National Gene Technology Scheme
An Australian, State and Territory Governments Collaboration

Additional Information and Stakeholder Questions

The Australian Government Department of Health, Disability and Ageing is conducting consultation on proposed changes to the Gene Technology Regulations 2001 (the Regulations), as summarised in the Consultation Paper - January 2026 - Gene Technology Amendment Regulations

On 6 February 2026, we hosted an information session to present all interested stakeholders with an overview of proposed changes set out in the consultation paper and answered questions. We have also engaged separately with some stakeholders during the consultation period.

The key points and questions from these constructive stakeholder engagements and from the information session have been summarised below.

Genetically Modified Organism (GMO) Register (GMO Register)

- The Office of the Gene Technology Regulation (OGTR) manages the GMO Register which lists activities with approved GMOs that can be safely carried out, without needing a licence.
- A recommendation of the Third Review was to improve the utility of the GMO Register to reduce regulatory burden for the lowest risk organisms.
- It is proposed that authorisation of certain gene-edited plants will be via the GMO Register.
- The Gene Technology Amendment Bill (the draft Bill) would provide for additional criteria to be prescribed in the GT Regulations, which would allow the Gene Technology Regulator (the Regulator) to be able to add gene-edited plants to the GMO Register on their own initiative, as well as on application.
- As with the existing framework, entries on the GMO Register may be made for specified dealings, or for dealings identified and expressed in broader and more generalised terms.
- The proposed GMO Register pathway would provide a simpler mechanism, with fewer conditions, than a GMO licence pathway for authorising environmental release of gene-edited plants. Field trials with certain species of gene-edited plants could fit within a permit class and may not utilise the GMO Register.
- Obligations would be placed on the applicants to ensure the gene-edited plants are properly characterised and meet criteria specified in regulations. Offence and civil penalty provisions would apply to unauthorised dealings with gene-edited plants and to breaches of conditions of the GMO Register.
- There are no statutory timeframes for the GMO Register. Applications will be considered as quickly as possible by the Regulator, noting that the Regulator is required to undertake appropriate consultation before making a legislative instrument. For GMO Register determinations, the Regulator consults with jurisdictions and the public.

- The intention of adding particular dealings into the GMO register is to be able to maintain transparency for the Australian public and interested stakeholders, including state and territory governments, enabling the Regulator to provide information and advice about included dealings, whilst ensuring regulatory effort is spent where it is most needed.

Authorisation pathways and the role of IBCs

Q: There is some concern amongst researchers that people may not seek advice from an Institutional Biosafety Committee (IBC) for some dealings such as pre-notified notifiable dealings.

A: Pre-notified notifiable dealings is a new authorisation pathway, and we are very interested in receiving feedback. This pathway is intended to be limited to very low risk dealings and there would be narrow cases where this would apply such as commercial supply of vaccines or import of bulk grain.

Q: Are there changes to the Emergency Dealing Determinations (EDD)?

A: There is no intention to make changes to the GT Regulations in relation to EDD's and so EDDs are not discussed in this consultation paper.

Q: Is field testing of GM microorganisms exempt, or will such trials be considered as novel dealings?

A: Field testing of GM micro-organisms is currently not an exempt dealing and would not be a non-notifiable dealing under the amended scheme. All proposed NND classes do not involve intentional release into the environment.

The question of novelty would arise, for the purpose of deciding consultation requirements, if a licence application were received for field testing of a GM micro-organism.

Q: What is the process for deciding whether a GMO dealing is a permit, notifiable dealing (ND) or non- notifiable (NND) dealing or is that something up to the applicant to decide prior to their application or for the Regulator to decide after receiving the application?

A: The same as under the current framework, proponents would pursue the most appropriate authorisation for their dealing. The framework outlined in the amendment Bill and underpinned by the proposed changes to the GT Regulations, indicates which type of dealing fits into each class. There continues to be a role for the Institutional Biosafety Committees (IBCs) in ensuring that proposed dealings would meet the requirements of a notifiable dealing.

Q: In Table 1 of the consultation paper, it seems that jurisdictions would only be consulted on dealings outside containment that are not limited or controlled. We are unclear why Risk Assessment and Risk Management Plans (RARMP) for limited or controlled dealings outside containment-such as

designated dealings like novel plant field trials-would not still require jurisdictional consultation.

This raises concern that novel or non-standard GMO plants could be released through field trials without jurisdictional input or whether the Regulator will consult Gene Technology Technical Advisory Committee (GTTAC) on such dealings. We are uncertain about the distinction between designated plant field trials and those classified as P1 permit dealings.

A: The intent of the P1 permit class is that this would only be applicable for well characterised dealings and would be limited only to dealings that have been assessed and approved by the Regulator, and the species and modifications for this class will be limited by the rules.

To clarify, proposed amendments to the Act would require RARMPs for novel limited and controlled dealings (including plant field trials) to be consulted with the public, jurisdictions, specified authorities and agencies, and GTTAC. For example, if the Regulator has not previously consulted the public on a RARMP for a particular plant species, this would be considered novel and trigger the public consultation requirement.

P1 permits would authorise a subset of plant field trials, where the parent plant organism has previously been authorised by the Regulator and is listed in rules, along with restrictions on genetic modifications (e.g., designated dealings could not be permit dealings). Proponents must work within standard field trial conditions prescribed by rules. Proposed amendments to the Act would require rules made for the purpose of class P1 to be consulted with the public, jurisdictions, specified authorities and agencies, and GTTAC. i.e. any new additions to the plant species for the permit class would require jurisdictional consultation.

Q: Please clarify the fourth category in Table 1: Licence class descriptions and proposed consultation requirements of the consultation paper (page 14) that requires public consultation but has no description.

A: Table 1 should be read alongside the preceding page 13 of the consultation paper, which summarises the GMO licence application assessment process.

As summarised on page 13, section 49 of the draft Bill would specify when the Regulator must consult the public on a RARMP and would allow for regulations to prescribe who must be consulted on a RARMP. Regulations made for the purposes of section 49 will describe different classes of GMO licence applications and the bodies the Regulator must consult, including states and territories and the GTTAC. The policy intention is that consultations would be only undertaken when it adds value such as applications where GMOs are novel or high risk.

In relation to Table 1 – The first three rows of Table 1 indicate different licence classes that are proposed to be prescribed for the purpose of section 49 and the requirements for consultation in developing a RARMP. When public consultation is not undertaken for the licence classes in the first 3 rows, consultation with other bodies or the states is required as indicated in the right-hand column of the table for each row. The Regulator retains the discretion to consult the public if it is in the public interest to do so.

The fourth row in Table 1 is intended to indicate the consultation requirements that will apply for a RARMP when public consultation is undertaken. For those RARMPs, the Regulator must also consult the bodies in the right-hand column of the table, being (in addition to the public) the States, GTTAC, specified authorities and agencies.

Legislative Timeframes & Gene Technology Rules Development

Q: will the Rules come into effect alongside the Act and the Regulations? Will there be consultation on the Rules?

A: Yes, all the legislative instruments will need to be in place to be able to function effectively, including the Regulations and Rules. Some jurisdictions may need to go back to Parliament to ensure the new legislation can come into effect. The Rules are being developed and will be subject to a separate consultation process. They are linked and informed by the proposed new Regulations. The consultation paper provides an overview of the intended approach for both the amended Regulations and the Rules.

Some rules will look very similar to the existing guidelines that are in place. As an example, the physical containment guidelines will be moved into the Rules. IBCs will already have familiarity with these.

Q: Will the rules be similar to the most recently released physical containment guidelines?

A: There is likely to be a change in language due to being embedded in legal rules. The intention is for physical containment requirements to be consistent between the current administrative guidelines and the legal rules during the period of transition.

Definitions

Q: Some of the terminology used for GMO dealings such NDs, NNDs or pre- and post-notified notifiable dealings could potentially confuse researchers or typographical errors might occur (particularly if referenced as acronyms). Are the names of the authorisation pathways set in stone?

A: We are interested in suggestions for alternative terminology, and we are open to suggestion or feedback through submissions to the consultation.

Q: The term 'novel' might benefit from having a clear definition

A: We are interested in hearing suggestions and examples of what might be useful.

Regulatory overlap

Q: Re avoiding regulatory overlap for certain dealings and intention for risk considered by other regulators being excluded from needing the Gene Technology Regulator's consideration – How will this be approached in

practice? Will it be specified in the rules? For example, a GM animal vaccine

A: Section 15A(2) of the draft Bill provides that the Gene Technology Regulator or minister is not required to consider a particular risk posed by dealings with a GMO if the risk is dealt with under specified Commonwealth legislation, or the risk is prescribed by the regulations.

The intention is that where particular risks are already considered by another regulator – the Gene Technology Regulator or minister will not be required to also consider them under the amended scheme. However, the Gene Technology Regulator and minister would retain discretion to be able to do so if appropriate in the circumstances.

In practice, Risk Assessment and Risk Management Plans (RARMPs) describe the remit of other regulators in the context of a particular application, and the Office of the Gene Technology Regulator has a good understanding of the role of other regulators in assessing particular risks. The overall intention is to apply appropriate regulation rather than duplicate regulatory efforts.

Q: What is the process to ensure that there are no gaps that result in some risks not being assessed at all by the appropriate regulatory authority?

A: Liaison with relevant agencies has been underway for an extended time to ensure clarity around which risks are considered by each regulator. This occurs under the current legislative scheme and will continue.

For example, the Therapeutic Goods Administration authorisation requirements do not cover the environmental risks, and this will remain with the Gene Technology Regulator to consider those risks in line with the objectives of the GT Act.

Q: Will section 15A require changes to other legislation?

A: We are not proposing to make consequential changes to other legislative schemes as part of these amendments. Section 15A and supporting regulations are intended to clarify the risks that the Gene Technology Regulator must consider under the National Gene Technology Scheme, which when established was designed to be a ‘gap filler’ regulatory scheme (ie filling gaps between other regulatory schemes).