

# Legislative and Governance Forum on Gene Technology

## FORUM ACTION PLAN

2018–2023

In response to the Third Review of the Gene Technology Scheme (the Scheme), and in addition to the ongoing activities of the Legislative and Governance Forum on Gene Technology (the Forum), all Australian Governments represented on the Forum have agreed to pursue this Forum Action Plan. This Forum Action Plan prioritises activities to be undertaken to update the Scheme over the 2018–2023 period.

This Forum Action Plan is a working document, and provides a framework for implementation by the Gene Technology Standing Committee, comprising of senior officials from each jurisdiction, that will report annually to the Forum on progress.

This Forum Action Plan seeks to identify indicative timeframes for the commencement of implementation activities. However, on a practical basis, it is recognised that through monitoring implementation progress, timeframes may need to be revised.



Recommendation from the Third Review of the National Gene Technology Scheme	Actions	Commencement Timeframe (indicative)				
		18–19	19–20	20–21	21–22	22–23
<p>1 To build upon and futureproof the Scheme, which is highly regarded, the Review recommends:</p> <p>a) the Forum progress options to update and enhance the operations of the Scheme; and</p> <p>b) these options be implemented in short, medium and long-term tranches, according to an action plan to be developed by the Forum.</p>	The Standing Committee to develop a detailed Implementation Plan, taking into account Forum agreed priorities	●				
	Ongoing identification and Forum consideration of options to update and enhance operations of Scheme	▶				
	Forum considers outcomes of consultation		●			
	Implement outcome, including legislative amendment where required			▶		
<p>4 The Review recommends updating, where required, the existing definitions in the <i>Gene Technology Act 2000</i> 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.</p>	Develop options for public consultation on proposed revisions to definitions	▶				
<p>6 The Review recommends:</p> <p>a) the definition of a genetically modified organism under the <i>Gene Technology Act 2000</i> (Cth) be amended to clarify that humans are not [considered to be] GMOs; and that</p> <p>b) subject to consideration, the 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.</p>	Development of options for public consultation on GMO definition (undertaken during broader consultation arising from Rec 4)	▶				
	Forum considers outcomes		●			
	Implement outcome, including legislative amendment where required	▶				
	Refer the issue (as outlined in Recommendation 6b) to COAG Health Council for consideration, and if required, development of options to address.			●		
<p>7 The Review recommends clarifying, and where necessary strengthening, the mechanisms for regulating the:</p> <p>a) broader environmental release of genetically modified organisms; and</p> <p>b) environmental release of GM gene drive organisms (as well as any additional requirements for contained work).</p>	Identify any regulatory mechanisms that require strengthening, and develop administrative and legislative options to address; consult as needed	●				
	Forum considers outcomes		●			
	Implement outcome, including any administrative and legislative amendment (if required)			▶		

Recommendation from the Third Review of the National Gene Technology Scheme		Actions	Commencement Timeframe (indicative)				
			18–19	19–20	20–21	21–22	22–23
9	<p>The Review recommends the introduction of additional risk tiering into the Scheme, to facilitate flexibility of the regulatory Scheme and ensure:</p> <p><b>a)</b> the level of regulation remains proportionate to risk, and protects against under regulation and over-regulation; and</p> <p><b>b)</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.</p>	Further develop the current risk tiering framework; consult as needed to inform approach	●				
		Report to Forum on administrative and legislative amendments to adopt improvements			●		
		Consider implementation of actions, including any administrative and legislative amendment (if required)			▶		
10	<p>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.</p>	Identify any regulatory processes and requirements that can be streamlined; consult as needed to inform	▶				
		Report to Forum on administrative and legislative amendments to adopt improvements		●			
		Implement agreed outcomes			▶		
11	<p>The Review recommends that changes be made to enable the GMO Register to be more effectively utilised within the Scheme.</p>	Identify opportunities to optimise the GMO Register; consult as needed to inform.		●			
		Report to Forum on administrative and legislative amendments to adopt improvements		●			
		Implement agreed outcomes			▶		
		Regular updates to Forum on 'DIY biology' activity and risks (ongoing)		▶			
		Forum considers options		●			
		Implement outcome, including any legislative amendment (if required)			▶		
		Standing Committee <i>Progress Report</i> to Forum at end of first year of implementation, and ongoing		▶			
12	<p>The Review recommends that, to ensure the Scheme's current monitoring and enforcement activities remain adequate:</p> <p><b>a)</b> regular reviews of these activities are undertaken;</p> <p><b>b)</b> regulatory requirements for working with gene technologies are widely communicated and known; and</p> <p><b>c)</b> the scope and associated risks of 'DIY biology' activity continue to be monitored.</p>	Review the adequacy of the Scheme's monitoring and enforcement activities	●				
13	<p>The Review recommends that to better respond to changes in scientific understanding and understandings of risk, consideration should be given to:</p> <p><b>a)</b> enabling the Regulator to make decisions on the applicability of regulation to any technological developments, until such time as a policy approach has been agreed; and</p> <p><b>b)</b> introducing elements of principles-based regulation to some parts of the Scheme, focusing on areas of the Scheme with a history of safe use.</p>	Identify appropriate legal instruments and principle-based regulation options; consult as needed to inform	▶				

Recommendation from the Third Review of the National Gene Technology Scheme	Actions	Commencement Timeframe (indicative)				
		18–19	19–20	20–21	21–22	22–23
14 The Review recommends reaffirming and clarifying governance arrangements to increase the agility of the Scheme, including more effective use of mechanisms for: <b>a)</b> the Gene Technology Standing Committee to consider and recommend changes to the legislation for Forum endorsement; and <b>b)</b> delegating certain activities and work programs of the Legislative and Governance Forum on Gene Technology to the Gene Technology Standing Committee.	Forum agree on activities to be progressed by Standing Committee	●				
17 The Review recommends that states and territories continue to ensure that their gene technology Acts remain corresponding and that appropriate mechanisms are in place to update corresponding state and territory legislation following amendment of the <i>Gene Technology Act 2000</i> (Cth).	Forum considers status of corresponding legislation and impacts for national consistency of the GT Scheme.	■	■			
	Ongoing Forum consideration of corresponding legislation status as changes are made to the Commonwealth legislation.			■	■	■
18 The Review recommends that states and territories give ongoing consideration to the economic effects, value and scope of moratoria.	Forum considers status of moratoria legislation and identifies any impact on national consistency of the GT Scheme	■	■			
	Forum considers options, including policies and other arrangements, for addressing any ongoing national impacts from moratoria.					
21 The Review recommends clarifying the intersection between the Gene Technology Regulator, other regulators and legislation, which may include: <b>a)</b> identifying opportunities to enhance communication mechanisms and linkages; <b>b)</b> identifying any emerging areas where legislative or administrative changes can be made, to reduce any unnecessary duplication; and <b>c)</b> adopting relevant effective mechanisms from other schemes (for example, the <i>Therapeutic Goods Act 1989</i> Special Access Scheme) where they may strengthen the Scheme.	In consultation with all relevant gene technology regulators, determine; • Regulatory intersection enhancements • Feasibility of e-business solutions (e.g. regulator shared web portal) • Feasibility of adopting effective mechanisms from other Schemes.		●			
	Develop action plan for GT Forum consideration		■	■		
	Implement outcome, including any legislative amendment (if required)			■	■	■
22 The Review recommends that further consideration be given to the most appropriate funding mechanisms to support the ongoing operation of the Scheme, and to appropriate funding levels for the Gene Technology Regulator's activities, taking into account any changes to the Scheme.	Determine and consult on funding options to ensure effective ongoing operation of the Scheme (taking into account changes to regulatory activity arising from review reforms)					●
	Report to GT Forum		●			
	Implement agreed outcome, including any legislative amendment (if required)			■	■	■
23 The Review recommends that targeted communications be developed to aid public understanding and confidence in the Gene Technology Scheme and identify the most appropriate body/bodies to deliver communications materials.	Develop targeted communication strategy and action plan (including materials, platforms, and trusted agencies)	■	■			
	Identify most appropriate body to deliver communication materials and monitor delivery		■	■	■	■
	Report to Forum on administrative and legislative amendments to adopt improvements		●			
	Implement agreed outcomes, including any administrative and legislative amendment (if required)			■	■	■
26 The Review recommends a science-based review of monitoring arrangements to ensure that any post release risks continue to be appropriately managed.	Review the adequacy of the Scheme's monitoring and enforcement activities		●			

## Ongoing oversight by the Forum and GTSC

### Recommendation from the Third Review of the National Gene Technology Scheme

	Recommendation	Actions
2	The Review recommends that the object of the <i>Gene Technology Act 2000</i> be maintained.	
3	The Review recommends that the Gene Technology Agreement be maintained.	
5	The Review Recommends that: <b>a)</b> extensions and advancements of gene technology, such as synthetic biology, continue to remain within the scope of the Scheme; and <b>b)</b> a watching brief on synthetic biology should be maintained, to ensure the appropriate level of regulation is applied to further applications of synthetic biology.	Regular updates to the Forum on outcomes of watching brief on synthetic biology
8	The Review recommends that a process-based trigger be maintained as the entry point for the Scheme at the present, to allow for any potential risks associated with new technologies to be initially considered within the scope of the Scheme.	
15	The Review recommends that the Australian Government, including the Gene Technology Regulator on regulatory matters, continues to: <b>a)</b> engage with appropriate international fora on matters relevant to market access and international trade; and <b>b)</b> ensure that any relevant international obligations continue to be met.	The Regulator to update the Forum, as required, on any changes to relevant international obligations, and how they are met.
16	The Review recommends maintaining current governance mechanisms to ensure that the Scheme's current levels of credibility, integrity and legitimacy are upheld. This includes maintaining: <b>a)</b> high level governance oversight provided by all states and territories through a Legislative and Governance Forum on Gene Technology; <b>b)</b> the independence and credibility of the Gene Technology Regulator; and <b>c)</b> robust governance processes providing oversight of advisory structures and appointments.	
19	The Review recommends that consideration of benefits (e.g. potential economic, environmental and health benefits) should not be introduced as an element of regulatory decision making at this time.	
20	The Review recommends that the Scheme ensure regulation remains commensurate with the level of risk posed by a dealing (see Recommendations 9 and 10) so that no unnecessary regulatory burdens are imposed.	Identify opportunities to ensure regulation remains commensurate with the level of risk posed by a dealing; consult as necessary  Forum considers outcomes  Implement outcome, including any legislative amendment (if required)
24	The Review recommends that the Gene Technology Regulator continue to lead communication activities on topics related to the assessment of risk associated with gene technology.	
25	The Review recommends that the Gene Technology Regulator continue to identify and manage the risks posed by, or as a result of, gene technology, and to increase transparency and understanding.	
27	The Review recommends that the Gene Technology Regulator continue to make relevant information publicly available, to maintain a high level of transparency within the Scheme.	

### Outstanding Recommendations from 2011 Review of the Gene Technology Scheme

Recommendations from 2011 Review	Explanation	Addressed by current Review
<b>Rec 7:</b> The Ministerial Council review the definition of 'dealings' in the Act with a view to clarifying the scope of the regulatory scheme.	Current definition of GMO dealing is not adequate to cover all the matters addressed by the Act. There are regulatory gaps which could be addressed by reviewing definition of a 'dealing'.	Recommendations 4 and 6
<b>Rec 8:</b> The Ministerial Council review the conditioning of GM products in the Act with a view to clarifying the scope of the regulatory scheme.	Currently there is no express legislative limit on the scope of conditions that can be placed on a GM product. The 2011 Review considered that the Regulator should have the power to put conditions on the use of a GM product where appropriate to meet objectives of the Act.	Recommendations 7, 21 and 26
<b>Rec 9:</b> The Department of Health and Ageing explore with the Attorney General's Department and the Ministerial Council ways in which the process for amending the gene technology legislation could be streamlined.	The Review was concerned that new technologies and existing technologies considered to have a history of safe use, are classified and dealt with in the same way. More flexibility is needed to allow the Regulator the ability to address these technologies in a more timely manner.	Recommendations 9 and 21