AUSTRALIAN ACADEMY OF TECHNOLOGY AND ENGINEERING

AUSTRALIAN ACADEMY OF SCIENCE

JOINT SUBMISSION TO THE REVIEW OF THE NATIONAL GENE TECHNOLOGY SCHEME 2018 (THIRD PHASE CONSULTATION)

The Australian Academy of Technology and Engineering and the Australian Academy of Science (collectively, the Academies) welcome the opportunity to participate in the Review of the National Gene Technology Scheme (the Review) in the third phase of consultation, based on the Review's Preliminary Report of March 2018. The Preliminary Report provides a summary of the Review's activities to date and presents 33 findings based on extensive consultation throughout the sector and the community.

The Academies are generally supportive of the Review, which covers many aspects of gene technology regulation in Australia and synthesises a number of diverse perspectives from across the community. As stated in our joint submissions to the previous phases of the consultation, the Academies support a flexible regulatory arrangement that allows the Gene Technology Scheme to respond to new technological developments and accumulated experience. We are pleased to see this reflected in the broad thrust of the preliminary report's findings.

The Academies also consider that applications of gene technology that are indistinguishable from the results of standard breeding methods pose no greater risk than those standard breeding methods. We note the recent US Department of Agriculture bulletin to this effect (see USDA Animal and Plant Health Inspection Service bulletin of 28 March 2018).

The Academies consider the use of gene technology applications with a history of safe use and no reasonable apprehension of elevated risk should have their regulatory burden reduced. To this end, the Academies support the preliminary report's suggestion of applying a principles-based approach to mature areas of the scheme.

Responses to findings:

> **Finding 1** – The Review found that the object of the *Gene Technology Act 2000* remains appropriate and should be maintained.

The Academies support this Finding.

> **Finding 2** – The Review found that the *Gene Technology Agreement (2001)* is working well and continues to facilitate effective national cooperation on gene technology. As such, the *Gene Technology Agreement (2001)* should be maintained.

The Academies support this finding.

> **Finding 3** – The Review found that there are existing definitions in the *Gene Technology Act 2000* and *Gene Technology Regulations 2001* that may not appropriately classify a range of

advances in technology (for example, the definitions of 'gene technology' and 'genetically modified organism', including use of the terms 'other genetic material' and 'foreign').

In both the Australian and international context, the value of having consistent definitions is well understood, as is recognition that definitions have a primary role in the classification of technologies and subsequent regulatory requirements. Any examination of definitions should therefore take into account concurrent work, including the current Technical Review of the Gene Technology Regulations 2001, as well as ongoing work internationally.

The Academies support this finding.

Finding 4 – The Review found that synthetic biology is currently within the scope of the Scheme, and there is a high degree of support for this to continue. Work is currently being undertaken by the Australian Council of Learned Academies (ACOLA) which may further inform this issue going forward, including determining the most appropriate mechanism(s) to ensure the appropriate level of regulation of synthetic biology is applied.

The Academies support this finding. While the Academies would expect synthetic biology applications to fall within the scope of the Gene Technology Scheme, the legislated definition of gene technology is unlikely to capture all aspects of the broader field of synthetic biology.

Finding 5 – The Review found that the Scheme was not designed to regulate humans, including those who have received or inherited germline therapies (or who have received somatic therapies that were not envisaged when the Gene Technology Act 2000 was drafted). Therefore, the Scheme is not the most appropriate means to regulate the application of human gene therapies (including any ethical, legal and social issues).

Any consideration of whether additional regulatory oversight is needed in this area may benefit from national collaboration across the health sector, to identify the most appropriate body to undertake this work.

The Academies support this finding. It is inappropriate for humans to be regulated under the Gene Technology Scheme. Government should consider the NHMRC Embryo Research Licensing Committee as an appropriate body to regulate research which involves human germline modification.

Nevertheless, there is no technical impediment to the application of gene technology to humans. For this reason, it is important for the Gene Technology Regulator to work closely with the regulatory body for human gene technology applications to ensure regulatory consistency and appropriate oversight.

Finding 6 – The Review found that there would be benefit in further work being undertaken to determine the most appropriate approach for regulating the broader environmental release of genetically modified organisms. Subject to administrative and legal considerations, this could include:

- a new licence category with additional requirements specifically relevant to genetically modified biological control agents;

- the application of current risk assessment and risk management approaches and information requirements;
- consideration of the role of the *Environment Protection and Biodiversity Conservation Act 1999*, the scheme set up by the *Biological Control Act 1984* and related state and territory laws, and the intersection of these laws with the *Gene Technology Act 2000*;
- a new Policy Principle, set of guidelines or code issued by the Legislative and Governance Forum on Gene Technology; and
- other appropriate approaches that may be suggested to achieve the desired outcome (for example, post-release monitoring).

The Academies support this finding. Without wishing to pre-empt proper legal and administrative considerations, the Academies strongly favour an approach which is scientifically rigorous and well informed, which would include at a minimum an advisory capacity in environmental science and ecology on the GTTAC (as is currently the case).

It is imperative for the risks associated with environmental releases to be effectively identified and well managed, and it is vital for the legal frameworks to be set up in advance of any deployment and "technology ready". The Academies welcome future consultation on the regulation of broader environmental releases. As noted by the review, the envisaged releases differ from current Dealings involving Intentional Release (DIRs) in that they are not expected to be restricted to a particular field or farm. It is likely, therefore, for such releases to require significant engagement with local communities, a consideration which should be included in developing the necessary regulatory frameworks.

> **Finding 7** – While both contained work and any future environmental releases of genetically modified gene drives should be clearly within the scope of the Scheme, the Review found that there would be benefit in further work being undertaken to determine the most appropriate approach for regulating environmental release of genetically modified gene drive organisms (as well as any additional requirements for contained work). This could include mechanisms similar to those suggested for **Finding 6.**

The Academies suggest that regulatory measures for broad environmental releases (under **Finding 6**) should be established such that organisms modified to contain gene drives may be treated as a subset of broader environmental releases. Again, it is important that the legal and regulatory frameworks are set up in advance of the technology to provide certainty to researchers and confidence to other stakeholders.

> **Finding 8** – The Review heard strong arguments to support the maintenance of a process-based trigger as the entry point for the Scheme (i.e. a broad range of technologies, including new technologies, are within the scope of the Scheme).

The Academies accept this finding, noting the opportunities for more targeted regulatory oversight identified in Finding 9, and the recognition that aspects of the Scheme may appropriately evolve towards a product-based trigger over time.

> **Finding 9** – The Review found that there are opportunities for additional risk tiering to be applied within the Scheme. An additional body of work could be undertaken to determine

the most appropriate risk tiers and the types of regulatory requirements assigned to each tier.

Where appropriate, flexibility to move organisms between categories, based on a history of safe use, or the identification of new risks or other relevant factors (see **Findings 13 and 14**), could be considered. Any changes should aim to ensure the level of regulation remains proportionate with risk and protects against over-regulation or under-regulation.

The Academies support this finding, in particular the proposal to develop flexible mechanisms to move organisms between categories based on safe-use or new data. Over-regulation of low-risk gene modification technologies restricts research and technology development. Additionally, the Scheme must be able to adapt to newly identified risks.

Finding 10 – The Review heard that there are a number of opportunities to streamline current regulatory requirements, such as through the introduction of IT and other solutions across a range of areas, including facility certifications, application processes, classification levels, harmonisation of requirements and confidential commercial information assessment timeframes.

The Academies support streamlining and aligning the administrative processes of the regulatory system.

Finding 11 – The Review heard that changes could be made to enable the GMO Register to be more effectively utilised within the Scheme. In progressing any changes, consideration could be given to whether:

- the requirement for a dealing to have been authorised by a licence before being included on the GMO Register should be removed; and
- an alternative mechanism for adding dealings to the GMO Register should be introduced that is more time and resource efficient, and better reflects the level of risk than the current system requiring a disallowable legislative instrument.

The Academies support more effective use of the GMO Register along the lines proposed. The proposed changes will allow more efficient research conduct and improve the capacity of industry to diversify proven GM applications to commercial scale.

Finding 12 – The Review heard that there are opportunities for further work to be undertaken to quantify the scope of 'DIY biology' activity, ensure that regulatory requirements are widely known, and to further investigate whether current monitoring and enforcement activities are appropriate for all sectors of the Scheme.

The Academies support quantifying the scope of 'DIY biology' activity and initiatives to connect with this community. Irresponsible or unregulated use of GM technology carries at a minimum a risk of reducing community support. At the same time, the entry of SMEs into the biotech field should be encouraged and supported, and the regulatory environment should be equally manageable for smaller entities as for research organisations and large research-intensive companies.

Finding 13 – The Review heard that there is a need for increased flexibility within the Scheme to enable it to appropriately respond to changes in scientific understanding and

understandings of risk. Options to increase this flexibility that could be investigated further (subject to administrative and legal considerations) could include:

- enabling the Gene Technology Regulator to make determinations or orders on the applicability of regulation to any technological developments. These determinations (or orders) could be recognised by the Gene Technology Regulations 2001, until such times that they are included in legislation; and
- introducing elements of principles-based regulation to some parts of the Scheme, initially focussing on areas of the Scheme with a history of safe use.

The Academies strongly support this finding. The proposed options would improve the flexibility of the Scheme and enable regulatory focus to be directed towards potentially higher risk applications.

Finding 14 – The Review heard that there may be scope to increase the agility of the Scheme, while maintaining appropriate oversight measures. This might include introducing mechanisms to enable certain activities of the Legislative and Governance Forum on Gene Technology to be driven by the Gene Technology Standing Committee.

The Academies strongly support this finding, which would enhance the responsiveness of the governance process while maintaining national accountability for the operation of the Scheme.

Finding 15 – The Review heard that the Australian Government has an important role in coordinating internationally on matters relevant to market access and international trade. There is benefit in the Australian government, including the Gene Technology Regulator on regulatory matters, continuing to engage with appropriate international fora in this area and ensuring that any relevant international obligations continue to be met.

The Academies strongly support this finding. International harmonisation of regulatory regimes promotes the exchange of knowledge and technology resources and provides certainty to both researchers and industry.

Finding 16 – The Review found that the operation of the Scheme has shown to be credible, and that the Scheme operates with integrity and legitimacy as evidenced by:

- high level governance oversight provided by all states and territories through the Legislative and Governance Forum on Gene Technology;
- the independence and credibility of the Gene Technology Regulator; and
- robust governance processes providing oversight of advisory structures and appointments.

The Academies support this finding.

Finding 17 – The Review heard that ensuring national consistency of the Scheme is valued, and that maintaining consistency between all state and territory Acts and the Gene Technology Act 2000 helps provide certainty for stakeholders in relation to current regulatory requirements.

The Academies support this finding. National consistency is a critical enabler of effective collaborative research and innovation in all technology fields.

> **Finding 18** – The Review found that there are conflicting views among stakeholders regarding the advantages and disadvantages of state and territory moratoria legislation. Further, there is a lack of conclusive evidence on this matter, particularly on the economic effect of moratoria legislation, as economic calculations are context-specific and complex (based on non-stable factors).

The Academies acknowledge moratoria based on economic considerations are a policy matter for jurisdictions and have no comment on this finding.

> **Finding 19** – The Review found that some stakeholders believe that the focus of some moratoria legislation extends beyond marketing purposes, and there may be benefit in further consideration of whether all restrictions (for example, transport restrictions) are appropriate to meet this objective.

The Academies have no comment on this finding.

> **Finding 20** – The Review found that consideration of benefits (e.g. potential economic, environmental and health benefits) should not be introduced at this time as it could risk the effective operation of the Scheme. Consideration of benefits may be an area of ongoing focus in future reviews.

While the Academies consider it important for the benefits of GM technology to be evaluated and understood, they should remain beyond the scope of the Gene Technology Scheme, which focusses appropriately on safety through the assessment and management of health and environmental risks. The benefits of GM technology should be considered in other fora.

> **Finding 21** – The Review heard that in order for the potential economic and health benefits of gene technology to be harnessed now and into the future, the Scheme should not impose unnecessary regulatory burdens. The Review found that this may be achieved through regulation that is commensurate with the level of risk posed by a dealing (see Findings 9 and 10).

The Academies support this finding, and strongly support the principle that the level of regulation should be commensurate with risk.

> **Finding 22** – The Review found that there is an opportunity for the Legislative and Governance Forum on Gene Technology (the Forum) to lead a forward work program to consider a range of matters. This may include identifying areas where the Forum could issue Policy Principles, Policy Guidelines and Codes of Practice to provide or clarify policy positions on key matters, noting the responsibility of the Forum to consult and collaborate with other relevant government forums in the conduct of its business. In operationalising a forward work program, the Forum might consider opportunities to leverage the role of the Gene Technology Standing Committee.

The Academies support the establishment of a forward work program for the Legislative and Governance Forum as proposed and would be keen to participate in consultations regarding Policy Principles, Policy Guidelines and Codes of Practice. This approach would provide policy clarity for stakeholders, increase transparency and enhance the operational effectiveness of the Scheme.

Finding 23 – The Review found that consideration could be given to using the current provisions of section 21 of the Gene Technology Act 2000 to enable Policy Principles to be issued on a wider range of topics.

The Academies support this finding. This will allow the Forum to provide clarity on policy matters, and to respond more rapidly to developments in technology or the regulatory environment.

Finding 24 –The Review heard that there is lack of clarity for some stakeholders regarding the roles of the Office of the Gene Technology Regulator and genetically modified product regulators, which might be addressed through the development of a dedicated gene technology regulation web portal.

Finding 25 – The Review heard that there may be areas of overlapping regulatory oversight between the Gene Technology Regulator and some product regulators, and that work could be undertaken to investigate potential solutions and any required legislative changes.

Finding 26 – The Review heard that there are potential mechanisms in other schemes (for example, the Therapeutic Goods Act 1989 Special Access Scheme) that could be adopted to strengthen the Scheme, and there may be benefit in additional investigation being undertaken.

The Academies have no comment on these findings beyond noting that improving clarity about the role of the OGTR and the roles of the regulatory agencies is to be supported. The Academies strongly supports inter-agency harmonisation and a coherent, cross-government regulatory environment.

Finding 27 – The Review heard that full cost recovery may have detrimental effects on the sector (for example, by stifling innovation, impacting international competitiveness and eroding trust). This should be taken into account in any work to determine appropriate ongoing funding mechanisms to support the ongoing operation of the Scheme.

The Academies strongly support this finding. Full cost recovery would add a financial burden to the already substantial regulatory burden and provide further disincentive to the use and development of gene technology.

Finding 28 – The Review found that current funding levels provided for the Gene Technology Regulator's operational activities may not be sufficient to support future regulatory activities. However, there is scope for additional work to be undertaken to determine appropriate funding levels going forward.

The Academies note the Review identified an increasing workload for the OGTR. The implementation of the report findings, if accepted, collectively represent an extensive future work program for the OGTR and the Department of Health, as well as other government bodies, that would require additional resourcing. Given that the Academies support the bulk of the Review's recommendations, they also support the resourcing of these activities.

Finding 29 – The Review heard that public understanding and confidence in the Scheme may be aided by additional communication mechanisms (building on existing bodies of work). There may be benefit in additional work to determine the most appropriate body to lead

communication activities. Any additional communication activities would need to be appropriately funded.

The Academies support this finding.

> **Finding 30** – The Review heard that it is appropriate for the Gene Technology Regulator to continue to lead communication activities on topics related to the assessment of risk associated with gene technology.

The Academies support this finding.

> **Finding 31** – The Review found that despite current regulatory arrangements, there remain ongoing concerns within some sections of the community about the safety of genetically modified organisms, and in particular the safety of genetically modified foods.

The Academies acknowledge this finding, but consider genetically modified organisms to be appropriately regulated and so represent a relatively low risk to human or environmental health and safety. Given the increasing versatility of the technology, there will always remain potential for high-risk applications, but such risks can be identified and managed within the present regulatory environment provided that Scheme is enabled to respond to new developments in technology.

> **Finding 32** –The Review heard that there may be benefit in additional consideration being given to whether current post-release review mechanisms are sufficient, whether additional public communication of activities undertaken is required to increase transparency, and whether mechanisms and resourcing for the Gene Technology Regulator to undertake additional surveillance activities are required.

The Academies consider the current post-release review mechanisms sufficient, but support increased communication efforts regarding decisions affecting gene technology post-release.

> **Finding 33** – The Review found that a high level of transparency and public access to information can be achieved through the Gene Technology Regulator continuing to make relevant information publicly available, and through increased communication with the public (see Findings 29 and 30).

The Academies support this finding. Transparency is one of the Scheme's signature strengths.