Australian Academy of Technology & Engineering

Australian Academy of Science

Submission to the Legislative and Governance Forum on Gene Technology

Response to the National Gene Technology Scheme Consultation Regulation Impact Statement

17 March 2021

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Submission to the consultation on the National Gene Technology Scheme, Consultation Regulation Impact Statement

The Australian Academy of Science and the Australian Academy of Technology and Engineering (jointly, "the Academies") welcome the opportunity to comment on the proposed regulatory framework to support the implementation of the Third Review of the National Gene Technology Scheme.

The Academies strongly support the objectives of the Legislative and Governance Forum to future-proof and modernise the gene technology system. Accumulated experience has shown that the National Gene Technology Scheme is no longer fit for purpose in its current form. The Scheme needs significant reform to keep pace with gene technology advancements and to address the policy problems outlined in the Consultation Regulation Impact Statement (CRIS).

The Academies have considered the options for the introduction of a risk-tiering framework outlined in the CRIS and accompanying explanatory paper. The direction of the proposed changes to the regulations is consistent with, and supportive of, the continued achievement of the stated purpose of the *Gene Technology Act 2000* (the Act): the identification and management of risk to human health and safety and the environment (HHS&E).

The Academies support the adoption of **Option B: Risk-tiering model**. Option B is a substantial improvement on the status quo, offering the best conditions for more streamlined and responsive regulatory processes while also supporting continued innovation.

There are significant streamlining opportunities in the proposed reforms. The Academies consider it a very positive development to allow years of practical experience with genetically modified organisms (GMOs) to be taken into account, providing ways to respond rapidly and appropriately to the evolution of gene technology while continuing to ensure public confidence in the effective oversight of gene technology.

The Academies also strongly support the proposal to introduce delegated legislation under the Act, which will enable the Scheme to more rapidly adapt to change and remain current.

Option B: Risk-tiering model – Preferred option

Categorising all dealings on the basis of indicative risk would substantially enhance the sophistication of the regulatory system and enable the Office of the Gene Technology Regulator (OGTR)'s resources to be focussed on consideration of the highest risk dealings. Adopting the risk-proportionate model will allow greater flexibility and ensure the Gene Technology Scheme is better positioned for emerging developments in gene technology across any application.

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However, there are still several considerations to be addressed in this model. Notably, the operation of the Scheme could become more opaque to both users and the broader community. As the consultation documents recognise, there will be a requirement for high levels of proactive transparency in developing eligibility criteria and allocating responsibility for assessing risk tiers. This will require extensive consultation, time and resources to train system users to create confidence and ensure effective implementation. Providing the regulator with powers to make binding determinations of where a particular product or planned product may fall within the risk tiers, would also be useful to give developers confidence in progressing products through to commercialisation. Regulatory uncertainty is often the largest impediment to innovation in this field.

Impacts of Option B that have not been identified in the CRIS include the availability of relevant previous risk analyses. The proposal that risk assessments could be informed by those conducted for previous authorisations is logical and desirable, but may in practice stifle innovation. Particularly where field trials are involved, this may generate reluctance to be the first applicant to expend time and resources to generate data that then benefits future applicants, who may be competitors. This process may also raise issues of commercial confidentiality.

Option B could promote science innovation through the availability of relevant *international* risk analyses. However, the significant differences in scope and transparency between Australian and international regulatory systems mean that international risk assessments merit further exploration and consultation. International companies with approval from countries with reputable regulatory systems could be encouraged to apply to introduce their technology or products in Australia via recognition of their existing data, which would promote science innovation.

Option C: Matrix model – not preferred due to complexity and uncertainty, limited benefit

The proposed Option C: Matrix model is similar to Option B but retains some existing categories of dealings and, therefore, a degree of familiarity for existing users. As outlined in the CRIS, Option C requires applications to be first sorted by dealing type before any risks to HHS&E associated with the dealings are considered. However, applications now being submitted do not fit readily within the existing categories. Various other proposed changes, including that clinical trials and medical applications, are automatically allocated to a new, separate category to allow faster responses for urgent medical or clinical applications. Although the latter change would undoubtedly expedite the evaluation of some clinical applications, it creates a precedent for the creation of other special categories in the future. Furthermore, the CRIS acknowledges that circumstances could arise where dealings have features relevant to two or more categories. Therefore, the Academies consider that Option C would generate both complexity and uncertainty without significant benefit to achieving the primary purpose of the regulatory process.

The Academies note that Option C does not currently include a permit system under Contained Dealings. If Option C is chosen, a permit system should be included to capture some applications currently classed as dealings involving intentional release, such as large-scale fermentation of well-characterised GMOs that may not require further assessment, or that have previously gone through an expedited assessment. In addition, consideration should be given for dealings involving intentional release where there is a high risk of escape from containment or high consequence of release to require a full assessment.

Additional comments on Options B and C:

- The Academies endorse the introduction of the permit system for small scale field trials of low-risk releases and the expedited assessment for medium-risk field releases.
- Neither model should include an option for non-notifiable dealings for environmental releases or clinical applications. Instead, the model should, at minimum, be notifiable for these situations to encourage public confidence in regulatory oversight.

- Reforms must address the important gap in regulation of bioremediation agents and the anticipation of emerging 'orphan' (i.e. currently unregulated) products, such as fertilisers and soil amendments. The Act requires the identification and management of risks to HHS&E from GMO dealings, but OGTR is not, and should not be, set up to be a product regulator. Remaining gaps in product efficacy and quality may require further review of the scope of the Acts for existing product regulators, such as the Australian Pesticides and Veterinary Medicines Authority.
- The GMO register has not functioned as envisaged and remains an underused authorisation pathway. However, the CRIS does not clearly explain what the proposed changes to the GMO register aim to achieve. For example, if the objectives are to increase use of the GMO register in place of the ongoing licensing category for commercial releases of GMOs, then the application process for the GMO register will need to be streamlined.

Explanatory Paper – Proposed changes to definitions

In response to the proposed changes to definitions as outlined in the Explanatory Paper (Page 10-17), the Academies make the following comments:

- The revised definition of 'Gene Technology' accommodates the ongoing evolution of gene technology. Changing part (a) of the definition to include 'created' enables organisms produced via synthetic biology to be captured, but the definition could more clearly encompass the creation of synthetic genomes. For example: '*for the creation or modification of genes, genomes, or other genetic material*'. It will also be important to determine if this definitional change would result in the regulation of techniques that are indistinguishable from random mutation.
- Limited revision of the definition of a 'GMO' should again encompass synthetic biology, raising the same question as above. Since consideration of regulatory oversight of germline/somatic modification of humans is continuing, the exclusion of humans from the Scheme is not clear at this time.
- The proposed amended definition of 'dealings' is less prescriptive, but could broaden the scope of the regulation substantially. The suggestion that this definitional change would enable regulatory gaps for 'orphan' products to be filled is potentially problematic, as the expertise and regulatory responsibility of the OGTR is the assessment of risks to HHS&E. If the proposed definition of 'use' introduces a requirement to assess issues such product quality and efficacy (a requirement under other product regulation, as opposed to process-triggered regulation), then this represents a fundamental change that is beyond the current remit of the OGTR.
- The recommendation to enable consideration of other regulators' assessments in the context of defining the risk tier is sensible. However, this may not eliminate duplication or 'regulatory creep'. This would require the OGTR to assess and be satisfied with the adequacy of other regulators' assessments from a GTA perspective, to fulfil its regulatory responsibilities. In addition, this could adversely affect regulatory clarity, since different regulators have different time frames for decision-making. It is possible that this could lead to conditional approvals being issued.
- The regulation of environmental release of gene drive GMOs is under separate consideration, so further work is required (as noted on page 34 of the explanatory paper). However, Australian researchers are already beginning to evaluate the potential applications of gene drives in feral animal or pest control. It may be preferable for this assessment to be accommodated within the proposed risk tier framework now

and be included in the guidance materials to be developed during the implementation of the proposed changes to the Scheme.

- The provision of interpretive guidance materials is essential to ensuring widespread understanding of revised definitions.

Other technical changes

- The Academies endorse the proposed changes to section 27 of the Act to clarify that the OGTR can engage in international capacity-building activities, including assistance to establish appropriate regulatory regimes.
- The proposal to update the current requirements for confidential commercial information (CCI) applications to 'better align with contemporary provisions of other regulators' is unclear and could be further clarified.

Conclusion

The current regulatory system presents barriers to technological development and the adoption of new gene technologies.

Adopting a risk-tiering regulatory model would allow more streamlined authorisation processes and provide the most supportive environment for innovation and investment in emerging technologies. The proposed reforms will ensure the Gene Technology Scheme is better positioned for emerging developments in gene technology.

Model B would allow more flexible responses to new technological developments and accumulated experience in a risk-proportionate way while preventing the over-regulation of low-risk gene modification technologies.

The Academies strongly favour a regulatory system that responds to new information, reduces regulatory burden for applications that present few practical risks, and appropriate regulation for applications identified as high risk.

If you would like to discuss any aspect of this submission, please contact Dr Stuart Barrow, Senior Policy Analyst, Australian Academy of Science (stuart.barrow@science.org.au) or Dr Harry Rolf, Senior Policy Analyst, Australian Academy of Technology and Engineering (harry.rolf@atse.org.au).