In Confidence

Office of the Minister of Science, Innovation and Technology

Cabinet

Gene Technology Bill: Approval for Introduction

Proposal

1 This paper seeks approval for the introduction of the Gene Technology Bill (the Bill). It also seeks decisions on final policy settings to address matters identified during drafting. Introducing the Bill is item 24 on the Coalition Government's Q4 Action Plan.

Policy

2 On 12 August 2024, Cabinet agreed the policy proposals and to issue drafting instructions for the Bill [CAB-24-MIN-0296]. The purpose of the Bill is to enable the safe use of gene technologies and regulated organisms by managing their risks to the health and safety of people and the environment. It will do this by introducing a new regime primarily based on Australia's Gene Technology Act 2000, adapted for New Zealand's circumstances where required. Key features of the Bill are listed in Appendix One.

Further policy decisions are required

3 I seek approval of the following further policy decisions for the Bill that were identified during the drafting process.

Objective of the regulator

4 Cabinet agreed the purpose and scope of the new gene technology regime[1] and a range of related functions, powers and duties for the Gene Technology Regulator. I seek your agreement that the Bill also set out an objective for the regulator that is consistent with the purpose of the Act and the regulator's functions, powers and duties, proposed (subject to wording refinement through drafting) as:

4.1 To develop and maintain an independent, efficient and transparent system to regulate the use of gene technologies and regulated organisms to achieve the purpose of the Gene Technology Act (the Act).

Streamlining interactions with other regulators

5 The Bill allows for joint risk assessments with both domestic and overseas regulators, to reduce duplication. In practice, I expect the regulator will undertake joint assessments primarily with recognised overseas gene technology regulators, and with

[1] CAB-24-MIN-0296 at 3-9.

the Environmental Protection Authority (EPA) as the regulator of new organisms. It is with this regime that risks assessed under the Act are most likely to overlap.

6 Following further work on drafting instructions, officials advise that certain powers Cabinet agreed for the regulator as part of proposals to streamline interactions with other regulators will not, in practice, be effective. I therefore seek agreement to rescind two Cabinet decisions:

6.1 The decision that the regulator be given the power to deem approvals of new organisms under Hazardous Substances and New Organisms Act 1996 (HSNO) as approvals under the Act, if the regulator is satisfied that HSNO adequately addresses the risks to human health and safety and the environment.[2] There is no efficiency to be gained from such a power as the regulator would still need to effectively make its own decision, and it could blur lines of accountability for review and appeals.

6.2 The decision that the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) be amended to create the necessary powers to support joint assessments or joint decision-making.[3] The risks assessed under the ACVM Act and the Gene Technology Act are not similar enough to gain efficiencies from the two regulators collaborating on a risk assessment, or for the Gene Technology Regulator to be able to use a risk assessment completed under the ACVM Act to decide how to manage risks to human health and safety and the environment under the Act.

7 To support decision making where approval is sought from more than one regulator in parallel or sequentially, the Bill will empower relevant agencies to share information, reducing the burden on applicants and regulators.

Information sharing

8 Cabinet has already agreed the overall approach to information sharing.[4] To lower the burden on applicants, achieve administrative efficiencies, and support effective compliance, monitoring and enforcement, I now seek Cabinet's agreement that the Bill include provisions to give effect to the following information sharing proposals:

8.1 agencies may share relevant information (including personal, confidential or commercially sensitive information) collected under the Gene Technology Act with another relevant agency to support the performance of their functions or duties or exercise of powers under their Acts; and

8.2 agencies may share relevant information (including personal, confidential or commercially sensitive information) collected under relevant Acts with another relevant agency to support the performance of the Act.

9 The relevant Acts to be listed in the Gene Technology Act for the purpose of these information sharing proposals are set out at Appendix Two.

[2] CAB-24-MIN-0296 at 31.3.
[3] CAB-24-MIN-0296 at 32.
[4] CAB-24-MIN-0296 at 43 [refer to CAB-24-SUB-0296 Appendix One at 131, 143, 144 and 145].

10 I also seek Cabinet's agreement that the Gene Technology Regulator may disclose information (including personal, confidential or commercially sensitive information) to a recognised overseas gene technology regulator under an agreement between the two regulators. This will support the leveraging of international expertise, e.g., through joint assessments with overseas regulators. Before doing so, the Gene Technology Regulator would be required to first consult the Privacy Commissioner about the agreement between the two regulators, which would set out a range of parameters about the collection, use and disclosure of the information.

Protection of confidential information

11 It is important, as part of supporting the development and use of innovative medicines and other products, that the regulator protect confidential information about products, their potential applications, and supporting data. New Zealand also has binding international treaty obligations concerning the confidentiality of information related to certain medicines applications.[5]

12 I seek Cabinet's agreement that the Bill provide for confidential information to be protected by the regulator by:

12.1 Deeming that the Official Information Act 1982 (OIA) will not apply to information received by the regulator that is likely to relate to a licence application that has not yet been made until the application is received – this will carry over an existing HSNO provision; and

12.2 Applying specific confidentiality provisions from the Medicines Act and the ACVM Act to the regulator, where certain conditions are met.[6] In situations where these provisions apply, the regulator will still be required to make available summary information of the relevant risks regarding the activity, and will be able to disclose confidential information to persons prescribed by regulations. This will also carry over an existing HSNO provision and gives effect to New Zealand's international treaty obligations referred to above.

Offences, defences and penalties

13 Changes are required to the offences, defences, and penalties regime designed for the Act. I have made these decisions in line with Cabinet's delegated authority, and agreement that these elements carry over from HSNO where practicable, subject to modifications to reflect current legislative best practice.[7]

14 I have decided, in consultation with the Minister of Justice, that the Bill will create offences for undertaking activities with regulated organisms without authorisation, undertaking other activities in breach of the Act, breaching conditions attached to an authorisation, or breaches of other requirements of the Act (such as obstructing or providing false information to enforcement officers). The regime includes some strict liability offences and the defences associated with them. To illustrate the bounds of

[5] These are obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and other trade agreements, including the Comprehensive and Progressive Agreement for Trans-Pacific Partnership.
[6] These are Sections 23A-23C of the Medicines Act (with necessary modifications) and Part 6 of the ACVM Act (with necessary modifications).
[7] CAB-24-MIN-0296 at 39 and 40.

the regime, the minimum penalty (that is not an infringement) in the Bill is a fine not exceeding $5000 for an individual.

15 The maximum criminal penalty in the Bill is imprisonment for a term not exceeding five years or a fine not exceeding $200,000, or both, for a natural person, or otherwise a fine not exceeding $1 million.

16 The Bill also provides for pecuniary penalties when offending occurs during the course of business or to make a gain or avoid a loss. The maximum pecuniary penalties are $500,000 for an individual and, for a body corporate, the greater of $10,000,000 or three times the value of the commercial gain from the breach (or if that cannot be readily ascertained, 10 percent of turnover).

17 However, I seek Cabinet agreement to take a different approach in respect of civil liability than previously agreed by Cabinet, which was to carry over from HSNO its civil liability provisions.[8] HSNO takes a strict liability approach to civil liability, in which a person is liable for damages for any loss or damage caused while carrying out activities in breach of HSNO. The person is liable regardless of whether they intended to do the thing that resulted in the breach or took reasonable care.

18 To better reflect the enabling intention of the new regime, I propose that the Bill does not include provisions for civil liability, and instead plaintiffs rely on the common law (law of torts) which makes a person liable in nuisance for an unreasonable interference with another person's use or enjoyment of their land causing actual or imminent harm, and liable in negligence if the plaintiff proves, among other things, that the defendant has a duty of care and breached that duty by failing to take reasonable care which resulted in damage or loss that was reasonably foreseeable.

19 This may be contentious because this departs from HSNO's provisions and there may be perceptions of insufficient incentives on those undertaking activities with regulated organisms to avoid causing harm. I consider that criminal offences and the law of torts provides adequate incentives for parties undertaking activities with regulated organisms to act properly and to meet their statutory duties.

Compliance with international obligations

20 New Zealand has binding international obligations under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD) in respect of the transboundary movement of living modified organisms and management of risks to the conservation and sustainable use of biodiversity arising from GMOs. We also have legal obligations and commitments in some of our free trade agreements to effectively implement multilateral environmental agreements and associated protocols, and to protect intellectual property.

21 We currently implement our obligations regarding introduction of living modified organisms into the environment through HSNO. Provisions in this Bill will enable us to continue to meet our obligations.[9] Cabinet agreed that the Gene Technology Regulator's assessment of individual licence applications will not include assessment

[8] CAB-24-MIN-0296 at 39.
[9] The relevant provisions relate to the functions of the regulator, protection of confidential information, risk assessment requirements, and criteria for assigning activities to risk tiers.

of trade, international agreements and market access risks.[10] I do not recommend any change to this policy, but I seek agreement to include a specific overarching requirement for the regulator to have regard to New Zealand's international obligations under the CBD and the Cartagena Protocol in its decision-making. This duty will ensure the regulator must act in line with New Zealand's commitments and key trading partners' expectations. Operating arrangements to give effect to these obligations will be developed in due course.

Minor and technical issues

22 I also seek agreement to the following additional policies identified during the drafting process:

22.1 Enforcement agency: as agreed by Cabinet, the Ministry for Primary Industries (MPI) will be responsible for compliance, monitoring, and enforcement activities.[11] In addition, Cabinet agreed that the Bill would provide the regulator with a standard set of compliance, monitoring and enforcement powers.[12] However, MPI and the EPA consider that the regulator and enforcement agency having overlapping powers is duplicative and it is unnecessary for the regulator to have the powers given MPI will be the enforcement agency.

22.2 Developing, adopting and amending standards: the Gene Technology Regulator should have powers to develop, adopt, or amend standards for non-notifiable, notifiable, licensed activities and the different categories of activity: contained, environmental and medical, and any subcategories of activities (e.g., transport, treatment, fermentation, and disposal).

22.3 Transhipment of regulated organisms: this refers to the process of importing a regulated organism into New Zealand with the intent to export it within 20 working days. Providing for a specific transhipment licence type would enable the efficient transit of regulated organisms through New Zealand. This will carry over a similar HSNO provision.

22.4 Levies: Cabinet agreed to the regulator undertaking cost recovery to offset a proportion of its costs and to provide the ability to make regulations to prescribe fees. This regulation-making power should also include levies, as it is possible some of the regulator's activities for which fees cannot be charged may benefit certain groups and a decision to recover these costs may be made in future.

22.5 Application of the Ombudsmen Act 1975 and the OIA to the Technical Advisory Committee and the Māori Advisory Committee (as well as the Gene Technology Regulator): these statutory committees, appointed by the minister responsible for the Act, will be subject to the Ombudsmen Act and the OIA. For clarity, it is also necessary to stipulate that information held by these

[10] CAB-24-MIN-0296 at 43 [refer to CAB-24-SUB-0296 Appendix One, at 90.3].
[11] CAB-24-MIN-0296 at 41.
[12] CAB-24-MIN-0296 at 43 [refer to CAB-24-SUB-0296 Appendix One at 130].

committees is official information held by the EPA, and that the EPA would be responsible for deciding on requests for that information.

Other matters

23 I made a number of decisions under the delegated authority of Cabinet.[13] Appendix Three sets out the key decisions.

Impact analysis

24 A regulatory impact statement was prepared in accordance with the necessary requirements and was submitted at the time Cabinet approval of the policy relating to the Bill was sought [CAB-24-MIN-0296].

Compliance

25 The Ministry of Justice is currently vetting the Bill to determine if it complies with the rights and freedoms contained in the New Zealand Bill of Rights Act 1990.

26 The Bill complies with:

26.1 the Human Rights Act 1993;

26.2 the disclosure statement requirements – a disclosure statement has been prepared and is attached as Appendix Four;

26.3 relevant international standards and obligations, notably the obligations under the Cartagena Protocol on Biosafety and its parent the Convention on Biological Diversity;

26.4 the Legislation Guidelines (2021 edition), which are maintained by the Legislation Design and Advisory Committee.

27 In respect of compliance with the Information Privacy Principles (IPPs) and guidelines set out in the Privacy Act 2020, the Bill will override certain IPPs. The information sharing proposals set out above mean that personal information may be used for a different purpose than why it was originally collected, disclosed to another agency without first obtaining express consent, or disclosed outside New Zealand under an agreement with a recognised overseas gene technology regulator.

28 The Office of the Privacy Commissioner (OPC) has indicated it is concerned that the need to override the IPPs has not yet been justified, noting that the Privacy Act provides information-sharing mechanisms for this scenario. Officials will work with OPC to identify any protections for personal information that may be required.

29 In respect of compliance with the principles of the Treaty of Waitangi, the Bill seeks to balance the broader policy goal with active protection of Māori relationships to taonga by:

[13] CAB-24-MIN-0296 at 29, 33, 36, 37, 40 and 52.

29.1 requiring the regulator to consider potential impacts on Māori kaitiaki interests in native species before making decisions related to risks to those interests;

29.2 establishing a dedicated advisory mechanism through the Māori Advisory Committee; and

29.3 requiring the regulator to have regard to that advice before making a decision.

Consultation

30 Consultation has taken place as follows:

30.1 Consultation was undertaken with the Department of Conservation, EPA, Ministry for the Environment, Ministry of Health, MFAT, Ministry of Justice, MPI, Office of the Ombudsman, OPC, Parliamentary Counsel Office (PCO), Public Service Commission (PSC), Te Puni Kōkiri and Treasury. The Department of the Prime Minister and Cabinet was informed.

30.2 Public consultation was not undertaken on the policy proposals. MBIE conducted targeted engagement with industry and research stakeholders most likely to be affected by the proposals including universities and research institutes, iwi and Māori groups, industry associations, Crown Research Institutes, biotech companies, and primary industry and export groups. A Technical Advisory Group and Industry and Māori Focus Groups were also established to advise MBIE on the policy proposals.

30.3 The Labour Party, Te Pāti Māori and The Green Party of Aotearoa New Zealand were briefed on the policy proposals.

Binding on the Crown

31 The Act will bind the Crown [CAB-24-MIN-0296 refers].

Creating new agencies or amending law relating to existing agencies

32 The Ombudsmen Act 1975 and the OIA will apply. However, the application of the OIA will be limited by the Bill. It will not apply to information supplied to the regulator if it likely relates to a licence application and the application has not yet been made. The OIA will only apply to that information once the licence application is received by the regulator. This carries over an existing HSNO provision, which officials consider is necessary to ensure protection of confidential information while an application is being developed and to avoid discouraging pre-application engagement.

33 Regarding this proposal, the Chief Ombudsman "*considers that this limitation is unjustified because there are already grounds within the OIA designed to protect the relevant interests and it is intrusive on the fundamental rights of New Zealanders (to seek and receive information, as enshrined in section 14 of the New Zealand Bill of Rights Act 1990). The Chief Ombudsman notes that such a carve out carries a risk of absolutely protecting information even where it ought to be released in the public interest*."

34 The legislation creates a new statutory officer, the Gene Technology Regulator. The regulator will be appointed by the responsible minister and employed and supported by the EPA. The regulator will be accountable to the EPA for employment matters and accountable to the minister in relation to carrying out their statutory functions. The EPA remains accountable to the Minister for the Environment under the Crown Entities Act in relation to the exercise of its functions, including employing and supporting the Regulator.

35 Regarding this, PSC "*opposes [Cabinet's previous decision] that the regulator would be directly appointed by the minister responsible for the Act. It notes such an arrangement runs contrary to the legal accountability of the EPA for the work of the regulator and will undermine public confidence in their statutory independence. It also undermines the principle embodied in the Public Service Act 2020 and the Crown Entities Act 2004 that those with legal accountability for an organisation's work appoint its staff*".

Associated regulations

36 Regulations will need to be made to implement the technical and operational detail for the new regulatory system to begin operation; other regulations will be required in due course.

37 The indicative timeframe for the first tranche of regulations is to seek Cabinet agreement on proposals for consultation in March 2025. Following consultation and final policy decisions by Cabinet in April/May, PCO will draft the regulations (estimated six-month timeframe given their complexity and technical nature). This would see the regulations approved and notified by early December and the new regulatory regime able to commence operation by the end of 2025.

Other instruments

38 The Bill includes provisions empowering the making of secondary legislation that is not drafted by PCO and is subject to review by the Regulations Review Committee. These powers are for:

38.1 the Gene Technology Regulator to issue standards; to declare activities as non-notifiable, notifiable, and approved as eligible for a pre-assessed licence; and to grant mandatory medical authorisations; and

38.2 the responsible minister to grant emergency authorisations.

39 The provisions are necessary because the regulator requires the ability to make decisions about technical matters in accordance with the scheme of the Act and associated regulations, and it is important that a temporary authorisation for use of gene technology can be granted in the event of an actual or imminent threat to public health and safety or to the environment. The powers comply with the principles in the Deemed Regulations Report of the Regulations Review Committee: the secondary legislation will concern detailed, technical matters; the Gene Technology Regulator and minister will be supported by competent personnel to draft the secondary legislation; and the Bill prescribes the processes for making the secondary legislation.

Definition of Minister/department

40 For the purposes of clause 6 – Interpretation, the Minister is the Minister of Science, Innovation and Technology, and the chief executive is the Chief Executive of the Ministry of Business, Innovation and Employment.

Commencement of legislation

41 The Bill will come into force in stages. On the day after Royal assent, a number of parts of the Bill will come into force to enable the institutions of the new regime to be established and regulations and secondary legislation to be made, and to amend the RMA.

42 The Bill provides for commencement of all other sections on one or more dates set by Order in Council because secondary legislation is required to be in force before the new regulatory regime can begin operation. Confidential advice to Government based on the time required to develop the secondary legislation, as discussed above. However, the Bill stipulates that, if no Order in Council specifying a commencement date for these sections is made, the commencement shall be two years after Royal assent. The explanatory note to the Bill sets out the reasons for commencement by Order in Council.

Parliamentary stages

43 I propose the Bill be introduced before the House rises this year to meet the Coalition Government's commitment in its Q4 Action Plan. Confidential advice to Government

44 I propose the Bill be referred to the Health Committee.

Proactive Release

45 I propose to release this paper proactively, subject to any redactions that may be required consistent with the OIA, within 30 business days.

Recommendations

I recommend that Cabinet:

1 **note** that the Gene Technology Bill holds a category 5 priority on the 2024 Legislation Programme (to proceed to select committee by the end of 2024);

2 **note** that the Bill will enable the safe use of gene technologies and regulated organisms by managing their risks to the health and safety of people and the environment;

Further policy decisions

Objective of the Gene Technology Regulator

3 **agree** that the objective of the regulator will be to develop and maintain an independent, efficient and transparent system to regulate the use of gene technologies and regulated organisms to achieve the purpose of the Gene Technology Act;

Streamlining interactions with other regulators

4 **note** Cabinet previously agreed [CAB-24-MIN-0296 refers]:

4.1 that the regulator be given the power to 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 HSNO adequately addresses the risks to human health and safety and the environment [31.3];

4.2 to amend the Agricultural Compounds and Veterinary Medicines Act 1997 (AVCM Act) to create the necessary powers to support joint assessments or joint decision making [at 32];

5 **agree** to rescind the decisions noted in 4.1 and 4.2 above because the powers will not, in practice, be effective;

Information sharing

6 **agree** to enable agencies to share information collected under the Gene Technology Act with other relevant agencies to support the performance of their functions, duties or exercise of powers under specified Acts;

7 **agree** to enable agencies to share information collected under specified Acts with other relevant agencies to support the performance of the Gene Technology Act;

8 **agree** the specified Acts referred to in recommendations 6 and 7 above are those listed in Appendix Two;

9 **agree** that the Gene Technology Regulator may disclose information (including personal or commercially sensitive information) to a recognised overseas regulator under an agreement between the two regulators on which the Privacy Commissioner has first been consulted;

Protection of confidential information

10 **agree** that the Official Information Act 1982 will not apply to information received by the Gene Technology Regulator that is likely to relate to a licence application that has not yet been made until the application is received;

11 **agree** that the regulator will be subject to specific confidentiality provisions from the Medicines Act 1981 and the ACVM Act;

12 **agree** that, in situations when confidentiality provisions from the Medicines Act and the ACVM Act apply, the regulator will, in respect of the relevant activity authorisation:

12.1 be required to make available summary information of the relevant risks regarding the activity; and

12.2 be able to disclose confidential information to persons prescribed by regulations;

Civil liability

13 **note** Cabinet previously agreed to carry over from HSNO its civil liability provisions [CAB-24-MIN-0296 at 39 refers];

14 **note** the criminal offences and associated penalties in the Bill and the common law of torts provide adequate incentives for parties undertaking activities with regulated organisms to act properly and to meet their statutory duties, and not carrying over the civil liability provisions will better support the enabling intention of the new regime;

15 **agree** to rescind the decision noted at recommendation 13 above;

16 **agree** that the Bill does not include provisions for civil liability and that the common law of torts will apply;

Compliance with international obligations

17 **agree** that the Bill include an overarching requirement for the Gene Technology Regulator to have regard to New Zealand's international obligations under the Convention on Biological Diversity (CBD) and the Cartagena Protocol in its decision-making;

18 **note** that operating arrangements to give effect to New Zealand's obligations under the CBD and the Cartagena Protocol will be developed in due course;

Minor and technical issues

19 **note** that Cabinet previously agreed that the Bill would provide the regulator with a standard set of compliance, monitoring and enforcement powers [CAB-24-MIN-0296 at 43, refer to CAB-24-SUB-0296 Appendix One at 130];

20 **agree** to rescind the decision noted in 19 above because it is unnecessary for the regulator to have the powers given MPI will be the enforcement agency;

21 **agree** the Gene Technology Regulator should have powers to develop, adopt, or amend standards for non-notifiable, notifiable, licensed activities and the different categories of activity: contained, environmental and medical, and any subcategories of activities (including transport, treatment, fermentation, and disposal);

22 **agree** to establish a specific transhipment licence to enable the efficient transit of regulated organisms through New Zealand;

23 **agree** to include the power to charge levies in the Bill's cost recovery regulation making powers;

24 **agree** that the Bill clarify that the Ombudsmen Act 1975 will apply to the Technical Advisory Committee and the Māori Advisory Committee, and that information held by these committees is official information held by the Environmental Protection Authority for the purposes of the Official Information Act 1982;

Approval, introduction and progress of the Bill

25 **note** that for the purposes of clause 6 of the Bill (Interpretation), the Minister is the Minister of Science, Innovation and Technology, and the chief executive is the Chief Executive of the Ministry of Business, Innovation and Employment;

26 **approve** the Gene Technology Bill for introduction, subject to the final approval of the government caucus and sufficient support in the House of Representatives;

27 **agree** that the Bill be introduced on [10] December 2024;

28 **agree** that the Parliamentary Counsel Office can continue to make changes to the Bill that are approved by the Minister and consistent with Cabinet's policy decisions up until the Bill is printed for introduction; and

29 **agree** that the Government propose that the Bill be:

29.1 referred to the Health committee for consideration;

29.2 Confidential advice to Government

Authorised for lodgement

Hon Judith Collins KC

Minister of Science, Innovation and Technology

Appendix One: Key features of the Gene Technology Bill

The Gene Technology Bill will:

- establish a Gene Technology Regulator as the independent decision-maker, and a Technical Advisory Committee and a Māori Advisory Committee (MAC) to advise the regulator (the MAC will also advise the Minister on specific matters);
- regulate activities proportionate to their risk based on the techniques used, and exclude from regulation the products of some minimal risk gene-editing techniques;
- ensure regulatory oversight of activities with regulated organisms is proportionate to the level of risk through adoption of a risk-tiering framework for activities and a new risk management approach;
- support streamlined decision-making by enabling joint assessments where efficient and drawing on overseas regulators' expertise;
- manage risks to Māori kaitiaki relationships with native species;
- update definitions to account for current and potential future changes to gene technologies;
- ensure a nationally consistent approach to regulation of gene technology by removing local authorities' ability to restrict its use, and
- ensure New Zealand continues to be able to comply with our international obligations.

Appendix Two: Relevant Acts for information sharing proposals

1 Agricultural Compounds and Veterinary Medicines Act 1997

2 Animal Products Act 1999

3 Animal Welfare Act 1999

4 Biosecurity Act 1993

5 Food Act 2014

6 Imports and Exports (Restrictions) Act 1988

7 Customs and Excise Act 2018

8 Hazardous Substances and New Organisms Act 1996

9 Human Assisted Reproductive Technology Act 2004

10 Health Act 1956

11 Human Tissue Act 2008

12 Medicines Act 1981

13 Misuse of Drugs Act 1975

14 Psychoactive Substances Act 2013

Appendix Three: Key decisions made under delegated authority

1 As authorised by Cabinet, the Minister of Science, Innovation and Technology (the Minister) made detailed decisions on a range of matters, including in consultation with relevant ministers as necessary. Key decisions the Minister made are outlined below.

Reviews and appeals under the Gene Technology regime

2 In line with Cabinet decisions, the Bill allows applicants and licence holders to request the Gene Technology Regulator review specified licence decisions the regulator has made, mirroring the Australian regime.[14] This is a first opportunity to identify and correct errors with the original decision, prior to any further appeals process and is therefore efficient.

3 Appeal provisions in the Bill broadly align to the HSNO regime, as agreed by Cabinet, providing a direct right of appeal to the High Court (and further to the Court of Appeal) on questions of law for applicants, licence holders and directly affected third parties.[15]

4 The Minister decided to treat statutory determinations like a licence decision given they are comparable types of decision, and therefore to provide the same rights of review and appeal outlined above. This differs from HSNO, which does not have review process prior to appeal.

Changes to the Resource Management Act 1991 (RMA)

5 To provide a nationally consistent and predictable regulatory environment for gene technology, Cabinet agreed to remove from the RMA the ability for regional councils and territorial and unitary authorities to restrict the use of GMOs.[16]

6 In addition, there are some regional, unitary and district plan rules concerning GMOs that are, or may become, operative and there may be related resource consents in force, or applications in train, at the time the Act commences. The Minister decided to amend the RMA through the Bill to give effect to the following policies to address operative plan rules, and consents and consent applications:

6.1 Any operative plan rules about GMO activities cease to have effect immediately, so that the transition to a nationally consistent regime for regulating GMOs can occur as quickly as possible; and

6.2 Consent holders and applicants (if any) may choose to continue with the consent or application if that suits their circumstances, or choose to surrender or withdraw it.

7 Activities with GMOs will require a HSNO approval, or appropriate authorisation under the Act once that part of the Act comes into force, and this will not be affected by plan rules ceasing to have effect or resource consents (if any) being surrendered.

[14] CAB-24-MIN-0296 at 28 and 43 [refer to CAB-24-SUB-0296 Appendix One, at 110].
[15] CAB-24-MIN-0296, at 28 and 43 [refer to CAB-24-SUB-0296 Appendix One, at 111].
[16] CAB-24-MIN-0296, at 34.