Ministry for the Environment
Manatū Mō Te Taiao

# PROACTIVE RELEASE COVERSHEET

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| **Minister** | Hon David Parker | **Portfolio** | Environment |
| **Name of package** | Proposal to publicly consult on changes to the regulations for genetically modified organisms to support laboratory and biomedical research | **Date to be published** | 20/9/2023 |

| **List of documents that have been proactively released** | | |
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| 22 June 2023 | Cabinet paper: Proposal to publicly consult on changes to the regulations for genetically modified organisms to support laboratory and biomedical research | Ministry for the Environment |
| 22 June 2023 | ENV-23-MIN-0026 – Cabinet Environment, Energy and Climate Committee Minute of Decision | Cabinet Office |
| 26 June 2023 | CAB-23-MIN-0263 – Cabinet Minute of Decision | Cabinet Office |

**Information redacted** **YES**

Any information redacted in this document is redacted in accordance with the Ministry for the Environment's policy on proactive release and is labelled with the reason for redaction. This may include information that would be redacted if this information was requested under Official Information Act 1982. Where this is the case, the reasons for withholding information are listed below. Where information has been withheld, no public interest has been identified that would outweigh the reasons for withholding it.

**Summary of reasons for redaction**

Some information has been withheld from *CAB-23-MIN-0263 Report of the Cabinet Environment, Energy and Climate Committee Minute* under Section 9(2)(f)(iv) of the Official Information Act to maintain the confidentiality of advice tendered by Ministers of the Crown and officials.

**In Confidence**

**Office of the Minister for the Environment**

**Chair, Cabinet Environment, Energy and Climate Committee**

# Proposal to publicly consult on changes to the regulations for genetically modified organisms to support laboratory and biomedical research

## Proposal

1 This paper seeks Cabinet's agreement to publicly consult on changes to the legislation and regulations for genetically modified organisms (GMOs), where the legislation and regulations concern laboratory research and biomedical research & development (R&D).

## Relation to government priorities

2 This proposal relates to the Government's broader support for, and investment in, innovation and better health services for New Zealanders. These changes to the regulations for laboratory research and biomedical R&D aim to reduce unnecessary barriers to scientific innovation and biomedical therapies.

## Executive Summary

3 Following engagement with stakeholders in the New Zealand research community in November 2021, the Ministry for the Environment (MfE) has developed policy options to improve the GMO regulations for laboratory research and biomedical R&D.

4 The consultation document that I am seeking Cabinet agreement to release for public consultation outlines 10 proposed policy changes. These policy changes, which cover primary legislation, secondary legislation, and non-legislative changes, were developed to address specific issues highlighted by stakeholders and other issues identified by MfE. For each of the proposals, the current regulatory status quo, identified issues and proposed policy change are outlined below.

5 Under the Hazardous Substances and New Organisms Act 1996 (HSNO Act), GMOs are included under the definition of 'new organisms'.[1] While the scope of this work is generally limited to regulatory requirements for GMOs, for several proposals limiting the scope to just GMOs has the potential to create issues or unnecessary differential regulations. As such, the scope of these proposals has been widened to also include new organisms, while still being limited to laboratory and biomedical research.

[1] New organisms under the HSNO Act primarily covers organisms that are new to New Zealand, either because they were not present in New Zealand before a certain point in time (29 July 1998) or because they have been genetically modified. Examples of non-genetically modified new organisms could include biocontrol agents such as insects or fungi that are new to New Zealand or samples of SARS-CoV-2 (the causal agent of Covid-19) for research and diagnostic purposes.

6 As an example of the potential for a limited scope to create issues or unnecessary differential regulations, currently there are four standards that outline the controls for new organisms in containment facilities. Changing the controls for GMOs while maintaining the current controls for new organisms would double the number of controls facility operators have to comply with. Given low-risk non-GMO new organisms are unlikely to differ substantially to low-risk GMOs in terms of risk, these different controls would likely create unnecessarily complex regulatory requirements.

7 This policy work is not a full review of the regulatory framework for GMOs and does not cover provisions for field trials, conditional releases, and full releases of GMOs. The scope also specifically excludes any changes to regulatory provisions for heritable cells. While some New Zealanders are wary of genetic modification used on livestock and food crops, genetic modification used for human medical treatments enjoys a high level of support from New Zealanders.[2]

8 The proposed policy changes largely focus on research undertaken within laboratory settings, the approval of biomedical therapies, and changes to ensure the regulatory framework is both up to date and future-proof. These policy changes include:

8.1 the introduction of a risk-tiering framework for laboratory research;

8.2 reducing the assessment and approval requirements for medicines that are, or contain, new organisms (which include GMOs);

8.3 adjusting administrative compliance requirements to be more proportionate to risk;

8.4 clarifying the regulatory status of certain biotechnologies;

8.5 implementing a legislative requirement for MfE to regularly review the regulatory settings for GMOs.

9 Should Cabinet agree to the recommendations outlined in this paper, the attached consultation document *Improving our GMO regulations for laboratory and biomedical research* will be released on the Ministry for the Environment's website for public comment starting in July. In response to feedback from Te Arawhiti, also included will be a supplementary consultation document for consultation with hapū, iwi and Māori.

## Background

10 In May 2021, in response to reports by the Royal Society Te Apārangi and the Prime Minister's Chief Science Advisor, I requested that MfE provide advice on options for reducing any unnecessary regulatory restrictions on human biomedical R&D using GMOs in New Zealand.

11 Following this advice, in November 2021, MfE engaged with stakeholders conducting research in New Zealand using GMOs, to understand their experience of working with the current regulatory framework, to identify any specific issues, and to establish whether there was a case for regulatory change.

[2] Kathlene, L., Munshi, D., Kurian, P., & Morrison, S. L. (2022). Cultures in the laboratory: mapping similarities and differences between Māori and non-Māori in engaging with gene-editing technologies in Aotearoa, New Zealand. *Humanities and Social Sciences Communications*, *9*(1), 1-10.

12 While the general stringency of New Zealand's regulatory framework for GMOs has been highlighted by numerous individuals and groups over the years, no engagement has been undertaken to understand the specific issues and restrictions that affect researchers. Additionally, unlike the rapid changes in biotechnology in the last 20 years, the regulatory framework for GMOs has not been reviewed since changes were made in response to the Royal Commission on Genetic Modification's 2001 report.

13 Responses were received from 11 universities, research institutes and biotechnology companies representing the views of over 32 researchers, research directors and laboratory managers. These included seven Professors, six Associate Professors, three principal scientists, five senior lecturers and two senior research scientists.

14 Those surveyed frequently described the current regulatory requirements as convoluted, time-consuming, expensive, onerous, and frustrating. Respondents were of the view that these requirements increased the amount of time, effort and funding required to carry out their research without any subsequent improvements to safety.

15 Researchers also highlighted the time and financial cost of regulatory restrictions on small labs, PhD students and start-ups, and the impact of restrictions on research decisions made. Those areas that were particularly noted as having issues included the requirements for assessments and approvals, record-keeping, and regulatory restrictions on low-risk organisms more generally.

16 Based on this feedback, and in consultation with the Environmental Protection Authority (EPA), the Ministry for Primary Industries (MPI) and the Office of the Prime Minister's Chief Science Advisor (OPMCSA), policy options to address these issues and other issues identified by MfE, have been developed. Following feedback from the OPMCSA, the scope of this policy work was also widened beyond just human biomedical R&D in order to ensure future regulations are both workable and deliver the best health and research outcomes possible.

17 While the HSNO Act regulates GMOs across a wide range of scenarios, this policy work is not a full review of the regulatory framework for GMOs and does not cover the provisions for field trials, conditional releases, and full releases.[3] The proposed policy changes developed by MfE largely focus on:

17.1 research undertaken within laboratory settings;

17.2 the assessment and approval of medicines that are, or contain, new organisms;

17.3 ensuring that the regulatory framework is both up to date and future-proof.

18 While the scope of this work is generally limited to regulatory requirements for GMOs, for several proposals limiting the scope to just GMOs has the potential to create issues or unnecessary differential regulations. As such, the scope of Proposals 2, 3, 4, 5 and 9 have been widened to include new organisms rather than just GMOs.

19 Objectives for this policy work were to ensure that New Zealand's regulatory framework for GMOs:

[3] Excluding the provisions for the "release" of medicines that are or contain new organisms.

19.1 proportionately manages the risks that laboratory research poses to the environment and health and safety of people and communities;[4]

19.2 contributes to better health outcomes for New Zealanders through greater biomedical research outcomes and innovation, and greater access to therapies and medicines;

19.3 is not only up to date but also future-proof, to anticipate and flexibly accommodate future technological developments to the best extent possible.

20 MfE sought feedback on the proposed policy changes from a small number of key stakeholders in the New Zealand research community. Feedback from these stakeholders was positive and they were excited by the prospect of improvements being made to address concerns they have had for a number of years.

## Proposal 1: Risk-tiering framework for laboratory research

*Status quo*

21 Under the current regulatory settings, the importation into, or development of, GMOs in containment (ie. within a laboratory) requires assessment and approval from the EPA. These applications are either assessed under a full approval pathway or, if meeting the criteria for being "low-risk", are assessed under a rapid assessment pathway.[5]

22 Additionally, several existing importation approvals can also be used by individuals or groups that can meet the requirements specified by those importation approvals, such as having a laboratory with the required stringency of control measures.

*Proposed change*

23 The most significant policy change being proposed in the accompanying consultation document is the creation of a risk-tiering framework modelled on the risk-tiering framework used under Australia's GMO regulations.[6] This risk-tiering framework would shift New Zealand's regulatory approach for laboratory research from one that is regulator-centric to one that is higher-trust and more risk proportionate.

24 This shift to a more trust-based and more risk-proportionate approach is based on the greater understanding of the risks of genetic modification research that has accumulated over the past four decades. This understanding allows the codification of classes of research below a certain level of risk, rather than that research needing to be assessed by a regulator such as the EPA.

25 Under the proposed risk-tiering framework individuals and groups would be able to import or develop GMOs according to the requirements of a risk tier provided their research meets the criteria of that risk tier. Risk tiers, for instance, may require that research be reviewed by an internal biosafety committee instead of the EPA, or may

[4] Including the health and safety of laboratory staff.
[5] The criteria for "low-risk" are set out under the *Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003*.
[6] The full details of the Australian risk-tiering framework can also be found under Schedule 2 and Schedule 3 of the Gene Technology Regulations 2001 at https://www.ogtr.gov.au/about-ogtr/legislative-documents.

not require a containment facility approved by a regulator, both of which have been features of Australia's risk-tiering framework since 2001.

26 Criteria of each risk tier would outline the characteristics of research allowed under that risk tier, including what organisms could be modified, what genetic modifications could be made, and what genetic tools could be used. For example, if a research project proposed to use a very-low-risk bacteria strain routinely used in laboratories (like *E.coli K12*), then that research would likely meet the criteria of risk tier 1 (outlined below).

27 The requirements associated with each risk tier would outline the specific measures that would need to be put in place, and the specific steps that would need to be taken, before research could be undertaken. These would include what type of laboratory would be required and whether an assessment by a biosafety committee would also need to be carried out. Under the framework, as the risk of research increases so would the requirements placed on research increase.

28 Under the proposed risk-tiering framework, as under the current Australian framework, the type of laboratory required would range from laboratories/buildings that would not require prior approval from MPI to laboratories that would require prior MPI approval. MPI approves laboratories as 'containment facilities', which must be operated according to certain standards and at certain levels of stringency based on the research undertaken in those facilities.[7] A key requirement of all risk tiers will be that any unapproved release of GMOs into the environment is prohibited.

29 The key proposed features and requirements for each risk tier are as follows:

| Risk tier | Features and requirements |
|---|---|
| Risk tier 1<br><br>Research presenting no to very low risk to the environment and the health and safety of people and communities.[8] | Research meeting the criteria of this risk tier would be exempt from EPA assessment and approval requirements, including for "release" in or as a medicine.<br><br>In addition, the laboratory in which the research is undertaken would not need to be a containment facility approved by MPI. |
| Risk tier 2<br><br>Research presenting very low to low risk to the environment and the health and safety of people and communities. | Research meeting the criteria of this risk tier would be exempt from EPA assessment and approval requirements, but the research would need to be assessed by a biosafety committee as meeting the criteria.<br><br>The research would be required to be undertaken in an approved containment facility operated according to the relevant standard at Physical Containment Level 1 (PC1). |

[7] The stringency of containment facilities range from those operated at Physical Containment Level 1 (PC1) (the least stringent level of containment) to those operated at Physical Containment Level 4 (PC4) (the most stringent level of containment).

[8] Research that presents no risk to the environment and the health and safety of people is included under the proposed framework so that restrictions are still able to be applied to this research. For instance, inclusion under the framework would allow restrictions to still be placed on research using human cells or cells of taonga species that might be deemed inappropriate by hapū, iwi or Māori.

| | |
|---|---|
| Risk tier 3<br><br>Research presenting low risk to medium risk to the environment and the health and safety of people and communities. | Research meeting the criteria of this risk tier would be exempt from EPA assessment and approval requirements, but the research would need to be assessed by a biosafety committee as meeting the criteria.<br><br>The research would be required to be undertaken in an approved containment facility operated according to the relevant standard at Physical Containment Level 2 (PC2). |

30 All other research that does not meet the criteria for risk tiers 1 to 3 would require assessment and approval by the EPA before being undertaken. Research not meeting the criteria of risk tiers 1 to 3 would likely encompass research:

30.1 requiring a containment facility operated at Physical Containment Level 3 (PC3);

30.2 where it is unclear whether it requires a containment facility operated at PC2 or PC3;

30.3 the EPA considers an assessment by them would be necessary.

31 Under risk tiers 2 and 3, biosafety committees would assess research proposals to ensure they meet the criteria of those risk tiers. These biosafety committees would be accredited by the EPA to become an Accredited Biosafety Committee (ABSC). Organisations would have the option of forming their own ABSC, using another organisation's ABSC, or using the EPA biosafety committee.

32 Because the criteria of the risk tiers will be explicit rather than interpretive, assessments by ABSCs will not be as time-consuming as the case-by-case assessments undertaken by the EPA.[9] It is also intended that existing assessment processes by the likes of internal biosafety committees could function as a risk-tier assessment so as not to unnecessarily duplicate existing processes.

33 MfE, in collaboration with the EPA, would consult on the specific criteria and details of risk tiers, should Cabinet agree to the implementation of a risk-tiering framework. This additional consultation will also allow feedback received during the proposed consultation to be incorporated into the risk-tiering framework, including feedback from hapū, iwi and Māori on matters of importance to them.

34 The details of the Australian framework have also been included as Appendix 3 of the attached consultation document to invite feedback on what aspects of that framework should or should not be included in any New Zealand framework.

35 Benefits of implementing the proposed risk-tiering framework is that it would lower administrative requirements for researchers to gain approval for low-risk research, lower startup costs for new organisations and companies,[10] and remove the

[9] For instance, explicitly listing organisms that are included under that risk tier rather than using interpretive criteria such as '*an organism that is not normally able to cause disease in humans, animals, plants, or fungi*'.

[10] It would also allow the likes of high schools to demonstrate and teach very low risk genetic modification in a hands-on way to their students.

requirement for EPA assessment and approval for medicines using organisms under the lowest risk tier, such as personalised cancer therapies (eg, CAR T-cell therapies).

## Proposal 2: Assessment and approval of medicines that are or contain new organisms

*Status quo*

36 Currently, medicines that are, or contain, new organisms (which includes GMOs) must be assessed and approved for "release" by the EPA, in addition to being approved by Medsafe in the case of human medicines and MPI in the case of veterinary medicines.

37 While most medical release applications have until now been rapidly assessed by the EPA under section 38I of the HSNO Act, a number of improvements could still be made to improve the assessment and approval provisions for these medicines. The definition of these medicines under the HSNO Act also does not encompass medical devices, meaning they cannot be rapidly assessed and approved under section 38I.

*Proposed changes*

38 Proposed changes to the provisions for these medicines are:

38.1 streamlining medical release assessments by removing the current first evaluation stage from section 38I;

38.2 introducing an alternative assessment pathway for medicines that are, or contain, new organisms that are unlikely to result in new organisms making their way into the environment;

38.3 amending the current rapid assessment provisions to include medical devices that are, or contain, new organisms.

39 These changes would have the benefits of lowering the amount of time required of researchers to prepare applications, reducing the time and resources required of the EPA to assess applications, and reducing the time and funding required for the approval of medical devices that are, or contain, new organisms.

40 Throughout the development of policy options, MfE has remained cognisant of the replacement of the Medicines Act 1981 by the Therapeutic Products Bill, which is currently before the Health Select Committee. None of the changes proposed to the HSNO Act for medicines that are, or contain, new organisms are expected to affect the proposed provisions of the Therapeutic Products Bill.

41 Section 38I of the HSNO Act also encompasses veterinary medicines that are, or contain, new organisms. In their feedback on MfE's proposed changes, the EPA noted that they saw no reason to exclude veterinary medicines from benefiting from the improvements made to these provisions.[11]

[11] Veterinary medicines that are or contain new organisms also require approval under the Agricultural Compounds and Veterinary Medicines Act 1997 before they can be used.

## Proposal 3: Record-keeping requirements

*Status quo*

42 Under current regulatory requirements, researchers are required to record several details of each GMO they hold. These record-keeping requirements were one of the most frequently cited issues during MfE's engagement with the New Zealand research community. In the view of many researchers, the time and effort required to maintain these records for the many GMOs created on a daily basis was excessive considering the low risk of their research.

43 It is also not clear how the details required of current records further reduce the risk of already low-risk new organisms (and to a degree that would sufficiently outweigh the cost incurred by researchers). Additional to the current prescriptive record-keeping requirements, researchers frequently keep records tailored to their research and current best-practice.

*Proposed change*

44 The proposed change to address this issue is to replace these record-keeping requirements with two requirements:

44.1 new organisms, or containers that contain new organisms, must be labelled to indicate that they are, or contain, new organisms;

44.2 a documented system for accounting must be in place for:

44.2.1 new organisms in containment facilities operated at PC3;

44.2.2 animals with the ability to escape their cages/containers, in all containment facilities.

45 Because GMOs are included under the definition of new organisms under the HSNO Act, a label indicating an organism is a GMO, or a container contains a GMO, would also satisfy the new labelling requirement.

46 These two new requirements would decrease the non-research administrative time required of researchers while:

46.1 decreasing the likelihood of accidental cross-contamination between GMOs and non-GMOs (as well as new organisms and not-new organisms);

46.2 ensuring that researchers and compliance officers can confirm higher risk organisms have not escaped or been taken by unauthorized persons.[12]

47 The consultation document will also ask whether a new labelling requirement should include that a new organism or container should be able to be linked to the relevant HSNO Act approval/risk tier. This is a requirement that is currently set under the broad approvals given to the University of Auckland, University of Otago and Massey University.

[12] In addition to other control measures to ensure new organisms are contained and unauthorized persons are not able to gain entry to those containment facilities.

## Proposal 4: Audit frequency for containment facilities

*Status quo*

48 Currently, internal audits of containment facilities are required to be carried out by facility operators every 6 months. This is regardless of whether the containment facility is operated at PC1, PC2, or PC3. Containment facilities operated at PC1 are currently used for those organisms with the lowest risk profile.

49 In addition, inspections of containment facilities at every Physical Containment Level are generally carried out every 12 months by MPI (and may be carried out at any time by MPI, if required).

*Proposed change*

50 The change being proposed would reduce the frequency of internal audits for containment facilities operating at PC1 to a *minimum* of 12 months. This would have the benefit of freeing up researcher time, lowering the costs associated with audits, and freeing up time for biosafety officers to concentrate on areas of higher risk.

51 Internal audit frequency for containment facilities operating at PC2 and PC3 would remain unchanged, as would the current frequency of inspections and the ability for MPI to conduct inspections at any time.

## Proposal 5: Movement of new organisms between laboratories

*Status quo*

52 To move new organisms (which includes GMOs) between two containment facilities currently requires a number of conditions to be met, including that prior authorisation for the movement is obtained from MPI, the packaging to transport the new organisms meets certain requirements, prior authorisation is obtained from both facilities, and shipped items are tracked.

53 A potential issue with these requirements is that they are not proportionately set based on the risk of the new organisms in question and, in particular, may be set too high for low-risk new organisms.

*Proposed changes*

54 The first change proposed would remove the requirement for MPI authorisation for the movement of GMOs that meet the criteria of risk tier 1 under the risk-tiering framework proposed under Proposal 1. Movement of these GMOs between laboratories would be permitted provided they are packaged, labelled, and transported appropriately.

55 The second change proposed would remove the requirement for MPI authorisation for the movement of GMOs that meet the criteria of risk tier 2 under the risk-tiering framework proposed under Proposal 1. This requirement would also be removed for non-genetically modified new organisms that require a containment facility operated at PC1.

56 The movement of these GMOs and non-genetically modified new organisms between containment facilities would be permitted provided they are:

56.1 packaged, labelled and transported appropriately;

56.2 the containment facility they are being sent to is operated at a Physical Containment level that is equal to or greater than PC1;

56.3 the sending facility operator confirms the movement meets those requirements;

56.4 both the sending and receiving facilities record the movement in a register.

57 The current regulatory requirements for the movement of new organisms required to be kept in containment facilities operated at PC2 and PC3 would remain unchanged.

## Proposal 6: Requirements for working with cells

*Status quo*

58 A common frustration expressed by researchers concerns the stringency of regulatory restrictions to work with cells, and in particular human cells. In the view of researchers and the EPA, human and animal cells pose essentially zero risk to the environment or people due to their biological characteristics and the reliance of these cells on highly specific lab conditions.

59 Cells are included under the definition of 'organism' under the HSNO Act and as such the genetic modification of these cells is regulated under the HSNO Act like other organisms. This means that approval is required from the EPA to import, develop, field test, and release genetically modified cells (including the "release" of cell-based medical therapies).

*Proposed change*

60 To reduce any unnecessary regulatory requirements on these cells, the change proposed is to include certain eukaryotic somatic cells under risk tier 1 of the risk-tiering framework under Proposal 1. As under Australian regulations, the range of eukaryotic somatic cells under this risk tier would likely include animal cells, human cells, and plant cells (as long as these plant cells are not able to spontaneously generate into a whole plant).

61 Eukaryotic cells are cells of eukaryotes, which include animals, plants, fungi, and many unicellular organisms. Eukaryotes are a group of organisms distinct from bacteria and archaea. Somatic cells are cells that are non-heritable, while heritable cells refer to the reproductive cells of an organism. As such, eukaryotic somatic cells are non-heritable cells of animals, plants, fungi, and many unicellular organisms.

62 By including certain types of these cells under this risk tier, this change would enable researchers to work with these cells without having to meet the conditions imposed for higher risk organisms. It would also ensure that biomedical therapies that use these cells would only require Medsafe approval, rather than also requiring EPA assessment and approval.

63 Māori are likely to take an interest in what regulatory restrictions are placed on the genetic modification of cells and tissues of taonga species.[13] Under Article Two of the Treaty of Waitangi, the Crown promises that Māori will have the right to exercise rangatiratanga over their lands and taonga.

[13] Changes to the regulatory restrictions on the genetic modification of whole animals or plants that are considered taonga are not in scope of this review. The genetic modification of these whole animals or plants will still require EPA assessment and approval.

64 MfE will specifically engage with hapū, iwi and Māori on how to provide for their interests in these matters. Regulatory restrictions may include that consultation with relevant hapū and iwi must be conducted before research is undertaken. As noted in paragraph 33, MfE's consultation on the specific criteria and details of a risk-tiering framework will allow feedback received during the proposed consultation from hapū, iwi and Māori to be incorporated into the risk-tiering framework.

## Proposal 7: Regulatory status of certain biotechnologies

*Status quo*

65 Whether the use of a biotechnology is regulated by the HSNO Act is determined by the definitions of the HSNO Act, regulations under the HSNO Act, and statutory determinations made by the EPA.[14]

66 While statutory determinations made under section 26 of the HSNO Act can and do function as a means by which the regulatory status of biotechnologies under the HSNO Act can be clarified, the utility of statutory determinations is limited in a number of ways. The first is that statutory determinations must be applied for and cannot be initiated by the EPA. In addition, existing statutory determinations are publicly available but may not be easily discoverable by researchers or organisations.

*Proposed changes*

67 Under the changes proposed, three types of biotechnologies would be specified under regulations as not resulting in the creation of GMOs. These biotechnologies are:

67.1 introduction of RNA into an organism (an example of this technology being mRNA vaccines);

67.2 introduction of DNA into an organism (an example of this being DNA vaccines, which are an advancing technology);

67.3 epigenetic modifications (which are defined as changes to the expression of genes without changing the underlying genetic sequence).

68 Genetic modification is generally considered to be the modification of an organism's genetic makeup (ie, the modification of the DNA in their genome). According to the conditions that would be placed on them, the use of these three biotechnologies would not result in modifications to the genetic makeup of an organism.

69 An example of the exclusionary criteria that might be applied to these biotechnologies is that the introduction of RNA or DNA "*cannot result in an alteration of the organism's genome sequence*". This would exclude from the scope of these biotechnologies genetic modification and gene editing in any form.

70 It is intended that clarifying the regulatory status of these biotechnologies under regulations would provide certainty and clarity to researchers, and likely lead to their increased use in research and in biomedical therapies in future. The clarification of the status of RNA technologies may also support the Ribonucleic Acid (RNA) Development Platform, which was given $70 million of funding in Budget 2022.

[14] At its simplest, biotechnology is technology based on biology. Biotechnology harnesses cellular and biomolecular processes to solve problems and develop useful products.

## Proposal 8: Low-risk fermentation

*Status quo*

71 Fermentation ("bulking up") of GMOs is an essential part of the manufacture of a range of biotechnology products including vaccines. The HSNO Act currently requires that those wishing to carry out fermentation of GMOs at volumes greater than 10 litres per vessel must gain approval for that fermentation, either by applying for a fermentation approval or including a fermentation application in an application they are making.

*Proposed change*

72 The change proposed is to link fermentation approval requirements to the risk-tiering framework proposed under Proposal 1. For research meeting the criteria of risk tier 1, which would not normally require a containment facility, fermentation above a volume of 10 litres per vessel would have to meet the requirements of risk tier 2. That is, the research would have to be carried out in a containment facility operated at PC1 and assessment of the research would have to be carried out by an ABSC.

73 For research meeting the criteria of risk tiers 2 and 3, fermentation above 10 litres per vessel would require a containment facility operated at PC1 (for risk tier 2) or PC2 (for risk tier 3). Proposals for the fermentation would also require assessment by an ABSC, as in general under the risk-tiering framework.

74 Fermentation of organisms not meeting the criteria of risk tiers 1-3 would require EPA assessment and approval. The consultation document will also seek feedback on whether the current maximum vessel size not requiring EPA assessment and approval (10 litres) should be increased.

## Proposal 9: Standards for containment facilities

*Status quo*

75 Requirements for facilities that handle GMOs are currently specified under four standards approved under the HSNO Act and the Biosecurity Act 1993. These standards cover both containment facilities and transitional facilities for micro-organisms and cell cultures, vertebrate laboratory animals, plants, and invertebrates.[15]

76 Since their publication, the EPA has moved towards using 'outcome-based' standards, which allow containment facility operators to use control measures that may contain GMOs to the same degree or better than prescriptive controls.

77 However, one challenge of outcome-based controls is that identifying adequate containment measures requires technical knowledge and expertise from both those who implement and those who verify the measures (ie, compliance officers). Although large organisations, such as universities, may have the funding and human resources available to implement outcome-based controls, smaller organisations may find prescriptive controls easier to implement.

[15] Standards for containment facilities are approved by the EPA under section 11(1)(fc) of the HSNO Act, and standards for transitional facilities are approved under the Biosecurity Act 1993.

*Potential options*

78 In contrast to the other nine proposals in the consultation document, Proposal 9 will present three potential approaches to standards for containment facilities rather than present a single proposed change. This is because each of these options has potential benefits and downsides, and I consider it prudent to invite feedback on these options and their potential impacts from the research community. These three options are:

78.1 maintaining the status quo;

78.2 shifting to outcome-based standards;

78.3 shifting to hybrid standards.

79 Under the status quo approach, controls under the current four standards would remain prescriptive. That is, the measures required to be taken by facility operators would be explicitly outlined under these standards. A benefit of this approach is that the standards for both containment facilities and transitional facilities would have the same (prescriptive) approach. Prescriptive standards may also be easier to comply with for smaller facility operators. A potential downside of prescriptive standards is that prescriptive controls may not be the best measure to ensure the containment of a new organism in particular instances.

80 The outcome-based approach would see the replacement of the current four standards with one, or multiple, 'outcome-based' standards and a number of guides on how facility operators and researchers can meet outcome-based controls. This shift from prescriptive to outcome-based controls would allow researchers to use validated, peer-reviewed solutions that may be more appropriate for containing new organisms in specific instances.

81 Under the hybrid approach, aspects of the current prescriptive standards (the status quo) would be combined with outcome-based standards. Under this approach, outcome-based standards would be specified for containment facilities that hold new organisms, as under the outcome-based standards option outlined in paragraph 80. In addition, default measures that would meet these outcome-based controls would be specified (these would likely be the same as those currently under the existing standards). Under this approach, facility operators could either choose to implement the default measures that would meet the outcome-based controls or could implement other non-default measures that would also meet the outcome-based controls.

82 Guides produced for the outcome-based and hybrid options would outline how outcome-based controls under these standards could be effectively implemented. A committee consisting of stakeholders from the research community and representatives from relevant government agencies could also be formed to develop and regularly update these guides.

83 Due to the technical nature of these standards and their incorporation of both containment and transitional facility controls, we anticipate further work and analysis by MPI and the EPA will be required following the proposed consultation. Feedback from the proposed consultation would inform discussions between MPI and the EPA and the approach to standards that are agreed to by these agencies.

## Proposal 10: Future regulatory reviews

*Status quo*

84 With the rapid pace of advances in biotechnology, there is likely a need for our GMO regulations to be reviewed regularly to ensure they are not out of date and regulate research appropriately. While there are no barriers to reviews being undertaken, competing priorities reduce the probability of necessary reviews being undertaken.

*Proposed change*

85 The change proposed would insert a provision into the HSNO Act that would require MfE to conduct a review of the regulatory settings for GMOs at least every five years (or another similar amount of time). A report of this review, which would include any recommendations for changes to the regulatory settings, would then be provided to the Minister for the Environment.

86 This change would have the benefit of reducing the likelihood of regulatory settings remaining inappropriate and out of date for long periods of time and would encourage horizon scanning and regulatory work in anticipation of advances in biotechnology.

## Financial Implications

87 MPI and EPA would require additional funding if the proposed changes outlined above are incorporated into legislation or regulation. Specifically, for both agencies, additional resources would be required if a shift to outcome-based or hybrid standards was agreed to by these agencies.

88 EPA would require additional resources to develop and consult on the criteria for the proposed risk-tiering framework alongside MfE, to accredit biosafety committees, form an EPA biosafety committee, and to develop the risk assessment criteria for medicines that are unlikely to result in new organisms making their way into the environment.

89 MPI would require additional resources to update internal documents and processes as a result of changes to the requirements for record-keeping, audits and movements, as well as changes to import health standards and import approval processes as a result of the proposed risk-tiering framework. Should a shift to outcome-based or hybrid standards be agreed to by MPI and the EPA, additional training for MPI compliance officers to carry out the verification of outcome-based controls.

90 MfE estimates that around 1 FTE of additional resourcing would be required at both agencies (that is, around 2 FTE in total) over the span of a year to make these changes, equivalent to around $200,000 to $400,000.

## Legislative Implications

91 Depending on final policy decisions, amendments would likely be made to the following legislation and regulations:

91.1 Hazardous Substances and New Organisms Act 1996;

91.2 Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998;

91.3 Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003.

92 Changes to the *Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998* would be made through an Order in Council and would implement any agreed-to policy changes proposed under Proposal 7 (Regulatory status of certain biotechnologies).

93 A legislative bill to make any agreed-to policy changes to the HSNO Act could be introduced to the House in 2024. Minor consequential amendments may be required to the Medicines Act 1981. Minor consequential amendments to the Biosecurity Act 1993 will be required to implement the proposed changes.

## Impact Analysis

### *Regulatory Impact Statement*

94 An Interim Regulatory Impact Statement has been prepared for this policy work and is included with this Cabinet paper (see Appendix 3). A quality assurance panel with members from MfE has reviewed the Interim Regulatory Impact Statement. The panel considers that it meets the Quality Assurance criteria.

95 The Interim Regulatory Impact Statement clearly sets out the context for the issues that it analyses and shows adequate consultation with affected parties. Furthermore, the Interim Regulatory Impact Statement contains a clear analysis of the options relative to the selected objectives. The quality assurance panel found the impact and cost-benefit analyses to be comprehensive. Overall, the quality assurance panel considers that the information and analysis in the Interim Regulatory Impact Statement meets the criteria necessary for Ministers to make informed decisions.

### *Climate Implications of Policy Assessment*

96 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to this proposal as the threshold for significance is not met.

## Treaty of Waitangi/Tiriti o Waitangi Assessment

97 As outlined above, an aspect of Proposal 6 has relevance to Article Two of the Treaty of Waitangi and is likely to be of significant interest to Māori.

98 Proposal 6 (Requirements for working with cells) would lower the regulatory restrictions on the use of cells and tissues from animals and plants, given their very low risk. Māori are likely to take an interest in what regulatory restrictions are placed on the genetic modification of cells and tissues of taonga species.[16] Under Article Two of the Treaty of Waitangi, the Crown promises that Māori will have the right to exercise rangatiratanga over their lands and taonga.

[16] Changes to the regulatory restrictions on the genetic modification of whole animals or plants that are considered taonga are not in scope of this review. The genetic modification of these whole animals or plants will still require EPA assessment and approval.

99 MfE intends to engage with hapū, iwi and Māori on how to provide for their interests in these matters. Regulatory restrictions may include that consultation with relevant hapū and iwi must be conducted before research is undertaken.

## Population Implications

*Implications for Māori*

100 Māori have a lower life expectancy and suffer from several diseases and health conditions at higher rates than the general population. As such, improving health and research outcomes would be likely to have relatively greater benefits for Māori than the general population.

101 Proposal 6 (Requirements for working with cells) encompasses regulatory restrictions on the genetic modification of human cells and tissues. Māori have a strong interest in informed consent being obtained from individual Māori and their whanau, hapū and iwi before the cells and tissues of those individuals are used in research, including research involving genetic modification.

102 Currently, requirements for obtaining informed consent are prescribed and given legislative power under the Human Tissues Act 2008. The supplementary consultation document for hapū, iwi and Māori will invite feedback from hapū, iwi and Māori on how research involving the genetic modification of human cells and tissues from Māori should be regulated.

103 The use of genetic material from Māori and genetic material from taonga species is also likely to have implications for Māori, particularly their kaitiaki relationship with these taonga species. The supplementary consultation document will invite feedback from hapū, iwi and Māori regarding how the use of genetic material from Māori and genetic material from taonga species should be regulated.

*Gender implications*

104 There are no specific gender implications of the proposals in this paper.

*Disability implications*

105 There are no specific disability implications of the proposals in this paper.

## Human Rights

106 The proposals in this paper and the attached consultation document are consistent with the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

## Consultation

107 The following government departments and agencies have been consulted on this paper and their views have been taken into account: Environmental Protection Authority, Department of Conservation, Ministry of Business, Innovation and Employment, Ministry of Health, Ministry for Primary Industries, Te Arawhiti, and Te Puni Kōkiri.

108 The Office of the Prime Minister's Chief Science Advisor was also consulted on this paper and their views were taken into account. The Department of the Prime Minister and Cabinet has been informed of the proposals in this paper.

109 The Ministry for Primary Industries (MPI) raised several concerns about the changes proposed. At a high level their main concerns relate to differential regulation, potential costs of outcome-based standards, and the evidential basis for identified issues.

110 They raised concerns about the potential for differential regulation of genetically modified new organisms and non-genetically modified new organisms. To reduce this risk, the scope of Proposals 2, 3, 4, 5 and 9 have been slightly widened to include new organisms rather than just GMOs.

111 MPI also raised concerns about the potential costs of outcome-based standards to some facility operators. As such, Proposal 9 presents three options rather than a single proposed change. The consultation document will specifically invite feedback from facility operators on whether they would incur extra costs due to a shift to outcome-based or hybrid standards.

## Communications

112 Should Cabinet agree to the recommendations outlined in this paper, the attached consultation document *Improving our GMO regulations for laboratory and biomedical research* will be released on MfE's website for public comment. Also released will be the supplementary consultation document for consultation with hapū, iwi and Māori.

113 Due to this being an area of particular interest to a number of groups, including for hapū, iwi and Māori, and because this is the first review of the GMO regulatory framework in 20 years, I am recommending that the proposed public consultation run for an eight-week period.

114 A press release will be issued alongside the publication of the consultation document and officials will contact relevant stakeholders to inform them of the consultation.

## Proactive Release

115 I propose to proactively release this paper on MfE's website within 30 business days, including any redactions as appropriate under the Official Information Act 1982.

## Recommendations

I recommend that the Committee:

1 **note** that the proposed policy changes contained within the consultation document focus on:

1.1 research undertaken within laboratory settings;

1.2 the assessment and approval of medicines that are or contain new organisms (which includes GMOs);

1.3 ensuring that the regulations for GMOs are both up to date and future-proof.

2 **note** that the proposed policy changes do not cover the provisions for field trials, conditional releases, and full releases of GMOs;

3 **approve** the release of the consultation document *Improving our GMO regulations for laboratory and biomedical research*, and the supplementary consultation document for hapū, iwi and Māori, for an eight-week public consultation period from the start of July;

4 **authorise** the Minister for the Environment to make minor design, editorial and technical changes to the consultation document as needed prior to its release.

Authorised for lodgement

Hon David Parker

Minister for the Environment

**Appendix 1. Consultation document -** ***Improving our GMO regulations for laboratory and biomedical research***

## Appendix 2. Supplementary consultation document for consultation with hapū, iwi and Māori

## Appendix 3. Interim Regulatory Impact Statement

ENV-23-MIN-0026

# Cabinet Environment, Energy and Climate Committee

## Minute of Decision



## Proposal to Publicly Consult on Changes to the Regulations for Genetically Modified Organisms to Support Laboratory and Biomedical Research

**Portfolio** **Environment**

On 22 June 2023, the Cabinet Environment, Energy and Climate Committee:

1 **noted** that following engagement with stakeholders in the New Zealand research community, the Ministry for the Environment (MfE) has developed policy options to improve the genetically modified organism (GMO) regulations for laboratory research and biomedical research & development;

2 **noted** that the proposed policy changes contained within the consultation document focus on:

2.1 research undertaken within laboratory settings;

2.2 the assessment and approval of medicines that are or contain new organisms (which includes GMOs);

2.3 ensuring that the regulations for GMOs are both up to date and future-proof.

3 **noted** that the proposed policy changes do not cover the provisions for field trials, conditional releases, and full releases of GMOs;

4 **approved** the release of the following consultation documents, attached to the submission under ENV-23-SUB-0026, for an eight-week public consultation period from the start of July:

4.1 Improving our GMO regulations for laboratory and biomedical research;

4.2 Improving our GMO regulations for laboratory and biomedical research: supplementary consultation document for hapū, iwi and Māori;

5 **authorised** the Minister for the Environment to make minor design, editorial and technical changes to the consultation document as needed prior to its release.

Rebecca Davies
Committee Secretary

**Present:**
Hon Dr Megan Woods
Hon Dr Ayesha Verrall
Hon Willie Jackson
Hon David Parker (Chair)
Hon Peeni Henare
Hon Kieran McAnulty
Hon Willow-Jean Prime
Hon Rachel Brooking

**Officials present from:**
Office of the Prime Minister
Officials Committee for ENV

CAB-23-MIN-0263

# Cabinet

## Minute of Decision



## Report of the Cabinet Environment, Energy and Climate Committee: Period Ended 23 June 2023

On 26 June 2023, Cabinet made the following decisions on the work of the Cabinet Environment, Energy and Climate Committee for the period ended 23 June 2023:

s 9(2)(f)(iv)

ENV-23-MIN-0027

ENV-23-MIN-0020

ENV-23-MIN-0024

ENV-23-MIN-0021

ENV-23-MIN-0022

ENV-23-MIN-0023

ENV-23-MIN-0025

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|---|---|---|
| ENV-23-MIN-0026 | **Proposal to Publicly Consult on Changes to the Regulations for Genetically Modified Organisms to Support Laboratory and Biomedical Research**<br>Portfolio: Environment | CONFIRMED |
| ENV-23-MIN-0028 | s 9(2)(f)(iv) | |

Diana Hawker
Acting Secretary of the Cabinet