



## BRIEFING

### Regulation of Biotechnology: Legislation bid

<b>Date:</b>	12 February 2024	<b>Priority:</b>	Medium
<b>Security classification:</b>	In Confidence	<b>Tracking number:</b>	2324-2057

Action sought		
	Action sought	Deadline
Hon Judith Collins Minister of Science, Innovation and Technology	<b>Agree</b> that the bill is called the Gene Technology Bill  <b>Agree</b> that the legislation bid does not include an exposure draft  <b>Agree</b> to submit the legislation bid for the 2024 Legislation Programme.  <b>Sign and send</b> the cover letter along with the legislation bid to the legislation coordinator by 19 February.	19 February 2024

Contact for telephone discussion (if required)				
Name	Position	Telephone		1st contact
Simon Rae	Policy Director, Emerging Technologies		s 9(2)(a)	✓
Zachary Clarke	Senior Policy Advisor		s 9(2)(a)	

The following departments/agencies have been consulted
Parliamentary Counsel Office

**Minister's office to complete:**

- |   |  |
|---|--|
| <input type="checkbox"/> Approved             | <input type="checkbox"/> Declined            |
| <input type="checkbox"/> Noted                | <input type="checkbox"/> Needs change        |
| <input type="checkbox"/> Seen                 | <input type="checkbox"/> Overtaken by Events |
| <input type="checkbox"/> See Minister's Notes | <input type="checkbox"/> Withdrawn           |

**Comments**



# BRIEFING

## Regulation of Biotechnology: Legislation bid

Date:	12 February 2024	Priority:	Medium
Security classification:	In Confidence	Tracking number:	2324-2057

### Purpose

To seek your approval of the attached gene technology legislation bid and your agreement for MBIE to lodge it on your behalf.

### Recommended action

The Ministry of Business, Innovation and Employment (MBIE) recommends that you:

- a **Agree** that the draft bill is called the Gene Technology Bill  
*Agree / Disagree*
- b **Agree** that the gene technology legislation bid does not include an exposure draft  
*Agree / Disagree*
- c **Agree** to submit the legislation bid for the 2024 Legislation Programme.  
*Agree / Disagree*
- d **Sign and send** the attached cover letter along with the legislation bid to the legislation coordinator by 12 noon 19 February.  
*Agree / Disagree*

Simon Rae  
**Policy Director, Emerging Technologies**  
Labour, Science and Enterprise, MBIE

12 / 02 / 2024

Hon Judith Collins  
**Minister of Science, Innovation and Technology**

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## Background

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1. You are required to submit a legislation bid to Cabinet as the biotechnology reforms will involve legislative change to establish a new act and regulator.
2. Legislation bids are brief summaries of the issues, processes and timeframes involved in the proposed legislation. They will be considered by the Cabinet Legislation Committee (LEG), who will make an initial determination of their respective priority in the government's legislative programme for 2024.
3. We have developed a biotechnology bid for your approval, using the content proposed in our recent process briefing (2324-1836). The bid is attached as Annex Two.
4. Your office must deliver the bid to the Legislation Coordinator, Sam Moffett ([sam.moffett@dpmc.govt.nz](mailto:sam.moffett@dpmc.govt.nz)), in the Cabinet Office by 12 noon next Monday (19 February), along with a cover letter signed by you. A draft cover letter is attached as Annex One.
5. The Parliamentary Counsel Office (PCO) has reviewed the bid. It noted that the proposed timeframes are tight and will only be feasible if consultation does not result in significant changes. However, it was satisfied that the bid was plausible and did not require a warning comment to be included.

### We propose calling the bill the Gene Technology Bill

6. Legislation bids must include the proposed name of the bill. We propose calling the bill the Gene Technology Bill, within the wider biotechnology reforms.
7. This is because:
  - we understand the proposed legislative changes are to be focused on gene technologies, while broader biotechnologies do not require regulation
  - the name would reduce confusion with other legislation or agencies that consider biotechnology, such as Medsafe.

### Exposure drafts are best practice, but would delay commencement to March 2026

8. To make the December 2025 deadline for passage of legislation, we have not included an exposure draft in the bid. Exposure drafts are full or partial versions of the legislation that are prepared by PCO for non-government reviewers prior to introduction to the house, such as by independent panels or public consultation.
9. PCO advises that an exposure draft would require at least two additional months in our timeline (moving commencement to probably March 2026). We could only save time elsewhere in the bid if we reduced the public consultation or select committee stages. We do not recommend this given the high public interest in the reforms.
10. Without an exposure draft, MBIE's technical advisory group (TAG) would not be able to review the legislation before it would be introduced. However, while these drafts are considered best practice to ensure bills meet their intended outcomes, the TAG would still be able to input into technical matters such as scientific definitions.

### Next Steps

11. Attached is a draft legislation bid letter, which your office needs to be send along with the legislative bid to the Legislation Coordinator by 12 noon on Monday 19 February. We can work with your office to finalise the draft letter, if you have any comments on this.

## **Annex**

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Annex One: Draft letter to the Legislation Coordinator

Annex Two: Proposed legislation bid

**Annex One: Draft letter to the Legislation Coordinator**

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Sam Moffett  
Legislation Coordinator  
Cabinet Office

By email: [sam.moffett@dpmc.govt.nz](mailto:sam.moffett@dpmc.govt.nz)

Dear Sam

**2024 Legislation Programme: Submission of Bids for the Science, Innovation and Technology Portfolio**

Attached is the sole bid that I am submitting for inclusion in the 2024 Legislation Programme for the Science, Innovation and Technology portfolio. The details for the bid are as follows:

Rank	Bill	Category
1	Gene Technology Bill	6 – Drafting instructions to be issued by the end of 2024

Yours sincerely

Hon Judith Collins  
**Minister of Science, Innovation and Technology**



## Gene Technology Bill: Request for priority in the 2024 Legislation Programme

### Summary information

- 1 The proposed bid has the following details:
  - 1.1 the portfolio of the sponsoring Minister is Science, Innovation and Technology
  - 1.2 the department responsible is the Ministry of Business, Innovation and Employment. The departmental contact is Simon Rae, Policy Director Science, Innovation and International; s 9(2)(a)
  - 1.3 the title of the proposed Bill is the Gene Technology Bill.
  - 1.4 the proposed ranking of the Bill is 1 of 1 bid for the Science, Innovation and Technology portfolio.
  - 1.5 the size of the Bill is estimated to be large and the complexity is high.
  - 1.6 the proposed priority category is Category 6: drafting instructions to be issued by the end of 2024; and
  - 1.7 this priority is necessary to achieve the Government's commitments (outlined in the National Party's 2023 *Harnessing Biotech* manifesto document, and referred to in coalition agreements) to reform gene technology legislation in this term of government.

### Policy

- 2 The Government, in its coalition agreements, is committed to enabling the greater use of gene technologies that would provide benefits to New Zealand.
- 3 The current use of genetically modified organisms (GMOs) is regulated in New Zealand primarily through the Hazardous Substances and New Organisms Act 1996 (HSNO Act). The HSNO Act has a broad scope, encompassing both hazardous substances and new organisms (which includes GMOs), and the provisions relating to GMOs are widely considered to be out of date and unaligned with current scientific understanding of the risks presented by GMOs.
- 4 The most effective approach to reforming legislation related to gene technologies and GMOs would be to establish a dedicated Gene Technology Act and associated gene technology regulator.
- 5 The new legislation would be:
  - 5.1 **Risk-based**, with a focus on regulatory settings that are risk proportionate, recognising that overly stringent requirements can just as easily result in negative outcomes as those that are overly permissive.

- 5.2 **Future proof**, so that it will remain fit-for-purpose and New Zealand can capture potential benefits from advances in technology, increases in scientific understanding, and changing approaches in other jurisdictions.
- 5.3 **Enabling**, to facilitate beneficial innovation through regulations that are clear and understandable, and processes and decisions that are consistent, transparent, and cost-effective.

6 There is likely to be high public interest in the Bill given both the strong support for and opposition to the use of GMOs and gene technologies in New Zealand.

### **Need for legislation**

- 7 Legislative action is required as gene technologies are currently governed by existing legislation (such as the HSNO Act) that are no longer fit for purpose.
- 8 The proposed priority is Category 6: drafting instructions to be issued by the end of 2024. This timeframe is necessary to achieve the Government's commitment to establish new dedicated legislation and for a new regulator to begin processing applications before the end of the electoral term.
- 9 This would be a new piece of legislation.
- 10 Amendments will also be required to existing legislation, namely the HSNO Act and the Biosecurity Act 1993, to ensure consistency and reduce any duplication with existing processes carried out by agencies such as the Environmental Protection Authority.

### **Compliance**

- 11 The Bill is expected to comply with each of the following:
  - 11.1 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993;
  - 11.2 the principles and guidelines set out in the Privacy Act 2020
  - 11.3 the principles of the Treaty of Waitangi;
  - 11.4 the relevant international standards and obligations; and
  - 11.5 the [Legislation Guidelines \(2021 edition\)](#)

### **Binding on the Crown**

- 12 The provisions in the Bill will bind the Crown.

### **Consultation**

- 13 Consultation will be conducted with the following departments throughout 2024:
  - 13.1 Ministry for the Environment, Ministry for Primary Industries, Ministry of Health, the Treasury,



- 14 A public discussion document on the Bill will be developed and is planned for consultation for two months from June 2024.
- 15 Targeted consultation with key stakeholders and independent experts will be conducted throughout 2024.
- 16 Officials will consult with the Legislation Design and Advisory Committee on the establishment of the new regulator and whether the draft Bill, once developed, should be referred to the Committee for advice.
- 17 An exposure draft of the Bill is not planned.
- 18 Although not yet confirmed, a Ministerial group is expected to be established to oversee work on the Bill and coordinate consultation with coalition parties. This group is likely to include the Minister of Science, Innovation and Technology, the Minister of Agriculture, the Minister for Biosecurity, the Minister for Māori Development, the Minister of Health, and the Minister for the Environment.

Secondary legislation

- 19 Secondary legislation is likely to be required for the proposed Gene Technology Act and will be determined through policy development in the first half of 2024.

20 s 9(2)(f)(iv)

Timeline

- 21 The Bill should come into force in late 2025 to enable the gene technology regulator to be established and processing applications by the end of the electoral term.

Step	Proposed date	Consistency assurance
Date on which final policy approvals were, or will be, obtained from Cabinet	October 2024	This provides for consultation throughout 2024 (see earlier) and subsequent policy development.
Date on which complete drafting instructions were or will be sent to PCO	December 2024	

Date by which the Bill will go to the Ministry of Justice (or Crown Law if applicable) for an assessment of consistency with the New Zealand Bill of Rights Act 1990	April 2025	This date will be at least two weeks prior to the paper being considered by LEG.
Dates on which the Bill will be before LEG and Cabinet for approval for introduction	April - May 2025	
s 9(2)(f)(iv)		
Date requested for introduction of the Bill	May 2025	
Date of report back from select committee	November 2025	This date will be after a six month select committee process.
Date by which final drafting instructions for any associated secondary legislation will be sent to PCO	TBC	To be confirmed, pending policy development to determine required secondary legislation.
Date of enactment	December 2025	Day after Royal Assent
Date of commencement	December 2025	Day after Royal Assent

## Recommendations

- 22 The Minister of Science, Innovation and Technology recommends that the Committee:
- 22.1 note that the Gene Technology Bill will enable New Zealand to access the benefits of gene technologies responsibly and safely.
  - 22.2 note that the Gene Technology Bill is the only bid from my Science, Innovation and Technology portfolio;
  - 22.3 approve the inclusion of the Gene Technology Bill in the 2024 Legislation Programme, with a priority 6: drafting instructions to be issued by the end of 2024;
  - 22.4 note that drafting instructions will be provided to the Parliamentary Counsel Office by December 2024;
  - 22.5 note that the Bill should be introduced no later than May 2025;
  - 22.6 note that the Bill should be passed no later than December 2025.

Authorised for lodgement

Hon Judith Collins  
Minister of Science,  
Innovation and  
Technology



## EVENT BRIEFING

### Meeting with the Life Sciences Network

Date:	21 June 2024	Priority:	Medium
Security classification:	In Confidence	Tracking number:	2324-2230

Action sought		
	Action sought	Deadline
Hon Judith Collins KC MP <b>Minister of Science, Innovation and Technology</b>	<b>Note</b> the contents of this briefing to support your meeting with the Life Sciences Network on Tuesday 23 June.	

Contact for telephone discussion (if required)			
Name	Position	Telephone	1 <sup>st</sup> contact
Simon Rae	Policy Director – Emerging Technologies		✓
Caitlin Elborough	Policy Advisor, Innovation Policy		

The following departments/agencies have been consulted

Minister's office to complete:

☐ Approved

☐ Declined

☐ Noted

☐ Needs change

☐ Seen

☐ Overtaken by Events

☐ See Minister's Notes

☐ Withdrawn

Comments



## EVENT BRIEFING

### Meeting with the Life Sciences Network

Date:	21 June 2024	Priority:	Medium
Security classification:	In Confidence	Tracking number:	2324-2230

### Purpose

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To provide you with background information and talking points to support your meeting with the Life Sciences Network chair Dr William Rolleston, at 3:30 – 4:30pm on Tuesday 23 June.

### Recommendations

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The Ministry of Business, Innovation and Employment recommends that you:

- a **Note** the contents of this briefing to support your meeting with the Life Sciences Network on Tuesday 23 June.

*Noted*

Simon Rae  
Policy Director, Emerging Technologies  
LSE, MBIE

24 / 06 / 2024

Hon Judith Collins KC MP  
Minister of Science, Innovation and  
Technology

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## Background

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1. You are meeting with the Life Sciences Network from 3:30 to 4:30pm on Tuesday 23 June.
2. Attendees will include the Life Sciences Network chair, Dr William Rolleston, and executive director, Nathan Mills. Biographies for attendees are attached at **Annex One**.
3. Simon Rae, Policy Director, Ministry of Business, Innovation and Employment (MBIE) will attend the meeting to support you.
4. This meeting provides an opportunity to engage with industry on the ongoing legislative reform programme addressing regulation of genetic technologies.
5. The Life Sciences Network is an organisation which represents the interests of science and industry in public debates on science issues, in particular the regulation of genetic modification.
6. It is chaired by Dr William Rolleston, who has previously advised local and central government on science strategy and is also a member of the Gene Technology Technical Advisory Group.
7. The Life Sciences Network have indicated they would like to discuss the Network's function and their current projects which are relevant to the development of new legislation for genetic technologies. They are also interested in providing further information and support for the policy development ahead of establishing the Gene Technology Regulator.


### **The Network's objectives for the regulatory reform are consistent with your own**

8. The Life Sciences Network wrote to you in December last year and outlined their support for the Government's regulatory reform and are in favour of a comprehensive review and replacement of current legislation to ensure we have a system which is world leading and meets international best practice.
9. They have provided a further note ahead of this meeting reporting their view that a new regulatory regime should be:
  - Proportionate to the risk
  - Evidence-based rather than responding to conjecture
  - Efficient
  - Internationally aligned and compatible
  - Enabling
  - Flexible and able to respond to scientific advances
  - Designed to:
    - manage risk, rather than eliminate hazard or trade-off benefits; and
    - appropriately respond to the Treaty of Waitangi
10. These objectives are consistent with Ministers agreed objectives for the regime. We believe the approach Ministers have decided on to date also conforms with these goals. As a member of our Technical Advisory Group on Gene Technology, Dr Rolleston is aware of the proposals Ministers have considered so far.

11. The note also includes a suggestion that Ministers might consider a regime similar to the Canadian system, which is technology neutral, focusing on plants with novel traits. While we agree that the Canadian approach is a conceptually robust model that has strong support in some sectors, we are not convinced that the Canadian system provides a better model because:
- It only applies to plants. Canada has no effective regulation of genetically modified micro-organisms or animals, and therefore no experience in whether the regulatory model can be robustly applied to these organisms
  - It requires the regulator to make a judgement about what constitutes a novel trait, which presents challenges in deciding the scope of the regulation.

**The Network is planning further work which will usefully contribute to public debate**

s 9(2)(b)(ii)



13. We consider there will be significant value in science-based information being produced by third parties when the reforms are announced and ahead of select committee consideration of the legislation, as this should support broader public acceptance of the regulation. We have considered liability, and other countries regulations already, but we welcome further work on these topics.
14. The work on co-existence has the potential to be particularly valuable. Our expectation is that this will be addressed in part by risk management plans that will form part of the regulatory approval, but, based in part on what we have heard from Australian industry, that the main mechanism for achieving co-existence will come through strengthened assurance processes. In Australia industry has played a key role in developing its own assurance mechanisms, and key Australian contacts have offered their experience in this regard. We would be happy to connect these contacts with the Life Sciences Network if they are not already.

**The Network are likely to have relevant views on wider industry development**

While the Life Sciences Network and wider industry is supportive of the proposed regulatory reforms, a number of our stakeholders have indicated there is a capability issue in the sector that may lead to a lag between the regulator being established and products utilising genetic technologies being market ready. Through his biotechnology company South Pacific Sera, Dr Rolleston is also an active participant in health biotechnology in New Zealand (and a key participant in the government's RNA Platform). The Life Sciences Network are likely to have useful observations about other steps the government might take to support the biotechnology industry more broadly.

## **Risks and mitigations**

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15. We regard this meeting to be low to medium risk, as the views presented by the Life Sciences Network broadly align with the current proposals for gene technology reform. Dr Rolleston has been an active participant in the Technical Advisory Group, and our proposals have generally agreed with most of the points he has made in that context.

## **Communications / Media**

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16. There are no media or communications planned for this meeting.

## **Annexes**



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Annex One: Biographies of attendees

Annex Two: Suggested talking points



## Annex One: Biographies of attendees

	<p><b>Dr William Rolleston</b></p> <p>Dr William Rolleston is the chair of the Life Sciences Network. He is also chair of Biotech NZ and Genomics Aotearoa.</p> <p>He co-founded the biotech and vaccine manufacturing company South Pacific Sera Ltd, and has previously been president of both New Zealand Federated Farmers and the World Farmers Organisation.</p> <p>He has advised local and central government on science strategy, economic development and biosecurity through the Science and Innovation Boards, Aoraki Development Trust and as external advisor to the Governor of the Reserve Bank.</p> <p>Dr Rolleston is a member of the Gene Technology Technical Advisory Group.</p>
	<p><b>Nathan Mills</b></p> <p>Nathan Mills is the Executive Director of the Life Sciences Network.</p> <p>He is also the chair of the Board of Trustees for The Community Trust of Mid and South Canterbury.</p> <p>Previously he worked in the private equity and banking sectors, as co-founder and business development manager for Genesis Capital and as a commercial partner for BNZ.</p> <p>Prior to that he had a career with Radio New Zealand as a Broadcast News Reporter</p>

## Annex Two: Suggested talking points

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- I share the Life Sciences Network's objectives for reform of the gene technology regulatory regime. William, as a member of the Technical Advisory Group, do you have any observations about what you have seen so far of the proposals? Do you think we are on the right track?
- I am pleased to see the Life Sciences Network looking to contribute to public debate on reform of gene technology regulation. While we campaigned on reform of the legislation, and I am confident we have a mandate to undertake it, the credibility and longevity of the new regime will benefit from a good public understanding of the technology as it is used today, and its potential benefits.
- We know co-existence is a concern for parts of the agricultural sector. Where do you see solutions lying? Do you have a sense of the best balance between industry self-regulation, and conditions placed on licenses by the regulator?
- I am keen to hear your thoughts on the opportunities for the biotech sector arising from a reform of genetic technology regulation, including any New Zealand specific opportunities. What other challenges does the industry face?