



Meeting Note: Joint ministers meeting on gene technology regulator – 11 June 2024

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Actions sought from ministers	
Name and position	Action sought
To Hon Penny SIMMONDS Minister for the Environment	None

Appendices and attachments
1. Talking points for the joint ministers meeting on gene technology regulator – 11 June 2024

Key contacts at Ministry for the Environment			
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Meeting note: Joint ministers meeting on gene technology regulator – 11 June 2024

Purpose

1. Minister Collins is chairing a virtual joint ministers' meeting on the proposed gene technology regulator on 11 June 2024. This document provides you with notes and talking points to support you if you are able to attend. Glenn Wigley, General Manager Waste and HSNO Policy will be attending the meeting to support you and represent the Ministry for the Environment (MfE).

Background

2. This will be the third meeting of the Gene Technology Ministerial Group. The group last met on 8 May 2024 where you discussed the contents of a briefing (ref # 2324-3096) from Minister Collins KC, which discussed some of the key issues that Cabinet will have to decide on before drafting new gene technology legislation. At this meeting, it was agreed that:
 - i. the new regulatory regime should adopt a risk-tiering approach, which incorporates three distinct risk pathways: for containment in a laboratory or industrial process, for release into the environment, and for medical use
 - ii. the gene-editing techniques to be exempted should include template-guided mechanisms mimicking natural gene repair, and officials should continue exploring the potential to go further for some host organisms
 - iii. if approvals are required across multiple regulatory systems, these should be streamlined where possible
 - iv. international alignment is a further important objective for the way New Zealand regulates gene technology and genetically modified organisms (GMOs).
3. MBIE have produced another briefing (ref # 2324-3529) outlining further aspects of the proposed Gene Technology Regime. MfE officials have been sent a copy of this briefing. Key aspects of this briefing are outlined below.

Narrower basis for decision-making

4. The Ministry for Business, Innovation and Employment (MBIE) propose excluding the assessment of potential benefits as well as economic and ethical consideration from the new gene technology regulator's decision-making process.
5. For comparison, under the Hazardous Substances and New Organisms (HSNO) Act 1996 decision-makers must take a range of matters into account, including weighing economic costs and benefits, when considering approving new organisms. As a result, the HSNO Act is considered strict. The purpose of Australia's Gene Technology Act 2000 is focused on identifying and managing risks.
6. Alongside this, MBIE recommends that:

- i. The new Act should not include a specific reference to the precautionary approach
- ii. Ethical consideration should not be included as they are already considered under existing regimes (such as the Animal Welfare Act 1999).

The regulator should be an independent decision-maker with access to relevant advice and input

7. MBIE states that the new gene technology regulator will need to make evidence-based, technical decisions to achieve the purpose of managing risk to the environment and the health and safety of people.
8. Relating to this, MBIE officials propose:
 - i. a single statutory decision-maker rather than a committee (due to the success of the Australian model)
 - ii. Public consultation requirements are integrated into the risk tiering model (so that not all approval types require consultation)
 - iii. The Minister should not possess a call-in power (This is because there is no requirement to weigh the risks with the benefits, which may be a decision more appropriately made in the public interest by a Minister)

There are two main options for the organisational form of the regulator

9. MBIE and the Public Services Commission (PSC) have identified two options for forming the new gene technology regulator:
 - i. establishing the regulatory function within a public service department. MBIE is a good fit given the alignment with the innovation and economic development objectives outlined in the manifesto document *Harnessing Biotech*
 - ii. altering the role of the Environmental Protection Authority (EPA) so that it becomes the regulator under the new Gene Technology Act. MBIE has been unable to identify another suitable Crown entity to take on this role. This would require structural change in the organisation to implement new functions in line with the new Act.
10. Both of these options assume that the Ministry for Primary Industries (MPI) would continue to be the enforcement agency for the gene technology regulatory regime. Many compliance functions will overlap with MPI's responsibilities under the HSNO and Biosecurity Acts.

Advice on proposals

11. MfE officials are broadly supportive of the proposals outlined by MBIE. However, we note the proposal to not include an ethics component. This would be inconsistent with the Australian approach which includes ethical issues in its decision-making processes and even has a specialist gene technology ethics committee. We are not convinced it would be necessary to go to that length but consider the decision-making process for GMOs needs to go beyond purely scientific and technical assessments, to ensure it aligns with societal values and ethical standards. In future, there could be some genetic development proposals that are not adequately covered by the proposed or existing arrangements. We believe that providing ethics provisions would pre-empt these issues and allow for a more robust regulator.

Future briefings

12. MBIE officials plan to provide Minister Collins KC a further briefing in mid-June which will include advice on:
 - i. options to ensure the new regime protects Māori rights and interests
 - ii. whether the regulator should take into account market access issues when making decisions
 - iii. whether territorial authorities should retain the ability to set restrictions on the planting of genetically modified crops under regional policy statements and plans, as they are currently able to do under the Resource Management Act (RMA) 1991
 - iv. proposed offences and penalties.

Non-GM new organisms

13. The proposed gene technology regime will replace some of the new organism aspects from the HSNO Act. MfE is currently progressing work to determine what components of the new organism regime will remain after the gene technology aspects are removed. These changes will not involve the hazardous substances aspects of the HSNO Act.
14. MfE officials provided you with a briefing (BRF-4747) on this on 31 May 2024 which described the aspects of the new organism regulatory regime that will remain after the proposed Gene Technology Bill removes the regulation of genetically modified organisms from the HSNO Act. These include, but are not limited to:
 - i. Importing into containment weed plant species from Pacific countries to allow New Zealand scientists to develop weed control strategies for Pacific countries.
 - ii. Importing into containment animals for zoos and aquariums.
 - iii. Importing for release animal and human vaccines, such as the Mpox vaccine or the infectious bronchitis vaccine for poultry.
 - iv. Importing for field trials various new foraging crops, such as the forage plant kochia.
 - v. Keeping certain new organisms outside New Zealand, such as invasive weeds, snakes, and cane toads.
 - vi. Importing for the release of biocontrol agents to mitigate pest populations, such as beetles to control the weeds heather and broom, and the hoverfly to control the German and common wasps.
 - vii. Importing for the release of biocontrol agents as a biosecurity tool in case of a pest incursion, such as a parasitic wasp for the control of the brown marmorated stink bug.
15. MfE officials are working with MBIE officials to determine how the remaining new organism regime will interact with the new gene technology regime. It will be important to understand how the various regulators interact with each other and what issues, if any, they may have overlapping responsibilities for.

Appendix 1: Talking points for joint ministers meeting on gene technology regulator – 11 June 2024

- MfE officials are broadly supportive of the approach proposed by MBIE regarding the legislation to support the gene technology regulator.
- Establishing the gene technology regime will require amendments to the *New Organisms* part of the HSNO Act as genetically modified organisms are considered new organisms. MfE officials are working on the remaining new organism regime and how it will interact with the gene technology regime. However, this will not require changes to the hazardous substances parts of the Act as this operates separately.
- MfE officials will find it challenging to progress changes to the new organisms part of the HSNO Act at the same pace as the Gene Technology Bill due to resourcing and key staff having been seconded to MBIE.
- Officials from the Ministry for the Environment are developing options for streamlining approvals of hazardous substances under the HSNO Act, but these changes will happen at a different timeline to the work to establish the gene technology regulatory.