MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

Te Kāwanatanga o Aotearoa
New Zealand Government

Gene Technology Bill

Officials' report to the Health Committee
May 2025

New Zealand Government

The Chair

Health Committee

Introduction

This is the officials' report on the Gene Technology Bill (**the Bill**). The Bill was introduced to the House on 10 December 2024 and referred to the Health Committee (**the Committee**) after its first reading on 17 December 2024.

The Bill is a Government Bill that establishes a new gene technology regulatory regime to enable the safe use of gene technologies. The Bill will regulate gene technologies and organisms modified by gene technologies through managing their risks to the health and safety of people and the environment.

Please note that the final wording of any provision that is the subject of a recommendation in this report is subject to Parliamentary Counsel Office (**PCO**) advice, and that the PCO may also advise other minor or technical changes to improve the workability of the Bill and the clarity of the drafting.

Submissions on the Bill

The Committee received 14,458 written submissions and heard 287 oral submissions on the Bill.

Structure of this report

This officials' report is in five parts:

- **Chapter 1:** Overview of the Bill and submitters
- **Chapter 2:** Main themes across submissions
- **Chapter 3:** Part-by-part issues analysis
- **Chapter 4:** Ongoing policy work
- **Chapter 5:** Outstanding responses to Committee information requests.

The report has three appendices:

- **Appendix One:** Clause-by-clause analysis
- **Appendix Two:** Submitter information
- **Appendix Three:** Feedback received unrelated to core policy of the Bill

Contents

Summary of tables and figures

Summary of recommendations

Table 1 below sets out changes to the Bill recommended by officials. Clauses where no changes are proposed are not included.

The recommendations are numbered based on the relevant recommendation number in the clause-by-clause analysis at Appendix One and are linked through Chapter 3. Some recommendations need to be considered alongside other recommendations or are dependent on them, and we have stated this alongside the rationale for the recommendation in Appendix One.

Table 1: Summary of recommendations

Rec #	Recommendation
1	**Recommend** that the Parliamentary Counsel Office (PCO) can make any additional minor and technical drafting changes to the Bill consistent with the policy intent and that may not be identified at the time the Departmental Report was presented to the Committee.
2	**Amend clause 2** to specify that subpart 9 of Part 6 (amendments to the Resource Management Act 1991) comes into force the day after the date of Royal assent.
3	**Amend clause 2** to specify that clause 23 (Regulator may declare pre-assessed activities), clauses 26-29 (which set out the process for making such a declaration) and subpart 4 of Part 2 (non-notifiable and notifiable activities) come into force the day after the date of Royal assent.
4	**Amend clause 5** by removing "and every other person who carries out a function or duty or exercises a power under this Act," from the clause.
5	**Amend the definition** of activity to ensure clarity and consistency, as follows: - **include** "constructing" in 7(1)(a) - **add** "with" after "fermenting" in 7(1)(a) - make it clear in the 7(1)(b) definition of "activity" that "modifying" is the modification to any organism – not just those already regulated. - include "conducting experiments" in clause 7(1)(d) and removing "undertaking research" - **amend clause 7(1)(e)** in the definition of "activity" to make it clear that any introduction of a regulated organism to the environment falls within the definition of "activity".
6	**Amend** to provide a regulation making power to include any other method of containment for the purposes of the Bill. This enables future flexibility and other methods to be considered.
7	**Delete the definition** of *conventional processes*.
8	**Amend the definition** of enforcement agency by deleting limb (b), to remove unintended uncertainty that the enforcement agency could be an agency other than the Ministry for Primary Industries (MPI).

Rec #	Recommendation
9	**Amend the definition** of "environmental activity" to make it clear it captures import and introduction of a regulated organism into the environment where the organism does not first go into a containment facility.
10	**Add a definition** of exportation into the Bill, referring to the definition of exportation in the Imports and Exports (Living Modified Organisms) Prohibition Order 2005 (Prohibition Order) where **exportation** means any shipment in any craft for transportation to a point outside New Zealand; and **export, exported and exportation** have corresponding meanings.
11	**Amend the definition** of gene technology to not include technologies specified in the Act or regulations, for completeness.
12	**Amend the definition** of *gene technology* to remove limb (b)(i) referring to conventional processes, for consistency with other recommendations to delete this definition.
13	**Amend the definition** of "kaitiaki relationship" in clause 7 to "kaitiaki relationship, in relation to a species, means the relationship that any kaitiaki has, or Māori in general have, as guardian, trustee, or caretaker of an indigenous species or a non-indigenous species of significance, in accordance with tikanga."
14	**Insert a new definition into clause 7** for "Non-indigenous species of significance". This definition should be based on the definition used in the Plant Variety Rights Act 2022 (PVR Act) with modification to include organisms that are not plants. The policy intent is for this list to initially be limited to the ten non-indigenous plant species listed in the PVR Act Regulations, plus one animal species, the kiore rat. We recommend PCO consider the following definition based on the PVR Act: **non-indigenous species of significance** means a species of organism— (a) believed to have been brought to New Zealand before 1769 on waka migrating from other parts of the Pacific region; and (b) listed in the regulations as a non-indigenous plant species of significance.
15	**Amend the definition** of "organism" to include in limb (a) reference to "genes" as well as other genetic material.
16	**Amend the definition** of "manufacturer" to include a person who manufactures and distributes benchtop nucleic acid synthesis equipment for trade or reward.
17	**Amend the definition** of regulated organism to exclude an organism or a category of organisms declared by the Act or regulations not to be regulated organisms, for consistency with related recommendations.
18	**Recommend PCO consider whether to remove the brackets in clause 7(a)(ii)**, provided the meaning does not change.
19	**Amend the definition** of synthetic nucleic acid to clarify that it only encompasses nucleic acids synthesised *de novo* and without the use of a template, and also includes non-naturally occurring nucleic acid analogues.
20	**Amend clause 8** definition of medical activity: - at 8(a)(iv) to enable the undertaking of clinical trials on humans or testing of veterinary medicines on animals

Rec #	Recommendation
	- to delete clause 8(a)(iii) and add 'medical device' in (b) to read 'includes the administration of medicines, medical devices or veterinary medicines using a gene technology or regulated organism', and - at clause 8(a)(ii) to read 'to an animal for a therapeutic purpose or as a veterinary medicine'.
21	**Amend clause 12(1)** to replace 'technique' with 'technology' to ensure consistency with the definition of gene technology.
22	**Amend clause 12** to: - **clarify** the right of review relates to when the Regulator has made a determination under 12(1), in response to an application by a person; and - **outline** the process leading up to and if the Regulator decides not to make a determination, when a person has applied for one (i.e. the Regulator would request more information prior to making a decision not to make a determination, and when the decision is made, notifying the person in writing with reasons).
23	**Amend clause 12** to enable previous statutory determinations to be amended and revoked.
24	**Amend clause 15** so the Regulator can impose conditions relating to the location a regulated activity may occur.
25	**Amend clause 15** so that the Regulator may also impose conditions requiring that data and samples be verified.
26	**Amend** the Bill at relevant places to make clear that conditions are imposed to manage risks pursuant to the purpose of the Bill (i.e. risks to the environment and to the health and safety of people).
27	**Amend** the Bill to make clear that, where a body corporate is the applicant for a licence, the Regulator will assess fitness of the officers of a body corporate as well where appropriate.
28	**Amend clause 23** as necessary to add the ability limit the declared activity to a specified person or class of persons in relation to pre-assessed activities.
29	**Amend clause 25** to require the Regulator to consider any reply from the applicant arising from clause 25(2), but that this does not affect the Regulator's ability to prepare a Risk Assessment and Risk Management Plan (RARMP).
30	**Amend clause 30** to implement the policy intent that the Regulator must prepare a new or amended risk assessment or risk management plan if they consider the current one is no longer materially accurate.
31	**Insert a clause** for the Regulator to provide an updated version of an RARMP to the licence holder and on the website, following minor and technical changes having been made.
32	**Amend clause 35(2)** to add the Health and Safety at Work Act 2015 as relevant law when the Regulator is determining if a person is fit and proper to hold a licence.

Rec #	Recommendation
33	**Delete reference in clause 37(1)(c)** to the Regulator having been made aware, to clarify that the licence holder must notify the Regulator if the circumstances in clauses 35(1)(a)-(c) apply.
34	**Replace** "1 month" with "20 working days" **in clause 37(1)(f)(i)**, for consistency with similar provisions.
35	**Amend clause 46** to insert a subclause similar to clause 40(2) so the Regulator does not need to notify the licence holder of the proposal and give them 30 working days to respond if the Regulator considers the variation is necessary or desirable in order to avoid imminent risk of death, or serious injury to people or serious damage to the environment.
36	**Amend clause 49** to make clear the Regulator need not seek advice from the Māori Advisory Committee (MAC) under clause 126 if the proposed variation to a declaration is minor in effect or corrects a minor error; or the proposed variation or revocation of a declaration is necessary or desirable in order to avoid an imminent risk of death, serious illness, or serious injury to people or serious damage to the environment.
37	**Amend clause 49** to state that a failure to comply with requirements to consult does not affect the validity of Notices, similar to section 3B(6) Climate Change Response Act 2002.
38	**Insert new clause in Part 2** to make it clear no compensation is payable where the Regulator cancels, suspends, revokes, or varies a licence, declaration or other authorisation under Part 2.
39	**Replace** 'mandatory medical authorisation' with alternative language such as 'recognised medical authorisation' in Part 2 Subpart 5 (and other relevant parts of the Bill).
40	**Amend clause 50** to be clear that the Regulator, in making its decision on any conditions to impose as per clause 50(4), may seek advice from Technical Advisory Committee (TAC).
41	**Amend clause 50** to require the Regulator to publicly notify on its website that it is beginning the process to grant an authorisation, to support transparency of the regime.
42	**Amend clause 50** to make it clear clinical trials are on humans and testing of veterinary medicines is on animals.
43	**Add a clause to Part 2 Subpart 5** to enable the Regulator to vary conditions of an authorisation and that in doing so the Regulator must have regard to any conditions imposed by recognised overseas authorities.
44	**Amend clause 50** to: - **require** the Regulator to notify the overseas authorisation holder, if known, that it is beginning the process to grant an authorisation, and - **enable** the Regulator to pause or cancel the authorisation process if it receives a request from the overseas authorisation holder to do so.
45	**Amend clause 50** so that the matter of who may carry out a medical activity is specified as part of setting conditions, rather than as set out in current drafting.

Rec #	Recommendation
46	**Amend clause 51** to clarify that the Regulator may revoke a mandatory medical authorisation if one or more of the recognised overseas authorities revokes the equivalent authorisation.
47	**Amend clause 57** to provide timeline of no less than 30 working days for public consultation.
48	**Amend clause 58** to include more specific details for each declaration and authorisation type as to what needs to be kept on the register, which will be published on the Regulator's website, including, where relevant: For declarations, mandatory medical authorisations and emergency authorisations: - the declaration or authorisation (which will describe the class of persons, activities and regulated organisms authorised - a description of the status (whether subject to variation, revocation, suspension or extension where relevant) - any written decision documents including risk assessments - any advice provided by the TAC, MAC, or other persons (including other agencies) - a summary of written submissions For notifications of notifiable activities [and non-notifiable activities if a person voluntarily notifies the Regulator]: - the name of the person or organisation undertaking the activity - a description of the activities and regulated organisms - the date of notification For licence applications and licences: - the name of the applicant as well as the name of the licence holder and persons authorised to undertake the activity. For determinations under section 12: - any amendments or revocations according to Item 98.
49	**Amend clause 59(2)** to include information supplied by manufacturers of benchtop nucleic acid synthesis equipment, providers of synthetic nucleic acid and third-party vendors before they seek formal approval.
50	**Amend clause 60(2)** to clarify that this clause does not affect the operation of the Privacy Act 2020 (Privacy Act).
51	**Amend clause 60(2)** by deleting 60(2)(a)-(c) and adding in a subclause that provides for information to be withheld under sections 6 or 9 of the Official Information Act 1982**.**
52	**Recommend** that PCO consider whether any changes to clause 61 are necessary to improve clarity for how long protection periods apply for.
53	**Add a new provision** to ensure that, where information provided to the Regulator in relation to a mandatory medical authorisation or emergency authorisation, and which is required to be protected under the Medicines Act 1981 or the Agricultural Compounds and Veterinary Medicines Act 1997, that the Regulator is also required to keep that information confidential for the duration of the protection provided for under those Acts.

Rec #	Recommendation
54	**Add to clause 65(1)** that an enforcement officer may require a person to give the enforcement agency information about screening policies related to synthetic nucleic acid and benchtop nucleic acid synthesis equipment.
55	**Add a new provision** to empower enforcement officers to obtain person identity information if they believe that person may have committed an infringement offence.
56	**Insert a new clause** to empower Biosecurity Act 1993 (Biosecurity Act) inspectors to require a person importing any organism, to give a statutory declaration that an organism is not a regulated organism.
57	**Amend clause 69** to ensure enforcement officers can enter and inspect any place where the enforcement officer has reasonable grounds to believe it is a place where an activity or organism regulated by the Act, or related devices, equipment or information is or <u>was present.</u>
58	**Amend clause 69** to include reference to places where benchtop equipment is <u>distributed</u>.
59	**Remove clause 79(1)(b)**.
60	**Amend clause 83** to include reference to 'synthesize or distribute, and 'manufacture or distribute', so that third-party vendors are captured.
61	**Amend clause 86** to include <u>or omission</u>, for consistency with clause 87.
62	**Recommend officials and PCO** work to finalise policy proposals in relation to the functions of the EPA and to clarify accountability arrangements, with a view to drafting new provisions for the Bill.
63	**Insert a new subclause in clause 108** to provide for the EPA to recruit, in consultation with the Minister, a person to be the Regulator. **Amend clause 108(2) and 108(4)** such that the Minister must appoint an employee of the EPA or a person becoming an employee.
64	**Amend clause 111** to include a subclause clarifying that the Regulator is accountable to the EPA for their obligations as an employee.
65	**Consider amendment** to include independent audit of decision-making process.
66	**Add an annual reporting provision**, similar to that in the Australian Gene Technology Act 2000, that is coherent with the overall accountability arrangements for the Regulator.
67	**Amend clause 114(3)** to include additional areas of expertise: plant and animal breeding and seed production, as particular areas of relevance for gene technologies.
68	**Add criteria and requirements** for membership of the MAC to Part 4 Subpart 4, based on the criteria for the Māori Plant Varieties Committee in section 57 of the PVR Act.
69	**Amend clause 142** to clarify that people other than applicants and licence holders may appeal a decision.
70	**Amend clause 149(5)** by adding 'If required by regulations' to the start of the clause, to easily cross-reference with clause 157.

Rec #	Recommendation
71	**Amend clause 150** to add a similar consultation requirement for the issuing and approval of standards as under clause 150(4).
72	**Amend clause 151(5)** from "thinks" to "reasonably believes" for consistency with comparable provisions in the Privacy Act.
73	**Add to the list of Acts at clause 151(3)**, <u>any other Act specified by Order in Council.</u>
74	**Add the Health and Safety at Work Act 2015** to the list of Acts at clause 151(3).
75	**Add an additional subpoint to clause 151(4)** to allow for information sharing under this Bill <u>for the purposes of this Bill</u>.
76	**Amend clause 151** as follows: - **remove** "that is supplied or obtained under or for the purposes of this Act" from clause 151(2)(a) because 151(4) deals with the "obtained for the purpose of this [or another] Act" point; and 151(2) is actually not about information obtained or for the purpose of this Act, it relates to information sharing with other agencies which may not be for the purposes of this Act. - **replace** "and" with "or" in clause 151(2).
77	**Amend clause 152** as follows: - **remove** "that is supplied or obtained under or for the purposes of this Act" from clause 152(2)(a). - **replace** "and" with "or" in 152(2).
78	**Amend clauses 151 and 152** to clarify the relationship between clause 151 and Information Privacy Principles (IPPs) 2 and 11, and the relationship between clause 152 and IPP 12.
79	**Amend clause 153** to clarify that the Regulator may disclose information under an agreement made with a recognised overseas authority to undertake joint assessments of licence applications under this Bill **Amend 153(2)(b)(ii)** to include language like "help monitor compliance with this Act or a relevant law in the overseas country."
80	**Add clause** to explicitly allow information sharing with Biosafety Clearing–House established under the Cartagena Protocol.
81	**Add a regulation making power** to declare organisms or classes of organisms that are not regulated organisms. **Add a regulation making power** to declare technologies that are not gene technologies.
82	**Add details** on the levy making power in line with similar powers, for example, in section 168 of the Offshore Renewable Energy Bill and section 344 of the Therapeutic Products Act 2023.
83	**Add a regulation making power** for the Regulator to develop and consult on non-indigenous species of significance to be added as a list in the Bill's Regulations.

Rec #	Recommendation
84	**Amend clause 158** to correct the reference from 'notifiable activity' in the brackets of (b) to be 'non-notifiable activity'.
85	**Amend clause 167**, the procedure for making regulations, to ensure wider consultation is mandatory when making regulations.
86	**Amend clause 159** to replace "requirements" with "conditions", and cross-reference this clause with 48(3)(c).
87	**Insert a clause empowering regulations** to prescribe the criteria for the Regulator to be satisfied with before declaring an activity as a pre-assessed activity.
88	**Amend clause 160** to: - **delete** 160(2)(f), (h), and (i)(i). - **add** to 160(2) a timetable for the Regulator to make decisions about approving manufacturers, providers and third-party vendors.
89	**Amend clause 160** to: - at 160(3), enable the Regulator to extend, shorten, pause, reactivate or replace the timetables set in regulations. - **insert** a provision similar to section 59(6)-(9) of the Hazardous Substances and New Organisms Act 1996 (HSNO Act), to ensure that, where public submissions are invited in relation to an application or declaration, the time limits for such submissions must be extended if appropriate to give effect to Comprehensive and Progressive Agreement for Trans-Pacific Partnership or Trans-Pacific Partnership Agreement provisions.
90	**Delete clause 161(a) and (c)**.
91	**Amend clause 163(2)(a)** to reflect that regulations cannot be recommended unless that organism or class of organisms is indistinguishable from those that are either not regulated by the Act, or could be produced using a technology that is not regulated by the Act.
92	**Amend clause 163(2)(a)** to reflect that an equivalent conventional organism is not required for an organism to meet the criteria of exempt, only that it could be produced.
93	**Amend clause 163(1)(b)** to only refer to gene technology to ensure consistent language with the definition of gene technology.
94	**Add a supplementary prescriptive list of** items that are not regulated by this Act, including organisms that are not regulated organisms and technologies that are not gene technologies. **Amend clause 163(4)** to refer to the prescriptive list as items not regulated by the Act and **delete** reference to the specific legislation in (a)-(c).
95	**Amend clause 163(3)(a) and 163(3)(b)** to remove the ability of the Regulator to impose or amend conditions on, and revoke, exemptions, which was not the policy intent.
96	**Insert a clause as an empowering provision for regulations** that prescribe person to whom confidential information may be disclosed as per section 55 in HSNO Act.
97	**Amend clause 167** to state that failure to comply with consultation requirements does not affect the validity of the Regulations.

Rec #	Recommendation
98	**Amend clause 167** to ensure public consultation is mandatory.
99	**Amend clause 173** to impose a requirement for persons subject to levies to have to pay those levies.
100	**Amend clause 182** to reflect that the EPA will in practical terms be undertaking cost recovery functions, for example**:** - **replace** 'to the Crown' with 'to the EPA'. - **replace** "debt due to the Regulator" with "debt due to the EPA" in clause 175(1)(a) and (2) - **replace** "by the Regulator" with "by the EPA" in clause 175(1)(b)
101	**Amend clause 184(b)** to provide for EPA, on behalf of the Regulator, to receive and recover fees, charges, levies or penalties.
102	**Insert requirements** for service of notice to body corporates and partnerships similar to s 113(5)-(7) Fast Track Approvals Act 2024.
103	**Amend clause 187** so all persons exercising powers or performing functions or duties under the Act are protected from civil and criminal liability in relation to acts or omissions done in good faith and with reasonable cause.
104	**Add a requirement in Part 5, subpart 8 of the Bill** for the Minister to, as soon as practicable after the expiry of four years from the commencement of this Act: - commence a review of the operation of the Act, including the Office of the Gene Technology Regulator, and - prepare a report on the review and present it to Parliament. **Add** a requirement that the Minister be informed by the Regulator on workability of the regime, to inform the review of the operation of the Act.
105	**Amend clause 203** to clarify that an inspector cannot give biosecurity clearance to a regulated organism unless it is an authorised regulated organism and not a new organism.
106	**Amend clause 204(3)(b)** to appropriately provide in the Biosecurity Act for determinations made under clause 12 of the Bill.
107	**Amend clause 217(2)(a)** to exclude field-testing from the definition of "develop" in relation to new organisms other than incidentally imported organisms, as this was removed in error.
108	**Amend clause 204** to reflect an organism is also not a new organism solely because it is subject to an exemption made under section 163 of the HSNO Act.
109	**Amend the Summary Proceedings Act 1957 section 2**, to include a definition of infringement notice for the Gene Technology Act.
110	**Amend the Bill** so already approved emergency and special emergency authorisations remain valid under the HSNO Act for two years from the date of approval or earlier date set by EPA.
111	**Refer to PCO to consider** amending the Bill to ensure the first set of secondary legislation made under clauses 23, 47, 48, and 155, are not invalid because of a failure to comply with the prerequisites including seeking advice from the TAC and MAC.

Rec #	Recommendation
112	**Insert a new transitional provision** to enable MPI to update provisions required for the commencement of the gene technology without following the current, full Biosecurity Act process.
113	**Amend Schedule 2** so that the Regulator can make decisions under the Prohibition Order for authorised activities (including for export) under the Bill.
114	**Amend Schedule 3** to: - **delete** third row that refers to a transhipment decision as this type of licence is already captured by the second row, and - **delete** 'or in risk assessment and risk management plan' from description in fourth row.

Chapter 1: Overview of the Bill and submitters

Key features of the regulatory regime established by the Bill

1. The Bill establishes a new gene technology regulatory regime to enable the safe use of gene technologies. The Bill will regulate gene technologies, and organisms modified by gene technologies (referred to as "regulated organisms"), through managing the risks they may pose to the health and safety of people and the environment.

2. The purpose of the new regulatory regime is to provide for:

    a. risk-proportionate regulation

    b. efficient application and decision-making processes

    c. a flexible legislative framework able to accommodate future technological and policy developments without requiring frequent amendments to primary legislation

    d. international alignment, including with key trading partners, to facilitate trade and improve access to new technologies and products, and

    e. ways to recognise and give effect to the Crown's obligations under the Treaty of Waitangi.

3. To establish the new regime, the Bill:

    a. **Creates a risk-tiered authorisation system** to proportionately manage the risks that activities relating to regulated organisms and gene technologies may pose to the health and safety of people and the environment. Risk tiers will apply to three categories of activity: contained activities, medical activities, and environmental activities. Risk assessment processes will apply depending on the activity, and conditions may be applied to manage relevant risks.

    b. **Establishes a Gene Technology Regulator (the Regulator)**, an independent statutory decision-maker located within the Environmental Protection Authority (EPA), appointed by the Minister responsible for the Gene Technology Act (the Minister). The Regulator will be supported in its decision-making by a Technical Advisory Committee (TAC) and a Māori Advisory Committee (MAC); and supported administratively by the EPA.

    c. **Sets out that the Ministry for Primary Industries (MPI) will be the enforcement agency for the regime**, responsible for the compliance, monitoring, and enforcement functions. The Bill provides powers to carry out these functions and creates offences, defences, and penalties to manage and enforce compliance.

    d. **Makes consequential amendments** to other legislation, particularly to the Hazardous Substances and New Organisms Act 1996 (HSNO Act) which will no longer regulate genetically modified organisms (GMOs); to the Biosecurity Act 1993 (Biosecurity Act) to align enforcement settings with the new regime; and to the Resource Management Act 1991 (RMA) to achieve a nationally consistent approach to the treatment and use of GMOs.

Overview of submitters

4. The Committee received 14,458 written submissions.[1] Written submissions were provided by 396 organisations and 14,062 individuals.

5. The Committee also divided into two sub-committees to hear 287 oral submissions between the full Committee and sub-committees. The oral submissions included 119 organisations and 168 individuals. A list of all oral submitters is at Table 8 in Appendix Two.

Methodology

6. The Ministry of Business, Innovation and Employment (MBIE) identified 2,264 submissions as 'form' submissions, e.g., based on several identified templates. MBIE[2] analysed all submissions.

7. For this report, the following guide was used to establish the strength of themes that came through from submitters.

Table 2: Guidance on terms that quantify submitters views

Description	Approximate number of submissions
Few	Fewer than 5% of submitters
Some	5% - 25% of submitters
Many	25% - 50% of submitters
Most	50% - 90% of submitters
Almost all	90% or more
All	100%

8. For Chapter 2, which discusses thematic feedback, references to 'few', 'most', 'many' etc is as a proportion of all submissions. Note that submissions often covered multiple themes, so the total of the percentages across themes does not equal 100.

9. From analysis of all submissions, MBIE captured 1,364 comments relating to specific provisions of the Bill, recommending changes or indicating support. This subset of submissions is discussed in Chapter 3.

[1] Some submitters made duplicate or supplementary submissions, meaning the total number of submissions received exceeds the number of submitters.
[2] Including a small number of contracted surge policy support to manage the volume of submissions received (as agreed by the Committee).

High-level summary of submitter's views

10. Overall positions on the Bill are illustrated in the table below.

Table 3: Overall position of submissions

Submission position on the Bill	Number of submissions	%
Oppose	14,321	97.1%
Oppose in part	99	0.7%
Support	178	1.2%
Support in part	98	0.7%
Unclear	49	0.3%
Total Submissions	**14,745**	**100%**

11. MBIE classified submitters by a 'submitter type' to assist with analysis. Table 4 below provides a high level breakdown of submitter types based on submissions analysed.[3]

Table 4: High-level breakdown of submissions by submitter category

Submitter Category	Count	%
Agriculture (non-dairy)	72	0.49%
Agritech	5	0.03%
Apiary	10	0.07%
Biotech	16	0.11%
Dairy	29	0.20%
Environmental Non-Governmental Organisation (E-NGO)	32	0.22%
Fisheries	2	0.01%
Forestry	3	0.02%
Horticulture	41	0.28%
Iwi/hapū	25	0.17%
Legal	6	0.04%
Māori Non-Governmental Organisation (Māori NGO)	12	0.08%
Māori sector	2	0.01%
Officers of Parliament	1	0.01%
Organics	99	0.67%

[3] Note that where a submitter fits the description for more than one submitter type, they were only counted in one category.

Submitter Category	Count	%
Other	56	0.39%
Research institute	17	0.12%
Researcher (Individual)	43	0.29%
Sector group	22	0.15%
Seeds	12	0.08%
Think tank	4	0.03%
University	6	0.04%
Individual	14,230	96.60%
Total	**14,745**	**100%**

12. While it was impractical to include in this report a list of all submitters, we have provided a list of organisations on whose behalf a submission was made at Table 9 in Appendix Two.

13. Officials identified 2,264 submissions as 'form' submissions, based on 12 different templates. Table 5 below lists these by frequency of submission.

Table 5: Identified form submissions, by frequency

Form submission	Count of Form submission
Form 5 - Unknown origin	1,162
Form 1 - Guy Hatchard Report	401
Form 3 - Organics Aotearoa New Zealand	256
Form 9 - Greenpeace	254
Form 8 - NZ Doctors Speaking Out With Science	135
Form 4 - GE Free New Zealand	23
Form 10 - GoodFor Limited	11
Form 2 - Unknown origin	9
Form 6 - Unknown origin	7
Form 7 - Unknown origin	4
Form 12 - Unknown origin	1
Form 11 - Unknown origin	1
Total	**2,264**

14. As for non-form submissions, MBIE analysed themes of support and opposition in each form template and attributed that position to the submitter of the form. Themes identified are discussed in Chapter 2.

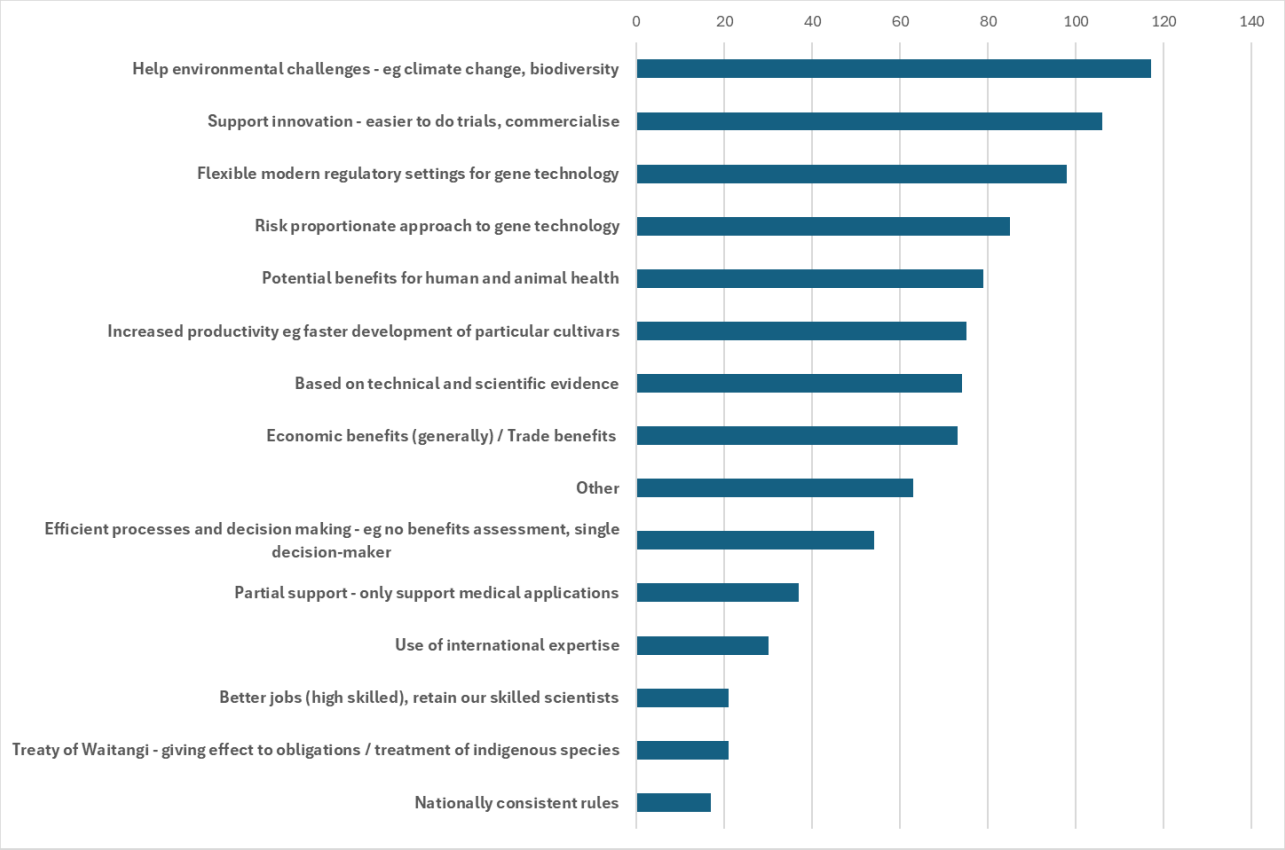
Chapter 2: Main themes across submissions

15. This chapter canvasses the most common themes raised by submitters, in support of and in opposition to the Bill.[4] Several themes are discussed in further detail in Chapter 3.

Submissions in support of the Bill

16. Few submissions (1.9%) supported the Bill, or supported it in part. Figure 1 below illustrates the themes from submissions supporting the Bill.

Figure 1: Themes in submissions supportive of the Bill



17. The most common themes raised by supporters of the Bill – and discussed further in this section – were that the Bill would:

    a. help with environmental challenges

    b. support innovation

    c. provide flexible, modern regulatory settings for gene technology

    d. implement a risk-proportionate approach to gene technology, and

    e. support potential benefits for human and/or animal health.

[4] While submissions on the Bill are public, we have chosen not to include names of individual submitters when quoting them.

18. Other themes raised by supporters (not discussed further in this section) were that the Bill:

    a. will result in increased productivity

    b. is supported by technical and scientific evidence

    c. will result in economic or trade benefits

    d. has efficient processes and decision-making, and

    e. utilises international expertise

Help with environmental challenges

19. Many supportive submissions (42% or 117 submissions) said that the Bill will help with environmental challenges, including addressing climate change, safeguarding native species, and improving animal welfare.

20. Some submitters, such as CropLife Australia, said that the Bill, by shifting New Zealand away from a rigid genetic modification-free (GM-free) status, may increase export opportunities:

> *"…into markets such as the EU that require sustainability measures, where biotechnology can be used to address climate change, food security, and environmental degradation. Moreover, GM can open novel markets for NZ farmers. A flexible regulatory approach would better support New Zealand's long-term economic and environmental goals."*

21. Submitters provided a wide range of examples of how gene technology could potentially benefit the environment. For example, Federated Farmers noted the:

> "*…potential benefits that this technology could provide if a reform is implemented correctly. These benefits include reaching our predator and pest-free targets, mitigating wilding pines and other pest plants, reducing water use in crops, reducing greenhouse gases and nitrogen loss, tools to combat Kauri dieback disease, increased yield, decreasing reliance on pesticides, and improved access to modern medical techniques."*

22. Tāngata Huawhenua – Māori Horticulture Council Aotearoa Incorporated (Tāngata Huawhenua) submitted in support of the Bill for several reasons, including that *"Gene technologies might offer solutions for controlling invasive species and protecting indigenous taonga, aligning with our obligations as kaitiaki Māori*." Examples provided by Tāngata Huawhenua of positive environmental outcomes that could be enabled by the Bill included:

    a. enhanced crop resilience and yield reducing reliance on chemical pesticides and aligning with sustainable and traditional Māori growing practices, and

    b. developing unique plant varieties and products, and

    c. climate change adaptation with gene editing assisting to develop crop varieties more tolerant to extreme weather conditions.

23. The Dairy Companies Association of New Zealand (DCANZ) said that:

> *"DCANZ believes it is possible for New Zealand to progress a pathway to liberalise genetic technologies that improve productivity, animal welfare, and environmental outcomes while protecting market access."*

24. While expressing reservations regarding aspects of the Bill and the process to develop it, the New Zealand Institute of Forestry (NZIF) noted the following environmental benefits in its submission:

    a. The development of sterile trees to mitigate the risks associated with the spread of wilding pines, which could only be sustained in the environment through deliberate breeding and replanting.

    b. Rapid response to biosecurity threats, including to the introduction of tree pests or diseases.

    c. Conservation of native biodiversity, where trapping and poison may not be sufficient to achieve the elimination of pests across vast landscapes.

25. A few submissions opposing the Bill in its current form acknowledged the need for reform and that the Bill's reform could result in positive environmental outcomes. For example, a submission from The Ngāti Koata Trust, a Post Settlement Governance Entity for the Iwi of Ngāti Koata, one of Te Tau Ihu Iwi o Te Waka a Maui, states:

> *"Under limited circumstances, gene technology may offer opportunities to better look after our native species and their environment. However, it is crucial that communities such as iwi which are affected by these decisions are informed and contribute to decisions which may affect the future use of new technologies."*

Supports innovation

26. Many supportive submissions (38% or 106 submissions) indicated that they thought the Bill would support innovation.

27. For example, research institute Scion states:

> *"Modern gene technology is already playing an increasingly valuable role in global innovation and presents exciting opportunities. For example, the potential to produce non-animal casein and other analogue milk proteins such as whey proteins using modified microorganisms and fermentation, otherwise known as precision fermentation, is a technology currently under development by a growing number of start-up[s]".*

28. Some submitters expressed frustration with New Zealand's existing regulation of gene technology, noting that it was outdated and was stifling innovation and technological advancement. T&G Global, apple growers and produce exporters, supported the need for reform, stating that modernising New Zealand's regulatory framework to enable the safe adoption of gene technologies will:

> *"…support and enhance New Zealand's competitive advantage on the world stage, boost innovation and productivity, improve sustainability, and help secure economic growth and long-term prosperity."*

29. Some submitters viewed that the Bill could enable the economic benefits of gene technologies without risking existing non-GMO production. DCANZ noted that dairy exporters

currently rely on New Zealand's de facto GM-free status to meet market preferences but stated that:

> *"DCANZ believes it is possible for New Zealand to progress a pathway to liberalise genetic technologies that improve productivity, animal welfare, and environmental outcomes while protecting market access."*

30. Fonterra's submission, which largely supports the Bill, states:

> *"Modern gene technology is already playing an increasingly valuable role in global innovation and presents exciting opportunities. For example, the potential to produce non-animal casein and other analogue milk proteins such as whey proteins using modified microorganisms and fermentation, otherwise known as precision fermentation, is a technology currently under development by a growing number of start-up companies including Vivici BV, a start-up venture in the Netherlands spun-out of a collaboration between Fonterra and DSM."*

31. Some submissions focused on innovation opportunities with environmental benefits, such as AgriZeroNZ who are a partnership between the New Zealand Government and major agribusiness companies focused on helping farmers reduce methane and nitrous oxide emissions whilst maintaining profitability and productivity. AgriZeroNZ's submission noted that:

> *"Gene technologies play a crucial role in developing some innovative tools to reduce on-farm emissions of the greenhouse gases methane and nitrous oxide."*

A better regulatory framework for gene technology

32. The next most common theme raised by supporters of the Bill (36% or 98 submissions) was that the Bill would provide a better regulatory framework for gene technology compared with existing settings.

33. These submitters were often researchers, research institutes, or from university backgrounds. They noted evidence that gene technologies can be used safely and that regulation should reflect this. Some commented that the current regulatory framework under the HSNO Act is out of date, acts as a barrier to innovation, and does not reflect the current scientific understanding of the risks and benefits of gene technologies.

34. Submitters supporting the need for reform include Prevar Limited, a joint venture developing and commercialising new varieties of apples and pears, that stated:

> *"The proposed Bill represents a critical step toward modernising New Zealand's regulatory framework for genetic technologies, ensuring that our horticulture sector remains globally competitive while meeting the evolving needs of consumers, growers, and the environment. We strongly support the responsible use of gene editing as a breeding tool to develop improved apple and pear varieties, addressing some of the most pressing economic, environmental, and social challenges facing our industry."*

35. Medicines New Zealand's submission included similar arguments, noting that:

> *"The HSNO Act is now so out of date that it has become a barrier and has a deterrent impact on companies' willingness to consider bringing innovative gene technology therapies to New Zealand. Aside from the commercial ramifications of this situation, this has a significant adverse consequence for patients who may have high health needs that are not met by available treatments. Our membership is agreed that reform*

of the HSNO Act a key step towards enabling increased access to innovative gene technology medicines and vaccines for the New Zealand health system and patients."

36. Indicating overall support for the Bill, New Zealand Plant and Food Research said:

"For New Zealand to benefit successfully from a new era of world class biotechnology, we require supporting regulations and standards that are enabling."

37. Bayer New Zealand, a life science company, noted that New Zealand is well positioned to learn from other jurisdictions, and supported the Bill seeking to establish:

"…a regulatory framework for gene technology that enshrines scientific rigour, encourages innovation and investment, and allows for flexibility in assessing emerging and future technologies."

38. Further to this, Bayer also stated support for the overall regulatory approach in the Bill, stating:

"We support the expedited assessment pathway outlined in the Bill to take advantage of the work of similar regulators, reducing duplication and ensuring the Regulator's resources can be focused on areas requiring the most attention."

39. Some supportive submitters highlighted their support for specific regulatory processes accounted for in the Bill. For example, on the inclusion of a process to enable the management of risk to Māori kaitiaki relationships with indigenous species, Plant and Food Research said:

"We hope that as well as mitigating risks to Māori relationships with the environment, this will also enable Māori-led projects and innovation that particularly support Māori economic development goals."

40. On the proposed advisory functions in the Bill, AgResearch supported the establishment of the TAC because the Regulator *"…can't be expected to be sufficiently expert in all fields necessary to have an informed view on all types of decisions needing to be made…".*

A risk proportionate approach

41. Nearly a third of supportive submissions (31% or 85 submissions) noted their support for the Bill's proportionate approach to risk.

42. Many supportive submissions noted the Bill's risk-proportionate approach, including BioValeo and Medicines New Zealand in the medical sector. Medicines New Zealand also noted that over-regulation could have a negative effect on health outcomes because it may result in fewer opportunities for treatment for the already small population of patients eligible for clinical trials.

43. Bayer New Zealand's submission also supported the Bill's approach to risk:

"Bayer supports the Bill's risk-tiering approach and expedited assessment pathways, which align with global practices. We support the exemption of certain genome edited organisms from regulation if they could also be produced through conventional methods. This harmonises New Zealand's approach with the majority of global regulatory schemes".

44. Zespri submitted:

> *"The Gene Technology Bill provides a framework that can deliver the intended outcomes. We support an independent regulator bound by the primary legislation with full authority to regulate gene technologies and modified organisms on their scientific merits/risks in secondary legislation. We also support leaving international trade, product co-existence, and other socio-economic considerations to the market."*

45. Some submissions from the agricultural and horticultural sectors agreed with the Bill's focus on a risk-proportionate regulatory regime, these included AgResearch, the Australian Seed Federation, Beef + Lamb New Zealand, Plant and Food Research, and CropLife Australia. CropLife Australia stated that:

> *"By adopting a risk-proportionate regulatory framework that supports both GM and non-GM production, New Zealand can diversify its agricultural offerings and strengthen its global market competitiveness."*

46. In addition to comments on the Bill's support for innovation, Fonterra noted the Bill's risk-tiered approach, stating:

> *"Currently, precision fermentation activities at commercial scale can only be conducted offshore. The Bill's risk-tiered approach – allowing non-notifiable contained activities – could encourage local investment, creating jobs, building scientific capability, and expanding New Zealand's export portfolio."*

Potential benefits for human or animal health

47. Many supportive submissions (27% or 79 submissions) thought the Bill would result in potential benefits for human or animal health.

48. Positive health outcomes for people supported by enabling gene technologies were commonly cited. For example, the Malaghan Institute's submission explained that clinical trials of Chimeric antigen receptor (CAR) T-cell therapy, *"a personalised cell and gene therapy of curative potential for some blood cancers, involving gene-engineering of a patient's own immune cells to recognise their cancer"*, had faced delays while seeking authorisation under the HSNO Act regime because the cells are classified as GMOs. Malaghan stated that regulating clinical trials and manufacturing is important, but that EPA is not the appropriate regulatory body for this aspect of that regulation.

49. Tāngata Huawhenua's submission also noted the opportunities for positive health advancements, stating:

> *"Genetic engineering, especially technologies like gene editing, holds promise for developing treatments for genetic disorders prevalent among smaller populations of people with particular genetic characteristics, this has huge potential for improving health outcomes."*

50. Some submitters focused on the potential of the Bill to enable the development of new medical treatments, medicines, and gene therapies, including South Pacific Sera Ltd, Medicines New Zealand, and Rare Disorders New Zealand, an advocacy organisation that supports patients and family affected by rare disorders. Medicines New Zealand stated that advances in gene therapies and editing can benefit people with Type 1 diabetes, multiple sclerosis, chronic pain, inflammatory bowel disease, and many more conditions.

51. Regarding positive outcomes for animal health, Animal and Plant Health NZ support the Bill and stated that:

> *"New Zealand needs to adopt biotechnology innovations to remain globally competitive in the production of safe, nutritious and affordable food, animal feed and high-quality fibre, and protect animal health, while being environmentally sustainable."*

52. Lanaco, a New Zealand technology company, supports the Bill on the basis that gene technologies may lead to improved livestock welfare (and other benefits unrelated to animal health, such as environmental and productivity benefits).

53. Animal Justice Auckland's submission highlighted the potential of precision fermentation to reduce or replace reliance on the animal agricultural industry, therefore significantly reducing harm to production animals.

54. AgResearch's submission included specific examples of gene technologies that can positively impact animal health, including:

> *"High Metabolisable Energy (HME) Ryegrass. Increased levels of plant oils compared to non-modified ryegrass increase the amount of metabolisable energy available to livestock, potentially increasing productivity. Researchers have also demonstrated that HME Ryegrass reduces methane emissions from livestock.*
>
> *High-Condensed Tannin White Clover. Condensed tannins produced in flower petals can also be produced in the leaves of clover. This is expected to result in a similar level of methane reduction as HME Ryegrass, as well as reducing nitrogen losses and increasing animal health."*

55. A submission from the InterChurch Bioethics Council noted that it is time to re-evaluate gene technology use and regulation in New Zealand, and that this provides opportunity to protect our biodiversity and taonga species.

56. Some of supportive submissions (13%) stated that they only support the use of gene technology for medicines (animal or human). A few of these submitters recommended that the Bill is split, for example: "*[The Bill] could proceed on those aspects of gene technology that already have a high level of social licence, other, highly contentious parts related to food crops and agriculture require a far greater degree of work, research and consultation before being allowed to proceed".*

Submissions that oppose the Bill

57. Approximately 97.8% of submissions (14,420 submissions) opposed the Bill or opposed it in part. Figure 2 on the next page illustrates the themes from submissions opposing the Bill.

58. The most common themes raised by submitters opposing the Bill were that:

    a. gene technologies are not safe

    b. gene technologies will damage New Zealand's reputation, trading relationships or the economy

    c. there will be negative impacts for non-GMO and organic producers

    d. consultation on the proposals in the Bill was inadequate, and

    e. there are insufficient liability and compensation provisions.

59. Chapter 3 discusses other themes commonly raised by opposing submitters included concerns about:

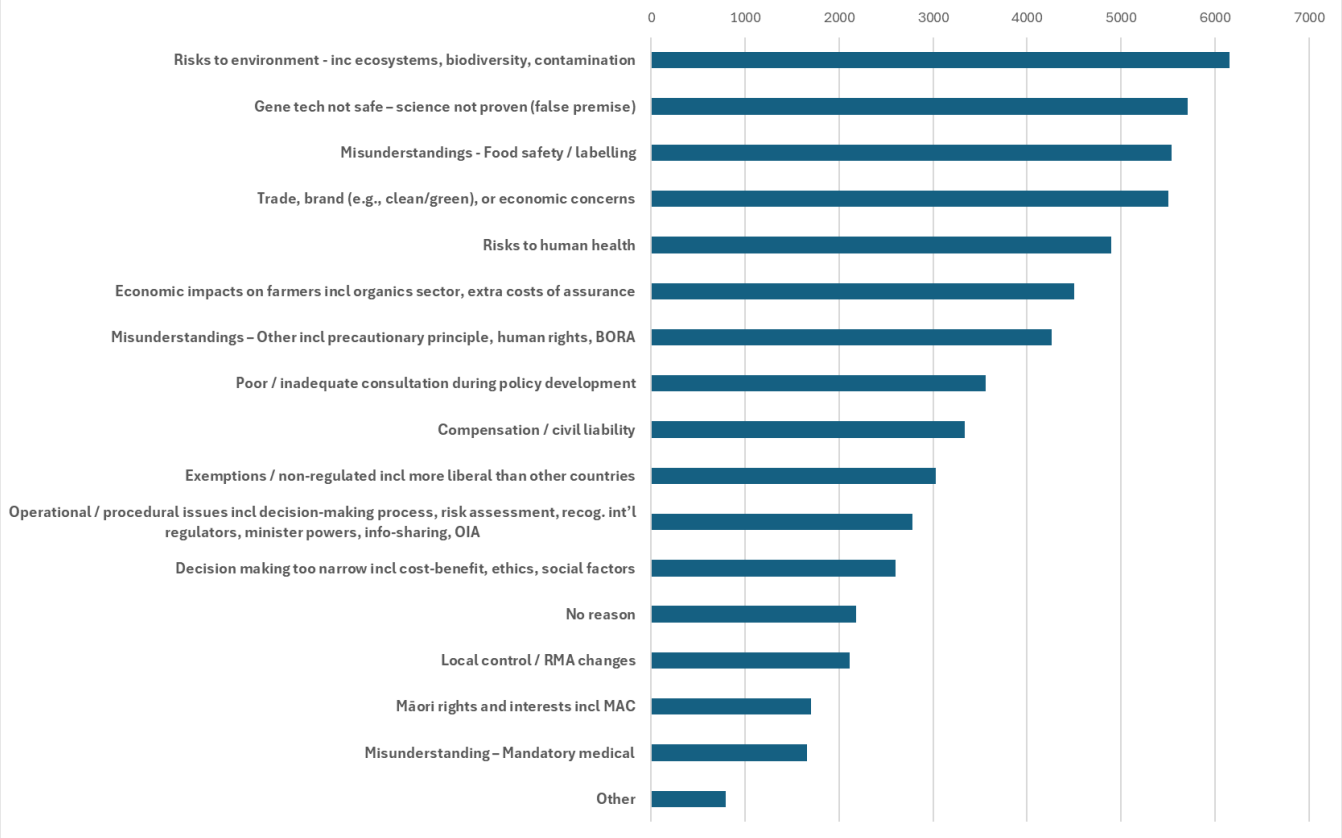
    a. provisions relating to exemptions and non-regulated organisms (refer Chapter 3.12)

    b. operational or procedural processes, for example concerns about ministerial or regulatory powers (refer Chapter 3.9), the membership and operation of the TAC (refer Chapter 3.10) and the information sharing provisions (refer Chapter 3.6, and

    c. the scope of the decision-making process, which submitters thought should be expanded to include considerations such as ethics, cost-benefit analysis or social factors (refer Chapter 3.2).

60. Officials note that some opposing submissions (15% or 2,180 submissions) were categorised as 'no theme'. Many of these submissions simply said, "keep NZ GE-free" or expressed similar sentiment, while others just stated "no" or "I don't support this Bill".

Figure 2: Themes in submissions opposing the Bill



Concerns were raised that gene technology is not safe for the environment or humans

61. About a third of submissions that opposed the Bill thought that gene technology is unsafe, unproven or risky, of which:

    a. 43% said that it poses risks to the environment, ecosystems and biodiversity

    b. 40% said the science was not proven or that there was a lack of evidence,

    c. 34% said that human health at risk directly.

62. Submitters provided a wide range of reasons for holding these views, including that:

    a. gene technologies are inherently harmful and/or present potentially significant and irreversible risks to health or the environment

    b. there is no evidence gene technologies are safe, or that current research is limited or cannot be relied on, and

    c. that there is increasing evidence that gene technology is unsafe.

63. A few submitters who expressed these types of concerns also provided research article citations, news articles or social media posts to support their assertions.

64. While many of these submissions were strongly opposed, it was not uncommon for submissions to caveat opposition that submitters could be convinced through scientific evidence. However, many of these submissions considered that most research on the safety of gene technology had been funded by industry.

65. A few submitters framed concerns about environmental risks in the context that gene editing and gene modification is "playing God" and is not appropriate for anyone to do. Others had broader objections to gene technology on moral, religious or ethical grounds.

Risks to trade and the economy

66. Many submissions (38% or 5,504 submissions) opposing the Bill said that it will harm New Zealand's trading relationships, clean/green image, or that it will not deliver on claims of economic benefits. Many of these submissions focused on the risks the Bill poses to the economic value derived from New Zealand's de facto GM- and GMO-free status. This theme is covered at a relatively high level because it is discussed in greater detail in Chapter 3.1.

67. A few submissions assert that the productivity and innovation benefits associated with gene technologies may not be justified or may not be realised. These submissions consider that the Bill poses risk to New Zealand's economy without any certainty that the risk will be paired with any substantive benefit to productivity or innovation.

68. Some submissions that cited trade concerns based this around a conception of New Zealand's national identity, as an agricultural trading nation and our clean/green image. Many such submissions referenced sentiments such as "keep NZ GE free".

69. Other submitters argued that claims of productivity and innovation benefits associated with gene technologies are not justified, or that any financial benefit will go to large overseas corporations or biotech companies and not to New Zealanders. As one submitter stated:

> *"The gene tech bill is short sighted and dangerous. Please stop, or at least slow down. The primary winner is major corporations not the average kiwi. Invest instead in initiatives that help get more kiwis working on the land, growing food and healing ecosystems."*

Impact on non-GMO and organic producers

70. Some opposing submissions (31% or 4,504 submissions) were concerned about the Bill's impact on non-GMO and organic producers. Like the previous theme, these issues are discussed in greater detail in Chapter 3.1 and are only briefly covered here.

71. Many such submissions argued that GMO contamination is highly likely and that organics producers may be not able to avoid the presence of GM- and GMO-inputs, for example in

animal feed. Concerns about GMO contamination were often concerned about the exempt and non-notifiable categories of activities.

72. The Ira Tātai Whakaeke Charitable Trust, an all-Māori collective of health and gene technology researchers and specialists noted in its submission that the Bill will "*marginalize both Māori primary sector producers, as well as Māori communities – particularly kaitiaki."*

73. Organics Aotearoa New Zealand's submission also noted that it considers the Bill marginalises Māori and that:

> *"The Bill holds the potential to devastate the Hua Parakore verification system, which is recognised globally for its holistic approach to food and primary products. This system is grounded in Te Ao Māori, derived from the wisdom of Māori tūpuna (ancestors) and supported by both tangata whenua and tanga Tiriti, who are seeking indigenous growing kaupapa led by indigenous knowledge reclamation."*

74. Some submitters noted that the presence of GMOs in New Zealand would impose additional costs on producers and exporters wishing to maintain GM- and GMO-free production because they would need to maintain supply chain separation, participate in coexistence frameworks, and seek verification of their product's status. Whereas producers and exporters who are not seeking a premium based on GM- and GMO-free status would not need to invest in such precautions. As noted by the Sustainability Council, the additional costs imposed on GM- and GMO-free producers and exporters may not always be certain:

> *"This leaves enormous uncertainty for food producers, including the scale and allocation of the costs."*

75. Some organic producers and exporters indicated that the Bill threatens the entire organic sector due to the Bill's inadequate safeguards against contamination. OrganicFarmNZ, a not-for-profit that offers organic farming education and certification, noted:

> *"The organic brand, which has taken decades to build, will be jeopardised by GMO tech which has not been tested in New Zealand, cannot be controlled properly and the environmental impact will be significant."*

76. This sentiment is echoed by Organics Aotearoa New Zealand, who state that the Bill will make GMO-free certification impossible to guarantee. These submitters consider that the loss of New Zealand's de facto GM- and GMO-free status will lead to poorer economic outcomes for organic producers and exporters in general.

Inadequate consultation

77. A quarter of opposition submissions (25% or 3,559 submissions) described the Bill's consultation process as inadequate, poor, or too short. Many submitters said that consultation with Māori, the organics industry, and GM- and GMO-free producers and exporters was inadequate.

78. Organics Aotearoa New Zealand submitted that the Government should extend consideration of the Bill and undertake a six-month consultation process to allow for genuine public consultation and consultation with relevant groups such as the organic sector, experts, and Māori communities.

79. Tainui o Tainui submitted that the 2001 Royal Commission on Genetic Modification noted that the gene modification debate is made unique because of the partnership between tangata whenua and tanga tiriti. Tainui o Tainui recommend that the Committee extend the

consultation period to enable the public an opportunity to further participate in the development of the Bill. This concern is conveyed by Te Kaahui o Rauru[5], the post settlement governance entity of Ngaa Rauru Kiitahi, who reference the Royal Society and the Prime Minister's Chief Science Advisor (Dame Juliet Gerrard) who recommended that any regulatory reform be informed by widespread public engagement. Te Kaahui o Rauru commented that:

> *"The Crown has failed in its obligations to actively protect these rights, enable meaningful participation in decision-making, and work in true partnership with Māori on legislation that will significantly impact the natural environment—the very foundation of Māori culture, language, and identity."*

80. The Te Kaahi o Rauru submission also notes that MBIE's Regulatory Impact Statement acknowledges that officials did not consult with the public or Māori at that stage due to the timeframes for developing the proposal.

81. Another submitter commented:

> *"If Māori perspectives are not adequately considered or integrated into legislation on gene editing, it could be argued that this violates the Treatys [sic] principle of partnership and participation."*

82. A few submitters said that the Bill should be subject to a referendum or that the issue was so important that there needed to be a national conversation on the issue. Other submitters were surprised at the speed of the Bill process compared to the last time the issue was considered a national level (the 2001 Royal Commission).

83. Some submitters were concerned that the lack of public engagement will exacerbate existing concerns about gene technology, which is known to be a highly contentious issue in New Zealand. Other submitters indicated a preference for much greater public consultation, education and engagement in the future, including for secondary legislation.

84. Some submitters, including some that are generally supportive of the Bill, were unhappy with the timeframes for submitting to the Committee. For example, Beef + Lamb New Zealand said:

> *"The adoption of gene technologies is a complex issue, and one that is polarising within the farming community. As the Committee will already be aware, B+LNZ does not consider that the deadlines set for submissions to be provided to the Committee were appropriate given that context, and given that the time of year over which submissions could be developed provided limited opportunity to engage with farmers".*

85. Organic Farm New Zealand also expressed concern regarding engagement with farmers, saying they:

> *"…are concerned with the short time frame between the Bill being introduced to parliament and the closing date of the submissions. This has taken place over summer,*

[5] Te Kaahui o Rauru is the post settlement governance entity of Ngaa Rauru Kiitahi recognised by the Government's Ngaa Rauru Kiitahi Claims Settlement Act 2005 as the mandated Iwi and therefore makes this submission on behalf of the 7,300 uri, 14 hapuu and 12 marae affiliated to it.

which is one of the busiest times of the year for most of our farmers and growers and for our community of interest."

Insufficient compensation and civil liability provisions

86. Some submissions (23% or 3,334 submissions) opposing the Bill raised concerns about compensation and civil liability. This theme is discussed substantively in Chapter 3.7 so is only briefly covered here.

87. Many of these submitters said that gene technology users should be fully liable for any costs resulting from intentional or accidental contamination. Other submitters said that the Regulator should ensure applicants have insurance cover for such circumstances. Other submitters recommended copying over the civil liability provisions from the HSNO Act into the Bill.

88. Some submitters considered that without a robust civil liability regime, there is no incentive for applicants and regulated parties to avoid contaminating the products and the production of GM- and GMO-free producers and exporters or to avoid causing broader environmental harms.

89. Many submitters disagreed with clause 187, which provides civil and criminal liability protection to statutory and administrative officers when performing their legislative duties and functions under the Bill.

Form submissions in opposition of the Bill

90. All identified form submissions opposed the Bill. The concerns raised broadly aligned with those in the non-form submissions which opposed the Bill. Key specific points from the form submissions are:

    a. The GE Free New Zealand form submission recommends three courses of action; to reject the Bill because it does not meet its stated objectives, to pause the Bill allowing for more economic analysis, or to significantly modify it if the Bill progresses. It recommended retaining the precautionary principle, retaining the power of local authorities to create and enforce local bans, and holding GMO users liable for contamination.

    b. The Greenpeace form submission recommends retention of the precautionary principle, stated that the Bill is inconsistent with the Crown's responsibility to protect Māori interests, and discusses alternative approaches to combatting climate change.

    c. The Guy Hatchard Report's form submission notes that many other countries have restrictive gene technology regulation and states risks of gene technology are not understood.

    d. The Organics Aotearoa New Zealand form submission recommends New Zealand retain regulation under the HSNO Act, arguing that the precautionary approach best manages risks. The submission also noted that if the Bill is not cancelled, then consultation should be extended for a further six months.

    e. The GoodFor Limited form submission considers the HSNO Act to effectively protect consumer choice, the environment, and our export markets. It recommends New Zealand retain the precautionary principle, ensure full transparency and mandatory labelling, protect non-GM and organic producers, and extend the consultation process.

91. MBIE did not determine the origin of the remaining form templates identified, but note the key points as follows.

    a. The Bill will not appropriately manage risks, the Regulator is susceptible to regulatory capture, and removal of the power for local authorities to make rules or ban GM undermines local decision-making.

    b. Foreign authorisations will be prioritised over New Zealand assessments (regarding mandatory medical authorisations), safety studies of GM are funded by industry and dissenting opinions are suppressed or discredited, and no long-term safety studies exist.

    c. Opposing the removal of case-by-case assessment for gene edited food and noting that companies should be held accountable for any harm caused through contamination of non-GMO food systems.

    d. Rather than embracing gene technology, New Zealand could further invest in sustainable agricultural practices and emerging technologies that do not carry the same risks.

    e. The Bill is a large-scale intervention in our biological systems through our food and medicine. The submission recommends mandatory labelling of all GMO products, independent long-term safety studies, retention of decision-making by local authorities, and companies to be held liable for any harm caused.

Submissions on matters unrelated to the core policy of the Bill

92. Some submissions opposing the Bill, including form submissions, included concerns based on misunderstandings of the purpose or scope of the Bill, specific provisions in the Bill, and how it interacts with other regimes.

93. The most commonly raised themes by submitters that do not fall within the policy scope of the Bill were concerns that the Bill:

    a. removes food labelling requirements for foods that have been produced by gene technologies or include GM or GMO components or ingredients (raised by around 38% of opposing submissions)

    b. will enable the Government to force vaccinations or medical treatments on people (raised by around 12% of opposing submissions), and

    c. violates the Bill of Rights Act 1990 by removing people's freedom of choice and bodily autonomy.[6]

94. Appendix Three provides a detailed explanation of why these and some other issues raised by submitters fall outside the policy scope of the Bill.

[6] Estimating the number of submissions that touched on this is difficult due to crossover with the above two issues and concerns regarding the precautionary principle from the HSNO Act not being copied over into this Bill

Chapter 3: Part-by-part issues analysis

95. This section provides a summary of MBIE's responses to key issues and recommendations that relate to a specific part of the Bill.

96. The items discussed in this Chapter cover substantive issues and/or matters the Committee has requested information on. This section is supplemented by Appendix One, which provides detailed clause-by-clause analysis of all suggested amendments raised by submitters.

Part 1: Preliminary provisions

97. Part 1 sets out the preliminary provisions. These cover the purpose of the Bill, how the Bill recognises and respects the Crown's obligations under the principles of the Treaty of Waitangi, a requirement on decision makers to have regard to the Convention on Biological Diversity and the Cartagena Protocol, an outline of the Bill, definitions used in the Bill, transitional and savings, and binding on the Crown clauses.

98. The main feedback from submitters on this part related to the Bill's purpose, and the Crown's obligations under the Treaty of Waitangi. Some submitters also made suggestions on definitions used in the Bill, which are addressed in Appendix One.

3.1 Trade, market access, coexistence and traceability

99. Many submissions opposing the Bill and some submissions supporting the Bill have expressed concerns about its impact on trade and market access for products. Of submissions opposing the Bill, approximately 38% included concerns regarding trade and market access and approximately 31% included concerns about the economic impacts on specific producers and exporters. While submissions regarding trade and market access came from a range of sectors, most came from the Organics sector.

100. The concerns in submissions stem from the fact that the Bill will lead to use in the environment of both GMOs / regulated organisms, and organisms that have been gene-edited but are exempt from regulation because they are indistinguishable from organisms created through conventional processes.

101. The main concerns of submitters were the potential effect of the use of these organisms in the environment in relation to:

    a. assurance requirements of overseas importers or governments to maintain the market access of certain products

    b. trade impacts should there be less demand for certain products from overseas consumers, and

    c. cost impacts of mitigating the risks above, including maintaining supply chain segregation and coexistence.

102. Concerns expressed by submitters about traceability and coexistence relate primarily to market access risks, i.e. the risk that overseas importers or governments might restrict the importation of certain New Zealand non-GM or organic products. On the other hand, concerns expressed by submitters around trade risks or impacts relate to the potential negative effects on the export earnings of certain New Zealand products or sectors due to less demand for these products from overseas consumers. Submitters who expressed these

concerns argued that there would be lower demand for these products due to the perception of overseas consumers that New Zealand was no longer GM-free (which in the opinion of these submitters is a key product attribute for overseas consumers).

103. Consideration of both trade and market access issues in the Bill is a complex issue. The section below provides significant additional detail and discusses the broader regulatory context. This section covers the impacts of exempt and regulated organisms in the environment, assurances, the distribution of costs, and submitters' views, including proposals for the Bill to consider trade and market access risks.

GMOs vary in the properties that are most relevant to market access and coexistence

104. The different properties of the GMOs most likely to be used in the New Zealand environment will mean that the assurances required for market access and coexistence will vary. For instance, in relation to unintended GMO presence (sometimes referred to as "contamination"), GMOs will vary in this property, from those where unintended GMO presence would be impossible to occur, to those where unintended GMO presence could occur.

105. For example, sterile Douglas Fir would not release any pollen (due to its sterility) and ryegrass endophytes do not spread through pollen but are instead associated with a particular ryegrass and its seed. On the other hand, other organisms that are wind pollinated, (such as ryegrass), would have a higher likelihood of causing unintended GMO presence.

106. Countries and jurisdictions also range in their tolerance levels for the unintended presence of GMOs in non-GM products (if it occurs). Tolerances also vary between food and animal feed, seeds, and organic products. For instance, for food and animal feed material, the European Union (EU) does not require labelling if a crop or product contains GM content no higher than 0.9%; Brazil, Israel, and Saudi Arabia set this level at 1%; Malaysia 3%; and Japan, Canada, Hong Kong, Indonesia, Taiwan, Mexico and Thailand set this level at 5%.

107. It should also be noted that unintended presence of GMOs can be further differentiated into two types. The first is unintended presence that may cause the inadvertent alteration of the genetic makeup of a non-GM species. An example of this type of unintended presence would be if the pollen from a GM corn were to pollinate a non-GM corn. The second type is unintended presence that could not cause the inadvertent alteration of the genetic makeup of a non-GM species. An example of this type of unintended presence would be if the pollen from a GM ryegrass were to fall onto a non-GM corn. The second type is of least concern to the topic of coexistence and market access as this type of unintended presence would not result in products or consignments that unintentionally contain a mix of non-GM and GM components.

108. The types of management and approaches required for coexistence will also be inherently different for plants, microorganisms, and animals. Additionally, systems will already be in place in a range of supply chains that may support coexistence should it be required. For instance, under the National Animal Identification and Tracing programme, cattle and deer farmers are required to register their farms, tag and register their animals, and record all animal movements.

When GMOs/regulated organisms and exempted organisms are in the environment, farmers and exporters may need to be able to assure trading partners about their supply chain

109. Countries have differing requirements and thresholds for approvals and imports of GM products. Currently most of our major trading partners require some form of pre-market assessment and approval within their own territories before most GM foods and animal feed

can be allowed to be imported or sold. These requirements vary from market to market and are also product and technology/modification dependent. There are also markets which require a declaration by the importer/exporter to confirm freedom from GMOs in their products or consignments.

110. Assurances regarding the status of a trade product may be required by the importer (business-to-business), or to facilitate entry at the border (business-to-government), or as a government-to-government assurance.[7] The level and type of assurance depends on what risk the trading partner is trying to manage. In the case of government-to-government assurances, the best-case scenario is that other governments accept the New Zealand regime as being equivalent and therefore that no official assurances are required to facilitate entry. We note that this best-case scenario may not be possible in all markets. We also note that this is unlikely to obviate business-to-business assurance requirements concerning the status of the good (which may include that it is non-GM).

111. Once exempted and regulated organisms are being used in the environment, exporters may need to provide assurances about their supply chain for their products to maintain existing market access (or gain new market access). For example, is the apple they are exporting, which has a non-browning attribute, the product of gene-editing or a conventional process? Or, for an organic product, is the milk powder the product of a cow that has not eaten any GM feed (among other standards that must be met).[8]

112. These assurances may be provided by the exporter themselves or provided by third-party verifiers, as in the case of organic products. In the case of organic products, an organic assurance confirms compliance with an organic standard, which prohibits the deliberate use or negligent introduction of GMOs or GMO derivatives to organic farming systems or products.

113. There is also variation across New Zealand's trading partners regarding whether they consider as GMOs gene-edited organisms that are indistinguishable from those created through conventional processes (which New Zealand proposes to exempt). Policies are evolving internationally, including in the EU through its proposed legislation amendments to exempt gene-edited plants which have genetic changes that could have been created through conventional processes.

Potential cost impacts

114. Primary sector growers and suppliers of GM-free and/or organic products whose supply chains could include these regulated or exempted organisms will need to maintain records and develop new or modified co-existence approaches. Co-existence approaches are already in place for organic products, but GMOs in the environment are not specifically considered at present because no non-medical GMOs have been released into the New Zealand environment.[9] It should also be noted that under the HSNO Act, the EPA does not need to consider trade and market access risks as part of its risk assessments for GMOs.

[7] MPI provides a range of government assurances for the export of New Zealand's primary products if required by an overseas authority. These include assurances stating that the exported consignment does not contain a GMO, which may take the form of an attestation on the phytosanitary certificate, sanitary certificate or in a letter.

[8] MPI is currently developing standards and regulations for organic primary products, which will set out specific technical requirements for the production and processing of primary products: general, livestock, plant products and fungi, wild harvest, aquaculture, apiary, and processed products.

[9] Coexistence approaches are set in the organic standards that operators must meet to be certified organic, including in MPI's administrative (regulatory, but not legislative) export programme.

115. There may be additional costs for producers – whether producing non-GM or organic produce – to maintain supply chain segregation and other co-existence mechanisms (e.g. buffer strips, spray management, managing flowering times, farm location) to ensure the presence of any GMOs, exempted organisms, or the derivatives of both, are minimised. This will vary based on product-type and assurances required by trading partners.

116. For instance, non-organic products (such as milk powder) from animals that have been fed GM animal feed are not themselves considered GM products and as such do not require assurances relating to non-GM status from trading partners. In addition, GM animal feed, such as soybean meal and Distiller's Dried Grains with Soluble (DDGS), already make up over 20% of all animal feed imported into New Zealand for use in the primary sector.

117. The table below shows the regulated or exempt organisms most applicable to the New Zealand primary sector and the likely assurances that would be required from either organic producers or non-GM producers to maintain or gain market access. As shown, the majority of likely assurances required from non-GM or organic producers are either achievable or no different from current requirements.

Table 6: Likely market assurance requirements for non-GM or organic producers (for primary sector organisms)

Organism	Primary use	Likely assurance required from non-GM producers or organic producers
Perennial ryegrass	Ryegrass is used as animal feed on pasture-based farms.	Organic producers, such as organic dairy producers, would need to confirm, as now, that the seed they use is organic (which must be non-GM).
White clover	White clover is used as animal feed on pasture-based farms.	Organic producers, such as organic dairy producers, would need to confirm, as now, that the seed they use is organic (which must be non-GM).
Maize	Maize is mostly used for animal feed domestically. A minority is exported to Australia and the Pacific.	Organic producers using maize as a supplemental feed, such as organic dairy producers, would need to confirm, as now, that the feed was organic (which must be non-GM). Organic or non-GM producers of corn for human consumption would need to ensure that their corn only contain a certain level of unintended GMO presence. (Noting that the majority of maize pollen shed only moves 15 metres or less.)
Fruit tree	Fruit is both exported and sold domestically.	Both organic and non-GM growers will need to confirm the grafts or trees they buy are non-GM. (Most fruit trees are propagated vegetatively, rather than by seed, due to a number of commercial advantages.)
(Sterile) Douglas Fir	Timber is mostly exported.	It is unlikely that overseas importers would request assurance for a non-food product like timber.
Ryegrass endophyte	Ryegrass is used as animal feed on pasture-based farms. (Ryegrass endophytes are fungi that form a	Organic producers, such as organic dairy producers, would need to confirm, as now, that the seed they use is organic (which must be non-GM).

Organism	Primary use	Likely assurance required from non-GM producers or organic producers
	symbiotic relationship with ryegrass.)	

118. In the scenario where producers, growers, and suppliers cannot supply the information required to substantiate an assurance required by a trading partner (either because the records are unavailable or the necessary supply chain segregation is not in place), this could lead to restrictions in their ability to trade in that particular product until the assurances can be provided. Similarly, an instance of unintended presence of GMOs beyond a certain level identified at the foreign border could result in a shipment being rejected and closing the market to those products until the cause has been identified and rectified.

119. It should be noted, though, that exports currently have to deal with the unintended presence of a range of non-GM organisms and chemicals (such as those resulting from spray drift), and systems are already in place to address these issues.

Notifiable and licensed activities will be known to industry and producers

120. As noted above, New Zealand has an obligation under the Cartagena Protocol to notify a country before exporting a GMO and to publish risk assessments and decisions on any GMO that it has approved for use in the environment. The Bill also requires the Regulator to have regard to the Protocol when exercising their powers. As the Bill is currently drafted, it is therefore unlikely the Regulator would authorise regulated agricultural or horticultural organisms for use in the environment under the non-notifiable risk tier, unless they had been previously authorised under a licence.

121. Organisms that have been licensed for use in the environment (after undergoing a risk assessment) or notified to the Regulator will be listed on the Regulator's website. That means that industry and producers will know of these organisms which will support the traceability of these organisms in primary sector supply chains and support the ability for producers and exports to provide assurances about their products.

122. As noted above, producers of certain non-GM products may need to ensure that their products are not the products of exempt organisms or that exempt organisms have not been used as inputs into their farming systems. Because exempted organisms will not be subject to regulatory oversight under the Bill, their use in the environment and in the primary sector will not be automatically known to industry and producers as a result of regulatory mechanisms of the Bill or through the Regulator's website, as in the case of regulated organisms. That will mean that the traceability of such organisms in the primary sector will not be supported by the gene technology regime.

Submitter recommendations

<u>Inclusion of trade and market access risks as part of Bill's purpose</u>

123. Approximately 114 submissions commented on the purpose of the Bill and noted the absence of considerations of risks to trade and market access. The current focus of the Bill's purpose (modelled on the Australian regime) is managing risks to the environment and the health and safety of people.

124. Most of the submitters who commented on the purpose clause in relation to trade and market access considerations (including Fonterra, Horticulture NZ, DCANZ, DairyNZ, Meat Industry Association of New Zealand, and Apiculture NZ) recommended that trade and market access risks be included in the Bill's purpose so that risks to trade and market access be considered

by the Regulator in its risk assessments and decision making. For example, Fonterra stated that the Bill's purpose:

> *"Adding 'trade and market access risks' as an additional risk alongside the two in the Bill would help better meet the legislation's stated outcome to enable the greater use of safe gene technologies to deliver better outcomes for New Zealand. Avoiding economic cost through unexpected compliance for farmers or loss of market access, while enabling new technologies that deliver clear economic benefits will support those better outcomes."*

125. DairyNZ noted that, along with others in the dairy sector and wider primary industry, it was concerned that the Bill does not provide for trade and market access risks. Like Fonterra, it also recommended that the purpose of the Bill be amended to require the Regulator to consider trade and market access risks as part of their risk assessments.

126. In contrast, some submitters (including Federated Farmers, the New Zealand Initiative, Zespri, and Seed and Grain New Zealand) recommended that the current focus of the Bill's purpose on risks to the environment and the health and safety of people remain unchanged. They specifically opposed the addition of trade and market access considerations to the purpose of the Bill and that those considerations are best left to the market. For example, Federated Farmers stated that:

> *"Pushing back on a reform for [trade risk reasons], or asking for additional trade-oriented checks, would be doubling up on protections that already exist through consumer demand and customer specification. We would be concerned for a doubling up of requirements complicating the approval process and making the system unworkable."*

127. Beef + Lamb New Zealand's submission recommended that the assessment of risks should remain scientifically objective, and the Regulator should not be asked to consider customer or consumer preference in its risk assessment. It also recommended that the Bill be considered alongside the Animal Products Act 1999 and other export-enabling legislation to ensure market access requirements are considered and coherent.

Officials' response

Most comparable countries do not require consideration of trade risks

128. Officials note that many other countries, including some with similar export profiles to New Zealand (i.e. a reliance on primary sector exports), do not require that decision-making about the use of GMOs in the environment takes account of trade risks or market access risks. Australia's federal legislation for gene technology, which the Bill is modelled on, does not include consideration of trade risks or market access risks as part of the Australian Gene Technology Regulator's risks assessments. Other countries that also do not have such a requirement include the United States (US), Canada, the United Kingdom (UK), Ireland, Denmark, the Netherlands, and Japan.

129. One exception to this is Argentina, which considers market access and economic factors if a GMO is proposed to be grown commercially in Argentina. This assessment is undertaken by the National Directorate of Agricultural Food Markets (DNMA) rather than Argentina's gene technology regulator, the Argentinian Biosafety Commission. Of note, Argentina exempts

SDN-1, SDN-2 and SDN-3 *cisgenic* organisms from regulation as GMOs, so this assessment requirement only applies to *transgenic* GMOs.[10]

130. The key consideration of this assessment is whether the product is approved for use as a food or animal feed in Argentina's key export markets for that class of commodity.[11] When a product is not approved in a key market, preliminary approval is provided contingent on the product's approval in that key market. Conditions are also imposed to ensure coexistence with non-GM producers. The economic assessment undertaken by DNMA includes the costs and benefits for producers, supply chain implications, possible commercial risks that may affect producers, production chains and/or exporters and whether mitigations of these risks are available.

Assessing trade and market access risks would add considerable cost and time and require speculative economic judgements by the Regulator

131. It would increase the complexity of the risk assessment process if the Regulator had to consider trade and market access risks. The EPA have advised that considering these risks would increase the resource burden on applicants, who would likely be required to provide an assessment of these risks as part of their application. This is the case for the assessments undertaken in Argentina, which requires that applicants provide a report to inform the assessment of the DNMA.

132. This assessment would take time, and for smaller firms without in-house capability, would likely require contracting specialists to complete an economic assessment. The resource associated with this assessment could be partially mitigated by including specific criteria in the Bill for the assessment of trade risks and market access risks to guide the scope, however, this assessment would still likely represent a significant resource burden.

133. An assessment of trade risks would also need to be considered in the context of the GM product's benefits because a risk-only approach would necessarily focus on threats to certain producers without considering the product's benefits to other producers. However, as noted in the *'Ethics and assessment of benefits'* section below, the assessment of benefits carries its own challenges. Like those for risks noted in the paragraph above, the addition of consideration of benefits to the Regulator's assessment process would also place additional resource burdens on applicants.

134. The assessment of both benefits and risks would also require the Regulator to make speculative economic judgements outside of its area of scientific expertise. As currently drafted, the Bill does not contemplate the Regulator having the appropriate expertise to assess these risks (or benefits). Adding this consideration would require either the Regulator to have broader experience and expertise to perform their functions and duties (clause 108) or an alternative approach establishing a dedicated committee to advise the Regulator.

135. Regardless of the way these risks are considered, inclusion of these in the purpose (and other relevant parts of the Bill) would have a negative impact on the enabling objective of the regime by increasing the burden on applicants, the Regulator, and the support provided to the Regulator.

[10] Cisgenic refers to organisms that have received genes from a sexually compatible species, which could also have occurred through traditional breeding. Transgenic refers to organisms that have received gene from a sexually incompatible species, an outcome that could *not* have occurred through traditional breeding.
[11] For example, if a GM soybean is proposed to be grown commercially in Argentina, an assessment would include whether the GM soybean has been approved for use as food and/or animal feed in China, one of largest importers of Argentinian soybeans.

GMO-free is not a core aspect of New Zealand's brand

136. Regarding trade risks, officials also consider that it is highly unlikely that New Zealand's overall food and fibre brand will be significantly affected by the introduction of GM crops. A number of studies have been undertaken to explore this issue across a range of contexts, focussed on New Zealand products; these have consistently found that while consumers will pay premium for non-GM and organic products, the credibility of this labelling is highly unlikely to be influenced by individual regulatory decisions in New Zealand.[12] This conclusion is reinforced by the fact that Australian States with a GM moratorium received no additional premium for non-GM canola, or for other non-GM grain products, when GM canola was introduced into Australia.[13] While studies undertaken by some stakeholders have sought to forecast the potential impact of damage to New Zealand's country image from regulatory change, they do not cite any evidence that this will actually occur. [14]

137. Additionally, in November 2024, MPI surveyed 5,241 consumers in key export markets (including China, India, the US, and Australia) to gauge their food and drink preferences and how those preferences related to their perceptions of genetic technology. Of particular note, the survey found that GMO-free is not a core positioning variable for the New Zealand brand. While New Zealand demonstrates consistent performance across brand positioning attributes with notable strength in high-importance food and drink areas including safety, health, quality and taste, non-genetically modified is the attribute least associated with New Zealand and not a core reason why consumers buy New Zealand products. Compared to features such as 'High quality' and 'Great tasting' which were analytically linked to the New Zealand brand at 17.6% and 11.3%, respectively, the 'Non genetically modified (GMO-free)' attribute was only linked at 0.2%.

New Zealand's largest export markets are also large importers of GM animal feed

138. In terms of GM food and animal feed, New Zealand's largest export markets have approved a significant number of GM products for food, feed and processing. For example, China has approved 74 GM products for use as food, animal feed and processing. It is also the world's largest importer of GM animal feed, importing nearly 100 million metric tons of soybeans as animal feed in 2023 of which over 90% would be GM varieties, alongside a further 30 million tons of maize, the majority of which would also be GM varieties.[15]

139. Likewise, the EU, which has a regulatory regime for GM imports and labelling that is often regarded as one of the most stringent in the world, has approved more than 80 GM varieties of maize, soybean, cotton, canola, and sugar beet for use as food and feed. The EU is the world's second largest importer of GM animal feed. In 2022, the EU imported 30 million metric tons of soybeans and soybean meal for animal feed (mainly from Brazil, the US and Argentina), over 90% of which would be GM varieties.[16] The EU also imported nearly 25 million tons of corn for animal feed in 2022, of which a significant proportion was imported from Brazil (nearly 90% of corn grown in Brazil is GM).

140. Taken together, officials consider that the addition of trade and market access risks to the purpose of the Bill would add additional costs to applicants and the Regulator, would likely

[12] Summarised in Knight, J.G. (2016). *GM crops and damage to country image: much ado about nothing?* Acta Horticulturae 1124, 23-32.
[13] See Anderson, K. *Independent Review of the South Australian GM Food Crop Moratorium,* available from https://www.adelaide.edu.au/saces/ua/media/388/Independent_Review_0319.pdf
[14] For example, the 2024 NZIER report for Organics Aotearoa New Zealand.
[15] *2024 Agricultural Biotechnology Annual – China*, United States Department of Agriculture – Foreign Agricultural Service.
[16] *2023 Biotechnology and Other New Production Technologies Annual* – European Union, United States Department of Agriculture – Foreign Agricultural Service.

necessitate the consideration of benefits (which would itself also add additional costs and present challenges), and is likely to be unnecessary given evidence suggests that premiums for non-GM and organic products are highly unlikely to be influenced by the introduction of GM crops in New Zealand, and that New Zealand's largest overseas markets are significant importers of GM animal feed.

141. We do not recommend including the consideration of trade and market access risks in the Bill's purpose.

Regulatory measures relating to traceability, co-existence and supply chain management

142. Submitters commented on the importance of traceability to manage trade risks associated with co-existence (between non-GM and GM products) in the New Zealand supply chains, with some recommending that the government support the development and administration of co-existence frameworks or standards. This included the DCANZ, Organics Aotearoa New Zealand, DairyNZ, and New Zealand Winegrowers.

143. Other submitters also recommended traceability/identify preservation measures for all modified organisms – including those proposed to be exempted – through either registration (a non-regulatory measure if voluntary, or a regulatory option if mandatory), expanding the scope of conditions the Regulator can impose (regulatory), or providing government support for a traceability/identity preservation programme (non-regulatory measure).

144. For example, Ceres Organics expressed a range of concerns, including regarding traceability. One of its recommendations is that the Bill should provide for traceability and labelling of all GM-food. The Organic Exporters Association of New Zealand recommend the Bill provide for GM- and GMO-free zones for non-GM and organic producers, and that the Bill provide for strict segregation protocols to manage supply chain separation and traceability.

145. On exemptions, Te Kaahui o Rauru submitted that its fundamental concern is with food sovereignty for whānau, hapū, and Iwi and that the Bill will *"…compromise the cultural integrity of the Māori food system…"* because exempted products will enter the country and once released, cannot be recalled. This sentiment was shared by Te Rūnanga o Ngāti Kuia, which expressed significant concern regarding the Regulator's ability to exempt organisms and states that all forms of GM need to be identified, registered, and traceable.

146. On the issue of traceability of exempted organisms, Fonterra recommended that disclosure of exempt organisms in some form be required under the Bill. In its view, this would enable industry to assure overseas markets that would still consider exempt organisms to be GMOs. Without this disclosure, it noted that costs to provide assurance may fall on a greater number of producers. Disclosure, in its view, would enable targeted traceability processes in supply chains. However, in its oral submission, Fonterra stated that it would not expect closure/loss of markets due to regulatory change in New Zealand, but that if there is no disclosure of exempted organisms that its ability to provide assurance to markets would be much harder.

147. In contrast, in its submission, Federated Farmers argued that any traceability system does not necessarily need to be a government-run traceability system, but that it would be worth government undertaking engagement with and provide advice for concerned farmers.

148. Some submitters also raised concerns about the effect on their supply chains from activities involving organisms declared by the Regulator as either non-notifiable or notifiable environmental activities (i.e. either very low risk or low risk to the health and safety of people and the environment). Submitters noted that they would need time to adjust and to develop co-existence assurance processes. Under the Bill's current provisions, people seeking to carry out an activity declared as non-notifiable or notifiable would be able to commence that activity 28 days after gazettal of the Regulator's declaration (in the form of a notice).

Officials' response

149. We have not identified a market failure that would require additional regulatory requirements on the primary sector to manage traceability and the co-existence of non-GM and GM products within New Zealand supply chains. We consider that primary sector participants, including producers, industry associations and exporters, are better placed and able to manage their supply chains and processes, as they do in similar jurisdictions. Knowledge of the most suitable processes and frameworks to enable co-existence will sit with producers and exporters, who will already have relevant market knowledge and insights.

150. It is common for GMO and non-GMO supply chains to coexist in the same country. Implementing assurance and supply chain separation programmes can prevent unintentional crossover and help manage trade risks. These tools are used successfully internationally for GMOs, such as in Australia and North America, both of which have thriving organics sectors. Similarly, these tools are already used in New Zealand for the organics sector.

151. In Australia, sectors have developed their own arrangements to support their ongoing trade and market access where GM products have been developed. For example, the Australian canola coexistence framework, developed to allow the concurrent production of GM and non-GM canola. This framework is managed by the Australian Oilseeds Federation and focuses on meeting market requirements for domestic and export trade through supply chain management.

152. Submitters have highlighted that some elements of the proposed New Zealand regime differ from those overseas, which would require New Zealand-specific approaches to managing coexistence. However, as noted above, we consider that industry would be best placed to manage coexistence, especially if it requires a New Zealand-specific approach.

153. Organisms that have been licensed for use in the environment (after undergoing a risk assessment) or notified to the Regulator will be listed on the Regulator's website. That means that industry and producers will know of these organisms which will support their traceability in primary sector supply chains and the ability of producers and exports to provide assurances about their products.

154. As noted above, because exempted organisms will not be subject to regulatory oversight under the Bill, their use in the environment and in the primary sector will not be automatically known to industry and producers as a result of regulatory mechanisms of the Bill or through the Regulator's website, as in the case of regulated organisms. We consider there may be merit in the establishment of a register for exempt organisms to enable the traceability of these organisms in the primary sector supply chain.

155. Regarding the time that may be required by industry and producers to develop co-existence assurance processes, officials consider it likely that potential applicants would engage relevant industry participants prior to application. Additionally, the time taken to assess applications for the environmental use of regulated organisms will provide further opportunity to enable primary sector participants to develop or adapt co-existence processes

Recommendation: No changes proposed.

3.2 Consideration of ethics, consideration of benefits, and the precautionary principle

Consideration of ethics

156. Approximately 33 submissions commented on the consideration of ethics as part of the legislative framework created by the Bill.

157. Some submitters who commented on ethics (including the Nathaniel Centre for Bioethics and the Auckland GE-Free Coalition) recommended that ethics be a consideration for the Regulator in undertaking its risk assessments and making its decisions. This would be alongside consideration of risks to the environment and the health and safety of people. For example, one submission stated that the balance of various considerations and perspectives is important, and that scientific and economic considerations require transparent balancing with ethical and cultural considerations.

158. Submitters (including the Auckland GE-Free Coalition, Nelson Seed Library, and IFOAM Organics International) also recommended that the Bill re-establish a Bioethics Council, which was establish under the HSNO Act in 2002 and disestablished in 2009. Similarly, other submitters recommended that the Bill establish a Gene Technology Ethics and Community Consultative Committee, as under the Australian regime.

Officials' response

159. Officials note that ethical considerations are adequately covered by other legislation including the Animal Welfare Act 1999 (AWA), the Human Assisted Reproductive Technology Act 2004, Pae Ora (Healthy Futures) Act 2022, and the Health Research Council Act 1990.

160. For instance, the AWA regulates research, testing or teaching (RTT) involving the use of animals (including when genetic modification is used) and animal ethics committee approval is required before RTT projects can commence. The AWA also establishes the National Animal Ethics Advisory Committee to advise the Minister responsible for the AWA and the Director-General of MPI on relevant ethics issues and in approving codes of ethical conduct.

161. Officials also note that other New Zealand legislation, such as the Fair Trading Act 1986 and the Contract and Commercial Law Act 2017, prohibit trading practices and commercial activity that many would regard as unethical. While this legislation does not involve the consideration of ethics per se, their regulatory requirements apply broadly to trading practices and commercial activity, including those that would involve regulated organisms.

162. As such, officials consider that the inclusion of the consideration of ethics under the Bill or the establishment of an advisory committee for bioethics would likely lead to an unnecessary duplication of ethical consideration as well as greater costs imposed on applicants and the regime overall.

Recommendation: No changes proposed.

Consideration of benefits

163. Some submitters commented on considerations of benefits. Most of these submitters recommended that the Regulator be required to assess benefits, alongside risks, as part of its assessment and decision making. These submitters included T&G Global, Cawthron, and the Livestock Improvement Corporation (LIC). These submitters considered that the consideration of benefits as part of the Regulator's assessment and decision-making

processes would ensure that the regime is sufficiently enabling and would maximise economic growth and innovation.

164. In contrast, other submitters opposed the consideration of benefits as part of the Regulator's assessment and decision-making processes. These submitters included Midland Seeds, the Life Sciences Network, and the New Zealand Plant Breeding and Research Association. For instance, Midlands Seeds considered that balancing risk and benefit could result in a lowering of the risk threshold. Midland Seeds was also of the view that the market, rather than the Regulator, would be best placed to assess the benefit given that if there would not be enough potential benefit then it would be unlikely to be financed through to a commercial application.

Officials' response

165. The Bill does not require benefits to be considered as part of the application process and does not require the Regulator to balance science-based risks against the subjective weighing of benefits. This replicates the approach of Australian's Gene Technology Act 2000 (Australian Act), which does not require the consideration of benefits when deciding whether an application should be approved.

166. This was a deliberate choice to focus the Regulator's decision-making on a scientific evaluation of potential risks to the environment and the health and safety of people, and to avoid making value-laden judgments about social, economic and cultural factors which are more difficult to assess and compare.

167. In addition, there are likely to be a number of issues with requiring the Regulator to take account of both costs and benefits. Most importantly, an assessment of benefits alongside an assessment of the risks to the health and safety of people and the environment may lead to an assumption that a certain level of benefit justifies a certain level of risk.

168. Benefits assessments would also require applicants to prove benefits outweigh the risks. This increases the evidential burden on applicants and creates a practical problem, which is that benefits can be difficult to assess and challenging to compare to potential environmental or human health risks. This is a particular problem when benefits are uncertain or unproven, which is typically the case for innovative products. This may, paradoxically, be counterproductive to enabling benefits of gene technology, as applicants are unlikely to have invested time and effort in developing a regulated organism using gene technology unless they consider there will be benefit.

169. There would also likely be a significant cost to the Regulator as doing robust cost-benefit analysis is more challenging for emerging technologies where both benefits and costs are uncertain, or even unknown. The critical issue is how to manage or prepare for risks associated with the technology.

170. It also invites the Regulator to make judgments about the appropriate distribution of benefits and risks that the Regulator may be not well-placed to make or inappropriate for the Regulator to make. cost-benefit analysis may incline the Regulator to focus on known short term benefits at the expense of longer-term costs, or vice versa.

171. It should also be noted that requiring the Regulator to balance risks against benefits is not the same as a cost-benefit analysis, although the two overlap. Moreover, requiring the

Regulator to take a "pure" risk management approach is not the same as just focussing on the costs in the way that some people infer that it is.

Recommendation: No changes proposed.

The precautionary principle

172. Some submitters who opposed the Bill supported the inclusion of a 'precautionary principle'. Reference to the precautionary *approach* exists in the current HSNO Act but has been criticised because it creates operational ambiguity and does not specify how decision makers should implement this approach. This has led to more decisions being subject to judicial challenge.

173. The Bill instead enables the Regulator to develop a Risk Analysis Framework that will incorporate precautionary elements into its specific risk management processes to provide clearer guidance to decisions makers on how they should act with caution and consider scientific uncertainty.

174. The Report of the Royal Commission on Genetic Modification (2002) noted that "*we were not convinced that a single principle could be applied across the board to the use of genetic modification in New Zealand. Decisions on the use of technology must rest on a range of factors, including the risks and acceptability to the public of the proposed use.*"

175. Officials consider that the approach in the Bill will reduce operational ambiguity and is better than referring to a broad and ambiguous precautionary principle or precautionary approach. To allow New Zealand to safely benefit from the advancements of gene technology, a more precise and efficient application the precautionary approach or principle is warranted. As such, neither the precautionary principle or precautionary approach is included as a provision in the Bill but the Bill's purpose is to manage the risks associated with gene technologies.

Recommendation: No changes proposed.

3.3 Māori rights and interests

176. This section discusses issues raised relating to framing of the Treaty of Waitangi clause, the MAC, indigenous species, and kaitiaki relationships.

Limited scope of Māori interests covered by the Bill

177. Submissions from Māori groups on Māori rights and interests in the Bill consistently argued that the kaitiaki relationships with native species was an overly narrow framing of Māori interests. They noted the importance of other concepts such as whakapapa, wairua, mana and mauri as well as noting the range of Māori interests including health interests, commercial interests, and cultural interests. Similarly, submitters from Māori organisations identified that they held important relationships with a wider range of entities than just species, and, in particular, noted that they also held important cultural relationships with places or localities.

Officials' response

178. The policy intent is not to address the full range of Māori concepts as they apply to the environment or gene technologies at large. Instead, the functions of the MAC are intended to support the incorporation of tikanga and mātauranga relevant to the identification of a kaitiaki relationship, and potential risks to that relationship, into the assessment and decision-making

process where it is most critical to the operation of the regulatory regime (see clause 122). A kaitiaki relationship operates as a trigger for an engagement with the MAC that we envisage would suitably address the broader range of relevant Te Ao Māori concepts with the aim of providing practical advice to the Regulator for how the kaitiaki relationship might be protected. We understand concepts such as whakapapa, wairua, mana and mauri as integral to the kaitiaki relationship, and that impacts on them arising from environmental effects will be relevant to the Regulator's decision-making.

179. We recognise that Māori have a wide and varied range of interests in gene technologies. By design, the Bill does not seek to govern the way in which gene technologies might be used in society, and leaves regulation of activities that are not specific to gene technologies, such as intellectual property, economic relationships, healthcare and ethics, to the regulatory regimes and systems already established to regulate those activities.

180. A trade-off has been made in the Bill between place-based environmental rule-making through the RMA and the desire for a nationally consistent approach to the approval of gene technologies. This trade-off could potentially be addressed by the Regulator consulting the MAC on all applications to capture potential place-based impacts, including on wāhi tapu and other sites of cultural significance, but the Government has decided that it does not want consultation with the MAC to be compulsory for all applications.

Recommendation: No changes proposed.

Insufficient involvement of Māori in decision-making

181. Submissions from Māori groups consistently critiqued the Bill for making insufficient provision for Māori participation in decision-making, and specifically the advisory nature of the MAC. Submitters addressed this through a variety of recommendations, including:

    a. increased obligations to consult Māori on decisions

    b. integration of kaupapa Māori or tikanga into the decision-making process

    c. granting Iwi control of decisions to release regulated organisms in their rohe or takiwā

    d. shared decision-making between Māori and the Crown, and

    e. granting the MAC decision-making rights.

Officials' response

182. The Bill moves regulation of gene technology from a model based on a balancing of interests across the community to a technically focused management of risk. Inputs from the community at large, including Māori, remain important in identifying important sources of risk that need to be managed and options for mitigating these risks. Instead, the balance of interests is set by Parliament in the construction of the Bill itself.

183. In this context the advisory role of the MAC is less salient because as a rule its advice is not being weighed against potentially contrary advice. The definition of a risk assessment in clause 11 requires assessments to identify any material adverse effects on kaitiaki relationships, and the definition of risk management plan is a plan that mitigates any such effects where they are identified. The definition of a risk assessment in clause 11 requires assessments to identify any material adverse effects on kaitiaki relationships, and the definition of risk management plan is a plan that mitigates any such effects where they are identified.

184. As such the Regulator is under a statutory obligation to identify and mitigate these risks in licensing, and, because of the way the legislation is constructed, these cannot be traded off against other considerations. The Regulator's primary source of advice on these risks is the MAC. While it would be expected that the Regulator will receive different viewpoints (most likely from Māori) through a public consultation process, a responsible Regulator will test these further with their specialist committee. A scenario where the Regulator is ignoring the advice of the MAC would require either for the Regulator to be acting inconsistently with their statutory obligations to manage these risks, or for the MAC to be failing to provide robust advice.

185. The MAC is an important group to support the Regulator to uphold the Crown-Māori relationship and give effect to the Crown's Treaty obligations. Additionally, members of the MAC, and the Committee itself, will not necessarily carry a mandate from Iwi or hapū and therefore has no inherent decision-making authority from Iwi Māori leaders. Whether decision rights are given are a design choice and does not remove the Crown's responsibility to uphold its obligations. Fewer decision-making layers may support a more efficient regime.

186. We do not recommend additional provisions in the Bill extending the scope of Māori participation in decision-making.

Recommendation: No changes proposed.

Kaitiaki relationships with non-indigenous species

187. Some submissions from Māori groups, Iwi, Māori firms, and individuals note that the Bill limits kaitiaki relationships to indigenous species only and that this does not represent the range of species that Māori may have a kaitiaki relationship with. Submissions suggest that the Bill take a broader view that includes non-indigenous species to better reflect the kaitiaki role of Māori and to better give effect to the Crown's Treaty obligations.

Officials' response

188. As noted by submitters, Iwi and hapū have kaitiaki relationships with both indigenous and non-indigenous species. As such, the current scope of the Bill is unlikely to fully meet the Crown's Treaty obligations, and may not meet the Crown's obligations under existing or future Treaty settlements.

189. Officials note that the approach in the Bill to give effect to Treaty obligations is based largely on the Plant Variety Rights Act 2022 (the PVR Act), which protects kaitiaki relationships through the Māori Plant Varieties Committee (MPVC). Because the policy intent in the Bill is to balance the broader purpose with the active protection of Māori relationships to species of which they have a kaitaiki relationship, the Bill should provide for kaitiaki relationships with non-indigenous species. However, the Bill should not include all non-indigenous species because that would broaden the MAC's role to consider all species.

190. We recommend that the Bill include provisions to include non-indigenous species of significance, in line with the approach used in the PVR Act. We also recommend that the Bill include the ten plant species set out in the PVR Regulations 2022 and one vertebrate species of significance, the kiore (Polynesian rat).

191. Due to the limited number of non-indigenous species that would be listed, it is unlikely this list will impose direct or indirect costs on applicants or the Regulator. We consider that this change would allay the specific concerns expressed by some submitters without materially affecting the enabling objectives of the regime and better contribute towards upholding the Crown's obligations in relation to taonga species.

192. We note that the list used in the PVR Regulations 2022 is based on a point in time and may not accurately capture all non-indigenous species of significance and recommend that the Bill include provision a regulation making power so that an explicit list of non-indigenous species of significance can be developed, consulted on, then agreed by Cabinet.

Recommendation 13:	**Amend** the definition of "kaitiaki relationship" in clause 7 to include non-indigenous species of significance. This change, and those recommended directly below, will need to flow through to several other clauses in the Bill as identified signalled in the clause-by-clause analysis in Appendix One.
Recommendation 14:	**Insert** a new definition into clause 7 for "Non-indigenous species of significance". This change will require other changes throughout the Bill to ensure that any reference to "indigenous species" is accompanied by a reference to "non-indigenous species of significance."
Recommendation 83:	**Insert** a new regulation making power for the Regulator to develop and consult on non-indigenous species of significance to be added as a list in the Bill's regulations.

Inclusion of benefit sharing

193. Several submitters sought for the Bill to include provisions to regulate access to genetic resources and the sharing of benefits arising from that access ("access and benefit sharing") in line with expectations set out in the Nagoya Protocol to the Convention on Biological Diversity. New Zealand has not acceded to the Nagoya Protocol.

Officials' response

194. We consider that regulation of access and benefit sharing to be a separate regulatory domain to the regulation of the environmental and human health risks of gene technologies, and this should be addressed by other legislation. Aspects of an access and benefit sharing regime exist already in the PVR Act through the recognition that an agreement or undertaking between the plant breeder and the holder of kaitiaki relationship may be able to mitigate risks to a kaitiaki relationship.

195. We note that Te Puni Kōkiri's (TPK) work on a biodiscovery framework includes considering mechanisms to address these issues. This work is discussed further below at paragraph 211.

196. We do not recommend the inclusion of access and benefit sharing provisions in the Bill.

Recommendation:	No changes proposed.

Expertise of the Māori Advisory Committee and consideration of mātauranga in decision-making

197. Some submitters argued that the MAC should have access to expertise in tikanga Māori, mātauranga Māori and environmental science.

198. Some submissions noted the importance of considering mātauranga in decision making about gene technologies and specifically included a requirement that expertise in mātauranga be included in the TAC and/or the MAC.

Officials' response

199. Officials agree that it would be useful to have criteria and requirements for membership of the MAC.

200. The Government has not included mātauranga specifically on the list of expertise for selection of members of the TAC. As noted above officials support the inclusion of knowledge of mātauranga being part of the criteria for participation in the MAC.

201. As noted, the MAC is based on the MPVC in the PVR Act 2022, which officials consider to be an effective and transparent mechanism to take into account Māori interests in environmental risk management.

202. We do not recommend inclusion of mātauranga in the list of expertise for the TAC but we do recommend its inclusion in the list of expertise for the MAC (refer to recommendation above).

Recommendation 68:	**Add** criteria and requirements for membership of the MAC to Part 4 Subpart 4, based on the criteria for the Māori Plant Varieties Committee in section 57 of the PVR Act 2022.

Crown's use of GMOs and Treaty obligations

203. A number of submissions from Māori organisations highlighted the Crown's obligations in a range of contexts relating to Crown land, including the conservation estate. In some cases the submissions argue that changes set out in the Bill are counter to the Crown's obligations in this regard.

Officials' response

204. We have not been able to identify specific circumstances set out in submissions where the regulatory framework in the Bill conflicts with the Crown's obligations under settlement Acts. Where the Crown has obligations under Treaty settlements that would include its use of regulated organisms, the Bill does not override those obligations. The approval of a regulated organism under the Bill does not approve its use across all contexts and arrangements, and the Crown's obligations under various Treaty settlements will continue to apply.

205. Some submitters also commented on the proposal to remove local authority consideration of the use of genetically modified organisms under the RMA and the implications for settlements.

206. We consider the Crown can continue to meet existing settlement obligations by virtue of:

a. clause 21(2), which requires, for certain licence applications, the applicant to provide information relating to any kaitiaki that has asserted an activity would create a risk to the environment that may have a material adverse effect on a kaitiaki relationship with a regulated organism that uses an indigenous species as a host species (if the applicant knows the kaitiaki has made such an assertion).

b. clause 122, which enables the MAC to provide advice to the Regulator about whether material adverse effects on kaitiaki relationships may result from an environmental risk posed by an activity, including relating to issuing standards, policies, processes and decisions of the Regulator under the Act, and imposing conditions to mitigate effects.

c. clause 128, which requires, where the Regulator has requested advice, the MAC to consider, where an Iwi, hapū, Māori individual or Māori entity asserts a kaitiaki relationship, whether the kaitiaki relationship has been demonstrated and, if so, the

effect of the activity on their relationship, any agreement to mitigate the effects, and whether there is evidence the applicant and kaitiaki have not acted in good faith during any prior engagement.

207. We consider these provisions provide opportunities for the relevant Iwi/hapū to engage with the Regulator on the proposed use of the genetically modified organism within their rohe.

208. We do not recommend any changes to the Bill to accommodate specific provisions in Treaty settlements.

Recommendation: No changes proposed.

Delaying environmental release until WAI262 claim are addressed

209. A number of submitters requested that environmental use of gene technologies or release of GMOs be delayed until all relevant issues in the Waitangi Tribunal's WAI262 claim are addressed to the satisfaction of Māori.

Officials' response

210. There is no clear timeline for when all WAI262 claims may be addressed, which would delay gene technology reform indefinitely. We also note that this Bill may not be the appropriate mechanism for addressing these issues.

211. As noted, TPK is currently undertaking policy work to develop a domestic biodiscovery framework to link up access and use of genetic resources across the value chain. This work includes considering how a biodiscovery framework may complement the Bill and mitigate some of the nuances regarding kaitiaki relationships through regulatory recognition of these relationships to taonga species. Elements of WAI262 and recommendations from Ko Aotearoa Tēnei are being considered throughout this mahi as it progresses.

Recommendation: No changes proposed.

Introducing a moratorium until regulatory frameworks are co-developed with Māori

212. Some submitters sought the introduction of a moratorium on the use of gene technology until its risks are fully understood and regulatory frameworks are co-developed with Māori. Some sought to ensure that consultation with tangata whenua is meaningful, robust, and consistent with Treaty principles, recognising Māori as equal partners in all stages of decision-making.

Officials' response

213. Government policy here is to balance the broader policy goal with the interests of Māori through a specific process in the Bill (i.e. kaitiaki relationships and the MAC) as a mechanism to honour the Crown's Treaty obligations and to provide certainty to the Regulator, applicants, and the courts on how Parliament intends to manage Māori kaitiaki relationships

with taonga species.

Recommendation: No changes proposed.

Part 2: Regulation of gene technology

214. Part 2 covers provisions for determinations regarding what is considered a regulated organism or gene technology, general provisions for regulated activities, establishes the licence system and requirements for risk assessments and risk management plan and decision making. This part provides for the Regulator to declare activities as non-notifiable, notifiable or pre-assessed and when the Regulator must grant medical authorisations based on approval by recognised overseas authorities, the process for emergency authorisations granted by a Minister, that the Regulator may recognise overseas authorities for certain purposes, that the Regulator must maintain a register of information, and how the Regulator must treat information.

215. The main feedback from submitters on this part related to risk assessment, mandatory medical authorisations, and the role of overseas regulators in the regime.

3.4 Risk assessment and risk proportionate approach

216. Approximately 94 submissions commented on aspects of the Bill related to risk assessments and the risk proportionate approach taken by the Bill.

Definition of levels of risk

217. A few of these submitters (including PGG Wrightson Seeds, DairyNZ, and the New Zealand Plant Breeding and Research Association) commented on terms such as 'very low risk', 'low risk' and 'no more than medium risk', recommending that these terms should be defined in the Bill. It was noted by these submitters that these terms seemed too open to interpretation and their intent not clear. Related, Apiculture NZ recommended that these terms should be defined in primary legislation because secondary legislation would be unlikely to be subject to the same amount of scrutiny as primary.

Officials' response

218. Officials note that secondary legislation will describe in further detail what the terms 'very low risk', 'low risk', 'medium risk' refer to (secondary legislation may also describe in further detail other terms such as 'minimal risk' and 'high or uncertain risk'). In particular, clauses 158(a), 159(a) and 161(a) of the Bill enable regulations to be made for this purpose, which the Regulator would refer to in carrying out its functions, for instance when developing and making declarations for non-notifiable, notifiable and pre-assessed activities. The process to develop these regulations will also require public consultation.

219. Officials do not recommend that the terms such as 'very low risk', 'low risk', 'medium risk' (or other similar terms) be defined in the Bill as these are intended to be defined under secondary legislation following public consultation.

Recommendation: No changes proposed.

Use of recognised overseas authorities

220. Other submitters expressed concern that the Regulator could decide that public consultation is not required for certain licence application risk assessment and risk management plans, if that activity has already been assessed by a recognised overseas authority and the information used by the overseas authority is readily accessible to the Regulator. Submitters considered that this would result in a loss of autonomy and freedom for people to decide what is appropriate for New Zealand.

Officials' response

221. Officials acknowledge the concerns from submitters that the ability for the Regulator to decide not to publicly consult could result in information worthwhile to a risk assessment not being included. On balance, officials do not consider this a likely outcome: clause 28(2)(b) only enables the Regulator to not publicly consult on a risk assessment, it does not require the Regulator not to; and clause 28(3) clarifies that the Regulator may still publicly consult despite not being required to do so. Officials consider that the costs associated with mandating public consultation for all licences (rather than allowing discretion as currently provided by clause 28(2)(b)) would outweigh the likelihood of relevant information being received through mandated public consultation.

222. The policy intent of using risk assessments from recognised overseas authorities is to leverage international expertise for the efficiency of the regime, as part of the risk proportionate and enabling approach of the regime. The Regulator may be able to supplement this information with other knowledge it already has of the relevant risks of the activity in a New Zealand context. If the Regulator decides it needs further information to assess the risks, it may:

    a. seek advice from the TAC, and/or

    b. seek advice from the MAC, and/or

    c. release drafts of the Risk Assessment and Risk Management Plan (RARMP) for public consultation.

223. Officials recommend retaining discretion for the Regulator to publicly consult if an activity has already been assessed and approved by a recognised overseas regulator.

224. Officials anticipate the Regulator developing policy guidance on the process for using information from recognised overseas authorities in the regime.

Recommendation: No changes proposed.

3.5 Mandatory medical authorisations

General misunderstandings

225. The policy of mandatory medical authorisations (refer Part 2 Subpart 5 of the Bill) was the subject of many submissions. Almost all these submitters understood this policy to be about mandating vaccines or other medical treatment on people. Some submitters suggested replacing the use of 'mandatory' throughout the Bill as it will lead to misinterpretation of the intent.

Officials' response

226. It is not the policy intent of the Bill to mandate medical treatment. The policy intent of Part 2 Subpart 5 is to require the Regulator to authorise the gene technology aspect of a medical activity, within a certain period, if it has already been approved by two recognised overseas gene technology regulators. The purpose of these provisions is to ensure the Regulator keeps pace with evidence-based international developments that may benefit New Zealanders.[17] The medicine or medical device that is or contains the gene technology will still need to be approved by Medsafe for use (as signposted by clauses 50(7) and 16), and the Bill does nothing to change the right of patients to choose their treatment.

227. We accept that the use of the word 'mandatory' is not the best language to convey the intent of the policy and recommend substituting with an alternative word such as 'recognised'.

Recommendation 39: **Replace** 'mandatory medical authorisation' with alternative language such as 'recognised medical authorisation' in Part 2 Subpart 5 (and other relevant parts of the Bill).

Specific concerns

228. Approximately 30 submissions commented on specific aspects of this policy.

229. Most of these submitters (including Auckland GE-Free Coalition, Doctors Speaking Out With Science, and Physicians and Scientists for Global Responsibility New Zealand) were concerned that the policy would introduce a reliance on foreign approvals or would otherwise mean the Regulator yielding accountability for decision making. Some commented on the need for local trials and consideration of risks specific to New Zealanders.

230. Several of these submitters (GE Free NZ, Homeopathy New Zealand, Inspire Equine, Ishasha Trust) were concerned about "fast-tracked" approvals and a lack of transparency and robustness in decision making.

231. Medicines New Zealand sought clarity on the practical implementation of the policy, specifically how the Regulator would become aware of authorisations by recognised overseas authorities, which regulatory agencies would satisfy the requirements of a recognised overseas authority, and the likelihood of such authorities being able to provide required information to the New Zealand Regulator.

Officials' response

232. Officials continue to support the inclusion of this policy as part of the gene technology regulatory regime, as a means to achieve regulatory efficiency and international alignment, while retaining the ability to tailor the authorisation to the New Zealand context through imposing conditions. As outlined at paragraph 226 above, the Medicines Amendment Bill contains a similar provision, proposing a verification pathway under which medicines can be approved for distribution in New Zealand if they have been approved by two recognised overseas jurisdictions.

233. Officials acknowledge submitters' concerns about the applicability of overseas' jurisdictions decisions to the New Zealand context, and the speed of consideration. We take this opportunity to clarify the following.

[17] Similar to the proposal in the Medicines Amendment Bill, enabling a faster pathway for medicines approval if the product already has approval from two recognised overseas jurisdictions. Available at: https://www.legislation.govt.nz/bill/government/2025/0134/5.0/LMS1035396.html

234. Only those overseas regulators that the New Zealand Regulator is satisfied meet the requirements under the Bill will be declared as a 'recognised overseas authority'. The Regulator will also be required to publicly consult on the overseas regulators it proposes to recognise.

235. The Regulator can tailor the authorisation to the New Zealand environment through placing conditions on the authorisation.

236. The Regulator must follow a prescribed process before granting the medical authorisation, involving:

    a. ruling out that the authorisation would result in an imminent risk of death, serious illness, or serious injury to people or serious damage to the environment (clause 50(3)), then

    b. having regard to conditions imposed by overseas regulators (clause 50(5)), then

    c. considering any additional conditions for the authorisation appropriate for the New Zealand context (clause 50(4)).

237. The policy intent is for this process to occur within a shorter timeframe compared to a typical licence application, including the pre-application period, on the basis that the authorisation holder would not be required to prepare a specific New Zealand application, and the Regulator's decision making would be focused on which conditions are to be applied to the authorisation.

238. Authorisations will be secondary legislation (under clause 50(8)), meaning each authorisation will be presented to the House. Unless disallowed by the House, the authorisation will be published in the Gazette and must be available on the Regulator's website.

239. The Register on the Regulator's website will contain information supporting the Regulator's decision to grant a medical authorisation (clause 58(1)(c)).

240. We recommend the following amendments to the Bill to address submitters' concerns about transparency and robustness of decision making on these medical authorisations:

    a. Making it explicit that the Regulator has discretion to seek advice in making its decision from either the TAC or the MAC (noting that clauses 115(a) and 122(c) respectively already allow the Regulator to request such advice).

    b. Adding a requirement that the Regulator notify publicly on its website that it is beginning the process to grant a recognised medical authorisation (e.g. at point of becoming aware) – this will support transparency of the regime. (For the avoidance of doubt, officials do not recommend requiring the Regulator to invite public feedback to inform the Regulator's decision, as for expedited assessments.)

    c. Technical amendments to clause 58 to clarify what must be on the register for these authorisations, including the class of persons authorised, a description of the activities

and regulated organisms (refer to item 201 in Appendix One clause by clause analysis for further proposed details).

Recommendation 40:	**Amend clause 50** to clarify that the Regulator may seek advice from the TAC and/or the MAC on conditions to apply to an authorisation.
Recommendation 41:	**Amend clause 50** to require the Regulator to publicly notify on its website that it is beginning the process to grant an authorisation, to support transparency of the regime.
Recommendation 48:	**Amend clause 58** to include detail on what must be on the register for these medical authorisations.

241. In response to implementation concerns raised by Medicines New Zealand:

    a. we expect the Regulator to maintain awareness of international approvals through informational releases from recognised overseas authorities, operational processes to regularly check whether new overseas authorisations exist, and through interagency relationships as they develop over time

    b. we would anticipate gene technology regulators in Australia, the EU, and Japan to meet requirements of a recognised overseas authority (at clause 57(2)), but this would be subject to further detailed assessment by the Regulator

    c. we remain of the view that overseas gene technology regulators would be able to provide the relevant required information; we envisage overseas regulators having produced detailed publicly available information to make their own approval (e.g. comparable to a risk assessment and risk management plan under the New Zealand system), and for that to be sufficient for the Regulator to make its decision, and

    d. we do not anticipate the need to receive confidential or commercially sensitive information for the Regulator to make its decision, as any risks to the health and safety of people or the environment would need to be covered in decision material from other regulators.

242. Recognising the unlikely but potential case of an overseas authorisation holder not wanting its gene technology to be authorised in New Zealand, we recommend amendments to:

    a. notify the overseas authorisation holder when the Regulator is beginning the process to grant an authorisation, and

    b. enable the Regulator to pause or cancel the authorisation process if it receives a request from the overseas authorisation holder to do so.

Recommendation 44:	**Amend clause 50** to: • **require** the Regulator to notify the overseas authorisation holder that it is beginning the process to grant an authorisation, and • **enable** the Regulator to pause or cancel the authorisation process if it receives a request from the overseas authorisation holder to do so.

243. Officials note the potential for confusion among the public of how authorisation of a medical activity under the Act intersects with approval of a medicine or medical device under the Medicines Act 1981. We consider the Bill appropriately manages this from a legislative

perspective (refer clause 16) but anticipate a need for clear communications on this matter when the regime is operational.

244. Officials anticipate that the Regulator will develop guidance on this policy.

3.6 Official information, confidential information, and information sharing

245. Approximately 18 submissions commented on the provisions related to official information, confidential information, and information sharing between agencies and internationally.

Concerns related to Official Information Act 1982 (OIA)

246. Some submitters objected to the exemption from the OIA for information held by the Regulator likely to relate to an application before that application is received (clause 59).

247. The New Zealand Council of Civil Liberties raised several further concerns about compliance with the OIA. Specifically, that the ability for agencies to impose conditions when sharing information with each other (clause 151), and the grounds for withholding information when there is a requirement or permission for the Regulator to publish information (clause 60), are inconsistent with the OIA. On the second point, the submitter recommended

> *"[the grounds] are deleted and replaced with a paragraph (a) that states "could be withheld under sections 6 or 9 of the Official Information Act 1982"".*

Officials' response

248. Regarding the OIA exemption for materials likely to relate to an application, the policy intent of the exemption is to provide potential applicants certainty that while making enquiries with the Regulator, their confidential information will be protected. This policy encourages a potential applicant's early connection with the Regulator, inquiring into the appropriate authorisation pathway that may apply. Once the application has been made, the OIA will apply to information held by the Regulator. This provision is comparable to section 55(1) of the HSNO Act.

249. Regarding the provision enabling agencies to impose conditions on one another when information sharing, the intent of this is not to override the OIA. Ministers and agencies are only able to withhold information from an OIA request if one of the withholding grounds applies under the OIA.

250. Regarding the concern that clause 60 is inconsistent with the OIA, this clause relates to information required or permitted for proactive release. The OIA does not concern proactive release, therefore there is no inconsistency.

251. No changes are proposed regarding compliance with the OIA.

Recommendation: No changes proposed.

Withholding of information

252. A few submitters commented on clause 60, which allows the Regulator to withhold information from proactive release on certain grounds.

253. One submitter commented that the ground for withholding information that could pose a risk to national safety or security (60(2)(a)) is not worded strongly enough, and that any gene

technology could arguably pose a risk. The submitter recommended that the language instead be information that "would be likely to prejudice the safety and security of the nation".

254. Another submitter commented that the ground for withholding information that is likely to cause serious offence under tikanga Māori if published is inappropriate when the Regulator is not required to be an expert in tikanga Māori and the ground itself is subjective.

Officials' response

255. Officials disagree that the current language concerning national safety and security creates a bar that is too low. This is the same language as in section 20B of the HSNO Act that enables EPA to withhold information.

256. Officials also disagree that the ground related to tikanga Māori is inappropriate. The Regulator can access advice from the MAC that is an expert in this area. Some traditional knowledge is considered tapū, and as such may be against the public interest to release (noting that the public interest test in the OIA would apply as normal). This provision is similar to others in New Zealand legislation, including section 42 of the RMA and section 158 of the Exclusive Economic Zone and Continental Shelf (Environmental Effects) Act 2012. No changes are proposed to the grounds for withholding information.

Recommendation: No changes proposed.

Confidential information

257. Some submitters had feedback regarding the provisions on protection of confidential information (clause 61). Medicines New Zealand was concerned there is no description for how information will be protected when the organism is not a licensed activity. It also noted the length of the protection periods are unclear when there could be different timings in approvals under different legislation.

258. On the other hand, Environment and Conservation Organisations of Aotearoa New Zealand recommended that the Bill contain an override to disclose confidential information if there is an imminent danger to human life or the environment.

Officials' response

259. Officials recognise the concern that there is no description for how information will be protected when an organism is not a licensed activity. The intent of the confidential information provisions is to extend the protections given by other legislation (namely the Medicines Act 1981 and the Agricultural Compounds and Veterinary Medicines Act 1997) to an organism in scope of this Bill, so that information is equally protected. Officials agree that the lack of regulatory clarity could disincentivise innovation in New Zealand.

260. Given clause 61 relates to information received in respect of a licence application, a new provision would need to be created if the protections were to apply to information received by the Regulator in respect to non-licensed activities. The policy intent for extending the protections would be to ensure that information related to an innovative medicine or trade name product (TNP) application (as classified under the two Acts named above) that is not a licensed activity under the Bill is not disclosed by the Regulator when it would be protected under the other two Acts. The Regulator may reasonably possess confidential information related to mandatory medical authorisations and emergency authorisations.

261. Regarding the concern that it is unclear how long protection periods for confidential information will apply, this might be a misunderstanding of how clause 61 is intended to

operate. Clause 61 provides for, if at a given point of time, the information is protected under the other legislation, it is also protected under this Bill. However, officials view that the provision is drafted in a complex way and the policy intent (as just described) could be clearer. Therefore, we recommend that PCO consider whether any changes are necessary to improve clarity.

262. Regarding the recommendation to include an override that would force the Regulator to disclose confidential information, this would create an inconsistency with the other legislation referenced in this provision. The other two Acts include the ability for the authority to disclose confidential information if it is necessary to protect the health or safety of members of the public, however it is not mandated and it is not inclusive of risk to the environment. If this recommendation was adopted, this could create scenarios where the Regulator is forced to disclose information that would not otherwise be allowed to be disclosed, which is directly against the policy intent of these provisions. Hence, we do not recommend including an override.

Recommendation 52:	**Recommend** that PCO consider whether any changes to clause 61 are necessary to improve clarity for how long protection periods apply for.
Recommendation 53:	**Add** a new provision that replicates the confidential information protections in clause 61 in relation to licensed activities for mandatory/recognised medical authorisations and emergency authorisations.

Information sharing with recognised overseas authorities

263. Some submitters had feedback regarding information sharing with recognised overseas authorities. Fonterra indicated preference for overseas regulators to be removed from involvement in the regime. Grasslanz suggested that standards of confidentiality required for information sharing with an overseas regulator should be better described.

Officials' response

264. Regarding the feedback on the involvement of overseas regulators in the regime, officials recommend that recognised overseas authorities are retained as a facet of the regime.

265. Officials recognise the concern regarding the lack of description for standards of confidentiality required for information sharing with an overseas regulator. If gene technology users see a risk that their confidential information may be inappropriately disclosed by an overseas regulator, this may discourage innovation to occur in New Zealand. Clause 153(3) requires the Regulator to enter into an agreement with the overseas authority which states criteria for information sharing. The criteria could include that the overseas regulator protect personal information to the same extent as the Privacy Act 2020 (Privacy Act) and that it treats confidential information in the same way as the Bill. The Regulator could publish an operational policy or similar about this to signal to industry what protections are being included in agreements with overseas regulators.

266. We recommend no changes to the confidential information provisions, as we consider this can be managed operationally by utilising clause 153(3) to include information protection requirements in agreements.

Recommendation:	No change proposed.

Application of the Privacy Act 2020

267. The Office of the Privacy Commissioner (OPC) commented that since the Bill explicitly speaks to some parts of the Privacy Act – e.g. collection, disposal, and storage – but is silent on others, suggests that that Act as a whole might not apply.

268. OPC also commented that although the information sharing provisions in the Bill meant there would be overrides to some of the information privacy principles (IPPs), this had not been justified (this was reported in the legislative scrutiny memo).

Officials' response

269. We view that the Bill does not meet the threshold to displace the Privacy Act and therefore it is not necessary to state that that Act as a whole applies.

270. We have worked to demonstrate to OPC that clauses 151 and 152 are necessary for the operation of the regime. This is further discussed in Chapter 5.

271. In response to OPC's concerns regarding the IPP overrides, officials recommend that the Bill should clarify the relationship between clauses 151 and 152 and relevant IPPs.

Recommendation 78:	**Amend clauses 151 and 152** to clarify the relationship between clause 151 and IPPs 2 and 11, and the relationship between clause 152 and IPP 12.

Part 3: Inspection, enforcement, and ancillary powers

272. Part 3 stipulates that the Director-General of MPI is the enforcement agency for the gene technology regime and contains provisions relating to enforcement, compliance, offences, and penalties.

273. The main feedback from submitters on this part related to civil liability, strict liability offences, and the level of the penalties proposed.

3.7 Liability

274. Approximately 3,334 submissions commented on the lack of, or inadequate provision for, liability provisions in the Bill. Many of these submitters raised concerns that without a civil liability regime in the Bill, there would be no incentives for applicants and regulated parties to avoid contaminating GM- and GMO-free producers and exporters or to avoid causing broader environmental harms. Other submitters raised concerns about provisions regarding the liability of the Regulator.

Civil liability

275. Many of the submitters who commented on civil liability (including Organics Aotearoa New Zealand, the Parliamentary Commissioner for the Environment (PCE), and the Organic Exporter Association of New Zealand) recommended that the civil liability provisions from the

existing HSNO Act should be included in the Bill. For example, Organics Aotearoa New Zealand stated that:

> *"An extension of the civil liability provision in the Hazardous Substances and New Organisms Act 1996 (HSNO) for all regulated and unregulated GMOs and gene technology under the Bill [should be adopted]."*

276. An individual submitter noted that producers of GM-free products should be protected in the Bill, with all applicants fully liable for any costs for intentional or accidental contamination. Several other submitters suggested the Bill include insurance requirements to cover the costs of any contamination or environmental harm.

Officials' response

277. The intention of a civil liability regime would be to incentivise compliance with rules and to provide for compensation for damages. However, it is possible that such a regime could also reduce overall activity by incentivising a prohibitively high degree of caution among gene technology researchers, producers, exporters, and users. The Bill does not include a civil liability regime, however, the Bill contains a range of measure to incentivise parties to comply with regulatory requirements, including infringement offences (Part 3, Subpart 4) (which are not criminal offences), criminal offences (Part 3, Subpart 3), and pecuniary penalties Part 3, Subpart 5).

278. Regarding compensation for damages, the common law (law of torts) makes a person liable in nuisance for an unreasonable interference with another person's use or enjoyment of their land causing actual or imminent harm, and liable in negligence if a plaintiff proves, among other things, that the defendant has a duty of care and breached that duty by failing to take reasonable care which resulted in damage or loss that was reasonably foreseeable. However, we do note that there can be barriers to civil proceedings and that the burden to seek that is on the affected party. We also note that tort law may not be a workable avenue in some potential events related to gene technology, particularly when harm is diffuse, there is a time lag between action and harm, or it is difficult to show causation.

279. On the other hand, any civil liability regime, regardless of design, may not provide comprehensive coverage for possible damages because of the complex nature of overlaps with other legislation and regulatory regimes. Additionally, we view that a civil liability regime would be a disincentive to undertake desirable activity in New Zealand. This is particularly the case considering that many gene technology startups are cash poor.

280. Requiring insurance in the legislation would not likely align with where the insurance market currently is at regarding gene technology. This means users may have a legislative requirement to seek insurance that the private insurance market cannot provide for. Additionally, we view insurance requirements as a burden on regulated entities, and a further disincentive to undertake activity in New Zealand.

281. On balance, we do not recommend adding in a civil liability regime or insurance requirements to the Bill.

Recommendation: No change proposed.

<u>Liability of the Regulator and other actors in the gene technology regime</u>

282. Most of submissions intending to comment on civil liability focused on clause 187, which provides protection from civil and criminal liability to the Regulator, its employees, enforcement officers, and members of the advisory committees, in the performance of duties

and functions where that person is following the requirements of the regime in good faith and with reasonable cause. Many submitters have misinterpreted this provision as protection from liability for applicants and regulated parties under the regime, viewing it as providing "immunity from civil and criminal liability to gene technology users" and exempting regulated parties from any civil or criminal consequences of their actions. This interpretation is not correct. While the Bill does not provide for a civil liability regime, it establishes a number of new criminal offences, creates an infringement regime, and provides for pecuniary penalties. These are discussed further below.

283. One submission noted that the Bill's provision for protection from civil and criminal liability for the Committees is appropriate, stating that for people to be willing to serve on those Committees they should be afforded legal protection when acting in good faith and to the best of their abilities.

Officials' response

284. Clause 187 provides necessary security to parties administering and enforcing the regime that, provided they are acting in good faith and in accordance with the requirements of the Bill, they will not face prosecution. Without this assurance, the regime may not be able to find appropriate people to form the advisory committees, work for the Regulator, or work for the enforcement agency. This kind of protection is consistent across different regulatory regimes including the Food Act 2014 (refer to section 351), while enforcement officers have this protection under the HSNO Act.

285. We do not recommend any change to the clauses in the Bill providing protection from civil and criminal liability for people performing functions, duties or exercising powers under this Bill.

Recommendation: No change proposed.

3.8 Offences and penalties

286. Only a few submitters commented on offences and penalties under the Bill. This included comment on the level of penalties of offences, strict liability offences, and references to 'property' in offences.

Level of penalties

287. Of those submitters that commented on the level of penalties applied to offences, one submitter recommended that the level of penalties should be tripled to "reflect the seriousness of the offences listed" while another submitter recommended that the infringement fees should be "significant". Another submitter recommended that penalties applied by the courts should take into account the revenues of offending companies.

288. In contrast, other submitters argued that the penalties in the Bill were too high and were likely to result in behaviour that is risk-averse rather than risk proportionate, leading to New Zealand not deriving the desired benefits from gene technology.

Officials' response

289. The offences, defences, and penalties regime in this Bill is based largely on the HSNO Act, however penalties have been adjusted upwards. The rationale for the differences between

the penalties in the HSNO Act and the Bill are that:

a. the proposed provisions are more specific to gene technology and activities than the HSNO Act's equivalent provisions, which manage a broader range of issues

b. the penalties are proportionate to the misconduct and the potential impact on New Zealand

c. they are in line with modern legislative practice, and

d. the penalties clearly distinguish between the penalties applicable to both individuals and body corporates.

290. Officials view that the penalties as defined are proportionate based on the risks and scale of potential harms involved and the misconduct actions – including from minor breaches of the regime through to more serious offences.

291. MBIE referred to advice from the Legislation Design and Advisory Committee (LDAC) and notes that infringement offences can generally be no higher than $1,000 so there is limited ability to increase these.

292. MBIE engaged with the Ministry of Justice on the offence and penalty development and its advice helped to inform the regime in this Bill.

293. We recommend no change to the level of penalties for offences in the Bill.

Recommendation: No change proposed.

Strict liability offences

294. Of those submitters that commented on strict liability offences, one submitter recommended either the removal of all or most strict liability offences or improving the defences for strict liability offences. Another submitter also recommended that strict liability offences be reconsidered where pecuniary penalties exist because strict liability can be a strong deterrent from using gene technology.

295. Another submitter recommended that it should not be a strict liability offence to give false or misleading information (clause 80). In contrast, one submitter recommended that a strict liability offence for unforeseen harm caused by the field trial of an agricultural GMO be added to the Bill.

Officials' response

296. Regarding strict liability offences, while we acknowledge that strict liability offences could be a deterrent to using gene technology, officials note that defences for strict liability offences have been provided in the Bill (refer to clause 84) which in our view would effectively mitigate the potential deterrent. We have sought to avoid too broad or too many strict liability offences. Officials also note that strict liability offences are often necessary to protect the public against risk creating activities and encourage people undertaking the activities to implement necessary precautions to prevent breaches. The defendant is best placed to establish an absence of fault on reasonable grounds or a balance of probabilities, given their knowledge of the matter.

297. We also note that tools are already available to the courts through pecuniary penalties, which provide a form of punishment where a person is commercially incentivised to breach the law and harm is caused; the court does not need to be satisfied the person intended to breach.

298. When there is evidence of knowledge or recklessness, the pecuniary regime applies. Otherwise, strict liability will be sought.

299. Scenarios where unforeseen harm or damage has been caused by an activity that does not constitute a breach of the Bill is, in the view of officials, best left to the law of torts.

300. We recommend no change to the strict liability offence provisions of the Bill.

Recommendation: No change proposed.

References to 'property'

301. Two submitters recommended that references to 'property', particularly under the *Subpart 3 – Offences*, be removed. In the view of these submitters, reference to property in relation to offences might signal that the new regime has incorporated the civil liability provisions under the HSNO Act whereas the best legal avenue through which compensation for property damage should be sought is through the law of torts.

Officials' response

302. The references to 'property' in *Subpart 3 – Offences* includes clause 85 "Other orders instead of or in addition to other sentencing options" which provides for a District Court to order a person convicted of an offence under the Bill to mitigate or remedy the adverse effects resulting from their offending. This provision is substantively different from the civil liability provisions in the HSNO Act. For example, section 124G of the HSNO Act provides for strict liability in damages if a person breaches the Act and causes any loss or damage. In contrast, under clause 85 of the Bill, a person is not strictly liable for any loss or damage caused. Clause 85 also includes more specificity regarding what matters the court must have regard to before imposing any order, including the nature and extent of the breach, the nature and extent of loss or damage, and the circumstances in which the breach took place.

303. We recommend no change to the references to property in *Subpart 3 – Offences*.

Recommendation: No change proposed.

Part 4: Administration

304. Part 4 describes the administrative arrangements for the regime, including the functions of the Minister, the Regulator, the TAC, the MAC, and subcommittees of those advisory committees.

305. The main feedback from submitters on this part related to the Regulator's independence and the Minister's role in the regime.

3.9 Regulator's independence and the Minister's role

306. Approximately 60 submissions commented on the independence of the Regulator and how the role of the Minister impacts the perception or reality of that independence. These submissions covered the appointment of the Regulator, the power of the Minister to issue a general policy direction to the Regulator, and the resourcing of the Regulator. The resourcing of the Regulator is outside of the policy scope of the Bill and discussed in Appendix Three.

Ministerial appointment of the Regulator

307. Some submissions focused on the impact that Ministerial appointment of the Regulator would have on the independence of the Regulator. Several of these submissions, including from The Nathaniel Centre for Bioethics, the University of Otago's Institutional Biological Safety Committee, and the Environment and Conservation Organisations of New Zealand noted that a Ministerial appointment may introduce perceived or actual political interference or bias.

308. Other submitters recommended changes to the Bill to safeguard the Regulator's independence, including that the Regulator be established as an Independent Crown Entity, that the appointment process involve the Minister but not be subject to their approval, or that the Regulator be a Parliamentary Commissioner.

Officials' response

309. We note that ministerial appointment may create the perception of political interference or bias. However, we consider that this approach does not create a risk of substantive political bias because the Bill provides for the Regulator to be statutorily independent and that they must act independently of the EPA and the Minister (clause 111(1)(a)).

310. There is a concern that ministerial appointment creates difficulties regarding the performance management of the Regulator. We note that the Bill provides for the Regulator to be accountable to the Minister for the performance of their functions and duties under the Bill. Because the Bill requires the EPA to support the functions of the Regulator, an element of the Regulator's performance will also depend on, and be accountable to, the EPA. The EPA, in turn, is accountable to a different minister, the Minister for the Environment. We note that there is nothing in the Crown Entities Act 2004 (CEA) that prevents another minister, other than the Minister responsible for a crown entity, from involvement in discussions regarding the performance of that crown entity. Meaning that while there is added complexity with this arrangement, it is possible for the Regulator to be accountable to the Minister responsible for the gene technology regime.

311. On the appointment of the Regulator, we do not recommend that the Regulator be an officer of Parliament (a Parliamentary Commissioner) because the purpose of an officer of Parliament is to provide independent, non-political scrutiny of the Government, not to exercise the duties and functions required of a regulatory regime.

312. We also note that Te Kawa Mataaho – The Public Service Commission (PSC) have raised concerns regarding ministerial appointment of a Regulator who is also an employee of Crown Entity, an approach which it notes is bespoke and creates some functional difficulties. PSC is concerned that direct ministerial appointment:

    a. undermines the principle that an organisation appoints its own employees

    b. contradicts the legal accountability of the EPA, who will provide administrative support for the Regulator, for the performance of the Regulator, and

    c. creates uncertainty as to whether the EPA would be the entity responsible as the respondent in the case of a judicial review or an appeal to the courts under the Bill.

313. PSC advises that these issues can be avoided by the EPA appointing the Regulator. It suggests that to reflect the Minister's interest, the legislation could mirror the Public Service Act 2020 process for appointing chief executives, where the appropriate Minister is:

    a. consulted on membership of the appointment panel, and

b. invited to identify matters to take into account in the appointment.

314. PSC also note that if the Bill retains ministerial appointment of the Regulator in line with current policy settings, that the Minister could appoint an employee of the EPA to be the Regulator. There is potential drafting precedent where a staff member is appointed to a statutory officer role in clause 28 of the Corrections Act 2004 (appointment of Inspectors), and to a more limited degree, in the Health Act 1956 clause 7A.[18]

315. In practice, unless a strong candidate was already employed by the EPA, this framing would likely mean that the EPA would run a recruitment process for a person with the requisite skills in close consultation with the Minister, such that as soon as that person started at the EPA the Minister could formally appoint them to the Regulator role.

316. MBIE and PSC consider that liability concerns can be mitigated by making it explicit in the Bill that the EPA would be the entity responsible as the respondent in case of a judicial review or appeal to the courts under the Act. However, the EPA consider that it may be appropriate for the Regulator to be the respondent in any legal cases. Another related outstanding policy question is whether the Regulator is covered under the EPA's liability insurance. These policy proposals are still be finalised and we recommend MBIE, PSC, the EPA, and the PCO work to resolve these issues.

317. On balance, we consider the issues created by ministerial appointment of the Regulator are manageable. Specifically, with an approach where the EPA run a process, in consultation with the Minister, to recommend a person to appoint as the Regulator. If that person is not already an employee of the EPA, the EPA hire them, and they are subsequently appointed as Regulator by the Minister. This approach is in line with current policy settings.

318. We also recommend changes to provide specificity on liability. The Regulator should not be the respondent in any legal action. The EPA should be the court case respondent, and the Regulator should be covered by the EPA's liability insurance.

Recommendation 62:	**Recommend** officials and PCO work to finalise policy proposals regarding liability insurance and the EPA's powers with a view to drafting new provisions for the Bill.
Recommendation 63:	**Insert** a new subclause in clause 108 to provide for the EPA to recruit, in consultation with the Minister, a person to be the Regulator. **Amend clause 108(2) and (4)** such that the Minister must appoint an employee of the EPA, or a person becoming an employee, to be the Regulator.
Recommendation 64:	**Amend clause 111** to provide that the Regulator is accountable to the EPA for delivery of their obligations as an employee.

Power of Minister to issue general policy directions to the Regulator

319. Another issue regarding the independence of the Regulator that was raised by submitters is that the Bill provides for the Minister to issue a general policy direction to the Regulator. This power is covered in Part 4 – Administration in clauses 106(d), 107(b), 111(1)(b), and 111(2). Some submissions state that this power may reduce the Regulator's independence,

[18] Provisions for designation of medical officers of health is less specific but does involve the Director-General of Health appointing people in other substantive roles to this statutory office.

compromise their expertise, and could allow future ministers to block the use of gene technologies.

320. Others commented that the Bill does not provide enough specificity regarding the general policy direction power and that this may reduce the transparency of the regime. The PCE recommended that the Bill:

> *"Explicitly state the matters on which the Regulator may not be directed, similar to section 30 of the Gene Technology Act 2000 (Australia).*
>
> *Remove the ability for the Minister to impose general policy directions in clause 111(1)(b)."*

321. Providing a similar comment, CropLife Australia stated that while the Bill provides for limits to the general policy direction:

> *"… under the Australian system such policy directions come from the Ministerial Council, but before issuing a policy principle, appropriate consultation needs to be undertaken."*

Officials' response

322. We note that the PCO received approval from the Committee for minor drafting changes, including aligning provisions regarding the Minister's general direction power with the relevant provisions in the CEA. This change may address submitters' concerns regarding this power.

323. We do not recommend further changes to provisions for the general policy direction than those already made by the PCO.

Recommendation: No change proposed.

3.10 Technical Advisory Committee and other committee-related issues

324. Approximately 45 submissions provided detailed feedback on the proposed role and function of the TAC. While there was broad support for the use of scientific and technical expertise informing regulatory decision making, submitters raised concerns about the TAC's advisory role, scope of advice, and limitations of membership as discussed below.

TAC advisory role

325. Some submitters who commented on the TAC expressed concern that the language requiring the Regulator to 'have regard to' the advice of the TAC may not provide a strong enough obligation. Some submitters also queried whether the TAC may provide advice only when requested, or whether there was an ability to proactively raise new information regarding emerging risks to human health and the environment. Beyond this, some submitters acknowledged the workload of TAC could be substantial and recommended the TAC be able to delegate work to local committees such as institutional biosafety functions.

Officials' response

326. The language used in the Bill, *have regard to*, reflects appropriate wording regarding advice consideration while maintaining the Regulator is the sole decision maker in the new regime and officials consider this delivers the intended outcome of the submitters request. The ability of the TAC to proactively provide advice in the event new risks emerge will be set out in

operational documentation, such as the Terms of Reference to ensure the TAC uphold their obligations as per the purpose of the regime. The risk proportionate regime intends to reduce the administrative burden of low-risk applications of gene technology; this will be delivered through the risk tiers and proportionate Regulator oversight. This extends to the advice required from the TAC, resulting in their capacity being utilised for higher risk applications.

327. Officials do not recommend any changes based on the points raised.

Recommendation: No change proposed.

Scope of TAC advisory function

Expanding the technical expertise

328. Several submitters recommended including further areas of technical expertise for membership of the TAC, including plant and animal breeding, seed production, and general primary production.

Officials' response

329. The Regulator's consideration will be concentrated on risks to the health and safety of people and the environment, and as such the proposal to include animal and plant breeding, and seed production is appropriate to include in the expertise required for the TAC. While the proposal to include knowledge and experience in primary production has merit, it would not be required to satisfy the function of the TAC and agricultural and aquacultural systems are already provided for in the Bill.

330. Officials recommend including animal and plant breeding, and seed production as an area TAC members may have skills, knowledge, or experience in.

Recommendation 67: **Amend clause 114(3)** to include additional areas of expertise: plant and animal breeding and seed production, as particular areas of relevance for gene technologies.

Expanding the scope of advisory function

331. Several submitters recommended altering the scope of TAC advisory expertise to include ethics, social science, and commercial expertise. This recommendation was expanded on by the recommendation to set up a separate commercial advisory committee.

Officials' response

332. The Regulator's consideration will be concentrated on risks to the health and safety of people and the environment. Additional considerations to the technical advice regarding scientific risk provided by TAC would add more subjectivity to the Regulator's decisions. A separate committee for commercial advice would result in the same expanded scope of considerations. This does not align with policy intent.

333. Officials do not recommend any changes based on the points raised. Any commercial considerations would be more appropriately addressed through trade and market access considerations as discussed in section 3.1.

TAC membership qualifications

334. Several submitters recommended that only individuals actively engaged in research using gene technologies should be appointed to the TAC, to ensure up to date expertise. Others emphasised that members should not have personal or financial interests in the outcomes of decisions, including being proponents of gene technology.

Officials' response

335. The Bill provides a broad range of relevant expertise required for TAC appointments and the Minister must be satisfied that appointees have relevant subject-matter expertise. Clause 117(3) regarding procedure of TAC sets out the requirements for the committee to have arrangements in place to avoid or manage conflicts of interest relating to the performance of its functions. Processes for this will be laid out in operational documentation.

336. Officials do not recommend changes based on the points raised.

Recommendation: No change proposed.

3.11 Reporting and review of the regime

Reporting about the regime

337. Four submissions discussed public reporting on the regime, suggesting clear reporting would aid transparency and public engagement, and an interest in regular public reporting on activities and outcomes to maintain confidence in the regulatory framework.

Officials' response

338. We note that section 136 of the Australian Act requires its Regulator to prepare a report following each financial year including certain information, to provide the report to the relevant Minister, and for the Minister to provide that report to Parliament.

339. MBIE supports the addition of an annual public reporting provision in the Bill and considers this would align with the transparency objective of the reform. We note that there may be opportunities for operationalising a legislative requirement for annual reporting within existing reporting functions of the host entity of the Regulator (i.e. the EPA's reporting functions as a Crown entity). Annual reporting would complement routine publication of information by the Regulator in relation to individual decisions as required by the Act, and maintenance of the register as required by clause 58.

Recommendation 66: **Add** an annual reporting provision, similar to the Australian gene technology legislation, that is coherent with the overall accountability arrangements for the Regulator.

Review of the regime

340. Four submissions considered there should be provisions for a review of the regime, with one noting the Australian regime has such provisions. Submissions varied on whether they sought regular review and/or independent review.

Officials' response

341. Officials consider that given the novelty and complexity of the regime, and the pace at which policy development has progressed, it would be beneficial to include a review provision in the

Bill. There are choices around the level of detail to be included in the Bill in respect of timing, scope, and commissioner of the review. We note that:

a. The Australian Act's section 194 sets out a requirement for 'an independent review of the operation of the Act, including the structure of the Office of the Gene Technology Regulator (OGTR), to be undertaken as soon as possible after the fourth anniversary of the commencement of this Act.'[19]

b. A domestic example of a review provision is the Outer Space and High-altitude Activities Act 2017 which sets out at section 86 that the Minister must, as soon as practicable after the expiry of three years from the commencement of that Act, commence a review of the operation and effectiveness of the Act; and prepare a report on that review and present it to Parliament.

342. In terms of timing and scope, MBIE notes that because the New Zealand gene technology regime will hold significant detail in regulations, the review timeframe will either need to account for sufficient time for regulations to have been operational, or treat a review of regulations separately (which may be ineffective given their centrality to the regime). We recommend a review commence no earlier than four years from the commencement of this Act, given the planned staged implementation of the Act. We recommend the review be focussed on the operation of the Act including its regulations, and the structure and effectiveness of the Office of the Gene Technology Regulator. We further recommend the Bill require that the Minister be informed by the Regulator on the workability of the whole regime, to inform the review.

343. On balance, MBIE is not recommending specifying that the review must be independent, so as not to limit choices for how the Minister of the day resources and conducts a review. However, if desirable, the Australian legislation offers a definition of independent review that could be adapted to the New Zealand context: 'a review undertaken by persons who: in the opinion of a majority of the Ministerial Council possess appropriate qualifications to undertake the review; and include one or more persons not employed by the Commonwealth or a Commonwealth authority.'

Recommendation 104:	**Add** a requirement for the Minister to, as soon as practicable after the expiry of four years from the commencement of this Act: • commence a review of the operation of the Act, including the Office of the Gene Technology Regulator; and • prepare a report on the review and present it to Parliament. **Add** a requirement that the Minister to be informed by the Regulator on workability of the regime, to inform the review of the operation of the Act

Part 5: Miscellaneous

344. Part 5 sets out miscellaneous provisions, including reviews and appeals, issuing or approving notices and standards, disclosure of information to support the performance of the GT regime, regulation-making powers, rules for incorporation of material by reference, and fees, charges and cost recovery provisions.

[19] The resulting report from this independent review is available from https://www.genetechnology.gov.au/sites/default/files/2022-02/2006-statutory-review-final-report.pdf

345. The main feedback from submitters on this part related to exemptions and non-regulated techniques and organisms, cost recovery and synthetic nucleic acid (SNA) provisions.

3.12 Non-regulated organisms and technologies, and exemptions

Non-regulated organisms and technologies

346. Several submitters requested greater clarity around clause 163(4) which specifies what is not regulated under the new regime. The current Bill refers to the HSNO Act's regulations, HSNO Act's statutory determinations, and the Australian regulations which could lead to inconsistent interpretation of regulatory status due to required checking of multiple pieces of legislation or uncertainty in practical application.

347. Additionally, submitters raised that as the drafting currently stands any changes made to the Australian regulations regarding non-regulated organisms or technologies would be automatically adopted by the New Zealand regime, removing any ability to consider whether it is appropriate to exclude these organisms or technologies in the New Zealand context. For example, the New Zealand Institute for Plant and Food Research Limited stated:

> *"We believe this direct alignment with another jurisdiction's regulations may not allow for activities required or desired in a New Zealand context."*

Officials' response

348. The policy intent is to ensure that organisms and technologies not regulated under the HSNO Act continue to not be regulated, ensuring the new regime is not more restrictive than the status quo, as well as excluding organisms and technologies that are currently not regulated under the Australian Act. Officials agree that more clarity could be provided on which organisms and technologies are not regulated to give the public more certainty in their regulatory status.

349. Officials recommend deleting the references to specific legislation in clause 163(4) and instead providing a prescriptive list of these organisms and technologies in the Bill, such as a Schedule to the Act, removing any ability for future Australian regulatory changes to impact regulatory status under the New Zealand regime and aid in public interpretation.

Recommendation 94:	**Add** a supplementary prescriptive list of items that are not regulated by this Act, including organisms that are not regulated organisms and technologies that are not gene technologies. **Amend clause 163(4)** to refer to the prescriptive list as items not regulated by the Act and delete reference to the specific legislation in (a)-(c). ***Note*** *clause 163(1) provides regulation making power for exempting organisms or gene technologies, and as such the equivalent items from Schedule 1 and 1A of Australia's Gene Technology Regulations 2001 will be addressed in regulations.*

Definition of gene technology and regulated organism

350. Currently the definition of gene technology excludes conventional processes and any other technology specified in the regulations. This is to ensure that the regime only captures modern gene technologies used to modify or construct the genetic makeup of organisms.

351. A common concern raised by submitters focuses on the ambiguity they would experience in interpreting 'conventional processes' without any guidance and may impact conventional breeding programmes currently underway in the New Zealand industry.

352. In recommendation 94 above we seek to provide more clarity on what is out of scope of the regime, and therefore not regulated under this Act. We recommend the definition of gene technology is amended to accommodate this approach. We recommend this be amended to only exclude technologies specified in the Act and the regulations, removing reference to conventional processes.

353. This change would also align with our policy intent to maintain a wide scope for the definition of gene technology to ensure any future technological advancements are captured, with specific technologies excluded from the regime through the prescriptive list and clarity provided by the Regulator through issuing statutory determinations.

Recommendation 11:	**Amend** the definition of *gene technology* to not include technologies specified in the Act or regulations.
Recommendation 12:	**Amend** the definition of *gene technology* to remove limb (b)(i) referring to conventional processes.

354. The current definition of regulated organism excludes any organism or class of organisms specified in regulations. This is to ensure any product of gene technology is captured by the regime.

355. With recommendation 94 proposing to change how we provide clarity on what is out of scope of the regime, and therefore not regulated under this Act, we recommend the definition of regulated organism is amended to reflect this approach (if recommendation 94 is accepted). We recommend this be amended to only exclude organisms or classes of organisms specified in the Act and the regulations.

Recommendation 17:	**Amend** the definition of regulated organism to exclude an organism or a category of organisms declared by the Act or regulations not to be regulated organisms.

Regulation making powers for organisms that are not regulated organisms and technologies that are not gene technologies

356. Both the definition of gene technology and regulated organism reference any exclusions made in the regulations. As the Bill is currently drafted there are no empowering provisions to enable the creation of these regulations. Officials consider the ability to create these

regulations in the future is required for the regime to address any future technological advancements.

Recommendation 81:	**Add** a regulation making power to declare organisms or classes of organisms that are not regulated organism. **Add** a regulation making power to declare technologies that are not gene technologies.

Exemptions

357. Many submitters expressed general opposition to exemptions, including not supporting the inclusion of this policy in the regime and that New Zealand would be straying too far from international standard approaches.

358. Most of the submitters who commented on the exemptions component of clause 163 (including 163(1), 163(2)) recommended that no organism or technology should be exempt from the Act, and gene technologies and all products of gene technology should be in scope of regulation. For example, the Auckland GE-Free Coalition recommend:

> *"no exemptions of products from new Gene Editing techniques from the Bill."*

Officials' response

359. Regarding the inclusion of exemptions in the new regime, officials consider the core policy intent of delivering a risk proportionate regime to be settled and do not recommend any change to this proposal. Where submitters have raised concerns about specific aspects of implementation, officials have considered these points and where appropriate, recommended adjustments to improve clarity and feasibility.

360. In contrast, approximately 30% of submissions in favour of the Bill expressed support for exemptions, on the basis that this provides a risk proportionate regulatory approach to organisms that could be produced using conventional processes, leading to proportionate regulatory oversight and removing unnecessary barriers to market. For example, The New Zealand Plant Breeding and Research Association stated:

> *"Minor gene edits (with no foreign DNA introduced) are widely being applied overseas... Such minor, gene edits are indistinguishable from traditional cultivars while leaving no traceable evidence. Some change to the regulatory environment (HSNO Act) is essential if NZ is to maintain access to a wide range of crops on which horticulture, forage and arable crops depend."*

361. Some submitters raised concerns related to exemptions having trade implications, for example, due to products of gene technology being present in the domestic market, and an inability to trace exempt organism presence through a register. Horticulture New Zealand stated that:

> *"there are potential risks to primary production and trade from a lack of certainty about which exempt organisms may be present in New Zealand in the future. We seek a process of registration to manage this risk."*

Officials' response

362. Officials acknowledge concerns of this nature and while they are important considerations, they extend beyond the specific scope of this policy and are more effectively managed and addressed through broader trade and market access proposals as discussed in section 3.1.

Assessment and verification of exempt organisms

363. Some submitters recommended a case-by-case risk assessment of exempt organisms, including verification by the Regulator of meeting criteria required to be considered exempt from the Act. For example, GE Free New Zealand sought to:

> *"introduce a specific obligation of the proposed Regulator to require that evidence provided to prove that an organism meets the exemption criteria or satisfies the risk assessment is of the highest scientific standards and is current with the most recent scientific techniques."*

Officials' response

364. The policy intent is to establish secondary legislation to provide technical detail regarding organisms that meet the criteria in the Bill and are therefore exempt from the regime, constructed using robust scientific evidence and with opportunity for public consultation. As such, including a provision in the Bill would not be necessary.

365. Officials do not propose regulations exempt any technologies from the outset of the new regime, as current scientific understanding of risk does not support exempting these from the regime. The inclusion of the exemption-making power in clause 163(2)(b) is intended to provide a future avenue for delivering these exemptions if there are future developments in scientific understanding of risk of gene technology.

366. Because the new regime is modelled on the Australian regime, the Regulator providing case-by-case verification of exempt organisms is not part of the policy intent, as is currently the status quo under the Australian regime. Clarity for users will be provided through secondary legislation, including scientific descriptions of the required characteristics of organisms captured as exempt from the Act. Officials recommend no change.

Criteria required for any organism or class of organism to be exempt from the regime

367. The policy intent for exemption is to provide a risk proportionate regulatory approach for organisms that could be produced using technologies that are not gene technologies. The underlying justification being that similar products pose similar risk to human health and the environment and as such should be subject to similar regulatory burden.

368. As it is currently drafted, clause 163(2)(a) refers to equivalence to organisms created through 'conventional processes'. In line with recommendation 94 for improved user clarity on organisms and technologies that are not regulated by the Act, we recommend amending this to refer to the prescriptive list of what is not regulated by the Act.

369. The definition of conventional processes refers to sexual reproduction and natural homologous recombination, and any processes specified in the Act or regulations as non-regulated for the purposes of this Act. In line with introducing a prescriptive list of organisms and technologies that are not regulated by this Act, we recommend amending 163(2)(a) to include criteria that reflect whether an organism is indistinguishable from one that is either

not regulated by the Act, or could be produced using a technology that is not regulated by the Act.

Recommendation 91:	**Amend clause 163(2)(a)** to reflect that regulations cannot be recommended unless that organism or class of organisms is indistinguishable from those that are either not regulated by the Act, or could be produced using a technology that is not regulated by the Act.

Evidential burden and clarity

370. Several submitters raised concerns about the drafting of clause 163(2)(a), regarding reference to conventional organisms. For example, Grasslanz stated:

> *"Exemptions under section 163 are confusing, particularly with regard to clause 163(2) which suggests that a conventional organism with the same genetic structure already exits. Either delete or reword indicating that they could be created through conventional means."*

Officials' response

371. While officials have recommended amending the criteria to be based on organisms or technologies not regulated by the regime, there is still a risk that current drafting of clause 163(2)(a) places an unnecessary evidential burden on users to provide evidence of a pre-existing organism with the same genetic structure in order to be exempt from regulation. The policy intent for clause 163(2) is to enable organisms that could be produced using non-regulated technologies (subject to detail as set out in secondary legislation) to be exempt from regulation. Officials recommend amending the language used in clause 163(2)(a) to reflect this intent.

Recommendation 92:	**Amend clause 163(2)(a)** to reflect that an equivalent conventional organism is not required for an organism to meet the criteria of exempt, only that it could be produced.

Definition of conventional processes

372. If the above recommendations are incorporated into the Bill, there are no references to *conventional processes* and we recommend deleting this from the interpretation section.

Recommendation 7:	**Delete** the definition of *conventional processes*.

Regulator's ability to impose or amend conditions

373. Some submitters raised concerns about clause 163(3) regarding the Regulator's ability to impose or amend conditions on any exemption. For example, one individual questioned:

> *"How could the Regulator impose conditions on any exemption and amend or revoke an exemption? If the organism is actually exempt from the Act how could such conditions be imposed?"*

Officials' response

374. Officials agree with this concern, as if exemptions are outside of the regulatory scope then the Regulator should not be able to impose conditions on anything that meets the criteria. In line with policy intent, any exemption would pose minimal risk to the health of humans and the environment or be equivalent to products developed using processes not regulated by the regime and would therefore not require any conditions to be placed on them to manage the risks.

Recommendation 95: **Amend clause 163** to remove the ability of the Regulator to impose or amend conditions on, and revoke, exemptions.

Cost Recovery

375. Approximately eight submissions commented on the cost recovery provisions in the Bill. Many submissions related to cost recovery said the provisions for fees, charges and levies related to applications need to fair and proportionate. The primary concern raised was that the regime should keep administrative costs low to support the potential for innovation and lower barriers to entry for new research.

Officials' response

376. The Bill empowers the Governor-General by Order in Council on recommendation of the Minister to prescribe fees, charges and levies in secondary legislation. While we note submitters' concerns to ensure fairness and proportionality, clauses 177 and 178 of the Bill already provide for the principles of cost recovery, which accurately reflect the criteria needed to be taken into consideration when setting administrative costs (including fairness and proportionality).

377. We do not recommend changes to the provisions relating to cost recovery.

Recommendation: No change proposed.

3.13 Synthetic nucleic acid (SNA) screening

378. Approximately 37 submissions commented on the SNA screening provisions under the Bill.

379. Some of the submitters who commented on these provisions (including CropLife Australia, Bayer and BiotechNZ) expressed concern that the regulation of SNA imported into New Zealand would cause delays to research and that restrictions on the use of SNAs by researchers would be detrimental to beneficial research. Some of these submitters recommended removal of these provisions.

380. In contrast, other submitters (including the Johns Hopkins Center for Health Security, the International Gene Synthesis Consortium, and the International Biosecurity and Biosafety Initiative for Science) strongly supported the inclusion of these provisions. For example, the International Gene Synthesis Consortium (IGSC), which includes within its membership companies like Twist Bioscience and Thermo Fisher Scientific, commended New Zealand's

leadership on the issue of nucleic acid screening and noted that the Bill aligns with the IGSC's belief that...

> *"… [the gene synthesis] industry is ready for mandated biosecurity practices–that these methods have matured, that best practices are well-understood and that commercial software-based screening solutions are available at reasonable cost."*

381. Some submitters also recommended that the specification of requirements for SNA screening would be best suited to secondary legislation rather than under primary legislation. Other submitters noted that as currently drafted, the definition of SNA used could imply that the amplification of nucleic acid via polymerase chain reactions within thermocyclers would be subject to regulation.

382. One submitter also recommended that the import of benchtop nucleic acid synthesis equipment into New Zealand should be regulated to ensure that only those with a legitimate use case are able to procure this equipment.

Officials' response

383. Officials stress that the SNA provisions will not regulate or restrict the importation or use of SNA by researchers. Regulations for SNA, when developed, would only impose conditions on *New Zealand-based* commercial providers of SNAs and *New Zealand-based* manufacturers of SNA synthesis equipment. While there are currently no commercial SNA providers or manufacturers based in New Zealand, the intention of the SNA provisions is to future-proof the legislation should the creation of these regulations become necessary in future.

384. The provisions relating to SNA would not regulate non-commercial sharing or exchange of SNA between researchers or organisations, including within arrangements like consortiums (i.e. an arrangement in which a group of organisations purchases synthesis equipment to use collectively). The Bill makes it clear that only the provision of SNA or synthesis equipment *in trade or for reward,* essentially commercial transactions, would be subject to regulation.

385. Regarding recommendations that the regulation of SNAs should be done through secondary legislation, officials note that this is the case in the Bill. Clause 157 establishes the ability for regulations (secondary legislation) to be made that would prescribe requirements on providers and manufacturers. Additionally, the requirements placed on providers and manufacturers would only come into force when these regulations are developed and passed through an Order in Council.

386. Officials acknowledge the concern that the current definition for 'synthetic nucleic acids' might imply that the amplification of nucleic acids via polymerase chain reactions within thermocyclers (a common laboratory technique) would be subject to regulation. It is not the intention of these provisions to regulate those laboratory techniques. Officials agree that improvements to the definition of 'synthetic nucleic acids', like that proposed by the New Zealand Institute for Plant and Food, would both clarify the intent of the provisions and further future-proof the definition.

387. Regarding the recommendation to regulate the import of benchtop nucleic acid synthesisers into New Zealand, officials acknowledge that while this may strengthen oversight of this equipment, it is not intended that the scope of these provisions would include imports of

either SNA or SNA synthesis equipment due to the operational challenges of such requirements.

Recommendation 19:	**Amend** the definition of synthetic nucleic acid to clarify that it only encompasses nucleic acids synthesised *de novo* and without the use of a template, and also includes non-naturally occurring nucleic acid analogues.

Part 6: Amendments to other legislation

388. Part 6 covers amendments to other Acts.

RMA amendments

389. Approximately 2,114 submissions (or 14% of total submissions) commented on the amendments to the RMA. All such submissions were opposed to the RMA amendments, principally due to objections to the loss of local autonomy.

Officials' response

390. The Bill amends the RMA to:

a. prohibit local authorities from treating GMOs differently from other organisms, including in regional plans, district plans and regional and district rules

b. require that any part of a regional or district plan that does not comply with that prohibition be treated as void and be amended as soon as practicable to comply, and

c. provide transitional, savings and related provisions for persons carrying out activities in reliance on a rule or plan provision concerning GMOs, or who have made a consent application.

391. These amendments are necessary to create a nationally consistent scheme.

Recommendation:	No change proposed.

Schedules

392. Schedule 1 sets out transitional, savings and related provisions for the transition from the HSNO Act to the Act.

393. Schedule 2 makes a consequential amendment to the Imports, and Exports (Living Modified Organisms) Prohibition Order 2005.

394. Schedule 3 lists the decisions that are reviewable by the Regulator, and who may request a review.

395. Schedule 4 amends Schedule 12 of the RMA to include transitional, savings and related provisions concerning amendments to the RMA.

Alternative recommendations suggested by submitters

396. Several alternative recommendations to progressing the Bill were made. These issues have largely been discussed above but are captured to represent these views. The alternative recommendations made include the following:

Splitting the Bill

397. The proposition of "splitting the Bill", proceeding with it as it relates to medical and containment activities, but removing reference to activities involving environmental release. Add the following to schedule 1, Part 1, (3): "(c) any application for field trial or release under the HSNO Act sections: 34, 34A, 38 and 40."

Officials' response

398. Splitting the Bill creates unnecessary administrative complexity and uncertainty. In practice, decisions on environmental release are made separately through regulation making processes with further public consultation.

Strengthening the HSNO Act instead

399. Some submitters recommended strengthening the existing HSNO Act regime.

Officials' response

400. The Government has committed to liberalising the gene technology regime in New Zealand. Strengthening the existing HSNO Act regime would be unlikely to deliver an enabling, future-focused, risk-proportionate regime. This is in part because many of the proposals in this Bill seek to remedy issues with the current HSNO Act regime.

Chapter 4: Ongoing policy work

401. Work is ongoing to develop the secondary legislation that will cover the more specific and technical details of the new gene technology regime created by the Bill. As per LDAC guidelines, secondary legislation provides for technical, mechanical and administrative matters, which is at a level of detail not appropriate for primary legislation.

402. Subpart 5 of Part 5 sets out the regulations that may be made by the Governor-General, on the recommendation of the responsible Minister, by Order in Council. The Bill also empowers the Regulator to make secondary legislation including declarations specified under clauses 23, 47 and 48.

403. It is intended that MBIE, in collaboration with other agencies, will develop and publicly consult on the following secondary legislation prior to the new gene technology regime becoming operational:

    a. *Technical detail on what is an exempt organism or category of organism modified by gene technology*: Under the Bill, organisms that fall within the parameters under clause 163(2)(a) are able to be exempted from regulation by the Act. These exemptions are made through an Order in Council. Technical detail developed and consulted on as part of the secondary legislation workstream will specify in greater detail molecular changes that would be permissible in exempt organisms.

    b. *Criteria that must be satisfied for an activity to be classified by the Regulator as a non-notifiable activity, notifiable activity, or pre-assessed activity:* The Bill enables the Regulator to declare activities a non-notifiable activities, notifiable activities and pre-assessed activities under each of the three categories of the regime (contained, environment, and medical). Currently, the only criteria for classification in the Bill is that these activities must be no more than very low risk, low risk or medium risk, respectively. These regulations, made through an Order in Council, would specify in further detail what ‘very low risk’, ‘low risk’, and ‘medium risk’ refers to.

    c. *Matters to be taken into account by the Regulator in preparing and finalising RARMPs:* When preparing and finalising a RARMP, as part of its assessment of a given application, the Regulator will take into account a number of matters. These regulations, made through an Order in Council, would set out the matters that the Regulator would be required to take into account for the RARMP.

    d. *Requirements relating to notifiable activities, including verification and the timing of notifications:* Under the new regime, it is intended that notifiable activities would be subject to a number of requirements in addition to the requirement to notify the Regulator of those activities.

    e. *Statutory timeframes for the Regulator to process, consult and decide on matters:* These regulations will outline the timeframes within which the Regulator must undertake certain matters such as the timeframes to make certain determinations, to prepare and finalise RARMPs, to make decisions, and to publicly consult.

    f. *Declarations for, pre-assessed. non-notifiable and notifiable activities:* The secondary legislation workstream will also include the development of declarations of pre-assessed, non-notifiable and notifiable activities under each of the three categories of the regime (contained, environmental and medical). Following consultation and once the Regulator is appointed, MBIE will provide the information developed for these declarations, including the submissions received during the public consultation, to the

Regulator.[20] The Regulator will then assess this information against the criteria for under regulations and then make these declarations.

404. The below table indicates intended sequencing of milestones that collectively establish and enable operationalisation of the gene technology regulatory regime. This reflects current policy thinking and is subject to change.

Table 7: Milestones for establishing and operationalising the regulatory regime

When	Milestone	What happens
Late 2025	Bill passed into law (i.e. Royal assent given)	The Gene Technology Act becomes law.
Day after Royal assent	Commencement: the Act comes into force (with exception of specific parts that will come into force later)	Parts of the Act will come into force immediately to enable the appointment of Regulator, TAC, MAC, the making of secondary legislation, and to amend the RMA.
When Order in Council approved, or the second anniversary of Royal assent, whichever is earlier	Rest of the Act come into force	Other parts of the Act come into force enabling the licensing regime to commence.
Prior to the OGTR receiving first application	Regulations made by Governor-General	The regulations will have been made as per the descriptions above.
Following recruitment	Regulator appointed	
Once Regulator appointed, but prior to receiving first applications	Declarations of pre-assessed, non-notifiable and notifiable activities, by the Regulator	Informed by public consultation on the criteria for these risk tiers, MBIE will have developed declarations of activities under each of the activity categories of the regime, and consulted on the proposed activities. MBIE will provide prepared lists to the Regulator for it to assess the activities against the criteria set in regulations, and when satisfied, to make those declarations.
	Office of the Gene Technology Regulator (OGTR) operational	Applications under the gene technology regulatory regime can be received

[20] Schedule 1, Part 1, clause 14 of the Bill states that: "*Any consultation undertaken before the commencement of **section 49** in order to satisfy the prerequisites set out in that section for making, amending, or revoking declarations is deemed to have been undertaken on and after the commencement of that section.*"

When	Milestone	What happens
Following the end of the first financial year that the OGTR is operational	First annual report	Regulator provides report to the responsible Minister, who must provide that report to Parliament (as recommended at Chapter 3.11).
As soon as practicable after the expiry of four years from the commencement of this Act	Review of the operation of the Act	Minister to commence review of the operation of the Act, including the OGTR, and prepare a report on the review and present it to Parliament (as recommended at Chapter 3.11).

Chapter 5: Outstanding responses to Committee information requests

405. MBIE has previous responded to various information requests from the Committee. The responses to the two requests below were considered more appropriately answered through this report following analysis of submissions.

Update on the information sharing provisions and consultation with the Office of the Privacy Commissioner (OPC)

406. Part 5, Subpart 4 sets out information sharing provisions that enable disclosure of information (including personal information) to support the effective operation of the gene technology regime. The Bill provides for information to be shared between agencies (clause 151) and with overseas regulators (clause 152) for prescribed purposes. The Bill also enables agencies to impose conditions on each other relating to the disclosure of information, which may place further limitations over and above what is provided in the Privacy Act. The provisions enabling information sharing will interact with the IPPs contained in that Act (specifically principles 2, 11, and 12), and provides for overrides of these principles when justified.

407. The legislative scrutiny memo reported on "the concern of [OPC] that the need for the bill to override the Information Privacy Principles has not yet been justified... MBIE officials will work with [OPC] to identify any necessary safeguards that are required to ensure the protection and proper use of personal information under the Bill." The Committee requested an update on consultation with OPC.

408. MBIE has now engaged with OPC regarding the justification for the overrides, and necessary safeguards for protection and proper use of personal information. MBIE demonstrated the operational need for clauses 151 and 152. This has been accepted by OPC.

409. The operational need includes information sharing with other agencies and internationally to enable regulatory functions, including application processing, compliance monitoring and enforcement. MBIE also suggested some operational measures for information management once the Regulator is established, including developing information sharing templates and undertaking a Privacy Impact Assessment. Privacy and information management policies are likely to already exist in the agency where the Regulator is housed, as well as regular training for all staff.

410. In response to OPC's concerns, MBIE recommends changes to the information sharing provisions in the Bill, to clarify the relationships between clauses 151 and 152 and certain IPPs, as detailed in Chapter 3.6.

Appointment and accountability of the Regulator

411. The legislative scrutiny memo noted that, "Under clause 108 of the bill, the Regulator would be appointed by the Minister responsible for administration of the Act. However, the Regulator would be an employee of the EPA. This is an unusual arrangement, as Ministers do not normally appoint Crown Entity staff. The Regulator will be a statutory officer, employed by but not accountable to the EPA board in relation to their statutory functions."

412. The Committee requested advice on how this arrangement is intended to work. The Initial Briefing outlines the appointment and accountability provisions for the Regulator [paragraphs 134-139] and provides information about the Regulator's independence from the Minister

[paragraphs 211-213]. This issue is discussed substantively above in Chapter 3.9. We note that this is an unusual arrangement and that it raises concerns regarding the accountability of the Regulator. MBIE, PSC, and the EPA recommend that the EPA manage the process to recruit the Regulator in consultation with the Minister. This aligns with the current policy settings where the Minister appoints the Regulator and ensures that the Regulator is accountable to the EPA because they will be an employee of the EPA.

Appendix One: Clause-by-clause analysis

1. The clause-by-clause analysis provides summarised comments by submitters relating to specific Bill clauses. Officials note that only a small proportion of overall submissions received included comments on specific clauses. Not every clause was commented on and some clauses did not receive any comments but are included because officials are providing recommendations regarding them.

2. Comments are attributed to submitters according to submitter type (refer Table 9 for organisations included in particular submitter types).

3. Agency recommendations (predominantly from MBIE) are also included in the clause-by-clause analysis, providing suggested approaches to respond to issues officials have identified with clauses since the Bill's introduction in December 2024.

4. The analysis does not include very minor issues identified by officials. The Parliamentary Counsel Office (PCO) has received permission from the Committee to consider drafting changes for these minor issues.

5. Officials defer to PCO for advice on specific wording to enact the changes recommended, and note that the PCO may also make other minor or technical changes to improve the workability of the Bill and the clarity of the drafting.

Part 1: Preliminary provisions

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
1	1	All		**MBIE**	**Recommend** that the Parliamentary Counsel Office (PCO) can make any additional minor and technical drafting changes to the Bill consistent with the policy intent and that may not be identified at the time the departmental report was presented to the Health Committee.
Commencement					
2	2	2	Government policy is that subpart 9 of Part 6 (Amendments to the Resource Management Act 1991) – commence immediately and not by Order in Council as currently drafted.	MBIE	**Amend clause 2** to specify that subpart 9 of Part 6 (amendments to the Resource Management Act 1991) comes into force the day after the date of Royal assent.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
3	3	2	The powers for the Regulator to declare activities as non-notifiable, notifiable and pre-assessed activities need to come into force ahead of the rest of the Bill to enable these to be in place when the regime is operational as soon as the Regulator is appointed.	MBIE	**Amend clause 2** to specify that clause 23 (Regulator may declare pre-assessed activities), clauses 26-29 (which set out the process for making such a declaration) and subpart 4 of Part 2 (non-notifiable and notifiable activities) come into force the day after the date of Royal assent. Clause 58 (which requires the Regulator to maintain a register of declarations) and clause 112 (which allows the Regulator to delegate the power to make declarations) should also come into force the same day.
4		2	That a two-year transitional period should be considered during which decisions made by the Regulator and/or Minister affecting the primary sector are subject to greater transparency, helping to build trust and confidence in the new system. This transition should also ensure an appropriate sequencing of provisions, for example the creation of regulations relating to exempt and non-notified activities before any declarations are made exempting certain technologies or organisms from regulation.	Sector group	**No change proposed.** The policy intent is for the new regime to come into force once necessary regulations have been approved by the Governor-General and declarations have been made by the Regulator (refer to Chapter 4 for further information). These regulations and declarations will be consulted on to allow the public, including primary sector stakeholders, to provide feedback and to learn more about the details of the regime contained in this secondary legislation. This process for secondary legislation also aims to build confidence and familiarity in the new system, and to adapt processes if needed.
Purpose					
5		3	Recommend societal, cultural and ethical matters are added to the purpose.	E-NGO	**No change proposed.** We do not support this change as it is not consistent with the general approach outlined in Chapter 3.3. Regarding ethical matters, officials consider that these issues are presently addressed through dedicated

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
					legislation such as the Animal Welfare Act 1999 and the Human Assistive Reproductive Technologies Act 2004. *This issue is discussed further in Chapter 3.2.*
6		3	Noted that the health and safety of humans does not capture the well-being of humans or society except on the basis of 'health and safety' of humans.	E-NGO	**No change proposed.** We consider such a change would duplicate the functions of other pieces of New Zealand legislation.
7		3	Recommend the Regulator consider economic factors and benefits	Primary and Organic sectors	**No change proposed.** The Australian legislation on which the Bill is based (the Gene Technology Act 2000; Australian Act) does not consider economic factors or benefits. The intent of the legislation is to focus on management of risks to health and safety of people and the environment. *This issue is discussed further in Chapter 3.2.*
8		3	Recommend that the Regulator is required to protect natural ecosystems, including soil, aquatic life, bees and pollinators.	E-NGO	**No change proposed.** The Bill's purpose includes the management of risks to the environment, which would encompass natural ecosystems, including soil, aquatic life, bees and pollinators.
9		3	Recommend incorporating Te Tiriti o Waitangi Principles Amendment to Part 1, Clause 3: Purpose. Currently, Clause 3 states: "The purpose of this Act is to enable the safe use of gene technologies and regulated organisms by managing their risks to— (a) the health and safety of people; and (b) the environment." Proposed Amendment: 6 "The purpose of this Act is to enable the safe use of gene technologies and regulated organisms by managing their risks to— (a) the health and safety of people; (b) the	Iwi/hapū	**No change proposed**. Clause 4 signposts how the Act recognises and respects the Crown's obligations under the principles of the Treaty of Waitangi. *Refer to Items 18 and 19.*

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			environment; and (c) uphold the principles of Te Tiriti o Waitangi.		
10		3	That it is unclear if people and communities are included in 'environment', and if domesticated animals, non-native plants, or non-native insects are included in the definition of 'ecosystem'. The current definition does not include the social /cultural /economic dimensions. This narrowing alongside the removal of district and regional Resource Management Act 1991 (RMA) regulation, reduce the scope of risk assessments and management of gene technologies considerably compared with the regulation under the RMA and Hazardous Substances and New Organisms Act 1996 (HSNO Act). The submitter noted it could accept the narrower definition of 'environment' provided the Bill includes and provides for 'managing risks to primary production and trade'.	Horticulture	**No change proposed.** 'People and communities' are encompassed in the term 'people' (as part of 'health and safety of people'). The definition of 'environment' is intended to encompass domesticated animals, non-native plants and non-native insects. The Bill's purpose is modelled on the Australian regime, which does not consider trade and market access risks in the Regulator's decision making. *This issue is discussed further in Chapter 3.1.*
11		3	Recommended including in the purpose: To prevent contamination of organic farms by genetically engineered (GE) crops and ensure the integrity of organic certification, supporting farmers who adhere to organic standards.	Organics	**No change proposed**. Making this change would be inconsistent with Government policy for the Act's purpose being to manage risks to the environment and the health and safety of people. *This issue is discussed further in Chapter 3.1.*
12		3	Noted the use of mitigation versus protection, specifically that the wording of the Bill's purpose "to enable the safe use of gene technologies and regulated organisms by managing their risks to the health and safety of people and the environment". would imply mitigation of harm rather than protection. The submitter noted that Australia has set a higher bar for "protection", with the object of Australia's Gene Technology Act 2000 being "to	Individual	**No change proposed**. The proposal for protection sits outside the policy settings agreed by Cabinet to provide an enabling regime whilst managing risks to the health and safety of people and the environment.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs." Harm is not accepted in the Australian Act. Neither should it be in NZ legislation.		
13		3	Noted the Committee should seek advice from officials whether any of the differences between regimes would cause significant trade issues, particularly in light of the limited assessment of costs and benefits in the regulatory impact statement. The Committee may also want to question different industry sector groups about risks or benefits of the proposed regime they have identified for trade in their sector.	Parliamentary Commissioner for the Environment (PCE)	**No change proposed.** *This issue is discussed further in Chapter 3.1.*
14		3	Recommended adding reference to trade and market access risks to the purpose of this Act, e.g.. to enable the safe use of gene technologies and regulated organisms by managing their risks to (a) human health and safety; (b) the environment and (c) trade and market access.	Dairy, Organics. Sector group	**No change proposed**. The Bill's purpose is modelled on the Australian regime, which does not consider trade and market access risks in the Regulator's decision making. *This issue is discussed further in Chapter 3.1.*
15		3	Suggest that food and agriculture are excluded from the scope of the Bill.	Individual	**No change proposed**. The policy intent is for the regulatory regime to manage risks to the environment and the health and safety of people from contained, medical and environmental activities with gene technologies and regulated organisms. Excluding particular sectors or types of activities, such as those relating to food or agriculture, has not been within scope of policy consideration, and could reduce the benefits from the new regulatory regime.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
Treaty of Waitangi					
16		4	Recommend deleting any reference to 'the principles of the Treaty of Waitangi' and replace with 'have regard to the Treaty of Waitangi'.	Individual	**No change proposed.** It is well established that the Crown must uphold the principles of the Treaty of Waitangi.
17		4	The submitter requested officials to review provisions relating to Māori rights and interests and identify other options that more meaningfully enable Māori participation in the new regulatory framework, noting commonly raised concern in its discussions with Māori levy payers was whether the new framework would provide for Māori relationships with both indigenous and non-indigenous species and receiving environments. Based on this feedback the submitter urges the Committee to take the time to consider a wider range of options for protecting Māori rights and interests and more meaningfully enabling Māori involvement. It noted it is vital that the Regulator have sufficient internal capability in Māori rights and interests as they relate to gene technologies and organisms.	Dairy	**No change proposed.** MBIE agrees that the Regulator should in its decision making consider kaitiaki relationships with both indigenous species *and* non-indigenous species of significance. This change is recommended to be implemented by amending clauses other than clause 4. *Refer to Items 19, 20, 21, 65, 70, 126, 299, 300, and 337.* *This issue is discussed further in Chapter 3.3.*

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
18		4	Proposed an additional clause on Iwi participation in decision-making, whereby the Regulator must: - ensure that Iwi authorities have meaningful participation in decision-making processes relating to gene technology applications that may affect their role - provide for consultation with relevant Iwi and hapū in the development of policies, guidelines, and regulations under this Act - ensure that Iwi authorities have the resources and capacity necessary to participate effectively in decision-making processes - establish mechanisms for Iwi authorities to nominate representatives to participate in decision-making bodies concerning gene technology applications - give particular regard to the views of Iwi representatives when making decisions under this Act.	Iwi/hapū	**No change proposed.** Government has agreed to recognise Māori interests through a specific process in the Bill (i.e. kaitiaki relationships and the Māori Advisory Committee; MAC), as a mechanism to honour the Crown's obligations under the Treaty of Waitangi. *This issue is discussed further in Chapter 3.3.*
19		4	Recommend the Bill requiring decision-makers to have regard to the impacts on Ngāi Tahu values, not just the kaitiaki relationships we have with our taonga species. Limiting Ngāi Tahu rights and interests to kaitiaki relationships with native species ignores the rangatiratanga Ngāi Tahu has over its Takiwā. Furthermore, the genetic modification and release of non-native species will likely indirectly impact native and treasured species and ecosystems.	Iwi/hapū, Ngāi Tahu	**No change proposed.** The policy intent is not to address the full range of Māori concepts as they apply to the environment or gene technologies at large. The approach in the Bill to give effect to the Treaty of Waitangi is based largely on the Plant Variety Rights Act 2022 (the PVR Act), which protects kaitiaki relationships through the Māori Plant Varieties Committee. The policy intent in the Bill is to balance the broader purpose with the active protection of

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
					Māori relationships to indigenous species and non-indigenous species of significance. *This issue is discussed further in Chapter 3.3.*
20		4	That the provision of a MAC in the Bill as the method to recognise and respect the Crown's obligations under the principles of te Tiriti o Waitangi does not meet the Crowns obligations to actively protect taonga as required by Article 2 of te Tiriti. Submitter also considers it also does it fulfil the Crown's obligations to provide for participation in decision-making and partnership in relation to the protection of taonga through the design of legislation.	Iwi/hapū	**No change proposed.** *Refer to Items 18 and 19.*
21		4	Clause 4 of the Bill does not meet and respect the Crown's obligations under the principles of Te Tiriti.	Iwi/hapū	**No change proposed.** *Refer to Items 18 and 19.*
22		4	That the Bill lacks explicit provisions for public consultation and meaningful engagement with Māori communities in decision-making processes related to gene technologies. This omission undermines the principles of partnership and participation enshrined, for all, in Te Tiriti o Waitangi.	Iwi/hapū	**No change proposed.** Clause 122(d) provides for the MAC to issue engagement guidelines. Clause 167 provides a procedure for making regulations that enables the Minister to consult persons or representative of persons the Minister considers are likely to be affected by the proposed regulations. *This issue is discussed further in Chapter 3.3.*
23		4	The Bill, in its current form, is inconsistent with the rights and interests of Waikato Tainui, including those recognised and confirmed in existing Treaty settlement agreements between Waikato Tainui and the Crown. This includes the protection of mana whakahaere, Kaitiakitanga and customary	Iwi/hapū	**No change proposed.** *Refer to Items 18 and 19.*

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			rights, as well as environmental, cultural, and legislative interests.		
24		4	The submitter considered that the Bill should provide direction on benefit sharing / access to benefits, and that Māori economic and trade interests are at significant risk under the proposed Bill, particularly for industries that rely on New Zealand's GMO-free status as a key market advantage.	Iwi/hapū, Legal	**No change proposed.** Regulation of access and benefit sharing is a separate regulatory domain to the regulation of the environmental and human health risks of gene technologies, and this should be addressed by other legislation. *This issue is discussed further in Chapter 3.3.*
25		4	That any gene technology legislation must contain the same protections of Māori rights and interests as those in the HSNO Act – or better. Suggested improvements centre on according more weighting to Māori values rather than them being subordinate to scientific considerations.	Iwi/hapū	**No change proposed.** Consistent with LDAC guidance, rather than inserting a general obligation on decision-makers to act consistently with the principles of the Treaty of Waitangi, the operative provisions of the Bill contain specific mechanisms and requirements to ensure consistently with the Treaty.[21] *Refer to Items 18 and 19.*
26		4	Recommend retaining the HSNO Act's Treaty of Waitangi provision, noting that while this Bill contains a provision which explains how it 'recognises and respects the Crown's obligations under the principles of the Treaty of Waitangi', it does not impose a similar requirement on the Regulator and others who will exercise powers and functions under the Bill.	Legal	**No change proposed.** *Refer to Item 25.*

[21] The existing provision in the HSNO Act "All persons exercising powers and functions under this Act shall take into account the principles of the Treaty of Waitangi (Te Tiriti o Waitangi)."

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27		4	Suggest an advocacy role of the Regulator for Māori communities and other Māori entities to incorporate Māori into decision making.	Māori sector	**No change proposed**. The Regulator does not have an advocacy role. The functions for the Regulator are provided in clause 110.
Convention on Biological Diversity including Cartagena Convention					
28	4	5	Requiring other employees assisting the Regulator, such as EPA employees supporting the Regulator in their role, or enforcement officers exercising their powers under the Bill, to have regard to the Convention on Biological Diversity (CBD) and the Cartagena Protocol is impractical and unnecessary.	MBIE and the Ministry for Primary Industries (MPI)	**Amend** clause 5 by removing "and every other person who carries out a function or duty or exercises a power under this Act," from the clause. This will mean that clause 5 requires only the Regulator to have regard to the CBD and the Cartagena Convention - not others acting under the Bill – which is more practicable.
29		5	Suggest removing the 'Cartagena Protocol' section to provide stakeholders with greater clarity and avoid arbitrary or evolving interpretations of these instruments. Failing the removal of the section, we would suggest that it be reworded to read: This Act recognizes and respects the Crown's obligations under the principals of the CBD including Cartagena Convention.	Biotech organisation	**No change proposed.** Government has agreed that the Regulator should have regard to the Cartagena Protocol in decision making, as a relevant international obligation.
30		5	Ensure HSNO's continued regular, safe and progressive transfer of living modified organism (LMOs) microbes, seeds, plants and animals across to collaborating partners and countries through the Cartagena Protocol Biological Clearing-House.	ENGO	**No change proposed.** The Imports, and Exports (Living Modified Organisms) Prohibition Order 2005 (Prohibition Order) will continue to apply for the Regulator.
31		5	Suggest adding to both the Cartagena Protocol and the CBD interpretations … 'while in accord with New Zealand's sovereign position."	Individual	**No change proposed.** Officials consider it is implicit that New Zealand holds sovereignty.
32			Recommend reinstating the Precautionary Principle	ENGO, Individuals	**No change proposed.**

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					The Bill does not carry over the precautionary approach provision from section 7 of the HSNO Act. The HSNO Act does not specify how decision makers should implement the precautionary approach and their decisions have been subject to judicial challenge. The policy intent is that the Regulator will develop a Risk Analysis Framework that will incorporate precautionary elements into its specific risk management processes to provide clearer guidance to decision makers on how they should act with caution and consider scientific uncertainty. In adhering to clause 5 (international obligations under the Cartagena Protocol and CBD), the Regulator will need to have regard to the precautionary approach. Officials consider this mechanism will reduce operational ambiguity.
Interpretation: Activity definition					
33	5	7	Amendments are required to ensure clarity and consistency: - 7(1)(a) should include "constructing" to be consistent with the definition of "regulated organism" which uses the term "constructing". - 7(1)(a) "fermenting" should be "fermenting with" to better reflect what the activity is in practice. - 7(1)(b) states "modifying an regulated existing organism". This should include modifications to an existing organism that	MBIE	**Amend the definition of activity** to ensure clarity and consistency, as follows: - **include** "constructing" in 7(1)(a) - **add** "with" after "fermenting" in 7(1)(a) - make it clear in the 7(1)(b) definition of "activity" that "modifying" is the modification to any organism – not just those already regulated. - **include** "conducting experiments" in clause 7(1)(d) and removing "undertaking research" - **amend** clause 7(1)(e) in the definition of "activity" to make it clear that any introduction

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			may not yet be regulated. Following from this the phrase in the chapeau "in relation to a regulated organism" could be deleted. - in 7(1)(d) using the regulated organism should include "through conducting experiments" as this might not be adequately covered by testing, trials and field tests. This will also remove the need for "undertaking research". - in 7(1)(e) the term "releasing" into the environment could be associated with an unconditional release under the HSNO Act. However, the intent is to include any introduction of a regulated organism into the environment, including in field trials.		of a regulated organism to the environment falls within the definition of "activity".
34		7	Noted that there appears to be an error with clause 7(1)(b), querying: should it read "modifying an unregulated existing organism"?	Researcher	**No change proposed.** Error corrected by recommendation 5. *Refer to Item 33.*
Interpretation: Containment definition					
35		7	Proposed a change to the containment definition: "containment means restricting an organism or substance to a containment facility to prevent escape.".	E-NGO	**No change proposed.** Containment facility has a different meaning in the Bill. The policy intent is to provide for containment options without requiring containment facility standards to be met.
36		7	That the definition of containment should be amended and expanded upon to include biological, process, and physical containment.	Researcher, Research institute and Agriculture (non Dairy) sector, Biotech	**No change proposed.** The policy intent is for containment to include enclosed facilities. *Refer to Item 37.*

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				organisation and Māori NGO	
37		7	That the definition of containment could more fully reflect the established practices for biological safety, proposing an enabling, risk-proportionate and also flexible and future looking extended definition of: containment— (a) means to confine a regulated organism in any manner that will manage the risk of harm to human health or the establishment of the organism in the natural environment (for example, the use of biological containment, process containment or physical containment or a combination of any and all where appropriate) (b) any processes specified in this Act or regulations as containment for the purposes of this Act *biological containment* where the risks for human health and the environment are managed by reducing exposure potentials and their consequences by using attenuated organisms that have reduced replicative capacity, infectivity, transmissibility, and virulence. *process containment* where the risks for human health and the environment are managed by reducing exposure potentials and their consequences by using procedures and practices. (for example axenic tissue culture, standard hygienic microbial laboratory practice) *physical containment* where the risks for human health and the environment are managed by reducing exposure potentials and their	Research institute	**No change proposed.** The policy intent is for containment to include enclosed facilities. The issue raised by the submitter could be managed by the Regulator imposing conditions (clause 15), and in regulations setting criteria and conditions for activities etc. (clause 161).

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			consequences by using physical structures (for example and where appropriate, fenced enclosures, a building, or part of a building, a laboratory, an aviary, a glasshouse, an insectary, an animal house, an aquarium or a tank, or a containment facility).		
38		7	That a broader definition of **containment** include contained outdoor activities.	Horticulture	**No change proposed.** The containment definition in the Bill enables enclosed outdoor activities.
39	6	7	That the containment definition is addressed through secondary legislation development to ensure the definition of containment is relevant specifically in the context of the activity or the organisms risk assessment and is not generalised, which may unintentionally impact the benefit/risk.	Horticulture	**Amend to provide a regulation making power** to include any other method of containment for the purposes of the Bill. This enables future flexibility and other methods to be considered**.** We also note the role of conditions in clause 15, which provides that conditions can be imposed in relation to authorisation providing prescriptive containment measures if needed.
40		7	Recommend adopting an outcome-based definition modifying Section 7(1) to define containment as: "Containment means employing biological characteristics, process controls, physical barriers or any combination thereof to confine a regulated organism and prevent its unintended release or spread." Rather than providing an indicative list of containment methods in the Bill, the submitter proposes these be addressed in secondary legislation, which can be more readily updated as technology develops. Possible methods include: • Biological containment: Organisms unable to survive or reproduce outside controlled conditions	Research institute	**No change proposed** to the definition of containment. Secondary legislation will set out in greater detail what types of containment measures are needed for different activities. As the ability to persist in the environment would be a key aspect of this criteria, the Regulator will be enabled in the future to take into account biological containment measures in their risk assessments and authorise activities utilising biological containment measures in a risk proportionate way if the evidence supports it. *Refer to Items 35, 36, and 37*.

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			• Process containment: Sealed fermentation vessels and associated systems designed for industrial-scale production • Physical containment: Structures appropriate to the organism and scale of operation.		
Interpretation: Conventional processes definition					
41	7	7	As per recommendations 12 and 91 to remove reference to conventional processes for the definition of gene technology and clause 163(2)(a) respectively officials consider the definition of conventional processes is no longer required.	MBIE	**Delete** the definition of *conventional processes*. *Refer to Items 57, 355, and 363.* ***Dependencies with recommendations 12, 91, and 94.*** *This issue is discussed further in Chapter 3.12.*
42		7	Proposed a change to the conventional processes definition: "conventional processes means processes used to reproduce organisms that amplify or concentrate desired traits or functions through culturing (e.g. asexual organisms) or crossing (i.e. sexually compatible) organisms. A conventional process does not increase the rate or specificity of mutations within an organism."	E-NGO	**No change proposed.** This is addressed through recommendation 7**.** *Refer to Item 41.*
43		7	That the exemption for conventional breeding processes is not clear, recommending that the definitions outlining the scope of the regulatory framework and the risk tiers are edited to clarify the exempt technologies and organisms (e.g. conventional breeding).	Agritech	**No change proposed.** This is addressed through recommendation 7**.** *Refer to Item 41.*
44		7	Suggest amended definition: conventional processes means processes used to reproduce organisms, including, but not limited to,—	Research institute	**No change proposed.** This is addressed through recommendation 7**.** *Refer to Item 41.*

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			(a) sexual reproduction, in conjunction with selection techniques or alone; and (b) asexual reproduction (clonal propagation) of plants and microbes in conjunction with selection techniques or alone; and (c) collection from the natural environment of mutant isolates of existing organisms; and (d) any processes specified in this Act or regulations as non-regulated for the purposes of this Act.		
45		7	That the definition of 'conventional processes' includes 'natural homologous recombination', but the word natural is undefined and is not included in the Australian context. Reference to natural in this context should be removed.	Biotech organisation	**No change proposed.** This is addressed through recommendation 7**.** *Refer to Item 41.*
46		7	Suggest this broad definition is completely undermined by the exclusion of 'conventional processes' that itself has an open-ended definition. Noting that in the Australian Act, the definition does not contain the same open-ended exclusion of various unspecified 'processes': the use of the term 'but not limited to' allows various unspecified 'processes used to reproduce organisms' to be encompassed as 'conventional processes'.	Researcher	**No change proposed.** This is addressed through recommendation 7**.** *Refer to Item 41.*
Interpretation: Enforcement Agency					
47	8	7	Enforcement agency definition. Limb (b) "any organisation exercising relevant powers under this Act delegated to it" is not necessary because it would be implied that a reference to the	MBIE	**Amend** the definition of enforcement agency by deleting limb (b), to remove unintended uncertainty that the enforcement agency could be an agency other than MPI.

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			enforcement agency is also a reference to a delegate if the power is delegated.		
Interpretation: Environment definition					
48		7	Recommend that the definition of environment is expanded to explicitly include the human-created-and-occupied environment, in addition to the natural environment.	Research institute	**No change proposed.** We consider 'human-created-and-occupied environment falls within limb b) *natural and physical resources*.
49		7	Suggest that environment incorporate biodiversity, interactions and life supporting systems, biophysical and biogeochemical systems and processes, ecosystems and biotic and abiotic interacting systems and drivers, as well as the human and non-human life and biodiversity within.	E-NGO	**No change proposed.** The policy intent is for the definition of *environment* to encompass biodiversity and wider ecosystems.
50		7	Recommends 'environment' be amended as follows (proposed changes underlined): 'environment includes — (a) ecosystems, including primary production systems, and their constituent parts; and (b) natural and physical resources; and (c) the qualities and characteristics of locations, places, and areas. The sector's reasoning is so that coexistence factors are considered as part of the risk assessments.	Dairy and Agriculture (not dairy)	**No change proposed.** We consider primary production systems falls within limb b) *natural and physical resources*.
51		7	That the definition of "environment" in clause 7 does not clearly allow the contemplation of risks to agricultural environments and domestic animals. The submitter recommends that a definition of "natural and physical resources" is inserted that reflects the definition in the RMA but further clarifies its application to domesticated plants and animals: natural and physical resources includes land, water, air, soil, minerals, and energy, all forms of plants	Agritech	**No change proposed.** *Refer to Items 49 and 50.*

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			and animals (whether native to New Zealand or introduced, and including domesticated plants and animals), and all structures.		
52		7	Note that while this definition has served Australia well, considering the higher risk of litigation in this area in New Zealand, the submitter asks the Committee to consider if "qualities and characteristics of locations, places, and areas" risks a much broader interpretation than intended and should therefore be removed.	Biotech organisation	**No change proposed.** We consider that this definition adequately balances the need to provide enough specificity in the definition to enable the Regulator, applicants, and interested parties to understand and apply this definition across the regime's provisions, without being so prescriptive as to define environment too narrowly, compromising the Regulator's ability to manage the risks of gene technologies and regulated organisms to the environment.
Interpretation: Environmental activity					
53	9	7	It is unclear what "importation of a regulated organism for immediate release or use in the environment" means. The policy intent is to capture import of a regulated organism that is then introduced to the environment without first going into a containment facility.	MBIE	**Amend** definition of "environmental activity" to make it clear it captures import and introduction of a regulated organism into the environment <u>where the organism does not first go into a containment facility</u>.
Interpretation: Export – new definition					
54	10	7	There is no definition of export. However, exporting is in the definition of activity and regulations can be made under clause 159 imposing requirements on export of regulated organisms.	MBIE	**Add** a definition of exportation into the Bill, referring to the definition of exportation in the Prohibition Order where **exportation** means any shipment in any craft for transportation to a point outside New Zealand; and **export, exported and exportation** have corresponding meanings.
Interpretation: Gene technology					

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55		7	Recommend that clause 7(1)(a) is simplified to: "any technology used to modify or construct heritable genetic material".	Research institute, Biotech organisation, Agriculture (not dairy)	**No change proposed.** The proposal wants to capture all technology capable of modifying heritable genetic material. There are technologies that could be interpreted as capable of this which should not be captured by the regime as they are not modern gene technologies and do not modify genetic material in a predictable or precise manner (e.g. selective breeding or sexual reproduction). As the definition is currently drafted these are excluded in the regulations to ensure the new regime is not more restrictive than the status quo, additionally recommendation 11 expands this to exclude any technology specified in the Act. *Refer to Item 56.*
56	11	7	In line with recommendation 94 to provide a prescriptive list of technologies out of scope of the regime in the Act, the exclusion of technologies in the definition of *gene technology* needs to refer to both the Act and regulations.	MBIE	**Amend the definition** of gene technology to not include technologies specified in the Act or regulations, for completeness. *Refer to Items 41, 56, 57, and 363.* ***Dependencies with recommendations 7, 12, 81, and 94.*** *This issue is discussed further in Chapter 3.12.*
57	12	7	In line with both recommendation 94 to provide a prescriptive list of technologies out of scope of the regime in the Act and recommendation 91 to refer to this prescriptive list with regards to criteria for exempt organisms established in clause 163(2)(a), reference to conventional processes is no longer required.	MBIE	**Amend the definition** of *gene technology* to remove limb (b)(i) referring to conventional processes, for consistency with other recommendations to delete this definition. *Refer to Items 41, 56, 355, and 363.* ***Dependencies with recommendations 7, 11, 91, and 94.*** *This issue is discussed further in Chapter 3.12.*

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
58		7	That the definition of 'gene technology' is too broad and it should exclude organisms and products indistinguishable from conventional breeding.	Biotech organisation	**No change proposed.** The definition of gene technology is intended to be broad to capture any technological advancements. Excluding organisms indistinguishable from conventional breeding is appropriately addressed by powers to exempt organisms through regulations.
59		7	That the definition should be amended to follow that of Food Safety Australia New Zealand (FSANZ) P1055 and add the italicised text: gene technology— (a) means any technology used to modify or construct genes or other genetic material; but (b) does not include— (i) conventional processes; *or* *(ii) induced mutagenesis wherein genetic changes are cause by* *a. radiation; or* *b. chemical exposure; or* *c. directed nuclease where nucleic acid template was not added to guide homology.; or* *(iii) introduction of RNA into an organism, if:* *a. the RNA cannot be translated into a polypeptide; and* *b. the introduction of the RNA cannot result in an alteration of the organism's genome sequence; and* *c. the introduction of the RNA cannot give rise to an infectious agent.; or* (iv) any other technology specified in the regulations for the purposes of this paragraph	Biotech organisation	**No change proposed.** Specific processes not intended to be captured by the definition of gene technology will be excluded by an appropriate mechanism and should not be included in the definition of gene technology.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
60		7	Recommend removing part of the definition of conventional processes and amend the definition of 'regulated organism' to ensure all gene technologies are captured and considered in the Bill.	Dairy	**No change proposed.** Gene technology is defined with a wide scope to capture all gene technologies and any technological advancements.
61		7	That the definition could be clarified further to better define 'genes' and 'genetic material' considering these terms are not scientifically unambiguous.	Researcher	**No change proposed.** The Bill's definition of *organism* includes genes or genetic material. Inclusion of genes and genetic material are not required in the definition of *regulated organism,* on the basis that any regulated organism must first satisfy the definition of *organism* in the Bill. *Refer to Item 71.*
Interpretation: Indigenous species					
62		7	Recommend clarifying the definition of indigenous species.	Research institute	**No change proposed.** The definition of indigenous includes endemic or native, which matches the standard definition, and the definition used in other parts of Government, for example by the Department of Conservation.
63		7	Recommends that for Te Tiriti o Waitangi compliance the definition of taonga is expanded to anything of value to Māori, thus necessitating a holistic risk (and benefit) assessment process by Māori interests on the basis of cultural and technical competencies (including expertise and knowledge of the science and how it might impact Māori communities by addressing mana whenua-based notions of risk).	Māori sector	**No change proposed.** Taonga is not defined in the Bill.
64		7	Protection of kaitiaki rights: Strengthen provisions that uphold the collectively held rights and	Māori NGO	**No change proposed.**

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			responsibilities of kaitiaki Māori, allowing for active participation in decisions affecting taonga species and ecosystems: c) Better define 'native to New Zealand' in the definition of 'indigenous species'. d) To be consistent with the PVR Act, include 'species of significance to Māori' in the species involved in applications that trigger advice from the MAC.		Addressed through recommendation 13 to amend definition of *kaitiaki relationship*. *Refer to Item 65.*
Interpretation: Kaitiaki relationship					
65	13	7	Recommend that non-indigenous species be included within the scope of kaitiaki relationships. The PVR Act includes non-indigenous species brought to New Zealand on waka prior to 1769 from around the Pacific. These non-indigenous species may be considered taonga to Māori and kaitiaki relationships may exist with them.		**Amend** definition of "kaitiaki relationship" in clause 7 to "kaitiaki relationship, in relation to a species, means the relationship that any kaitiaki has, or Māori in general have, as guardian, trustee, or caretaker of an indigenous species or a non-indigenous species of significance, in accordance with tikanga." Māori brought with them several species of plants and animals, of which there may be a kaitiaki relationship. This change aligns the Bill with the approach used in the PVR Act. Changes will be required to other clauses in the Bill where there is reference to "indigenous species", to also reference "non-indigenous species of significance", including clauses 21(1)(a),122(a), 126(1), 127(1)(a), 127(2)(a), 127(2)(b), 127(3), 128, 128(a), 129(a)(i), 131(2)(a)(i), and 131(2)(a)(ii). *Refer to Items 17, 19, 20, 21, 70, 126, 299, 300, and 337*. ***Dependencies with recommendations 14 and 83 regarding amendment to kaitiaki relationship.*** *This issue is discussed further in Chapter 3.3.*

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
Interpretation: Low risk medical activity					
66		7	That the low-risk medical definition is clearer that clause 47(a) and 48(a) don't apply, (i.e. that clause 49 does not apply). The definition of low-risk medical activities excludes clause 47 (a) and 48 (a) from the requirement and this exclusion causes confusion as it is not obvious. The submitter considered it may provide clarity if the exclusion of clause 47(a) was stated more clearly in the definition (i.e. that the requirements of clause 49 do not apply).	Biotech organisation	**No change proposed.** Such a change would further complicate the definition. The submitter's comment likely stemmed from not understanding the difference between low-risk medical activity licences, and non-notifiable/notifiable activities. A low-risk medical activity does not need to be declared and the Regulator needs to be satisfied the risk is low or very low and any criteria in regulations are met.
Interpretation: Medical activity					
67		7	Recommend that "veterinary purpose" is defined.	Agriculture (not dairy)	**Refer to Item 89 (amend definition of medical activity).** Addressed by recommendation 20 to include 'veterinary medicine' in clause 8(a)(ii) for the meaning of medical activity. Veterinary medicine is already defined in the Bill. *Refer to Item 89.*
68		7	Recommend methane inhibitor products applied directly to animals fall within scope of the Medical Category. There are some medicines that the Agricultural Compounds and Veterinary Medicine Act 1997 (ACVM Act) considers 'compounds', and	Agritech	**No change proposed.** Veterinary medicine is defined in the Bill and refers to the ACVM Act for meaning, with agricultural compounds including veterinary medicines. However, for the purposes of the submitters example, the policy intent is that methane inhibitors will also be

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			these need to be in the medical category for gene tech.		considered in the Bill's definition of therapeutic purpose (refer to limb (b)).
69		7	That as gene technology advances and the range of conditions that may be addressed expands, the likely need for a regulatory compassionate access license-exemption mechanism for human treatments that present very low/negligible risk to the environment and wider public will increase. Suggests that consideration is given to this issue by the Committee as part of ensuring that the legislation remains fit for purpose.	Other (Medicines NZ)	**No change proposed.** Officials anticipate that the low-risk medical activity licence could be used for the Regulator to consider applications for compassionate purposes.
Interpretation: Non-indigenous species of significance					
70	14	7	The kaitiaki provisions in the Bill are based on the approach used in the PVR Act, which includes non-indigenous species that were brought to New Zealand by Māori prior to 1769. For the MAC to consider a kaitiaki relationship with a non-indigenous species, a definition must be added to clause 7. The scope of this provision should be limited so that it does not include all non-indigenous species. As such, the Bill should include a definition of **non-indigenous species of significance**, in line with the PVR. Note PVR Act section 56 and Schedule 2 of the PVR Act 2022 Regulations.	MBIE and other submitters	**Insert a new definition into clause 7** for "Non-indigenous species of significance". This definition should be based on the definition used in the PVR Act with modification to include organisms that are not plants. The policy intent is for this list to initially be limited to the ten non-indigenous plant species listed in the PVR Act Regulations, plus one animal species, the kiore rat. We recommend PCO consider the following definition based on the PVR Act: **non-indigenous species of significance** means a species of organism— (a) believed to have been brought to New Zealand before 1769 on waka migrating from other parts of the Pacific region; and (b) listed in the regulations as a non-indigenous plant species of significance. *Refer to Items 17, 19, 20, 21, 65, 126, 299, 300, and 337.*

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
					Dependencies with recommendations 13 and 83 regarding amendment to kaitiaki relationship. *This issue is discussed further in Chapter 3.3.*
Interpretation: Organism					
71	15	7	Limb (a) should refer to "genes or other genetic material' to be consistent with the definition of "gene technology".	MBIE	**Amend the definition** of "organism" to include in limb (a) reference to "genes" as well as other genetic material.
72		7	That the term 'viable' is defined.	Research institute, and Biotech organisation	**No change proposed.** Defining 'viable' would compromise the adaptability of the regime to future technological advances.
73		7	Consider defining 'Living modified organism' and 'biotechnology' to ensure consistency of terminology with the Cartagena Protocol.	Agritech	**No change proposed.** Clause 5 already provides that the Regulator must have regard to the provisions of the CBD and the Cartagena Protocol and as such these definitions will be considered.
Interpretation: Manufacturer					
74	16	7	That a manufacturer should be a person that manufactures AND distributes benchtop nucleic acid synthesis equipment in trade or for reward rather than just a person who does either of those things.	MBIE	**Amend** definition of "manufacturer" to include a person who manufactures <u>and</u> distributes benchtop nucleic acid synthesis equipment for trade or reward.
Interpretation: Regulated organism					
75	17	7	The definition of regulated organism currently excludes an organism or a category of organisms declared by regulations not to be regulated organisms. In line with recommendation 95 (introduce prescriptive list) officials recommend	MBIE	**Amend** definition of regulated organism to exclude an organism or a category of organisms declared by <u>the Act or</u> regulations not to be regulated organisms, for consistency with recommendation 94 to introduce a prescriptive list in the Act of organisms that are not

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			including the ability to exclude organisms specified in the Act.		regulated organisms to maintain current regulatory status. *Refer to Item 363.* ***Dependencies with recommendation 94.*** *This issue is discussed further in Chapter 3.12.*
76		7	New Zealand should enforce a full moratorium on germline editing (both globally and in New Zealand).	Individual	**No change proposed.** Human germline editing is addressed in and prohibited by the Human Assisted Reproductive Technology Act 2004 (Refer to Schedule 1, Prohibited Actions include: Implant into a human being a genetically modified gamete, human embryo, or hybrid embryo). Authorisation for animal germline editing can currently be sought through relevant agencies administering the HSNO and Animal Welfare Acts.
77	18	7	That clause 7(1) regulated organism (a)(ii) be modified to remove brackets: “an organism that has inherited from a host organism genes or genetic material that occurred in the host organism because of gene technology.”.	Research institute	**Recommend PCO consider whether** to remove the brackets in **clause 7(a)(ii),** provided the meaning does not change.
78		7	Suggest the definition of 'regulated organisms' too broad, should exclude organisms and products indistinguishable from conventional breeding and does not include patented organisms.	Biotech organisation and Individual	**No change proposed.** Definition of regulated organism is intended to be broad, and to include organisms whether patented or not. Organisms indistinguishable from conventional breeding will be addressed appropriately by powers to exempt organisms from the operation of the Act. An organism’s status as patented or not does not change whether that organism presents risks, as such we do not support excluding them.

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					Note that intellectual property and organism patents are not addressed by this Bill.
79		7	Recommend the definition of regulated organism is amended (refer to italicised text) (a) means— (i) an organism that has been modified or constructed by gene technology; or (ii) an organism that has inherited (from the host organism) genes or genetic material that occurred in the host organism because of gene technology; or (iii) an organism or a category of organisms declared by regulations to be regulated organisms; but (b) does not include— *(i) an organism that is descended from a genetically modified organism (the initial organism), if none of the traits it has inherited from the initial organism are traits that occurred in the initial organism because of gene technology; or* *(ii) an organism that was modified by gene technology but in which the modification, and any traits that occurred because of gene technology, are no longer present; or* (iii) an organism or a category of organisms declared by regulations not to be regulated organisms; or (iv) a human being.	Biotech organisation	**No change proposed.** The definition of regulated organism is intended to be broad and referring to traits would be limiting in terms of the interpretation of phenotypes. The suggested exclusions will be included through an appropriate mechanism. *Refer to Item 363.*
80		7	Consider replacing the term ‘regulated organism’ with ‘designated organism’ or ‘scheduled organism’.	Biotech organisation	**No change proposed.** The term regulated organism provides clarity of regulatory status while mitigating any issues associated with ‘genetically modified organism’ due to

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					inconsistent international definitions and interpretation. 'Designated' and 'scheduled' would not deliver transparency for the public or be in line with international approaches.
81		7	Recommend the term 'regulated organisms' should be replaced with 'genetically modified organisms' (GMOs) for consistency with usage in the international scientific community and in other jurisdictions.	PCE	**No change proposed.** GMO is defined inconsistently by NZ legislation, international jurisdictions and the scientific community. Further, some products of gene technology will not be regulated under the new regime. Therefore, 'regulated organism' provides clarity and transparency on regulatory status.
82		7	Replace 'regulated organism' with 'Genetically Engineered Organism' and define as "Any organism whose genetic material has been altered through biotechnology, excluding traditional breeding methods".	Organics	**No change proposed.** 'Regulated organism' provides clarity and transparency on regulatory status. *Refer to Item 81.*
Interpretation: Synthetic nucleic acid (SNA)					
83	19	7	The definition is amended to: synthetic nucleic acid— (a) means molecules of polymeric nucleic acids that have been synthesised de novo (without template) and (b) includes— (i) DNA and RNA, whether single- or double-stranded; and (ii) whole-organism genomes (for example, viruses or bacteria); and	Research institute, Researcher	**Amend the definition** of synthetic nucleic acid (SNA) to clarify that it only encompasses nucleic acids synthesised *de novo* and without the use of a template, and also includes non-naturally occurring nucleic acid analogues. This recommended definition would ensure that nucleic acids amplified through polymerase chain reaction (PCR) in thermocyclers are not captured by the provisions for SNA. This definition would also future proof the definition and provisions by ensuring that non-naturally occurring nucleic acid analogues would be included.

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			(iii) molecules containing non-naturally occurring nucleic acid analogues		*This issue is discussed further in Chapter 3.13.*
84		7	That references to 'synthetic nucleic acids' be clarified, as reference to 'benchtop nucleic acid synthesis' could be interpreted to include PCR machines which should not be (and could not be) regulated in the manner proposed.	Individual	**Refer to Item 74 (amendment to definition of SNA).** The recommended changes would ensure that nucleic acids amplified through PCR in thermocyclers are not captured by the provisions for SNA.
85		7	References to 'synthetic nucleic acids' should be shifted away from primary legislation and regulated at the level of secondary legislation, which would also help future-proof the legislation against inevitable improvements in gene synthesis technology.	Individual	**No change proposed.** The specific requirements for SNA providers and manufacturers will be set under secondary legislation. *This issue is discussed further in Chapter 3.13.*
86		7	Recommended SNA be in secondary legislation not primary. As it is currently drafted, 'benchtop nucleic acid synthesis equipment' could be interpreted to include polymerase chain reaction (PCR) machines which should not be (and could not be) regulated in the manner proposed. Suggest using the term 'de novo synthesis of nucleic acids'.	Individuals, Otago University, and Researcher	**Refer to Item 74 (amendment to definition of SNA).** The recommended changes will avoid capturing PCR thermocyclers. Clause 157 provides that requirements on SNA providers and manufacturers of benchtop nucleic acid synthesis equipment will be set in secondary legislation. *This issue is discussed further in Chapter 3.13*
87		7	Suggest removing the clauses around DNA synthesis, as these are not genetic modification technologies, and DNA sequences can be assembled in many different ways, meaning this wording is both ineffective, and may severely inhibit the use of gene technologies.	Research institutes	**No change proposed.** SNAs are an integral component of genetic modification technologies. This definition is for SNA as an input into gene technology and not an outcome of gene technology. These provisions will not place requirements on the import of SNAs into New Zealand and will not place requirements on researchers in New Zealand.

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					Once implemented under secondary legislation, these provisions will place requirements on New Zealand-based commercial providers of synthetic nucleic and New Zealand-based manufacturers of nucleic acid synthesis equipment. *This issue is discussed further in Chapter 3.13*
88		7	Suggest that the proposed regulations for SNAs in the Bill are unrealistic and could be detrimental to research. The submitter noted concerns that the current definition of "provider" and "third party" is overly broad and could be interpreted to include researchers who share nucleic acids with other researchers, where the "reward" is the mutual benefit derived from publication. Applying this interpretation would create unnecessary obstacles to collaborative research and the sharing of valuable resources within the scientific community. They recommend that the definitions of "provider" and "third party" should be revised to specifically target commercial distributors of SNAs, excluding researchers who share materials for non-commercial collaborative purposes. This clarification will prevent unintended restrictions on academic collaboration and ensure that the regulations focus on commercial entities involved in the distribution of SNAs.	Research institute	**No change proposed.** The definitions of “Provider” and “Third party” are not intended to include individuals or groups that *non-commercially* share nucleic acids with other individuals or groups, such as researchers that share nucleic acids with other researchers.
89	20	8	In clause 8(a)(iv) “clinical trials” should be limited to humans and (a)(iv) should refer also to “testing of veterinary medicines on animals”. Clause 8(a)(iii) should also be deleted and reference to medical devices should be moved to 8(b). This is because medical devices may contain	MBIE	**Amend clause 8** definition of medical activity: • at 8(a)(iv) to enable the undertaking of clinical trials on humans or testing of veterinary medicines on animals.

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			material for a therapeutic purpose that includes a gene technology or regulated organism. For clarity, clause 8(a)(ii) should refer to veterinary medicine not veterinary purpose.		• to delete clause 8(a)(iii) and add 'medical device' in (b) to read 'includes the administration of medicines, medical devices or veterinary medicines using a gene technology or regulated organism'. • at clause 8(a)(ii) to read 'to an animal for a therapeutic purpose or as a veterinary medicine'.

Part 2: Regulation of gene technology

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90		11	A range of primary sector submitters recommended that market access and trade be added as a third relevant risk in clause 11: Relevant risks, in relation to an activity, means any risks posed by the activity to – - the health and safety of people; or - the environment; or - market access and trade.	Dairy, Apiary	**No change proposed.** The Bill is modelled on the Australian regime, which does not consider trade and market access risks in the Regulator's decision making. *This issue is discussed further in Chapter 3.1.*
91		11	Proposes amended definition of "relevant risks": Relevant risks, in relation to an activity, means any risks posed by the activity to— (a) protect the health and safety of people; or (b) protect the environment (c) provide for primary industry (d) provide for regulated market access and trade	Horticulture	**No change proposed.** This is a definition of the risks that the Regulator must identify and consider. It does not follow to include 'protecting' or 'providing for', as risk is a combination of the likelihood and the severity of an activity with a gene technology or regulated organism to cause harm. The Regulator will examine whether there is a real probability that an activity with a regulated organisms will actually cause harm and seek to manage those risks rather than ban regulated organisms that have an intrinsic ability to cause harm.
92		11	That thresholds for risk tiers need to be defined in primary legislation with reference to specific types of activities as secondary legislation is unlikely to be subject to the same scrutiny as primary legislation.	Apiary	**No change proposed.** The Bill describes the risk tiers for authorisations at the relevant risk. clauses (i.e. clause 163(2)(b) *minimal level of risk* for exemptions; 47 for *very low risk* non-notifiable activities, 48 for *low-risk* notifiable activities; 23 that risks are *no more than medium* for pre-assessed licence activities; 26 for licenced

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					activities requiring public consultation where relevant risks are *high or uncertain)*. The Bill enables criteria to be set for these risk tiers (at clauses 158, 159 and 161). The policy intent is that terms such as very low risk will be defined in secondary legislation following a public consultation process, to provide for flexibility and future proofing in the regime. *This issue is discussed further in Chapter 3.4.*
Subpart 1 - Determinations					
93	21	12	Clause 12(1)(b) and (c) refer only to "technique" but not "technology". This should be changed to "technology" to be consistent with the definition of "gene technology" which already includes gene-editing techniques because those techniques are technologies that are used to modify or construct genes or genetic material.	MBIE	**Amend** clause 12(1) to replace 'technique' with 'technology' to ensure consistency with the definition of gene technology.
94	22	12	Clause 12(4) creates ambiguity as to when there is a right of review. The policy intent is that there is a right of review when the Regulator has made a determination under clause 12(1) in response to an application by someone. The right of review is only relevant for determinations made arising from applications; if the Regulator has made the determination on its own initiative, the Regulator itself does not need a right of review. Note that if someone directly affected by the determination (other than the applicant) wishes to appeal the determination decision, the policy intent is that they are able to under the Bill's appeals provisions.	MBIE	**Amend clause 12** to: • clarify the right of review relates to when the Regulator has made a determination under 12(1), in response to an application by a person, and • outline the process leading up to and if the Regulator decides not to make a determination, when a person has applied for one (i.e. the Regulator would request more information prior to making a decision not to make a determination, and when the decision is made, notifying the person in writing with reasons).

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			There is no policy intent to provide a right of review if the Regulator has *decided not to make a determination*. For example, the Regulator may receive an application to make a determination, but feel they do have enough information to make such a determination. The outcome in this situation is not a determination of whether something is or something isn't an organism/gene technology; instead, it is a decision not to make a determination. In this situation, the policy intent is only that the Bill require the Regulator to notify the person of the reasons for its decision not to make a determination.		
95		12	That TAC advice to be sought when Regulator is determining what constitutes a regulated organism or gene technology.	Research institute	**No change proposed.** Clause 12(3)(c) provides for this.
96		12	Clarify provisions relating to licensed, regulated and unregulated organisms in order to address trade and market access risks.	Dairy	**No change proposed.** *Refer to Item 90.*
97		12	The submitter supports the differentiation of the risk profile, but notes concerns there are potential risks to primary production and trade from a lack of certainty about which exempt organisms may be present in New Zealand in the future. The submitter seeks a process of registration to manage this risk. Propose amendment (in italics) to clause 12 Regulator may determine what constitutes regulated organism or gene technology (1) The Regulator may, on its own initiative or on application by any person, determine whether or not — (a) any organism is a regulated organism; or (b) any technique is a gene technology; or (c) any	Horticulture	**No change proposed.** Officials consider that a register of exempt organisms has merit and could be considered further.

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			organism or technique falls within an exemption made by section 163(4), *and is defined as a registered exempt organism or technique or technology.*		
98	23	12	That a mechanism allowing for review of previous determinations and any controls imposed must be accessible via the gene technology regulatory process.	Sector group	**Amend clause 12** to enable previous statutory determinations to be amended and revoked. Officials support this amendment which would be consistent with section 26(6) of the HSNO Act.
99		12	Recommend the Regulator's power under clause 12(1)(c) be amended to reflect the explanatory note: (1) The Regulator may, on its own initiative or on application by any person, determine whether or not— (a) any organism is a regulated organism; or (b) any technique is a gene technology; or (c) any organism or technique *is exempt from the operation of the Bill*. Note that if this amendment is not made and the Regulations are the only way for new exemptions to be obtained, it is even more vital that they are brought into force as soon as possible.	Agritech	**No change proposed.** As correctly noted, the regulations are the only way for new exemptions to be made and not via clause 12. Clause 12 enables the Regulator or any person to seek clarification (a determination) on the status of any organism, gene technology, or promulgated exemption.
100		12	Note that in the situation a Person needs clarity, that Person should be able to call on the Regulator to make such a determination of whether something is *non-notifiable or notifiable*. The following amendments are suggested: (1) The Regulator	Biotech organisation	**No change proposed.** The policy intent is that substantive detail will be available in guidance materials on the website. The Regulator will publish lists of non-notifiable and notifiable activities to enable people to readily identify

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			may, on its own initiative or on application by any person, determine whether or not— (a) any organism is a regulated organism; or (b) any technique is a gene technology; or (c) any organism or technique falls within an exemption made by section 163(4); or (d) any organism is a non-notified organism; or (e) any organism is a notified organism.		whether an activity with a regulated organism is notifiable or non-notifiable, without requiring a formal determination. If further clarification is required, this can be sought informally from the Regulator.
Subpart 2 – General provisions					
101		13	Suggest this provision should be amended to extend to also prohibit any persons from assisting or facilitating in activities in relation to regulated organisms except where subsections (a)-(e) apply.	Individual	**No change proposed.** Extending liability to someone assisting or facilitating activities with regulated organisms without authorisation may risk too broad a prohibition, with it potentially extending to actions such as providing someone with lab equipment, renting them facility space, or other standard actions. This may have a chilling effect on the sector and would contravene the enabling purpose of the Bill.
102		13	Propose that (b) should read “the activity is notifiable and the Regulator has been notified;.”	Researcher and Research institute	**No change proposed.** Notifying the Regulator is a condition of all declarations of a notifiable activity so if a person does not notify the Regulator they will breach clause 14(b).

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103		13	That the Bill should ban the following uses: - Biological warfare - Human augmentation - Gain of function research (making pathogens more virulent) - Gene drive research - Synthetic Biology - De-extinction - GE plants containing pharmaceutical genes	E-NGO	**No change proposed**. The Bill's purpose is to enable the safe use of gene technologies and regulated organisms by managing their risks to the health and safety of people and the environment. Some of the activities suggested, such as biological warfare, are already illegal. Where a use case is not specifically prohibited, the gene technology or regulated organism will be managed through the Bill's purpose.
104		13	Some submitters asked why 'exempt activities' are not included under clause 13, and proposed that clause 13 include exempt activities (i.e. activities involving exempt organisms).	Researcher, Horticulture	**No change proposed**. Clause 13 relates to the authorisation of activities with *regulated* organisms. Exempt organisms, which are not regulated organisms, would not require prior authorisation under the Act and therefore the addition of 'exempt activities' under clause 13 would be incorrect.
Conditions					
105	24	15	Clause 15 should refer to "location" as well as "geographic area" to enable the Regulator to restrict an activity to a certain location (e.g. a laboratory).	MBIE	**Amend clause 15** so the Regulator can impose conditions relating to the location a regulated activity may occur.
106	25	15	The policy intent of clause 15(f) 'data and sample collection, including details of the studies to be conducted', is to enable the Regulator to impose conditions on the authorised user to verify the genetic changes of a regulated organism at the	MBIE	**Amend clause 15** so that the Regulator may also impose conditions requiring that data and samples be verified.

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			culmination of the study. This is unclear from current drafting.		
107		15	Noted that part (m) which requires insurance against any loss is potentially extremely punitive and likely to make commercialisation of regulated organisms highly risky.	Researcher, Legal	**No change proposed.** The application of conditions outlined in this clause are at the discretion of the Regulator and the list is indicative only.
108		15	Proposed a mandatory condition requiring insurance to remedy harms occurring from licenced activities. Recommended clause 15(m) be amended to read: - (m) insurance against any loss, damage, or injury that may be caused by the activity to human health or cultural wellbeing; physical or cultural property; or the environment; and for any fines any fines related to Subpart 3 – Offences, Clause 76. Suggested a new subclause (o) be added, as follows: - (o) upon exiting the licence, sufficient insurance to cover the complete remediation of the site/s used for activities, unless otherwise stipulated.	Individual	**No change proposed** as clause 15(m) sufficiently addresses the submitter's concerns. Clause 15(m) does not extend to cultural wellbeing. However, clause 15(m) is not time limited and may consider remediation at a future date.
109		15	Recommend that all GMOs and gene technology regardless of their classification under the Bill should be required to comply with certain traceability obligations (conditions). Similar provision to sections 25 and 26 of the Organic Products and Production Act 2023 should be inserted into the Bill. The Bill should require persons using or releasing GMOs and gene	Organics, Dairy, Sector group, Agriculture (not Dairy)	**No change proposed**. Traceability requirements could be set through conditions imposed by the Regulator (noting that the conditions the Regulator can impose on

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			technology to have in place procedures for tracing and recalling them and any products made from them. It should also require those persons using or releasing GMOs and gene technology to keep specified records, have in place contingency plans for accidental releases, to make those records and plans available to the Regulator upon request and to provide any reasonable assistance requested by the Regulator. These provisions should apply to all persons using or releasing GMOs or gene technology in New Zealand regardless of whether they are exempt, non-notifiable, notifiable or licensed activities.		authorisations in clause 15 regarding record keeping, auditing, reporting and contingency planning). *This issue is discussed further in Chapter 3.1.*
110		15	Propose the following condition is added to clause 15: companies to prove financial fitness to pay for compliance/fines as condition of approval	Individual	**No change proposed.** The Regulator will consider this in principle when assessing if a person is fit and proper to hold a licence under clause 35.
111		15	Propose the following condition is added to clause 15: Require buffer zones to prevent unintended release of GMOs into wider environment.	Individuals, Organics	**No change proposed**. Clause 15 provides a non-exhaustive list of conditions, and the Regulator would already be able to impose this condition.
112		15	Propose the following condition is added to clause 15: Require long term monitoring and post-release evaluations for all approved enviro releases	Individual	**No change proposed**. The Regulator can impose conditions on authorisations for monitoring and reporting under clause 15.

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113		15	Propose adding a 'checking' mechanism into any new policy on gene technology. This should include removing permission to use this technology if there are any breaches of conditions. Compliance costs should be fully recovered from applicants.	Research institute	**No change proposed**. Clause 39 allows the Regulator to suspend or cancel an authorisation if conditions have been breached. Breaching a condition is an offence and comes with penalties.
114		15	Recommend mandatory GE Crop Mapping as a condition: Farmers planting GE crops must register their locations to help prevent cross-pollination.	Organics	**No change proposed.** The Regulator can impose conditions relating to geographic area. *Refer to Item 105.*
115	26	15	Support powers to impose conditions, especially in the case of release of a regulated organism from containment (15(h)). However, such conditions should only be imposed if they are needed to mitigate risk to human health and safety, or risk to the environment as per the purpose of the Act. Suggest rewording to "…includes a power to impose conditions in order to manage risks relating to- (a)…".	Researcher, Biotech organisation	**Amend** the Bill at relevant places to make clear that conditions are imposed to manage risks pursuant to the purpose of the Bill (i.e. risks to the environment and to the health and safety of people). This change will include amendments to other clauses, including 23, 33, 37, 47, 48, 50, and 55.
Subpart 3 - Licences					
116		19	Propose adding a condition that an applicant for outdoor use of GMOs must accept strict liability for any loss or damage caused.	E-NGO	**No change proposed**. *This issue is discussed in Chapters 3.7 and 3.8.*
117		19	Propose that sponsorship of an application under this legislation by agents of another country's government/military should be part of the declarations made upon application, and be either illegal or require approval of the relevant Minister(s).	Individual	**No change proposed**. Clause 35 requires the Regulator to assess whether a person is fit and proper to hold a licence. One of the reform's objectives is to attract foreign investment into New Zealand. We consider that other

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					regimes or powers are more appropriate to manage any future potential national security concerns arising.
118		19	Recommend a provision to ensure that a pre-application consultation be available to guide and assist the applicant in understanding the critical information required for an informed decision by the Regulator.	Biotech organisation	**No change proposed**. This is an operational matter for which the Regulator will determine the need and consider developing guidance materials to assist potential applicants.
119		19	Noted that the HSNO Act allows for institution-level approvals. The University of Auckland holds all the HSNO approvals used by its researchers. In the current wording of the Bill, only individuals can apply for a licence and the responsibilities outlined in Sections 35 and 43 are for specific individuals. It would be a significant change for our researchers if they were held individually liable, and this would also have significant legal implications for the University of Auckland. Consideration should be made as to the impact of changing the legal responsibility for GMO work in New Zealand. It should be noted that most research institutions in New Zealand oversee individual staff members' GMO work through institutional safety committees and are well-positioned to hold approvals that allow staff members to undertake GMO work.	University	**No change proposed.** Whereas with the HSNO Act, the Bill uses the term 'a person' which includes both legal and natural persons (e.g. individuals, organisations, institutions). We expect the university to be the applicant and licence holder and staff be authorised under the licence to carry out activities.
120	27	19	Noted that clarification is needed on how the licencing authorisation would work in practice, i.e. who would hold the licence and would background checks be required of employees?	Biotech organisation, Agriculture	**Amend** the Bill to make clear that, where a body corporate is the applicant for a licence, the Regulator will assess fitness of the officers of a body corporate as well where appropriate. Clause 35 provides for determining whether a person is fit and proper to hold a licence. This includes body

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					corporates and officers. We note that section 52(3) of the Outer Space and High-Altitude Activities Act 2017 provides a model for PCO consideration. It is expected that the Regulator will provide guidance materials on how the licensing system will operate in practice.
Joint applications					
121		20	Proposed that joint approvals should be included for Medsafe, MPI (veterinary medicines), and FSANZ.	Researcher	**No change proposed.** Officials explored options to achieve this and provided advice to Government that it would in practice be ineffective for the Act to enable the Regulator to process and assess joint applications with either Medsafe or MPI (as ACVM Regulator), as the risks considered by those regulatory regimes do not sufficiently overlap for there to be efficiencies in assessment. Further, joint approval (even between the Gene Technology Regulator and the EPA as Regulator of new organisms) are not possible as each Regulator must issue a decision under its own regime to be valid (including for review and appeal purposes). Information sharing under the Bill enables opportunities for operational efficiencies.
122		20	A number of submitters support joint assessments between domestic agencies to improve efficiencies. Regulatory duplication serves as a significant barrier to an efficient and cost-effective regulatory framework. Section 20 permits joint applications to the Gene Technology Regulator, for applications	Sector groups, Biotech organisation, Seeds	**No change proposed.** *Refer to Item 121.*

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			under this proposed Act, and the EPA, for applications under the HSNO Act. This acknowledgement should be extended to other potential regulatory intersections ensuring that assessments are not duplicated and undertaken by the most appropriate agency.		
123		20	Recommend that the secondary legislation provide clear guidance on permitted activities to ensure clarity and establish predictable timelines for application processing to prevent delays. The framework should be adequately resourced to ensure it delivers genuine efficiency improvements, rather than replicating existing delays.	Research institute	**No change proposed**. The Bill has a regulation making power to set timetables for the Regulator to process, consult and decide on matters under the Bill (clause 160). While the Bill provides a regulation making power in respect of joint applications between the EPA and the Regulator, no regulations are planned at this time. The Regulator and the EPA as regulator of new organisms will work together to outline clear guidance and maximise efficiencies.
Certain licence applications must contain additional information about kaitiaki relationships					
124		21	Recommend the Bill require that any application for the release of a GMO into the environment be subjected to a rigorous assessment of its potential impact on New Zealand's indigenous biota and ecosystems, and its potential to create risks overseas.	PCE	**No change proposed.** Officials consider these aspects are already covered by the Bill – see risk assessment provisions in Part 2 subpart 3, the Cartagena Protocol in clause 5, the Treaty of Waitangi clause 4, and the MAC role in Part 4 subpart 4.
125		21	An additional clause was recommended by Iwi/hapū: 21A. Additional requirements for applications affecting Māori cultural and environmental values (1) This section applies to any licence application	Iwi/hapū	**No change proposed.** Government has agreed that for this Bill, Māori rights and interests would be provided for by providing for the Regulator to consider in its decisions, through advice from the MAC, kaitiaki relationships with non-indigenous species of significance explicitly listed in

			made under section 21 where the proposed activity may have an impact on— (a) the cultural values, tikanga, or mātauranga Māori associated with taonga species or ecosystems; or (b) indigenous biodiversity, biosecurity, water quality, or ecosystem health in a manner that may affect the relationship of Māori with the environment. (2) An application to which this section applies must include— (a) a Cultural Impact Assessment, prepared in consultation with relevant Iwi and hapū, that assesses the potential effects of the proposed activity on taonga species, the whakapapa and mauri of affected ecosystems, and Māori customary rights and interests; and (b) an Environmental and Biosecurity Risk Assessment, which must— (i) assess the risks of gene flow, cross-contamination, and unintended ecological effects; and (ii) evaluate the long-term impact on indigenous species, biodiversity, and ecosystem resilience; and (c) where the proposed activity involves potential impacts on freshwater or marine environments, a Water Quality and Ecosystem Health Assessment, identifying any risks to culturally significant waterways and aquatic species. (3) The Regulator must refer any application to which this section applies to the Māori Advisory Committee for review. (4) In considering an application under this section, the Regulator must—		regulations. Government has further agreed that the regime take a risk-proportionate approach. The proposals outlined in this recommendation go beyond the agreed decision making scope of the Regulator which is to assess the risks to the environment and the health and safety of people associated with the gene technology and determine whether those risks can be managed. The proposal would significantly expand the role of the Regulator and/or the MAC. *This issue is discussed further in Chapter 3.3.*

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			(a) have particular regard to the recommendations of the Māori Advisory Committee; and (b) provide a written statement outlining how those recommendations have been considered in the decision-making process; and (c) if a recommendation is not adopted, provide reasons for the decision. (5) The Regulator must apply the precautionary principle when considering applications under this section, ensuring that genetically modified organisms are not approved where there is scientific uncertainty regarding risks to cultural, environmental, or biosecurity values. (6) The exercise of functions and powers under this section must be consistent with the principles of Te Tiriti o Waitangi (the Treaty of Waitangi)		
126		21	Noted that the Regulator must be required to protect indigenous flora and fauna.	E-NGO	**No change proposed.** The Government has agreed to focus on indigenous species for this Bill. *Refer to Items 17, 19, 20, 21, 65, 70, 299, 300, and 337.* *This issue is discussed further in Chapter 3.3.*
127		21	Noted that Kaitiakitanga responsibilities are usually distributed /shared within or between whānau, hapū, different rohe, and Iwi. There will rarely, if ever, be one kaitiaki (as in a single person) with the authority to provide a sign-off for a licence or activity.	Iwi/hapū	**No change proposed.** The role of the MAC is set out in Part 4, subpart 4. *This issue is discussed further in Chapter 3.3.*

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
128		21	Recommend that this section also includes the use of DNA sequences encoding unique traits of an indigenous species	Research institute	**No change proposed.** Government agreed only to host organism**.** The suggested change would significantly expand the scope of potential changes.
129		21	Recommend that clause 21(1)(b)(i) states that pre-assessed activities do have to provide additional information on kaitiaki relationships and the MAC engaged for advice.	Researcher	**No change proposed.** The assessment of adverse effects to kaitiaki relationships will already have taken place prior to the Regulator declaring an activity (in relation to a particular organism or category of organism) as pre-assessed. Clause 126 sets out where the Regulator must refer matters to the MAC. This includes declarations for pre-assessed activities.
130		21	Recommend that clause 21 should include a subclause requiring applications to be declined if no acceptable solution is found.	E-NGO	**No change proposed.** The Bill already provides for the assessment of risks and proposed mitigations process to take place when the Regulator refers the application to the MAC. Clause 131 requires reporting by the MAC and the requirements for when it must advise the Regulator not to proceed with the application or proposal.
131		New	Before an application can be processed, the Regulator should identify whether the application is complete and, if not, return the application with requests for further information. If the applicant fails to respond after a time frame defined in regulations, the Regulator can withdraw the application. This is consistent with other legislation such as the RMA and enables applications to be processed efficiently.	MBIE	**Insert** a new clause to require the Regulator to identify whether the application is complete and, if not, return the application to the applicant. The Regulator should be able to withdraw the incomplete application if the applicant fails to respond with the information requested within a timeframe set in regulations. This will support operational processing and certainty for applicants.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
Regulator may declare pre-assessed activities for purposes of licence applications					
132		23	Noted that declaration that an activity is of no more than medium is unacceptable when there could be a small (or larger) probability of a very harmful and irreversible consequence for the environment.	E-NGO, Individual	**No change proposed.** The Regulator can impose conditions to manage those risks.
133		23	Propose subsection 23(1)(b) ought to be amended to include a requirement that the Regulator also have regard to the availability of alternative technological solutions that may achieve the same goal as the intended activity without requiring the use of genetically modified material and/or that carries lower risks than the activity to which the application applies.	Individual	**No change proposed**. The suggestion to consider other technological solutions goes beyond the intended role of the Regulator which is to assess the risks associated with the gene technology and determine whether those risks can be managed. The proposal would significantly expand the role of the Regulator.
134	28	23	The Regulator may need to specify who can carry out a pre-assessed activity when making a declaration.	MBIE	**Amend clause 23** as necessary to add the ability limit the declared activity to a specified person or class of persons in relation to pre-assessed activities.
Risk assessment and risk management plans					
135		25	That assessment of risks should remain objective and the Regulator not be asked to consider customer or consider consumer preference in its risk assessment.	Sector group, Agritech, Organics	**No change proposed**. The Regulator is expected to objectively assess risks and is not expected to consider customer or consumer preference in its risk assessment.
136	29	25	It is not clear what the Regulator should do once it has received a request to reconsider its proposal. Clause 25 requires a subclause (3) that sets out what the Regulator should do once it has received a request to reconsider its proposal.	MBIE	**Amend clause 25** to require the Regulator to consider any reply from the applicant arising from clause 25(2), but that this does not affect the Regulator's ability to prepare a Risk Assessment and Risk Management Plan (RARMP).
137		26	Suggest adding the following to section 26: "(3) The Regulator must prepare a net economic benefit	E-NGO	**No change proposed**.

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			assessment for any applications concerning outdoor use of GMOs, in accordance with any timetable prescribed by the regulations.".		The policy intent is that the Regulator's assessment is limited to assessing the risks to the environment and the health and safety of people as referred to in the purpose - economic benefit assessment would go beyond this.
138			Suggest economic and social impact assessments and reports are required on all applications on a case by case basis and made publicly available.	E-NGO	**No change proposed**. In line with the purpose of the Bill, the Regulator's assessment is limited to assessing the risks to the environment and the health and safety of people as referred to in the purpose – economic and or social impact assessment would go beyond this.
139			To be 'risk-proportionate' the Regulator must have the powers to assess the risk, which is a function of both hazard and exposure.	Other	**No change proposed.** This is addressed in the Bill under the Regulator's role for risk assessment.
140		Part 2, Subpart 3	Noted that there appears to be no provision for the issuing of a licence for an inadvertent activity with a regulated organism as provided for in the Australian Act. Persons finding themselves in this situation could be open to criminal prosecution and must rely on the defences set out in section 84. This would mean that a researcher would have to incriminate themselves in order to make the activity legitimate and that the Regulator has no discretion to allow the activity to continue while a licence is being sought even if it is deemed negligible risk by the Regulator at the time. The submitter seeks that a clause be added to enable the licencing of inadvertent activities.	Biotech organisation	**No change proposed.** The Bill provides for offences for *knowingly* or *recklessly* undertaking an activity with a regulated organism without authorisation (clause 76), there is also a strict liability offence (clause 76(3)) for this offence. However, the Bill also provides for several defences to this offence. The defence "circumstances outside the defendant's control" at clause 84(2)(a)-(b) provides for a defence in the case of inadvertent activity.
141			Suggest that risk levels and criteria are defined so these can be consistently applied. Propose that the Bill envisage separate regulatory procedures for applications of genome-engineering	Agriculture, Seeds, Researcher, Biotech organisation	**No change proposed**. The Bill sets out the risk levels and the regulations will specify the criteria.

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			biotechnologies in different areas – medical, agricultural and food, forestry, environmental and biodiversity applications and so on. The risks, scientific uncertainties and public acceptability differ significantly across application types.		Operationally the Regulator will develop and publish a Risk Analysis Framework, specifying the procedures to be undertaken when assessing risk and outline the conditions that could be imposed to manage risks for each of the categories and tiers.
142		26	Noted it is unclear why this section (which requires that the Regulator prepare a RARMP) expressly does not apply where an applicant has self-declared that the activity is a low-risk medical activity as part of their licence application, by virtue of subsection (1)(a)(iii).	Individual	**No change proposed**. While the applicant can self-declare, ultimately to Regulator must be satisfied of the criteria in the risk assessments at clauses 47(1)(a) and (b) and 48(1)(a) and (b).
143		27	Clarify when the Regulator should seek advice from the Technical Advisory Committee (TAC) in clause 27 - it is unnecessary, and contrary to official advice, for the Regulator to seek advice from the TAC prior to developing a draft RARMP. The Australian experience is that its TAC had "not identified any additional risks that the OGTR themselves weren't aware of at the application stage.". Suggest amending clause 27: 27(2) The Regulator must seek advice from the Technical Advisory Committee on matters relevant to the preparation of the risk assessment and the risk management plan in accordance with any timetable prescribed by regulations. 27(3) In seeking advice pursuant to section 27 (2), the Regulator must provide the Technical Advisory Committee with,— (a) if applicable, the licence application in respect of which the risk assessment and the risk management plan are being prepared; and	Biotech organisation	**No change proposed.** The Regulator may seek advice from its TAC at any time, however the Regulator *must* seek advice from the TAC when preparing its draft RARMP. The draft RARMP is publicly consulted on. The policy intent is that there are not multiple versions of draft RARMPs, and the Bill refers to draft RARMP for the purpose of seeking submissions on whether all relevant risks have been identified, assessed and managed.

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			(b) drafts of the risk assessment and the risk management plan		
144		27	The submitter considered it is not clear that the advice from the MAC is to be incorporated into the RARMP before public consultation, and that it should be made clear that the advice be incorporated before public consultation.	Biotech organisation	**No change proposed.** The definitions of RARMP in clause 11 include assessment of adverse effects on kaitiaki relationships and mitigating those. Therefore, the RARMP must include the MAC advice when read with clause 126.
145		28	Recommend that Clause 28(2)(b) should be removed from the Bill. Some submitters do not agree the Regulator should be able to decide that public consultation is not required in respect of certain activities approved by overseas authorities. All decisions affecting New Zealand communities should be made by New Zealanders and this is seen as a loss of autonomy and freedom to decide what is appropriate for Aotearoa New Zealand.	PCE, Organics, E-NGO, Agriculture, Individuals, Dairy (see next row)	**No change proposed**. This policy intent is to enable risk proportionate and efficient decision making where there is readily available information on the risks of the activity and where risk management has been demonstrated to be effective. If the Regulator considers they require further information in the New Zealand context, they can choose to consult. The Regulator must have regard to advice from the TAC (clause 27). Clause 126 sets out the role of the MAC in relation to risk assessments and risk management plans. *This issue is discussed further in Chapter 3.4.*
146		28	The submitter supports the Regulator's ability to recognise risk assessments conducted in other jurisdictions; as this will help streamline the application and decision-making process, but considers, these overseas assessments may need to be supplemented with additional assessments to ensure these are fit for purpose here. For example, the Bill currently allows the Regulator to withhold draft risk assessments and risk management plans from public consultation if a recognised overseas authority has already	Dairy	**No change proposed**. *Refer to Item 145.*

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			authorised the activity and provided the relevant information to the Regulator (clause 28(2)(b)). However, by not seeking input on draft risk documents, critical New Zealand-specific context could be excluded in identifying, assessing and managing risks posed by gene technologies and organisms.		
147		28	That section 28 (5)(d) be deleted. The purpose of public notification should be to allow the public an unbiased input into the risk assessment. This clause biases the opinion of the public unnecessarily.	Researcher	**No change proposed** as public notification of the draft RARMP is essential in increasing public awareness of high or uncertain risk activities and seeking their input. The policy intent for public consultation for the draft RARMP is to ensure the Regulator is aware of any and all significant new information in relation to the relevant risks and how the Regulator proposes to manage those risks so it can finalise the RARMP. For the purposes of making a decision under clause 33, the Regulator must have regard to the finalised RARMP.
148		28	Some submitters considered the Regulator be given more leniency here in the need to engage and should only do so if sufficient public interest - consultation should be based on whether there is a reasonable public interest, based on similar wording as found in section 95B of the RMA. It was suggested that clause 28 be amended as follows: 28 Public consultation on draft risk assessment and draft risk management plan (2) The Regulator must release drafts of the risk assessment and the risk management plan for public consultation, or for limited consultation with affected parties if the Regulator considers this to be	Agritech, Researcher, Biotech organisation	**No change proposed**. *Refer to Item 147.*

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			justified, in accordance with any timetable prescribed by regulations, unless— (a) both of the following conditions are met: … (d) The Regulator considers that public interest does not warrant consultation.		
149		28	That hearings be provided for public consultation on draft RARMPs (not just written submissions).	E-NGO, Agriculture	**No change proposed.** To enable an efficient and cost-effective system, the policy settings follow the Australian regime enabling written submissions for public consultation processes.
150		28	That consideration is given to either to lengthening this period, or to a mechanism by which an extension to the 30-day period can be granted. The submitter suggested that the limitation of 30 days for the applicant to provide further information to the Regulator as part of a license application assessment may be insufficient for applicants that are the local representatives of global companies, noting there is a high likelihood that in the case of gene technology products developed by international companies the local affiliates will need to refer to their global counterparts to obtain any further information necessary in support of their application. The submitter noted that due to the size of the NZ market and the fact that the Regulator assessment will not be the only assessment required before the product can be marketed in New Zealand, and that that other markets may get prioritised in a global company.	Other	**No change proposed**. Officials consider that 30 days is reasonable. In the situation described by the submitter, public consultation would be anticipated by the applicant pursuant to clause 25 that the Regulator must notify applicant if proposing to prepare a RARMP. Thereby further time for the consultation period is not required.
151			Engagement with Recognised Overseas Authority (particularly in regard to declaring pre- assessed activities) has a better description of the standards	Seeds	**No change proposed**. Clause 153(3) allows the gene technology Regulator to set criteria for information sharing with an overseas

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			required to control the information to be shared. Levels and requirements of confidentiality need to be better described, so at the very least these contain conditions which are no less onerous than those imposed on the Regulator with respect to the confidential information provided.		regulator. The criteria could include that the overseas regulator protect personal information to the same extent as the Privacy Act 2020 (Privacy Act) and that it treats confidential information in the same way as the Bill. The Regulator could publish an operational policy or similar about this to signal to industry what protections are being included in agreements with overseas regulators. So, although we recognise the issue raised by the submitter, we consider this can be managed operationally by utilising clause 153(3).
New or amended risk assessment and risk management plan					
152	30	30	This clause only applies if the Regulator becomes aware of significant new information. However, the key trigger for requiring the Regulator to prepare a new risk assessment or risk management plan is that the Regulator considers the current one to no longer be materially accurate (regardless of whether they become aware of significant new information or otherwise).	MBIE	**Amend clause 30** to implement the policy intent that the Regulator must prepare a new or amended risk assessment or risk management plan if they consider the current one is no longer materially accurate.
153		31	That the notice being in effect in clause 31(2)(c)(ii) for one year is far too long and this should be 30-50 days at most. If 30 days is sufficient for a brand-new risk assessment then amending a risk assessment should not take longer.	Researcher	**No change proposed**. Clause 31(2)(c) provides that the temporary restriction remains in force until the earlier of certain requirements, with one year being the maximum requirement.
154	31	32	That the Regulator updates the licence holder and publishes on website corrected version of RARMP after amending to correct minor and technical changes.	MBIE	**Insert a clause** for the Regulator to provide an updated version of an RARMP to the licence holder and on the website, following minor and technical changes having been made.

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155		33	Suggest adding the following to clause 33(5): "(d) "The net economic benefit assessment conducted by the regulator for any outdoors activity is positive"	E-NGO	**No change proposed**. The policy intent is that the Regulator assesses risks to environment and health and safety of people. The proposal would significantly expand the Regulator's role.
156		33	Suggest adding to clause 33 (5): "(e) The activity is insured against any loss, damage, or injury that may be caused to human health, property, or the environment by the activity, and a performance bond is posted to cover the insurance excess.	E-NGO	**No change proposed**. Officials consider mandatory insurance not appropriate in all cases. The Regulator can impose conditions specified in clause 15 (in particular note clause 15(m) insurance against loss).
157		33	Clarification is sought as neither the legislation nor the Explanatory Note to the Bill provide clarity as to why some low-risk medical activities may require licences rather than being treated as notifiable activities.	Other	**No change proposed.** The low-risk medical activity licence allows applicants to seek a licence if their activity has the same risk profile as a non/notifiable activity but is not already declared as a non/notifiable activity. Obtaining this kind of licence is intended to be faster than either seeking a licence, or waiting for the Regulator to declare the activity. Officials anticipate the Regulator developing guidance to clarify the policy and process for low-risk medical activity licences, which does not require a change to the Bill.
158		34	That for clause 34(2) there should also be some obligation on the Regulator and/or the TAC to assist the applicant to address any deficiencies in the application.	Researcher	**No change proposed.** This is an operational matter for the Regulator to engage with the applicant at the application stage. The Regulator provides its decision to the applicant with reasons at clause 34(2)(a). *Refer to Items 131.*

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159	32	35	Add the Health and Safety at Work Act 2015 to the list of Acts and associated secondary legislation that the Regulator consider the relevant law for the fit and proper person test.	MBIE	**Amend clause 35(2)** to add the Health and Safety at Work Act 2015 as relevant law when the Regulator is determining if a person is fit and proper to hold a licence.
Licences are subject to conditions					
160		37	Licence conditions should include boundaries to prevent contamination would need to take the length of honeybee flight into account to avoid potential contamination of honey products.	Apiary	**No change proposed.** The Regulator must consider the relevant risk to the environment, undertake a risk assessment and provide for a risk management plan. The Regulator will impose licence conditions to manage the risks. *This issue is discussed further in Chapter 3.4.*
161		37	That subsection (3) is inappropriate and should be removed. The Regulator ought to retain the ability to place any additional conditions (beyond those identified in subsections (a) and (b)) which they consider reasonably necessary.	Individual	**No change proposed.** A pre-assessed activity must be no more than medium and meet the requirements for declaration. A RARMP will be prepared for declaration and conditions to manage risks of the activity applied at the declaration stage. The conditions in clause 37(3) are to enable the Regulator to monitor the licence holder's activities on a case-by-case basis, for example, to ensure a new entrant has the capability to manage the risks.
162		37	Clause 37 should empower the Regulator to deregulate licenced activities which have no conditions.	Biotech organisation, Researcher	**No change proposed**. The Bill provides several mechanisms to manage lower risk activities (e.g. declared activities under Part 2 subpart 4), as well as regulation making powers to exempt organisms and technologies from operation of the Act.
163	33	37	Under clause 37(1)(c) the licence holder must notify the Regulator if any circumstances in clauses 35(1)(a)-(c) or (e) apply (relating to whether a	MBIE	**Delete reference in clause 37(1)(c)** to the Regulator having been made aware, to clarify that the licence

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			person is fit and proper) "and the Regulator has not been made aware of them". This phrase should be removed to avoid creating uncertainty whether a person needs to notify the Regulator or not.		holder must notify the Regulator if the circumstances in clauses 35(1)(a)-(c) apply.
164	34	37	Clause 37(1)(f)(i) requires the licence holder to publish the conditions of a licence within one month of being issued the licence. This should be changed to 20 working days to be consistent with other time periods in the Bill.	MBIE	**Replace** "1 month" with "20 working days" **in clause 37(1)(f)(i)**, for consistency with similar provisions.
165		38	That this clause is amended to include expiry dates for licences that relate to environmental release, as the adverse consequences of environmental release will arise gradually and it is appropriate that the licence for environmental release be time limited and reviewed/renewed at regular intervals. This would ensure the licence for environmental release applications, and the associated risk assessments that the licence is based upon, remain current and accurate.	Individual	**No change proposed.** Clause 38(1)(b) provides that a licence can be in force for a particular period.
166	35	46	Clause 46(1) requires the Regulator to give the licence holder 30 working days to respond to a proposed variation. However, a variation may need to be made immediately if the Regulator considers it necessary or desirable to avoid imminent risk of death, or serious injury to people or serious damage to the environment. The Regulator should be able to make an immediate variation without notifying the licence holder of the proposal and giving them time to respond. This is consistent with clause 40 for suspensions and cancellations.	MBIE	**Amend clause 46** to insert a subclause similar to clause 40(2) so the Regulator does not need *to* notify the licence holder of the proposal and give them 30 working days to respond if the Regulator considers the variation is necessary or desirable in order to avoid imminent risk of death, or serious injury to people or serious damage to the environment.
Subpart 4 – Non-notifiable and notifiable activities					

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
167		47	That the Bill does not provide a specific, fulsome criterion as to what types of activities should constitute non-notifiable activities when making regulations, nor does it outline detailed processes for making declarations of non-notifiable activities under clause 47.	Dairy	**No change proposed.** Criteria will be provided in secondary legislation to provide future flexibility. Clause 49 provides the process for making a declaration.
168		47	Consider whether it is appropriate to limit non-notifiable activities associated with the agricultural sector to those conducted in containment, so that any environmental release associated with activities related to the agricultural sector have notification to the Regulator as a minimum requirement, enabling visibility for the sector that will help with market requirements associated with traceability.	Dairy	**No change proposed.** Officials consider this proposal has merit and could be considered further. *This issue is discussed further in Chapter 3.1*
169		47	Suggest the Bill clarify risk assessment regards biosafety / population risks, not risks to individual patients.	Research institute and Researcher	**No change proposed.** The purpose of the Bill is clear by using the term 'people' and not 'individual'. The Ministry of Health and Medsafe will undertake clinical assessments for patients. This is not the role of the Regulator. Clause 16 clarifies that authorisation of medical activities does not count as approval for other purposes.
170		49	Recommend clarifying in subclause 6 "is minor in effect".	Research institute and Researcher	**No change proposed.** The issue of the Regulator being able to make a variation if it is minor in effect or corrects a minor or technical error has been considered and approved by the Committee.
171	36	49	Clause 49(7) refers to clause 126 in relation to when the Regulator must seek advice from the MAC before making, varying or revoking a	MBIE	**Amend clause 49** to make clear the Regulator need not seek advice from the MAC under clause 126 if the proposed variation to a declaration is minor in effect

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			declaration. Clause 49 requires the Regulator to seek advice from the TAC in relation to proposals to make, vary and revoke declarations. However, the Regulator also need not seek advice if a variation is minor in effect or corrects a minor or technical error. The Regulator need not seek advice if the variation or revocation is necessary or desirable in order to avoid an imminent risk of death, serious illness, or serious injury to people or serious damage to the environment. These exceptions should also apply to when advice need not be sought from MAC.		or corrects a minor error; or the proposed variation or revocation of a declaration is necessary or desirable in order to avoid an imminent risk of death, serious illness, or serious injury to people or serious damage to the environment.
172	37	49	Insert a clause to state that failure to comply with requirement to consult does not affect validity of notices. This will prevent the entire notice from becoming invalid based on a technicality which could create uncertainty for people relying on the law.	MBIE	**Amend clause 49** to state that a failure to comply with requirements to consult does not affect the validity of Notices, similar to section 3B(6) Climate Change Response Act 2002. This is a standard drafting clause.
173	38	New	Consistent with section 65 of the HSNO Act (which provides for no compensation following reassessment), there should be no compensation payable where the Regulator makes a decision to cancel, suspend, revoke or vary a licence, declaration, or other authorisation under Part 2.	MBIE	**Insert new a clause in Part 2** to make it clear no compensation is payable where the Regulator cancels, suspends, revokes, or varies a licence, declaration or other authorisation under Part 2. This is consistent with section 65 of the HSNO Act.
Subpart 5 – Mandatory medical authorisations					
174	39	50	Recommend replacing the use of the term 'mandatory' throughout the bill as it will lead to misinterpretation.	Researcher, Individuals, Other	**Replace** 'mandatory medical authorisation' with alternative language such as 'recognised medical authorisation' in **Part 2 Subpart 5** (and other relevant parts of the Bill). *This issue is discussed further in Chapter 3.5.*

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
175		50	Mandatory medical authorisations are described as 'unethical', immoral, antidemocratic and should be removed.	Individuals, Other, E-NGO	**No change proposed**. The Bill does not mandate medical treatment. Officials continue to support the inclusion of this policy as part of the gene technology regulatory regime, as a means to achieve regulatory efficiency and international alignment, while retaining the ability to tailor the authorisation to the New Zealand context through imposing conditions. Clause 16 clarifies that authorisation of medical activities does not count as approval for other purposes. *This misunderstanding of the policy is discussed in Chapter 3.5.*
176	40	50	That any decision of the Regulator has to have the endorsement of the TAC. For example: Mandatory authorisations should not be the sole decision of the Regulator but also have the endorsement of the TAC.	Individual	**Amend clause 50** to be clear that the Regulator, in making its decision on any conditions to impose as per clause 50(4), may seek advice from TAC. Clause 115(a) already enables the Regulator to request advice from the TAC on any matters relating to what the Regulator does under the Act, and the use of gene technologies, regulated organisms, and management of their risks – so amending the clause just makes it explicit in relation to these types of authorisations. Officials consider it should be discretionary for the Regulator to seek advice from the TAC, rather than mandatory as the submitter suggested, as the Regulator may feel comfortable making a decision without TAC advice, and a mandatory requirement would undermine the policy intent of this provision as improving efficiency in process and decision making. Officials do not consider a comparable provision is required for advice from the MAC because

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					authorisation of a gene technology or regulated organism that is or contains a medicine authorised overseas is highly unlikely to involve the use of an indigenous species or non-indigenous species of significance as a host species, where there may exist a kaitiaki relationship, and because the Regulator will assess whether the authorisation would pose significant risks to the New Zealand environment, which would by extension include risks to indigenous species. *This issue is discussed further in Chapter 3.5.*
177	41	50	Add a requirement that the Regulator notify publicly on its website that it is beginning the process to grant a recognised medical authorisation (e.g. at point of becoming aware) – this will support transparency of the regime.	MBIE	**Amend clause 50** to require the Regulator to publicly notify on its website that it is beginning the process to grant an authorisation, to support transparency of the regime.
178		50	That New Zealand-specific testing, assessment and public consultation is necessary.	Agriculture, Individuals, Researchers	**No change proposed.** The policy is to enable a risk proportionate and efficient decision-making process where the risk management has already been demonstrated and information is available to the Regulator.
179		50	The submitter opposes the Bill's proposed mandatory medical approval of human medicines that have been approved by at least two overseas regulators, suggesting this could result in the forced use of a product with insufficient oversight, disregarding specific circumstances in Aotearoa New Zealand, including Te Tiriti o Waitangi and tikanga Māori.	E-NGO	**No change proposed**. *Refer to Item 175.*
180	42	50	Consistent with the proposed amendment to clause 8, clause 50(1)(a)(iii) should refer to clinical trials on	MBIE	**Amend clause 50** to make it clear clinical trials are on humans and testing of veterinary medicines is on animals.

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			humans only and testing of veterinary medicines on animals.		*Refer to Item 89.*
181	43	New	The Regulator should be able to vary conditions of the authorisation if it considers it necessary or desirable and must have regard to any conditions imposed by the recognised overseas authorities (consistent with clause 50(4) and (5)).	MBIE	**Add a clause to Part 2 Subpart 5** to enable the Regulator to vary conditions of an authorisation and that in doing so the Regulator must have regard to any conditions imposed by recognised overseas authorities.
182	44	New	It is unlikely but possible that an overseas authorisation holder does not want their gene technology authorised under the New Zealand gene technology regime. We propose amendments to make them aware that an authorisation is being initiated, and to enable the process to be paused or stopped if the overseas authorisation holder requests it. The overseas authorisation holder would be the person / company most likely to utilize that authorisation, which in most instances would be the Intellectual Property holder of the regulated organism in question.	MBIE	**Amend clause 50** to: • **require** the Regulator to notify the overseas authorisation holder, if known, that it is beginning the process to grant an authorisation, and • **enable** the Regulator to pause or cancel the authorisation process if it receives a request from the overseas authorisation holder to do so. *This issue is discussed further in Chapter 3.5.*
183	45	50	The Regulator needs to be able specify as conditions who may carry out a medical activity authorised under clause 50, and who that activity will relate to (e.g. to whom a medicine may be administered).	MBIE	**Amend clause 50** so that the matter of who may carry out a medical activity is specified as part of setting conditions, rather than as set out in current drafting. The policy intent that the Regulator may authorise a medical activity using a regulated organism, and specify as a condition the class of persons able to carry out a medical activity for a particular purpose, and the class of persons subject to the medical activity.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
					Officials understand that the current references to group A and group B persons is so that the clause is not restricted to specific persons.
184		51	That any mandatory medical authorisations be time-limited in their approval.	Individual	**No change proposed.** Clause 38(1)(b) provides for licence to be in force for a particular period.
185	46	51	Clause 51(a) refers to 50(2) instead of 50(1). The intent is that the Regulator may revoke an authorisation if one or more of the recognised overseas authorities also revoke the authorisation.	MBIE	**Amend clause 51** to clarify that the Regulator may revoke a mandatory medical authorisation if one or more of the recognised overseas authorities revokes the equivalent authorisation.
Subpart 6 – Emergency authorisations					
186		52	That there should be explicit mention of the threat to the economy, including threat to the plants and animals essential to our primary industries.	Researcher	**No change proposed**. Plants and animals are covered under the definition of 'environment. Primary industries do not require special mention when plans and animals are already included in environment.
187		52	That widespread consultation is vital in the case of an emergency as the pressure "to do something" in a moment of crisis can outweigh considered and essential assessment of the intended and unintended effects of authorisation of GMOs.	Individual	**No change proposed.** An emergency authorisation is an authorisation considered and granted by the Minister in an *emergency*, whereby a decision is required under urgency. An emergency authorisation is for a temporary period.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
188		52	Suggest 'Emergency' be defined and exclude emergencies that may be commercial in nature.	E-NGO	**No change proposed.** Emergency is described in clause 52(1) as an actual or imminent threat to health and safety of people or to the environment and examples are provided in 52(2).
189		52	Consider extending emergency exemptions to explicitly include serious threats to the health of animals and plants of economic, cultural or social importance to NZ. Submitters considered that this would support development of options to address any new pest or disease incursions that are likely to create immediate serious damage or destruction of animal or plant populations.	Research institute, Horticulture	**No change proposed.** The Minister can receive advice from a relevant Minister at clause 52(1)(a) of which this may be the Agriculture Minister (for example). Relevant Minister is defined in clause 11.
190		52	Suggest "Imminent threat" is defined in the Bill.	Individual	**No change proposed.** Officials consider that 'imminent threat' should be considered on a case-by-case basis, as it is dependent on the context and emergency should not be confined to a definition of imminent.
191		52	Some submitters strongly oppose bypassing of proper risk assessment and risk management, and noted that expert advice is essential to prevent rash decisions, including emergencies.	E-NGO, Iwi/hapū	**No change proposed.** A risk assessment is still conducted for an emergency authorisation. However, it is conducted rapidly to respond to the emergency. The Minister will be informed by the Regulator and other Ministers (and departments) about the threat and associated risks.
192		52	That the Emergency Authorisation process should not be permitted, as it can be opaquely carried out as secondary legislation and bypass Parliamentary process, and subvert democratic norms of transparency and accountability. Submitters considered that if there is an emergency then bespoke legislation can be enacted.	Researcher, Other	**No change proposed.** The HSNO Act provides for special emergency approvals and these have proven necessary to respond to emergencies like COVID-19. This authorisation follows the Australian Act and has been agreed by Cabinet and similar provisions are included in the HSNO Act. Provisions to respond

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
					rapidly to an emergency are crucial to ensure that gene technologies or regulated organisms (if appropriate) can be used to address the emergency.
Subpart 7 – Recognised overseas authorities					
193		57	Some submitters support the Regulator's ability to recognise risk assessments conducted in other jurisdictions; this will help streamline the application and decision-making process. However, given the critical role of the pastoral sector and trade in New Zealand's economy, these overseas assessments may need to be supplemented with additional assessments to ensure they are fit for purpose here.	Research institute, Agriculture	**No change proposed.** Officials agree that additional information beyond that supplied by a recognised overseas authority may be required for the Regulator to make its decision. The Bill does not preclude the Regulator from supplementing assessments from recognised overseas authorities with whatever the Regulator sees fit to make its decision, such as seeking advice from the TAC or other relevant persons, and then publicly consulting on a draft RARMP. *Refer to Item 145*, and discussion of clause 28(2)(b) where the Regulator has discretion to not consult on a draft RARMP; officials consider this provision remains appropriate as an enabling and efficient feature of the regime. *This issue is discussed further in Chapter 3.4.*
194		57	Some submitters are against NZ's regime recognising overseas authorities, considering this cedes NZ's decision-making obligations, the Crown's obligations to Te Tiriti, and is not flexible enough to adapt to NZ's changing environment.	Iwi/hapū, Researcher, E-NGO, Dairy, Agriculture and Individuals	**No change proposed.** The Regulator is not ceding decision-making power to overseas authorities, only gaining the ability to use relevant information in making its own, New Zealand-specific regulatory decisions. Clause 57(4) provides the Regulator must invite written submissions in relation to its proposal to recognise an overseas authority.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
					Refer to Item 193.
195		57	That the Bill should include specific criteria for recognising overseas regulatory bodies, ensuring transparency in the selection process. A mechanism for regular review of recognised overseas regulators should be established to ensure ongoing alignment with New Zealand's standards and values.	Research institute	**No change proposed.** Clause 57(2) provides that the authority must operate in a manner comparable to the Regulator in regulating gene technology, and operate under a legislative framework for regulating gene technology comparable to New Zealand's; and ability for Regulator to revoke declaration at clause 57(5).
196		57	Consider whether subsection (2) is amended to expressly include that private or for-profit entities cannot be declared as being a "recognised overseas authority", for the avoidance of doubt. This would ensure no entities with moderate to high risks of a conflict of interest could be declared as being a "recognised overseas authority", which is of particular importance given the effective power delegated to "recognised overseas authorities" under the Bill.	Individual	**No change proposed.** This issue would be considered by the Regulator under clause 57(2) that the person operates in a manner comparable to the Regulator in regulating gene technology. The Regulator is not delegating decision making power. *Refer to Item 194.*
197	47	57	Suggest subsection (4)(a)(iii) is amended to include a timeframe of no less than 30 working days for public consultation. Given the implications of the declaration of a "recognised overseas authority" (e.g. the bypassing of public consultation for specified licence types, and mandatory approval of medical authorisations without public consultation), it is essential that public consultation is comprehensive and genuine. The current reference to "a reasonable time" is vague and inappropriate, particularly where at other section the Bill specifies a minimum timeframe for public consultation (e.g. section 28(5)(f)).	Individual	**Amend clause 57** to provide timeline of no less than 30 working days for public consultation.
Subpart 8 - Register					

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
198		58	That clarification is needed as to the purpose of the Register, activity entry, and the timeframe for entries and in particular how this addresses non-notifiable activities.	Research institute, Other, Agritech, Dairy, University	**No change proposed.** The purpose of the register is to provide information to the public about the matters listed in clause 58(1). It is an operational matter for the Regulator to decide how and when to list things on the register, but it is expected this would be within a reasonable timeframe after decisions are made. There will be a list of all activities declared as non-notifiable activities (and a list of activities voluntarily declared).
199		58	Consideration should be given to the merits of maintaining some form of efficient register or record of the proposed "unregulated" genetic technology applications. This may provide some insight into the uptake and use of this technology, while also contributing to the evidence base.	Forestry, Dairy, Biotech	**No change proposed.** Officials consider that a register of exempt organisms has merit and could be considered further.
200		58	That there are risks to trade from a lack of certainty about which exempt organisms are present in New Zealand, and that a process of registration is established to manage this risk. Propose: Section 58 Regulator to maintain register (1) The Regulator must maintain a register with details of all (aa) registered exempt organisms (ab) registered exempt techniques or technology.	Horticulture	**No change proposed.** *Refer to Item 168.*
201	48	58	That to support transparency of the regime it needs to be clearer exactly what details for declarations and authorisations are required to be kept on the register.	MBIE	**Amend clause 58** to include more specific details for each declaration and authorisation type as to what needs to be kept on the register, which will be published on the Regulator's website, including, where relevant:

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
					For declarations, mandatory medical authorisations and emergency authorisations: - the declaration or authorisation (which will describe the class of persons, activities and regulated organisms authorised - a description of the status (whether subject to variation, revocation, suspension or extension where relevant) - any written decision documents including risk assessments - any advice provided by the TAC, MAC or other persons (including other agencies) - a summary of written submissions For notifications of notifiable activities [and non-notifiable activities if a person voluntarily notifies the Regulator]: - the name of the person or organisation undertaking the activity - a description of the activities and regulated organisms - the date of notification For licence applications and licences: - The name of the applicant as well as the name of the licence holder and persons authorised to undertake the activity. For determinations under section 12: - any amendments or revocations according to Item 98.
Subpart 9 – Information held by the Regulator					

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
202	49	59	Clause 59 states the Official Information Act 1982 (OIA) does not apply to information likely to relate to a licence or determination application until that application is received. The policy intent is to provide protection for commercially sensitive information to encourage applicants to engage early with the Regulator. Manufacturers of benchtop nucleic acid synthesis equipment, providers of SNA and third party vendors may also provide commercially sensitive to the Regulator before formally submitting an application for approval.	MBIE	**Amend clause 59(2)** to include information supplied by manufacturers of benchtop nucleic acid synthesis equipment, providers of SNA and third-party vendors before they seek formal approval.
203		59	The submitter considers clauses 59 and 151 will unjustifiably limit the public's right to information, as guaranteed by both section 14 of the New Zealand Bill of Rights Act 1990, and the OIA. They also consider that the insertion of a 'secrecy clause' is contrary to the statutory duty on the Chief Executive of MBIE to 'foster a culture of open government'. It is also contrary to guidance issued by the Ministry of Justice on such clauses.	Other	**No change proposed.** The policy intent of this provision is to give potential applicants confidence that sensitive information will be protected. This provision is comparable to section 55(1) of the HSNO Act.
204		59	That there appears to be no justification for placing this information outside of the scope of the OIA, which is capable of protecting legitimate interests from likely prejudice, and that clause 59(3) is removed.	Legal	**No change proposed.** *Refer to Item 203.*
205	50	60	Clause 60(2) could be interpreted as overriding the Privacy Act. This is not the policy intent.	MBIE	**Amend clause 60(2)** to clarify that this clause does not affect the operation of the Privacy Act.
206	51	60	That paragraphs (a)-(c) of clause 60(2) are deleted and replaced with a paragraph (a) that states "could be withheld under sections 6 or 9 of the OIA".	Other	**Amend clause 60(2)** by deleting 60(2)(a)-(c) and adding in a subclause that provides for information to be withheld under sections 6 or 9 of the Official Information Act 1982**.**

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
					For clarity, we note that we are not proposing to remove subclause 60(2)(d) which enables withholding information that would be likely to cause serious offence under tikanga Māori if published.
207		60	That subsection (2)(a) is amended to create a higher threshold before information can be withheld on the basis of national safety or security. While it is accepted that there will likely be information that would create material risk to national safety and security, it seems arguable that almost all gene technologies could arguably "pose a risk" to national safety and security. This could be amended to permit withholding of information where the Regulator considers that disclosure of the information "would be likely to prejudice the safety and security of the nation". This would align with the withholding grounds for information requested pursuant to the Privacy Act (see section 51 of that Act). This would prevent the Regulator from withholding information merely on the basis that disclosure "could" pose a risk to national security and safety, which is a low and subjective threshold.	Individual	**No changes proposed.** Officials disagree that the current language creates a bar that is too low. This is the same language as in section 20B of the HSNO Act that enables EPA to withhold information.
208		60	The submitter seeks clarification for why subsection (2)(d) has been included, considering it to be a subjective assessment by the Regulator (who is not required to be an expert in tikanga Māori) regarding what information "is likely to cause serious offence under tikanga Māori if published". Given the importance of disclosure and the public's ability to review and scrutinise information gathered under the Bill, this subjective and opaque exclusion criterion appears inappropriate.	Individual	**No change proposed.** The Regulator can access advice from the MAC that is an expert in this area.
209		60	That for clarity, it may be preferable to use language in for clause 60(1)(b) such as 'The	Legal	**No change proposed.**

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			Regulator is not required to publish any information that the Regulator…'.		Officials do not consider that this language change is necessary or would do anything to change the meaning of the clause.
210		61	There must be provision such as in the Aarhus Convention where there is imminent danger to human health and safety or that of the environment is concerned, there must be a public interest override to force disclosure. An example can be found in the Aarhus Convention 1998 in Article 5(c).	E-NGO	**No change proposed.** An override like that suggested would create an inconsistency with the other legislation referenced in this provision.
211	52	61	A submitter considers that in the case of authorisations granted as licences, the alignment of protection periods for confidential information under the Medicines Act 1981 and the Gene Technology Act appears problematic. There may be a significant difference in the timing of approvals of a licence under the Act and approval under the Medicines Act, it is unclear as to how the respective protection periods will be appropriately aligned. As New Zealand offers a relatively poor patent term protection period, if this issue is seen to present a weakening in the protected period, it may deter Sponsors with highly innovative gene technology products from seeking a licence to bring the product to New Zealand.	Other	**Recommend that PCO consider whether any changes to clause 61** are necessary to improve clarity for how long protection periods apply for.
212		61	A submitter commented that clauses 60 and 61 show an extraordinary amount of leeway to withhold information and keep other information confidential, considering that these provisions appear to protect pharma and bio-tech corporations interests rather than the health and safety of New Zealanders.	Individual	**No change proposed.** The intent of the confidential information provisions is to extend the protections given by other legislation to an organism in scope of this Bill, so that information is equally protected. Without these provisions, information may be disclosed by the Regulator that would otherwise be protected under other legislation.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
213	53	61	That the Bill fails to provide any clarity with respect to the provisions for protection of confidential information and intellectual property associated with the authorisation of a medicine or vaccine under any of the non-licence authorisation mechanisms (e.g., mandatory medical authorisation, notifiable activity etc). Lack of protection of this information will be a clear deterrent to market participation in New Zealand and thus limit access to innovative therapies and vaccines.	Other	**Add a new provision** to ensure that, where information provided to the Regulator in relation to a mandatory medical authorisation or emergency authorisation, and which is required to be protected under the Medicines Act or the ACVM Act, that the Regulator is also required to keep that information confidential for the duration of the protection provided for under those Acts. *This issue is discussed further in Chapter 3.6.*

Part 3: Inspection, enforcement, and ancillary powers

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
Subpart 1 - General					
214			Suggests that the regime is missing a monitoring function.	Other	**No change proposed.** The Bill provides relevant powers for monitoring and inspection to the enforcement agency in clauses 65, 68, 70, 71, 73, and provides for the Regulator to issue standards relating to supervision, monitoring, or verification in clause 150(3)(b).
215		63	Clarify the enforcements agency's role and responsibility for biosecurity compared to its role under the gene technology regime, noting that its biosecurity role is operating in a restrictive, preventative and risk minimisation way.	Research institutes, Researcher	**No change proposed.** The enforcement agency's role under the Bill is described in clause 63 and further in Part 3. The enforcement agency's role under the Biosecurity Act 1993 (Biosecurity Act) regarding unwanted organisms is covered in that Act.
216		63	A submitter raised concerns raised that the interactions with other legislation may have unintentionally restrictive outcomes, in particular the impact of the Biosecurity Act on border movements of both research and commercial materials. The efficient and predictable transfer of plants and seeds will be crucial to maintain an enabling regime and secure a future where research, product innovation, and commercial use can progress smoothly. The careful consideration of import health standards and their application to both regulated and exempt organisms will be required.	Research institute	**No change proposed.** MPI is currently reviewing relevant standards and taking into account interactions with the Bill.
217		63	A submitter commented that the rationale for MPI assuming the role of enforcement agency for all medical activities regulated under the Bill has not been satisfactorily explained. The operational implications of this choice with respect to those	Other	**No change proposed.** The enforcement agency's responsibility for medical activities is limited to the purpose of the Bill.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			medical activities which will also be overseen by the Medicines Regulator (Medsafe), appears likely to create unnecessary regulatory burden and inefficiencies of regulatory practice.		Part 5, Subpart 4 provides for information sharing to mitigate the creation of unnecessary regulatory burden.
218		63	That the Bill should be clear about the biosecurity status of organisms whose approval has been revoked, and that the Committee should seek further advice from officials about how GMO regulation and the biosecurity system will interact.	PCE	**No change proposed.** MPI recently consulted on proposed changes to the Biosecurity Act and as such will be making a range of changes during this process. The proposals include changes to the interface between that Act and other Acts. We consider that this MPI-led biosecurity process is a better vehicle for proposals such as this one.
219		63	Recommendation to amend the Bill to give the EPA, as the host organisation of the Regulator, powers to enforce the Act in addition to those given to MPI. Given that the EPA's primary role focuses on protecting the environment, in contrast to MPI's, and that the EPA has relevant compliance and enforcement expertise for enforcing the GMO regulations.	PCE	**No change proposed.** This approach was considered during the drafting process but not progressed because the Government considered it would create unnecessary complexity and overlap of functions.
220		63	That enforcement should be primarily undertaken by dedicated personnel under the supervision of the Regulator; and enforcement triggers or oversight should come from the Regulator. Concerns have been raised as to the existing burden on Biosecurity Officers; availability of specialist expertise, and ongoing co-ordination.	Biotech organisation	**No change proposed.** Capacity concerns are noted; however, this is being managed as part of establishing the regime. Enforcement officers can only be appointed under clause 64 if they are appropriately qualified and meet any specified requirements.
221		65	Propose the Regulator has powers to require disclosure of intended and unintended genetic changes in all GMO organisms.	Other	**No change proposed.** Officials have recommended amendment to clause 15(f) for the Regulator to impose a condition requiring validation of genetic changes made.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
					Refer to Item 106. Clause 65 provides the power to obtain information, including regarding genetic changes when required under the Bill and when the request is considered reasonable.
222	54	65	As currently drafted, clause 65(1) does not clearly capture the intent of the SNA provisions of the Bill, which would specify screening policies that providers and manufacturers must undertake. Currently, clause 65(1) specifies that an enforcement officer may require a person to provide information on "synthetic nucleic acid" and "benchtop nucleic acid synthesis equipment".	MBIE	**Add to clause 65(1)** that an enforcement officer may require a person to give the enforcement agency information about screening policies related to SNA and benchtop nucleic acid synthesis equipment.
223	55	65	Consider amending this clause to enable an enforcement officer to obtain personal identity information.	MBIE and MPI	**Add a new provision** to empower enforcement officers to obtain person identity information if they believe that person may have committed an infringement offence. This regime may foreseeably involve infringement offences for members of the public whose identity is not be easily ascertainable. What is an infringement offence will be defined in the secondary legislation.
224	56	New clause	Consistent with section 123 of the HSNO Act, Biosecurity Act inspectors should have the power to require a person importing any organism to give a statutory declaration that the organism is not a regulated organism. This is necessary to avoid import delays or organisms to be retained at the border for unnecessarily long periods.	MBIE	**Insert a new clause** to empower Biosecurity Act inspectors to require a person importing any organism, to give a statutory declaration that an organism is not a regulated organism.
225	57	69	The intent of clause 69 is to allow officers to enter premises to inspect a place to check compliance with the Act or determine whether an organism is a regulated organism. Currently this is limited to	MBIE	**Amend clause 69** to ensure enforcement officers can enter and inspect any place where the enforcement officer has reasonable grounds to believe it is a place where an activity or organism

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			where a regulated organism is present, where SNA is distributed, where benchtop nucleic acid synthesis equipment is manufactured, or where devices, equipment, or information connected to the activities or regulated organisms are located. However, officers may also need to check places where an organism, equipment or information was located or where the activities were being carried out.		regulated by the Act, or related devices, equipment or information is or was present. The policy intent behind this recommendation is to ensure that the enforcement agency can still enter a place where there was a regulated organism or activity but it is no longer present. This would enable the enforcement agency to check for compliance with the Act in a period after an activity ends.
226	58	69	Clauses 69(2)(d) and 69(3)(d)(ii)(D) should refer to benchtop equipment being "distributed" as well as manufactured.	MBIE	**Amend clause 69** to include reference to places where benchtop equipment is distributed.
227		70	Suggest subsection (1) be amended to clarify that an enforcement officer may only enter a dwellinghouse or a marae or building associated with a marae with a search warrant except where the dwellinghouse or marae or building associated with a marae was expressly listed as the relevant location for the intended licence-holder within their licence application.	Individual	**No change proposed.** The policy intent of clause 70 requiring a search warrant to enter a dwellinghouse or marae is to recognise the different status (private and/or sacred) of those places compared to commercial premises. Non-compliant activities could occur at a dwellinghouse or marae or building associated with a marae that is not listed on a licence application. This suggestion would limit enforcement officer's ability to enter that place to conduct a search warrant.
Subpart 2 – Compliance orders					
228		72	That when undertaking a compliance order and where the enforcement officer faces an uncommon situation, the officer and licensee may call upon an external opinion or refer to an accepted practice overseas to ensure that compliance is practical and effective.	Biotech organisation	**No change proposed.** The enforcement agency can share information with external agencies. Refer to the information sharing provisions in Part 5, Subpart 4. Clause 75 provides for a person to apply to the enforcement agency to change or cancel a compliance order. This application provides a person

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
					a standard avenue to provide relevant information regarding accepted practice overseas.
Subpart 3 – Offences					
229		76	Remove all or most of the strict liability offences. (Refer to clauses 76(3), 77(4), 78(3), 79(2), and 80(5) of the Bill), or alternatively improving the defences for strict liability offences to an absence of negligence standard.	Legal, Research institute	**No change proposed.** *This issue is discussed in Chapter 3.8.*
230		76	Remove strict criminal liability for: engaging in a regulated activity without authorisation; breaching a condition of an authorisation; or breaching the nucleic acid regime; stating that the threat of criminal conviction for inadvertently engaging in even a low-risk activity or breaching a condition of an activity which may be of little, or no, consequence will have a chilling effect on the use of gene technologies. It raises the possibility of turning honest scientists into criminals.	Biotech organisation	**No change proposed.** *This issue is discussed in Chapter 3.8.*
231		76	Propose including strict liability for unforeseen harm caused by field use of agricultural GMOs	Agriculture	**No change proposed**. Adding a strict liability offence for unforeseen harm would preclude any defence that a person took all reasonable precautions and exercised due diligence, including adhering to the requirements of the Act.
232		76	That all fines and penalties be at least tripled to reflect the seriousness of the offences listed.	Individual	**No change proposed.** *This issue is discussed in Chapter 3.8.*
233		76	That the penalties and enforcement settings are set too high and as such are likely to encourage 'precautionary' attitudes to risk. So, while the intent of the legislation may be to enable the use of gene	Research institutes, Researcher,	**No change proposed.** *This issue is discussed in Chapter 3.8.*

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			technologies, the levels of penalty are likely to create conditions that are more likely to be risk adverse than risk-proportionate. This may have the unintended consequence of maintaining the current precautionary approach and therefore New Zealand may not derive the desired benefits from the technology.	Individual, Biotech organisation	
234		105	The fines provided for under Subpart 3 for criminal offence appear inadequate, particularly where it is an organisation. Fines and restrictions for entities responsible for repeated contamination incidents.	Organics, Individual	**No change proposed.** *This issue is discussed in Chapter 3.8.*
235		76	Propose penalising anyone using gene technology outside regulated and contained laboratory facilities legally liable for any adverse impacts on habitats, public health, and wellbeing;	E-NGO	**No change proposed**. The Bill prohibits undertaking activities with regulated organisms unless authorised (clause 13); and that a person must not breach conditions (clause 14). Offences, penalties, and infringements apply otherwise. Wellbeing is outside the scope of risks managed by the Bill.
236		76	Suggest providing an "honest belief" defence for strict liability offences, to avoid penalising unintentional errors should not be provided for.	Māori NGO	**No change proposed.** This would be akin to claiming ignorance of the law as a defence.
237		76	Propose a legal exemption for farmers who did not intentionally plant or cultivate patented GM crops.	Individual	**No change proposed**. The Bill considers offences to be committed if the person *knowingly* or is *reckless* as to carrying out an activity in relation to a regulated organism, meaning that inadvertent activity does not constitute an offence.
238	59	79	Suggest removing clause 79(1)(b) referring to border information for the Joint Border Management System (JBMS), as offences appear excessive.	MBIE	**Remove clause 79(1)(b)**.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
					The Biosecurity Act or the Customs and Excise Act 2018, which both require JBMS use, do not provide an offence for this.
Failure to comply with SNA regime					
239		83	That the SNA provisions should be removed from the primary legislation. If a clear need is identified, and their effectiveness demonstrated, their inclusion would be more appropriate in secondary legislation.	Biotech organisation, Horticulture	**No change proposed.** The specific requirements for SNA providers and manufacturers will be set under secondary legislation. *This issue is discussed further in Chapter 3.13.*
240	60	83	Clauses 83(1)(a) and (2)(a) and (b) need to change to "synthesize or distribute" and "manufacture or distribute", in order to include third party vendors.	MBIE	**Amend clause 83** to include reference to 'synthesize or distribute, and 'manufacture or distribute', so that third-party vendors are captured.
241		85	Remove all references to property in clauses 15(m), 85(3)(b) and (5)(c), 101(1)(c), and 102(2)(b), to avoid signals of a return to the civil liability regime established by controversial 2003 amendments to the HSNO.	Legal, Individual, Biotech organisation	**No change proposed.** The references to 'property' in clause 85 provides for a District Court to order a person convicted of an offence under the Bill to mitigate or remedy the adverse effects resulting from their offending. This clause does not provide strict liability, nor is it a civil liability provision, and it includes several factors which the Court must have regard to before imposing any order. *This issue is discussed further in Chapter 3.8.*
242	61	86	Clause 86(2)(a) should include 'omission' to read "…act or omission…." (This will then be consistent with clause 87(a)).	MBIE	**Amend clause 86** to include or omission, for consistency with clause 87.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
243		88	Clarify why the limitation period under subsection (1) is only two years when the comparable criminal limitation period under the Criminal Procedure Act 2011 is five years (see section 25(3)(c) of that Act).	Individual	**No change proposed.** Clause 88(1) differs from clause 25(3)(c) of the Criminal Procedure Act 2011 such that the Bill enables charges to be filed for category 1 offences dates year after the date **"**on which the matter giving rise to the charge first became known, or should have become known, to the enforcement agency" rather than "within 5 years after the date on which the offence was committed". This difference factors in the potential period between an offence occurring and the effect of the offence becoming known.
Subpart 4 – Infringement offences					
244		91	That Infringements fees should be significant and required to be made public in the annual report of the Regulator.	Research institute	**No change proposed.** Infringement fees are appropriate. Level of infringement fees align with LDAC guidance and have been vetted by the Ministry of Justice.
Subpart 5 – Pecuniary penalties					
245		100	Recommend removing strict liability for those offences which also have pecuniary penalties, that is for undertaking an activity without authorisation, breaching a condition of an authorisation or breaching the SNA regulations.	Biotech organisation, Individual	**No change proposed.** Including both strict liability offences and pecuniary penalties enables the enforcement agency to decide to proceed with the appropriate penalty for the offence, with pecuniary penalties being appropriate for commercially motivated offending.
246		104	That clause 104(4) suggests that fines may preclude criminal charges, even if the offence has severe consequences, and that 'this loophole must be closed'.	E-NGO	**No change proposed.** Clause 104(4) is not a loophole. Including both criminal offences and pecuniary penalties enables the enforcement agency to decide to proceed with the appropriate penalty for the offence, with

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
					pecuniary penalties being appropriate for commercially motivated offending.
247		105	That section 105 appears to create a perverse incentive that, to secure a conviction the enforcement agency would need to forgo pursuing the pecuniary penalties that would disgorge the offender of the financial gains obtained as a result of the offence, and vice versa. Propose that the Bill is amended to ensure that those who commit breaches of the Bill that result in extensive harm will be required to provide compensation or otherwise correct the harm caused by their breach.	Individuals	**No change proposed**. Clause 105 extends liability for pecuniary penalties to employers and does not affect or remove any other person's liability.

Part 4: Administration

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
Part 4: Administration					
248	62	New	Subpart 1A A new section that clarifies responsibilities and functions of the EPA (where appropriate), which are currently spread across multiple provisions. Final policy proposals for this section have not been reached but will include clarifying who is the respondent in legal cases and whether the Regulator is covered by the EPA's liability insurance.	MBIE and the EPA	**Recommend officials and PCO** work to finalise policy proposals in relation to the functions of the EPA and to clarify accountability arrangements, with a view to drafting new provisions for the Bill. The policy intent is that the Regulator is accountable to the EPA for their obligations as an employee, and that the Regulator is accountable to the Minister for the performance of their statutory functions.
249			That a Market Access and Trade Advisory Committee be provided for in the Bill, comprised of trade and market access specialists from MFAT and MPI, to advise the Regulator on risks to market access and trade, and possible conditions to manage those risks when considering decisions related to primary products.	Dairy, Agriculture, Individual	**No change proposed**. Making this change would be inconsistent with Government policy for the Bill's purpose being to manage risks to the environment and the health and safety of people. *This issue is discussed further in Chapter 3.1.*
250			Submitters recommended that a Bioethics Committee or Bioethics Council or Gene Technology Ethics and Community Consultative Committee is established to advise the Regulator on ethics. Suggested that the Gene Technology Ethics and Community Consultative Committee has expertise in community consultation, risk communication, ethics, law and environmental issues. Robust evaluation of gene technologies requires consideration from a variety of perspectives. Scientific and economic considerations require	E-NGO, Individuals, Organics, Seeds, Other, Researcher	**No change proposed**. Making this change would be inconsistent with Government policy for the Regulator to be supported by two advisory committees. *A Bioethics Council is discussed further in Chapter 3.2.*

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			transparent balancing with ethical and cultural considerations.		
251			That other advisory committees are needed, including at the status of the MAC including for organics, medical applications, agricultural and food applications, and environmental applications.	Sector Group, Researcher, Apiculture	**No change proposed**. The Regulator can establish subcommittees for the TAC or the MAC for the purpose of advising on specific matters or classes of matter (clause 132).
252			That the Bill lacks detail on how the Regulator will receive advice.	Individual	**No change proposed**. Clauses 24, 49 and 115 provide for TAC advice and clause 122 for MAC advice.
253			Suggested a Monitoring Committee (similar to Australia) to address issues of long-term monitoring and compliance.	Researcher, Agritech	**No change proposed**. The enforcement agency is responsible for monitoring and enforcing compliance (clause 63). *Refer to Item 385.*
254			That the expertise and research relevance of members of the Committees is important; that both include members with relevant, up-to-date expertise, and be comprised of individuals actively engaged in modern gene technologies, including Māori researchers with relevant technical experience, to ensure informed and balanced decision-making. All possible precautions must be taken to ensure these committees do not have conflicts of interest.	Researcher	**No change proposed.** The Committees must have arrangements in place to avoid or manage conflicts of interest relating to the performance of its functions (refer to clause 117(3) and 124(4)).
Subpart 1 – Functions of the Minister					
255		106	Submitters recommend that the Regulator must be independent and that the policy direction should not be set by the Minister, citing perceived political bias and interference. While acknowledging the need for governmental accountability, the current provisions	Horticulture, Individuals, University, E-NGO, Research Institute, Researcher, Māori	**No change proposed**. We note that concerns regarding general policy directions may be addressed by changes that the Committee has already agreed to (i.e. to align the

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			for ministerial oversight raise concerns regarding potential political interference in scientifically based decision-making. The Bill lacks robust safeguards to guarantee the Regulator's independence, especially in areas requiring specialised scientific expertise. This raises the risk that shifting political priorities could lead to inconsistent regulatory application, potentially eroding public trust and creating uncertainty for researchers and industry. Recommendations: The Bill should establish clear boundaries between ministerial guidance and scientific autonomy, incorporating transparent oversight mechanisms that protect scientific integrity.	NGO, Iwi/hapū, Biotech Organisation	general direction power to the approach used in the Crown Entities Act 2014). *This issue is discussed in Chapter 3.9*.
256		106	Recommend insulating the decisions of the Regulator from political influence, the Committee should consider amendments that: - Explicitly state the matters on which the Regulator may not be directed, similar to section 30 of the Australia Act. - Remove the ability for the Minister to impose general policy directions in clause 111(1)(b). - Remove the regulation-making powers in clause 161(b) and (c).	PCE	**No change proposed**. *Refer to Item 255.*
257		106	That the 'general policy directions' issued by the Minister to the Regulator are published. Publishing details such as Ministerial policy direction to the Regulator, would enhance transparency and trust in the decision-making process.	Dairy, Agriculture	**No change proposed**. The objective of the Regulator in clause 109 specifically mentions transparency. *Refer to Item 255.* *This issue is discussed further in Chapter 3.9.*

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
Subpart 2 - Regulator					
258	63	108	Ministerial appointment of the Regulator may cause difficulties regarding the performance management of the Regulator, who would be accountable to the Minister, but who's performance will in part depend on the support provided by to them by the EPA. If the Regulator was not an employee of the EPA prior to appointment, it would be unclear what responsibility the EPA has for the Regulator's performance as an employee.	MBIE, PSC, and the EPA	**Insert a new subclause in clause 108** to provide for the EPA to recruit, in consultation with the Minister, a person to be the Regulator. **Amend clause 108(2) and 108(4)** such that the Minister must appoint an employee of the EPA or a person becoming an employee. We note that the EPA running the recruitment process in consultation with the Minister and hiring the person to become the Regulator preserves the ministerial appointment of the Regulator while clarifying the relationship of the Regulator to the EPA regarding their performance as an employee. *Refer to Item 248.* *This issue is discussed further in Chapter 3.9.*
259		108	That the Regulator should be an Officer of Parliament, with inputs from all parties, but including nominations from the research organisations, civil society, Conservation, Environment, and Health Ministers, and the New Zealand Māori Council or other Māori organisations, Science and Technology, and MPI.	E-NGO	**No change proposed**. Officials do not support the Regulator being an Officer of Parliament because the purpose of an Officer is to provide independent, non-political scrutiny of the Government, not to exercise the duties and functions required of a regulatory regime.
260		108	Suggested protecting the Regulator from interference by future governments through establishing it as an Independent Crown Entity	Legal	**No change proposed**. This proposal was considered and was not considered cost-effective.
261		108	A number of submitters sought assurance that if the independent Regulator is housed within the EPA, that perceived issues with the hazardous chemical approval system (such as having a slow approval process) are not replicated across into the gene	Agriculture, Research institute, Horticulture, Individual, University, Māori	**No change proposed.** The Objective of the Regulator is to develop and maintain an independent, efficient, and transparent system to regulate the use of gene technologies and

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			technology Regulator, and that the Regulator is sufficiently resourced.	NGO, Biotech organisation, Seeds	regulated organisms to achieve the purpose of this Act (refer to clause 109). *A brief discussion on resourcing the Regulator is in Appendix Three.*
262		108	That the Regulator should be a totally independent statutory officer within MBIE or EPA.	Apiary, Biotech organisation	**No change proposed**. The Bill provides for the Regulator to be statutorily independent already, however, it provides for them to be located within the EPA, not MBIE.
263		108	The Regulator should be accountable to the board of the EPA, to align with the functions of the EPA, and increase the credibility of the Regulator's independence.	PCE	Refer to Item 248 (finalise functions of the EPA and clarify accountability arrangements).
264		108	Oppose the establishment of an individual as the sole decisionmaker regarding gene technology. A single decision-maker lacks the benefit of diverse viewpoints, which can result in biased decision-making.	Iwi/hapū, Researcher	**No change proposed.** The policy of 'single decision maker' was agreed by Government consistent with the approach used in Australia's regime. A departure from the approach under the HSNO Act (in which decisions are typically made by an EPA-appointed expert committee), this approach reflects the idea that assessing gene technology activity risks should be a technical, science-based process, and removes the challenges that come with committee-based decision making, such as the length of time required to make decisions. Officials note that two advisory committees are intended to provide input from diverse viewpoints and range of skillsets, to support the Regulator's decision making.
265		108	That MBIE house the Regulator. MBIE has existing scale and expertise as a commercially focused regulatory agency with responsibilities for the	Agritech	**No change proposed**.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			broader technology and trade regulatory system. MBIE's focus on innovation and sustainable economic growth aligns closely with the purpose of the Bill to enable the safe use of gene technology and regulated organisms in New Zealand.		This proposal was considered and not progressed because the EPA contains significant relevant expertise to support the Regulator.
Objective of the Regulator					
266		109	Suggest a wording change to the Objective: Rather than the objective of the Regulator is to "regulate", replace with "to enable regulated use of gene technologies" to better align with the intent of the Bill.	Research institute, Researcher	**No change proposed.** The Bill and its Regulator prohibits activity with regulated organisms unless authorised. Thereby a Regulator's decision may be not to authorise and thereby "not enable regulated use".
Functions of the Regulator					
267			Suggested that a function of the Regulator is to require the Regulator maintain engagement and consultation with the community, Tangata whenua, farmers and growers, and the food and fibre sector and to inform and educate the public.	E-NGO, Individual, Organics	**No change proposed.** Clause 110(g) requires the Regulator to provide information and advice to the public.
Performance of functions, duties and exercise of powers					
268	64	111	As discussed in Item 248 above, ministerial appointment of the Regulator creates difficulties regarding the EPA's relationship to the Regulator as an employer.	MBIE, PSC, and the EPA	**Amend clause 111** to include a subclause clarifying that the Regulator is accountable to the EPA for their obligations as an employee. This change is not intended to remove the Regulator's accountability to the Minister for the performance of their statutory functions. *Refer to Item 248* ***Dependency with recommendation 62.***

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
269		111	That clause 111(1)(b) is deleted. The Regulator should not be subject to general policy directions given by the Minister.	Researchers, Apiary, E-NGOs, Biotech organisation, Horticulture, Seeds, Individuals, Legal	**No change proposed**. Government has agreed on having a mechanism to provide general policy direction to the Regulator as a means of ensuring the regime achieves reform objectives. The Minister will not be able to issue direction in relation to individual decisions. *Refer to Item 255.*
270		111	A submitter opposed to a general policy direction power commented that that if clause 111(1)(b) is to remain, then: (a) the clause should be amended to provide that the Regulator may take into account any general policy directions (GPDs) given by the Minister. This would enable the Regulator to simply take into account any GPDs given by the Minister, without any obligation or requirement to comply with or implement them. (b) Providing greater certainty as to what GPDs are, what topics and matters they can cover, and the process for making GPDs (including any process the Minister must follow). The submitter noted that these matters are not specified in the Bill, and are largely discretionary, which is not desirable given the potential to interfere with the Regulator's independence. (c) Amending the Bill to require the Minister to undertake public consultation on proposed GPDs.	Legal	**No change proposed**. *Refer to Item 255.*
271		111	Noted that clause 111(1)(a) says the Regulator must act independently of the EPA, which is their employer, although this is common practice, the submitter is not sure that is realistically achievable.	Researcher	**No change proposed**. The Regulator is statutorily independent and therefore will act in line with their responsibilities in the Bill.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
272	65	111	Suggest introducing an independent review process to audit the Regulator's performance. Regular external reviews, for example five-yearly, would provide accountability and identify areas for improvement.	Dairy, Agriculture	**Consider amendment to include independent audit of decision-making process**. This proposal has merit and warrants further consideration, but we have not developed policy on this in the time available. Officials consider such a review process should be limited to the Regulator's decision-making role, for example how it seeks and considers advice, its risk assessment and management approach - pursuant to the purposes of the Act.
273		112	That subclause (1) is changed to: (1) Subject to subsection (2), the Regulator may delegate to any suitably qualified and trained person any of their functions, duties, or powers, other than this power of delegation.	Research institute	**No change proposed**. The Regulator is appointed by the Minister to fulfil their role, as such, we consider that any delegation of their powers should be limited.
274	66	New	Sought clear public reporting from the regime, on various matters (including gene technology applications, real-world benefits, regulatory activities and outcomes) as a way to ensure transparency, engagement and public confidence.	Dairy, Agritech, Agriculture (not dairy), Individual	**Add an annual reporting provision**, similar to the Australian legislation, that is coherent with the overall accountability arrangements for the Regulator. *This issue is discussed further in Chapter 3.11.*
Subpart 3 – Technical Advisory Committee					
Appointment and membership of the Technical Advisory Committee					
275		114	Recommend that the person requirements include that some of the members must be knowledgeable practitioners of genetic modification technologies, and that there are clear term limits for being on the group. This should ensure that technically competent people are appointed, and that the committee remains up to date with the latest technologies.	Research institute, Individuals, Biotech organisation, University, Agritech, Seeds	**No change proposed.** These are operational matters which should not be addressed through primary legislation. They could be provided for through the Terms of Reference referred to in clauses 117(1) and 124(5).

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
276	67	114	Recommend including primary sector, plant breeding and animal breeding, seed production expertise in the TAC.	Agritech, Agriculture, Biotech organisation, Seeds	**Amend clause 114(3)** to include additional areas of expertise: plant and animal breeding and seed production, as particular areas of relevance for gene technologies.
277		114	That the TAC also includes social science skills, particularly a person with human and animal ethics experience.	Research institute, Individual	**No change proposed.** The purpose of the TAC is to advise the Regulator on risk to human health and the environment, including the suggested expertise would go beyond this purpose. *This issue is discussed further in Chapter 3.10.*
278		114	That it is a requirement for the Minister to ensure that the TAC has an appropriate diversity of skills and that the majority of the disciplines listed are represented.	Research institute	**No change proposed.** Due to the potential crossover of expertise provided by 114(3) officials consider it may be limiting to require the majority of disciplines represented. The list prescribed in clause 114(3) is to guide the Minister in selecting members with skill sets capable of assist the Regulator in performing its functions under the Act and ensuring there is a diverse range of skills in the TAC. The flexibility in size of the committee also enables the size to adjust to accommodate workload.
279		114	That mātauranga be included in the list of applicable skills to ensure that the TAC has the capacity to understand the role mātauranga may have in the use of genetic technology, particularly in understanding its impacts on the environment or indigenous ecosystems.	Iwi/hapū	**No change proposed**. This skillset is appropriately addressed by the MAC.
280		114	That there is no requirement for TAC to include primary sector expertise, which submitters were most likely to be impacted by the Bill. Submitters recommend that this issue is addressed by inserting	Agriculture, Horticulture, Dairy	**No change proposed.** While there is merit in this suggestion, officials consider that any further expertise required can be appropriately managed via clause 114(3)(t), which is

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			a new subsection (3A) into clause 114 of the Bill, stating: The membership of the committee must include: (a) skills, knowledge, or experience in the primary sector, including food safety, biosecurity, fisheries, agriculture and animal welfare, and forestry.		the "catch all" for expertise in any other area recommended by the Regulator. Clause 114(3)(f) refers to agricultural or aquacultural systems.
281		114	That 'international trade and market access' experience should be referenced as a committee appointment consideration. Industry representation should also be considered.	Sector group, Researcher, Dairy, Horticulture	**No change proposed**. Making this change would be inconsistent with Government policy for the Bill's purpose being to manage risks to the environment and the health and safety of people.
282		115	To reflect the intent of the Bill, clause (a)(ii) should be redrafted to: the use of gene technologies and regulated organisms and the appropriate management of their risks to enable their use.	Research institute	**No change proposed**. The purpose of the TAC is purely to advise on risk management as it relates to the purpose of the Act.
283		115	Horticulture sector submitters recommended a commercial advisory function be established within the proposed TAC to provide support to the Regulator. This advisory function would help evaluate the commercial benefit/risk assessment and support the development of regulations for operational application of the technologies and how they are communicated/marketed.	Horticulture	**No change proposed**. *Refer to Item 282*. *This issue is discussed further in Chapter 3.10.*
284		116	Some submitters queried that the Bill only requires the Regulator to "have regard" to the advice of the TAC and recommend that this be strengthened to ensure the Regulator, and the Minister are actively taking the recommendations of the Committee into consideration.	Agriculture, Dairy	**No change proposed.** 'Have regard' to is appropriate for an advisory function. The Regulator must seek and have regard to advice from the Committees.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
285		117	Noted that clause 117(4) regarding the terms of reference should include the aim of the Bill which is to enable safe use of gene technology.	Researcher	**No change proposed.** *Refer to Item 282*.
Subpart 4 – Māori Advisory Committee					
286	68	120	The PCE and other submitters recommended that the appointment criteria for committee membership should be amended to include considerations, similar to those of the PVR Act, on which the Bill's MAC was loosely based.	PCE, Research institute, University, Individual, Dairy, E-NGO, Organics, Iwi/hapū, Māori NGO	**Add criteria and requirements for membership of the MAC to Part 4 Subpart 4**, based on the criteria for the Māori Plant Varieties Committee in section 57 of the PVR Act.
287		120	That the Bill adopts the PVR Act model for the Committee, and that the Committee is a decision making body for organisms where direct kaitiaki relationships exist.	PCE, Research institute, University, Individual, Dairy, E-NGO, Organics, Iwi/hapū, Māori NGO	**No change proposed.** Government policy was to model the MAC on the PVR Act but in an advisory role. An advisory role complements the advisory function of the TAC. Advisory committees are a feature of the Australian regime on which the Bill is based, and support the Regulator being the single decision maker.
288		120	That given Māori capabilities and interests in gene technologies, Māori communities nominate and elect kaitiaki/representatives to the Māori committee and that members should not be appointed by the Minister.	Research institute, E-NGO	**No change proposed.** Government policy is for the Minister to appoint committee members. This is consistent with the approach taken for such committees under the Australian regime.
289		120	That the Bill utilises the EPA's Ngā Kaihautū Tikanga Taiao (NKTT) as the Māori Advisory Group. The submitter does not support the establishment of a MAC as detailed in clauses 120 to124 as: - Māori advisory committees do not discharge the obligation the Crown has to	Iwi/hapū	**No change proposed**. The MAC and the EPA's NKTT have different functions under their respective Acts. The Bill does not prohibit members of the NKTT from being considered for appointment to the MAC.

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			under Te Tiriti and under the submitter's Settlement. - Establishing this Committee duplicates the expertise, roles and responsibilities undertaken by NKTT - NKTT has developed frameworks and guidance during its operation that ensure advice to decision-makers within the EPA does not limit the ability of mana whenua to exercise rangatiratanga. These frameworks and guidance were developed in consultation with Te Herenga (the EPA's pan Iwi network).		
290		120	That the Minister's appointment and membership of the MAC must ensure pan-Iwi representation and appropriate levels of public consultation to reflect diverse hapū, Iwi and Māori perspectives on gene technologies that will be seriously considered by the Regulator.	Research Institute	**Refer to Item 286** (adding criteria and requirements for appointment of the MAC members).
291		121	Decisions about MAC membership should be co-developed between the Crown and Māori, reflecting a genuine partnership that aligns with the principles of Te Tiriti o Waitangi. The submitter stated that a co-developed appointment process would involve collaboration with Iwi and hapū to identify candidates who possess the necessary expertise in tikanga Māori, mātauranga Māori, environmental science, and regulatory frameworks, and would ensure that the committee is not only representative but also equipped to address the complex cultural, scientific, and environmental considerations associated with gene technology.	Iwi/hapū	**No change proposed**. *Refer to Items 286 and 287.*

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
292		121	That the establishment of clear criteria for expertise would enhance the Committee's capacity to provide robust and informed advice. This approach would affirm the importance of Māori knowledge systems and ensure that decision-making processes are guided by a holistic understanding of the potential impacts of gene technology on Aotearoa's unique ecosystems and cultural values.	Iwi/hapū	*Refer to Item 286 recommending adding criteria and requirements for appointment of the MAC members.*
293		122	Recommend the MAC has sufficient funding, access to technical expertise, and capacity-building resources to perform its duties effectively	Individual	**No change proposed.** This is an operational matter.
294		122	That the Committee's role should be expanded to cover advice on broader Treaty considerations such as commercial impacts on settlement assets.	Sector group	**No change proposed**. *Refer to Item 18.*
295		122	That the Bill incorporate a more inclusive, empowering role for the MAC and Māori with respect to tikanga, with the submitter considering the success of this Bill is contingent on the provision of Māori sovereignty and the safeguarding of the natural environment and its resources for future generations. The submitter considers that 'material adverse effect' does not adequately comprehend the nature of mauri, mana, and whakapapa of taonga species and the Māori relationship to the environment. A 'material adverse effect' implies a significant reduction in the value or profit of a company or service. They commented that gene technologies pose a threat to kaitiakitanga not only through economic implications, but also through the disruption of the integrity of taonga, whakapapa, and mauri, and that furthermore, the current language of the Bill insinuates that the functions of	Research institute, Researcher	**No change proposed**. *Refer to Item 18.*

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			the MAC are only to identify adverse effects, and environmental risks posed by an activity. The MAC may identify proposed activities to have emancipatory or positive outcomes through utilisation of gene technologies. The submitter recommended the term "material adverse effects" be removed from the Bill, with advice from the MAC instead given in relation to kaitaiki relationships more generally.		
296		123	Adopt the PVR Act model (or similar) for the committee, giving effect to the Crown's obligations to te Tiriti and that the committee is a decision making body for organisms where direct kaitiaki relationships exist.	Research institute, University, Individual, Dairy, E-NGO, Organics, Iwi/hapū, Māori NGO, Māori sector	**No change proposed**. *Refer to Item 286.*
297		123	An Iwi/hapū proposed implementation of tikanga-based evaluation by the Regulator, stating that a range of tikanga Māori based frameworks for gene technology evaluation have been developed over the past 25 years by various Māori scholars. These frameworks were developed for various applications including genetic modification, and typically by teams of Māori academics with an understanding of both the specific gene technology, as well as tikanga and mātauranga Māori.	Iwi/hapū	**No change proposed**. We consider this to be an operational matter for the Regulator and the MAC.
298		123	Waikato-Tainui stated concerns that the Bill does not clearly provide a pathway for Waikato-Tainui to exercise its mana whakahaere by participating in decision making under the Bill, including through the MAC. It noted it has existing frameworks and mechanisms that provide Waikato-Tainui with governance and decision-making roles, provided for in the Waikato-Tainui Raupatu Claims (Waikato	Iwi/hapū	**No change proposed.** *Refer to Item 18.*

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			River) Settlement Act 2010, where specific provision is made for co-management and the protection of Māori interests in environmental matters. Its submission also noted that the MAC could not speak on behalf of Waikato-Tainui and it considered the Bill needs to be amended to enable Waikato Tainui to directly input into decision making regarding applications within its takiwaa.		
299		123	That the Bill marginalises Māori as it does the public and wider community. It limits the scope of the MAC to gene technology issues involving indigenous species or "material adverse effects on kaitiaki relationships". Therefore the Bill does not take into account whakapapa and a range of cultural and ethical considerations, including mana, mauri, whakapapa and wairua, while also recognising that Māori concerns extend beyond indigenous species.	Organics	**Amendment proposed elsewhere.** The change recommended will broaden the scope of the MAC to include consideration of non-indigenous species of significance. *Refer to Items 17, 19, 20, 21, 65, 70, 126, 300, and 337.* *This issue is discussed further in Chapter 3.3.*
300		123	Submitters noted that Te Tiriti o Waitangi rights and interests extend beyond the current framing of 'management of risks to Māori kaitiaki relationships with indigenous species.' For the Committee to have any chance of working, this scope must be broadened to include whakapapa and a range of cultural and ethical considerations, including mana, mauri, and wairua, while recognising that Māori concerns extend beyond Indigenous species and also includes inter alia locality.	Researcher	**Amendment proposed elsewhere.** The change recommended will broaden the scope of the MAC to include consideration of non-indigenous species of significance. *Refer to Items 17, 19, 20, 21, 65, 70, 126, 299, and 337.* *This issue is discussed further in Chapter 3.3.*
301		123	An individual submitter recommended deleting any reference to the MAC, kaitiaki relationship, and any actions pertaining to, in particular Subpart 4 in its entirety.	Individual	**No change proposed.**

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
					Government policy is to recognise Māori rights and interests under the gene technology regulatory regime through specific provisions in the Bill. *Refer to Item 18*.
302		126	The PCE recommends that clause 126(1) of the Bill should be amended so that any licence application or proposal that relates to an activity involving, or that is likely to impact on, indigenous species is referred to the MAC. Corresponding amendments will also be required for clauses 21(1)(a), and 122 to ensure alignment for any activity, or regulated organism, involving indigenous species.	PCE	**No change proposed.** Government policy is for MAC advice to be compulsory only for activities in relation to a regulated organism that use an indigenous species as a host organism. The change suggested by the submitter would increase the scope of referrals to the MAC significantly, to any activities involving an indigenous species, reducing efficiencies and requiring reconsiderations of resource. Clause 122 allows the Regulator to request advice from the MAC on matters beyond what it is required to seek MAC advice on under clause 126.
303		126	Include specific provisions to protect Māori cultural sites and traditional knowledge from the negative impacts of GM organisms.	Individual	**No change proposed**. The Regulator will be making technical decisions about managing risk. Government has decided to focus the scope of compulsory MAC advice to the Regulator on kaitiaki relationships and indigenous species. Extending the scope of MAC advice to place-based and cultural considerations would have implications for the scope of the regime. *This issue is discussed further in Chapter 3.3.*
304		126	That provision should also be made for the Regulator to receive advice on the effects for kaitiaki, Iwi and hapū of applications for organisms not hosted by indigenous species, noting that all gene technologies released into the environment have potential to effect indigenous species, whether they are the host organism or not. This could	Iwi/hapū, University, Researcher	**No change proposed.** *Refer to Item 286 and 292.*

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			include hybridisation with indigenous species or other unforeseen implications.		
305		126	That given the Bill must recognise and give effect to the Treaty of Waitangi under Section 4, it would be appropriate to expand this remit to include other activities that impact Māori. Examples include areas of Māori health and activities that may impact culturally significant land or commercial interests of Māori.	University	**No change proposed**. *Refer to Item 18.*
306		128	Recommendation to provide sufficient guidance for Māori entities navigating the proposed activities, application, and implementation of gene technologies. The primary legislation must incorporate clear guidelines, particularly in the definition and assertion of 'kaitiaki relationships', that are respectful of tikanga Māori. This is critical to ensuring Māori maintain tino rangatiratanga over Indigenous species, lands, forests, and other resources, as per Article Two of Te Tiriti o Waitangi.	Research Institute	**No change proposed.** The Bill includes a definition for kaitiaki relationship and process for when a kaitiaki relationship has been asserted (clause 128) and when general information is provided (clause 131). *This issue is discussed further in Chapter 3.3.*
307		128	A submission sought to strengthen provisions that uphold the collectively held rights and responsibilities of kaitiaki Māori, allowing for active participation in decisions affecting taonga species and ecosystems, by: a) Clarifying the threshold to 'demonstrate' a claim to a kaitiaki relationship with a taonga. b) Including a requirement for applicants to ensure all 'relevant' kaitiaki have been consulted on any application involving a taonga species.	Māori NGO	**No change proposed.** Officials anticipate the Regulator to develop operational guidance to be developed in respect of kaitiaki relationships, and that this would be supported by the MAC, noting one of the MAC's functions at clause 122 is to issue engagement guidelines and provide advice to applicants for licences. The requirements for public consultation set out in the Bill intend to balance transparency and efficiency.
Subpart 5 - Subcommittees					

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
308		132	Recommend establishing a primary sector sub-committee to the TAC. Such a grouping would work alongside the Regulator and Government in designing appropriate regulatory settings for co-existence, rather than relying on industry self-regulation.	Agriculture	**No change proposed.** Clause 132 enables the Regulator to create such a subcommittee, if desired. We note MPI is developing coexistence frameworks. *This issue is discussed further in Chapter 3.1.*
309		132	A submitter considered that the TAC may be overwhelmed in the first years of the regime and that it should be able to delegate some of the initial assessments to local committees within the larger research organisations (e.g. Universities and PROs). However, as written, there is no specific power within the TAC to delegate any activity to local committees (but that the Regulator does have that power).	Researcher	**No change proposed.** This proposal is not consistent with the policy intent of the role of the TAC in providing advice to the Regulator. However, we note that the Bill provides for the Regulator to establish subcommittees of both the TAC and MAC for the purpose of advising on specific matters or classes of matters (clause 132).

Part 5: Miscellaneous

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
Subpart 1 – Reviews					
310		134	Recommend broadening the scope of clause 134 and Schedule 3, so others who are also directly affected by a decision have the ability to seek a review. This clause could be modelled on section 120 of the RMA, which allows any person who made a submission on an application or review of consent conditions to appeal to the Environment Court (in addition to the applicants and consent holders themselves).	Legal	**No change proposed.** As for the Australian regime, the Bill proposes a review process be available to an applicant and a licence holder. Other people who may be directly affected by a decision can use the appeals process. The review process is a first opportunity for the Regulator to identify and correct any factual errors in their own decision. Enabling parties other than the applicant or licence holder to access this process would introduce uncertainty about decisions for licence holders and undermine the enabling intent of the regime. *Refer to Item 315.*
311		134	That the scope is widened further to persons that represent aspects of the public interest (e.g. commercial or environmental groups) who think the risks have not been appropriately considered, those persons should also be able to seek a review of the Regulator's decision.	PCE	**No change proposed.** *Refer to Item 310.*
312		135	That an independent process should be established for reviewing decisions by the Regulator, rather than the Regulator doing this itself.	Dairy, Agriculture, and E-NGO	**No change proposed.** The purpose of the review process is a first opportunity for the Regulator to identify and correct any factual errors in their own decision. This is consistent with Chapter 28 of LDAC guidance. If it was desirable to add a dimension of independence to the review, officials note there are alternative entities that could be considered to carry out a review of the facts of the Regulator's decision –

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					for example, another employee of the EPA, or an independent expert, or even a recognised overseas authority, if they met relevant criteria such as being suitably qualified. Officials note the facts of the Regulator's decisions will be of a technical and scientific nature and that the pool of such expertise in New Zealand is limited. On balance officials see the purpose of the internal review as being to check for factual errors, prior to a court-based process, and therefore we consider that the existing provision satisfies that purpose. It is also a low-cost first step for what is expected to be a small volume of decisions eligible for review. Note that on matters of process, Part 5 subpart 2 provides for appeal on points of law by anyone directly affected by a decision, consistent with the HSNO Act regime.
313		135	Suggest amending clause 135 to specify an appropriate timeframe for making a decision on a review, in order to provide more clarity and certainty for all parties involved in the review process.	Legal	**No change proposed**. Officials consider the current provision at clause 135 of "…as soon as reasonably practicable…" is appropriate as it requires the Regulator to act in a timely manner in the circumstances. We note that Australian legislation on which the review process is modelled does not indicate a timeframe for carrying out a review. Rather than putting a particular timeframe in, given there could be varying reasons for and requirements of a review, the Bill uses similar language to section 144(6) of the Climate Change Response Act 2002 ("the EPA must, as soon as practicable, give notice to the person who requested the review of the decision on the review, and of the reasons for it").

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Subpart 2 – Appeals					
314		139	That the District Court, which is the only Court which will be able to consider questions of fact under this Bill, is a generalist court with a high workload and a high volume of cases.	Legal	**No change proposed.** The Bill provides for a small number of decisions that may be appealed to the District Court (these are set out in clause 139 and relate to compliance orders and seizure of property or disposal of material). These are generalist matters and appropriate to be considered by the District Court.
315		Part 5, Subpart 2	Raised whether the Bill should provide for an appeal on facts to the Environment Court	Legal	**No change proposed.** In line with Government policy decisions, the Bill's appeals provisions are consistent with comparable HSNO Act appeals provisions, which allow appeal to the High Court on questions of law only. MBIE sought advice from the Ministry of Justice on the potential for a merit-based appeal to the Environment Court. Officials at the Ministry of Justice agreed with the current policy position of aligning appeal rights with the current HSNO Act regime. They noted that the Environment Court's current technical focus is on land use, environmental contaminants, and other resource management issues; gene technologies are a distinct area, and the Environment Court could require upskilling or other measures. Potential operational and resourcing impacts on the Environment Court would also need to be carefully worked through, before recommending this jurisdiction to hear appeals on questions of fact.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
316	69	142	Noted that the Bill contains provision for appeals directly to the High Court on a point of law by 'eligible persons', being 'a person directly affected by a decision' (clause 142(4)). Unlike the definitions contained in Schedule 3, the meaning of 'a person directly affected by a decision' is ambiguous. To provide clarity to applicants and decision-makers on the appeal process the submitter recommended that consideration be given to further defining eligible persons.	Seeds	**Amend clause 142** to clarify that people other than applicants and licence holders may appeal a decision. The policy intent is not to limit the appeals process to only applicants and licence holders. Rather, it is to allow the broader set of people who may be directly affected by a licence decision a pathway for appeal. This broader set would include but is not limited to people who may have submitted on the draft RARMP for the relevant licence decision, or people/groups who have asserted a kaitiaki relationship. We note the HSNO Act section 126(1) as having comparable intent.
317		142	A submitter suggested it was unfair that appeals to the courts can only be taken on matters of law by 'eligible persons' which is only applicants and licence holders.	E-NGO	**No change proposed**. *Refer to Item 316.*
Subpart 3 – Notices and Standards					
318		149	That the Regulator under the Act create clear guidance on key terms like "sequences of concern" and the procedure for screening customers, including determining legitimate end-uses for potentially dangerous nucleic acids. The Regulator should be allowed to conduct regular empirical evaluations of industry screening practices and the broader risk landscape we recommend the Regulator has the mandate to update screening requirements.	Think tank	**No change proposed**. The policy intent is for regulations for SNA screening requirements (clause 157) to outline the role, functions and powers of relevant agencies, including the Regulator.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
319	70	149	That clause 149(5) be amended: 149(5) **If required by regulation**, no person may act as a provider, manufacturer, or third party vendor unless - (a) they are approved by a notice issued under this section; and (b) they comply with the conditions specified in the notice."	Biotech organisation	**Amend clause 149(5)** by adding 'If required by regulations' to the start of the clause, to easily cross-reference with clause 157.
320		150	A submitter supported the use of private standards and assurance, and regulatory recognition of private standards so they can be used to support government to government assurances when these are required to facilitate trade. It suggested adding subclause to clause 150(3) to support this: (e) actions, documentation and audit processes to provide market and import and export assurance that the definition for the registered exempt organism or activity is met	Horticulture	**No change proposed.** MPI is responsible for standards for trade and market access.
321	71	150	Clause 150 does not specify that public consultation is required for the issuing or approval of standards, only when standards are amended, revoked or replaced.	MBIE	**Amend clause 150** to add a similar consultation requirement for the issuing and approval of standards as under clause 150(4).
Subpart 4 – Information and sample sharing					
322		151	A submitter recommended that clause 151 be amended to add a subclause stating "Nothing in this section limits the Official Information Act 1982 or Local Government Official Information and Meetings Act 1987 (LGOIMA) or Privacy Act 2020." It also considered that the provisions of clause 151 could lead to claims that a statutorily-backed obligation of confidence has been created when	Other, Individual	**No changes proposed.** It is not clear how either the OIA or LGOIMA are relevant to this section. The provision enabling agencies to impose conditions on each other does not override the OIA.

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			information is shared between two government agencies, and thus override the OIA.		PCO have advised that there is not a need to include a provision that the Privacy Act applies, as the Bill does not meet the threshold of displacing the Privacy Act. *This issue is discussed further in Chapter 3.6.*
323	72	151	Amend language at 151(5) to align with the Privacy Act. Currently the Bill reads "An agency may impose conditions the agency thinks fit relating to the disclosure…". The language should be "reasonably believes", not "thinks", to align with the Privacy Act.	OPC	**Amend clause 151(5)** from "thinks" to "reasonably believes" for consistency with comparable provisions in the Privacy Act.
324	73	151	Amend the list of Acts to allow disclosure to agencies that perform functions of duties or excess powers under any other Act specified for the purpose of section 151(3) by Order in Council.	OPC	**Add** to the list of Acts at clause 151(3), <u>any other Act specified by Order in Council.</u>
325	74	151	Add the Health and Safety at Work Act 2015 (HSWA) to the list at clause 151(3). Even if the Regulator can add Acts to the list by Order of Council, it would be more efficient to name this one in the Act to save later analysis.	MBIE	**Add** the Health and Safety at Work Act 2015 to the list of Acts at clause 151(3).
326	75	151	The way 151(4)(a) and (b) are written may be too restrictive for the necessary information sharing. The Regulator may want to share information supplied under this Bill with other agencies to support the facilitation of this Bill (rather than sharing information under the Bill, for the purposes of another Act).	MBIE	**Add** an additional subpoint to clause 151(4) to allow for information sharing under this Bill <u>for the purposes of this Bill</u>.
327	76	151	Clause 151(2)(a) and (b) are different – private information is only that supplied or obtained under (or for) the purposes of the Act but this limitation doesn't apply to confidential or commercially	MBIE	**Amend clause 151** as follows: • **remove** "that is supplied or obtained under or for the purposes of this Act" from clause 151(2)(a) as151(4) deals with the "obtained

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			sensitive info (as two separate types of information). This also applies to 152(2) (as discussed in the next item) Also 151(2)(a) replace "and" with "or" - as these are two separate types of information.		for the purpose of this [or another] Act" point; and 151(2) is not about information obtained or for the purpose of this Act, it relates to information sharing with other agencies which may not be for the purposes of this Act. • **replace** "and" with "or" in clause 151(2).
328	77	152	As above, clause 152(2)(a) and (b) should be synchronised. Additionally, replace "and" with "or" in 152(2).	MBIE	**Amend clause 152** as follows: • **remove** "that is supplied or obtained under or for the purposes of this Act" from clause 152(2)(a). • **replace** "and" with "or" in 152(2).
329	78	152	The OPC commented that as the Bill explicitly speaks to some parts of the Privacy Act - e.g. collection, disposal, storage - but is silent on others, this suggests that the Privacy Act as a whole might not apply. This is relevant for clauses 151 and 152.	OPC	**Amend clauses 151 and 152** to clarify the relationship between clause 151 and Information Privacy Principles (IPPs) 2 and 11, and the relationship between clause 152 and IPP 12. *This issue is discussed further in Chapter 3.6.*
330		153	Noted that engagement with Recognised Overseas Authority (section 153), particularly in regard to declaring pre-assessed activities need a better description of the standards required to control the information to be shared. Levels and requirements of confidentiality need to be better described, so at the very least they contain conditions which are no less onerous than those imposed on the Regulator with respect to the confidential information provided.	Biotech organisation, Agriculture, Agritech	**No change proposed.** Safeguards for information sharing with overseas regulators can be managed operationally by utilising clause 153(3) to include information protection requirements in agreements.
331		153	Noted it is important that New Zealand regulators, who are accountable to the New Zealand public, regulate gene technologies in New Zealand alone,	Dairy	**No change proposed.** *Refer to Item 194.*

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			rather than overseas regulators that have no mandate or jurisdiction.		
332	79	153	Reference to joint assessments with applications under the HSNO Act needs to be deleted as clause 153 only relates to disclosure of information where the Regulator and a recognised overseas authority have agreed to undertake joint assessments under the Act. The clause as currently written also limits the ability to disclose information for compliance monitoring.	MBIE	**Amend clause 153** to clarify that the Regulator may disclose information under an agreement made with a recognised overseas authority to undertake joint assessments of licence applications under this Bill **Amend 153(2)(b)(ii)** to include language like "help monitor compliance with this Act or a relevant law in the overseas country."
333	80	153	Amend clauses 152 and 153 to permit disclosure of information overseas for the purpose of ensuring that New Zealand complies with its reporting requirements under the Cartagena Convention and Cartagena Protocol.	EPA	**Add** a **clause to explicitly allow information sharing** with the Biosafety Clearing–House established under the Cartagena Protocol.
Subpart 5 – Regulations					
334		155	Recommends creating the ability for the Regulator to fully release an organism; and create the authority in clause 155 for regulation to be made to deregulate an organism or technology. While this Bill is meant to be more enabling than the HSNO regime it omits the ability of the Regulator to fully release an organism. The power for an organism to be deregulated is also missing. These provisions exist in the HSNO Act without controversy so these omissions are a significant step backwards and will reduce flexibility in the future.	Biotech organisation	**No change proposed.** Clause 163 allows for regulations to exempt organisms from the operation of the Bill, which is equivalent to deregulation. Under HSNO, if a new organism was released, following release it would cease to be considered a "new" organism. This contrasts with the Bill, where a licence would be issued for an environmental activity with a regulated organism.
335	81	155	A submitter recommended modifying clause 155 to enable the declaration of what is or isn't a	Biotech organisation	**Add a regulation making power** to declare organisms or classes of organisms that are not regulated organisms.

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			"regulated organism", a "conventional process" or a "gene technology". The submitter also recommends that clause 163 (1)-(3) and clause 12(1)(c) be deleted and replaced with a power to make regulation under clause 155, and the following subclause be added to clause 155 [additions in italics]: 155 Regulations (1) The Governor-General may, on the recommendation of the Minister, by Order in Council, make regulations for 1 or more of the following purposes: (a) the matters listed in any or all of sections 156 to 163 and 165: … *(g) prescribing for the purposes of this Act:* *(i) organisms or categories of organisms which are regulated organisms* *(ii) organisms or categories of organisms which are not regulated organisms (iii) processes or technologies which are gene technology* *(iv) processes or technologies which are non-regulated* *(h) providing for anything incidental that is necessary for carrying out, or giving full effect to, this Act.*		**Add a regulation making power** to declare technologies that are not gene technologies. *This issue is discussed further in Chapter 3.12*
336	82	155	Noted the regulation making power in clauses 155 (d) for fees, charges, and levies may require additional detail to improve the usability of the power for making levies. This may include adding detail on:	MBIE	**Add detail on the levy making power** in line with similar powers, for example, in section 168 of the Offshore Renewable Energy Bill and section 344 of the Therapeutic Products Act 2023.

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			• the structure and content of the regulation • that the regulation may specify the people or classes of people required to pay a levy • when and how the levy is to be paid • who may collect a levy • and other matters in line with best practice for cost recovery powers. This reflects the approach taken with levy making powers in other Acts.		The policy intent is for the Regulator to be able recover the direct and indirect costs of administering the Act in line with the principles of cost recovery in clause 177. This regulation making power needs to be flexible to future proof the ability to recover these costs.
337	83	155	Officials' recommend that the Bill provide for kaitiaki relationships with indigenous and *non-indigenous species of significance*, based on the approach used in the PVR Act. We note that the list used in the PVR Regulations 2022 is based on a point in time and may not accurately capture all non-indigenous species of significance and recommend that the Bill include provision a regulation making power so that an explicit list of non-indigenous species of significance can be developed, consulted on, then agreed by Cabinet.	MBIE	**Add a new regulation making power** for the Regulator to develop and consult on non-indigenous species of significance to be added as a list in the Bill's Regulations. *Refer to Items 17, 19, 20, 21, 65, 70, 126, 299, and 300.* ***Dependencies with recommendations 13 and 14 regarding amendment to kaitiaki relationship.*** *This issue is discussed further in Chapter 3.3.*
338		157	That the provisions regarding SNA are too detailed and have no ability to consider future developments in DNA synthesis, and should be moved to secondary legislation.	Seeds, Biotech organisation, Researcher, Agriculture, Individual	**No change proposed.** The specific requirements for SNA providers and manufacturers are to be set under secondary legislation. *This issue is discussed further in Chapter 3.13.*
339		157	That there should be provisions in the secondary regulations that ensure suppliers and manufacturers of SNA (whether at home or abroad) should be of good standing to reduce risk of	Research institute	**No change proposed.** This is a matter for secondary legislation development and not relevant to the development of the Bill.

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			unlawful or unethical production and distribution. This may include a register of approved suppliers.		*This issue is discussed further in Chapter 4.*
340		157	A submission noted the intent of this section is to regulate the production of synthetic genes that encode unwanted protein products (such as toxins). It noted that most synthetic DNA used at Waipapa Taumata Rau | University of Auckland are short oligonucleotides for cloning or sequencing, and that these have been unregulated for decades and pose no risk to human health or the environment. It asked that consideration be made to allowing the production of oligonucleotides to be free from regulation. Otherwise, the Bill will risk introducing an additional unwarranted compliance burden to researchers.	University	**No change proposed.** The intent of the provisions for SNA screening is to not regulate short oligonucleotides, such as those used for cloning or sequencing. The intention is that the regulations, once created, would align with those of the UK and US which require that screening should be performed on sequences 50 nucleotides or longer. Requirements will not be placed on imports or the use of SNAs. Requirements will only be placed on New Zealand-based commercial providers of SNAs and New Zealand-based manufacturers of nucleic acid synthesis equipment. *This issue is discussed further in Chapter 3.13.*
341		157	That the Bill remove all provisions related to the screening of SNAs and benchtop synthesisers and instead New Zealand adoption more flexible, non-legislative guidance principles, similar to those implemented in other countries like the US and UK. These approaches typically focus on routine surveillance and international collaboration on 'sequences of concern' (SOC) databases, as exemplified by the Australia Group guidelines and the ISO 20688-2:2024 standards. The submitter specifically recommends aligning with these international best practices by updating the 'Import Health Standards: Biological Products' to incorporate guidelines for SNA providers and establishing a system of voluntary import permits for SOCs. This alternative approach would ensure that valuable research is not unnecessarily impeded	Research institute	**No change proposed.** Proposed requirements are based on those proposed by the US and UK, which place requirements on commercial providers of SNAs and manufacturers of nucleic acid synthesis equipment. Requirements will only come into force when regulations have been developed, consulted on, and approved by Order in Council. Non-legislative guidance may be used prior to legislative requirements coming into force. Officials consider that placing requirements on imports or establishing a system of voluntary import permits is likely to be administratively burdensome for regulatory agencies and potentially confusing for researchers in New Zealand.

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			by excessive and ultimately ineffective bureaucratic hurdles.		*This issue is discussed further in Chapter 3.13.*
342		157	Recommend implementing mandatory nucleic acid synthesis screening requirements based on international best practices (e.g., the Common Global Baseline for Nucleic Acid Screening). Establish clear guidelines on AI-assisted synthetic biology, including risk assessments for AI generated sequences. Introduce a national biosecurity monitoring system for gene technology applications to track and evaluate unintended consequences of synthetic biology advancements.	Individuals	**No change proposed.** The proposed SNA regime, once established under regulations, would set mandatory requirements for SNA screening for New Zealand-based commercial providers of SNA and New Zealand-based manufacturers of nucleic acid synthesis equipment. Officials agree that both the recommended guidelines on AI-assisted synthetic biology and a national biosecurity monitoring system would have merit. However, we consider that the Bill already provides the ability for the Regulator to issue guidelines to the New Zealand research community (clause 110(g)), including guidelines for the use of AI in the design of regulated organisms. Officials have also recommended that clause 15(f) be amended so that the Regulator may also impose conditions requiring that data and samples be verified, which would include the ability to request verification of genetic changes made to regulated organisms. *This issue is discussed further in Chapter 3.13.*
343		157	That AI-assisted genetic engineering tools be subject to regulatory review before use in New Zealand. Establish an AI and biosecurity risk advisory panel to provide expert assessments on AI-driven gene editing technologies. Encourage cross-sector collaboration between biosecurity agencies, AI regulatory bodies, and international gene synthesis screening groups.	Individual	**No change proposed.** Potential concerns raised in this submission will in part be addressed through the SNA provisions of the Bill. While the Regulator will be enabled to issue guidance on the use of AI in the design of regulated organisms, regulatory requirements on the use of AI is also addressed (or would be better addressed) through other regimes.

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344		157	That nucleic acid synthesis is covered and policed by intention and purpose, rather than by sequence. Although it might be feasible to screen imported or locally made nucleic acids for undesirable sequences against a limited data base, this would lead to delays in ordering routine nucleic acid sequences. Suggest regulations which include border screening of nucleic acid or nucleic acid synthesis equipment which is being supplied directly (not through an approved supplier or third party).	Individual, Biotech organisation	**No change proposed.** Requirements will not be placed on imports or the use of SNAs. Requirements will only be placed on New Zealand-based commercial providers of SNAs and New Zealand-based manufacturers of nucleic acid synthesis equipment. *This issue is discussed further in Chapter 3.13.*
345	84	158	Suggest clause 158(b) is amended from "a requirement that a notifiable activity be undertaken in a containment facility" to "a requirement that a non-notifiable activity be undertaken in a containment facility"	University, Researcher	**Amend clause 158** to correct the reference from 'notifiable activity' in the brackets of (b) to be 'non-notifiable activity'.
346		158	That the Regulator be able to prescribe requirements for non-notifiable and notifiable activities that do not utilise current containment standards.	University	**No change proposed.** Clause 158(b) provides 'containment facility' as an example but the policy intent is that other requirements may also be specified, including containment standards.
347	85	158	Recommend that wider consultation is a requirement for creating regulations relating to non-notifiable activities. Instead, the Bill allows the Minister to solely engage with the Regulator (clause 167).	Dairy, Biotech	**Amend clause 167**, the procedure for making regulations, to ensure wider consultation is mandatory when making regulations. Officials defer to the PCO to consider whether to replace 'or's' after clause 167(1)(a) and (b) with 'and's. It is important that the Minister consults the Regulator on the proposed regulations **and** consults affected persons or representatives of persons in addition to public consultation at clause 167(1)(a).

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
348		158	That the Bill does not adequately ensure the appropriate sequencing of the commencement of provisions so that declarations on non-notified activities occur after regulations have been created that prescribe criteria and requirements related to non-notifiable activities under clause 158. This means that declarations around non-notified activities could occur without more detailed, fulsome criteria as to what activities should be permitted.	Dairy	**No change proposed.** *Refer to Item 3.*
349	86	159	That "requirements" should be replaced with "conditions and cross-reference to this clause should be made in clause 48(3)(c). Requirements aren't mentioned anywhere else in the Act for notifiable activities and there's no empowering provision for conditions.	MBIE	**Amend clause 159** to replace "requirements" with "conditions", and cross-reference this clause with clause 48(3)(c).
350	87	New	A power is required to make regulations prescribing criteria that must be satisfied for an activity to be classified as a pre-assessed activity. *[Note if regulations are not also empowered to prescribe conditions, then conditions can only be imposed by the Regulator – this will be inconsistent with non/notifiable activities].*	MBIE	**Insert a clause empowering regulations** to prescribe the criteria for the Regulator to be satisfied with before declaring an activity as a pre-assessed activity.
351	88	160	Clause 160(2)(f) enables regulations to be made for timetables relating to advisory bodies providing advice under clause 27. However, clause 27 does not mention advisory bodies. Clause 160(2)(h) refers to clause 42 and 46 which already prescribe the time period as 30 working days – meaning this clause isn't needed. Similarly clause 160(2)(i)(ii) refers to clause 49(4) which already prescribes the time period.	MBIE	**Amend clause 160 to:** • **delete** 160(2)(f), (h), and (i)(i). • **add** to 160(2) a timetable for the Regulator to make decisions about approving manufacturers, providers and third-party vendors.

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			There should not be a time period on the Regulator to issue declarations relating to non-notifiable activities under clause 160(2)(i)(i). Clause 160(2) should also include timetables for applications in relation to manufacturers, providers and third party vendors.		
352	89	160	Clause 160(3) should specify that the Regulator can extend, shorten, pause, reactivate or replace timetables rather than having to specify in regulations. This will be needed to enable the Regulator and EPA to align time periods for joint applications. A provision similar to section 59(6) of the HSNO Act is required to ensure that, where public submissions are invited in relation to an application or declaration, the time limits for such submissions must be extended if appropriate to give effect to Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) or Trans-Pacific Partnership Agreement (TPP).	MBIE	**Amend clause 160** to: • at 160(3), enable the Regulator to extend, shorten, pause, reactivate or replace the timetables set in regulations. • insert a provision similar to section 59(6)-(9) of the HSNO Act, to ensure that, where public submissions are invited in relation to an application or declaration, the time limits for such submissions must be extended if appropriate to give effect to CPTPP or TPP provisions.
353		161	Recommend that as a matter of priority the Government prescribe how these risk assessments are undertaken to ensure that they are (a) scientifically robust and lead to accurate characterisation of the risks to human, animal and plant health, and the environment, (b) are conducted in a systematic and consistent way, and (c) that the risk mitigation measures subsequently developed are risk-proportionate. The prescription under clause 161 should carefully outline the scientific method that is to be taken for risk assessment.	Research institute, E-NGO	**No change proposed.** Clause 161 outlines the requirements that the submitter recommends**.** The policy intent is that as an operational measure the Regulator will develop and publish a Risk Analysis Framework prescribing the methodology to give effect to the Bill and Regulations. *This issue is discussed further in Chapter 4*.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
354	90	161	The power to make regulations prescribing criteria and conditions for licensed activities and regulations prescribing conditions to manage risk is not necessary because the policy intent is not to impose further criteria or conditions in regulations. Instead the Regulator will have the power to impose conditions after undertaking a RARMP in accordance with the regulations.	MBIE	**Delete clause 161(a) and (c).** These are duplicative of the power that the Regulator will have to impose conditions after undertaking a RARMP.
Power to make further exemptions from operation of Act and non-regulated activities					
355	91	163	Due to potential ambiguity in interpreting 'conventional processes' officials recommend replacing reference to conventional processes in clause 163(2)(a) with reference to the prescriptive list of technologies out of scope of the regime as per recommendation 94 to deliver improved user clarity on outcomes considered exempt due to equivalence to technologies out of scope of the regime.	MBIE	**Amend clause 163(2)(a)** to reflect that regulations cannot be recommended unless that organism or class of organisms is indistinguishable from those that are either not regulated by the Act, or could be produced using a technology that is not regulated by the Act. *Refer to Items 335 and 363.* ***Dependencies with Recommendations 81 and 94.*** *This issue is discussed further in Chapter 3.12.*
356	92	163	That the current drafting suggests that a conventional organism with the same genetic structure already exists, recommend amending wording to indicate they *could* be produced through conventional means.	Biotech organisation	**Amend clause 163(2)(a)** to reflect that an equivalent conventional organism is not required for an organism to meet the criteria of exempt, only that it could be produced. *This issue is discussed further in Chapter 3.12.*
357	93	163	Delete "gene-editing techniques or" from clause 163(1)(b).	MBIE	**Amend clause 163(1)(b)** to only refer to gene technology to ensure consistent language with the definition of gene technology.

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358		163	Recommend that decision-making powers for exemptions should sit with the Regulator, not the Minister.	Organics, Iwi/hapū, E-NGO, Biotech organisation	**No change proposed.** The Minister's decision-making power is appropriate regarding regulation to exempt products of gene technology from the regulatory regime. Regulations are delegated legislation made by Order in Council.
359		163	Support the criteria in the Bill for determining whether very low-risk organisms are exempt from regulatory risk assessment. However for plants such activities and the resulting organisms must be registered in a manner that does not compromise the ability to protect the intellectual property generated by the activity or organism through i.e. Patents and PVR Act applications.	Dairy, Biotech organisation, Horticulture	**No change proposed.** No aspect of the Bill limits the PVR Act.
360		163	That the exemption process should follow an evidence-based approach (robust risk assessment) and exemptions should have mandatory sequencing requirements first and provide evidence that there are no 'off-target' mutations. There needs to be clear distinction between SDN-1 and SDN-2 methods.	Individuals, Research institute, E-NGO, Researcher, Māori NGO	**No change proposed.** The development of secondary legislation regarding what organisms will be exempt, and in the future what technologies may be exempt, will follow an evidence-based approach. Distinctions regarding modification techniques will be addressed by detail to be provided in secondary legislation. *This is discussed further in Chapter 4.*
361		163	That activities and organisms relevant to the agricultural sector could have a streamlined pathway without requiring a declaration under the clause 48 notifiable activities pathway, following an appropriate risk assessment (for example to accelerate contained activities), but should not be able to be entirely exempt from the regulatory regime.	Dairy, Organics, Individual, Researcher	**No change proposed.** Government objective for the new regime is to have risk proportionate regulation.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
362		163	Suggest adding a reference to clause 163(2)(b) to 'trade and market access risks' so Ministers may not recommend regulations for non-regulated activities unless the technology or organism in question creates a no more than minimal level of risk to trade and market access.	Dairy, Agriculture	**No change proposed.** The Bill's purpose is modelled on the Australian regime, which does not consider trade and market access risks in the Regulator's decision making.
363	94	163(4)	Recommend removing the default deregulation of organisms specified in the Australian Regulation schedules at clause 163(4)(c) or establish a process whereby a New Zealand regulator determines which of the gene technologies in the Australian Regulations ought to be exempted from New Zealand regulations.	Dairy, Agriculture, Other, Organics, Researcher, Horticulture	**Add a supplementary prescriptive list** of items that are not regulated by this Act, including organisms that are not regulated organisms and technologies that are not gene technologies, consisting of items listed in HSNO regulations, the relevant HSNO statutory determinations, and the Australian Regulations. **Amend clause 163(4)** to refer to the prescriptive list as items not regulated by the Act and **delete** reference to the specific legislation in (a)-(c). Note that clause 163(1) provides regulation making power for exempting organisms or gene technologies, as such the equivalent items from Schedule 1 and 1A of Australia's Gene Technology Regulations 2001 will be provided for in regulations. *Refer to Items 41, 56, 57, 75, and 355.* ***Dependencies with recommendations 7, 11, 12, 17, and 91 regarding removing references to conventional processes.*** *This issue is discussed further in Chapter 3.12.*
364		163 (4)	A submitter agreed with the inclusion in clause 163(4) of the processes and organisms which are not regulated as this will make them less vulnerable to political interference, but consider these are more appropriate in the definitions of "Conventional Processes" and "Regulated Organisms".	Biotech	**No change proposed.** *Refer to Item 363.*

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
365		163	That all gene technology activities, including the proposed 'exempt activities', must be registered for traceability, regardless of whether the resultant GMOs advance to regulatory assessment and release.	Agriculture, E-NGO, Organics	**No change proposed.** Officials consider that a register of exempt organisms has merit and could be considered further. *This issue is discussed further in Chapter 3.1.*
366		163	Recommend a two-year (minimum) transitional period whereby no technologies or organisms can be fully exempted from the regulation. This addresses a sequencing issue in the Bill whereby declarations on non-notified activities can currently be made before underpinning regulations have been created that would prescribe the criteria and requirements relating to non-notifiable activities.	Agriculture,	**No change proposed.** Clause 163 relates to exemptions, not non-notifiable activities. The criteria for making exemptions are set out in clause 163(2). This is not reliant on any other regulations setting out criteria or requirements for exemptions.
367		163	Suggested that the Bill does not adequately and clearly define 'conventional processes' and 'cannot be distinguished' It is essential that the major terms of the legislation are defined clearly and unambiguously in the Bill.	Researcher, Agriculture, Seeds, Dairy, Agritech, Research institute, Biotech organisation, Horticulture	**No change proposed.** Concern is addressed through recommendation 7 to delete definition of conventional processes. *This issue is discussed further in Chapter 3.12.*
368		163	Suggested definition of 'Registered Exempt Organism' - needs to be defined. Proposed changes to the Biosecurity Act make it unclear how regulated but exempt activities are managed. The term 'exempt' is unclear and could inadvertently lead to an issue under our international treaty obligations or our trading partners. These organisms are regulated by default and conditions can be imposed. Proposes "Registered Exempt Organism means—the Regulator is satisfied the organism cannot be distinguished from organisms created through	Horticulture, Iwi/hapū	**No change proposed.** *Refer to Item 363.*

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			conventional processes, and is registered by the Regulator"		
369		163	Recommend requiring exempt or non-notifiable technologies and organisms to be registered with the Regulator and to trigger public consultation processes. This is to mitigate potential trade and market access risks due to the lack of certainty about which of these technologies and organisms may be present in New Zealand. It also means the Regulator is unable to undertake procedural steps that would otherwise allow it to receive relevant information from affected sectors. The submitter also considered that in addition to a more comprehensive register, that robust traceability will be important for managing trade and market access risks, and that the list of conditions that the Regulator may impose on a licence be strengthened to include requirements to enable product identification and tracing.	Dairy	**No change proposed.** *Refer to Item 365.*
370		163	That while the Bill aims to enable low-risk DNA alterations, such activities should be strictly confined to controlled laboratory settings, with all potential risks thoroughly managed.	Researcher, E-NGOs, Iwi/hapū	**No change proposed.** From the outset of the new regime no gene technology will be exempt from the operation of the Act. Any future exemption of gene technology must satisfy the criteria set out in clause 163(2)(b) in that it does not pose any more than a minimal risk to human health and the environment.
371		163	Recommend changing “exempt” to “permitted”, so as to clarify that all gene technologies are still captured by the regulatory system. This would bring the New Zealand system into closer alignment with most other countries, where while gene editing is	Dairy	**No change proposed.** The use of ‘exempt’ provides clarity to the public that these products of gene technology are not subject to regulation by the regime.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			liberalised, it is still subject to regulation. Other clauses would require slight amendment.		
372	95	163(3)	Clarification is required on how the Regulator can impose conditions on an exemption and amend or revoke an exemption. Noted that if the organism is actually exempt from the Act it was unclear on how such conditions could be imposed.	Researcher, University	**Amend clause 163(3)(a) and 163(3)(b)** to remove the ability of the Regulator to impose or amend conditions on, and revoke, exemptions, which was not the policy intent. *This issue is discussed further in Chapter 3.12.*
373		163	That by allowing genetically modified products to enter the food system without clear labelling and traceability, it removes consumer choice and the ability for Māori to maintain Kai Atua-food in its most sacred, unaltered state.	Māori NGO, Māori sector	**No change proposed.** This issue is regulated by the Food Act 2014 and FSANZ. *This issue is discussed further in Appendix Three.*
374		163 and 167	That the Government draft exemption regulations alongside the Bill and undertake consultation on the proposed regulations under cl 167 as soon as the Bill is enacted. Delays to making such regulations would hold up research, development and commercialisation of safe and proven low-risk gene technology applications that have the potential to provide enormous economic and environmental benefits to New Zealand.	Agritech	**No change proposed.** The policy intent is to commence public consultation on the regulations before the Act comes into force. *This issue is discussed in Chapter 4.*
375	96	New	Clause 61(3)(b) allows the Regulator to disclose confidential information to persons prescribed in regulations. However, there is no corresponding regulation-making power.	MBIE	**Insert a clause as an empowering provision** for regulations that prescribe person to whom confidential information may be disclosed as per section 55 in HSNO Act.
376	97	NEW	Suggest inserting a standard drafting clause to state that failure to comply with requirement to consult does not affect the validity of the regulations	MBIE	**Amend clause 167** to state that failure to comply with consultation requirements does not affect the validity of the Regulations.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
377	98	167	A submitter noted that the effect of clause 167 is that such regulations could be made without public consultation. In the submitter's view, it would be more appropriate for these matters to be prescribed in primary legislation (i.e. in the Bill itself), so they are passed into law with Parliamentary oversight and accountability and can be easily located alongside other key provisions.	Legal	**Amend clause 167** to ensure public consultation is mandatory. *Refer to Item 347*.
Subpart 7 – Fees, charges and cost recovery					
378	99	173	Levies should be able to be imposed on persons undertaking activities regulated by the Act including with regulated organisms and manufacturers, providers and third party vendors.	MBIE	**Amend clause 173** to impose a requirement for persons subject to levies to have to pay those levies.
379		173	That clear guidance be provided, indicating that cost recovery will not be implemented until the framework is operating efficiently and the impacts of any such provisions can be assessed. It is critical that adequate funding be provided for the administration of the Act, especially early on, to help support the growth of the biotechnology sector and foster innovation.	Biotech organisation	**No change proposed**. The policy intent is to consider such aspects through secondary legislation development. *Refer to Chapter 4.*
380	100	182	Several clauses refer to fees, levies, and debt due to the Crown. The EPA will, in practical terms, fulfil the cost recovery function for administering this Act. As such the EPA and not the Crown should receive any costs recovered. The EPA will spend and/or distribute the cost-recovered funds and recover any debt via a court. Otherwise the Regulator would need to be party to proceedings to recover the debt and debt recovery would need to be part of their statutory function.	EPA	**Amend clause 182** to reflect that the EPA will in practical terms be undertaking cost recovery functions, for example**:** • **replace** 'to the Crown' with 'to the EPA'. • **replace** "debt due to the Regulator" with "debt due to the EPA" in clause 175(1)(a) and (2) • **replace** "by the Regulator" with "by the EPA" in clause 175(1)(b)

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
381	101	184	Clause 184(b) should be amended so that the EPA can receive and recover fees, charges, levies, or penalties. A delegation power is then not needed, and the administrative role of the EPA will operate more efficiently.	MBIE and EPA	**Amend clause 184(b)** to provide for EPA, on behalf of the Regulator, to receive and recover fees, charges, levies, or penalties.
Subpart 8 – Miscellaneous					
382	102	186	The service of notice clause needs to include provision for service to body corporates and partnerships.	MBIE	**Insert requirements for service of notice** to body corporates and partnerships similar to s 113(5)-(7) Fast Track Approvals Act 2024.
Protection from civil and criminal liability					
383	103	187	This clause needs to be expanded to capture all persons exercising powers or performing functions or duties under the Act including the EPA, the enforcement agency and other agencies.	MBIE	**Amend clause 187** so all persons exercising powers or performing functions or duties under the Act are protected from civil and criminal liability in relation to acts or omissions done in good faith and with reasonable cause.
384		187	That officials should not have exemption from liability and immunity from prosecution, especially if precaution, liability on users, and commercial insurance are not in place, and there is risk of vested industry interests being promoted over safety or the public interest. Recommend this clause is removed, cited by many individual submitters that this is “just wrong” and “dangerously removes accountability”.	E-NGO, Māori NGO, Individuals	**No change proposed.** This is standard drafting, with similar provisions included in other New Zealand legislation. *This issue is discussed further in Chapter 3.7.*
385	104	NEW	Submitters noted the absence in the Bill of a regulatory system assessment, and noted that Australia conducts regular reviews of its legislation	Biotech organisation,	**Add a requirement in Part 5, subpart 8 of the Bill** for the Minister to, as soon as practicable after the

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			under the intergovernmental Gene Technology Agreement 2001. Some submitters discussed a regular assessment, others suggested an independent scientific panel, or more generally monitoring and evaluation of the impacts of gene technologies.	Agriculture (not dairy), Individuals	expiry of four years from the commencement of this Act: • commence a review of the operation of the Act, including the Office of the Gene Technology Regulator; and • prepare a report on the review and present it to Parliament. **Add** a requirement that the Minister be informed by the Regulator on workability of the regime, to inform the review of the operation of the Act. *This issue is discussed further in Chapter 3.11*.

Part 6: Amendments to other legislation

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
Subpart 3 – Amendments to the Biosecurity Act 1993					
386		202	Suggest amendment made to align with substantive submission proposing changes referring to registered exempt organism amend clause 202 (1)(b)) authorised by a licence or an emergency authorisation, or is a registered exempt organism as those terms are defined in section 7(1) of the Gene Technology Act 2024.	Horticulture	**No change proposed.** Suggested amendments are a follow on from a previously considered proposals addressed Item 365 recommending changes to clause 163 regarding *registered* exempt organisms where we have recommended no change.
387		203	Suggests definition of 'authorised regulated organism' is required, and authorised regulated organism means— a licensed organism.	Horticulture	**No change proposed.** There is already a definition in clause 202 and it means an organism that is approved for use in an activity.
388	105	203	Clause 203 requires an amendment to clarify that an inspector cannot give clearance unless the regulated organism is AND is an authorised regulated organism and not a new organism (as defined in the Biosecurity Act and HSNO Act).	MBIE	**Amend clause 203** to clarify that an inspector cannot give biosecurity clearance to a regulated organism unless it is an authorised regulated organism and not a new organism. This provides certainty of the relationship with the Biosecurity Act.
389	106	204	Clause 204(3)(b) requires amending because clause 12 determinations cannot be made for something is, or is not, an 'authorised regulated organism' or about 'any conditions as to its storage or release' as currently drafted. – Determinations under clause 12 can only be made as to whether or not an organism is a regulated organism or falls within an exemption made by clause 163(4).	MBIE	**Amend clause 204(3)(b)** to appropriately provide in the Biosecurity Act for determinations made under clause 12 of the Bill.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
390		204	Suggested redrafting for clause 204(3) Section 28A amended (Dealing with suspected new organism) or suspected genetically modified organism: A chief technical officer may permit an organism seized under this section to be held in the custody of the Director-General for as long as is necessary for the importer to— (a) apply to the Authority for a determination under section 26 of the HSNO Act that the organism is, or is not, a new organism; or (b) apply to the Gene Technology Regulator for a determination under section 12 of the Gene Technology Act 2024 that the organism is, or is not, an authorised regulated organism or is a **permitted organism** or is a **registered exempt organism** and for a determination about any conditions as to its storage or release.	Horticulture	**Refer to Item 389.**
390		209	A submitter suggested adding to this clause the following: "*provided that a risk assessment for primary production, market access and trade and environmental protection are included in the risk assessment*", or words to similar effect.	Horticulture	**No change proposed.** We do not see this amendment to the Biosecurity Act as necessary to enable the gene technology regime to be functional.
Subpart 6 – Amendments to the HSNO Act 1996					
391		217	Recommend amending clause 217 defining a containment facility as a facility approved in the Biosecurity Act, to have the containment facility approved under the Act for GM or GE regulated organisms.	Researcher	**No change proposed.** In the Bill "containment facility" means a facility registered as a containment facility under the Biosecurity Act.
392	107	217	The deletion of 'does not include field testing' from limb (a) of the definition of "develop" was an error.	MBE, EPA, and MfE	**Amend clause 217(2)(a) to exclude field-testing** from the definition of "develop" in relation to new

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			EPA suggests that this should be remedied by returning 'does not include field testing' to limb (a).		organisms other than incidentally imported organisms, as this was removed in error.
393	108	218	Suggest amendment to clause 218 Section 2A amended (Meaning of new organism) - Exempt activities should also be new organisms. Proposes for - 2A Meaning of new organism (4) to avoid doubt, if an organism is not a new organism, it does not become a new organism solely because it is a regulated or a registered exempt organism under the Act.	Horticulture	**Amend clause 204** to reflect an organism is also not a new organism solely because it is subject to an exemption made under section 163 of the HSNO Act.
394		235	Recommends that section 123 should not be repealed, i.e. declaration that organism not genetically modified. At the border, biosecurity will still need to determine if an organism is covered by the Act, exempt or is otherwise to be more specifically regulated. A declaration would assist with this and support the use of clear internationally acceptable standards for all classes of organisms.	Individual, Horticulture	**No change proposed.** GMOs will no longer be regulated under the HSNO Act. The function at the border will be the responsibility of the enforcement agency, MPI.
Subpart 7 – Amendments to the Medicines Act 1981					
395		242	Recommend that clauses 242 and 24D be deleted as these expose New Zealanders to hazardous gene technology which pretends to be medicine.	Individual	**No change proposed.** We do not accept the premise of the recommendation.
Subpart 9 – Amendments to the RMA					
396			Many submitters recommend that local authorities retain local government decision making rights. Allowing local authorities, in consultation with Iwi and hapu, to retain their ability to regulate or restrict GMO use in their regions, supporting regional autonomy and kaitiakitanga.	E-NGO, Organics, Individuals, Iwi/hapū, Māori NGO	**No change proposed.** The policy intent is that the regulation of gene technology is nationally consistent so that the assessment of gene technologies is undertaken in a science-based way by independent and suitably qualified officials, the range of potential benefits of gene technology is available across the country, and

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
					organisms that have been exempted from regulation under the Act will not be subject to potential regulation as GMOs by local authorities. If the RMA remains unchanged, this policy will not be achieved. *This issue is discussed in Chapter 3.6.*
397	109	New	Section 2 of the Summary Proceedings Act 1957 contains a definition of infringement notice referring to Acts which have an infringement regime. The Gene Technology Act should be added to the list.	MBIE	**Amend the Summary Proceedings Act 1957 section 2**, to include a definition of infringement notice for the Gene Technology Act.

Schedules

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
Schedule 1: Transitional, savings and related provisions					
398	110	NEW Sch 1	HSNO Act provides for both emergency and special emergency approvals for new organisms. A transitional provision may be required in the Bill to deal with applications already approved at the time the relevant provisions become law - noting however that HSNO emergency provisions have never been used to date. For not yet determined applications, as this situation is unlikely to occur, officials consider this could be dealt with under transitional regulations (clause 164) if necessary.	MBIE and EPA	**Amend the Bill** so already approved emergency and special emergency authorisations remain valid under the HSNO Act for two years from the date of approval or earlier date set by EPA.
399	111	Sch 1 clause 14	The policy intent is that secondary legislation will be in place soon after the Act comes into force. Consultation on the secondary legislation will take place before the Regulator is established and similarly, before the TAC and MAC are established.	MBIE	**Refer to PCO** to consider amending the Bill to ensure the first set of secondary legislation made under clauses 23, 47, 48, and 155, are not invalid

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
			An amendment may be required to ensure that the requirements under clauses 23, 49 and 167 do not need to be complied with and failure to comply with the prerequisites does not invalidate the secondary legislation made under clauses 23, 47, 48 and 155.		because of a failure to comply with the prerequisites including seeking advice from the TAC and MAC.
400		Sch 1	Suggest amending the Bill's transitional provisions, to ensure that new declarations cannot be made until regulations specifying the relevant criteria have come into effect.	Dairy	**No change proposed.** Regulations require promulgation prior to declarations made via a notice.
401	112	New	The Bill interfaces with several standards in the Biosecurity Act, for example the import health standards and standards for transitional facilities. Many of these standards will need to be updated by MPI where they refer to provisions in the HSNO Act and will need to also refer to the Bill. Some of these standards will need to be updated in a truncated timeframe for the regime in the Bill be operational. The Biosecurity Act provides for a standard process to update standards, which is the same as developing or introducing a new standard entirely, a process that may not be able to be completed in time to enable the regime in the Bill to be operational in the Government's current timeframes.	MBIE and MPI	**Insert** a new transitional provision to enable MPI to update provisions required for the commencement of the gene technology without following the current, full Biosecurity Act process. The policy intent is to enable MPI to make the minor and technical changes to relevant standards without having to undertake full risk assessment and consultation processes because these updates do not change the risks.
Schedule 2: Consequential amendment to other legislation					
402	113	Sch 2	Exporting is a regulated activity under the Bill (see definition of activity in clause 7). There are overlaps with the Bill and the Prohibition Order. The Minister responsible for the Gene Technology Act will be making decisions under the Order, however for administrative efficiency this should be the Regulator.	MBIE and EPA	**Amend Schedule 2** so that the Regulator can make decisions under the Prohibition Order for authorised activities (including for export) under the Bill. This would be more administratively efficient than requiring the Minister make such decisions.

Item	Rec #	Clause	Submitter Comment	Submitter	Recommendation
Schedule 3: Reviewable decisions					
403	114	Sch 3	A decision on a licence for transhipment is made under clause 33(1) which is a reviewable decision. Therefore, the reference to a transhipment decision under 33(3) should be deleted. The description of clause 36 refers to conditions imposed on a licence or in RARMP. However, while the RARMP might include measures to manage risk, conditions will be imposed on the licence and not in the RARMP.	MBIE	**Amend Schedule 3 to:** • **delete the third row** that refers to a transhipment decision as this type of licence is already captured by the second row • **delete** 'or in risk assessment and risk management plan' from description in fourth row.
404		Sch 3	It should be considered whether third parties should have standing to apply for a review where they can establish an actual or anticipated direct impact on them.	Individual	**No change proposed,** *Refer to Item 310.*

Appendix Two: Submitter information

Table 8: List of oral submitters

Submitter
A. Joy Mace
Aaron Torkil
AgResearch
AgriHealth NZ Ltd
Aileen Trip
Alana Alexander
Alastair Brickell
Allan Richardson
Alvina Edwards
Amore Food Shop and Café
Andrew Hamlin
Andrew Johns
Angeline Greensill
Animal and Plant Health NZ
Anna Johns
Anna-Maria Hunter
Apiculture New Zealand
Associate Professor Paul Gardner
Auckland GE-Free Coalition
Bayer New Zealand
Beef + Lamb New Zealand
Berakah Vineyard Management
BioGro New Zealand Ltd
Boud Hammelburg
Brand New Zealand
Bruce Nicol
Bryan Trenwith
Buy Pure New Zealand
Cathie Bell
Cawthron Institute
Centre for Integrated Research in Biosafety
Ceres Organics Ltd
Charles Drace
Chris Johnston
Churton Wines Ltd
Claire Bleakley
Cliff Mason
Collective for the Safe Use of Gene Technology
Concerned Farmers NZ
CropLife Australia
Dairy Companies Association of New Zealand
DairyNZ
Darren Utting
David Lovell-Smith
David Phillips
Deborah Murtagh
Denholm Crone
Dianne Downward
Dominic Harvey
Donna Pokere-Phillips
Dr Roz Buick
Dr Troy Baisden
Dr William Rolleston
Duncan Humm
Dylan Ditchfield
Edward Lee
Elizabeth Deborah Ferguson
Elizabeth Lock
Elizabeth Mundt
Elvira Dommisse
Emily Erith Baker
Emily King
Environment and Conservation Organisations of NZ Inc, ECO
Essential Touch NZ Ltd
Euan Haycock
Federated Farmers
Fonterra Co-operative Group Ltd
Forest Owners Association
Frank Rowson
Franks Ogilvie
Fugitive Organic Wines
Garth Cant
Gaylene Barnes
GE Free New Zealand in Food and Environment Inc
GE Free Tai Tokerau
Gene Ethics Ltd
Genomics Aotearoa
Genomics for Aotearoa New Zealand Incorporated
Gina Lee
GLOBE-Campaign for Global Legislation Outlawing Biotechnology Experimentation
GoodSense
Gordon Baird
Graeme Loh
Graham Grant
Grasslands Innovation Limited
Greenpeace Aotearoa
Gregory Bryan
Gretta Carney
Grey Power Howick Pakuranga and Districts Association (Inc)
Hāpai Te Hauora Tapui Ltd
Hapi Ora Limited
Harry Mowbray
Hayden Power
Hinepawhero Afeaki

Horticulture New Zealand

Howick Ratepayers and Residents Association (Inc)

Huakina Marae Forum

Hye-Song Goo

Ian Mulholland

Ian Stephenson

Iona Jelf

Jacqui Cottrell

James Wilkins

Jan Raymond

Jane Kelsey

Jane Russell

Janya Lobb

Jeanette Williams

Jennifer Lux

Jenny Campbell

Jenny Easton

Jim Bennett

Jim Capo

Jodi Ellis

John Barnes

John McDonald-Wharry

John Sanderson

Jon Carapiet

Jonathan Sargisson

Joy Bennett

Juanita de Senna

Kam Salt

Kara Vandeleur

Karen Silvers

Karen Summerhays

Karly Burch

Kate Turner

Katherine Smith

Kathryn Ennis

Kelmarna Community Farm Trust

Kete Ora Trust

Kiwi Quinoa Ltd

Kiwifruit Breeding Centre

Lanaco Ltd

Larry and Jane White

Life Sciences Network Inc

Linc Teale

Linda Grammer

Lisa Er

Livestock Improvement Corporation Limited

InterChurch Bioethics Council

Lou Gallagher

Louise Bleakley

Lynda Schoen

Mako Morris

Malaghan Institute of Medical Research

Malcolm Rands MNZM

Maniatutu Orchards Limited

Marie McEntee

Marilyn Park

Martin Robinson

Martin Whyle

Mary Hobbs

Maureen Ward

McGuinness Institute

Meat Industry Association

Medicines New Zealand

Melony Atkins

Merryn Bayliss

Michael Kay

Michael Trott

Michelle Ames

Midlands Holdings Ltd

Monique Pot

Nelson Lee

New Health New Zealand Inc

New Zealand Alpine Lavender Ltd

New Zealand Beekeeping Incorporated

New Zealand Council for Civil Liberties

New Zealand Doctors Speaking Out with Science – NZDSOS

New Zealand Initiative

New Zealand Outdoors and Freedom Party

New Zealand Plant Breeding and Research Association (NZPBRA)

New Zealand School of Food and Wine

New Zealand Winegrowers Inc

Ngā Hapū e Toru, Ngāti Hurungaterangi, Ngāti Taeotu me Ngati Te Kahu o Ngati Whakaue Hapu Trust

Ngā Iwi o Taranaki

Ngā Toki Whakarururanga

Ngāti Koata Trust

Nicola Scholes

Noel Josephson

NZ Farming

NZ Rock lobster Industry Council Limited and Seafood New Zealand Limited

Organic Farm New Zealand

Organic Farm New Zealand - Upper North Island region

Organic Winegrowers New Zealand

Organics Aotearoa New Zealand

Pacific Institute of Resource Management

Pākaraka Permaculture

Papawhakaritorito Trust

Parliamentary Commissioner for the Environment

Patients' Rights Advocacy Waikato

Patrick Dodson

Pāua Industry Council

Paul Bosher

Paul Butler

Paula Jameson

Peter Alexander

Peter Gordon

Peter Gunn

Peter Morgan

PGG Wrightson Seeds Limited

Philippa Jamieson

Physicians and Scientists for Global Responsibility New Zealand Charitable Trust (PSGR)

Pou Taiao, National Iwi Chairs Forum

Prevar

Professor Barry Scott

Professor Ocean Mercier

Quentin Jamieson

Rare Disorders New Zealand

Raukawa Settlement Trust

Reality Check Radio

Rebecca Fox

Regeneration Army

Renan Cataliotti

Revel Drummond

Richard Doehring

Richard Wallis

Robert Bull

Roger Bray

Sam Hogg

Samuel Dennis

Sandra Goudie

Sarah Beesley

Sarah Moss-Baker

Scion

Seed and Grain New Zealand

Setha's Seeds

Shannon Menehira

Sir Peter Gluckman

Soil and Health Association of New Zealand Incorporated

Sophie Parr

Sophie Taptiklis

Soraya Bradley

South Pacific Sera Ltd

Southern Seed Exchange

Sovereign

Steffan Browning

Stu Sontier

Sue Connor

Sue Kedgley

Susan Crawford

Susan Dyson

Susan Thorpe

Susie Lees

Sustainability Council

Sylvia Nissen

T&G Global Limited

Tangata Huawhenua

Tauukiuki Ltd

Tayla McHardie

Te Hunga Rōia Māori o Aotearoa

Te Ira Tātai Whakaeke Trust

Te Kāhui Maru Trust

Te Rūnanga o Ngāi Tahu

Te Waka Kai Ora Incorporated

Ted Howard

The Nathaniel Centre for Bioethics - Te Kupenga

The New Zealand Institute for Plant and Food Research Limited

The Wrekin Vineyard

Tina Armstrong

Tony Pitt

Tracey Buick

TranzAlpine Organics Limited

Tricia Cheel

Truth Freedom Health

Umami Life Ltd

Urs Signer

Valentina Dinica

Wilhelmina Jannetje Vermeulen

William Buckley

William Laing

Willie White

Wim Rosloot

Zespri International

Zuzana Oravcova-Wheeler

Table 9: Submissions by submitter type (excluding individuals)[22]

[Please note that while this classification is likely imperfect it does not meaningfully affect analysis presented in this report.]

Submitter type	Organisation	
Agriculture (non-dairy)	AgriHealth NZ AgriZero Biodynamics Association of New Zealand Council Churton Wines Ltd Clovalley Farms (2014) Ltd Concerned Farmers NZ FarmRight	Growing Point Harts Creek Farm Inspire Equine Lean Meats Limited Lietze Farm Ltd Velebit Farm WholeyHealth! Village Market
Agritech	Grasslands Innovation Ltd Livestock Improvement Corporation Ltd	
Apiary	Apiculture NZ Beeline Ltd Bela New Zealand Manuka Honey Heathstock Apiaries Ltd Honey Pai Ltd New Zealand Native Honey Products Limited	
Biotech	Bayer New Zealand BioTechNZ BioValeo CropLife Australia International Biosecurity and Biosafety Initiative for Science International Gene Synthesis Consortium KiwiNet NZeno Limited South Pacific Sera Ltd The New Zealand Society of Plant Biologists	
Dairy	Dairy Holdings Ltd Dairy NZ Fonterra Herd Partners Ltd RWP Trust (Certified Organic Dairy Farm) Tripark Farms Ltd	
E-NGO (Environment – NGO)	Pacific Institute of Resource Management	Papawhakaritorito Trust

[22] Where a submitter fitted the description for more than one submitter type, they were only counted in one category. Individuals are not represented in this list, even if that individual was counted as representing a sector in Table 4 in Chapter 1.

Submitter type	Organisation	
	Auckland GE-Free Coalition Environment and Conservation Organisations of New Zealand (Inc) ECO Greenpeace Aotearoa GE Free NZ GE Free Tai Tokerau GeneEthics Ltd Hauraki Islands Branch Committee of Forest and Bird Interchurch Bioethics Council Kete Ora Trust New Zealand Anti-Vivisection Society	Patients' Rights Advocacy Waikato Protect our Gulf Soil & Health Association of New Zealand Sustainability Council Sustainable Business Network Sustainable Taranaki The Germinate Collective Ltd The Nathaniel Centre for Bioethics The Peaceable Kin-dom The Sustainable North Trust Waiapu Catchment Kai Sovereignty Roopu (Collective) Waiheke Resources Trust
Fisheries	Aquafresh Products Limited	
Forestry	Friends of the Earth New Zealand Ltd New Zealand Institute of Forestry	
Horticulture	Barrett Farm Berakah Vineyard Management Botry-Zen (2010) Ltd Catalyst Fruit Wines Crooked Vege Ltd Kiwi Quinoa Kiwifruit Breeding Centre Maniatutu Orchards Limited New Zealand Alpine Lavender New Zealand and Māori Kiwifruit Growers	New Zealand School of Food and Wine Prevar Limited T&G Global Limited Tehana Nurseries The Coterie Limited Zespri
Iwi/hapū	Aroha Te Pareake Mead Huakina Marae Forum Ngā Hapū e Toru Ngā Iwi o Taranaki Ngā Toki Whakarururanga Ngāti Koata Trust Ngāti Raemahue Hapū Pou Taiao, National Iwi Chairs Forum Raukawa Settlement Trust Tainui o Tainui Tataiāhape Marae Trustees Te Kaahui o Rauru Te Kahu o Taonui Te Kāhui Maru	Te Kahui Maru Trust Te Kāhui o Taranaki Trust Te Kāhui Rongoā Trust Te Kahui Tiaki Tikanga Ki Kamo, Whangarei, Tai Tokerau, Me Te Niu Tireni Te Korowai o Ngāruahine Trust Te Pou Taiao o Patuharakeke Te Iwi Trust Board Te Rūnanga o Ngāi Tahu Te Taumata o Kaumātua Kuia o Ngāti Huia ki Poroutawhao ki Huia marae

Submitter type	Organisation	
Legal	Franks Ogilvie In LandsAirWater Counsel Private Trust Te Hunga Rōia Māori o Aotearoa (The Māori Law Society) New Zealand Law Society	
Māori NGO	Garden to Table Trust Hāpai Te Hauora Tāpui Ltd Ira Tātai Whakaeke Charitable Trust Māori Women's Development Incorporated Nga Rauru ki Te Tai Tokerau Sports and Culture Club Tai Tokerau District Māori Council Tāngata Huawhenua – Māori Horticulture Council Aotearoa Incorporated Tau Iho I Te Po Trust Tauukiuki Ltd Te Tira Whakamātaki Te Waka Kai Ora Incorporated Toi Tangata	
Māori sector	*Not listed here because they are all individuals*	
Officer of Parliament	Parliamentary Commissioner for the Environment	
Organics	Absolute Essential Amore Food Shop and Café Artemis Ltd Bayleaf Organics Limited BioGro New Zealand Buzi-B Flower Farm Ltd Ceres Organics Chantal Organics Coaltrack Farm Ltd Commonsense Organics Ltd Cornucopia Organics Earth Stewards Ltd Eat Right Foods Ltd GoodFor Limited Go Native New Zealand Hapi Ora Ltd Hibiscus Coast Organic Buying Cooperative IFOAM Organics International IFOAM Seeds Platform International Network of Organic Farmer Organisations FugitiveOrganicWines Juniper Hill Farm	Kohatu Limited Kokonati Little Bird Organics Monvale Blueberries Natural Leaders - Every Body is a Treasure Trust Organic Farm New Zealand - Upper North Island Organic Winegrowers New Zealand Organic Farm NZ Organics Aotearoa New Zealand Pakaraka Permaculture Sante New Zealand Ltd Sentry Hill Organics Seresin Estate Ltd Southern Humates Ltd Southern Organic Group Streamside Organics The C T R G Elvin Whanau Trust The Wrekin Vineyard Tomtit Farm TranzAlpine Organics Ltd Waiheke Herbs Ltd

Submitter type	Organisation	
	Kelmarna Community Farm Trust	
Other	AsureQuality Limited	Medicines New Zealand
	Brand New Zealand	New Zealand Council for Civil Liberties
	Centre for Urban Transport Studies	New Zealand Doctors Speaking Out With Science
	Chantal Shop	New Zealand Outdoors & Freedom Party
	Clendon Valley Music Foundation	Physicians & Scientists for Global Responsibility New Zealand
	Collective for the Safe Use of Gene Technology	Rare Disorders New Zealand
	Convex New Zealand Limited	Reality Check Radio
	Dea Ethical Clothing	Roots, Shoots & Fruits
	Essential Touch NZ Ltd	Safe Food Campaign
	GE Free New Zealand	Sapele Trustees Ltd
	GE Honesty Foundation Ltd	Save Animals from Exploitation
	Genomics for Aotearoa New Zealand	St Andrews Social & Ecumenical Committee
	GoodFor Snacks Store	SynBioNZ
	Grey Power Howick Pakuranga & Districts Association	Taste Nature organic supermarket and cafe
	Hāpai Te Hauora	Te Pāti Māori
	Hastings District Council	The Chartered Institute of Procurement and Supply
	Howick Ratepayers and Residents Association	The Opportunities Party
	Lanaco Ltd	
Research institute	AgResearch	
	Cawthron Institute	
	Centre for Integrated Research in Biosafety	
	Genomics Aotearoa	
	Health Research Council	
	Institute of Environmental Science and Research	
	Malaghan Institute of Medical Research	
	McGuinness Institute	
	New Zealand Institute of Plant and Food Research	
	Scion	
Sector group[23]	Animal & Plant Health	New Zealand Beekeeping Incorporated
	Animal Justice Auckland	New Zealand Certified Organic Kiwifruit Growers Association Inc
	Beef + Lamb New Zealand	New Zealand Plant Producers Inc
	Buy Pure New Zealand	New Zealand Plant Breeding and Research Association
	Cohasset Group Limited	New Zealand Winegrowers Inc
	Dairy Companies Association of New Zealand	Organic Exporter Association of New Zealand
	ExportNZ & Trade Works	Pāua Industry Council
	Federated Farmers	

[23] i.e. an industry body, as opposed to a company.

Submitter type	Organisation	
	Forest Owners Association	Seafood New Zealand
	Horticulture New Zealand	
	Meat Industry Association of New Zealand	
	Natural Health Alliance	
	New Health New Zealand Inc	
Seeds	Australian Seed Federation	
	Midlands Holdings Ltd	
	Nelson Seed Library	
	PGG Wrightson Seeds	
	Seed and Grain NZ	
	Seedsavers Taranaki	
	Setha's Seeds	
	Southern Seed Exchange	
Think tank	Asia Centre for Health Security	
	Centre for Long-Term Resilience	
	GLOBE (Campaign for Global Legislation Outlawing Biotechnology Experimentation)	
	New Zealand Initiative	
University	University of Auckland	
	University of Otago, Institutional Biological Safety Committee	

Appendix Three: Feedback received unrelated to core policy of the Bill

Food labelling and safety

1. Some submitters noted that they do not consider GM- or GMO-food to be safe and want to retain the right to choose what to consume. Many submissions stated that the Bill does not do enough to regulate food safety or labelling, or in some submissions, that the Bill removes this regulation.

Officials' response

2. The regulatory regime proposed by the Bill does not regulate food safety or food labelling. These issues were not included in the Bill because they are already regulated in other legislation. Food safety and food labelling are regulated under five Acts[24] and by the trans-Tasman independent statutory agency Food Standards Australia New Zealand (FSANZ). Under the Joint Australia New Zealand Food Standards Code, GM foods and ingredients (including food additives and processing aids) that contain novel DNA, or novel protein must be labelled with the words "genetically modified". This labelling statement is also required for GM foods that have an altered characteristic (e.g. altered nutritional profile) when compared to a counterpart non-GM food (e.g. soybeans with increased oleic acid content).

Mandatory medical authorisations

3. Some submitters were concerned that the Bill will lead to mandatory vaccinations or mass testing of gene therapies or other medicines based on gene technologies.

4. This misunderstanding is likely based on the use of the term "mandatory medical authorisation" used in clause 50. This clause provides that the Regulator must grant an authorisation for an activity where the gene technology activity has already been authorised by two recognised (by the Regulator) overseas authorities for the same proposed medical activity.

Officials' response

5. The Bill in no way mandates any medical treatment, nor does the Regulator approve any medicines to be used as a treatment for patients, which is the function of Medsafe under the Medicines Act 1981. For clarity, it will remain the choice of the patient with their healthcare provider as to what medicines they accept.

6. Refer to Chapter 3.5 for further discussion of this policy.

Violations of the Bill of Rights Act 1990 (BORA)

7. Another common concern is that the Bill violates BORA. Many submissions raising this concern link the violation to the absence or removal of food labelling requirements or the enforcement of mandatory vaccinations.

[24] The five pieces of legislation that regulate food safety are the Fair Trading Act 1986, the Agricultural Compounds and Veterinary Medicines Act 1997, the Animal Products Act 1999, the Food Act 2014, and the Wine Act 2003.

Officials' response

8. The Bill does not limit consumer choice, nor does it require anyone to eat GM food or accept any medical treatments. Prior to introduction to the House, the Acting Attorney-General found that the Bill is consistent with BORA.

Resourcing the Regulator

9. Some submitters were concerned that the Regulator would not be adequately and appropriately resourced. The Cawthron Institute noted that a "rigorous assessment of resourcing needs be undertaken to ensure the GT Regulator has the necessary resources at their disposal", while the University of Otago's Institutional Biological Safety Committee is concerned that if the Regulator and their office are not appropriately resourced it may take longer to reach decisions than the current regime under the HSNO Act.

Officials' response

10. The Bill requires the EPA to provide administrative support for the Regulator and the Bill also provides for the implementation of cost recovery in future. However, direct funding and resourcing discussions are operational matters.

Plant Variety Rights Act 2022 amendments

11. Some submissions recommended amendments to the PVR Act. The most common theme in the relevant submissions was advocating for the provisional protections provided for under section 9 of the superseded Plant Variety Rights Act 1987 to be reinstated into that Act. Some such submissions also advocated for a similar clause to be included in this Bill.

12. One submission asked for the duration of a plant variety right under that Act to be extended from 25 to 30 years to align with comparable international regulators.

13. One submission discussed the 'breeders' exemption' in the PVR Act, which allows for plant breeders to use protected plant varieties as a source of material for developing new varieties without infringing the original breeder's rights. It asked for a similar provision to be included in this Bill for developers of gene technologies.

Officials' response

14. The suggested amendments to PVR Act are not necessary for the operation of this Bill; therefore, such amendments are out of scope for consideration for this Bill.

15. Regarding the recommendation to copy the provisional protections from the superseded Plant Variety Rights Act 1987, this Bill does not deal with intellectual property.

16. Officials recognise that allowing gene technology users to use patented gene technology to develop new species may encourage innovation (which is the intention of the PVR Act provision). However, given that the Patents Act 2013 (which replaced a 1953 Act) was developed relatively recently, during a time when gene technologies were known and used in New Zealand, we see this framework as adequate to manage patenting for gene technologies and bespoke rules under this regime are unnecessary.

Secondary legislation

17. Submissions commenting on the secondary legislation were mostly concerned with how the regulations will be developed. Most relevant submissions highlighted the need for industry to be provided clarity on potential changes that would affect them. Many also emphasised the importance of stakeholder engagement throughout the process of developing regulations. A

few submissions queried how the risk tiers will be implemented. Few also noted that there should be a focus on finding a balance between science and the intent of the Bill itself being to enable innovation (e.g. when determining what is a low-risk activity).

Officials' response

18. Officials acknowledge the need and benefit for industry to be consulted during the development of regulations, and it is planned for consultation to be done. The risk tiers will be populated during the development of the regulations.

Māori Advisory Committee and Technical Advisory Committee

19. The submissions sitting outside the Bill's policy intent concerning the MAC and TAC sought clarity on the resourcing for each committee and operational details.

20. CropLife Australia queried how to resolve conflicts between the advice from each committee if these occurred, and whether the Regulator must publicly respond to or publish committee advice.

21. Some submissions expressed the need for adequate funding for the committees. The Health Research Council commented that:

> *"...the current rates set by Cabinet Office circular for similar committees are inadequate given the high levels of expertise and significant time required to serve on these committees"*

22. One submission recommended term limits of five years with possible reappointment for a maximum to 10 years' service. Another submission recommended that the Bill include consequences for the members of the committees when their decisions fail to protect public health and environmental quality.

Officials' response

23. The MAC and TAC have different mandates for providing advice, limiting the chance that their advice would conflict. Given it is an unlikely scenario, officials view that this is better dealt with operationally rather than in the legislation.

24. Regarding whether committee advice will be published, clause 58(3)(h) requires the publications of a summary of any advice provided by the committees.

25. Funding for the committees is an operational matter.

26. Regarding the recommendation to introduce term limits for committee members, officials note that term limits may have a detrimental effect on the level and diversity of expertise on each committee given the limited pool of relevant expertise in New Zealand.

27. We view that having penalties for individuals sitting on the committees would be a disincentive for people to serve on the committees and may make it difficult to find suitable individuals willing to serve. If the MAC or TAC gave a decision maker advice that was incorrect or irrelevant and the decision maker used that advice to inform their overall decision, the decision could be challenged through a judicial review.

Statutory timeframes

28. A few submissions recommended setting statutory timeframes for the Regulator to process applications. These submissions referenced the intention for the Bill to speed up regulatory

processing compared to the current HSNO Act framework. A common concern was that without explicit statutory timeframes, the delays under the HSNO Act would continue under the new legislation.

Officials' response

29. Officials view that any timeframes for regulatory processing should be in the secondary legislation, not the primary legislation, because the secondary legislation is easier to amend. It is difficult at this time to predict what is reasonable to expect for robust regulatory processing given this is a new regime.

Miscellaneous

30. Lanaco proposed that the Bill be amended to introduce animal variety rights for genetically modified livestock. The intention of this would be to have the same intellectual property protections for genetically modified animals as there are for plants in the PVR Act.

31. A few submissions recommended that Bill prevent patents for GMOs that would impose costs on farmers. One submitter recommended that the Bill prevent patents being issued for organisms that could be developed using conventional methods.

32. One submitter wanted a blanket ban on licences or approvals for foreign GMOs.

33. Rare Disorders New Zealand recommended that the Bill account for the unique needs of people with rare disorders and appropriately balance safety measures to protect them as they may be more vulnerable to potential harm arising from use of gene technology.

Officials' response

34. As already noted, this Bill does not deal with intellectual property or patenting.

35. Regarding the suggested ban on licensing for foreign GMOs, officials view that this would be stifling to innovation when multiple gene technology users in New Zealand are engaged in partnerships with foreign entities.

36. Regarding the recommendation from Rare Disorders New Zealand, the Bill mandates the Regulator assess risks to health and safety of people in its risk tiering. There is not an obvious benefit of listing out specific groups that should be considered, when the Bill already provides for people in general.

37. Officials recommend no changes to the Bill arising out of the issues discussed in this Appendix.