



Australian Government

Department of Health and Aged Care

Proposed amendments to the Gene Technology Act 2000 CONSULTATION QUESTIONS

Register your details to provide a submission (mandatory questions)

What is your name?

What is your email address?

What is your organisation?

Chapter One: Scope of Regulation

1. Do the proposed amendments to the definitions of 'deal with', 'gene technology' and 'genetically modified organism' provide sufficient clarity about what is captured under the Scheme?
2. Do you consider the proposed amendments to key definitions provide greater clarity with respect to the scope of regulation?
3. Do you consider the proposed amendments to key definitions help to future proof the Scheme?

Chapter Two: Risks considered under the Scheme

4. Is the mechanism in proposed section 15A suitable to manage circumstances where dealings with GMOs may also be regulated under other regulatory schemes?

Chapter Three: Authorisation Pathways

5. Are the proposed changes to consultation on risk assessment and risk management plans for licence applications appropriate?
6. Are the provisions dealing with GMO permits sufficiently clear?
7. Are there any practical concerns about the operation of the proposed statutory conditions for GMO licences and GMO permits?
8. Compared to notifiable low risk dealings, does the proposed use of rules for notifiable dealings sufficiently enable the Regulator to respond to technological changes in a timely way?
9. Across the risk-tiering framework, does the proposed use of rules achieve more risk-responsive regulation and sufficient flexibility for the Regulator to adjust categorisation of GMO dealings over time?
10. What should be considered for regulations to prescribe criteria for GMO dealings eligible for inclusion on the GMO Register?

Chapter Four: Compliance, monitoring and enforcement

11. Do you understand the obligations and responsibilities that flow from the proposed offences and civil penalties relevant to your scope of regulated activities?

12. Do the proposed new enforcement powers strike a suitable balance with the risk-tiering framework, which would increase flexibility and enable a greater range of authorisations with reduced up-front assessment?

13. Should the circumstances where Authorised inspectors are able to enter premises at s146 of the amended GT Act without a warrant or consent be extended to allow for entry to premises where notifiable dealings are being undertaken?

14. Should the Regulator's powers to issue directions be extended to situations where the Regulator suspects that an unauthorized dealing with a GMO is taking place, if necessary to manage risks to people and the environment?

Chapter Five: Certification and Accreditation

15. Do you have any concerns with the practical implementation of proposed amendments to certification and accreditation?

16. Should it continue to be a requirement for the accreditation of an organisation that the organisation has appropriate indemnity arrangements in place for the members of its Institutional Biosafety Committee(s)? If so, what type of indemnity arrangements should be regarded as appropriate?

17. Would the proposed offence for breach of accreditation conditions operate more fairly and clearly if organisations were directly accredited, rather than accreditation being held by the person who applied to accredit the organisation? Would such direct accreditation pose any difficulties for regulated entities?

Chapter Six: Use and Disclosure of Information

18. Do the proposed amendments relating to CCI strike the right balance between protecting the valuable information of those involved in the research and development of GMOs and transparency relating to the regulation of GMOs?

19. Are the proposals for use and disclosure of Regulator Information sufficiently clear?

20. Do stakeholders have any concerns with the revised definition of CCI noting the change in scope from the existing definition?

21. Do stakeholders have concerns with the new approach to information related offences noting that the intention is to further refine in line with any changes made to the offences in legislation administered by the Commonwealth?

Chapter Seven: Minor, Technical and Consequential Amendments

22. Are there any concerns about the scope and process proposed for rules made by the Regulator?

23. Are there provisions in the GT Act as amended that would be difficult for regulated entities to apply or that would operate unfairly?

Chapter Eight: Application, Savings and Transitional Provisions

24. Are there any concerns about the proposed approaches to transition to the reformed scheme?

Privacy information and consent to publish

The Department of Health and Aged Care, on behalf of the National Gene Technology Scheme (the Scheme), intends to publish submissions, including the name of the individual or organisation that made the submission, on the Scheme website. Please indicate your willingness for your details to be published by selecting the appropriate response below. The following question requires one answer to be selected. (mandatory question)

- I CONSENT to the submission being published in full on the Scheme website.
- I CONSENT to a redacted version of my submission being published on the Scheme website.
- I CONSENT to publication of the name I have provided in a list of submissions received on the Scheme website, but do not consent to any part of my submission being published.
- I CONSENT to publication of my anonymous submission on the Scheme website, but do not consent to any identifying information being published.
- I DO NOT CONSENT to any information about my submission, including my name or the name of my organisation, being published on the Scheme website. *If any part of your submission is confidential information that cannot be cited, please clearly mark these parts "IN-CONFIDENCE".

By making a submission, I acknowledge that: (Please select all that apply.)

- I understand that the giving of my consent is entirely voluntary.
- I am over the age of 18 years.
- I understand the purpose of the collection, use, publication or disclosure of any submission.
- I understand that, where I have provided consent to my submission being published, the Department has complete discretion as to whether my submission, in full or part, will be published.

Third Party personal information and evidence of consent to publish (Please select all that apply.)

- Please tick this box if your submission contains personal information of third-party individuals. You should not include personal information about third parties unless you are able to provide evidence of written consent.
- Please tick this box if you have attached evidence of written consent.
- Please tick this box if none of the above options apply.
- If you have indicated above that you have attached written evidence of third-party consent, please attach it here.