques

The draft amendments would list RNAi techniques involving directly **applying RNAs to temporarily induce RNAi** as **techniques that are not gene technology**. This would have the effect that organisms to which siRNAs, shRNAs and long dsRNAs have been introduced would not be GMOs, provided several requirements are met.

This measure would be limited to short-lived RNAi techniques through which:

- the organism's genomic DNA sequence cannot be changed (however, changes to genomic DNA methylation are permissible)
- the introduced RNA cannot be translated into a protein
- infectious agents cannot be produced.

RNAi techniques which involve inserting sequences into the genome or use of viral vectors would continue to result in GMOs which are subject to regulation.

Schedule 1 item 1

The amendments would **repeal item 1 of Schedule 1**. This would improve clarity in the GT Regulations, particularly in relation to organisms modified using SDN-1, SDN-2 and ODM. While OGTR does not consider item 1 broadly excludes these organisms from regulation, OGTR is aware some stakeholders consider item 1 could be interpreted in this way.

The vast majority of organisms excluded from regulation under this item in 2001 are now excluded through the listing of chemical and radiation-induced mutagenesis as techniques that are not gene technology in Schedule 1A. Two additional organisms that OGTR is aware are currently excluded from regulation through item 1, NoGall and VaxSafe PM, would be specifically listed in replacement items on Schedule 1.

Repeal of item 1 would commence operation 12 months later than other amendments, to allow time for those working with any remaining organisms covered solely by item 1 to apply for the necessary GMO dealing authorisations before item 1 is repealed. OGTR is seeking information from anyone who believes they would be in this situation.

Amendments updating contained GMO dealings classifications

Updating the categorisation of contained dealings with GMOs, to ensure they are commensurate with risk, has been a major focus of the Regulator's previous technical reviews of the GT Regulations. The techniques and organisms used in gene technology research have changed since the GT Regulations were last reviewed, together with understanding of risk, so there is again a need to update several aspects of contained dealings categorisation.

The key amendment proposal in this area would increase the categorisation of contained dealings with GMOs containing functional **gene drives** to require a **DNIR licence**. This would ensure case-by-case evaluation of risks and tailored risk management of activities with these organisms. This would also enable the Regulator to gather information and monitor research progress in this rapidly developing field. It would be appropriate to re-assess this position at the next Regulations review on the basis of any accumulated experience and scientific developments at that time.

The draft amendments would also:

- reduce the classification of some dealings involving cloned viral genomes in listed exempt host/vector systems to exempt, provided replication competent virus cannot be produced
- clarify, but not change, the classification of dealings with viral vectors with no host
- add two species to the list of host/vector systems for exempt dealings and
- clarify wording describing pathogenic determinants and introduced DNA, to provide outcome focused language; this would avoid dealings being classified at a lower level than is appropriate for the risks they may pose.

Clarifying amendments and administrative amendments

The definition of 'GMO' in the GT Act does not include organisms derived from GMOs that have not inherited traits that occurred because of gene technology, also known as **null segregants**. Queries to OGTR suggest this status is not readily apparent to all, so null segregants would be listed as **organisms that are not GMOs**, for the avoidance of doubt. For the same reasons, **organisms temporarily modified using gene technology that no longer have traits** that occurred because of gene technology would be listed as **organisms that are not GMOs**. Neither group poses risks as a result of gene technology because they do not possess traits as a result of gene technology.

Other clarifications and administrative matters in the draft amendments include:

- Clarifying that amendments from 2011 for risk group 3 and 4 organisms relate to the risk group of the unmodified parent organism – this amendment would not alter the intent of these provisions
- Reinforcing the role of the list of dealings that are not notifiable low risk dealings (NLRDs) in classifying contained GMO dealings, without altering the classification of any dealings
- Clarifying current requirements for facilities in which NLRDs may be undertaken – these proposals would not alter operational requirements
- Clarifying and updating requirements for NLRD records of assessment and NLRD notifications to the Regulator – these proposals would require very

minor changes to the content of records and notifications, and
- Updating an agency name, ceased provisions, out-dated cross-references, typographical errors and some aspects of drafting style.

How to provide feedback

As a broader consultation process in relation to new technologies has already been undertaken, feedback should be limited to the matters covered by the proposed amendments. Proposals to amend the classification of contained dealings have not been the subject of previous consultation, and for these further information is sought.

The Consultation RIS describes three options available through this consultation:

- Option 1 – retain the current GT Regulations
- Option 2 – amend the GT Regulations by introducing all elements of the draft amendments, as detailed in full in section 3 of the Consultation RIS
- Option 3 - amend the GT Regulations by introducing some, but not all, of the amendment elements from Option 2.

Comments and submissions that address any or all of the options and consultation questions below are welcome. You are not required to address all options; however, you should address the questions for your preferred option.

Consultation questions

1. What is your preferred option? Please explain why.
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?
3. If your preferred option is Option 3, please indicate which amendments (or parts thereof) you support being progressed and why.
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:
    - 4.1 Clarifying the GT Regulations to take technological developments into account (i.e. in relation to SDN-1, SDN-2, ODM and RNAi)
    - 4.2 Repeal of Schedule 1 item 1, specifically whether you currently work with organisms that are not GMOs solely because of this item
    - 4.3 Updating the categorisation of contained dealings with GMOs
    - 4.4 Clarifying the regulatory status of organisms derived from GMOs that are not themselves GMOs
    - 4.5 minor administrative changes.
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?[2]

[2] The Regulator is consulting on these proposals to amend NLRDs and exempt dealings under Section 142 of the *Gene Technology Act 2000*.

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.

To support further analysis of impacts, particularly changes to regulatory burden[3], OGTR encourages submitters to provide information on how the amendment proposals could directly impact them, including:

- the number of required NLRD, DNIR and DIR authorisations that would change (and in what way)
- how the need to maintain facility certifications would change, and
- how the amount of time needed to administer authorisations would change.

Submissions can be made by email to ogtr@health.gov.au or by mail to the Regulations Review, Office of the Gene Technology Regulator (MDP 54), GPO Box 9848, Canberra ACT 2601. **Submissions must be made by Wednesday 21 February 2018.**

Submissions will be published on the OGTR website after the consultation period closes, however, OGTR can treat information of a confidential nature as such. Please ensure that material supplied in confidence is clearly marked 'IN CONFIDENCE' and is in a separate attachment to non-confidential material.

For privacy reasons, all **personal** details (e.g. signatures, phone, mobile and fax numbers) will be removed from your submission before they are published on the website. Please do not include these details in your submission unless necessary.

Next steps

Submissions received through this consultation process will be taken into account by the Regulator in finalising the draft amendments and preparing a decision RIS which will be provided to the Legislative and Governance Forum on Gene Technology (LGFGT). In 2018 the Regulator will seek agreement from the LGFGT to any finalised amendments, as required by clause 40 of the Intergovernmental Gene Technology Agreement. If the LGFGT agrees to the amendments, the OGTR will commence the Commonwealth regulation-making process which requires approval from the Governor-General and tabling in Parliament.

Any progressed amendments will not commence until these steps have been completed. **Organisations or individuals working with GMOs are cautioned to continue complying with all current requirements** contained in the GT Regulations (as well as any guidance provided by the Regulator) until any amendments come into force.

Related documents available on the OGTR website

Draft amendment regulations, and future law compilation with the GT Regulations

Consultation Regulation Impact Statement, including:

- Section 3, detailing the intended outcome of the amendment proposals
- Appendix A detailing administrative amendments
- Appendix B listing which amendment items relate to which proposals.

[3] For further information about regulatory impacts please see this Office of Best Practice Regulation guidance note.