Forum Action Plan

IMPLEMENTATION STRATEGY

Oversighted by the Gene Technology Standing Committee

National Gene Technology Scheme

An Australian, State and Territory Governments Collaboration

The purpose of this document is to provide a high level annual strategy for implementing the Legislative and Governance Forum on Gene Technology' s (the Forum) Action Plan.

The Third Review of the National Gene Technology Scheme was undertaken by all Australian Governments.

On 11 October 2018, all governments, through the Forum, endorsed the Final Review Report (the Report).

The Report outlines 27 recommendations addressing technical, regulatory, governance, social and ethical issues.

These recommendations provide opportunities for reduced regulatory burden on industry through streamlined and risk-based regulation, while protecting the health and safety of humans and the environment.

In October 2018, the Forum also agreed to an Action Plan to implement the recommendations over the short, medium and long term.

The Action Plan demonstrates governments' commitment to overseeing and, where necessary, updating the Scheme, to ensure it can manage any risks that gene technology may pose to people and the environment.

The Forum's Action Plan is a five year plan that is reviewed annually to identify priorities. This document seeks to provide clarity about the approach to progress the implementation of prioritised recommendations.

Governance:

The Gene Technology Standing Committee (GTSC) - the senior officials group with representation from all jurisdictions supporting the Forum - will oversee implementation of the Action Plan referring matters back to the Forum as required.

An independent Expert Reference Panel will also be established to provide advice on specific areas of expertise as required.

Action Plan Priorities for 2019:

The Action Plan has prioritised the implementation of recommendations based on urgency, interdependencies and legislative complexity.

In line with the Forum Action Plan, in 2019 priority will be given to progressing recommendations relating to definitional considerations and the development of additional risk tiering.

These priorities have been identified to commence in 2019, as they are recognised as complex but important issues that need further development.

They are also issues which will need time to address and it is anticipated that work on these issues will be required beyond 2019.

2019 Priority Work Stream	Recommendation(s)	Summary
Review and Update Definitions	**Recommendation 4:** The Review recommends updating, where required, the existing definitions in the Gene Technology Act 2000 (Cth), to clarify the scope of regulation in light of ongoing technical advances. Any changes to definitions should take into account concurrent work, including relevant domestic reviews and ongoing work internationally. **Recommendation 6:** The Review recommends: a) the definition of a genetically modified organism under the Gene Technology Act 2000 (Cth) be amended to clarify that humans are not (considered to be) GMOs; and that b) subject to consideration, Council of Australian Governments (COAG) Health Council might also consider whether additional regulatory oversight is needed for humans who may receive or inherit germline therapies (or other somatic therapies not within the remit of the Scheme). The COAG Health Council should also consider which regulatory (or other) body would be most appropriate to undertake such oversight.	The Review identified a number of definitional issues which underpin the Scheme and have a bearing on the implementation of a number of the recommendations. Updating definitions will ensure that the Scheme remains fit-for-purpose and agile in an environment of rapidly developing technology, and supports innovation now and into the future.
Risk Proportionate Framework	**Recommendation 9:** The Review recommends the introduction of additional risk tiering into the Scheme, to facilitate flexibility of the regulatory Scheme and ensure: a) the level of regulation remains proportionate to risk, and protects against under regulation and overregulation; and b) where appropriate, there is flexibility to move organisms between categories, based on identification of new risks, a history of safe use, or other relevant factors.	Risk tiering looks to provide appropriate regulation for gene technologies, ranging from technologies with long histories of safe use through to emerging technologies, according to the risks these technologies pose. This will ensure regulation remains commensurate with risk, supports innovation and reduces unnecessary regulatory burden, while maintaining adequate protections for people and the environment.
Regulatory Efficiency	**Recommendation 10:** The Review recommends reducing regulatory burden through streamlining processes and current regulatory requirements where appropriate. For example, this may include streamlining facility certifications and application processes.	Recommendation 10 of the Review seeks to reduce regulatory burden through streamlining processes and current regulatory requirements where appropriate. Linked to the risk tiering recommendation.

Consultation:
During 2019, discussion/options papers will be developed to inform further development of the Action Plan on the priority areas identified. These discussion papers will also seek to address intersecting recommendations where relevant.

It is anticipated that these discussion papers will provide the foundation for further consultation with stakeholders. Consistent with the conduct of the Review of the Scheme, a range of consultation mechanisms and approaches will be used.

Contact Information:
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