Consultation document

Te whakapiki i ō mātou waeture GMO mō te rangahau taiwhanga pūtaiao me te rongoā koiora

Improving our GMO regulations for laboratory and biomedical research

Ministry for the Environment
Manatū Mō Te Taiao

Te Kāwanatanga o Aotearoa
New Zealand Government

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Abbreviations

Abbreviation	Meaning
ABSC	Accredited biosafety committee
DNA	Deoxyribonucleic acid
EPA	Environmental Protection Authority
GMO	Genetically modified organism
HSNO Act	Hazardous Substances and New Organisms Act 1996
MPI	Ministry for Primary Industries
Non-GMO Regulations	Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998
OGTR	Australian Office of the Gene Technology Regulator
PC	Physical Containment
RNA	Ribonucleic acid
SCOTT	Standing Committee on Therapeutic Trials
The Ministry	Ministry for the Environment

Message from the Minister

From cancer therapies to expanding our knowledge of biology, the use of genetic technologies in research and the development of biomedical therapies have advanced rapidly over the past three decades. But Aotearoa New Zealand's regulations have not kept pace with our better understanding of the benefits of genetically modified organisms (GMOs).

At its simplest, biotechnology is technology based on biology. Biotechnology harnesses cellular and biomolecular processes to solve problems and develop useful products. Biomedical therapies use biology and organisms, like cells, to create products that improve human health.

The Aotearoa research community has told the Government that the legislation and regulations for GMOs could be improved. Removing unnecessary barriers to research will have a greater positive impact for New Zealanders. It will foster innovative research and give us greater access to the most up-to-date biomedical therapies and medicines.

Like any technology, we need to learn to use genetic modification to our advantage. We are proposing changes to New Zealand's GMO regulations, so they contribute to better outcomes for New Zealanders through greater research and innovation.

This consultation is about the regulations and controls for GMOs used in laboratory settings and for biomedical research and development. We are not looking to change the rules related to field trials and releases of GMOs into the environment.

Our approach follows international practice. Across the world, other countries are modernising their GMO regulations, so they can more fully benefit from what these technologies offer.

These changes will allow our biotechnology research sector to advance scientific understanding and develop beneficial new technologies, by both simplifying the current system and ensuring appropriate checks and balances remain in place.

Ultimately, we all benefit from the work of our researchers throughout New Zealand and advancements in biomedical technologies that improve health outcomes.

I encourage you to have your say and look forward to receiving your input.

Hon David Parker
Minister for the Environment

Executive summary

This is a consultation on proposed improvements to the legislation and regulations concerning laboratory research, and biomedical research and development, for genetically modified organisms.

Genetic modification and genetically modified organisms (GMOs) are primarily regulated in Aotearoa New Zealand under the Hazardous Substances and New Organisms Act 1996 (HSNO Act), its regulations and related standards. Feedback from stakeholders and groups in the Aotearoa New Zealand research community suggest the legislation and regulations for GMOs could be improved, to remove unnecessary barriers to research and to have a greater positive impact for New Zealanders.

The 10 policy proposals in this document relate to the regulations and controls for laboratory research, the assessment and approval of medicines that are, or contain, new organisms (which includes GMOs), and to updating and future-proofing the legislation and regulations more generally. These proposed policy changes would require amendments to the HSNO Act, its regulations and related standards.

These policy proposals are intended to provide benefits to researchers, the research community and New Zealanders by:

- making more time and funding available for research by reducing the time and resources required for applications, approvals and day-to-day administrative tasks
- fostering new research efforts, innovation, educational opportunities and collaboration
- delivering better health outcomes for New Zealanders by streamlining assessment and approval processes for biomedical therapies
- providing greater certainty to researchers, organisations and biotechnology companies
- ensuring the regulatory framework for GMOs remains appropriately set and up to date.

How to have your say

The Government welcomes your comments on this consultation document. The questions throughout the document are a guide only and all comments are welcome. See appendix 4 for the full list of questions. You do not have to answer them all, and all comments are welcome. To ensure others clearly understand your point of view, you should explain the reasons for your views and give supporting evidence if needed.

Closing date for submissions

Send in your submission by 11:59pm, Friday 25 August 2023. For details on how to make your submission, see Part 3: How to get involved and have your say.

The consultation documents, and further details on how to make a submission, are available at https://consult.environment.govt.nz/comms/gmo-regulations. If you have questions or want more information about the policy proposals or the submission process, please email biomedicalreview@mfe.govt.nz.

What happens next?

After receiving submissions, we will analyse them to inform policy and government decisions. If Cabinet agrees to the proposed changes, amendments will be made to the HSNO Act (through an amendment Bill), to secondary legislation and to standards.

Part 1: Introduction

This document sets out policy proposals to improve the legislation and regulations for genetic modification in Aotearoa New Zealand. Genetic modification and genetically modified organisms (GMOs) are primarily regulated in Aotearoa New Zealand under the Hazardous Substances and New Organisms Act 1996 (HSNO Act), its regulations and related standards. These aim to ensure that the environment, and the health and safety of people and communities, are protected by preventing or managing the adverse effects of GMOs.[1]

Genetic modification, as it is generally understood, is the modification of an organism's genetic makeup (such as its deoxyribonucleic acid (DNA)), resulting in the creation of a GMO.[2] Genetic modification is used in numerous fields, including medicine, horticulture, agriculture, food production and industrial manufacturing. By altering gene function and expression, genetic modification enables applications ranging from gene therapies to treat diseases, to the development of plants resistant to pest species, to the production of useful enzymes, hormones and vaccines.

In November 2021, the Ministry for the Environment (the Ministry) engaged with stakeholders in the Aotearoa New Zealand research community to learn about their experience of working with the current GMO regulations. This engagement highlighted a number of issues with the current GMO regulatory settings that are likely to be hindering research and innovation to a degree disproportionate to the risks involved. Policy options to address these issues and improve the regulatory settings were developed across several areas.

Although the HSNO Act regulates GMOs across a range of scenarios, this policy work is not intended to be a full review of the regulations for GMOs, and it does not cover the provisions for field trials, conditional releases and full releases under the HSNO Act.[3]

The policy proposals in this document focus on:

- research undertaken within laboratory settings
- the assessment and approval of medicines that are, or contain, new organisms (which includes GMOs)
- ensuring that the regulations are both up to date and future-proof.

Although the scope of this work is generally limited to regulatory requirements for GMOs, for several proposals, limiting the scope to just GMOs could create issues or unnecessary differential regulations. In these instances, the scope of proposed changes has been widened to include new organisms rather than just GMOs. These proposed changes include those under Proposal 2, Proposal 3, Proposal 4, Proposal 5 and Proposal 9.

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1 The purpose of the HSNO Act (section 4) is to "protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms".

2 According to the HSNO Act (section 2(1)), a genetically modified organism is:

any organism in which any of the genes or other genetic material—

a) have been modified by *in vitro* techniques; or

b) are inherited or otherwise derived, through any number of replications, from any genes or other material which has been modified by *in vitro* techniques.

3 Excluding the provisions for the release of medicines that are, or contain, new organisms.

Changes that relate to GMOs under other legislation – such as the Biosecurity Act 1993 and the Medicines Act 1981 (which is currently planned to be replaced through the Therapeutic Products Bill) – are not within the scope of this policy work, though minor consequential amendments to this legislation would be required for the proposals outlined in this document. The scope of this policy work also specifically excludes changes to regulatory requirements for research on heritable human cells and tissue, otherwise referred to as germ cells.[4]

This consultation document outlines 10 proposed areas of improvement to the legislation and regulations for GMOs. Under each proposed area of improvement is an outline of the current regulatory status quo, issues identified with the status quo, and proposed changes to address these issues or improve the regulatory settings.

Objectives

We want to ensure that the regulatory framework in Aotearoa New Zealand for GMOs:

- proportionately manages the risks that laboratory research poses to the environment, and to the health and safety of people and communities[5]
- contributes to better health outcomes for New Zealanders through better biomedical research outcomes and innovation, and through greater access to therapies and medicines
- is not only up to date but also future-proof, to anticipate and flexibly accommodate future technological developments to the best extent possible.

These objectives were used when developing potential policy changes. The proposed policy changes were selected based on best meeting the objectives, compared with other changes considered.

Question	
1	In your view, are these objectives the most effective for developing policy changes to improve the regulatory settings for genetically modified organisms? If not, what should the objectives be, and why?
2	What features and overall approach would you like to see in a New Zealand regulatory framework for genetically modified organisms?

[4] Requirements under the HSNO Act for these cells will remain in place, as will other regulatory requirements for these cells under other regulations, such as the Human Assisted Reproductive Technology Act 2004, which also regulates activities involving human gametes (including both germ cells and gametocytes), embryos and foetuses.

[5] Including the health and safety of laboratory staff.

Part 2: Proposals to improve our GMO regulations

We are proposing 10 policy changes that we consider best meet the objectives listed above. These policy proposals are as follows.

1. Introduce a risk-tiering framework for laboratory research.
2. Reduce the assessment and approval requirements for medicines that are, or contain, new organisms.
3. Replace current record-keeping requirements.
4. Adjust internal audit frequency to be proportionate to risk.
5. Adjust the requirements for the movement of new organisms to be proportionate to risk.
6. Reduce regulatory requirements for the use of eukaryotic somatic cells.
7. Clarify the regulatory status of certain biotechnologies.
8. Reduce assessment requirements for low-risk fermentation.
9. Maintain or adjust the approach to standards for containment facilities.
10. Require regular reviews of regulatory settings.

Proposal 1: Introduce a risk-tiering framework for laboratory research

Proposed change

Introduce a risk-tiering framework for laboratory research that exempts certain research from Environmental Protection Authority assessment and approval requirements, and containment facility approval requirements.

Current situation and issues

Under the current regulatory settings, the importation into a containment facility or development of GMOs in containment requires approval from the Environmental Protection Authority (EPA). These applications are either assessed under a full approval pathway or, if meeting the criteria for being 'low risk', under a rapid assessment pathway.[6] A number of existing importation approvals can also be used by individuals or groups that can meet the specific requirements of those importation approvals. These requirements include being able to import those GMOs into a containment facility approved by the Ministry for Primary Industries (MPI), operated according to a relevant standard at a required Physical Containment (PC) level.

[6] The criteria for determining 'low risk' are set out under the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003.

Under current regulations, genetic modification research must be undertaken within laboratories that are approved by MPI as 'containment facilities'. These containment facilities must be operated according to specific standards relevant to the research being undertaken in those facilities, such as the MPI–EPA standard 154.03.02 (Facilities for Microorganisms and Cell Cultures: 2007a). These facilities must also be operated at a specific level of stringency based on the research being undertaken in those facilities, ranging from PC1 (the lowest stringency) to PC4 (the highest stringency).

The preparation of applications for laboratory research requires time and effort (and, by extension, funding) from researchers in the Aotearoa New Zealand research community. The time and effort taken to prepare these applications, along with the time and effort that may be required to apply for approval from internal biological safety committees, reduces the time and effort available for the research in question and naturally results in delays to research.

Although they have several important benefits, there are number of limitations to the low-risk rapid assessment provisions under the HSNO Act. The first is that the pre-assessment stage for a rapid assessment provision (the period when an application is being prepared by an applicant) can still be lengthy, running into weeks or months. Second, the current rapid assessment provisions do not allow research to be conducted in laboratories that are not approved as containment facilities by MPI.

Case-by-case assessment and approval by a regulator is appropriate for research that is not low risk, but applications to undertake research previously categorised as low risk are likely to be unnecessary.

It is also highly likely there is research that is of such low risk that a containment facility requirement may be unnecessarily stringent. Researchers surveyed by the Ministry noted that many low-risk organisms present essentially zero risk to the environment, or to the health and safety of people and communities.

As researchers noted, these organisms are incredibly dependent on specific laboratory conditions (one researcher described them as "cells on life support"). This dependence on specific laboratory conditions means these organisms are unlikely to survive, let alone proliferate, in the environment. In addition, many organisms, including human and animal cells, require stringent measures to ensure that contamination of the organism from the environment does not occur. Stringent measures to ensure nothing inadvertently gets in can naturally be expected to significantly reduce the likelihood of anything getting out.

Regulatory frameworks under other jurisdictions

Other international jurisdictions, most notably Australia, exempt certain research from needing to be assessed by a regulator, by explicitly outlining what research is exempt and the specific requirements and controls for these types of research.

For example, Australia's GMO regulations currently categorise research into risk tiers according to features such as host organism, vector, modification, and products of a modification. In addition, the conditions under which research is to be carried out, such as the type of laboratory required, are set out for each risk tier, both under the regulations and within guidelines published by Australia's Office of the Gene Technology Regulator (OGTR). Explicitly setting out the qualifying features and the conditions required for each risk tier removes the need for the OGTR to assess and approve low-risk research.

Included in the Australian framework is a risk tier under which very low-risk genetic modification research can be carried out in laboratories that are not certified by the OGTR. This is also the case under Canadian and United States legislative instruments, which do not regulate very low-risk genetic modification research or require facilities to be licensed to undertake this very low-risk research.

We consider there is likely to be genetic modification research of a similar risk profile (no risk or very low risk) that could be safely conducted in laboratories not approved as containment facilities by MPI. The relevant biological characteristics of the organisms used in this very low-risk research are likely to be:

- that they are not normally pathogenic to humans, animals, plants and fungi
- their low probability of survival in the environment if they are inadvertently released
- their inability to escape into the environment.

Proposed change

Our proposed change to reduce the administrative requirements associated with low-risk research is to establish a risk-tiering framework modelled on Australian regulations. According to specific criteria, certain low-risk research would be exempt from EPA assessment and approval for importation and development.[7] A key requirement of all risk tiers would be that any unapproved release of GMOs into the environment would be prohibited.

This framework would have risk tiers with the features and requirements outlined in table 1.

Table 1: Risk tiers and their features and requirements

Risk tier	Features and requirements
Risk tier 1	Research meeting the criteria of this risk tier would be exempt from Environmental Protection Authority (EPA) assessment and approval, including approval for the release of medicines that meet the criteria of this risk tier. In addition, the laboratory in which the research is undertaken would not need to be a containment facility approved by the Ministry for Primary Industries.
Risk tier 2	Research meeting the criteria of this risk tier would be exempt from EPA assessment and approval. 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). It would also be a requirement that a biosafety committee has confirmed that: • the research meets the criteria for this risk tier • the committee is satisfied the researcher can undertake the research • the facility is appropriate for the research. A record of each assessment would be sent to the EPA annually, and a short description of the research would be notified publicly.

[7] Inclusion of organisms under the 'host organism' part of a risk tier (as shown in appendix 3) would function as HSNO Act approval to import into containment, and subsequently develop those organisms into GMOs, according to the requirements of that risk tier.

Risk tier	Features and requirements
Risk tier 3	Research meeting the criteria of this risk tier would be exempt from EPA assessment and approval. The research would be required to be undertaken in an approved containment facility operated according to the relevant standard at PC2. It would also be a requirement that a biosafety committee has confirmed that: • the research meets the criteria for this risk tier • the committee is satisfied the researcher can undertake the research • the facility is appropriate for the research. A record of each assessment would be sent to the EPA annually, and a short description of the research would be notified publicly.

All other contained laboratory research that does not meet the criteria for risk tiers 1 to 3 would require assessment and approval by the EPA before being undertaken.

Provided research meets certain criteria and requirements, this proposed change would exempt certain low-risk laboratory research from EPA assessment and approval requirements. Risk tier 1 would also exempt research from containment facility requirements, functioning as a trust-based system for research that presents no risk or very low risk to the environment, or to the health and safety of people and communities.

In essence, the risk-tiering framework would function as HSNO Act approval for research that meets the specific criteria and requirements of the relevant risk tier. This would function in a similar way to existing import approvals that can be used by people other than the approved applicant if they meet the conditions associated with that approval, but it would also include development of GMOs.[8] This risk-tiering framework, like the existing import approvals, would not make redundant any existing import requirements under the Biosecurity Act 1993.

As noted under risk tier 1, medicines that meet the criteria of that risk tier would also be exempt from requiring EPA approval for their release. For example, should human cells be included under risk tier 1, personalised cancer treatments using human cells (such as CAR T-cell therapies) would be exempt from requiring EPA approval.[9] As with other medicines, these would still require approval from Medsafe before their use on patients.

Should Cabinet agree to implement a risk-tiering framework, the Ministry, in collaboration with the EPA, would undertake additional consultation on the details of each risk tier, including which organisms, modifications, vectors and exclusionary criteria would be included under each risk tier.

For illustrative purposes, appendix 3 includes the details of the current Australian risk-tiering framework, corresponding to the risk tiers 1 to 3 in table 1.[10] We invite feedback on whether any aspects or specific criteria in the Australian framework should or should not be included in any New Zealand risk-tiering framework.

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8 The EPA website provides a list of existing import approvals that can be used by people other than the applicant: Existing approvals you could use.

9 Provided these medicines meet the other criteria of risk tier 1 covering aspects like vectors and modifications.

10 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.

Of note, the rapid assessment provisions for low-risk GMO research will continue to be available for low-risk research that may fall outside the criteria of any of the risk tiers.

In our view, these changes would:

- lower the administrative requirements for researchers to gain approval for low-risk laboratory research, increasing the time available for research
- remove any disincentive to researchers using organisms and vectors that would be best for their research, which may not be included under their organisation's existing approvals
- lower start-up costs for new organisations and companies by removing the requirement to undertake certain research in a containment facility approved by MPI
- remove the requirement for EPA assessment and approval for therapeutic products and medicines that are, or contain, GMOs that would present little to no risk to the environment, or to the health and safety of people and communities.

For more on the costs, benefits and risks of this proposed change, see appendix 2.

Questions	
3	Do you agree with the proposed change: to establish a risk-tiering framework modelled on the risk-tiering framework under Australian regulations?
4	Do you agree with the issues outlined? Would you add any issues to the list? Why?
5	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?

Potential benefits of regulatory alignment with Australia

Several benefits would likely be gained from greater alignment with Australian regulations for genetically modified organisms.

Australia is a valuable partner for New Zealand in science and technology. More than 30 per cent of New Zealand's research community already has links with Australian counterparts, in areas such as agriculture, biotechnology, and environmental research. This relationship is growing, with collaborative arrangements between governments, Crown research agencies and tertiary institutions, as well as individual researchers.

By creating greater regulatory alignment, we would reduce the complexity of collaboration efforts, ease the transitions of researchers from one country to the other, and encourage biotech companies to expand from one country to another, bringing greater economic and employment opportunities to both New Zealand and Australia.

This will also build on other initiatives to increase cooperation between New Zealand and Australia in the science, research and innovation space. These include the 2017 Agreement Relating to Science, Research and Innovation Cooperation, which aims to create an adaptive, substantive and comprehensive foundation for developing a trans-Tasman innovation ecosystem.

Proposal 1.1: Biosafety committees

Under the proposed change presented in Proposal 1, certain risk tiers would require assessment by a biosafety committee, in place of assessment by the EPA. These biosafety committees would assess research proposals, including whether:

- the research meets the criteria for that risk tier
- the committee is satisfied the researcher can undertake the research
- the researcher's containment facility is appropriate for the research.

Proposed change

The proposal for implementing biosafety committees under a risk-tiering framework would contain three options for organisations.

1. Organisations would be able to form one or several biosafety committees and then apply to have the committee(s) accredited by the EPA, to become an accredited biosafety committee (ABSC).
2. Those organisations that do not wish to form, and gain accreditation for, their own biosafety committee could have their relevant research proposals assessed by another organisation's ABSC.
3. Organisations would also have the option of having their research assessed by a committee formed by the EPA for the purpose of assessing research proposals, like other ABSCs. This could potentially be modelled on the Health Research Council's Standing Committee on Therapeutic Trials (SCOTT), which meets at regular intervals to assess and decide on applications.[11]

Under this proposal, to ensure ABSCs are assessing research proposals correctly, the EPA would audit a proportion of assessment reports each year. For those ABSCs that require improvements to the quality of their assessments, the EPA would provide ongoing guidance or use other enforcement mechanisms, such as extra audits of future assessments.[12]

It has been noted that, because of the excessive administrative burden on delegation holders and the EPA, most of the previous delegations under the HSNO Act to Institutional Biological Safety Committees at many institutions were allowed to lapse. However, the functions of ABSCs under this proposal are intended to be significantly different from those of the previous delegations. This is because the criteria under the risk tiers will be more explicit than interpretive. For instance, organisms included under that risk tier will be explicitly listed, rather than using interpretive criteria such as "an organism that is not normally able to cause disease in humans, animals, plants, or fungi". The intention is that the assessment could be included as part of existing assessment processes by the likes of internal biosafety committees, to avoid unnecessarily duplicating existing processes.

In our view, these changes would:

- encourage, though not require, research organisations to establish biosafety committees, further promoting good biosafety practices in those organisations

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[11] Clinical trials that involve use of a new medicine require approval under section 30 of the Medicines Act 1981 (currently under review in the development of the Therapeutic Products Bill). The Health Research Council's SCOTT undertakes scientific assessment of applications to conduct trials and makes recommendations to the Director-General of Health on whether trials should be approved.

[12] Guidance could also be provided through an EPA-produced guide on assessing research proposals, similar to the Australian OGTR's Guidance on making a record of Assessment for NLRD and on responsibilities of those undertaking NLRDs.

- enable smaller organisations that do not have the capacity or need to establish an ABSC to have their research proposals assessed by another organisation's ABSC or the EPA biosafety committee.

Questions	
6	Do you agree with the proposed establishment of accredited biosafety committees and an Environmental Protection Authority biosafety committee?
7	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?

Proposal 2: Reduce the assessment and approval requirements for medicines that are, or contain, new organisms

Proposed change

Reduce the regulatory requirements for medicines that are, or contain, new organisms by:

- streamlining section 38I assessments
- creating an alternative assessment pathway for medicines unlikely to result in viable new organisms making their way into the environment
- enabling medical devices to be rapidly assessed.

Current situation and issues

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 (for human medicines) and MPI (for veterinary medicines).[13]

Applications to release organisms that are, or are contained in, medicines are made under section 34 of the HSNO Act. Section 38I of the Act also provides for the rapid assessment of these medicines if they are evaluated as low risk. Until now, nearly all of these medicines have been rapidly assessed and approved by the EPA under section 38I (that is, assessed in under 10 days).

For these new organisms to be rapidly assessed under section 38I, the EPA must evaluate and determine that they meet the criteria of a (low-risk) 'qualifying organism' set out under section 38I(3) of the HSNO Act.[14] If an organism meets these criteria, the EPA may make a rapid assessment of the adverse effects of the release of this organism and approve its release with or without controls.

Despite most applications so far being rapidly assessed by the EPA, the time taken to prepare application documents, and the delays before an application is formally accepted for rapid

[13] Approval for the release of a qualifying organism under the HSNO Act does not constitute an approval to use that qualifying medicine until the medicine has been given consent for distribution under the Medicines Act 1981, or for use under the Agricultural Compounds and Veterinary Medicines Act 1997.

[14] For a new organism to meet the definition of a 'qualifying organism' it must be, or be contained in, a 'qualifying medicine'. For a medicine to be a 'qualifying medicine', it must contain a new organism and meet the criteria set out under section 38I(3) of the HSNO Act.

assessment, mean the application process may run into several weeks or months. Researchers have described the approval process to release a qualifying organism as arduous and particularly lengthy, leading to delays for clinical trials.

Another issue with the current scope of section 38I of the HSNO Act is that it does not include medical devices. Under section 3(c) of the Medicines Act 1981, the definition of medicine specifically does not include medical devices. This therefore excludes medical devices that are, or contain, new organisms from being rapidly assessed under section 38I of the HSNO Act, instead requiring them to be assessed under a full publicly notified pathway. Although the Therapeutic Products Bill proposes to include both medicines and medical devices under the definition of a 'therapeutic product' (which would bring medical devices under section 38I of the HSNO Act), the time required to fully implement the Therapeutic Products Bill would leave this as a gap for several years.[15]

Because section 38I of the HSNO Act also covers the assessment and approval of veterinary medicines that are, or contain, new organisms, it is intended that changes proposed below (that are relevant) would also be applied to veterinary medicines that are, or contain, new organisms. This would ensure these changes do not result in differential regulation of human medicines and animal medicines under the same section of the HSNO Act.

Proposed changes

To improve the assessment and approval provisions for medicines that are, or contain, new organisms (which includes GMOs), we are proposing several changes.

The first proposed change is the removal of the current first stage of section 38I assessments, involving the evaluation of whether a new organism meets the criteria of a (low-risk) 'qualifying organism'. By removing this first stage, medical release applications could be straightforwardly rapidly assessed for adverse effects (the current second stage of section 38I assessments), reducing information required from applicants and the EPA's overall assessment time. Under this proposed change, the EPA would still retain the right to decline an application under section 38I, should it determine that a rapid assessment would be insufficient for a particular application. Those applications could then be evaluated under a full publicly notified assessment pathway.

The second proposed change is to introduce an alternative assessment pathway for medicines that are unlikely to result in viable new organisms making their way into the environment. Under this rapid assessment pathway, application information requirements would concentrate on whether, through shedding or excretion, the new organism is likely to make its way into the environment. Australia's regulations differentiate between medicines in this way through two approval types: Dealings involving intentional release and Dealings not involving intentional release. This change would have the benefit of reducing the amount of information and time required from researchers to complete applications.

The third proposed change is to amend the medical release provisions of the HSNO Act so that medical devices that are, or contain, new organisms would be able to be rapidly assessed, rather than requiring assessment under a full publicly notified pathway.

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[15] The intention is for the HSNO Act to use the definition of therapeutic product under the Therapeutic Products Bill, to ensure there is no conflict between the two legislative instruments for the purpose of section 38I applications.

In our view, these changes would:

- lower the information requirements for medical release applications, reducing the time, effort and funding required from researchers
- reduce assessment requirements for the EPA, freeing up time to assess other applications
- reduce unnecessary financial and time barriers for the approval of medical devices that are, or contain, new organisms.

For more on the costs, benefits and risks of these changes, see appendix 2.

Questions	
8	Do you agree with the proposed changes: to streamline assessments under section 38I of the Hazardous Substances and New Organisms Act 1996, to introduce an alternative assessment pathway for medicines unlikely to result in viable new organisms from being released into the environment, and to enable rapid assessment of medical devices?
9	Do you agree with the issues outlined? Would you add any issues to the list? Why?
10	Are there other policy changes that, in your view, would provide more benefits or better meet the objectives than the proposed changes above?

Proposal 3: Replace current record-keeping requirements

Proposed change

Replace current record-keeping requirements with two requirements, for:

- new organisms, and containers containing new organisms, to be labelled to indicate they are, or contain, new organisms
- a documented system of accounting for:
  - new organisms in containment facilities operated at Physical Containment level 3
  - animals with the ability to escape, in all containment facilities.

Current situation and issues

Record-keeping requirements for new organisms are prescribed under four containment facility standards, covering micro-organisms and cell cultures, vertebrate laboratory animals, plants, and invertebrates.[16] These requirements vary according to each standard but generally include the species and strains of the organisms held. They can also include details on genetic modifications, corresponding HSNO Act approvals, dates of import, dates of development, researchers responsible for the organisms, and the status of the organism.

Record-keeping requirements for low-risk research was one of the issues most frequently cited by researchers surveyed by the Ministry. In the view of researchers, the amount of time and effort required for maintaining these records was excessive, considering the low risk of

[16] These are: 154.03.02 Facilities for Microorganisms and Cell Cultures 2007a, 154.03.03 Containment Facilities for Vertebrate Laboratory Animals 2002, 155.04.09 Containment Facilities for Plants 2007 and 154.02.08 Transitional and Containment Facilities for Invertebrates 2002. Standards for containment facilities are approved by the EPA under section 11(1)(fc) of the HSNO Act.

their research. It is common for GMOs to be created daily in most laboratories. With record-keeping required for each new variant and sample created, the cumulative time and energy required to maintain these records across the many laboratories in New Zealand is likely to be very significant.

Unlike requirements that would lower the risk of accidental cross-contamination or enable researchers and compliance officers to verify that animals have not escaped, it is unclear how the details required in current records further reduce risk from already low-risk new organisms (and to a degree that would sufficiently outweigh the cost incurred by researchers).

In contrast to the record-keeping requirements set under the four standards mentioned above, Institutional Low-Risk Approvals given to the University of Auckland, University of Otago and Massey University require only that "the approved organism(s) must be identifiable as a new organism and be able to be linked to the relevant HSNO Act approval".[17]

Proposed change

The proposed change is to replace the current record-keeping requirements with two requirements, namely that:

- new organisms, or containers that contain new organisms, must be labelled to indicate that they are, or contain, new organisms[18]
- a documented system of accounting must be in place for:
  - new organisms in containment facilities operated at PC3
  - animals with the ability to escape, for all containment facilities.[19]

This requirement would apply to all new organisms (including GMOs) that are required to be held in a containment facility approved by MPI.

Additionally, if the risk-tiering framework under Proposal 1 is implemented, for laboratories that would not need to be approved as containment facilities (as under risk tier 1 of the proposed framework), regulations would also require new organisms, or containers containing new organisms, to be labelled to indicate they are, or contain, new organisms.

It would decrease the likelihood of accidental cross-contamination between GMOs and non-GMOs (as well as new organisms and not-new organisms), while still allowing researchers to keep records in a way most suitable to their research.

New organisms requiring a containment facility operated at PC3 have a higher risk of causing adverse effects, and there would be a higher risk of escape of animals. This means an accounting system would likely be a sensible requirement to enable both researchers and compliance officers to verify that those new organisms have not escaped or been taken by unauthorised persons.[20]

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17 At paragraph 8 of each EPA Institutional Low-Risk Approval: APP202708, APP201859 and APP203504.

18 Because GMOs are included under the definition of new organisms under section 2A(1)(d) of the HSNO Act, a label indicating that an organism is a GMO, or that a container contains a GMO, would also satisfy this new requirement.

19 'Animals with the ability to escape' here refers to those animals that have the ability to escape their cages/containers.

20 In addition to other control measures to ensure new organisms are contained and unauthorised persons are not able to gain entry to those containment facilities.

We are also interested in whether a new labelling requirement should also include that a new organism or its 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 Institutional Low-Risk Approvals given to the University of Auckland, University of Otago and Massey University.

In our view, this change would:

- reduce administrative burden on researchers, increasing time available for research
- retain a safeguard against accidental cross-contamination between new organisms and organisms
- enable researchers and MPI compliance officers to verify that higher-risk new organisms and animals are accounted for
- free up time for researchers, biosafety officers and compliance officers to concentrate on areas of higher risk.

For more on the costs, benefits and risks of this change, see appendix 2.

Questions	
11	Do you agree with the proposal to replace the current record-keeping requirements with a new labelling and accounting requirement?
12	Do you think labelling requirements should also include that new organisms should be able to be linked to the relevant HSNO Act approval? If not, why?
13	Do you agree with the issues outlined? Would you add any issues to the list? Why?
14	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?

Proposal 4: Adjust internal audit frequency to be proportionate to risk

Proposed change

Reduce the frequency of internal audits for containment facilities operating at Physical Containment level 1, from 6 months to a minimum of 12 months.

Current situation and issues

Currently, standards set under the HSNO Act require an internal audit of a containment facility to be carried out by a facility operator every six months. These standards also allow MPI compliance officers to inspect containment facilities at any time, though generally inspections of containment facilities are carried out every 12 months.

Researchers and laboratory managers surveyed by the Ministry noted that the frequency of internal audits for containment facilities operating at PC1 and PC2 seemed unnecessarily high, considering the low risk of research carried out in these facilities. Internal audits require time from facility staff and researchers, which likely takes away time that could be spent on research.

Proposed change

The proposed change is to reduce the frequency of internal audits for containment facilities operating at PC1 to a minimum of 12 months.

The proposed change in audit frequency for these containment facilities would apply to new organisms, rather than just GMOs.[21] This would ensure those facilities operating at PC1 that hold both non-genetically modified new organisms and GMOs (of similar risk profiles) would still benefit from a reduction in internal audit frequency.

The frequency of internal audits at those facilities operating at PC2 would remain at six months. In addition, the frequency of inspections for facilities operating at PC1 and PC2 would remain unchanged (at 12 months), with MPI retaining the right to conduct an inspection of a facility at any time.

These proposed audit and inspection frequencies are outlined in table 2.

Table 2: Proposed audit and inspection frequencies

	Internal audit frequency	Inspection frequency
Physical Containment level 1 facilities	12 months (minimum)	12 months / anytime
Physical Containment level 2 facilities	6 months (minimum)	12 months / anytime

Operators of facilities approved as both containment facilities and transitional facilities would not be adversely affected by these changes, because they could continue their current practice of conducting internal audits every six months.

In our view, this change would:

- reduce the administrative burden for facility operators, and their staff and researchers
- proportionately regulate facilities according to the level of risk they may pose to the environment, or to the health and safety of people and communities
- retain the ability for MPI to respond to significant non-compliances by conducting inspections at any time.

For more on the costs, benefits and risks of this option, see appendix 2.

Questions	
15	Do you agree with the proposed change: to reduce the internal audit frequency requirement for containment facilities operating at Physical Containment level 1?
16	Do you agree with the issues outlined? Would you add any issues to the list? Why?
17	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?

[21] However, it would not apply to zoo containment facilities, which must comply with controls set under 154.03.04 Standard for Zoo Containment Facilities 2018.

Proposal 5: Adjust the requirements for the movement of new organisms to be proportionate to risk

Proposed change

Remove current movement approval requirements for laboratories, and containment facilities operating at Physical Containment level 1, provided specific conditions are met.

Current situation and issues

Requirements for the movement of new organisms (which includes GMOs) between containment facilities are currently outlined under four MPI–EPA facilities standards covering micro-organisms and cell cultures, vertebrate laboratory animals, plants and invertebrates.[22] Movement of new organisms between facilities (containment facilities and transitional facilities) requires several conditions to be met, including prior authorisation granted by MPI, appropriate packaging and labelling (including double containment), prior authorisation from both facilities, and tracking of the movement.[23]

Meeting the requirements for the movement of new organisms requires time and effort from researchers in the Aotearoa New Zealand research community that may exceed the measures necessary to sufficiently reduce risk. The time and effort required also likely negatively effect collaboration between research teams in Aotearoa New Zealand and, by extension, eventual research outputs.

Proposed changes

The first proposed change is that, under the risk-tiering framework outlined in Proposal 1, movement authorisation from MPI would not be required for the movement of GMOs meeting the criteria of risk tier 1. The movement of such GMOs between laboratories would be permitted by regulations, provided the following conditions were met.

- The GMOs to be transported should be wholly contained inside a sealed, unbreakable primary container.
- The container should be labelled to indicate that it contains GMOs.
- The transport of these GMOs should be conducted in such a way as to prevent the inadvertent release of those GMOs into the environment.

The second proposed change is to remove the current MPI movement authorisation requirements for the movement of GMOs requiring a containment facility operating at PC1. This requirement would also be removed for non-genetically modified new organisms that require a containment facility operated at PC1.

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[22] These are: 154.03.02 Facilities for Microorganisms and Cell Cultures 2007a, 154.03.03 Containment Facilities for Vertebrate Laboratory Animals 2002, 155.04.09 Containment Facilities for Plants 2007 and 154.02.08 Transitional and Containment Facilities for Invertebrates 2002. Standards for containment facilities are approved by the EPA under section 11(1)(fc) of the HSNO Act.

[23] Section 25(4) and section 29 of the Biosecurity Act 1993 require that new organisms may only leave containment facilities on the authority of an inspector.

The movement of these GMOs and non-genetically modified new organisms would be permitted by regulations, provided the following conditions were met.

- The organisms to be transported should be wholly contained inside a sealed, unbreakable primary container.
- The container should be labelled to indicate that it contains GMOs/new organisms.
- The containment facility the organisms are being sent to is operated at a PC level equal to or greater than PC1.
- The facility operator of the sending facility confirms the movement meets these requirements.
- Both the sending and receiving facilities record the movement in a register.

Guidance on how to meet the container and labelling requirements for both changes would be published.

In our view, these changes would:

- reduce the administrative burden on researchers in transferring new organisms to other laboratories
- reduce barriers to greater collaboration between researchers and laboratories in Aotearoa New Zealand
- place requirements on the movement of new organisms that are proportionate to their risk.

For more on the costs, benefits and risks of this option, see appendix 2.

Questions	
18	Do you agree with the proposed change: to remove movement authorisation requirements for laboratories, and containment facilities operating at PC1, provided specific conditions are met?
19	Do you agree with the issues outlined? Would you add any issues to the list? Why?
20	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed option above?

Proposal 6: Reduce regulatory requirements for the use of eukaryotic somatic cells

Proposed change

Include eukaryotic somatic cells under risk tier 1 of the proposed risk-tiering framework.

Current situation and issues

A common frustration expressed by researchers surveyed by the Ministry was the level of regulatory restrictions to work with somatic cells in a laboratory setting, in particular, human cells. Somatic cells are cells that are non-heritable, making them distinct from heritable cells, which are the reproductive cells of an organism.

Currently, cells from all organisms, including human cells, are included under the definition of an 'organism' under section 2(1) of the HSNO Act. As such, genetic modification of these cells would result in those cells being classified as GMOs and regulated by the HSNO Act. This means approval is required from the EPA to import, develop, field test, and release genetically modified cells (including the release of cell-based medical therapies).

In the view of researchers, these cells pose essentially zero risk to the environment or people and communities, and are reliant on specific laboratory conditions, making their survival in the environment highly unlikely. In addition, stringent measures taken by researchers to eliminate environmental contamination to these cells means their inadvertent escape from their containers is also highly unlikely.

Proposed change

The proposed change is that, under the risk-tiering framework outlined in Proposal 1, certain eukaryotic somatic cells would be included under risk tier 1.[24]

Eukaryotic cells are cells of eukaryotes, which as a category include animals, plants, fungi and many unicellular organisms, and which are distinct from bacteria and archaea. Risk tier 1 would likely include the somatic cells and tissues of animals, humans and plants.

This proposed change would mean the genetic modification of these cells would be exempt from EPA assessment and approval requirements and would not need to be undertaken in a containment facility approved by MPI. Specifically, these cells would be exempt from EPA assessment and approval for importation, development and use as or in a medicine.

The genetic modification of these cells would likely include the following conditions.

- The donor nucleic acid must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy human beings, animals, plants or fungi.
- The donor nucleic acid must not code for a toxin with an LD_{50} of less than 100 micrograms per kilogram.
- If the donor nucleic acid includes a viral sequence, it cannot give rise to infectious agents when introduced into any potential host species.
- The cells or tissues must not include human embryonic stem cells, germ cells, oocytes, zygotes or early embryos.
- The plant cells or tissues cannot spontaneously generate a whole plant and cannot be regenerated into a whole plant.

In our view, this change would:

- reduce administrative burdens to use cells that pose no risk or very low risk to the environment, or to the health and safety of people and communities, increasing time and funding available for research
- likely increase research using human cells, in turn leading to increased biomedical research and development outcomes.

[24] These eukaryotic cells may be similar to those under the 'Exempt dealings' tier of Australia's risk-tiering framework described in the OGTR's Types of GMO dealings, details of which are included in appendix 3.

For more on the costs, benefits and risks of this option, see appendix 2.

Questions	
21	Do you agree with the proposed change – to include certain eukaryotic somatic cells under risk tier 1 of the risk-tiering framework outlined in Proposal 1?
22	Do you agree with the issues outlined? Would you add any issues to the list? Why?
23	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?

Proposal 7: Clarify the regulatory status of certain biotechnologies

Proposed change

Clarify the regulatory status of certain biotechnologies under the Hazardous Substances and New Organisms Act 1996, including introduction of ribonucleic acid (RNA) into an organism, introduction of deoxyribonucleic acid (DNA) into an organism, and epigenetic modifications.

Current situation and issues

Whether the use of a biotechnology is regulated by the HSNO Act is determined by the definitions of the Act, regulations under the HSNO Act and statutory determinations made by the EPA.[25]

Biotechnologies exempt from regulation under the HSNO Act are listed under the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998 (Non-GMO Regulations). For example, under these regulations, technologies such as chemical mutagenesis or cell fusion are specified as technologies that would not result in a GMO.

Section 26 of the HSNO Act provides a mechanism by which the EPA can make a statutory determination on whether an organism is a new organism for the purposes of the HSNO Act.

However, although statutory determinations clarify the regulatory status of biotechnologies under the HSNO Act, the utility of statutory determinations is limited in two ways. First, statutory determinations must be applied for and cannot be initiated by the EPA. Second, existing statutory determinations are publicly available but may not be easily discoverable by researchers, organisations or biotechnology companies.

Proposed change

The proposed change is to clarify that certain biotechnologies do not result in a GMO. Compared with statutory determinations, biotechnologies listed under the Non-GMO Regulations are likely to be more easily discoverable and likely to provide greater certainty to researchers, organisations and biotechnology companies. The proposed change will clarify, under the

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

Non-GMO Regulations, that the use of three biotechnologies, according to specific criteria, do not result in a GMO.

1. **The introduction of ribonucleic acid (RNA) into an organism** – examples of this technology include mRNA vaccines, such as the Pfizer vaccine for SARS-CoV-2. Exclusionary criteria associated with this clarification could include that the introduction of RNA:
   - cannot result in an alteration of the organism's genome sequence
   - cannot give rise to an infectious agent.
2. **The introduction of DNA into an organism** – examples of this technology include DNA vaccines, which are an advancing technology. Exclusionary criteria associated with this clarification could include that the introduction of DNA:
   - cannot result in an alteration of the organism's genome sequence
   - cannot give rise to an infectious agent
   - cannot be independently replicative.
3. **Epigenetic modifications** – these are modifications to the expression of genes that do not change the underlying genetic sequence of an organism.

Genetic modification is generally considered to be the modification of an organism's genetic makeup (that is, the modification of the DNA in their genome). The conditions placed on the above three biotechnologies would prohibit modifications to the genetic makeup of an organism, including gene editing techniques in any form.

In our view, these changes would:

- provide greater clarity and certainty to researchers, organisations and biotechnology companies, potentially encouraging increased use of these biotechnologies in research and in the development of biomedical therapies
- codify previous statutory determinations that researchers may not know of or be able to readily discover.

For more on the costs, benefits and risks of this option, see appendix 2.

Questions	
24	Do you agree with the proposed change: to clarify the regulatory status of the introduction of ribonucleic acid (RNA) into an organism, the introduction of deoxyribonucleic acid (DNA), and epigenetic modifications under the HSNO Act?
25	Are there any exclusionary criteria that, in your view, should or should not be associated with any of these three biotechnologies?
26	Do you agree with the issues outlined? Would you add any issues to the list? Why?
27	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above? In your view, should the status of any other biotechnologies be clarified under regulations?

Proposal 8: Reduce assessment requirements for low-risk fermentation

Proposed change

Remove Environmental Protection Authority approval and assessment requirements for fermentation of low-risk organisms under a risk-tiering framework.

Current situation and issues

Fermentation ('bulking up') of GMOs is an essential part of the manufacture of a range of products, including medicines such as vaccines. The HSNO Act currently requires that researchers or organisations wishing to carry out fermentation of GMOs at volumes greater than 10 litres per vessel must gain approval for that fermentation. This can be done either by applying for a standalone fermentation approval or by including fermentation approval with an importation or development application. Like other application types involving low-risk GMOs, applications for low-risk fermentation can be assessed by the EPA under a rapid assessment pathway.

In addition to any measures specified by the EPA, safety requirements for personnel at large-scale fermentation facilities are also prescribed under the Health and Safety at Work Act 2015, which specifies the duties of a Person Conducting a Business or Undertaking who manages, controls, installs, constructs or commissions fermentation vessels.[26]

Although fermentation applications can be rapidly assessed (or included in other applications), the time required from researchers and organisations to complete these applications would likely take time and funding away from research and development.

Proposed change

The proposed change is that, under the risk-tiering framework outlined in Proposal 1, for research that meets the criteria of risk tiers 1 to 3, EPA assessment and approval requirements would be replaced by ABSC assessment. Additionally, depending on the research in question, fermentation meeting the criteria of risk tiers 1 to 3 would require a containment facility operating at either PC1 or PC2.

For fermentation, risk-tiers would have the feature described in table 3.

Table 3: Risk tiers of fermentation

Risk tier	Conditions and requirements
Risk tier 1	Fermentation of genetically modified organisms meeting the criteria of this risk tier could be undertaken at a volume up to 10 litres per vessel. Fermentation at volumes greater than 10 litres would have to meet the requirements of risk tier 2: a containment facility operating at Physical Containment level 1 (PC1) and assessment of the fermentation proposal by an accredited biosafety committee (ABSC).

[26] These are specified under section 38 and section 43 of the Health and Safety at Work Act 2015. Fermentation vessels are included under the definition of 'plant' in section 16 of the Act.

Risk tier	Conditions and requirements
Risk tier 2	Research meeting the criteria of this risk tier would be exempt from Environmental Protection Authority (EPA) assessment and approval requirements, provided the research is: • conducted in a containment facility operated at PC1 • assessed by an ABSC, with a record of the assessment provided to the EPA on an annual basis. In addition to confirming that the research meets the criteria of risk tiers 1 or 2, the ABSC would also need to be satisfied that proposed controls would be adequate to fully contain a spill from the fermentation vessel.
Risk tier 3	Research meeting the criteria of this risk tier would be exempt from EPA assessment and approval requirements, provided the research is: • conducted in a containment facility operated at PC2 • assessed by an ABSC, with a record of the assessment provided to the EPA on an annual basis. In addition to confirming that the research meets the criteria of risk tier 3, the ABSC would also need to be satisfied that proposed controls would be adequate to fully contain a spill from the fermentation vessel.

All other contained laboratory research that does not meet the criteria for risk tiers 1 to 3 would require a fermentation approval from the EPA before being undertaken.

Assessment by an ABSC is likely to provide sufficient risk-management oversight for the fermentation of low-risk organisms within a containment facility.

In our view, this change would:

- reduce the administrative burden on researchers, organisations and companies, by removing the requirement for EPA assessment and approval
- proportionately regulate fermentation according to the level of risk it may pose to the environment, or to the health and safety of people and communities.

For more on the costs, benefits and risks of this option, see appendix 2.

Questions	
28	Do you agree with the proposed change: to remove EPA assessment and approval requirements for fermentation of GMOs meeting the criteria of risk tiers 1 to 3?
29	In your view, do you think that the current maximum vessel size not requiring EPA assessment and approval (10 litres) should be increased?
30	Do you agree with the issues outlined? Would you add any issues to the list? Why?
31	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?

Proposal 9: Maintain or adjust the approach to standards for containment facilities

Proposed change

Maintain or adjust the approach to setting control measures under containment facility standards for new organisms.

Current situation and issues

Requirements for facilities that handle GMOs are currently specified under four standards approved under the HSNO Act and the Biosecurity Act 1993.[27] These standards cover both containment facilities and transitional facilities for micro-organisms and cell cultures, vertebrate laboratory animals, plants and invertebrates.[28]

Since the publication of these four standards, the EPA has also moved towards 'outcome-based' controls for the approvals it grants. These outcome-based controls allow researchers to use control measures in their containment facilities that may be more appropriate to the specific organism and research in question, relative to prescriptive controls.

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 (such as 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.

Potential changes

Unlike the other nine proposals in this document, for this proposal, we invite feedback on three potential future options for standards:

- keeping the status quo approach
- shifting to outcome-based standards
- shifting to a hybrid approach.

Status quo

This option would maintain the current status quo: prescriptive standards for containment facilities that hold new organisms. Changes may be made to specific controls prescribed under these standards, but the overall approach would remain the same.

A benefit of this option is that standards for containment facilities and transitional facilities would have the same broad approach. Small organisations with containment facilities may also

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[27] These are: 154.03.02 Facilities for Microorganisms and Cell Cultures 2007a, 154.03.03 Containment Facilities for Vertebrate Laboratory Animals 2002, 155.04.09 Containment Facilities for Plants 2007 and 154.02.08 Transitional and Containment Facilities for Invertebrates 2002.

[28] 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.

find it easier to implement measures that meet prescriptive controls, compared with the extra effort that may be required to meet outcome-based controls.

As noted above, however, a potential downside to this approach is that prescriptive controls may not provide the best containment of new organisms in all scenarios.

Outcome-based standards

An alternative is to replace the current standards with one or multiple outcome-based standards (that is, standards specifying outcome-based controls) for containment facilities that hold new organisms. Outcome-based controls specify an outcome that must be achieved, for instance '*the containment facility must be designed, constructed, managed, and maintained to prevent new organisms from escaping*', but allow facility operators to choose how that outcome is achieved.

Where relevant, these controls would only supersede the containment facility controls for new organisms currently set under the four standards referred to above. They would not supersede any specific controls for not-new organisms or controls for transitional facilities, which may remain prescriptive. These outcome-based controls would likely be similar to the outcome-based controls required under the broad approvals granted to the University of Auckland, University of Otago and Massey University.[29]

In addition to these outcome-based standards for new organisms, several domain-specific and PC level–specific guides would be published. These guides would outline how outcome-based controls under these standards could be effectively implemented, likely through providing common principles for facility operators to consider, along with examples of best practice. The development of these guidance documents could also be done through collaboration between relevant government agencies and industry representatives.

An example of this is the guidance document for zoo containment facilities, prepared by MPI in collaboration with industry representatives.[30] This functions as a guide to understanding and implementing the requirements set out in the Standard for Zoo Containment Facilities 2018. It gives examples of how a zoo containment facility can meet the requirements of the standard, but it does not replace the requirements contained in the standard.

One consideration is that new organisms held in facilities that are approved as both containment facilities and transitional facilities would be technically subject to both outcome-based controls and prescriptive controls. It may be that in these scenarios, operators of these facilities would not incur extra costs, because they could meet outcome-based controls through continuing to use their existing prescribed control measures. However, we are interested in hearing from facility operators as to whether different approaches for containment facilities and transitional facilities would likely result in extra costs for them.

Hybrid option

The hybrid option would be similar to the outcome-based standards option above but would also combine aspects of the status quo. Under this approach, outcome-based controls would be specified for containment facilities that hold new organisms. In addition, default measures

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[29] These broad EPA approvals are referred to as 'Institutional Low-Risk Approvals': APP202708, APP201859 and APP203504.

[30] Ministry for Primary Industries. 2019. *Guidance Document: Generally Accepted Practice in New Zealand Zoo Containment Facilities*. Wellington: Ministry for Primary Industries.

that would meet these outcome-based controls would also be specified. Facility operators could choose to implement either the default measures that would meet the outcome-based controls or other non-default measures that would also meet the outcome-based controls.

This approach may benefit facility operators if non-default measures were easier or less costly to implement or would better contain new organisms. In addition, facility operators would also be able to continue to use their existing prescribed control measures. However, as with the outcome-based approach above, we are interested in hearing from facility operators as to whether this approach would result in extra costs for them.

Domain-specific and PC level–specific guides would also be published to provide guidance on how outcome-based controls could be effectively implemented.

We are also interested in hearing from biosafety officers, researchers and facility operators on what approaches might best upskill and improve biosafety practises in Aotearoa New Zealand. Specific approaches, for instance, may allow international manuals such as the International Organization for Standardization's 2019 International Standard for Biorisk Management (ISO 35001:2019) or the World Health Organization's Laboratory Biosafety Manual to be incorporated into guidance on best practise.

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 regulatory agencies will be required following this consultation. This would include ensuring that operational processes were updated to ensure sufficient verification of facilities should a shift in approach occur.

For more on the costs, benefits and risks of this option, see appendix 2.

Questions	
32	Of the three options presented above, which is your preferred option and why?
33	Do you agree with the issues outlined? Would you add any issues to the list?
34	Do you run a facility that is approved as both a containment facility and a transitional facility? Would the costs of a shift to outcome-based or hybrid standards for new organisms outweigh any benefits to you or those who use your facilities?
35	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the three options above?

Proposal 10: Require regular reviews of regulatory settings

Proposed change

Introduce a provision to the Hazardous Substances and New Organisms Act 1996 requiring the Ministry for the Environment to undertake a review of Aotearoa New Zealand's genetically modified organism regulations at least every five years.

Current situation and issues

A common criticism of the current GMO regulations in Aotearoa New Zealand is that they are out of date, having not been fully reviewed in more than 20 years. During this time,

biotechnologies have advanced significantly, as has the collective understanding of the benefits and risks of biotechnologies.

With the rapid pace of advances in biotechnology, there is likely a need for New Zealand's GMO regulations to be reviewed regularly, to ensure they are not out of date and to regulate research appropriately.

The HSNO Act currently has no provisions requiring regular reviews of the Act's GMO settings. This means reviews are dependent on the Ministry deciding to undertake them, either as part of its regulatory stewardship role or in response to ministerial direction.[31] Both options are affected by competing priorities, reducing the likelihood of necessary reviews being undertaken.

Proposed change

The proposed change is for a provision to be added to the HSNO Act requiring the Ministry to conduct a review of the regulatory settings for GMOs at least every five years (or within another similar timeframe).[32]

A written report of each review, which would include recommendations for changes to the regulatory settings (if applicable), would be provided to the Minister for the Environment.

This review would also encompass horizon-scanning for new biotechnologies (and the regulatory settings appropriate for these new biotechnologies). It could also include a summary of any relevant changes to regulations in other international jurisdictions.

In our view, this change would:

- reduce the likelihood of regulatory settings remaining inappropriate and out of date for long periods of time
- encourage horizon-scanning and beneficial regulatory work in anticipation of coming advances in biotechnology.

For more on the costs, benefits and risks of this option, see appendix 2.

Questions	
36	Do you agree with the proposed change: to require the Ministry for the Environment to review the regulatory settings for GMOs at least every five years?
37	Do you agree with the proposed frequency of reviews (that is, at least every five years)?
38	Do you agree with the issues outlined? Would you add any issues to the list? Why?
39	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?

[31] Although statutory determinations can function as a means by which regulations can be updated, a limitation is that they must be based on the drafting and definitions of the primary legislation, which may themselves be out of date.

[32] This provision could also allow an independent party to conduct the review on behalf of the Ministry.

Part 3: How to get involved and have your say

The Government welcomes your feedback on this consultation document. The questions posed throughout this document are listed in appendix 4. They are a guide only, and all comments are welcome. You do not have to answer all the questions.

To ensure your point of view is clearly understood, you should explain your rationale and provide supporting evidence where appropriate.

Timeframes

This consultation starts on 3 July 2023 and ends at 11:59pm on 25 August 2023.

When the consultation period has ended, we will analyse all the submissions. These will inform policies and government decisions. If Cabinet agrees, an amendment to the HSNO Act will be introduced to Parliament as an amendment Bill. Other changes would be made through secondary regulation amendments and non-legislative changes.

How to provide feedback

There are two ways you can make a submission:

- via Citizen Space, our consultation hub, available at https://consult.environment.govt.nz/comms/gmo-regulations
- by writing your own submission.

If you want to provide your own written submission, you can provide this as an uploaded file in Citizen Space.

We request that you don't email or post submissions, because this makes analysis more difficult. However, if you need to do so, please send written submissions to Biotechnology Policy, Ministry for the Environment, PO Box 10362, Wellington 6143 and include:

- your name or organisation
- your postal address
- your telephone number
- your email address.

If you are emailing your feedback, send it to biomedicalreview@mfe.govt.nz as a:

- PDF **or**
- Microsoft Word document (2003 or later version).

Submissions close at 11:59pm, Friday 25 August 2023.

More information

Please direct any queries to:

Email: biomedicalreview@mfe.govt.nz

Postal: Biomedical Policy, Ministry for the Environment, PO Box 10362, Wellington 6143

Publishing and releasing submissions

All or part of any written comments (including names of submitters), may be published on the Ministry for the Environment's website, environment.govt.nz. Unless you clearly specify otherwise in your submission, the Ministry will consider that you have consented to online posting of both your submission and your name.

Contents of submissions may be released to the public under the Official Information Act 1982 following requests to the Ministry for the Environment (including via email). Please advise if you have any objection to the release of any information contained in a submission and, in particular, which part(s) you consider should be withheld, together with the reason(s) for withholding the information. We will take into account all such objections when responding to requests for copies of, and information on, submissions to this document under the Official Information Act.

The Privacy Act 2020 applies certain principles about the collection, use and disclosure of information about individuals by various agencies, including by the Ministry for the Environment. It governs access by individuals to information about themselves held by agencies. Any personal information you supply to the Ministry in the course of making a submission will be used by the Ministry only in relation to the matters covered by this document. Please clearly indicate in your submission if you do not wish your name to be included in any summary of submissions that the Ministry may publish.

If you have any questions or want more information about the proposed changes or the submission process, please email biomedicalreview@mfe.govt.nz.

Appendix 1: Other options considered

Proposal 1: Introduce a risk-tiering framework for laboratory research

Alternative option

Similar to the proposed option under Proposal 1, an alternative option would be to establish a risk-tiering framework that exempts certain low-risk research from Environmental Protection Authority (EPA) assessment and approval requirements if that research is:

- conducted within containment facilities operating at either Physical Containment level 1 (PC1) or PC2 and
- assessed by an accredited biosafety committee (ABSC).

This framework would have risk tiers with the features outlined in table 4.

Table 4: Alternative option 1 risk tier conditions and requirements

Risk tier	Conditions and requirements
Risk tier 1	Research meeting the criteria for this risk tier would be exempt from Environmental Protection Authority (EPA) assessment and approval. 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). An accredited biosafety committee must also have confirmed that: • the research meets the criteria for this risk tier • the committee is satisfied the researcher can undertake the research • the facility is appropriate for the research. A record of each assessment would be sent to the EPA and notified publicly on an annual basis.
Risk tier 2	Research meeting the criteria for this risk tier would be exempt from EPA assessment and approval. The research would be required to be undertaken in an approved containment facility operated according to the relevant standard at PC2. An accredited biosafety committee must also have confirmed that: • the research meets the criteria for this risk tier • the committee is satisfied the researcher can undertake the research • the facility is appropriate for the research. A record of each assessment would be sent to the EPA and notified publicly on an annual basis.

All other contained laboratory research that does not meet the criteria for risk tiers 1 and 2 would require assessment and approval by the EPA before being undertaken.

Proposal 1.1: Biosafety committees

Alternative option

An alternative option to the proposed change under Proposal 1.1 is that organisations would apply for accreditation with the EPA, as under the Australian regulations. Accreditation would include the requirement that an organisation either has a biosafety committee, or has access to the biosafety committee of another accredited organisation, or plans to use the biosafety committee that would be formed by the EPA (which is also an aspect of the proposed change under Proposal 1.1).

However, unlike the proposed change, this option would require all organisations to apply for and gain accreditation from the EPA. This would be in addition to any assessment of research proposals by their own biosafety committee or the biosafety committee of another accredited organisation.

Proposal 4: Adjust internal audit frequency to be proportionate to risk

Alternative option

An alternative to the proposed change under Proposal 4 would be to reduce the frequency of internal audits to a frequency matching that in Australia. This would:

- remove the internal audit requirement for containment facilities operated at PC1
- reduce the minimum frequency of internal audits for containment facilities operated at PC2 from 6 months to 12 months.

Operators of containment facilities operated at PC1 would still retain the ability to perform internal audits if they see fit, and operators of containment facilities operated at PC2 would still retain the ability to perform internal audits at a frequency greater than once every 12 months.

Proposal 5: Adjust the requirements for the movement of new organisms to be proportionate to risk

Alternative option

A potential additional change under Proposal 5 would be to also remove the current movement authorisation requirements for genetically modified organisms (GMOs) requiring a containment facility operating at PC2.

Like the other changes under Proposal 5, the movement of these GMOs would be permitted provided the following conditions were met.

- The GMOs to be transported should be wholly contained inside a sealed, unbreakable primary container.
- The container should be labelled to indicate that it contains GMOs.

- The containment facility the GMOs are being sent to is operated at a PC level equal to or greater than PC2.
- The facility operator of the sending facility confirms the transfer meets these requirements.
- Both the sending and receiving facilities record the transfer in a register.

Proposal 6: Reduce regulatory requirements for the use of eukaryotic somatic cells

Alternative option

An alternative to the proposed change under Proposal 6 would be to exclude certain eukaryotic somatic cell types from the definition of 'organism' under section 2(1) of the Hazardous Substances and New Organisms Act 1996 (HSNO Act). Options under this proposed alternative include:

- excluding human cells from the definition of an organism
- excluding mammalian cells from the definition of an organism
- excluding animal cells (that is, all cells from organisms under the kingdom Animalia) from the definition of an organism
- excluding eukaryotic cells from the definition of an organism.

Proposal 8: Reduce assessment requirements for low-risk fermentation

Alternative option

An alternative to the change proposed under Proposal 8 would be to increase the maximum fermentation vessel size beyond which EPA assessment and approval is required. This maximum fermentation vessel size is currently set at 10 litres per vessel.

Under this option, existing and new approvals to import or develop GMOs would be able to ferment these GMOs at volumes less than this new maximum vessel size without requiring EPA approval. Potential maximum vessel sizes could be 20 litres, 25 litres or 50 litres.

Question	
40	Of the alternative options outlined, are there any that, in your view, would provide greater benefits or better meet the objectives of this policy work than the proposed changes under each proposal?

Appendix 2: Impacts of each proposal

Impacts of Proposal 1: Introduce a risk-tiering framework for laboratory research

Costs

Depending on the biosafety committee option chosen, there may be one-off costs to organisations to setup a biosafety committee and apply to the Environmental Protection Authority (EPA) for its accreditation. However, this cost is likely to be offset over time through lower costs and time being required from researchers, and through non-monetary benefits like more research outcomes.

Benefits

The risk-tiering framework in Proposal 1 is likely to encourage new research efforts, innovation and businesses by lowering the barriers to entry and initiation of research efforts. It is expected this proposal will also reduce the administrative requirements for researchers to gain approval for low-risk research. The proposal will also allow for the study of genetic modification in high school laboratories, potentially increasing the number of future biotechnology researchers.

Reducing administrative requirements will mean more time will be available to conduct research. Proposal 1 would also give researchers greater flexibility to use organisms and vectors that would be best for their research, rather than being disincentivised (as they are now) from using organisms and vectors that are not included in approvals already granted to their organisation.

The proposed removal of EPA assessment and approval requirements for therapeutic products that are, or contain, very low-risk genetically modified organisms (GMOs) would potentially increase the number of therapeutic products approved for use in New Zealand.

The risk-tiering framework would provide greater certainty to researchers, organisations and businesses planning future research efforts, relative to current EPA assessment processes, which set predictable (albeit not guaranteed) containment controls.

Risks

By allowing the genetic modification of certain organisms outside containment facilities, this framework is likely to increase the potential for the inadvertent release of GMOs into the Aotearoa New Zealand environment. However, these GMOs would present no risk or very low risk to the environment, or to the health and safety of people and communities. Additionally, the biological characteristics of these GMOs would make them unlikely to establish and survive in the environment, should they be inadvertently released.

Impacts of Proposal 2: Reduce the assessment and approval requirements for medicines that are, or contain, new organisms

Costs

No costs have been identified for this proposed change.

Benefits

By reducing the information required for applications involving new organisms that are unlikely to be released into the environment, this proposal is likely to reduce researcher time spent on these applications, increasing time available for research.

The proposal would also remove the initial 'qualifying medicine' assessment process under section 38I of the Hazardous Substances and New Organisms Act 1996 (HSNO Act), reducing the time taken to approve applications and likely freeing up time for the EPA to assess other applications.

Risks

No risks have been identified for this proposed change.

Impacts of Proposal 3: Replace current record-keeping requirements

Costs

The need to amend internal guidance documents at research organisations would impose a small cost.

Benefits

This proposed change would reduce administrative burden on researchers, increasing time available for research. Additionally, the reduction of the time required to maintain records as they are now would likely free up time for researchers, biosafety officers and compliance officers to concentrate on areas of higher risk.

The proposal would also retain a measure that would safeguard against accidental cross-contamination between GMOs and non-GMOs (and between new organisms and not-new organisms).

Risks

No risks have been identified for this proposed change.

Impacts of Proposal 4: Adjust audit frequency to be proportionate to risk

Costs

No costs have been identified for this proposed change.

Benefits

This proposed change would reduce the administrative burden for facility operators, their staff and researchers at containment facilities operating at Physical Containment level 1 (PC1). Additionally, by reducing the frequency of these internal audits, containment facilities would be more proportionately regulated, that is, according to the level of risk the research conducted in them may pose to the environment or to the health and safety of people and communities.

Risks

There is a risk the reduced frequency of internal audits would result in minor non-compliances not being picked up before they become more significant. However, evidence from Australia's Office of the Gene Technology Regulator does not suggest that lower internal audit frequency would lead to significant non-compliances. Under Australia's regulations, those operating PC1 facilities are not required to carry out any internal audits.

Impacts of Proposal 5: Adjust the requirements for the movement of new organisms to be proportionate to risk

Costs

The need to amend internal guidance documents at research organisations would impose a small cost.

Benefits

This option would reduce administrative burdens on researchers in transferring GMOs to other laboratories. This would lead to increased research time available, as well as greater collaboration between researchers and research groups in New Zealand.

Risks

A risk is that what is allowed under the risk-tiering framework may be misunderstood by facility operators or researchers, leading to the movement of new organisms that should not occur. However, this is unlikely, because relevant requirements for containment facilities operating at PC1 will be easy to understand: the new organism can only be sent to a facility with the same or greater level of stringency (that is, PC1 or greater).

Impacts of Proposal 6: Reduce regulatory requirements for the use of eukaryotic somatic cells

Costs

No costs have been identified for this proposed change.

Benefits

Benefits of this option include reductions in the administrative burden of using very low-risk cells, which would lead to increased research time and funding. This option may also increase research using human cells, in turn leading to increased biomedical research and development outcomes.

Risks

No additional relevant risks have been identified beyond those detailed under Proposal 1.

Impacts of Proposal 7: Clarify the regulatory status of certain biotechnologies

Costs

No costs have been identified for this proposed change.

Benefits

It is expected that these changes will provide greater certainty to researchers, leading to the increased use of these technologies in research and medical therapy development.

Risks

Improper drafting or insufficient conditions for a biotechnology listed in the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998 may inadvertently deregulate biotechnologies that are not intended to be deregulated.

Impacts of Proposal 8: Reduce assessment requirements for low-risk fermentation

Costs

No costs have been identified for this proposed change.

Benefits

By reducing assessment requirements, the proposed change would reduce administrative burdens on researchers, research organisations and biotech companies by requiring fewer (or no) fermentation applications to the EPA.

Risks

If adequate controls on fermentation vat design and use are not put in place, there may be an increased risk of spills.

Impacts of Proposal 9: Maintain or adjust the approach to standards for containment facilities

Costs

Additional resources would be required at both the EPA and Ministry for Primary Industries (MPI), should the overall approach to standards change to adopting an outcome-based or hybrid approach and developing associated guides. This would also likely include additional resources for MPI to update operational processes to ensure sufficient verification of facilities using outcome-based controls.

Operators of facilities that are both containment and transitional facilities may incur extra costs should the approaches for containment and transitional facilities differ.

Benefits

A benefit of retaining the status quo is that standards for containment facilities and transitional facilities would have the same broad approach. Prescriptive controls may also be easier to implement for small facility operators and their users.

Outcome-based or hybrid standards would have the benefits of allowing laboratories to implement validated, peer-reviewed control measures that are most appropriate to the specific organism and modifications in question. Biosafety knowledge and expertise would also be more widely disseminated through the publication of guides.

Risks

No risks have been identified for these options.

Impacts of Proposal 10: Require regular reviews of regulatory settings

Costs

This proposal would require resources at the Ministry for the Environment to complete regular reviews of the regulatory settings for GMOs.

Benefits

It is expected the proposed change would reduce the likelihood of regulatory settings remaining inappropriate and out of date for long periods. Additionally, the proposal would encourage horizon-scanning and regulatory work in anticipation of coming advances in biotechnology.

Risks

No risks have been identified for this proposed change.

Question	
41	In your view, have we overlooked any costs, benefits or risks for any of the proposals presented in this document?

Appendix 3: Australian risk-tiering framework

An outline of the Australian risk-tiering framework is provided here for feedback. The details of what will be included in any New Zealand risk-tiering framework will be consulted on at a later date (that is, what organisms, modifications, vectors and exclusionary criteria should be included). In the meantime, we would like to hear if you think any aspects of the Australian risk tiers below should or should not be included in any New Zealand risk-tiering framework.

Question	
42	Are there aspects or specific criteria of the Australian risk-tiering framework that, in your view, should or should not be included in any New Zealand risk-tiering framework?

Risk tier 1: Exempt dealings

Gene Technology Regulations 2001 under the Gene Technology Act 2000

Schedule 2—Dealings exempt from licensing

Part 1—Exempt dealings

Item	Description of dealing
2	A dealing with a genetically modified *Caenorhabditis elegans*, unless: (a) an *advantage* is conferred on the animal by the genetic modification; or (b) as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent.
3	A dealing with an animal into which genetically modified somatic cells have been introduced, if: (a) the somatic cells are not capable of giving rise to infectious agents as a result of the genetic modification; and (b) the animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells.
3A	A dealing with an animal whose somatic cells have been genetically modified *in vivo* by a replication defective viral vector, if: (a) the *in vivo* modification occurred as part of a previous dealing; and (b) the replication defective viral vector is no longer in the animal; and (c) no germ line cells have been genetically modified; and (d) the somatic cells cannot give rise to infectious agents as a result of the genetic modification; and (e) the animal is not infected with a virus that can recombine with the genetically modified nucleic acid in the somatic cells of the animal.
4	(1) Subject to subitem (2), a dealing involving a host/vector system mentioned in Part 2 of this Schedule and producing no more than 25 litres of GMO culture in each vessel containing the resultant culture. (2) The donor nucleic acid:

Item	Description of dealing
	(a) must meet either of the following requirements: (i) it must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy: (A) human beings; or (B) animals; or (C) plants; or (D) fungi; (ii) it must be characterised and the information derived from its characterisation show that it is unlikely to increase the capacity of the host or vector to cause harm; and Example: Donor nucleic acid would not comply with subparagraph (ii) if its characterisation shows that, in relation to the capacity of the host or vector to cause harm, it: (a) provides an advantage; or (b) adds a potential host species or mode of transmission; or (c) increases its virulence, pathogenicity or transmissibility. (b) must not code for a toxin with an LD50 of less than 100 micrograms per kilogram; and (c) must not code for a toxin with an LD50 of 100 micrograms per kilogram or more, if the intention is to express the toxin at high levels; and (d) must not be uncharacterised nucleic acid from a toxin-producing organism; and (e) if the donor nucleic acid includes a viral sequence—cannot give rise to infectious agents when introduced into any potential host species, without additional non-host genes or gene products that: (i) are not available in the host cell into which the nucleic acid is introduced as part of the dealing; and (ii) will not become available during the dealing; and (f) if the donor nucleic acid includes a viral sequence—cannot restore replication competence to the vector.
5	A dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in items 1 to 6 of the table in Part 2 of this Schedule, if the donor nucleic acid is not derived from either: (a) a pathogen; or (b) a toxin-producing organism.

Part 2—Host/vector systems for exempt dealings

2.1 Hosts and vectors

(1) A reference to a host mentioned in this Part is a reference to a host mentioned in column 2 of an item of the table in this clause.

(2) A reference to a vector mentioned in this Part is a reference to a vector mentioned in column 3 of an item of the table in this clause.

(3) A reference to a ***host/vector system*** mentioned in this Part is a reference to any of the following:

(a) a system involving a host mentioned in column 2 of an item of the table in this clause and a vector mentioned in column 3 of the same item;

(b) a non-vector system involving a host mentioned in column 2 of an item of the table;

(c) a system involving a GMO mentioned as a vector in column 3 of an item of the table (except item 7), without a host.

Note: Column 1 of the table is included for information only.

Hosts and vectors

Item	Host class	Hosts	Vectors
1	Bacteria	*Escherichia coli* K12, *E. coli* B, *E. coli* C or *E. coli* Nissle 1917—any derivative that does not contain: (a) generalised transducing phages; or (b) genes able to complement the conjugation defect in a non-conjugative plasmid	Any of the following: (a) non-conjugative plasmids; (b) lambda bacteriophage; (c) lambdoid bacteriophage; (d) Fd, F1 or M13 bacteriophage
2	Bacteria	*Bacillus*—asporogenic strains of the following species with a reversion frequency of less than 10^{-7}: (a) *B. amyloliquefaciens;* (b) *B. licheniformis;* (c) *B. pumilus;* (d) *B. subtilis;* (e) *B. thuringiensis*	Any of the following: (a) non-conjugative plasmids; (b) other plasmids and phages whose host range does not include *B. cereus*, *B. anthracis* or any other pathogenic strain of *Bacillus*
3	Bacteria	*Pseudomonas putida* strain KT2440	Non-conjugative plasmids
4	Bacteria	The following *Streptomyces* species: (a) *S. aureofaciens*; (b) *S. coelicolor*; (c) *S. cyaneus*; (d) *S. griseus*; (e) *S. lividans*; (f) *S. parvulus*; (g) *S. rimosus*; (h) *S. venezuelae*	Any of the following: (a) non-conjugative plasmids; (b) plasmids SCP2, SLP1, SLP2, pIJ101 and derivatives; (c) actinophage phi C31 and derivatives
5	Bacteria	Any of the following: (a) *Agrobacterium radiobacter*; (b) *Agrobacterium rhizogenes* (disarmed strains only); (c) *Agrobacterium tumefaciens* (disarmed strains only)	Disarmed Ri or Ti plasmids
6	Bacteria	Any of the following: (a) *Allorhizobium* species; (b) *Corynebacterium glutamicum*; (c) *Lactobacillus* species; (d) *Lactococcus lactis*; (e) *Oenococcus oeni* syn. *Leuconostoc oeni*; (f) *Pediococcus* species; (g) *Photobacterium angustum*; (h) *Pseudoalteromonas tunicata*; (i) *Rhizobium* species; (j) *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis*;	Non-conjugative plasmids

Item	Host class	Hosts	Vectors
		(k) *Streptococcus thermophilus*; (l) *Synechococcus* species strains PCC 7002, PCC 7942 and WH 8102; (m) *Synechocystis* species strain PCC 6803; (n) *Vibrio cholerae* CVD103-HgR; (o) *Zymomonas mobilis*	
7	Fungi	Any of the following: (a) *Kluyveromyces lactis*; (b) *Neurospora crassa* (laboratory strains); (c) *Pichia pastoris*; (d) *Saccharomyces cerevisiae*; (e) *Schizosaccharomyces pombe*; (f) *Trichoderma reesei*; (g) *Yarrowia lipolytica*	All vectors
8	Slime moulds	*Dictyostelium* species	*Dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2
9	Tissue culture	Any of the following if they cannot spontaneously generate a whole animal: (a) animal or human cell cultures (including packaging cell lines); (b) isolated cells, isolated tissues or isolated organs, whether animal or human; (c) early non-human mammalian embryos cultured *in vitro*	Any of the following: (a) plasmids; (b) replication defective viral vectors unable to transduce human cells; (c) polyhedrin minus forms of the baculovirus *Autographa californica* nuclear polyhedrosis virus (ACNPV)
10	Tissue culture	Either of the following if they are not intended, and are not likely without human intervention, to vegetatively propagate, flower or regenerate into a whole plant: (a) plant cell cultures; (b) isolated plant tissues or organs	Any of the following: (a) Disarmed Ri or Ti plasmids in *Agrobacterium radiobacter*, *Agrobacterium rhizogenes* (disarmed strains only) or *Agrobacterium tumefaciens* (disarmed strains only); (b) non-pathogenic viral vectors

Risk tiers 2 and 3: Notifiable low-risk dealings suitable for at least Physical Containment level 1 and Physical Containment level 2

Schedule 3—Notifiable low risk dealings in relation to a GMO

Part 1—Notifiable low risk dealings suitable for at least physical containment level 1

Note: Because of subregulation 12(1), a dealing mentioned in this Part is not a notifiable low risk dealing if it is also a dealing of a kind mentioned in Part 3

1.1 Kinds of dealings suitable for at least physical containment level 1

The following kinds of notifiable low risk dealings must be undertaken, unless paragraph 13(2)(c) or subregulation 13(3) applies, in facilities certified to at least physical containment level 1 and that are appropriate for the dealings:

(a) a dealing involving a genetically modified laboratory guinea pig, a genetically modified laboratory mouse, a genetically modified laboratory rabbit or a genetically modified laboratory rat, unless:

(i) an advantage is conferred on the animal by the genetic modification; or

(ii) the animal is capable of secreting or producing an infectious agent as a result of the genetic modification;

(c) a dealing involving virions of a replication defective vector derived from Human adenovirus or from Adeno-associated virus, either without a host or with a host mentioned in item 9 of Part 2 of Schedule 2, if the donor nucleic acid:

(i) cannot restore replication competence to the vector; and

(ii) does not confer an oncogenic modification or immunomodulatory effect in humans.

Part 2—Notifiable low risk dealings suitable for at least physical containment level 2 or 3

Note: Because of subregulation 12(1), a dealing mentioned in this Part is not a notifiable low risk dealing if it is also a dealing of a kind mentioned in Part 3.

2.1 Kinds of dealings suitable for at least physical containment level 2

The following kinds of notifiable low risk dealings must be undertaken, unless paragraph 13(2)(c) or subregulation 13(3) applies, in facilities certified to at least physical containment level 2 and that are appropriate for the dealings:

(a) a dealing involving whole animals (including non-vertebrates) that:

(i) involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism; and

(ii) does not involve any of the following:

(A) a genetically modified laboratory guinea pig;

(B) a genetically modified laboratory mouse;

(C) a genetically modified laboratory rabbit;

(D) a genetically modified laboratory rat;

(E) a genetically modified *Caenorhabditis elegans*;

(aa) a dealing involving a genetically modified laboratory guinea pig, a genetically modified laboratory mouse, a genetically modified laboratory rabbit, a genetically modified laboratory rat or a genetically modified Caenorhabditis elegans, if:

(i) the genetic modification confers an advantage on the animal; and

(ii) the animal is not capable of secreting or producing an infectious agent as a result of the genetic modification;

(b) a dealing involving a genetically modified plant;

(c) a dealing involving a host/vector system not mentioned in paragraph 1.1(c) or Part 2 of Schedule 2, if neither host nor vector has been implicated in, or has a history of causing, disease in otherwise healthy:

(i) human beings; or

(ii) animals; or

(iii) plants; or

(iv) fungi;

(d) a dealing involving a host/vector system not mentioned in Part 2 of Schedule 2, if:

(i) the host or vector has been implicated in, or has a history of causing, disease in otherwise healthy:

(A) human beings; or

(B) animals; or

(C) plants; or

(D) fungi; and

(ii) the genetic modification is characterised; and

(iii) the characterisation of the genetic modification shows that it is unlikely to increase the capacity of the host or vector to cause harm;

Example: A genetic modification would not comply with subparagraph (iii) if, in relation to the capacity of the host or vector to cause harm, it:

(a) provides an advantage; or

(b) adds a potential host species or mode of transmission; or

(c) increases its virulence, pathogenicity or transmissibility.

(e) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2, if the donor nucleic acid:

(i) is characterised, and the characterisation shows that it may increase the capacity of the host or vector to cause harm; or

(ii) is uncharacterised nucleic acid from an organism that has been implicated in, or has a history of causing, disease in otherwise healthy:

(A) human beings; or

(B) animals; or

(C) plants; or

(D) fungi;

(f) a dealing involving a host/vector system mentioned in Part 2 of Schedule 2 and producing more than 25 litres of GMO culture in each vessel containing the resultant culture, if:

(i) the dealing is undertaken in a facility that is certified by the Regulator as a large scale facility; and

(ii) the donor nucleic acid satisfies the conditions set out in subitem 4(2) of Part 1 of Schedule 2;

(g) a dealing involving complementation of knocked-out genes, if the complementation is unlikely to increase the capacity of the GMO to cause harm compared to the capacity of the parent organism before the genes were knocked out;

Example: A dealing would not comply with paragraph (g) if it involved complementation that, in relation to the parent organism:

(a) provides an advantage; or

(b) adds a potential host species or mode of transmission; or

(c) increases its virulence, pathogenicity or transmissibility.

(h) a dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in items 1 to 6 of the table in Part 2 of Schedule 2, if the donor nucleic acid is derived from either:

(i) a pathogen; or

(ii) a toxin-producing organism;

(i) a dealing involving virions of a replication defective viral vector unable to transduce human cells and a host not mentioned in Part 2 of Schedule 2, if the donor nucleic acid cannot restore replication competence to the vector;

(j) a dealing involving virions of a replication defective non-retroviral vector able to transduce human cells, either without a host or with a host mentioned in Part 2 of Schedule 2, if:

(i) the donor nucleic acid cannot restore replication competence to the vector; and

(ii) the dealing is not a dealing mentioned in paragraph 1.1(c);

(k) a dealing involving virions of a replication defective non-retroviral vector able to transduce human cells and a host not mentioned in Part 2 of Schedule 2, if:

(i) the donor nucleic acid cannot restore replication competence to the vector; and

(ii) the donor nucleic acid does not confer an oncogenic modification or immunomodulatory effect in humans;

(l) a dealing involving virions of a replication defective retroviral vector able to transduce human cells, either without a host or with a host mentioned in Part 2 of Schedule 2, if:

(i) all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble new virions without these functions being supplied in trans; and

(ii) viral genes needed for virion production in the packaging cell line are expressed from independent, unlinked loci with minimal sequence overlap with the vector to limit or prevent recombination; and

(iii) either:

(A) the retroviral vector includes a deletion in the Long Terminal Repeat sequence of DNA that prevents transcription of genomic RNA following integration into the host cell DNA; or

(B) the packaging cell line and packaging plasmids express only viral genes *gagpol*, *rev* and an envelope protein gene, or a subset of these;

(m) a dealing involving virions of a replication defective retroviral vector able to transduce human cells and a host not mentioned in Part 2 of Schedule 2, if:

(i) the donor nucleic acids does not confer an oncogenic modification or immunomodulatory effect in humans; and

(ii) all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble new virions without these functions being supplied in trans; and

(iii) viral genes needed for virion production in the packaging cell line are expressed from independent, unlinked loci with minimal sequence overlap with the vector to limit or prevent recombination; and

(iv) either:

(A) the retroviral vector includes a deletion in the Long Terminal Repeat sequence of DNA that prevents transcription of genomic RNA following integration into the host cell DNA; or

(B) the packaging cell line and packaging plasmids express only viral genes gagpol, rev and an envelope protein gene, or a subset of these.

Appendix 4: Questions

These questions appear throughout the consultation document. They may help you when making a submission.

Objectives	
1	In your view, are these objectives the most effective for developing policy changes to improve the regulatory settings for genetically modified organisms? If not, what should the objectives be, and why?
2	What features and overall approach would you like to see in a New Zealand regulatory framework for genetically modified organisms?
Proposal 1: Introduce a risk-tiering framework for laboratory research	
3	Do you agree with the proposed change: to establish a risk-tiering framework modelled on the risk-tiering framework under Australian regulations?
4	Do you agree with the issues outlined? Would you add any issues to the list? Why?
5	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?
Proposal 1.1: Biosafety committees	
6	Do you agree with the proposed establishment of accredited biosafety committees and an Environmental Protection Authority biosafety committee?
7	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?
Proposal 2: Reduce the assessment and approval requirements for medicines that are, or contain, new organisms	
8	Do you agree with the proposed changes: to streamline assessments under section 38I of the Hazardous Substances and New Organisms Act 1996, to introduce an alternative assessment pathway for medicines unlikely to result in viable new organisms from being released into the environment, and to enable rapid assessment of medical devices?
9	Do you agree with the issues outlined? Would you add any issues to the list? Why?
10	Are there other policy changes that, in your view, would provide more benefits or better meet the objectives than the proposed changes above?
Proposal 3: Replace current record-keeping requirements	
11	Do you agree with the proposal to replace the current record-keeping requirements with a new labelling and accounting requirement?
12	Do you think labelling requirements should also include that new organisms should be able to be linked to the relevant HSNO Act approval? If not, why?
13	Do you agree with the issues outlined? Would you add any issues to the list? Why?
14	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?
Proposal 4: Adjust internal audit frequency to be proportionate to risk	
15	Do you agree with the proposed change: to reduce the internal audit frequency requirement for containment facilities operating at Physical Containment level 1 (PC1)?
16	Do you agree with the issues outlined? Would you add any issues to the list? Why?

Objectives	
17	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?
Proposal 5: Adjust the requirements for the movement of new organisms to be proportionate to risk	
18	Do you agree with the proposed change: to remove movement authorisation requirements for laboratories, and containment facilities operating at PC1, provided specific conditions are met?
19	Do you agree with the issues outlined? Would you add any issues to the list? Why?
20	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed option above?
Proposal 6: Reduce regulatory requirements for the use of eukaryotic somatic cells	
21	Do you agree with the proposed change: to include certain eukaryotic somatic cells under risk tier 1 of the risk-tiering framework outlined in Proposal 1?
22	Do you agree with the issues outlined? Would you add any issues to the list? Why?
23	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?
Proposal 7: Clarify the regulatory status of certain biotechnologies	
24	Do you agree with the proposed change: to clarify the regulatory status of the introduction of ribonucleic acid (RNA) into an organism, the introduction of deoxyribonucleic acid (DNA), and epigenetic modifications under the HSNO Act?
25	Are there any exclusionary criteria that, in your view, should or should not be associated with any of these three biotechnologies?
26	Do you agree with the issues outlined? Would you add any issues to the list? Why?
27	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above? In your view, should the status of any other biotechnologies be clarified under regulations?
Proposal 8: Reduce assessment requirements for low-risk fermentation	
28	Do you agree with the proposed change: to remove EPA assessment and approval requirements for fermentation of GMOs meeting the criteria of risk tiers 1 to 3?
29	In your view, do you think that the current maximum vessel size not requiring EPA assessment and approval (10 litres) should be increased?
30	Do you agree with the issues outlined? Would you add any issues to the list? Why?
31	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?
Proposal 9: Maintain or adjust the approach to standards for containment facilities	
32	Of the three options presented above, which is your preferred option and why?
33	Do you agree with the issues outlined? Would you add any issues to the list?
34	Do you run a facility that is approved as both a containment facility and a transitional facility? Would the costs of a shift to outcome-based or hybrid standards for new organisms outweigh any benefits to you or those who use your facilities?
35	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the three options above?
Proposal 10: Require regular reviews of regulatory settings	
36	Do you agree with the proposed change: to require the Ministry for the Environment to review the regulatory settings for GMOs at least every five years?

Objectives	
37	Do you agree with the proposed frequency of reviews (that is, at least every five years)?
38	Do you agree with the issues outlined? Would you add any issues to the list? Why?
39	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?
Appendix 1: Other options considered	
40	Of the alternative options outlined, are there any that, in your view, would provide greater benefits or better meet the objectives of this policy work than the proposed changes under each proposal?
Appendix 2: Impacts of each proposal	
41	In your view, have we overlooked any costs, benefits or risks for any of the proposals presented in this document?
Appendix 3: The Australian risk-tiering framework	
42	Are there aspects or specific criteria of the Australian risk-tiering framework that in your view should or should not be included in any New Zealand risk-tiering framework?