Australian National University

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Gene Technology Implementation Team
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Dear Office of the Gene Technology Regulator,

Re: ANU Recombinant DNA Monitoring Committee submission on the Consultation RIS and Explanatory Paper for Modernising and Futureproofing the National Gene Technology Scheme

Please find attached, responses to the key consultation questions from the Consultation RIS and Explanatory Paper for Modernising and Futureproofing the National Gene Technology Scheme from the Recombinant DNA (rDNA) Monitoring Committee of the Australian National University.

The ANU is a large research-intensive university with two DNIR licenses and 71 NLRDs held by researchers. The Recombinant DNA monitoring committee, which serves as the Institutional Biosafety Committee (IBC) for this institution oversees all work involving GMOs. Under the existing framework, all dealings at ANU are considered contained dealings.

Overall, the ANU is highly supportive of the proposed regulatory framework to support implementation of the Third Review of the National Gene Technology Scheme. The proposed changes are proportionate and well considered. We generally endorse the proposed changes to definitions; we support authorisation pathway B and agree that updated IT system would be desirable.

Our support of option B is due to the increased streamlining of the application pathway, and the ease with which our existing application and assessment processes could be adapted to this option. In contrast, Option C requires an additional level of assessment and it is unclear how this would be easily achieved within our current framework.

Questions that are not relevant to our organisation have not been addressed. Where applicable, specific concerns/or requests for clarifications are raised in our responses below.

Please do not hesitate to contact our rDNA Officer <rdna.officer@anu.edu.au> if you require any clarifications.

Yours sincerely,

Professor Keith Nugent
Deputy Vice-Chancellor (Research & Innovation)

Key consultation questions – Option A

- Please provide further information, including quantitative data, on the costs associated with maintaining the status quo.

In the short term, costs-associated with maintaining the status quo would be lowest for option A as all systems and procedures are in place. However, we anticipate an expansion, in particular, of our medical research and clinical trials capacity in the coming years and so the status quo is in danger of becoming not fit for purpose which will create additional costs. At this point is it not possible to provide quantitative data.

- To what extent would maintaining the status quo stifle innovation?

We anticipate the increased use of GMO technology in the medical sphere in particular. Increased focus on translation at the ANU and in Australian science in general means that more GM technologies may need to be assessed under the licenced rather than the non-notifiable pathways. Noting that this is already a highly regulated area (e.g. TGA), streamlining the regulation of this area will be necessary to foster innovation.

- What are the benefits of maintaining the status quo?

The status quo has the short-term benefit of require little or no change in procedures and application processes as they stand.

Key consultation questions – Option B

- Would Option B address the identified policy problems?

Option B appears the most flexible for addressing the policy problem of dealings that do not conform strictly to definitions of contained and non-contained. It also provides a flexible regulatory framework that should facilitate the assessment of dealings that are of lower risk and have been assessed by other regulators.

- Please outline any additional impacts of Option B that have not been identified in the current impact analysis.

One impact that we foresee is that IBC decision-making may become more complicated. Our IBC has historically dealt with contained dealings and has experience in this area. We have strong institutional understanding of the science and the regulatory framework. Under Option B, some dealings would be defined as lower risk, in part, because the risk is assessed by other bodies (e.g. TGA/APVMA). Clear guidance from OGTR will be required to facilitate decision-making between notifiable low risk

dealings and licensed dealings. This will need to include a map of other regulators, otherwise IBC Members will be reluctant to make decisions outside of their area of expertise.

A second possible impact might be a breakdown of logic in the conditions under which pre-clinical work (easily contained), and clinical work (not easily contained) is done with some GMOs. If care is not taken in the guidance to IBCs and regulated entities, a situation where more stringent requirements are placed on laboratory components, including pre-clinical animal testing, of a translational program than might be placed on a clinical trial with the same or similar GMO. This will make Australia less attractive internationally for early-stage development, which in turn risks undermining the principle of science-based, risk-proportionate regulation.

- Please provide further information, including quantitative data, on any costs and benefits to your organisation associated with Option B.

Quantitative data are hard to provide without a clearer understanding of how the revised scheme will operate, however we anticipate that existing structures in place could be adapted to encompass the changes required. It would be preferable with any changes in regulation to ensure an appropriate lead in time for effective implementation.

- How might Option B promote science innovation?

We believe that having a unified framework proposed in Option B within which applications are assessed will promote science innovation. In contrast, we are concerned that the multiple pathways created in Option C will create regulatory confusion and lead to wasteful assessments under redundant criteria.

Key consultation questions – Option C

- Does Option C address the policy problems identified in the Consultation RIS?

Option C provides pathways for expediting assessment of medical research applications and crop trials where risks and procedures are already well understood; this only addresses one policy problem. However, it increases the regulatory burden by creating three streams of overlapping assessments. This is compounded by the fact that some applications may straddle the categories and so applications may need to be assessed under multiple different pathways.

- Please provide further information, including quantitative data, on the costs and benefits to your organisation associated with Option C.

As outlined above we consider that option C creates additional regulatory burdens without a consequent benefit. It is at this point unclear whether the applicant or the IBC would be primarily responsible for determining the stream in which an application is assessed.

We would have to create multiple forms and processes to assess different applications under the various types of dealings, and some dealings may have to be assessed under multiple frameworks.

- Please outline any risks or additional considerations that need to be taken into account with regard to this option.

A further potential complication (similar to Option B) is that previously the IBC could assess whether a dealing is low risk relatively straightforwardly for contained dealings we may not have the experience to do so in medical and agriculture applications. Moreover, we may not have the policy background to be able to understand and consider the findings of other regulatory bodies. This would create additional burden and challenges.

Key consultation questions – definition of gene technology

- Does the proposed definition of gene technology address the issues identified?

We agree that the proposed definition of gene technology by capturing the synthesis of genes addresses the identified issues.

- Does the proposed definition of gene technology introduce any new issues?

Our organisation has some concerns that the proposed new definition may inadvertently capture nucleic acid synthesis not associated with the creation of new genes for example PCR primers and synthetic DNA in plasmids. However, providing it remains the case that the use of a gene technology is a trigger for regulation only when it results in an organism this concern may have already been addressed. Clarity in regulation drafting will be essential.

- Would interpretative guidance on the definition of gene technology issued by the Regulator be adequate, or should the Regulator have the capacity to make binding determinations that something is or is not a technique for the modification of genes or genetic material?

The ANU supports the regulator having the capacity to make binding determinations on whether something is, or is not, a technique for the modification of genes or genetic material. Since its inception, the OGTR has generally taken a conservative and proportionate stance on what is, or is not, defined as gene technology and the risks associated with the regulator being granted this authority appear low. On the other hand, the costs associated with extended periods of time taken to make these determinations under the current framework are high, especially given the rapidity with which technology evolves.

Key consultation questions – definition of GMO

- Does the proposed definition of GMO address the issues identified?

The ANU agrees that the proposed definition of GMO addresses the issues identified.

Key consultation questions – definition of deal with

- Does consolidating the definition of deal with into the concepts of make, supply and use address the issues identified?
- Does consolidating the definition of deal with introduce any new issues?
- Is it preferable to consider the role of other regulators through the consideration of risk in the new pathways described in Chapter 4, or should the intersection be addressed through a revised definition of deal with?

(Reponse to all three questions above): The ANU is concerned that the proposed new definition of 'deal with' captures too many activities that are better assessed by other regulators. However, on the other hand excluding activities authorised by another regulator may lead to under regulation. Overall, we agree that that the roles of other regulators would best be considered in the assessment of risk under the new pathways.

Key consultation questions – Non-notifiable dealings/notifiable dealings/licensed dealings

To avoid repetition, we are combining our responses to questions around non-notifiable, notifiable and licenced dealings

- What types of dealings would be appropriate to include in the non-notifiable/notifiable pathway for Option B/ for each of the three categories for Option C, what types of dealings would be appropriate to include in the non-notifiable/notifiable pathway?

For contained dealings within laboratory contexts, the current delineation between exempt and low risk dealings works well and we believe this should be carried forward into the new framework. However, for applications involving release or medical applications (regardless of whether they are processed through Option B or Option C) it is hard to envision that many such dealings will be classifiable as non-notifiable or notifiable, unless clear guidance is provided by the regulator. For example, we question whether local IBCs will feel empowered to permit the use of GMOs in medical applications, even if other regulators (e.g. the TGA) have approved the treatment as safe and effective. What are the advantages and disadvantages of categorising dealings using existing concepts (e.g. contained dealings and intentional release) that do not account for risk or modern technology?

Existing concepts of contained release are well understood by local IBCs in a University context. It is possible that IBC members may not feel comfortable to assessment based on relative risk and may not feel that they have the necessary policy knowledge (as opposed to technical knowledge) to incorporate the determinations of other regulators which maybe beyond their expertise. We foresee that even though notifiable and non-notifiable dealings involving release or medical applications may be possible under the new framework these categories are unlikely to be extensively used.

- What risk indicators would inform the split between a permit, an expedited assessment or a full assessment for Option B?

The ANU supports the introduction of permits and expedited assessment. Permits may be best used in cases where there is extensive “in house” knowledge of the risks and their management for a particular scenario (e.g. bt corn). Expedited assessment might be more appropriate for novel situations in the Australian context (e.g. recombinant viral-vectored vaccines), but where other reputable regulators in other countries (e.g. UK MHRA) or in Australia (e.g. the TGA) have already assessed the risks to health and environment of release/ medical applications.