MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

COVERSHEET

Minister	Hon Judith Collins KC	**Portfolio**	Science, Innovation and Technology
Title of Cabinet paper	Regulation of gene technology - policy decisions	**Date to be published**	10 December 2024

List of documents that have been proactively released

Date	Title	Author
August 2024	Regulation of gene technologies – policy decisions	Office of the Minister of Science, Innovation and Technology
12 August 2024	Regulation of gene technologies – policy decisions CAB-24-SUB-0296 Minute	Cabinet Office
24 July 2024	2425-0421 Regulation of gene technology – regulatory impact statement	MBIE
7 December 2023	2324-1263 Regulation of Biotechnology: Initial Advice	MBIE
8 February 2023	2324-1836 Regulation of Biotechnology: Process	MBIE
13 March 2024	2324-2241 Regulation of biotechnology – joint ministers meeting	MBIE
1 May 2024	2324-3096 Regulation of gene technology – second joint ministers meeting	MBIE
5 June 2024	2324-3529 Regulation of gene technology – third ministers meeting	MBIE
19 June 2024	2324-3917 Regulation of Gene Technology – Fourth Ministers Meeting	MBIE
3 July 2024	2324-4026 Regulation of gene technology – draft Cabinet paper	MBIE
11 July 2024	2425-0261 Regulation of gene technology – draft Cabinet paper for Ministerial consultation	MBIE
16 July 2024	Ministerial call-in provisions, directions and appeals	MBIE

Information redacted **YES / NO** *(please select)*

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Some information has been withheld for the reasons of privacy of natural persons, national economy, national security, confidential advice to government, legal professional privilege and free and frank opinions.

CAB-24-MIN-0296

Cabinet

Minute of Decision

Regulation of Gene Technologies: Policy Decisions

Portfolio **Science, Innovation and Technology**

On 12 August 2024, Cabinet:

Background

1 **noted** that Coalition Agreements commit to enabling the greater use of gene technologies that would provide benefits to New Zealand, specifically:

1.1 ending the effective ban on genetic engineering and modification in New Zealand;

1.2 streamlining approvals for trials and the use of non-genetically engineered/ genetically modified biotech;

2 **noted** that the Gene Technology Ministerial Group, comprising a range of portfolios and parties, have developed the reform proposals outlined in the paper under CAB-24-SUB-0296;

Purpose and scope of the regime

3 **noted** that the proposed regime is based on Australia's Gene Technology Act 2000, with relevant updates and adaptations where required for the New Zealand context;

4 **agreed** that the scope of the legislation enacting the new regime will be focused on managing risks to health and safety of people and the environment;

5 **noted** that the risk management approach will allow for greater re-use of assessments and will increase predictability for applicants, and that the overall design of the regime allows for lower levels of regulatory oversight to be applied when experience demonstrates that types of organisms are safe over time;

6 **agreed** that the aim of the legislation be to enable the safe use of gene technologies, and that this should be reflected in the legislation's purpose;

7 **agreed** that the legislation will include all gene technologies within its broad scope, where gene technologies include any technique for the construction or modification of genes or other genetic material that is not used for traditional breeding or natural selection;

8 **agreed** that regulated organisms will be those that have been modified or constructed by gene technology, including human cells but excluding human beings;

9 **agreed** that the legislation will apply to specified activities in relation to an organism modified or constructed by gene technology unless the gene technology or organism is exempted;

Hybrid, risk-tiered regulatory approach, with clear exemptions

10 **noted** that key elements of the regime's design are set out below, and that a full design of the regime is described in Appendix One to the paper under CAB-24-SUB-0296;

11 **agreed** that the legislation take a hybrid approach to regulation of gene technologies, combining a process-based approach to higher risk activities while specifically exempting lower risk activities and techniques from regulation;

12 **agreed** that the legislation include provisions to enable secondary legislation to exempt technologies or organisms from regulation, where these either involve minimal risks, or if organisms cannot be distinguished from those achievable by conventional techniques;

13 **agreed** that from establishment, the regulator exclude from regulation all techniques and organisms that are explicitly and currently excluded from the definition of a genetically modified organism in either New Zealand or Australia;

14 **agreed** that organisms modified by gene editing techniques that produce specific minor changes, or were modified by template(s), and do not introduce new genetic material, would also be excluded from regulation;

15 **agreed** that the legislation provide a statutory determination power to enable the regulator to determine the status of an organism or technology;

A risk-proportionate authorisations framework

16 **agreed** that the regime take a risk-proportionate approach where conditions are applied based on the anticipated risks of the activities, with three primary categories through which activities can be regulated in a way most suitable to their use (contained activities, environmental release, and medical applications), and that:

16.1 each of these categories will have three tiers reflecting level of likely risk ('non-notifiable, 'notifiable', and 'licensed');

16.2 the 'licensed' risk tier for the environmental release and medical applications categories will then contain three types of licence process based again on risk (pre-assessed activity, expedited assessment, and full assessment);

16.3 the 'licensed' risk tier for the contained activities category to contain one type of licence process (expedited assessment);

17 **noted** that under the risk proportionate approach proposed for the non-notifiable and notifiable risk tiers, which will encompass very low risk and low risk activities, the regulator would have minimal operational oversight;

Decision making

18 **agreed** that decisions be made by an independent statutory decision-maker;

19 **agreed** that the independent statutory decision-maker be appointed by the Minister of Science, Innovation and Technology (the Minister);

20 **agreed** that Technical Advisory Committee and Māori Advisory Committee members be appointed by the Minister;

21 **agreed** that consistent with an enabling and risk proportionate approach, public consultation be:

21.1 required for licences that require a full assessment by the regulator (i.e. assigned to higher risk tier levels), with submissions invited on the draft Risk Assessment and Risk Management Plan regarding the suitability of the risk management controls;

21.2 at the regulator's discretion for Risk Assessment and Risk Management Plans for any expedited assessments;

22 **agreed** that, in making decisions consistent with the purpose of the legislation, the regulator focus only on managing risks to the health and safety of people and the environment, approving activities where it is satisfied the risks can be managed to a level that protects human health and safety of people and the environment;

23 **agreed** that the regulator must consider relevant impacts on Māori kaitiaki relationships with native species of significance in its decision making, where relevant to the purpose;

24 **agreed** that the regulator will be supported by a Māori Advisory Committee when considering adverse impacts on kaitiaki relationships, which will be modelled off the Plant Variety Rights Act 2022 but in an advisory role;

25 **agreed** that the legislation will not include a call-in power or an ability to appeal to the Minister;

26 **agreed** that the Minister be empowered to issue temporary emergency authorisations to respond to an actual or imminent threat to health and safety of people or the environment;

27 **agreed** to include a provision in the legislation for the responsible Minister to issue general policy directions to the regulator;

28 **agreed**, regarding reviews and appeals of decisions, that an applicant or licensee may request a review of the regulator's decision and will have the right of appeal;

29 **authorised** the Minister to take further decisions on the details of the review and appeals process;

Interaction with other legislation

30 **noted** that in certain instances, gene technologies will require approval under more than one regulatory system, and that it is not practicable to implement a single approval due to complexity and specialisation of expertise;

31 **agreed** that the regulator be given the power to:

31.1 undertake rapid assessments of regulated organisms that are also medicines or veterinary medicines, where these present lower risks to human health and safety and the environment;

31.2 undertake joint assessments or joint decision-making where there are overlaps in the risks addressed by the other regulator;

31.3 deem approvals of new organisms under the Hazardous Substances and New Organisms Act 1996 (HSNO) as approvals under the proposed Gene Technology Act, if the regulator is satisfied that the HSNO adequately addresses the risks to human health and safety and the environment;

32 **agreed** to amend the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM) to create the necessary powers to support joint assessments or joint decision-making;

33 **authorised** the Minister, in consultation with the Minister for Food Safety, to take further decisions on detailed ACVM changes to implement the decision in paragraph 32 above;

34 **agreed** to remove from the Resource Management Act 1991 the ability for regional councils and territorial and unitary authorities to restrict the use of genetically modified organisms (GMOs), to remove duplication and provide a nationally-consistent and predicable regulatory environment for gene technology;

35 **agreed** that the consequential changes to the HSNO include:

35.1 the removal of GMOs;

35.2 aligning definitions;

35.3 ways for the regulators to share information and work together;

35.4 application pathways in HSNO updated to allow for joint applications;

35.5 transitional provisions and other consequential amendments;

36 **authorised** the Minister, in consultation with the Minister for the Environment, to take further decisions on detailed HSNO changes;

37 **authorised** the Minister, in consultation with the relevant Ministers and in line with the above decisions, to take further decisions on changes required to the following Acts and associated secondary legislation:

37.1 Agricultural Compounds and Veterinary Medicines Act 1997;

37.2 Food Act 2014;

37.3 Biosecurity Act 1993;

37.4 Animal Products Act 1999;

37.5 Medicines Act 1981;

37.6 Human Assisted Reproductive Technologies Act 2004;

37.7 Human Tissue Act 2008;

37.8 Animal Welfare Act 1999;

37.9 Imports and Exports (Restrictions) Act 1988;

37.10 Conservation Act 1987;

37.11 Imports, and Exports (Living Modified Organisms) Prohibition Order 2005;

37.12 Resource Management Act 1991;

37.13 Reserves Act 1970;

37.14 National Parks Act 1980;

38 **noted** that in July 2024, the Cabinet Expenditure and Regulatory Review Committee agreed to a regulatory review into the approval path for agricultural and horticultural products [EXP-24-MIN-0033], and that this review will address approval pathways for non-genetically modified agricultural products;

Compliance monitoring and enforcement, and offences, defences, and penalties

39 **agreed** that the compliance, monitoring and enforcement, and offences, defences, and penalties regime (including pecuniary penalties and civil liability) from HSNO carry over where practicable, subject to modifications to reflect current legislative best practice;

40 **authorised** the Minister, in consultation with the Minister of Justice as relevant, to take further decisions in line with the above policy decisions on the details of compliance, monitoring, and enforcement provisions, and offences, defences, and penalties introduced by the regime;

41 **agreed** that the Ministry for Primary Industries be responsible for compliance, monitoring, and enforcement activities;

42 **agreed** that legislation provide for regulations to be made to require domestic commercial providers of synthetic nucleic acids and manufacturers of bench-top nucleic acid synthesiser equipment to comply with a customer screening framework and be approved by the regulator before they can operate in New Zealand;

Agreement to regime as outlined in Appendix One

43 **agreed** to the detailed design of the regime, described in Appendix One to the paper under CAB-24-SUB-0296;

Financial implications

44 **noted** that depending on regulator location, from establishment to the end of 2028/29:

44.1 the cost for the Ministry of Business, Innovation and Employment to set up and operate the regulator is estimated at Confidential advice to Government

44.2 the comparable cost for the Environmental Protection Authority (EPA) is Confidential advice to Government

44.3 the expected steady state cost from the third year of operation is approximately Confidential advice per annum, and that each option also includes approximately Confidential advice to over the same period for the Ministry for Primary Industries to undertake compliance, monitoring and enforcement of the new regime;

45 **noted** that it will not be practical or desirable to fully recover the costs of regulation from applicants and other regulated parties;

46 Confidential advice to Government

Location of the regulator

47 **agreed** that the regulator will be located within the EPA;

48 **agreed** that constraints will be added to the process for appointing the independent statutory officer that reinforce its independence from EPA decision-making processes;

Legislative implications

49 **agreed** that the above proposals will be given effect through the Gene Technology Bill (the Bill)Confidential advice to Government

50 **agreed** that the Bill will include a provision stating the Act will bind the Crown;

51 **agreed** that the Bill will include regulation-making powers, including the ability to make regulations to prescribe cost recovery, fees and charges;

52 **authorised** the Minister to further clarify and develop policy matters relating to the above proposals in a manner not inconsistent with Cabinet's decisions on the paper under CAB-24-SUB-0296;

53 **invited** the Minister to issue drafting instructions to the Parliamentary Counsel Office for the Gene Technology Bill and associated secondary legislation.

Rachel Hayward
Secretary of the Cabinet