SUBMISSION ON

Gene Technology Bill

17 February 2025

To: Health Select Committee
Name of Submitter: Horticulture New Zealand
Supported by: New Zealand Kiwifruit, New Zealand Apples and Pears, Tomatoes New Zealand, Tamarillos New Zealand, Vegetables New Zealand, Pukekohe Vegetable Growers Association, Hawkes Bay Vegetable Growers Association

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Ahumāra Kai Aotearoa

OVERVIEW

Submission structure

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Our submission

Horticulture New Zealand (HortNZ) thanks the Health Select Committee for the opportunity to submit on the Gene Technology Bill (Bill) and welcomes any opportunity to continue to work with the Health Select Committee] and to discuss our submission.

HortNZ wishes to be heard in support of our submission.

The details of HortNZ's submission and decisions we are seeking are set out in our submission below.

PART 1

HortNZ's Role

Background to HortNZ

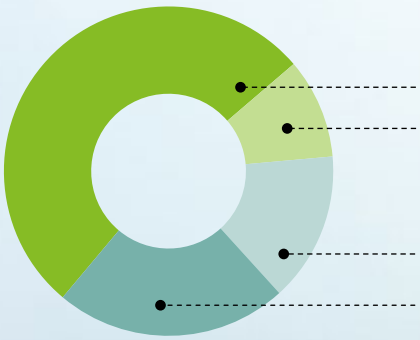
HortNZ represents the interests of approximately 4,500 commercial fruit and vegetable growers in New Zealand who grow around 100 different fruits and vegetables. The horticultural sector provides over 40,000 jobs.

There are approximately 80,000 hectares of land in New Zealand producing fruit and vegetables for domestic consumers and supplying our global trading partners with high quality food.

It is not just the direct economic benefits associated with horticultural production that are important. Horticulture production provides a platform for long term prosperity for communities, supports the growth of knowledge-intensive agri-tech and suppliers along the supply chain, and plays a key role in helping to achieve New Zealand's climate change objectives.

The horticulture sector plays an important role in food security for New Zealanders. Over 80% of vegetables grown are for the domestic market and many varieties of fruits are grown to serve the domestic market.

HortNZ's purpose is to create an enduring environment where growers prosper. This is done through enabling, promoting and advocating for growers in New Zealand.



Export value

Fruit $3.94bn

Vegetables $0.73bn

Domestic spend

Fruit $1.10bn

Vegetables $1.71bn

Industry value $7.48bn

Total exports $4.67bn

Total domestic $2.81bn

Source: Stats NZ and MPI

PART 2

Executive Summary

Purpose and Objectives of the Bill

Overall, HortNZ supports the objectives of the Bill but seeks several changes to ensure the Bill achieves its stated purpose and objectives. Namely that it is, risk proportionate and mitigates against potential trade and market access risks through international alignment.

The release of organisms bred using genetic technologies into the environment has potential benefits for primary industry. There are also potential risks to ecosystems, biosecurity, market access and trade. The risks and benefits of such an environmental release will not be borne by the same groups, and therefore, it is important that the regulator is appropriately tasked to assess and manage these risks and the trade-offs inherent in risk management.

Consultation and Decision-Making Process for the Bill

HortNZ participated as a member of the Industry Focus Group. The consultation with this group was very limited. HortNZ consulted with its member growers to inform this submission, but there has been limited time for full consultation since the draft Bill only became available in December. We therefore urge the Health Select Committee to carefully consider the views of all primary industry submitters, as the sector has had limited input into the development of this Bill. The secondary regulations developed under this legislation will be critical, and we seek meaningful involvement in the drafting of those regulations.

Suggested Amendments to the Bill

HortNZ recommends the following amendment are made to the Bill:

- Change the purpose of the Bill to be focused on regulating gene technologies to manage risks to important values, namely - protecting human health and safety, protecting the environment, and providing for primary industry, market access and trade.

- Remove the provisions for unregulated organisms and technologies which directly reference the Australian regulations, so all genetic technology organisms and technologies are only deemed non-regulated if the organism or technology is already recognised under HSNO as not being regulated as genetically modified, or is classified as conventional under an improved definition in this legislation.

- We support the exemption criteria, and seek that a minimum condition is applied to all exempt organisms and technologies, so these organisms and technologies are all registered, and approved for environmental release once it has been demonstrated that the exemption criteria has been met.

- Change the risk assessment for regulated organisms, so risks to primary industry and regulated market access and trade are assessed for when gene technologies are considered for environmental release.

- Provide for market access and trade through:

    - the registration of all organisms and technologies developed using genetic technology,

    - through the development and approval of standards to support market access and trade assurance for all organisms that have been developed using genetic technology, including those that meet the exemption criteria, and

    - by expanding the scope of the Technical Advisory Group to include commercial considerations including market access and trade.

- The language around unregulated exempt, regulated, authorised is currently unclear, and definitions are not provided for all terms. The Bill should be clearer that conventional breeding is excluded and unregulated by this legislation. Genetic technologies that meet the exempt criteria are regulated unless they are exempt by regulation. The term 'regulated' is confusing because it implies the regulation is only relevant to this category.

PART 3

Submission

1. The Proposed Gene Technology Bill

The intention of the proposed Gene Technology Bill ("the Bill") is to establish a new regulatory regime for gene technology and genetically modified organisms (GMOs). The Bill will replace the current regime with a more enabling and modern regulatory system for managing the use of gene technology.

The Bill seeks to provide for–

- risk-proportionate regulation
- efficient application and decision-making processes
- a flexible legislative framework able to accommodate future technological and policy developments without frequent amendment
- international alignment, including with key trading partners, to facilitate trade and improve access to new technologies
- ways to recognise and give effect to the Crown's obligations under the Treaty of Waitangi

A bespoke legislative regime is considered the most efficient way to achieve these objectives.

HortNZ's submission is focused on amendments we seek to the Bill, to clarify the purpose and improve the ability of the Bill to support its stated outcomes.

2. Consultation and Decision-Making Process for the Bill

HortNZ is concerned that the pre-consultation process for this Bill was very limited. HortNZ was a member of the Industry Focus Group; however, this group had few meetings, and limited details were shared by government officials with the group. Therefore, the ability of the Industry Focus Group to contribute to the analysis that supports the proposed Bill was constrained.

The Bill was sent to the Health Select Committee. HortNZ has no comments to make on the elements of the Bill related to medicine or the use of genetic technology within laboratory containment.

Our focus is on the management of risks to horticultural production, and the trade of horticultural products associated with the environmental release of regulated, exempt and non-regulated technologies and organisms.

Environmental release is of particular interest to the primary industries. In its current form, we do not think the Bill provides a framework to sufficiently identify and manage risks to primary industries, market access and trade. We urge the Committee to listen carefully to the submissions from the primary industry and seek additional support from those with knowledge of the primary industry in relation to the submissions points raised, as required.

3. HortNZ Engagement with Growers to Inform this Submission

Over the past year, HortNZ worked to raise awareness of gene technology and gene technology regulation amongst growers and other stakeholders. Most of the engagement between HortNZ and growers on this topic occurred prior to the introduction of the Bill.

To inform this submission, HortNZ engaged with growers in the following ways:

- Raising awareness of the review though the *NZGrower* and *Orchardist* magazines and our levy roadshow,
- Meetings with the primary industry, science sector and organic sector,
- Online grower meetings before the release of the Bill,
- Workshops at Horticultural Industry Forums,
- A workshop with the HortNZ Board,
- Sharing HortNZ's draft submission with district associations, product groups, a grower reference group and primary industry organisations,
- Online grower meetings to seek feedback on the draft submission, and
- Publishing the HortNZ submission on our website.

4. Critical Issues for the Horticulture Sector

Through our engagement process we have established the following key issues for growers.

4.1. Access to new breeding techniques and organisms bred using genetic technology

Growers and plant breeders expect the use of genetic technology to offer benefits, including to consumers. They want to ensure that risks are appropriately managed for growers and that their customers can access these benefits.

The purpose of the Bill is more enabling than New Zealand's existing Hazardous Substances and New Organisms Act 1996 (HSNO) and the Australian Gene Technology Act 2000.

We seek a purpose more like the Australian legislation, in which it is clearer that the purpose of the regulator is not to 'enable gene technology', but to regulate gene technology to

protect core values that could potentially be put at risk from the use of gene technology. In our view the core values that should be recognised in the purpose of the legislation are:

- Protect human health and safety,
- Protect the environment, and
- Provide for the primary industries, trade and market access.

The use of the words 'protect' and 'provide for', are important because they provide direction to the risk assessment. The Australian Gene Technology Act uses the word 'protect', and that carries through into the Australian Risk Analysis Framework.

We use the words 'provide for' in relation to the primary industry, because the definition of environment is narrowed in this legislation compared with the RMA and HSNO Act. The proposed definition in the Bill would preclude an assessment of risks to primary production. We do not seek to 'protect' primary production, but we do seek a regulatory framework that is supportive of primary production.

We also seek changes to the Plant Variety Rights Act 2022 (PVR). Currently no changes are proposed to the PVR Act as part of the Bill. However, we think the amendments we seek are required in response to the opportunity the Bill provides for breeders. The PVR Act, must be fit for purpose to enable New Zealand plant breeders to realise the opportunities of improved access to plant breeding technologies. This will support the sector's ability to create a fair return on investment in what will be an increasingly competitive, fast-paced and costly new product development industry.

4.2. Plants bred using gene technology that could have been bred using conventional breeding techniques

The biggest opportunity for the use of genetic technology in the horticulture sector is to breed plants that can breed in nature and could have been breed using conventional breeding techniques. The opportunity is related to genetic technology achieving an equivalent outcome faster than conventional breeding.

It is HortNZ's position that when genetic technology is used to develop a new plant variety from plants that could bred in nature and the new plant variety could have been bred using conventional processes, that the potential risks that these new plant varieties pose to human health and safety and the environment are equivalent to the risks posed by new plants varieties that are bred using conventional breeding.

HortNZ supports the criteria in the Bill for determining whether an organism is exempt from the regulatory risk assessment. However, we recognise that plants that have been bred using genetic technology meeting the Bill's exemption criteria could still create trade and market access risks because of international regulatory and market settings.

To manage the risks to market access and trade, we seek that those organisms that the regulator determines meet the exemption in the Bill (meeting the regulations set out under 155(1) (a)) would not be subject to the full risk assessment process, but would be subject to

regulatory registration and occur in containment until that assessment and registration process has been completed.

This regulatory registration process will provide certainty that only organisms and technologies that the regulator has assessed as meeting the exemption criteria are exempted from the full regulatory risk assessment and will also provide certainty about which organisms that have been bred using genetic technology are released in the New Zealand environment. Including those that are authorised under exemption in the regulation or under the regulatory risk assessment and authorisation process.

Registration should be supported by declaratory statements by the applicant as to the justification for their organism either being excluded from the application of the legislation (i.e. conventional) or exempt under regulation or authorised under the legislation. In that regard, standards should be established for the importation of all organisms not borne through conventional breeding, to manage that process.

4.3. International alignment

Growers seek that New Zealand gene technology legislation is aligned with our trading partners and our peer nations.

We support the ability of the gene regulator to recognise risk assessments undertaken in other approved countries to avoid duplication. In the case of environmental release, it may be necessary for organisms or technologies approved in other countries to have further risks assessed in New Zealand related to our unique ecosystems, culture and the relative importance of the primary industries and related trade to our economy.

We do not support the 'unregulated' category within the Bill's reference to the Australian Regulations. We expect that the organisms and technologies identified in Schedules 1 and 1A of the Australian Gene Technology Regulations 2001 would either not meet the definition of the 'genetic technology' (e.g. conventional breeding) or would meet the exemption criteria within the Bill.

In our view, all organisms and technologies, that are not already identified under HSNO legislation as not regulated under that Act, should be assessed against a clear definition of conventional breeding. The exclusion of conventional breeding, from the application of the Bill (and regulations), needs to be made explicit and clear. If an organism is not conventional or is not already identified in the HSNO legislation and regulations as excluded, it should be assessed against the exemption criteria in the Bill (and the regulations that will support that clause).

Our expectation is that the regulations developed under 155 1(a), would likely include all those organisms and technologies listed in the Australian Regulations, either as exempt or defined as conventional. We recognise that waiting for the regulations under Section 155 1(a) to be developed will take longer than declaring these organisms and technologies non-regulated in legislation. However, in our view, that additional time is warranted to provide a transition period and to build confidence in the process.

4.4. Providing for market access and trade

We seek changes to the purpose to recognise trade and market access as core values that the legislation must provide for.

We seek changes to the legislation, such that the gene regulator has a role in:

- approving standards to facilitate trade and market access,
- supporting the navigation of import requirements at our border, and
- supporting the navigation of export requirements in markets for organisms that have been developed in NZ using genetic technology.

The provisions related to regulated market and trade standards are necessary due to the complex assurance processes for gene technology in key export markets and the unpredictable nature of the international trading environment where gene technology has historically been controversial.

4.4.1. GLOBAL G.A.P. AND NZGAP

We support the use of private standards and assurance, and we support regulatory recognition of private standards, so they can be used to support government to government assurances when these are required to facilitate trade.

In the case of gene technology, we support the development of an Australian New Zealand joint standard, with assurance provided under the JASANZ framework.

All horticultural products that are exported from New Zealand are certified under Global G.A.P or NZGAP Global. Under these certification programmes growers are required to demonstrate documents and procedures for the growing, handling and use of GMOs and references the producing countries legislation. The standard also requires that the producers' direct clients have been informed of the GMO status of the product.

Different countries have different definitions of GMO, and some countries include SDN1 within the definition of GMO. Given this, we perceive there are market access risks of adopting the Australian Regulations as non-regulated, because it could make it difficult for NZ producers to meet their obligations under GAP programmes to verify the GMO status of their products.

We consider an exemption and registration process under the genetic technology legislation would better manage this risk and better provide for primary production, market access and trade.

4.5. Providing for co-existence

Growers hold a range of views on the use gene technology, from supportive to opposed, with many growers finding it difficult to engage with this topic.

There is general agreement amongst growers, however, that that the legislation should aim to support the coexistence of growers of plants that have been bred using genetic

technologies and growers of conventionally bred plants and organic growers, without any group imposing costs on another group due to their growing system.

Within the Bill, the definition of 'environment' is narrower than the definition of 'environment' in the RMA or HSNO. In the RMA and HSNO the term environment, includes people within ecosystems and includes social, cultural, aesthetic and economic conditions. Using the narrower definition in the Bill means that risks to primary production would not be assessed by the gene regulator.

In our view, it is important that the purpose and risk assessment for regulated organisms and technologies is expanded to provide for the primary industry and regulated market access and trade, so risks to primary industry production systems, market access and trade relationships are assessed and managed.

The current proposed changes to the RMA will also remove the ability of districts and regions to declare themselves 'GMO-free'.

It is vital that the powers under the Biosecurity Act 1993 to manage the risks to primary industry from incursions of pests are not in any way undermined by the Bill or subsequent regulations.

4.6. Robust decision making and transparency

We recommend some changes to the decision-making processes to ensure that appropriate advice is provided by the technical advisory group. We seek a broader scope for the advice to include commercial matters and a broader range of skills within the advisory group, including market access and trade.

The Bill provides broad scope for the imposition of conditions on regulated and exempt organisms and technologies. It is important that conditions are related to the mitigation of relevant risks and are proportionate, this will be addressed in secondary regulations.

It is essential that the regulator is independent and accountable, and that the power of the Minister is appropriate. We have sought the removal of the ability of the Minister to provide general policy directions.

PART 4

Submission on Gene Technology Bill

Without limiting the generality of the above, HortNZ seeks the following decisions on the Bill, as set out below, or alternative amendments to address the substance of the concerns raised in this submission and any consequential amendments required to address the concerns raised in this submission.

Additions are indicated by bolded underline, and deletions by strikethrough text.

Provision	Reason	Decision sought
Purpose 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	This purpose is much more enabling than the HSNO Act and much more enabling than the objective of the Australian Genetic Technology Act. The term 'safe' does not relate to the environment. It is more relevant when considering benefits and risks to the health of humans and animals. The term 'protect' provides better direction for the purpose of the risk assessment for environmental values and human health. In our view, the purpose of the Act should also reference primary production, market access and trade, to ensure risks that could create trade barriers, or adversely impact primary production, are identified and managed.	Adopt a purpose more similar to the Australian Legislation, which states: **The purpose of this Act is to protect the health and safety of people, to protect the environment, and provide for primary production, market access and trade by identifying risks posed by or as a result of gene technology, and by managing those risks through regulation and registration.**

Section 7 Interpretation environment includes– (a) ecosystems and their constituent parts; and (b) natural and physical resources; and (c) the qualities and characteristics of locations, places, and areas	This is the Australian definition of environment, Under the current definition in this Bill, it is unclear if people and communities are included in 'environment'. It is unclear 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 RMA regulation, reduce the scope of risk assessments and management of gene technologies considerably compared with the regulation under the RMA and HSNO. We can accept the narrower definition of 'environment' provided the Bill includes and provides for 'managing risks to primary production and trade'.	Retain, but make other changes to the purpose and risk assessment to address gaps in the risk assessment due to this narrow definition.
Definition of 'Registered Exempt Organism'	This term 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. The	**Registered Exempt Organism means**– **the Regulator is satisfied the organism cannot be distinguished from organisms created through conventional processes, and is registered by the Regulator.**

	exemption is as defined in regulation. We have suggested 'registered exempt' as an alternative, and different defined term could be used.	
Definition of Registered Exempt Technique or Technology	This term refers to exempt technologies or techniques. A definition is required to make the legislation clear.	**Registered exempt technique or technology means–** **the Regulator is satisfied that the gene-editing technique or gene technology in question creates no more than a minimal level of risk to the health and safety of people or the environment.**
Definition of 'Authorised Regulated Organism'	This term is undefined but referred to in Section 203.	**Definition of 'Authorised Regulated Organism'** **A licensed organism**
11 Interpretation **relevant risks,** in relation to an activity, means any risks posed by the activity to– (a) the health and safety of people; or (b) the environment	Like the Australian Legislation, the term 'protect' should be used to provide context for the risk assessment for people and the environment. The narrowing of the definition of 'environment', means that risks to the primary industry and market access will not be assessed. This creates gaps between this legislation, the RMA and the Biosecurity Act. New Zealand is more dependent on primary industry than other countries, and it is appropriate that the risks to primary industry, market access and	**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**

	trade are explicitly considered by the gene regulator.	
Section 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 organism or technique falls within an exemption made by section 163(4)	We support the differentiation of the risk profile of organisms that have been created using gene technology where the organism cannot be distinguished from conventional breeding, on the basis of no greater risk than a conventionally bred organism to human health and the environment. However, 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. We think the phrasing in the Bill should be changed to refer to licensed, registered exempt and unregulated organisms, as the term 'exempt' is unclear. Section 163 provides the power to make full or partial exemptions, so some exempt organisms or techniques may be partially regulated, and these activities are regulated and prohibited by default until they meet the criteria or the exemption of are authorised.	**Section 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 organism or technique falls within an exemption made by section 163(4), **and is defined as a registered exempt organism or technique or technology**

Section 13 Authorisation required for activities with regulated organisms	This change serves to link to the 'registered' activity status, which is for activities that are not unregulated but meet exemption criteria, and may be subject to conditions under Section 163 (3), and we suggest with all subject to a minimum condition of registration.	**Section 13 Authorisation required for activities with regulated organisms** **<u>aa) The activity is a exempt technique or technology, or</u>**
Section 58 Regulator to maintain register	There are risks to trade from a lack of certainty about which exempt organisms are present in New Zealand. We seek a process of registration to manage this risk.	Section 58 Regulator to maintain register (1) The Regulator must maintain a register with details of all **<u>(aa) registered exempt organisms</u>** **<u>(ab) registered exempt techniques or technology</u>**
111 Performance of functions, duties, and exercise of powers	It is important that the regulator is independent.	**111 Performance of functions, duties, and exercise of powers** (1)In performing their functions and duties and in exercising their powers, the Regulator– (a) must act independently of the EPA and the Minister; ~~but~~ ~~(b)~~ ~~is subject to general policy directions given by the Minister.~~
114 Appointment and membership of Technical Advisory Committee		**114 Appointment and membership of Technical <u>and Commercial</u> Advisory Committee** A person must not be appointed as a member of the committee unless the Minister is satisfied that the

		person has skills, knowledge, or experience in 1 or more of the following areas: (a – s) (t)any other area recommended by the Regulator **(u) market access** **(v)trade**
115 Functions of Technical Advisory Committee		115 Functions of Technical **and Commercial** Advisory Committee The functions of the Technical ***and Commercial*** Advisory Committee are– (a)to provide scientific and technical advice on any matters relating to– (i)the performance of the functions or duties or exercise of the powers of the Regulator under this Act or any other legislation; and (ii)the use of gene technologies and regulated organisms and the management of their risks; **and to:** (**b) provide commercial advice on any matters relating to –**

		(i)the performance of the functions or duties or exercise of the powers of the Regulator under this Act or any other legislation; and (ii) **the commercial application of gene technologies and regulated organisms and the associated commercial risks and benefits in connection with:** • **Imports (border implications)** • **Exports** • **Market access** • **Global industry insights** • **Customer/market impact** • **Engagement, marketing, labelling** • **Intellectual Property protection; and** **(c)to perform any other functions conferred or imposed on the committee under this Act.**
Section 150 Regulator may issue or approve standards for minimising risks to health and safety	We are concerned that for the importation of organisms that meet the definition of 'exempt', there may not be a robust and clear process for importers to demonstrate that they meet the criteria in the legislation. This could create a trade barrier at the New Zealand border for organisms such as seeds that may be SDN1. Currently, SDN1 seeds would be declared as a new organism and GMO. Under the proposed drafting, these	Section 150 Regulator may issue or approve standards for minimising risks to health and safety **of people, to protect the environment or to enable primary production and trade.** (1) The Regulator may issue or approve standards for the purpose of ensuring that risks to the health and safety of people, **to** ~~and~~ the environment **and to primary production, market access and trade** are minimised. (2) Standards may be issued or approved under subsection (1) for–

	would not be a new organism or a regulated organism, and there would be no requirement to declare GMOs. However, if the biosecurity system suspects the seed might be a regulated organism, (i.e. SDN2) they would have to seek advice from the gene regulator. This could result in barriers at our border for products entering New Zealand, due to a lack of clarity on the level of proof or assurance required at the border. This issue could also occur with exported products, with other countries being uncertain whether a product exported from New Zealand might be a GMO under their own legislation. We support the use of private standards and assurance, and we support regulatory recognition of private standards, so they can be used to support government to government assurances when these are required to facilitate trade. In the case of gene technology, we support the development of an Australian New Zealand joint standard, with assurance provided under the JASANZ framework.	(a)activities carried out in containment, activities carried out in the environment, and any other kinds of activities: (b) different kinds of authorised activities (for example, activities that are notifiable and activities that require a licence to carry out and activities that **are registered exempt** (c) activities related to a regulated organism of a category of regulated organisms or a subset of those activities (for example, an activity relating to a micro-organism or the disposal of micro-organisms): (d) containment facilities that have been developed by another agency. (3) Standards issued or approved under subsection (1) may include— (a)requirements for record keeping and reporting: (b) the conduct of internal audits or requirements relating to supervision, monitoring, or verification: (c) requirements for the collection of data and samples, and the conduct and details of studies to be undertaken: (d)actions to be taken in case of the release of a regulated organism from containment **(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.**

Section 163 Power to make further exemptions from operation of Act and non-regulated activities	We support the differentiation of the risk profile of organisms in section 163 2a. There are risks to trade from a lack of certainty about which exempt organisms are present in New Zealand. We seek a process of registration to manage this risk. Our understanding of the matters included in Schedule 1 and 1A of the Australian Gene Technology Regulations 2001 would likely meet the definition of 2 a) and 2b) or are conventional so would not meet the definition of gene technology. Therefore, we think it is more appropriate for those matters to be excluded as conventional or made specifically exempt under 2a or 2b. This protects against future inconsistencies and creates more transparency. It also means that our regulator can impose conditions or revoke an exemption under section 63 93.	163 Power to make further exemptions from operation of Act and non-regulated activities**, and requirement for registration of all exempt organisms and techniques** (1) Regulations may be made under section 155(1)(a) exempting from the operation of this Act– (a) organisms or categories of organisms specified in the regulations: (b) gene-editing techniques or gene technology specified in the regulations. (2) The Minister must not recommend the making of regulations– (a) referred to subsection (1)(a), in the case of an organism or a category or organisms, unless the organism or category of organisms cannot be distinguished from organisms or categories of organisms created through conventional processes: (b) referred to subsection (1)(b) unless the Minister is satisfied that the gene-editing technique or gene technology in question creates no more than a minimal level of risk to the health and safety of people or the environment. (3) Regulations made under section 155(1)(a) **must require that organisms meeting the definition of 63(2a) or techniques meeting the definition of 63(2b) are registered by the Regulator** and may empower the Regulator to (a) impose conditions on any exemption: (b) amend or revoke an exemption in any specified circumstances. The following are not regulated by this Act:

		(a) things that are determined under section 26 of the Hazardous Substances and New Organisms Act 1996 not to be genetically modified organisms: (b) gene technology to which the Hazardous Substances and New Organisms Act 1996 does not apply, being gene technology used in respect of organisms listed in the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998: ~~(c)any of the following:~~ ~~(i) organisms specified in Schedule 1 of the Gene Technology Regulations 2001 (Aust).~~ ~~(ii) techniques specified in Schedule 1A of the Gene Technology Regulations 2001 (Aust).~~
Part 6, Subpart 3, Amendments to the Biosecurity Act 1993 **Section 202** **Section 2 amended (Interpretation)**	This amendment provides alignment with the changes set out previously in this submission.	**Section 202 Section 2 amended (Interpretation)** (1) In section 2(1), insert in their appropriate alphabetical order: authorised regulated organism means a regulated organism that is approved by the Gene Technology Regulator for use in an activity that is– (a) a notifiable activity or a non-notifiable activity, as those terms are defined in section 7(1) of the Gene Technology Act 2024: (b) (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:

		(c) a mandatory medical authorisation under section 50 of the Gene Technology Act 2024
Section 204 **Section 28A amended (Dealing with suspected new organism)**	This process will make it simpler and more transparent for the biosecurity system to manage organisms that are suspected of being GMO, and where checks at the border will be required to determine whether the organism is registered exempt or authorised in New Zealand under NZ regulations	204Section 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 Hazardous Substances and New Organisms Act 1996 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 registered exempt organism** and for a determination about any conditions as to its storage or release

Section 209 **Section 45 amended (Notifiable organisms)**	While these words are the same as those in HSNO, the difference is that the proposed Gene Technology Bill has a much narrower assessment of risks, with the term 'protect' removed and the definition of 'environment' narrowed. Provided the changes we seek including risk assessment from primary production, market access and trade and environmental protection are included, then this is acceptable. Alternatively, if the gene technology regulator is not considering biosecurity risk at all in its decision making, it is unclear how this consultation process would operate.	Retain, provided risk assessment for primary production, market access and trade and environmental protection are included in the risk assessment.
Part 6, Subpart 6, Amendments to HSNO **Section 218** **Section 2A amended (Meaning of new organism)**	Exempt activities should also be new organisms.	**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 Gene Technology Act **2024**.
Part 6, Subpart 6, Amendments to HSNO **235 Section 123 repealed**	This would be useful to retain, because at the border biosecurity will still need to determine if an organism is regulated, exempt, registered or unregulated, and a declaration would assist with this, and support the use of clear international standards for	235 Section 123 repealed (Declaration that organism not genetically modified) **Retain Section 123 rather than repealing.**

	organisms that are regulated, but that are exempt.	
Amendments to the PVR Act These changes are not signalled in the Bill, but we consider these changes to the PVR are required to ensure the PVR Act is fit for purpose to meet the needs of accelerated plant breeding that we anticipate will result from changes to our genetic technology legislation of suitable for new plant varieties that may be developed using genetic technology.		
Section 19 Duration of PVR (new Section of the Gene Technology Bill)	Align the term of protection with our key trading partners from 25 to 30 years for trees and vines.	Section 19 (3) The expiry date for a PVR is the date that is,– (a)if the plant variety is a woody plant or its root stock or a potato, ~~25~~ **30** years after the PVR was granted; o
Provisional Protection (new Section of the Gene Technology Bill)	Reinstate the broader provisional protection provisions breeders held under the PVR Act 1987, which enabled them to enforce against theft of plant material in the time between applying for a PVR and having it granted – given this can be upwards of five years.	**Provisional protection** **(1) Subject to subsection (2), on and after the day on which an application is made, the applicant shall have the same rights to take proceedings under this Act as if on that day a grant had been made to the applicant in respect of the variety concerned.** **(2) The rights conferred by subsection (1) shall be deemed never to have been conferred if–**

		(a) the application concerned is withdrawn or lapses; or **(b) the Commissioner declines to make a grant in respect of that application.**