Gene Technology Bill

Government Bill

As reported from the Health Committee

Commentary

Recommendation

The Health Committee has examined the Gene Technology Bill and recommends by majority that it be passed. We recommend all amendments unanimously.

Introduction

This omnibus bill seeks to enable the safe use of gene technology in New Zealand by establishing a new regulatory regime for gene technology and genetically modified organisms (GMOs).

The current system

At present, gene technology and GMOs are regulated under the Hazardous Substances and New Organisms Act 1996 (HSNO Act). However, there have been major advances in gene technologies and there is now a better understanding of how risks to people and the environment can be managed. The HSNO Act is now widely seen as outdated and not reflective of best practice and new editing technologies like CRISPR.[1] Modern international practice assesses risks associated with a new trait in each organism on a case-by-case basis, while the HSNO Act focuses on the risks of the processes.

New Zealand's rules are considered among the strictest in the OECD. The assessment and decision-making requirements make it complex and costly to gain approval for biotechnology research and innovation. Over time, amendments and court rulings have made the regime even tighter. As a result, almost no genetically modified organ-

[1] Clustered Regularly Interspaced Short Palindromic Repeats, which are the hallmark of a bacterial defence system that forms the basis for CRISPR-Cas9 gene editing technology.

isms have been approved for use outside labs. Since 1998, only three GMOs have been released into the environment without conditions. Many promising domestic research projects that could have been conducted in New Zealand have instead had to be carried out overseas, in less restrictive regimes.

The bill is modelled on Australia's Gene Technology Act 2000, with relevant updates and adaptations where required for the New Zealand context.

Main features of the bill

The bill would regulate activities relating to gene technologies and regulated organisms—broadly defined to cover future developments. Activities involving regulated organisms would be prohibited unless authorised or exempt. A new risk-tiered system would manage the risks to the health and safety of people and the environment from activities relating to regulated organisms and gene technologies.

The bill would also establish a Gene Technology Regulator, who would be an independent statutory decision-maker within the Environmental Protection Authority (EPA), appointed by the Minister responsible for the Act. The Regulator would be supported by a Technical Advisory Committee (TAC) and a Māori Advisory Committee (MAC). The Ministry for Primary Industries would be the enforcement agency.

Legislative scrutiny

As part of our consideration of the bill, we have examined its consistency with principles of legislative quality. We are satisfied that the issues we raised have been appropriately addressed.

Proposed amendments and the structure of this commentary

This commentary covers only the main amendments we recommend to the bill as introduced. We have organised our comments by topic, rather than following the order of the clauses as they appear in the bill.

The main amendments we discuss fall under the following subjects:

- Kaitiaki relationships with indigenous and non-indigenous species of significance
- The role of the Gene Technology Regulator
- Non-regulated organisms and technologies, and exemptions
- Information sharing and access
- Medical authorisations
- Enforcement provisions.

Throughout the bill, we suggest changing the term "regulated organism" to "regulated genetically modified organism" ("regulated GMO" in this report). This would maintain consistency with general usage of the term "genetically modified organism" in the international scientific community and in other jurisdictions. We propose retaining

the use of "regulated" to clearly distinguish between organisms that fall within the bill's regulatory regime and those that fall outside the scope of regulation.

Kaitiaki relationships would include non-indigenous species of significance

Clause 7 would define kaitiaki relationships as "the relationship that any kaitiaki has, or Māori in general have, as guardian, trustee, or caretaker of an indigenous species, in accordance with tikanga". Some of us are concerned that this definition would limit kaitiaki relationships to indigenous species only, and would not cover the range of species that Māori may have relationships with.

We acknowledge that Māori have kaitiaki relationships with both indigenous and non-indigenous species. Māori brought with them to New Zealand several species of plants and animals, with which there may be a kaitiaki relationship. In line with the Plant Variety Rights Act 2022, on which the bill's approach to Treaty obligations is based, we aim to balance the broader purpose of the bill with the protection of Māori relationships to species with which there is a kaitiaki relationship.

Under clauses 120 and 122 in the bill as introduced, a Māori Advisory Committee (MAC) would be established, with the purpose of advising the Minister and the Regulator, issuing engagement guidelines, and performing other statutory functions. Clause 126 would require the Regulator to refer to the MAC certain licence applications and proposals to make a declaration about an activity in relation to a regulated GMO that would use an indigenous species as a host organism.

In recognition of kaitiaki relationships, we consider that the MAC should be consulted when an application or proposal would authorise an activity in relation to a regulated GMO derived from either indigenous or non-indigenous species of significance. We therefore recommend amending clause 126 to provide that licence applications or proposals in relation to a regulated GMO derived from a host organism that is an indigenous species, or a non-indigenous species of significance, must also be referred to the MAC.

Definition of "non-indigenous species of significance"

To give better effect to Treaty obligations, we recommend inserting a definition of "non-indigenous species of significance" in clause 7. This term would mean "a species of organism believed to have been brought to New Zealand before 1769 on waka migrating from other parts of the Pacific region", and that is listed in the regulations as a non-indigenous species of significance. This definition is modelled on the Plant Variety Rights Act 2022 (PVR Act). We also recommend amending the definition of "kaitiaki relationship" in clause 7 to include non-indigenous species of significance. Consequential changes throughout the bill would include non-indigenous species of significance in clauses that reference indigenous species.

Power to make regulations to list non-indigenous species of significance

The Plant Variety Rights Regulations 2022 list ten non-indigenous plant species of significance. We acknowledge this list is limited to plant species. We recommend inserting a new regulation-making power in clause 155 to allow the Minister to recommend regulations be made to specify non-indigenous species of significance, in keeping with the procedure for making regulations.

Criteria and requirements for membership of Māori Advisory Committee

We agree with suggestions that the appointment criteria and requirements for membership of the Māori Advisory Committee should be similar to those for the Māori Plant Varieties Committee in the PVR Act. To this effect, we recommend inserting subclauses (2A) and (2B) in clause 121.

Māori Advisory Committee timeframes and procedures

Some of us raised concerns that a lack of timeframes for the Māori Advisory Committee may cause delays in decision making. However, we understand that this is something that can be dealt with in secondary legislation.

The role of the Regulator

Part 4, subpart 2 of the bill would establish a Gene Technology Regulator and set out the objective and functions of the Regulator.

Recruitment and accountability of the Regulator

Submitters commented on the importance of the Regulator being independent, and expressed concern that the role of the Minister in the appointment could affect this independence. We also noted concerns regarding performance management of the Regulator. The bill would require the Regulator to be an EPA employee, but to be appointed by and accountable to the Minister for the performance of their functions and duties. As we noted in our legislative scrutiny of the bill, this would be an unusual arrangement.

We consider that the EPA should administer the recruitment process in consultation with the Minister. We recommend amending clause 108 to reflect that the Minister's appointment of the Regulator will be on the recommendation of the EPA, having run the recruitment process. We also recommend adding clause 111(3A) to specify that the Regulator would be accountable to the EPA for their obligations as an employee. These amendments would retain the ministerial appointment of the Regulator but clarify the employee–employer relationship between the Regulator and the EPA.

We recommend inserting clause 108A to make explicit the Regulator's term of office, vacation of office, and suspension or removal from office. This would specify that the Minister must appoint the Regulator for a maximum of 5 years, and may reappoint them. New clause 108A(4) would prescribe the grounds under which a Regulator may be removed or suspended (misconduct, inability to perform the functions of office, or neglect of duty). We also recommend inserting new clause 108B to provide for the

appointment of an Acting Regulator by the Minister, on the recommendation of the EPA.

Ministerial directions to the Regulator

Under clause 106(d), the Minister may give directions to the Regulator. To ensure that the Regulator's decisions on authorisations under the new regime remain independent, we recommend inserting clause 106A to set parameters for ministerial directions. Proposed clause 106A specifies that the ministerial direction is to be aligned with the purpose of the bill and the Regulator's objective. It makes clear that the Minister may not intervene in individual decisions by the Regulator. It also sets out consultation and publication requirements before and after the Minister gives a direction.

Reporting, consultation, and reviews

To maintain the public's trust, the new regime must remain transparent. Our suggestions below aim to enhance transparency.

Annual report by the Regulator

We recommend strengthening the accountability provisions in the bill as introduced by inserting clause 112A to require annual reporting by the Regulator, similar to the Australian legislation.

Consultation

Clause 167 as introduced would require the Minister, before making regulations, to:

- undertake public consultations, or
- consult the Regulator, or
- consult persons or representatives of persons who the Minister considers are likely to be affected by the proposed regulations.

We consider that all three of these consultation processes should be mandatory, and recommend amending clause 167 to replace "or" with "and". We also recommend adding subclause (3) to provide that a failure to comply with these requirements would not invalidate the regulations. This is in keeping with similar sections from other legislation.

Review of the legislation

We are concerned that there is no provision for assessment of the regulatory system, and note that Australia has conducted reviews of its legislation. We recommend adding clause 187A to require the Minister to review the operation of the Act and the structure of the office of the Regulator, and to consider whether any changes are necessary or desirable. The Minister would need to begin the review as soon as practicable after 4 years from the Act's commencement, and to present a report on it to Parliament. Our proposed clause 187A(2) would require the Minister to consult the Regulator on the workability of the regime, to inform the review.

Register

Part 2, subpart 8 of the bill would require the Regulator to maintain a register of matters relating to the Act (such as licences, authorisations and determinations), on a website readily accessible to the public.

Conditions imposed by the regulator

Clause 15 as introduced sets out conditions that may be imposed by the regulator in relation to the authorisation of activities involving regulated GMOs. We recommend amending clause 15(i) to refer to "location" in addition to "geographic area" so that the Regulator could constrain an activity to a particular location, such as a laboratory.

Clause 15(f) relates to the Regulator's ability to impose conditions on authorised users relating to data and sample collection for a study. However, it is unclear on the ability to impose conditions to verify the genetic changes of a regulated GMO at the conclusion of the study. We recommend adding "verification" to clause 15(f).

Licences are subject to conditions

Clause 37(1)(c) would require the licence holder to notify the Regulator in writing as soon as is reasonably practicable if the licence is for an activity that is not a transhipment activity, and if the circumstances of clauses 35(1)(a) to (c) or (e) apply and the Regulator has not been made aware of them. The circumstances in clauses 35(1)(a) to (c) or (e) are to do with whether a person is fit and proper to hold a licence. To avoid ambiguity, we recommend omitting the reference to the Regulator not being made aware of the circumstances.

We recommend amending clause 37(1)(f)(i), which currently requires the licence holder to publish the conditions of a licence within one month of being issued a licence. Replacing "1 month" with "20 working days" would be consistent with similar clauses.

Appeals to the High Court

The bill as introduced would permit an eligible person who is directly affected by a decision of the Regulator to appeal to the High Court. We have heard concerns from submitters that the meaning of "eligible person" is ambiguous. We consider that those who have asserted a kaitiaki relationship to an indigenous or non-indigenous species of significance affected by the Regulator's decision should be able to appeal to the High Court. We also consider that those who have submitted on the draft risk assessment or the draft risk management plan should be given the same right. Accordingly, we propose amendments to clause 142(4). We recommend consequential amendments to clauses 143 and 144.

Insurance for liability of Regulator

Although the Regulator would have an employment relationship with the EPA, performance of the Regulator's independent statutory functions would not be covered by the insurance taken out by the EPA for its employees. That insurance would cover

acts or omissions by those employees who perform the EPA's functions, whereas the Regulator would have independent statutory functions.

We recommend inserting clause 112B, which provides for the EPA to effect comparable insurance cover for the Regulator's independent statutory functions. We consider that without this insurance cover, the position of Regulator might seem unattractive to candidates, given the possibility of personal liability.

Non-regulated organisms and technologies, and exemptions from the Act

Clause 163 of the bill as introduced provides for regulations to be made to exempt organisms and technologies from the operation of the Act if criteria specified in 163(2) are satisfied.

We see an important distinction between an organism or technology being outside the scope of regulation, and being exempted from the operation of the Act.

We propose below a different approach for these two matters that we consider would enhance the clarity of the regime.

For non-regulated organisms and technologies, our proposed new clause 162AB would set out that the organisms and technologies in Schedule 3A are outside the scope of regulation as they are not regulated GMOs or gene technologies. In addition, our proposed new clause 162B would allow an organism or technology to be declared not to be a regulated GMO or gene technology, through regulations. These would sit outside the scope of regulation.

For exemptions, clause 163, as amended, would provide for specific exemptions from the operation of the Act for organisms or categories of organisms only (not technologies). We detail this approach in the three subsections below.

Organisms and technologies not regulated by the bill

We see merit in clarifying which organisms and technologies are not regulated, so the public has more certainty as to their regulatory status. As introduced, the bill would not regulate:

- things that are determined by the EPA under section 26 of the HSNO Act not to be genetically modified organisms
- gene technology to which the HSNO Act does not apply by being listed in the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998
- organisms specified in Schedules 1 and 1A of the Australian Gene Technology Regulations (2001).

This was intended to ensure that the proposed regime is not more restrictive than the current HSNO Act.

Instead of referring to the specific legislation in this way, we consider that it would be preferable to specify the items that are not regulated by the legislation. We recom-

mend inserting Schedule 3A to list the organisms that are not regulated GMOs, and technologies that are not gene technologies for the purposes of the bill. Consequently, we recommend removing clause 163(4) and replacing it with new clause 162AB, which sets out that items in Schedule 3A are not regulated by this regime. This change also addresses the concern that clause 163(4)(c) would inadvertently allow ongoing incorporation of changes made by Australian lawmakers to the schedules of Australian regulations into the New Zealand regime.

Power to make declarations about the status of organisms and technologies

We note that the science of gene technology is an evolving field. Therefore, in addition to the list in our proposed schedule 3A, we recommend adding clause 162B to introduce a regulation-making power enabling declarations to be made about the regulatory status of entities, organisms, and technologies. This would allow other organisms or technologies to be declared as outside the scope of regulation in the future, if appropriate. Specifically, this clause would allow regulations to declare:

- that specified entities are or are not organisms
- that specified organisms or categories of organisms are or are not regulated GMOs
- that specified technologies are or are not gene technologies.

To ensure appropriate oversight and scientific rigour, the Minister would need to receive advice from the Regulator before recommending such regulations, and any regulations would need to be consistent with that advice. We consider that this would provide certainty and transparency to both industry and the public, while retaining flexibility.

Power to make exemptions through regulations

As introduced, clause 163(1) would enable regulations to be made exempting organisms, categories of organisms, gene-editing techniques, or gene technology from the legislative regime. We recommend amending this clause to provide that regulations may not exempt gene technologies from the operation of the Act but may still exempt specified organisms.

In addition, we recommend inserting clause 163A, which would permit regulations to be made requiring a person who first introduces into the environment an organism or a category of organisms that is exempted to register that organism with the Regulator. It would also require the person undertaking the registration to provide the Regulator with their contact details, and details of the organisms or categories of organisms.

For transparency to the industry and the public, we recommend inserting clause 58(ja). This would require the Regulator to maintain a register with details of all introductions to the environment of an organism or category of organisms registered under regulations referred to in section 163A.

We also propose amending clause 163(2)(a) to provide that regulations cannot be made unless that organism or class of organisms is indistinguishable from those that

are either not regulated by the bill or could be produced using a technology that is not regulated by the bill.

Regulations

Under clause 161, regulations may be made that prescribe the criteria that the Regulator must be satisfied with before declaring an activity to be a pre-assessed activity. We recommend deleting clause 161(a) and (c) from the bill, as these relate to conditions. These powers for the Regulator to set conditions after undertaking a risk assessment and risk management plan are set out elsewhere in the bill. This would give the public more certainty with regard to licence applications.

We recommend inserting clause 164A to provide more detail on the levy-making power of the Regulator, in line with similar powers in other legislation. It would also ensure that the levy-making power of the Regulator is sufficiently flexible to support future cost recovery needs and adapt to changes in legislation.

Information sharing and access

Withholding of information

Clause 60 would allow the Regulator to withhold information on certain grounds when publishing information under the Gene Technology Act, in instances such as consulting on a licence application publicly, or publishing details on the register. We are concerned that clause 60 could be interpreted as overriding the Privacy Act 2020. We therefore recommend deleting clause 60.

Information sharing and access by agencies

Clause 151 sets out how information could be disclosed between agencies that perform functions under this bill and related legislation. We recommend several amendments to this clause to ensure it aligns with the Privacy Act, supports efficient agency cooperation, and allows for appropriate flexibility in information handling.

We are aware of concerns about how the information-sharing powers in the bill relate to the Information Privacy Principles (IPPs) set out in the Privacy Act. We recommend inserting clause 151(4A) to clarify its relationship with IPPs 2 and 11.

Disclosure of information outside New Zealand

We recommend similar amendments in clause 152, which deals with information sharing outside New Zealand. In particular, we propose adding subclause (4) to clause 152 so that its relationship with IPP 11 is clarified.

We recommend clarifying clause 153, which provides for the disclosure of information to a recognised overseas authority where there is an agreement to undertake joint assessments of licence applications.

As introduced, clause 153 refers to joint assessments with applications under the HSNO Act. This reference should be removed, as clause 153 relates specifically to joint assessments under this bill with recognised overseas authorities.

We also consider that the wording as introduced may unduly restrict the Regulator's ability to disclose information for the purpose of compliance monitoring. We therefore recommend amending clause 153(2)(b)(ii) to clarify that information may be disclosed where it would help monitor compliance with this bill or with a relevant law in the overseas country.

To ensure that New Zealand complies with reporting requirements under the Cartagena Protocol, we suggest inserting clause 153A to permit disclosure of information overseas, subject to confidential information provisions in the bill.

Medical authorisations

Renaming "mandatory" medical authorisation

As introduced, Part 2, subpart 5 of the bill would require the Regulator to authorise the gene technology component of a medical activity within a certain period if it has already been approved by two recognised overseas gene technology regulators.

We note that the word "mandatory" in the term "mandatory medical authorisations" may result in misinterpretation that the bill mandates medical treatment. We recommend replacing "mandatory" with "equivalent" in relevant parts of the bill to clarify the intent.

Recognised overseas authorities

We are aware of concern that the requirement in Part 2, subpart 5 could cause reliance on foreign approvals or result in the Regulator forgoing accountability for certain decisions.

We are satisfied that drawing on authorisations made by recognised overseas authorities would shorten the timeframe for authorisations, compared to a typical licence application. As introduced, the bill would require each authorisation to be published in the *Gazette*, be available on the Regulator's website, and be presented to the House of Representatives. The Register on the Regulator's website would have to include details of all equivalent medical authorisations.

We propose clarifying that the process of granting an equivalent medical authorisation should be initiated if a person notifies the Regulator that two or more recognised overseas authorities have granted the medical authorisation. Our amendments to clause 50(1) reflect this.

To improve transparency and robustness, we recommend amending clause 50 to:

- clarify that the Regulator may seek advice from the TAC or any person it considers necessary on conditions to apply to an authorisation (clause 50(5)(b))
- require the Regulator to notify on its website that it is beginning the process to grant an authorisation (clause 50(3)(a).

Should the Regulator decide to vary the conditions of an equivalent medical authorisation, we consider that they must have particular regard to the conditions imposed

by the recognised overseas authorities. Accordingly, we recommend adding subclause (1AAA) to clause 51.

We recommend inserting clauses 50(6), 50(6A), and 50(6B) to make clear that an equivalent medical authorisation must be granted in respect of the activities, regulated GMOs, and persons that are covered by the recognised overseas medical authorisations. We recommend clarifying that the authorisation may cover specified classes of, or all, activities and persons, and specified categories of regulated GMOs.

Consultation period

As introduced, clause 57 would enable the Regulator to declare a person to be a recognised overseas authority after the Regulator has opened for public consultation for "a reasonable time". We consider that this wording is vague and inconsistent with other provisions in the bill where a timeframe is specified. We therefore recommend amending clause 57(4)(a)(iii) to clarify that this timeframe is to be no less than 30 working days.

Enforcement provisions

Part 3 of the bill deals with inspection, enforcement, and ancillary powers. We consider that, similar to the HSNO Act, inspectors under the Biosecurity Act 1993 should have the power to require a person importing any organism to give a statutory declaration that the organism is not a regulated GMO. This provision does not exist in the bill as introduced. We propose inserting clause 65B to enable Biosecurity Act inspectors to exercise this power.

We also recommend inserting clause 65A to empower enforcement officers to obtain personal identity information from an individual if they have reasonable grounds to suspect that that person may have committed an infringement offence.

As introduced, clause 69 allows enforcement officers to enter premises to inspect for compliance with the regime, or to determine whether an organism is a regulated organism. This is limited to places where a regulated organism is present, where synthetic nucleic acid 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.

There may be instances when enforcement officers need to check places where an organism, equipment, or information was located, or where the activities were carried out. We recommend amending clause 69 so that an enforcement agency could still enter a place where a regulated GMO was, but is no longer, present, or where activities relating to synthetic nucleic acid or equipment have been carried out or where other devices or information connected to activities with regulated GMOs or gene technologies were located. This would permit the enforcement agency to check for compliance with the regime in a period after a certain state of affairs or an activity ends.

As introduced, clause 79 would make it an offence to fail to comply with requirements to supply border information in a particular manner and form. The penalty for

this offence would be significant. We recommend amending clause 79 to delete this offence and make it an offence to fail to comply with the new requirements in clauses 65A and 65B.

Risk assessments and risk management plans

Under clause 26, the Regulator must prepare a risk assessment and risk management plan when assessing a licence application for certain activities, or before declaring a pre-assessed activity. Under clause 25, the Regulator must notify applicants if it is proposing to prepare these. We recommend adding clause 25(3) to require the Regulator to have regard to any request and any further information provided by the applicant should they not agree with what the Regulator proposes.

We propose requiring the Regulator to prepare a new or amended risk assessment or risk management plan if they consider that the current one is not materially accurate. If they do so, or if they amend a minor or technical error, they must notify the licence holder or applicant and publish the corrected version on the website. We recommend amending clauses 30 and 32 to make these changes.

Notice requirements for variation of licence

Clause 46(1) would require the Regulator to give the licence holder 30 working days to respond to a proposed variation in conditions initiated by the Regulator. However, we note that situations may arise where the Regulator considers a variation necessary or desirable to avoid an imminent risk of death, serious illness, serious injury to people, or serious damage to the environment. We recommend inserting subclause (1A) so that clause 46(1) would not apply in such cases.

Prerequisites for making, varying, or revoking declarations

As introduced, the bill requires the Regulator to have regard to written submissions received during the public consultation period for varying, revoking, or making declarations. To give certainty to those affected by these notices, we recommend inserting clause 49(6A), which would prevent the entire notice from becoming invalid due to a failure to comply with the requirements of public consultation. This is in keeping with similar sections from other legislation. We recommend a similar amendment in clause 24.

In keeping with the HSNO Act, we also recommend inserting clause 18A in Part 2 of the bill. This would make clear that no compensation would be payable by the Regulator to any person for any loss incurred due to the cancellation, suspension, transfer, surrender, or variation of a licence, declaration, or other authorisation.

Fees, charges, levies, and cost recovery

We recommend amending clause 173 to make it clear that any person authorised to undertake activities regulated under the bill who is subject to levies is required to pay those levies. This amendment would ensure that the levy framework is enforceable and applies appropriately across the range of regulated activities. We also recommend

clarifying that any fees, charges, and levies would be payable to the EPA, as the administrator for the Crown.

Similarly, we recommend replacing "Regulator" with "EPA" in clauses 174, 176, 182, and 185. This would clarify that the Environmental Protection Authority would be responsible for administering cost recovery under the bill. In practice, the EPA would carry out the cost-recovery functions, recovering debt and distributing funds. We recommend a similar change in clause 184.

Other matters

We recommend several other changes to improve the clarity and workability of the bill.

Expanding the expertise of appointees to the TAC

Clause 114(3) lists the skills, knowledge, and experience required of a person on the Technical Advisory Committee. We recommend adding plant or animal breeding, and seed production to the list.

Relationship with the Biosecurity Act 1993

We recommend amending clause 204(3). This clause would replace section 28A(3) of the Biosecurity Act to reflect the actual scope of determinations that could be made under clause 12 of the bill. As introduced, clause 204(3) refers to determinations about whether something is an authorised regulated organism or the conditions of its storage or release. However, clause 12 in the bill refers to determinations about whether an organism is a regulated organism.

The bill interacts with several standards in the Biosecurity Act, which provide for a process to update standards. This process may not be able to be completed in time to enable the regime in this bill to be operational within expected timeframes. Our proposed new clause 210A would insert new section 166B into the Biosecurity Act. This would permit the Director-General to make changes to standards that they consider to be necessary or desirable to give in connection to legislation without following the process set out in the Biosecurity Act. We recommend inserting clause 237A to add new section 148A into the HSNO Act to give the EPA similar powers.

Amendments to commencement clause

We recommend amending clause 2(2) so that subpart 9 of Part 6 of the bill (amendments to the Resource Management Act 1991) comes into force on the day after Royal assent, and not by Order in Council as specified in the bill as introduced.

We also recommend that clauses 23, 26–29, and subparts 4, 7, and 8 of Part 2 come into force on the day after Royal assent. This would ensure that the powers for the Regulator to declare activities as non-notifiable, notifiable, and pre-assessed come into force ahead of the rest of the bill. Important aspects of the regime could therefore be operational as soon as the Regulator was appointed.

Convention on Biological Diversity and Cartagena Protocol

We recommend amending clause 5 to remove the requirement on people other than the Regulator to have regard to the Convention on Biological Diversity and the Cartagena Protocol. We consider that this requirement is unnecessary and unfeasible. Our amendment would mean that only the Regulator, as the statutory decision-maker, must have regard to these international agreements.

Amendments to interpretation clause

We recommend several changes to the interpretation clause (clause 7), and other definitions at clause 8, to clarify and make more consistent the meanings of various terms as they relate to this bill. We cover our main recommended amendments below.

Activity and medical activity

We recommend amending the definition of "activity" to clarify that an activity could include the modification of any organism and any use or experiment with a regulated GMO. We recommend in clause 7(1)(e) replacing "release into the environment" with more specific terminology of "introducing a regulated GMO, whether from containment or otherwise, into the environment", for clarity.

We recommend amending clause 8 to define categories of activities that include contained activity, environmental activity, and medical activity. Medical activity would include an activity related to a regulated GMO that is intended to be administered to enable the use of a medical device, medicine, or veterinary medicine on humans or animals, and to enable the undertaking of clinical trials on humans, or testing of veterinary medicines on animals.

Environmental activity

We recommend moving the definition of "environmental activity" to clause 8 and making clear that it captures the import, transportation, and introduction of a regulated GMO into the environment where the organism does not first go into containment. We also recommend specifying that it includes the following if they are conducted in the environment with regulated GMOs: testing, trials, field tests, and other research or experiments.

Containment

We recommend amending the definition of "containment" in clause 7 to include provision for any other thing or method specified by regulations as containment for the purposes of the bill. This would ensure flexibility should other methods be considered in the future.

Conventional processes

We note concerns that the phrase "conventional processes" is ambiguous. We have heard that this ambiguity may affect conventional breeding programmes currently under way in New Zealand industry. We recommend deleting this definition from the interpretation clause, and omitting reference to it in the definition of gene technology.

Gene technology

In keeping with our recommendation to provide a prescriptive list of organisms and technologies that are not regulated by this bill (under proposed Schedule 3A), we suggest amending the definition of "gene technology" to replace the exclusion of "conventional processes" with "any technology specified in Schedule 3A". In addition, we propose amending the definition to exclude from this definition any technology specified in the regulations as not being gene technology.

Synthetic nucleic acid (SNA)

We recommend amendments to clarify that SNA only encompasses nucleic acids synthetised de novo (without template), and also includes non-naturally occurring nucleic acid analogues.

Labour Party differing view

The Labour Party does not support the bill in its current form. While there is broad agreement that New Zealand's gene technology regulations are outdated and in need of modernisation, any reform must carefully balance innovation with protection. There is a clear opportunity to design a framework that enables scientific advancement while safeguarding the environment, our export economy, and public trust.

The Government did not consult the public while developing this bill. Stakeholders have had limited opportunity to engage with the proposed reforms, leaving critical questions around trade, liability, and environmental risk unresolved. This compressed process reduces confidence that the legislation has been developed with sufficient care, expertise, and in partnership with the sectors that will be directly impacted. A key omission is the lack of a purpose statement that explicitly articulates the need to safeguard people and the environment. Unlike the Australian Gene Technology Act, which clearly sets out its objective of protecting the health and safety of people and the environment, this bill contains no such consideration. This absence suggests a prioritisation of commercial expedience over careful custodianship and raises questions about the framework's guiding principles and motivations.

A fundamental concern is the lack of regulatory independence. By positioning a single regulator close to the Minister, the bill raises significant concerns about the potential for political influence where impartial oversight is essential. This structure increases the vulnerability of the policy framework to changes with a new Government or Minister, undermining certainty for science, industry, and the wider public. Equally concerning is the absence of meaningful Māori representation and engagement.

The bill does not adequately embed Māori perspectives or decision-making roles, despite the clear implications of gene technologies for te taiao, taonga species, and tikanga. Without this inclusion, the legislation fails to fully reflect our Treaty obligations and the holistic stewardship that is central to New Zealand's environmental governance.

The inclusion of an exemption clause contradicts the limited safeguards and protections the bill proposes. There is a significant prospect that any regulation will be undermined by the granting of exemptions for select activities. This risks undermining the purpose of the bill and eroding public trust and confidence that sufficient safeguards are in place and cannot be negotiated away.

The bill does not consider trade implications. This is a significant oversight and area of concern for legislation that stands to have such a significant, permanent, and irreversible impact across our core export sectors.

Despite this clear need for reform, the bill as it stands fails to provide the balanced and credible framework required for environmental release. Although reform is overdue, it must not come at the expense of independence, genuine consultation, Māori representation, environmental safeguards, or the confidence of our primary industries and trading partners. Rather than building consensus, the Government has advanced legislation that moves too far, too fast, risking both public trust in science and the potential for progress in areas where agreement is already broad.

This reform was an opportunity to modernise our framework in a way that strengthened New Zealand's science system, honoured Māori perspectives, safeguarded our primary industries, and protected our international reputation. The bill, in its current form, does not achieve that balance.

At its core, this bill asks New Zealanders to accept a rushed approach to a highly complex and consequential issue. The current bill bundles widely supported applications of gene science, such as medical research, lab-based work, and industrial fermentation, with far riskier outdoor uses. These are fundamentally different matters and should not be rushed through under the same framework. By trying to combine complex outdoor GM provisions alongside urgent medical applications, the Government has slowed progress on treatments and services that could improve the health of everyday New Zealanders.

Green Party differing view

Overview

Direct modification of life at the genetic level and the creation of novel organisms and products is a powerful technological ability that should be applied with utmost precaution, dispassionate consideration of scientific evidence, and consideration of wider ecological, ethical, economic, and Te Tiriti o Waitangi implications. The Gene Technology Bill fails to achieve these basic criteria.

We acknowledge the need for an updated regulatory framework for genetic modification (GM) technology that takes into account much broader considerations than the narrow scope of this legislation. We support a risk-tiered framework for GM regulation which does not exempt any genetically modified organism. As it stands, the bill affects a radical liberalisation and deregulation of GM technology in New Zealand and removal of appropriate protections for the environment including the right of food producers to be free from novel genetic contamination.

As such the bill has proved to be a missed opportunity to create a lasting legislative framework to facilitate more appropriate pathways for use of GM technology including experimental use and development in containment, and particularly medical use—which is widely supported and uncontentious.

Potential frameworks for environmental release or agricultural applications required far more rigorous consideration and development than the Government's timeframe allowed. The bill could have been split into two parts, with the first covering contained and medical use that could have been completed and passed in a timely way, and the second covering outdoor use which could have been given more appropriate time and rigour given its significant complexity, potential impact, and irreversibility.

The Green Party opposes this bill, and a future Green Government would amend any law substantially to enshrine the precautionary principle and provide sufficient protections and provisions for environmental, safety, ethics, animal welfare, trade, Te Tiriti o Waitangi, and te Ao Māori considerations.

The Government's hyperbolic promises for what gene technology can do are unhelpful for developing a sober risk-based approach to gene-tech which undeniably has valuable uses and potentials across multiple disciplines. However, even advocates for the technology, such as Sir Peter Gluckman, acknowledge that its actual capabilities are somewhat speculative.[2] Hence the original determination of the Royal Commission on Genetic Modification that we should "proceed with caution" is as relevant now as it was then.[3]

Evidence from over 30 years of extensive commercial production of genetically modified organism (GMO) crops abroad shows that far from being used to improve environmental outcomes or increase yields, GMOs are overwhelmingly used as an agriculture intensification strategy that combines monocultures with mechanised delivery of fertiliser and pesticides, primarily benefitting multi-national seed and agrichemical corporations in the production of low value commodity crops (used mostly as stock feed) that have led to increased herbicide use, higher seed costs to farmers, and in most instances, lower yields.[4] [5] Far from being a liberating silver-bullet, they are industrial agricultural business-as-usual.

The Green Party is left believing that New Zealand's current non-GMO producer status should be protected as offering a valuable point of difference in a global marketplace seeking high-quality naturally produced food and fibre goods.

---

[2] Sir Peter Gluckman, Written Submission to Health Committee on the Gene Technology Bill, 17 Feb 2025, page 2.

[3] Report of the Royal Commission on Genetic Modification, 2021.

[4] National Academies of Sciences, Engineering, and Medicine, Genetically engineered crops: Experiences and prospects, 2016.

[5] Noack, F et al, Environmental impacts of genetically modified crops. Science, 385(6712), 2024.

Amendments and improvements

While regarding the bill as having fundamental structural flaws the Green Party sought in good faith to find positive changes to improve the bill through seeking additional advice from officials and directly proposing amendments during the select committee process. Most of the amendments were voted against by Government members.

We wish to note that within the constrained time there was often constructive willingness of members across the committee to discuss these questions through the positive facilitation of the Chair. More in-depth scrutiny of details of the bill with officials were often constructive in increasing our shared understanding and we acknowledge the extensive work of ministerial staff and PCO. The Green Party believes that a willingness to take sufficient time could have led to greater cross-party consensus in creating lasting law on this significant field of science and technology.

These processes led to some constructive changes in the bill. Most notably the determination to change the terminology from "regulated organisms" to genetically modified organisms, noting that the EPA supported this change.[6] Another important clarification in official advice: MBIE correctly acknowledging that gene-editing is genetic modification. Blurring this line of definition is both unscientific and unhelpful for a regulatory framework.

The other notable change was the creation of a public register of GMOs exempted from regulation. The Greens strongly oppose any exemption of GMOs from regulation but, as was agreed by the committee, there can be no semblance of the possibility of tracing or avoiding GMO products if there is no record of what products are being used; therefore a publicly available register of these is necessary as a bare minimum.

Other proposed amendments included:

- Shift the purpose of the regulatory framework to focus on the Act's role to protect the health and safety of people and the environment.
- Require the regulator to specify the conditions that sit alongside a risk management plan including an assessment of trade and market access risks and specified conditions for risk management.
- Require that all regulatory decisions made in this system are made by the New Zealand Regulator and approvals from overseas authorities will not be transferrable to support regulatory sovereignty.
- Require that one of the conditions a licence is subject to is that GMO must be traceable. The bill has no standards set for segregation, and no responsibilities allocated for who will run the systems and who will pay, so no assurance about the levels of purity in a supply chain.

---

[6] Ministry of Business, Innovation and Employment, Response to the Health Committee's 4 June queries on the Gene Technology Bill, 11 June 2025, page 9, paragraph 10.

- Add a Te Tiriti o Waitangi clause to ensure that all persons exercising powers and functions under this Act must give effect to Te Tiriti o Waitangi.
- Require the Regulator, as well as all those operating under the Act, to consider the risks to trade and market access alongside other prescribed risks.
- Enable local authorities to continue to regulate activities in their area relating to GMOs to align with the local government GMO-free provision in the Resource Management Act 1991.
- Require that mandatory containment remains required for all gene technology processes so that all development is done in containment.[7]
- Delay the commencement of clauses relating to environmental release to provide time for the development of proper process for environmental release regime.

Key concerns

Fundamental problems with the bill that remain and are hereby outlined as the basis of the Green Party's opposition to the bill:

Fallacy of co-existence

The bill contains no strategies for achieving supposed co-existence of growers of plants or animals produced using genetic technologies and growers of conventionally bred plants or animals and organic producers but leaves this to industry to work out. Questions around GM microbes such as yeasts, or GM pest management systems are insufficiently considered.

Additionally, the definition of "environment" is narrower than the definition in the Resource Management Act 1991 or HSNO Act, meaning risks to primary production would not be assessed by the regulator.

Through Green members' cross-examination during hearings of AgResearch (who have developed a GMO ryegrass) we affirmed that, if released, GMO ryegrass will spread through pasture country. There is no practical containment.[8]

This affirmed the evidence from overseas that co-existence of GMO and conventional plant varieties is generally biologically impossible. Co-existence between non-GMO and GMO crops is only claimed through an ever-increasing tolerance of contamination of non-GMO producers by GMO ones. Organic certification regimes abroad, for example, are forced to tolerate percentages of cross-contaminated GM matter.

The Greens are deeply opposed to the disproportionate onus being placed on conventional producers to maintain or "obtain" that status at their own expense, thereby having to pay the cost of testing their products to prove they have avoided contamination

---

[7] Even where release is permitted this would ensure living organism products can be described and verified to meet exemption criteria, prior to registration and release from containment.

[8] AgResearch Oral Submission on Gene Technology Bill, 5 March 2025.

before claiming a non-GMO status. The Regulatory Impact Statement affirmed that this is what occurs in Australia now where conventional canola producers are liable for the cost of testing their crop's purity.[9]

The effect of this inversion of responsibilities from the potential handful of speculative and experimental GMO producers to the overwhelming majority of conventional New Zealand farmers and producers is to forfeit by legislative fiat New Zealand's current GMO-free producer status.

Stark absence of economic impact analysis

The bill has the potential to result in significant economic impacts and carries acute market access implications. There is a lack of recognition of the risks to New Zealand's trade and market access and the regulatory framework to manage risks to trade and market are unclear and insufficiently explored. There is also limited clarity around how non-notifiable, unregulated and/or exempt activities are determined and registered. Of significant concern is that once GMOs are out of containment, it will be difficult to trace leading to market risks, including uncertainty around acceptance by international trading markets.

Given the value of New Zealand's agricultural production and the sector's exceptional dependence on overseas markets and consumer preferences it is staggering that no substantive advice was offered on the value of our current non-GMO producer status and the impact of its forfeiture. The counterfactual of assessing the value of the growing non-GMO food market is entirely absent from the Government's consideration.

For example, the only economic analysis on the legislation was undertaken by the New Zealand Institute of Economic Research (NZIER) and found that "environmental release of GMOs in New Zealand could reduce exports from the primary sector by up to $10 billion to $20 billion annually."[10] This points to a huge economic risk for a speculative and uncertain return.

The Greens found the refusal of the Government to budge on requests in submissions from across the primary sector for trade and market access to be a consideration in the legislative structure bewildering.

The Greens proposed two amendments to require the consideration of trade and market access risk. These were supported by Labour but voted down by Government parties.

Fallacy of "substantial equivalence"

During hearings with officials the Green Party member questioned the logical fallacy of conflating substantial equivalence with safety.[11] The concept of substantial equiva-

---

[9] Ministry of Business, Innovation and Employment, Regulatory Impact Statement, Reform of Gene Technology Regulation, page 116.

[10] New Zealand Institute of Economic Research, Potential costs of regulatory changes for gene technology, Economic assessments of an MBIE proposal, 2024, page i.

lence suggests that if the character of genetic changes in a GMO product is similar to that which could be achieved through conventional breeding methods (a category designated to include not only conventional hybridisation but also chemical and radiation mutagenesis)[12] then the GMO product is substantially equivalent to a conventional one and therefore is safe. It is a logical fallacy that equivalence and safety are the same thing. There was no substantive response to this question.

Officials did confirm in closed oral consideration that transgenesis can be achieved by gene editing due to biological reagents. Only by high resolution whole genome sequencing of the modified organism can it be confirmed that transgenesis has not occurred. This is a further affirmation of the need for all experimentation and creation of novel organisms to be done in certified containment facilities.

Undue haste and limited consultation

The bill has been rushed, with limited opportunity for pre-consultation with the primary industry sector, including with farmers and producers and those in the organic sector. While industry organisations were part of the Industry Focus Group, the group had few meetings, and limited details were shared by government officials. Moreover, the Technical Advisory Group did not have representation from the organics sector and lacked diverse expertise and perspectives even within the field of genetics.

We are concerned to note that as discovered from OIA and responses to Written Parliamentary Questions[13] that in his visit to Australia the Minister did not engage with the highly impacted organics sector to understand their practical experience of that country's liberalised regime.

Removal of precautionary approach

This bill represents a significant policy shift from a precautionary approach oriented around protection of human health and the environment to one that is "enabling" and radically more permissive. The precautionary principle advises that "the absence of known risk does not mean no risk" and does not specifically prevent GMOs being released. By following the precautionary principle, the approval process would enable researchers to investigate potential hazards that may not have been identified already and allows unknown but rational risks to be factored into decision-making (such as requesting monitoring of an organism after release). Retaining the precautionary approach would have also ensured that we remain consistent with our international obligations, for example, the Convention on Biological Diversity and Cartagena

---

[11] Ministry of Business, Innovation and Employment, Response to the Health Committee queries on the Gene Technology Bill, 30 May 2025, pages 3–4.

[12] The Greens also believe that new products from chemical and radiation mutagenesis should be more rigorously regulated.

[13] Written Question 45223, Steve Abel to the Minister of Science, Innovation and Technology. Published date: 1 Oct 2025.

Protocol on Biosafety. We were also concerned with the removal of Clause 5's requirement for people other than the Regulator to have regard to the Convention on Biological Diversity and the Cartagena Protocol. It is unclear whether this gap will be picked up in regulations.

The bill's purpose is *more enabling* than New Zealand's existing HSNO Act and the Australian Gene Technology Act (2000) and would make ours one of the most permissive gene-tech regimes in the world. Our view is that the role of the regulator should be to "regulate" gene technology to protect human health, safety and the environment, and protect trade and market access.

No consideration of ethics

The legislation excludes any specified requirement or process for ethics to be considered. The decision-making process for GMOs needs to go beyond purely scientific and technical assessments, to ensure it aligns with societal values and ethical standards. While any approved gene-technology application will need to be in alignment with ethical requirements within existing legislation, there are unique ethical considerations specific to gene technology that are not covered by current legislation in New Zealand. For example, the use of genome editing on living organisms, and intellectual property rights on genetic material, particularly germplasm. The proposal is inconsistent with the Australian approach (which includes ethical issues in its decision-making processes and a specialist gene technology ethics committee) and is not aligned with Ministry for the Environment advice to provide ethics provisions to ensure a more robust regulator.

This should include the prevention of animal suffering and cruelty. There are unique unintended consequences from the use of gene technology in animals and a well-documented decades-long grisly history of that use in New Zealand[14] which certainly justifies specific ethical consideration of animal welfare in the application of genetic modification.

Limited decision-making power of the Māori Advisory Committee

We do not support the Māori Advisory Committee having limited decision-making powers. For the regulator to meet the Crown's obligations under Te Tiriti o Waitangi it must ensure that the advisory committee mechanism gives effect to the rights of Māori to make decisions regarding resources and taonga over which they hold rangatiratanga. Current provisions fail to adequately uphold Te Tiriti o Waitangi and the findings of WAI262. The regulator should therefore be required to act on the advisory committee's advice and recommendations to address identified risks to kaitiaki relationships. The advisory committee should also have the ability to veto applications of which they determine the risk cannot be appropriately managed or mitigated. We also

[14] Bleakley, C, GE Animals in New Zealand 2010 – 2025 years. The report, Genetically Engineered Animals: Part 2 - The Second Fifteen Years, is available here on the GE-Free New Zealand website.

raised concerns regarding representation of locally impacted hapū and iwi in decision making.

Lack of local control over gene technology in their area

We do not support councils losing their ability to restrict the use of GMOs under the Resource Management Act. The removal of local councils in decision making limits the ability of communities to make informed decisions around their GM status and what they are purchasing and consuming. Communities and councils are the ultimate risk bearers of GMO land uses and it is therefore a reasonable expectation that they are directly involved in decision-making around the level of risk they are prepared to carry and development of an appropriate management system to lower risks from GMO land uses to that agreed level.

Forfeiture of regulatory sovereignty

The Green Party does support easing of the pathways to access for safety approved medicines from overseas, however in regard to environmental release and other uses the bill diminishes New Zealand's regulatory sovereignty and independence. New Zealand's control over regulating activities will be ceded to the Australian classification system, despite being created for that specific jurisdiction under their own democratic process. Automatic exemption for externally determined gene technologies means there is no provision for a NZ regulator to review or for the public to participate in those provisions. Australian regulations may evolve and change in ways that have not been anticipated.

Conclusion

For these reasons, the Green Party opposes the bill and urges Parliament to reject it in its entirety.

ACT Party differing view

ACT supports the Gene Technology Bill and welcomes the modernisation of New Zealand's regulatory regime for gene technology. This bill is a necessary reform that aligns New Zealand's framework with international best practices. Reducing unnecessary regulatory barriers is crucial in enabling New Zealand to participate in the scientific and technological advancements of the 21st century. ACT supports a regime that allows scientists and farmers to innovate using gene technology while safeguarding the property rights of those who choose not to adopt it, ensuring the use of this technology is scientifically ethical and responsible, and considers impacts on all.

However, ACT is concerned with the existence of a Māori Advisory Committee within the regulatory framework. For gene technology to succeed and be trusted, it should be based on modern science, not cultural concepts that will make it difficult for the Regulator or applicants to navigate. The committee is entirely reliant on the concept of "tikanga." Tikanga is already a contentious and unsettled issue in New Zealand, and ACT does not believe it has a place in scientific legislation. Tikanga is not a fixed or universal concept; it varies between iwi and hapū and lacks consistent

content or application, making it unsuitable as a legal standard. A sound regulatory regime must be based on clear and stable definitions rather than vague, subjective, and spiritual cultural concepts.

ACT is concerned that the core intent of the bill, to promote the practical and beneficial use of gene technology by removing unnecessary barriers, risks being undermined by clause 122. We are concerned that the Māori Advisory Committee's functions under this clause may hinder the effective application of gene technology. ACT believes it is essential for the bill to remain firmly aligned with its intended purpose.

ACT believes the bill already provides comprehensive consultation. The inclusion of a Technical Advisory Committee ensures that the Regulator receives robust scientific and technical input. This evidence-based advice should be the cornerstone of regulatory decision making, and adding a parallel cultural advisory process risks diluting this focus and undermining confidence in the regulatory regime's neutrality and predictability.

New Zealand First differing view

New Zealand First's coalition agreement with National states we are open to liberalising genetic engineering laws while ensuring strong protections for human health and the environment.

In our First Reading contribution we noted the complexity of this issue, and the magnitude of this decision. New Zealand has a pre-eminent position in markets as a "GE Free Nation" and this should not be traded lightly.

This is not just an isolated scientific decision about GE's technological benefits. It is also about the very real concerns about the health, protection, and safety of the environment and our population. Importantly, it is also a consumer preference decision, and to what extent New Zealand might trade away a market advantage.

New Zealand First is not against a responsible, safe, and pragmatic pathway to genetic modification technology utilisation. But the bill as it stands is far too liberal, beyond our key trading partners, and lacks strong safeguards and protections. We will continue to work with and discuss our concerns with our coalition partners.

Appendix

Committee process

The Gene Technology Bill was referred to this committee on 17 December 2024. We invited the Minister of Science, Innovation and Technology, Hon Dr Shane Reti, to provide an oral submission on the bill. He did so on 5 March 2025.

We called for submissions on the bill with a closing date of 17 February 2025. We received and considered submissions from 14,458 interested groups and individuals. We heard oral evidence from 287 submitters.

Advice on the bill was provided by the Ministry of Business, Innovation and Employment, with support from the Ministry for Primary Industries, the Ministry of Foreign Affairs and Trade, and the Environmental Protection Authority. The Office of the Clerk provided advice on the bill's legislative quality. The Parliamentary Counsel Office assisted with legal drafting. The Regulations Review Committee reported to us on the powers contained in clauses 155 and 164.

Committee membership

Sam Uffindell (Chairperson)

Dr Hamish Campbell

Dr Carlos Cheung

Ingrid Leary

Cameron Luxton

Hūhana Lyndon

Jenny Marcroft

Debbie Ngarewa-Packer

Hon Dr Ayesha Verrall

Steve Abel, Reuben Davidson, Hon Mark Patterson, and Hon Dr Deborah Russell also participated in our consideration of this bill.

Related resources

The documents we received as advice and evidence are available on the Parliament website.

Key to symbols used in reprinted bill

As reported from a select committee

text inserted unanimously

~~text deleted unanimously~~

Hon Dr Shane Reti

Gene Technology Bill

Government Bill

Contents

The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Gene Technology Act **2024**.

2 Commencement

(1) This Act comes into force on the day after Royal assent.

~~(2) However, **Parts 2 and 3, subparts 1, 2, 4, 7, and 8 of Part 5, subparts 1 to 3, 5 to 7, and 9 and 10 of Part 6**, and the **Schedules 1 to 4** come into force on 1 or more dates set by Order in Council.~~

(2) However, the following provisions come into force on 1 or more dates set by Order in Council:

(a) **Part 2** (other than **sections 23, 26 to 29, subparts 4, 7, and 8**):

(b) **Part 3**:

(c) **Subparts 1, 2, 4, 7, and 8 of Part 5**:

(d) **Subparts 1 to 3, 5 to 7, and 10 of Part 6**:

(e) **Schedules 1 to 3** (other than **clauses 14, 16, and 17** of **Schedule 1**).

(3) Any provision that has not earlier come into force comes into force on the second anniversary of Royal assent.

(4) An Order in Council made under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Part 1
Preliminary provisions

3 Purpose

The purpose of this Act is to enable the safe use of gene technologies and ~~regulated organisms~~ regulated genetically modified organisms by managing their risks to—

(a) the health and safety of people; and

(b) the environment.

4 Treaty of Waitangi

This Act recognises and respects the Crown's obligations under the principles of the Treaty of Waitangi by—

(a) establishing (in **subpart 4 of Part 4**) a Māori Advisory Committee; and

(b) giving the Māori Advisory Committee a broad range of functions under **section 122**; and

(c) requiring the Regulator under **section 123** to have regard to advice from the Māori Advisory Committee, including advice about whether authorising an activity creates any risk to the environment that may materially affect a kaitiaki relationship.

(d) including in the risk assessment under **subpart 3 of Part 2** for an activity in relation to a ~~regulated organism~~ regulated genetically modified organism, the identification of any material adverse effect on a kaitiaki relationship that may result from ~~an environmental risk~~ a risk of an adverse effect on the environment posed by an activity.

5 Decision makers must have regard to Convention on Biological Diversity ~~including~~ and Cartagena ~~Convention~~ Protocol

The Regulator ~~and every other person who carries out a function or duty or exercises a power under this Act,~~ must, when ~~doing so, [~~ carrying out a function or duty or exercising a power under this Act, have regard to the provisions of~~]~~—

(a) the Convention on Biological Diversity; and

(b) the Cartagena Protocol.

6 Outline of this Act

(1) In this Act,—

(a) this Part (**Part 1**) deals with preliminary matters, including the purposes of this Act, the way the Act recognises the Crown's obligations under the principles of the Treaty of Waitangi, and this Act's interpretation:

(b) **Part 2** provides for the regulation of gene technology by—

(i) empowering the Regulator to make certain ~~rulings~~ determinations as to whether or not an organism is a regulated genetically modified organism, or a technology is a gene technology, or whether an organism is exempt from the operation of this Act ~~the application of the regulated organisms and gene technology definitions of this Act~~:

~~(ii) prohibiting activity relating to a regulated organism that is not authorised by this Act:~~

(ii) prohibiting—

(A) an activity relating to a regulated genetically modified organism that is not authorised by this Act:

(B) in certain circumstances, persons acting as a provider, manufacturer, or third-party vendor unless approved (*see* **section 13A**):

(iii) establishing a licensing regime to permit persons to carry out activities in relation to ~~regulated organisms~~ regulated genetically

modified organisms, and providing for ~~combined licence~~ joint applications to be made ~~jointly~~ to the ~~Environmental Protection Authority~~ EPA and the Regulator:

(iv) requiring a risk assessment ~~or~~ and risk management plan to be prepared ~~for all authorisations except emergency authorisations, and in response to significant new information received:~~—

(A) for pre-assessed activity declarations and all licences, except in respect of a pre-assessed activity, transhipment activity, or low-risk medical activity; and

(B) if the Regulator considers that an existing risk assessment or risk management plan is no longer materially accurate:

(v) requiring the Regulator to make decisions on licence applications, including specifying the contents of a licence and imposing conditions:

(vi) providing for the suspension, variation, cancellation, surrender, or transfer of a licence under this Act:

(vii) empowering the Regulator to issue declarations recognising overseas authorities that regulate organisms to enable joint assessment to be carried out under agreements:

(viii) requiring the Regulator to grant ~~mandatory~~ equivalent medical authorisations in certain circumstances:

(ix) permitting the Minister to grant emergency authorisations to carry out activities in relation to ~~a regulated organism~~ certain regulated genetically modified organisms in certain circumstances:

(x) empowering the Regulator to issue declarations regarding pre-assessed activities and non-notifiable and notifiable activities:

(xi) establishing a register of regulated activities, licence applications, ~~licenses,~~ licences, and other matters under this Act:

(c) **Part 3** provides for inspection, enforcement, and ancillary powers by—

(i) providing for the monitoring and enforcement of this Act by the enforcement agency, including by enabling it to require information to be provided, give directions in respect of ~~regulated organisms~~ regulated genetically modified organisms or SNA, and exercise powers of entry and inspection:

(ii) empowering enforcement officers to make compliance orders against persons:

(iii) creating an offences regime for failing to comply with provisions of this Act, or obstructing or impersonating an enforcement officer:

(iv) creating an infringement offences regime under this Act:

(v) providing for pecuniary penalties for breaches of this Act relating to ~~regulated organisms~~ regulated genetically modified organisms and SNA:

(d) **Part 4** provides for administrative functions under this Act, including—

(i) the functions and powers of the Minister and their powers of delegation:

(ii) the establishment, objective, and functions~~, and delegations~~ of the Regulator and their powers of delegation:

(iii) the establishment of, appointment to, and functions of the Technical Advisory Committee, Māori Advisory Committee, and related subcommittees:

(iv) specifying when the Regulator is required to refer matters to the Māori Advisory Committee:

(e) **Part 5** contains miscellaneous provisions, including provisions—

~~(i) providing a right of appeal to the District Court in respect of compliance orders and other matters:~~

(ii) setting out how a person may apply to have a decision of the Regulator reviewed and the process that will apply to reviews:

(iia) providing a right of appeal to the District Court in respect of compliance orders and other matters:

(iii) setting out a right of persons to appeal to the High Court, and the process that will apply to those appeals:

(iv) specifying notices that the Regulator may issue:

(iva) specifying standards that the Regulator may issue or approve:

(v) detailing how information and samples obtained under this Act may be~~ shared or disclosed~~ disclosed by or shared between specified agencies and under other specified Acts:

(vi) providing for the making of regulations under this Act:

(vii) providing for a range of material to be incorporated by reference into regulations:

(viii) setting out the fees, charges, levies, and cost recovery provisions that may be applied to users of this Act:

(ix) setting out information regarding the service of notices and other documents under this Act:

(x) setting out the duties of the Regulator when a matter must be publicly notified:

(f) **Part 6** makes related amendments to other enactments:

(g) the schedules provide as follows:

(i) **Schedule 1** provides for transitional and savings matters:

(ii) **Schedule 2** provides for consequential amendments to other legislation:

(iii) **Schedule 3** sets out decisions that are reviewable by the Regulator and who may request a review:

(iiia) **Schedule 3A** sets out descriptions of non-regulated organisms and technologies:

(iv) **Schedule 4** ~~inserts~~ contains additional provisions to be inserted into Schedule 12 of the Resource Management Act 1991.

(2) This section is only a guide to the general scheme and effect of this Act.

7 Interpretation

(1) In this Act, unless the context otherwise requires,—

activity, in relation to ~~a regulated~~ an organism, includes ~~means~~ —

(a) making, constructing, developing, fermenting with, regenerating, producing, breeding, propagating, manufacturing, growing, raising, or culturing ~~the regulated organism~~ a regulated genetically modified organism:

(b) modifying ~~an regulated existing~~ any organism (other than a human being):

(c) supplying, importing, exporting, storing, or transporting ~~the regulated organism~~ a regulated genetically modified organism:

(d) using ~~the regulated organism, including through testing, conducting trials, undertaking research, conducting field tests, or using the regulated organism in the course of manufacturing another thing:~~ a regulated genetically modified organism,—

(i) through testing, or conducting trials or experiments; or

(ii) conducting field tests; or

(iii) in the course of manufacturing another thing; or

(iv) in any other way:

(e) ~~releasing the regulated organism~~ introducing a regulated genetically modified organism (whether from containment or otherwise) into the environment:

(f) disposing of ~~the regulated organism~~ a regulated genetically modified organism:

(g) possessing ~~the regulated organism~~ a regulated genetically modified organism for the purposes of, or in the course of, an activity mentioned in **paragraphs (a) to (f)**

benchtop nucleic acid synthesis equipment means equipment produced and distributed by manufacturers that is intended to be used to synthesise nucleic acids for use—

(a) by an individual; or

(b) in a ~~core~~ research facility in an institution

Cartagena Protocol means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, done at Montreal on 29 January 2000, and any amendments to, or substitutions of, that protocol that are or will become binding on New Zealand

confidential information means information that includes either or both of the following:

(a) trade secrets:

(b) information with a commercial value that would, or would be likely to, be diminished by disclosure of the information

~~**contained activity** means to undertake any activity in containment, including the import and transport of a regulated organism and the placement of it into containment~~

containment ~~means to confine a regulated organism to an enclosed facility to prevent escape (for example, 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)~~ —

(a) means confining a regulated genetically modified organism to a secure location or facility to prevent escape (for example, 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); and

(b) includes any other thing or method specified in the regulations as containment for the purposes of this definition

containment facility, in relation to a ~~regulated organism~~ regulated genetically modified organism, means a facility ~~registered~~ approved as a containment facility under the Biosecurity Act 1993

Convention on Biological Diversity means the convention done at Rio de Janeiro on 5 June 1992, and includes the Annexes to the convention and any amendments to, or substitutions of, that convention that are or will become binding on New Zealand

~~**conventional processes** means processes used to reproduce organisms, including, but not limited to,—~~

~~(a) sexual reproduction and natural homologous recombination, in conjunction with selection techniques or alone; and~~

~~(b) any processes specified in this Act or regulations as non-regulated for the purposes of this Act~~

disposal, in relation to a ~~regulated organism~~ regulated genetically modified organism, means making the ~~regulated organism~~ regulated genetically modified organism biologically inactive in a manner that prevents the occurrence of any future biological activity

emergency authorisation has the meaning given in **section 52**

~~**enforcement agency** means—~~

~~(a) the chief executive of the department of State responsible for the administration of the Biosecurity Act 1993; or~~

~~(b) any organisation exercising relevant powers under this Act delegated to it~~

enforcement agency means the chief executive of the department of State responsible for the administration of the Biosecurity Act 1993

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

~~**environmental activity**—~~

~~(a) means any activity that is not a contained activity or a medical activity; and~~

~~(b) includes importation of a regulated organism for immediate release or use in the environment~~

EPA means the Environmental Protection Authority established by section 7 of the Environmental Protection Authority Act 2011

equivalent medical authorisation has the meaning given in **section 50**

exportation means any shipment in any craft for transportation to a point outside New Zealand, and **export** and **exported** have corresponding meanings

fees framework means the framework determined by the Government from time to time for the classification and remuneration of statutory and other bodies in which the Crown has an interest

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~~ any technology specified in **Schedule 3A**; or

(ii) any other technology specified as technology that is not gene technology in the regulations referred to in **section 162B** for the purposes of this paragraph

host organism means an organism that is the subject of a gene technology (including multiple applications of the same or different gene technologies)

import has the same meaning as in section 2A of the Biosecurity Act 1993

indigenous species means a species of organism that is endemic or native to New Zealand

inspector has the same meaning as in section 2(1) of the Biosecurity Act 1993

kaitiaki includes a hapū, iwi, individual who is Māori, or Māori entity

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

licence means a licence issued under **section 33**

licence application—

(a) means an application for a licence made under **section 19**; and

(b) includes a joint application made under **section 20** to the extent that it comprises an application for a licence under **section 19**

low-risk medical activity means a medical activity that meets the requirements under—

(a) **section 47(1)(b) and (c)**; or

(b) **section 48(1)(b) and (c)**

~~**mandatory medical authorisation** has the meaning given in **section 50**~~

manufacturer, in relation to benchtop nucleic acid synthesis equipment—

(a) means a person that ~~produces or~~ manufactures and distributes, in trade or for reward, benchtop nucleic acid synthesis equipment; and

(b) includes a third-party vendor

Māori Advisory Committee means the advisory committee established under **section 120**

Māori entity includes an entity that represents Māori interests, including, for example, a post-settlement governance entity or an iwi authority within the meaning of section 2(1) of the Resource Management Act 1991

medical device has the same meaning as in section 3A of the Medicines Act 1981

medicine has the same meaning as section 3(1) of the Medicines Act 1981

Minister means the Minister of the Crown who, under the authority of a warrant or with the authority of the Prime Minister, is for the time being responsible for the administration of this 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 species of significance

non-notifiable activity means an activity that is declared to be a non-notifiable activity under **section 47**

notifiable activity means an activity that is declared to be a notifiable activity under **section 48**

organism—

(a) means any biological entity or part of an entity containing genes or other genetic material that is—

(i) viable; or

(ii) capable of reproduction; or

(iii) capable of transferring genetic material and capable of replicating itself (whether it comprises all or only part of an entity, or all or only part of a the total genetic structure of an entity); but:

(b) includes an entity declared to be an organism by the regulations; and referred to in **section 162B**:

(c) does not include an entity declared not to be an organism by the regulations referred to in **section 162B**

pre-assessed activity means an activity that is declared to be a pre-assessed activity under **section 23**

provider—

(a) means a person that synthesizes synthesises and distributes synthetic nucleic acids in trade or for reward; and

(b) includes a third-party vendor

recognised medical authorisation has the meaning given in **section 50**

recognised overseas authority means a person who is declared to be a recognised overseas authority under **section 57**

regulations means regulations made under this Act

Regulator means the Regulator established by **section 108**

regulated genetically modified organism—

(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~~

(iii) an organism, or a category of organisms declared to be regulated genetically modified organisms, by the regulations referred to in **section 162B**; but

(b) does not include—

(i) an organism or a category of organisms ~~declared by regulations not to be regulated organisms~~ described in **Schedule 3A**; or

(ia) an organism or a category of organisms declared not to be regulated genetically modified organisms by the regulations referred to in **section 162B**; or

(ib) an organism or a category of organisms exempted by the regulations referred to in **section 163**; or

(ii) a human being

subcommittee means a subcommittee of the Technical Advisory Committee or the Māori Advisory Committee established under **section 132**

synthetic nucleic acid or SNA—

(a) means molecules~~, of any sequence length, that have been constructed outside living cells by joining nucleic acid 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

(iii) non-naturally-occurring nucleic acid analogues

Technical Advisory Committee means the advisory committee established under **section 113**

therapeutic purpose means any of the following purposes, or a purpose in connection with any of the following purposes:

(a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury:

(b) influencing, inhibiting, or modifying a physiological process:

(c) testing susceptibility to a disease or ailment:

(d) influencing, controlling, or preventing conception:

(e) testing for pregnancy:

(f) investigating, replacing, or modifying parts of anatomy

third-party vendor means—

(a) a person who obtains synthetic nucleic acid and distributes it or any parts of it (with or without reformulation) in trade or for reward; or

(b) a person who obtains ~~bench top~~ benchtop nucleic acid synthesis equipment ~~from a manufacturer~~ and distributes it in trade or for reward

trade means sell, and includes—

(a) selling for resale (including as a constituent part of another article); and

(b) offering or attempting to sell, or receiving for sale, or having in possession or exposing for sale, or sending or delivering for sale, or causing or permitting to be sold, offered, or exposed for sale; and

(c) supplying an article under a contract, together with other goods or services, or both, in consideration of an inclusive charge for the article and the other goods or services; and

(d) every other method of disposition for valuable consideration

~~**transhipment** means the importation into New Zealand of a regulated organism solely to enable exportation of that organism within 20 working days to destination outside New Zealand~~

unwanted organism has the same meaning as in section 2(1) of the Biosecurity Act 1993

veterinary medicine has the same meaning as in section 2(1) of the Agricultural Compounds and Veterinary Medicines Act 1997 (the **ACVM Act**).

(2) In this Act, unless the context otherwise requires, any reference to a **person**, however described or referred to (including applicant and licence holder), includes the successor of that person.

(3) In **subsection (2)**, **successor** includes, if ~~where a person is~~ a body of persons (**A**) ~~that~~ is unincorporated, ~~the successor includes~~ a body of persons (**B**) that is incorporated and composed of substantially the same members and that replaces A.

8 ~~What is~~ Categories of activities: contained activity, environmental activity, and medical activity

In this Act, unless the context otherwise requires, ~~**medical activity**~~—

contained activity means any activity carried out in containment, including the importation or transportation of a regulated genetically modified organism for the purpose of containment

environmental activity—

(a) means any activity that is not a contained activity or a medical activity; and

(b) includes importation or transportation of a regulated genetically modified organism for immediate introduction or use in the environment without going first into containment; and

(c) includes doing any of the following in the environment, in relation to a genetically modified organism:

(i) testing:

(ii) conducting trials or field tests:

(iii) undertaking research or experiments

medical activity means an activity in relation to a regulated genetically modified organism that is intended to be administered—

(a) to a human for a therapeutic purpose; or

(b) to an animal for a therapeutic purpose or as a veterinary medicine; or

(c) to enable the use of a medical device, medicine, or veterinary medicine on humans or animals; or

(d) to enable the undertaking of clinical trials on humans or testing of veterinary medicines on animals.

~~(a) means an activity involving administering a regulated organism or gene technology—~~

~~(i) to a human for a therapeutic purpose; or~~

~~(ii) to an animal for a therapeutic or veterinary purpose; or~~

~~(iii) to enable the use of a medical device on humans or animals; or~~

~~(iv) to enable the undertaking of clinical trials on humans or animals; and~~

~~(b) includes the administration of medicines or veterinary medicines using a gene technology or regulated organism.~~

9 Transitional, savings, and related provisions

The transitional, savings, and related provisions in **Schedule 1** have effect according to their terms.

10 Act binds the Crown

This Act binds the Crown.

Part 2
Regulation of gene technology

11 Interpretation

In this Part, unless the context otherwise requires,—

relevant Minister means a Minister of the Crown who, under the authority of a warrant or with the authority of the Prime Minister, is for the time being responsible for the administration of—

(a) the Agricultural Compounds and Veterinary Medicines Act 1997; or

(b) the Biosecurity Act 1993; or

(c) the Conservation Act 1987; or

(d) the Fisheries Act 1996; or

(e) the Hazardous Substances and New Organisms Act 1996; or

(f) the Health Act 1956; or

(g) the Medicines Act 1981; or

(h) the Civil Defence Emergency Management Act 2002

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

risk assessment, in relation to an activity, means a document that—

(a) identifies any relevant risks of the activity; and

(b) assesses the likelihood of harm occurring as a result of the risks; and

(c) assesses the likely degree of harm occurring as a result of the risks; and

(d) identifies any material adverse effect on a kaitiaki relationship that may result from ~~an environmental risk~~ a risk to the environment posed by the activity; and

(e) contains any information prescribed by regulations

risk management plan, in relation to an activity, means a document that—

(a) sets out a plan for reasonably managing and controlling any relevant risks, and adequately mitigating any material adverse effect on a kaitiaki relationship, identified in the risk assessment for the activity; and

(b) contains any information prescribed by regulations

transhipment activity, in relation to a ~~regulated organism~~ regulated genetically modified organism, means the importation into New Zealand of the ~~regulated organism~~ regulated genetically modified organism solely for the purpose of export within 20 working days to a destination outside New Zealand.

Subpart 1—Determinations about what constitutes ~~regulated organism~~ regulated genetically modified organism or gene technology

12 Regulator may determine what constitutes ~~regulated organism~~ regulated genetically modified 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~~ regulated genetically modified organism; or

(b) any technology ~~technique~~ is a gene technology; or

(c) any organism ~~or technique~~ falls within an exemption made ~~by~~ under **section 163(4)**.

(2) The Regulator may request the applicant to provide any information that the Regulator considers necessary for the purposes of making the determination.

(3) Before making a determination under this section, the Regulator must, ~~where~~ if relevant to the determination, have regard to—

(a) any previous determinations made under this section; and

(b) any information provided by the applicant; and

(c) any information provided by the Technical Advisory Committee or the Māori Advisory Committee; and

(d) any information provided by any department (as defined in section 5 of the Public Service Act 2020) or any Crown entity; and

(e) any other information held by the Regulator.

(4) If the Regulator decides not to make a determination that a person has applied for under **subsection (1)** or makes a different determination, the Regulator must—

(a) notify the person in writing with reasons; and

(b) specify in the notice that the person has—

(i) a right of review under **section 134**; and

(ii) a right of appeal under **section 142**.

(5) The Regulator must publish any determination made under this section on an internet site maintained by or on behalf of the Regulator.

(6) The Regulator must apply this Act in accordance with any determination made under this section.

Subpart 2—General provisions

13 Authorisation required for activities with ~~regulated organisms~~ regulated genetically modified organisms

A person must not carry out an activity in relation to a ~~regulated organism~~ regulated genetically modified organism unless the person is authorised to carry out the activity under—

(a) ~~the activity is~~ a declaration of a non-notifiable activity; or

(b) ~~the activity is~~ a declaration of a notifiable activity; or

(c) ~~the person is authorised to carry out the activity by~~ a licence; or

(d) ~~the person is authorised to carry out the activity by a mandatory~~ an equivalent medical authorisation; or

(e) ~~the person is authorised to carry out the activity by~~ an emergency authorisation.

Compare: Gene Technology Act 2000 s 32 (Aust)

13A Approval required for synthetic nucleic acid providers, manufacturers, and third-party vendors

If the regulations require a person to be approved in order to act as a provider, manufacturer, or third-party vendor, a person must not act as a provider, manufacturer, or third-party vendor unless they are approved by a notice issued under **section 149**.

14 Person must not breach conditions ~~of authorisation~~

A person must not breach any condition that applies to the person under—

(a) a declaration of a non-notifiable activity; or

(b) a declaration of a notifiable activity; or

(c) a declaration of a pre-assessed activity; or

(d) a licence; or

(e) ~~a mandatory~~ an equivalent medical authorisation; or

(f) an emergency authorisation~~.~~; or

(g) an approval under **section 149**.

Compare: Gene Technology Act 2000 s 34 (Aust)

15 Conditions that may be imposed in relation to authorisation

Unless the context otherwise requires, a power to impose conditions in relation to the authorisation of an activity or the declaration of a pre-assessed activity under this Part includes a power to impose conditions relating to—

(a) the scope of the activity ~~authorised~~:

(b) the purposes for which the activity may be carried out:

(c) documentation and record-keeping requirements:

(d) the required level of containment in respect of the activity:

(e) disposal requirements:

(f) data and sample collection and verification, including details of the studies to be conducted:

(g) auditing and reporting:

(h) in the case of the ~~release of a regulated organism~~ introduction of a regulated genetically modified organism from containment, actions to be taken:

(i) the location or geographic area in which the activity may occur:

(j) supervision and monitoring requirements:

(k) contingency planning in respect of unintended effects of the activity:

(l) limiting the dissemination or persistence of the ~~regulated organism~~ regulated genetically modified organism or its genetic material in the environment:

(m) insurance against any loss, damage, or injury that may be caused to human health, property, or the environment by the activity:

(n) any other measures to manage and control relevant risks or mitigate material adverse effects on kaitiaki relationships.

16 Authorisation of medical activities does not count as approval for other purposes

The authorisation of a medical activity under this Act is not an approval—

(a) to use any medicine or medical device involved in the activity until that medicine or medical device has been lawfully supplied for use under the Medicines Act 1981; or

(b) to use any veterinary medicine involved in the activity until that veterinary medicine has been approved for use under the Agricultural Compounds and Veterinary Medicines Act 1997.

17 Applications under this Part

(1) An application under this Part must—

(a) be in writing; and

(b) be in the form required by the Regulator; and

(c) contain any information required by the Regulator; and

(d) contain any information prescribed in regulations; and

(e) be accompanied by the fee (if any) prescribed in regulations.

(2) The Regulator may, within 20 working days after an application is first made under this Part, determine that the application is incomplete if the application does not meet the requirements of this Act.

(3) The Regulator must immediately return an incomplete application to the applicant, with written reasons for the determination.

(4) If an application is made again after the Regulator has returned the application,—

(a) that application must be treated as a new application; and

(b) the time period specified in **subsection (2)** begins again for the Regulator.

18 Consultation

In exercising any function under this Part, the Regulator may—

(a) commission any research or expert advice that the Regulator considers necessary; and

(b) consult any person that the Regulator considers necessary.

18A No compensation for loss resulting from change to authorisation

No compensation is payable by the Regulator to any person for any loss as a result of—

(a) the suspension, cancellation, surrender, variation, or transfer of a licence; or

(b) the variation or revocation of a declaration under **section 23, 47, or 48**; or

(c) the variation or revocation of an equivalent medical authorisation; or

(d) the variation, suspension, or revocation of an emergency authorisation.

Subpart 3—Licences

Licence applications

19 Licence applications

(1) A person may apply to the Regulator for a licence authorising ~~the person to carry out~~ an activity in relation to a ~~regulated organism~~ regulated genetically modified organism.

(2) The application may seek authorisation in respect of—

(a) 1 or more specified activities; or

(b) a specified class of activities; or

(c) all activities.

(3) The application may seek authorisation for the activities to be carried out in relation to—

(a) 1 or more specified ~~regulated organisms~~ regulated genetically modified organisms; or

(b) a specified category of ~~regulated organisms~~ regulated genetically modified organisms.

(4) The application may seek authorisation for the activities to be carried out by—

(a) 1 or more specified persons; or

(b) a specified class of persons; or

(c) all persons.

Compare: Gene Technology Act 2000 s 40 (Aust)

20 Joint applications

(1) A person may make a joint application to the Regulator and the EPA that comprises both—

(a) an application under **section 19** for a licence authorising a person to carry out an activity in relation to a ~~regulated organism~~ regulated genetically modified organism; and

(b) an application under 1 or more of the following provisions of the Hazardous Substances and New Organisms Act 1996 that relates to a new organism and is made in respect of the same person, activity, and ~~regulated organism~~ regulated genetically modified organism as the application mentioned in **paragraph (a)**:

(i) section 34 (application for approval to import or release):

(ii) section 38A (application for approval to import or release new organism with controls):

(iii) section 40 (application for containment approval for new organisms):

(iv) section 47 (application for approval to use hazardous substance or new organism in emergency):

(v) section 49D (application for approval to use agricultural compound or medicine in special emergency):

(vi) section 51 (transhipment of substances and organisms).

(2) Unless otherwise provided in regulations, a joint application must contain all information that would be required for each of the applications that the joint application comprises if those applications were made separately.

(3) The Regulator and the EPA must collaborate with each other for the purposes of assessing a joint application made under this section.

(4) If a person makes a joint application under this section, the person is to be treated as if the person had separately made each of the applications that the joint application comprises.

(5) *See* **sections ~~152~~ 151 and ~~153~~154** regarding sharing information and exchanging samples for the purposes of assessing a joint application made under this section.

21 Certain licence applications must contain additional information about kaitiaki relationships

(1) This section applies if a person applies for a licence in respect of an activity that—

(a) is to be carried out in relation to a ~~regulated organism~~ regulated genetically modified organism that ~~uses an indigenous species as~~ is derived from a host organism~~; and~~ that is—

(i) an indigenous species; or

(ii) a non-indigenous species of significance; and

(b) is not any of the following:

(i) a pre-assessed activity:

(ii) a transhipment activity:

(iii) ~~an activity that the licence application asserts is~~ a low-risk medical activity.

(2) If the person knows that a kaitiaki has asserted that authorising the activity would create a risk to the environment that may have a material adverse effect on a kaitiaki relationship, the licence application must include—

(a) the name of the kaitiaki; and

(b) a summary of any engagement the person has conducted with the kaitiaki; and

(c) if supplied to the applicant, any assessment by the kaitiaki of material adverse effects on the kaitiaki relationship that may result if the ~~application is granted~~ licence is issued; and

(d) if there is an agreement between the person and the kaitiaki about how any material adverse effect can be mitigated, a copy or summary of that agreement with redactions of any information that the kaitiaki considers is not relevant to the licence application.

22 Licence applications may be withdrawn

The applicant may withdraw a licence application at any time before the licence is issued.

Compare: Gene Technology Act 2000 s 41 (Aust)

23 Regulator may declare pre-assessed activities for purposes of licence applications

(1) The Regulator may declare that an activity (other than a contained activity) is a pre-assessed activity for the purposes of any licence application in respect of that activity, if—

(a) the Regulator has complied with the applicable requirements in **sections 26 to 29**; and

(b) the Regulator is satisfied that the relevant risks of the activity are no more than medium, having regard to—

(i) the nature of the relevant risks; and

(ii) the likelihood of harm occurring as a result of the risks; and

(iii) the degree of harm likely to result if the risks occur; and

(c) the Regulator is satisfied that the relevant risks can be reasonably managed and controlled, having regard to—

(i) the matters mentioned in **paragraph (b)(i) to (iii)**; and

(ii) the availability of mitigations (including the conditions that would apply under **subsection (2)**); and

(d) the Regulator is satisfied of any other matters prescribed in the regulations.

(2) A declaration is subject to any conditions specified in the declaration that the Regulator considers necessary or desirable.

(3) A declaration may be made in respect of—

(a) 1 or more specified activities; or

(b) a specified class of activities.

(4) A declaration may be limited to activities carried out in relation to—

(a) 1 or more specified ~~regulated organisms~~ regulated genetically modified organisms; or

(b) a specified category of ~~regulated organisms~~ regulated genetically modified organisms.

(4A) A declaration may be limited to activities carried out by—

(a) 1 or more specified persons; or

(b) a specified class of persons; or

(c) all persons.

(5) A declaration under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

24 Prerequisites for varying or revoking declarations of pre-assessed activities ~~Revocation of declaration of pre-assessed activity~~

~~(1) Before revoking a declaration of a pre-assessed activity,—~~

~~(a) the Regulator must first seek and have regard to advice (if any) from the Technical Advisory Committee; and~~

~~(b) the Regulator must then publish a notice on an internet site maintained by or on behalf of the Regulator that—~~

~~(i) explains what the Regulator proposes to do, with reasons; and~~

~~(ii) invites written submissions in relation to the proposal; and~~

~~(iii) specifies the last day on which written submissions may be made, which must be no earlier than 30 working days after the day on which the notice is published.~~

(1) The Regulator must seek and have regard to advice from the Technical Advisory Committee—

(a) before varying a declaration of a pre-assessed activity, unless—

(i) the Regulator considers that the variation 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; or

(ii) the variation is minor in effect or corrects a minor or technical error:

(b) before revoking a declaration of a pre-assessed activity, unless the Regulator considers that the 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.

(1A) After complying with any requirements under **subsection (1)**, the Regulator must publish a notice on an internet site maintained by or on behalf of the Regulator that—

(a) explains what the Regulator proposes to do, with reasons; and

(b) invites written submissions in relation to the proposal; and

(c) specifies the last day on which written submissions may be made, which must be no earlier than 30 working days after the day on which the notice is published.

(2) The Regulator must have regard to any written submissions received in the course of public consultation under ~~**subsection (1)**~~ **subsection (1A)**.

~~(3) However, **subsection (1)** does not apply if the Regulator considers that the revocation is necessary or desirable in order to avoid an imminent risk of death, serious illness, or serious injury to any person or serious damage to the environment.~~

(3) However, **subsection (1A)(b) and (c)** does not apply—

(a) in respect of a variation—

(i) if the Regulator considers that the variation 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; or

(ii) if the variation is minor in effect or corrects a minor or technical error:

(b) in respect of a revocation if the Regulator considers that the 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.

(4) A failure to comply with this section does not affect the validity of the variation or revocation of a declaration.

(5) *See* **section 126** about engagement with the Māori Advisory Committee in relation to declarations of pre-assessed activities.

Risk assessments and risk management plans

25 Regulator must notify applicant if proposing to prepare risk assessment and risk management plan

(1) When assessing a licence application, the Regulator must notify the applicant in writing if the Regulator proposes to—

(a) prepare a risk assessment and a risk management plan under **section 26** in relation to an activity for which authorisation is being sought where the licence application asserts that preparation of a risk assessment and a risk management plan is not required under that section:

(b) release drafts of the risk assessment and the risk management plan for public consultation under **section 28** where the licence application asserts that the release of the drafts is not required under that section.

(2) If the applicant does not agree with what the Regulator proposes, the applicant may, within 30 working days of receiving the notice,—

(a) request the Regulator to reconsider its proposal; and

(b) provide further information to the Regulator for that purpose.

(3) The Regulator must—

(a) have regard to any request and further information provided under **subsection (2)**; and

(b) notify the applicant of its decision, in writing with reasons.

26 Preparation of risk assessment and risk management plan

(1) This section applies if—

(a) the Regulator is assessing a licence application in respect of an activity that is not any of the following:

(i) a pre-assessed activity:

(ii) a transhipment activity:

(iii) ~~an activity that the licence application asserts is~~ a low-risk medical activity; or

(b) the Regulator is proposing to declare that an activity is a pre-assessed activity under **section 23**.

(2) The Regulator must prepare a risk assessment and a risk management plan in relation to the activity in accordance with any timetable prescribed by the regulations.

(3) If the Regulator considers that it does not have sufficient information to prepare the risk assessment or the risk management plan in respect of a licence application, the Regulator must—

(a) notify the applicant in writing; and

(b) specify the additional information that the Regulator requires; and~~.~~

(c) specify the time by which the information must be provided.

(4) The Regulator may reject the licence application if the applicant does not provide the information by the date specified under **subsection (3)(c)**.

Compare: Gene Technology Act 2000 s 50 (Aust)

27 Advice in relation to draft risk assessment and draft risk management plan

(1) This section applies if the Regulator is required to prepare a risk assessment and a risk management plan in relation to an activity under **section 26**.

(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.

(3) 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

(b) drafts of the risk assessment and the risk management plan.

(4) The Regulator must—

(a) have regard to any advice provided by the Technical Advisory Committee; and

(b) make any amendments to the drafts of the risk assessment and the risk management plan that the Regulator considers necessary on the basis of that advice.

(4A) The Regulator must also take into account any matters specified in regulations made under **section 161(b)**.

(5) *See* **section 126** about engagement with the Māori Advisory Committee in relation to risk assessments~~,~~ and risk management plans.

28 Public consultation on draft risk assessment and draft risk management plan

(1) This section applies if—

(a) the Regulator is required to prepare a risk assessment and a risk management plan in relation to an activity under **section 26**; and

(b) the Regulator has complied with the requirements in **section 27**.

(2) The Regulator must release drafts of the risk assessment and the risk management plan for public consultation in accordance with any timetable prescribed by regulations, unless—

(a) both of the following conditions are met:

(i) the Regulator has previously released drafts of a risk assessment and risk management plan for public consultation under this section in relation to an activity that the Regulator considers is substantially the same:

(ii) the Regulator has not become aware of any significant new information in relation to the relevant risks of that activity; or

(b) both of the following conditions are met:

(i) a recognised overseas authority has already authorised the activity:

(ii) the information, assessments, and conditions on the basis of which the recognised overseas authority has authorised the activity are readily accessible to the Regulator; or

(c) the activity is a contained activity.

(3) The Regulator may release drafts of the risk assessment and the risk management plan for public consultation in accordance with any timetable prescribed by regulations, even if the Regulator is not required to do so under **subsection (2)**.

(4) The Regulator must publish any drafts that it releases for public consultation on an internet site maintained by or on behalf of the Regulator.

(5) The Regulator must also publish a notice on that internet site that—

(a) states that the Regulator has released the drafts for public consultation; and

(b) includes a link to the drafts; and

(c) invites written submissions in relation to the drafts and specifies any requirements in relation to the form and manner of those submissions; and

(d) states whether the draft of the risk assessment includes an assessment that—

(i) the likelihood of any harm occurring as a result of a relevant risk is high or uncertain; or

(ii) the likely degree of harm if any harm occurs is significant or uncertain; and

(e) states whether the Regulator has collaborated with a recognised overseas authority or any other agency for the purposes of preparing the drafts; and

(f) specifies the last day on which written submissions may be made, which must be—

(i) no earlier than 50 working days after the day on which the notice is first published, if the draft of the risk assessment includes an assessment of the kind mentioned in **paragraph (d)(i) or (ii)**; and

(ii) no earlier than 30 working days after the day on which the notice is published, in any other case.

(6) The Regulator—

(a) must have regard to any written submissions received in the course of public consultation under this section; and

(b) may seek advice from the Māori Advisory Committee and the Technical Advisory Committee in relation to any written submission; and

(c) must make any amendments to the drafts of the risk assessment and the risk management plan that the Regulator considers necessary or desirable on the basis of those submissions, that advice, and any other information that the Regulator considers relevant ~~and that advice~~.

29 Finalising draft risk assessment and draft risk management plan

The Regulator must finalise the drafts of any risk assessment and risk management plan required to be prepared under **section 26** once the Regulator has— ~~complied with the requirements in **sections 27 and 28** in relation to those drafts.~~

(a) complied with the requirements in **sections 27 and 28** in relation to those drafts; and

(b) taken into account any matters specified in regulations made under **section 161(b)**.

30 New or amended risk assessment and risk management plan

~~(1) This section applies if the Regulator becomes aware of significant new information about the relevant risks of an activity in relation to which a risk assessment and a risk management plan have been finalised under **section 29**.~~

~~(2) If the Regulator considers that the new information means that the risk assessment or risk management plan is no longer materially accurate, the Regulator must prepare a new risk assessment or risk management plan in relation to the activity in accordance with any timetable prescribed by regulations.~~

(1) This section applies if—

(a) the Regulator considers that a risk assessment or risk management plan that has been finalised under **section 29** in relation to an activity is no longer materially accurate; and

(b) either—

(i) a licence in relation to the activity has been issued or is pending under **section 33**; or

(ii) a declaration in relation to the activity has been made or is pending under **section 23**.

(2) The Regulator must prepare a new risk assessment or risk management plan in relation to the activity in accordance with any timetable prescribed by regulations.

(3) However, if the inaccuracy ~~new information~~ concerns 1 or more specific aspects of the risk assessment or risk management plan, the Regulator may instead amend the risk assessment or risk management plan to address those specific aspects in accordance with any timetable prescribed by regulations.

(4) If the Regulator prepares a new or an amended risk assessment or risk management plan—

(a) in relation to an activity ~~authorised by a licence~~ for which a licence has been issued or is pending under **section 33**, the Regulator must give notice to the licence holder or applicant, in writing with reasons ~~in writing, with reasons~~; and

(b) in relation to an activity for which a declaration has been made or is pending under **section 23** ~~a pre-assessed activity~~, the Regulator must—

(i) give notice, with reasons, in the *Gazette* and on ~~the Regulator's internet site with reasons~~ an internet site maintained by or on behalf of the Regulator; and

(ii) if a declaration has been made in relation to the activity under **section 23**, give notice to each person who holds a licence in respect of the activity ~~the pre-assessed activity~~, in writing with reasons.

(5) **Sections 26 to 29** apply to the preparation of any new or amended risk assessment or risk management plan (with any necessary modifications).

(6) The Regulator must have regard to any new or amended risk assessment or risk management plan finalised under **section 29** for the purposes of deciding what action (if any) to take under this Act in relation to the licence or the declaration ~~of the pre-assessed activity~~.

31 Temporary restrictions while preparing new or amended risk assessment and risk management plan

(1) The Regulator may, by notice in the *Gazette* and on ~~the Regulator's internet site~~ an internet site maintained by or on behalf of the Regulator, prohibit or restrict any activity in relation to a ~~regulated organism~~ regulated genetically modified organism if—

(a) the Regulator has decided to prepare a new or an amended risk assessment ~~and~~ or risk management plan in relation to the activity under **section 30**; and

(b) the Regulator has reasonable cause to believe that there is actual or likely danger to the health and safety of people or the environment from the activity; and

(c) the Regulator has consulted the persons who the Regulator considers are likely to be directly affected by the restriction.

(2) The notice—

(a) may prohibit or restrict the activity in specified circumstances or places, or from being carried out by specified classes of persons; and

(b) must identify the nature of the prohibition or restriction, including any conditions; and

(c) remains in force until the earlier of the following:

(i) the date on which the Regulator finalises the new or amended risk assessment and risk management plan:

(ii) the date that is 1 year after the date on which the notice made under **subsection (1)** is published in the *Gazette*.

32 Minor amendments to risk assessment or risk management plan

(1) The Regulator may amend a risk assessment or risk management plan to correct minor or technical errors.

(2) If the Regulator prepares an amended risk assessment or risk management plan under **subsection (1)**—

(a) in relation to an activity for which a licence has been issued or is pending under **section 33**, the Regulator must give notice to the licence holder or applicant; and

(b) in relation to an activity for which a declaration has been made or is pending under **section 23**, the Regulator must—

(i) give notice, with reasons, in the *Gazette* and on an internet site maintained by or on behalf of the Regulator; and

(ii) if a declaration has been made in relation to the activity under **section 23**, give notice to each person who holds a licence in respect of the activity.

Licensing decisions

33 Regulator must make decision on licence application

(1) After taking any steps required under **sections 25 to 29** in relation to a licence application, the Regulator must, in accordance with any timetable prescribed by regulations,—

(a) issue the licence; or

(b) refuse to issue the licence.

(2) The Regulator may only issue a licence for a pre-assessed activity if the Regulator is satisfied that—

(a) the applicant is a fit and proper person to hold the licence (*see* **section 35**); and

(b) the applicant is willing and able to meet the conditions attached to the licence (*see* **sections 15 and 37**).

(3) The Regulator may only issue a licence for a transhipment activity if the Regulator is satisfied that—

(a) the ~~regulated organism~~ regulated genetically modified organism that is to be transhipped can be adequately contained so as to protect the environ-

ment from being exposed to the organism and any adverse effects of the organism; and

(b) the applicant is willing and able to meet the conditions attached to the licence.

(4) The Regulator may only issue a licence for an activity that the licence application asserts is a low-risk medical activity if the Regulator is satisfied that—

(a) the activity is a low-risk medical activity; and

(b) the applicant is a fit and proper person to hold the licence; and

(c) the applicant is willing and able to meet the conditions attached to the licence.

(5) The Regulator may only issue a licence for an activity that is not mentioned in **subsections (2) to (4)** if the Regulator is satisfied that—

(a) any relevant risks of the activity can be reasonably managed and controlled, having regard to—

(i) the nature of the relevant risks; and

(ii) the likelihood of harm occurring as a result of the risks; and

(iii) the likely degree of harm if harm occurs; and

(iv) the availability of mitigations (including the conditions that would apply under **section 37**); and

(b) the applicant is a fit and proper person to hold the licence; and

(c) the applicant is willing and able to meet the conditions attached to the licence.

(6) For the purposes of making a decision under this section, the Regulator must have regard to—

(a) any finalised risk assessment and risk management plan in relation to the activities; and

(b) any submissions or advice received under **sections 26 to 28**; and

(c) any applicable standards issued under this Act; and

(d) any matters prescribed in regulations.

Compare: Gene Technology Act 2000 s 55 (Aust)

34 Notice requirements for decision on licence application

(1) If the Regulator decides to issue a licence, the Regulator must—

(a) provide a copy of its decision to the applicant in writing; and

(b) specify in the decision that the applicant has, in relation to any conditions imposed on the licence under **section 37**,—

(i) a right of review under **section 134**; and

(ii) a right of appeal under **section 142**.

(c) publish the following on ~~the Regulator's internet site~~ an internet site maintained by or on behalf of the Regulator:

(i) a notice that the licence has been issued to the applicant; and

(ii) a copy of the written decision; and

(iii) a copy of the licence; and

(iv) a copy of any finalised risk assessment and risk management plan prepared in relation to the licence; and

(v) a summary of any written submissions received in the course of public consultation under **section 28**.

(2) If the Regulator refuses to issue a licence, the Regulator must—

(a) provide its decision to the applicant in writing with reasons; and

(b) specify in the decision that the applicant has—

(i) a right of review under **section 134**; and

(ii) a right of appeal under **section 142**; and

(c) publish the following on ~~the Regulator's internet site~~ an internet site maintained by or on behalf of the Regulator as soon as is reasonably practicable after the applicant's rights of review and appeal have been exhausted:

(i) a copy of the written decision; and

(ii) a copy of any finalised risk assessment and risk management plan prepared in relation to the licence; and

(iii) a summary of any written submissions received in the course of public consultation under **section 28**.

35 Determining whether person is fit and proper person to hold licence

(1) In determining whether a person is a fit and proper person to hold a licence, the Regulator must have regard to the following in relation to the person and any key officer of the person:

(a) any conviction of the person or key officer for—

(i) an offence against a relevant law; or

(ii) a crime involving dishonesty (as defined in section 2 of the Crimes Act 1961):

(b) any civil penalty order made against the person or key officer under a relevant law:

(c) if the person or key officer holds or has held a licence, permit, approval, registration, exemption, or other authorisation under a relevant law (an **authority**),—

(i) any suspension or revocation of the authority:

(ii) any enforcement or disciplinary action taken against the person or key officer in relation to the authority:

(iii) any disqualification from holding the authority:

(iv) any contravention by the person or key officer of the authority or a provision of a relevant law that applied to the person or key officer as the holder of the authority:

(d) whether there are other reasonable grounds to believe that the person or key officer is likely to contravene a provision of this Act:

(e) whether the person or key officer is or has been—

(i) bankrupt; or

(ii) subject to an insolvency event (as defined in section 6(4) of the Financial Markets Conduct Act 2013) or to an equivalent event under a law of another country:

(f) whether the person or key officer is of good character:

(g) any matter in regulations referred to in **section 162**:

(h) any other matters that the Regulator thinks are relevant.

~~(2) In this section, **relevant law** means any of the following Acts (or secondary legislation made under them):~~

~~(a) this Act:~~

~~(b) the Agricultural Compounds and Veterinary Medicines Act 1997:~~

~~(c) the Animal Products Act 1999:~~

~~(d) the Animal Welfare Act 1999:~~

~~(e) the Biosecurity Act 1993:~~

~~(f) the Customs and Excise Act 2018:~~

~~(g) the Conservation Act 1997:~~

~~(h) the Fair Trading Act 1986:~~

~~(i) the Food Act 2014:~~

~~(j) the Hazardous Substances and New Organisms Act 1996:~~

~~(k) the Human Assisted Reproductive Technology Act 2004:~~

~~(l) the Human Tissue Act 2008:~~

~~(m) the Imports and Exports (Restrictions) Act 1988:~~

~~(n) the Medicines Act 1981:~~

~~(o) the National Parks Act 1980:~~

~~(p) the Resource Management Act 1991:~~

~~(q) the Reserves Act 1977:~~

~~(r) any other New Zealand legislation that the regulations referred to in **section 162** specify is a relevant law:~~

~~(s) a law in another country that—~~

~~(i) the regulations specify is a relevant law; or~~

~~(ii) corresponds to all or part of a law referred to in **paragraphs (a) to (q)**.~~

(2) In this section,—

key officer, in relation to a person, means a director or manager of the person

relevant law means any of the following (including secondary legislation made under them):

(a) this Act:

(b) the Agricultural Compounds and Veterinary Medicines Act 1997:

(c) the Animal Products Act 1999:

(d) the Animal Welfare Act 1999:

(e) the Biosecurity Act 1993:

(f) the Conservation Act 1987:

(g) the Customs and Excise Act 2018:

(h) the Fair Trading Act 1986:

(i) the Food Act 2014:

(j) the Hazardous Substances and New Organisms Act 1996:

(k) the Health and Safety at Work Act 2015:

(l) the Human Assisted Reproductive Technology Act 2004:

(m) the Human Tissue Act 2008:

(n) the Imports and Exports (Restrictions) Act 1988:

(o) the Medicines Act 1981:

(p) the National Parks Act 1980:

(q) the Reserves Act 1977:

(r) the Resource Management Act 1991:

(s) any other New Zealand legislation that the regulations referred to in **section 162** specify is a relevant law:

(t) a law in another country that—

(i) the regulations specify is a relevant law; or

(ii) corresponds to all or part of a law referred to in **paragraphs (a) to (s)**.

Contents and conditions of licences

36 Contents of licence

(1) A licence issued by the Regulator must specify—

(a) the activities authorised by the licence; and

(b) the ~~regulated organisms~~ regulated genetically modified organisms in relation to which the activities are authorised; and

(c) the persons authorised to carry out the activities; and

(d) the conditions of the licence; and

(e) the particular period for which the licence is in force (if any).

(2) If a risk assessment and a risk management plan have been prepared in relation to the licence, a statement must be included in the licence that the risk assessment and risk management plan can be accessed on ~~the Regulator's internet site~~ an internet site maintained by or on behalf of the Regulator.

37 Licences are subject to conditions

(1) A licence is subject to the following conditions:

(a) the licence holder must notify the Regulator in writing within 10 working days of any change to the licence holder's name, address, or contact details; and

(b) the licence holder must notify the Regulator and the enforcement agency in writing as soon as is reasonably practicable if—

(i) the licence holder has failed to, or is no longer willing or able to, comply with ~~any~~ a condition attached to the licence; or

(ii) the licence holder becomes aware that a person authorised by the licence to carry out any activity has failed to, or is no longer willing or able to, comply with a condition attached to the licence; and

(c) in the case of a licence for an activity that is not a transhipment activity, the licence holder must notify the Regulator in writing as soon as is reasonably practicable if any of the circumstances mentioned in **section 35(1)(a) to (c) or (e)** apply in relation to the licence holder ~~and the Regulator has not been made aware of them~~; and

(d) the licence holder must notify the Regulator and the enforcement agency in writing within 10 working days of becoming aware of any significant new information about the relevant risks of an activity; and

(e) the licence holder must, if the licence authorises 1 or more specified persons to carry out an activity,—

(i) notify those persons in writing, before they start undertaking the activity, of any conditions attached to the licence that those persons must comply with; and

(ii) notify those persons in writing, as soon as is reasonably practicable, of any variation, surrender, suspension, or cancellation of the licence; and

(f) the licence holder must, if the licence authorises a specified class of persons or all persons to carry out an activity,—

(i) publish within 20 working days ~~1 month~~ of the licence being issued, in a place and manner that is readily accessible to those persons, any conditions attached to the licence that those persons must comply with; and

(ii) publish as soon as is reasonably practicable, in a place and manner that is readily accessible to those persons, notice of any variation, surrender, suspension, or cancellation of the licence; and

(g) if the licence authorises a person to carry out a contained activity in relation to a ~~regulated organism~~ regulated genetically modified organism, the person—

(i) must not ~~release the regulated organism~~ introduce the regulated genetically modified organism into the environment; and

(ii) must notify the Regulator and the enforcement agency in writing of any introduction of the ~~regulated organism~~ regulated genetically modified organism into the environment as soon as is reasonably practicable ~~and~~ but no later than 24 hours after becoming aware of it.

(2) The Regulator may impose any other conditions on a licence that the Regulator considers necessary or desirable.

(3) However, if the licence is for a pre-assessed activity, the Regulator may only impose conditions in addition to those imposed under **section 23(2)** if ~~that~~ the Regulator considers they are necessary or desirable for any of the following purposes:

(a) auditing and reporting on the activity:

(b) supervision and monitoring of the activity.

Compare: Gene Technology Act 2000 s 61 (Aust)

38 Period of licence

(1) A licence continues in force,—

(a) if the licence is expressed to be in force for a particular period, until the end of that period; or

(b) otherwise, until it is cancelled under **section 39** or surrendered under **section 41**.

(2) A licence is not in force throughout any period of suspension under **section 39**.

Compare: Gene Technology Act 2000 s 60 (Aust)

Suspension, cancellation, surrender, variation, and transfer of licences

39 Suspension and cancellation of licence

(1) The Regulator may suspend or cancel a licence if—

(a) the Regulator believes on reasonable grounds that a condition of the licence has been breached, whether by the licence holder or by a person authorised by the licence to carry out an activity; or

(b) the Regulator believes on reasonable grounds that the licence holder, or a person authorised by the licence to carry out any activity, has committed an offence against this Act; or

(c) the Regulator believes on reasonable grounds that the licence was obtained on the basis of false or misleading information; or

(d) the Regulator becomes aware of relevant risks associated with the continuation of the activity authorised by the licence, and is satisfied that the licence holder has not proposed, or is not in a position to implement, measures to reasonably manage and control those risks; or

(e) in the case of a licence for an activity that is not a transhipment activity, the Regulator believes on reasonable grounds that the licence holder is no longer a fit and proper person to hold the licence; or

(f) the Regulator is satisfied that all the persons who are authorised to carry out activities in relation to ~~regulated organisms~~ regulated genetically modified organisms under the licence are authorised to carry out those activities, or activities that are substantially the same,—

(i) by virtue of a declaration under **section 47 or 48**; or

(ii) under another licence; or

(iii) under ~~a mandatory~~ an equivalent medical authorisation; or

(iv) under an emergency authorisation; or

(g) the Regulator believes on reasonable grounds that there is no prospect that any of the persons who are authorised to carry out activities in relation to ~~regulated organisms~~ regulated genetically modified organisms under the licence will carry out those activities.

(2) The Regulator may request the licence holder to provide any information that the Regulator considers necessary for the purposes of exercising its discretion under this section.

Compare: Gene Technology Act 2000 s 68 (Aust)

40 Notice requirements for suspension and cancellation of licence

(1) If the Regulator proposes to suspend or cancel a licence, the Regulator must—

(a) give notice to the licence holder in writing with reasons; and

(b) give the licence holder at least 30 working days to respond; and

(c) consider any response provided by the applicant before making a decision.

(2) However, **subsection (1)** does not apply if the Regulator considers that the suspension or cancellation 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.

(3) If the Regulator decides to suspend a licence, the Regulator must—

(a) give notice to the licence holder in writing with reasons and publish the notice on ~~the Regulator's internet site~~ an internet site maintained by or on behalf of the Regulator; and

(b) specify in the notice the day on which the suspension takes effect; and

(c) specify in the notice the duration of the suspension, which must be no longer than 3 months from the day the notice is first published; and

(d) specify in the notice that the licence holder has—

(i) a right of review under **section 134**; and

(ii) a right of appeal under **section 142**.

(4) If the Regulator decides to cancel a licence, the Regulator must,—

(a) give notice to the licence holder in writing with reasons and publish the notice on ~~the Regulator's internet site~~ an internet site maintained by or on behalf of the Regulator; and

(b) specify in the notice the day on which the cancellation takes effect; and

(c) specify in the notice that the licence holder has—

(i) a right of review under **section 134**; and

(ii) a right of appeal under **section 142**.

41 Surrender of licence

(1) A licence holder may apply to the Regulator to surrender their licence.

(2) An application to surrender a licence must be accompanied by any ~~other~~ money outstanding to the EPA and the enforcement agency in relation to the licence.

(3) On receiving an application to surrender a licence, the Regulator may—

(a) request the licence holder to provide any information that the Regulator considers necessary or desirable; and

(b) impose conditions that the Regulator considers necessary or desirable that the licence holder must comply with before the Regulator consents to the surrender.

(4) The Regulator must consent to the surrender if—

(a) the licence holder complies with **subsection (2)**; and

(b) the licence holder has provided any additional information requested under **subsection (3)(a)**; and

(c) the licence holder has complied with any conditions imposed under **subsection (3)(b)**.

Compare: Gene Technology Act 2000 s 69 (Aust)

42 Notice requirements for surrender of licence

(1) If the Regulator does not intend to consent to the surrender of a licence, the Regulator must—

(a) give notice to the applicant in writing~~,~~ with reasons; and

(b) give the applicant at least 30 working days to respond; and

(c) consider any response provided by the applicant before making a decision.

(2) If the Regulator decides to consent to the surrender of a licence,—

(a) the Regulator must give notice to the licence holder in writing and publish the notice on ~~the Regulator's internet site~~ an internet site maintained by or on behalf of the Regulator; and

(b) the surrender takes effect—

(i) on the date specified in the notice; or

(ii) if no such date is specified, on the date the notice is given to the licence holder.

(3) If the Regulator decides not to consent to the surrender of a licence, the Regulator must notify the applicant in writing, with reasons.

43 Transfer of licence

(1) A licence holder and another person (the **transferee**) may jointly apply to the Regulator for a licence to be transferred from the licence holder to the transferee.

(2) If the Regulator receives an application to transfer a licence, the Regulator may—

(a) request the applicants to provide any information that the Regulator considers necessary or desirable; and

(b) impose conditions that the Regulator considers necessary or desirable that the applicants must comply with before the Regulator consents to the transfer.

(3) The Regulator may only consent to the transfer of a licence for a pre-assessed activity if the Regulator is satisfied that—

(a) the transferee is a fit and proper person to hold the licence (*see* **section 35**); and

(b) the transferee is willing and able to meet the conditions attached to the licence.

(4) The Regulator may only consent to the transfer of a licence for a transhipment activity if the Regulator is satisfied that—

(a) the ~~regulated organism~~ regulated genetically modified organism that is to be transhipped can be adequately contained following the transfer so as to protect the environment from being exposed to the organism and any adverse effects of the organism; and

(b) the transferee is willing and able to meet the conditions attached to the licence.

(5) The Regulator may only consent to the transfer of a licence for a low-risk medical activity if the Regulator is satisfied that—

(a) the activity will be a low-risk medical activity following the transfer; and

(b) the transferee is a fit and proper person to hold the licence; and

(c) the transferee is willing and able to meet the conditions attached to the licence.

(6) The Regulator may only consent to the transfer of a licence for an activity that is not mentioned in **subsections (3) to (5)** if the Regulator is satisfied that—

(a) any relevant risks of the activity can be reasonably managed and controlled following the transfer, having regard to—

(i) the nature of the relevant risks; and

(ii) the likelihood of the risks occurring; and

(iii) the likely degree of harm if the risks occur; and

(iv) the availability of mitigations (including the conditions that would apply under **subsection (2)(b)** and **section 37**); and

(b) the transferee is a fit and proper person to hold the licence; and

(c) the transferee is willing and able to meet the conditions attached to the licence.

Compare: Gene Technology Act 2000 s 70 (Aust)

44 Notice requirements for transfer of licence

(1) If the Regulator does not intend to consent to the transfer of a licence, the Regulator must—

(a) give notice to the applicants in writing~~,~~ with reasons; and

(b) give the applicants at least 30 working days to respond; and

(c) consider any response provided by the applicants before making a decision.

(2) If the Regulator decides to consent to the transfer of a licence, the Regulator must—

(a) give notice to the applicants in writing and publish the notice on ~~the Regulator's internet site~~ an internet site maintained by or on behalf of the Regulator; and

(b) specify in the notice the day on which the transfer takes effect.

(3) If the Regulator decides not to consent to the transfer of a licence, the Regulator must—

(a) give notice to the applicants in writing with reasons; and

(b) specify in the notice that the applicants have—

(i) a right of review under **section 134**; and

(ii) a right of appeal under **section 142**.

45 Variation of licence

(1) The Regulator may vary a licence—

(a) on the Regulator's own initiative; or

(b) on application by the licence holder.

(2) The Regulator may request the licence holder to provide any information that the Regulator considers necessary or desirable ~~for the purposes of exercising its discretion under this section~~.

(3) The Regulator may only vary a licence for a pre-assessed activity if the Regulator is satisfied that the applicant is willing and able to meet the conditions attached to the licence (as varied).

(4) The Regulator may only vary a licence for a transhipment activity if the Regulator is satisfied that—

(a) the ~~regulated organism~~ regulated genetically modified organism that is to be transhipped can be adequately contained under the licence (as varied) so as to prevent the environment from being exposed to the organism and any adverse effects of the organism; and

(b) the applicant is willing and able to meet the conditions attached to the licence (as varied).

(5) The Regulator may only vary a licence for a low-risk medical activity if the Regulator is satisfied that—

(a) the activity will be a low-risk medical activity under the licence (as varied); and

(b) the applicant is willing and able to meet the conditions attached to the licence (as varied).

(6) The Regulator may only vary a licence for any other activity if the Regulator is satisfied that—

(a) any relevant risks of the activity authorised by the licence (as varied) can be reasonably managed and controlled, having regard to—

(i) the nature of the relevant risks; and

(ii) the likelihood of harm occurring as a result of the risks; and

(iii) the likely degree of harm if the risks occur; and

(iv) the availability of mitigations (including the conditions that would apply under **section 37**); and

(b) the applicant is willing and able to meet the conditions attached to the licence (as varied).

Compare: Gene Technology Act 2000 s 71 (Aust)

46 Notice requirements for variation of licence

(1) If the Regulator intends to vary a licence on its own initiative or does not intend to consent to a variation that the licence holder has applied for, the Regulator must—

(a) give notice to the licence holder in writing~~,~~ with reasons; and

(b) give the licence holder at least 30 working days to respond; and

(c) consider any response provided by the licence holder before making a decision.

(1A) However, **subsection (1)** does not apply if the Regulator intends to make a variation on their own initiative that the Regulator considers 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.

(2) If the Regulator decides to vary a licence on its own initiative, the Regulator must—

(a) give notice to the licence holder in writing with details of the variation and publish the notice on ~~the Regulator's internet site~~ an internet site maintained by or on behalf of the Regulator; and

(b) specify in the notice the day on which the variation takes effect; and

(c) unless the variation is minor in effect or corrects a minor or technical error, specify in the notice that the licence holder has—

(i) a right of review under **section 134**; and

(ii) a right of appeal under **section 142**.

(3) If the Regulator does not approve an application to vary a licence, the Regulator must—

(a) give notice to the applicant in writing, with reasons; and

(b) specify in the notice that the applicant has—

(i) a right of review under **section 134**; and

(ii) a right of appeal under **section 142**.

Subpart 4—Non-notifiable and notifiable activities

47 Regulator may declare non-notifiable activities

(1) The Regulator may declare that an activity in relation to a ~~regulated organism~~ regulated genetically modified organism is a non-notifiable activity if—

(a) the Regulator has complied with the applicable requirements in **section 49**; and

(b) the Regulator is satisfied that the relevant risks of any person carrying out the activity ~~without notifying the Regulator~~ are very low, having regard to—

(i) the nature of the relevant risks; and

(ii) the likelihood of harm occurring as a result of the risks; and

(iii) the likely degree of harm if the risks occur; and

(iv) the availability of mitigations (including the conditions that would apply under **subsection (3)**); and

(c) the Regulator is satisfied of any other matters prescribed in regulations.

(2) A non-notifiable activity may be carried out by any person authorised under the declaration—

(a) without a licence; and

(b) without notifying the Regulator.

(3) A declaration is subject to the following conditions:

(a) if the activity is a contained activity in relation to a ~~regulated organism~~ regulated genetically modified organism, a person carrying out the activity—

(i) must not ~~release the regulated organism~~ introduce the regulated genetically modified organism into the environment in the course of the activity; and

(ii) must notify the Regulator and the enforcement agency in writing of any introduction of the ~~regulated organism~~ regulated genetically modified organism into the environment as soon as is reasonably practicable ~~and~~, but no later than 24 hours after becoming aware of it:

(b) any condition prescribed by regulations:

(c) any condition specified in the declaration that the Regulator considers necessary or desirable.

(4) A declaration may be made in respect of—

(a) 1 or more specified activities; or

(b) a specified class of activities.

(5) A declaration may be limited to activities carried out in relation to—

(a) 1 or more specified ~~regulated organisms~~ regulated genetically modified organisms; or

(b) a specified ~~class~~ category of ~~regulated organisms~~ regulated genetically modified organisms.

(5A) The declaration may authorise the activities to be carried out by—

(a) 1 or more specified persons; or

(b) a specified class of persons; or

(c) all persons.

(6) A declaration under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

48 Regulator may declare notifiable activities

(1) The Regulator may declare that an activity in relation to a ~~regulated organism~~ regulated genetically modified organism is a notifiable activity if—

(a) the Regulator has complied with the applicable requirements in **section 49**; and

(b) the Regulator is satisfied that the relevant risks of any person carrying out the activity ~~without notifying the Regulator~~ would be low, having regard to—

(i) the nature of the relevant risks; and

(ii) the likelihood of the risks occurring; and

(iii) the likely degree of harm if the risks occur; and

(iv) the availability of mitigations (including the conditions that would apply under **subsection (3)**); and

(c) the Regulator is satisfied of any other matters prescribed in regulations.

(2) A notifiable activity may be carried out by any person authorised under the declaration without a licence.

(3) A declaration under this section is subject to the following conditions:

(a) any person carrying out the activity must, in accordance with any requirements prescribed in regulations, notify the Regulator that they are carrying out the activity:

(b) if the activity is a contained activity in relation to a ~~regulated organism~~ regulated genetically modified organism, any person carrying out the activity—

(i) must not introduce the ~~regulated organism~~ regulated genetically modified organism into the environment in the course of the activity; and

(ii) must notify the Regulator and the enforcement agency in writing of any introduction of the ~~regulated organism~~ regulated genetically modified organism into the environment as soon as is reasonably practicable ~~and~~, but no later than 24 hours after becoming aware of it:

(c) any condition prescribed by regulations:

(d) any condition specified in the declaration that the Regulator considers necessary or desirable.

(4) A declaration under this section may be made in respect of—

(a) 1 or more specified activities; or

(b) a specified class of activities.

(5) A declaration under this section may be limited to activities carried out in relation to—

(a) 1 or more specified ~~regulated organisms~~ regulated genetically modified organisms; or

(b) a specified category of ~~regulated organisms~~ regulated genetically modified organisms.

(5A) The declaration may authorise the activities to be carried out by—

(a) 1 or more specified persons; or

(b) a specified class of persons; or

(c) all persons.

(6) A declaration under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

49 Prerequisites for making, varying, or revoking declarations under section 47 or 48

~~(1) Before making a declaration under **section 47 or 48**, the Regulator must first seek and have regard to advice (if any) from the Technical Advisory Committee.~~

~~(2) Before varying a declaration under **section 47 or 48**, the Regulator must first seek and have regard to advice (if any) from the Technical Advisory Committee, unless—~~

~~(a) the Regulator considers that the variation 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; or~~

~~(b) the variation is minor in effect or corrects a minor or technical error.~~

~~(3) Before revoking a declaration under **section 47 or 48**, the Regulator must first seek and have regard to advice (if any) from the Technical Advisory Committee unless the Regulator considers that the 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.~~

(1) The Regulator must seek and have regard to advice from the Technical Advisory Committee—

(a) before making a declaration under **section 47 or 48**:

(b) before varying a declaration under **section 47 or 48**, unless—

(i) the Regulator considers that the variation 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; or

(ii) the variation is minor in effect or corrects a minor or technical error:

(c) before revoking a declaration under **section 47 or 48**, unless the Regulator considers that the 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.

(4) After complying with any requirements under **subsection (1)** ~~**subsections (1) to (3)**~~, the Regulator must publish a notice on an internet site maintained by or on behalf of the Regulator that—

(a) explains what the Regulator proposes to do, with reasons; and

(b) invites written submissions in relation to the proposal; and

(c) specifies the last day on which written submissions may be made, which must be no earlier than 30 working days after the day on which the notice is published.

(5) The Regulator must have regard to any written submissions received in the course of public consultation under **subsection (4)**.

(6) However, **subsection (4)(b) and (c)** does not apply—

(a) ~~**subsection (4)** does not apply~~ in respect of a variation—

(i) if the Regulator considers that the variation 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; or

(ii) if the variation is minor in effect or corrects a minor or technical error:

(b) ~~**subsection (4)(b) and (c)** does not apply~~ in respect of a revocation if the Regulator considers that the 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.

(6A) A failure to comply with this section does not affect the validity of the making, variation, or revocation of a declaration.

(7) *See* **section 126** about engagement with the Māori Advisory Committee in relation to declarations made under **section 47 or 48**.

Subpart 5—~~Mandatory~~ Equivalent medical authorisations

50 Regulator must grant ~~mandatory~~ equivalent medical authorisation

(1) This section applies if a person notifies the Regulator that 2 or more recognised overseas authorities have granted an authorisation to the person (a **recognised medical authorisation**) that—

(a) authorises an activity (other than a clinical trial) in relation to a regulated genetically modified organism that is intended to be administered—

(i) to a human for a therapeutic purpose; or

(ii) to enable the use of a medical device or medicine on humans; and

(b) is not equivalent to an emergency authorisation.

(2) The Regulator must, in accordance with any timetable prescribed by regulations, grant an authorisation to that person on the same terms (an **equivalent medical authorisation**) if the Regulator is satisfied that—

(a) the recognised medical authorisations have been granted to the person; and

(b) granting the equivalent medical authorisation would not result in an imminent risk of death, serious illness, or serious injury to people or serious damage to the environment.

(3) If the Regulator intends to grant an equivalent medical authorisation, the Regulator must, as soon as is reasonably practicable,—

(a) publish a notice on an internet site maintained by or on behalf of the Regulator; and

(b) notify the person and the Director-General of Health in writing.

~~(1) This section applies if the Regulator becomes aware that 2 or more recognised overseas authorities have authorised a class of persons or all persons (**group A**) to carry out a medical activity in relation to another class of persons or all persons (**group B**) for a particular purpose, except if the authorisation is—~~

~~(a) for an activity involving the administration of a regulated organism or gene technology to—~~

~~(i) an animal for a therapeutic or veterinary purpose; or~~

~~(ii) enable the use of medical devices for animals; or~~

~~(iii) enable the undertaking of clinical trials on humans or animals; or~~

~~(b) equivalent to an emergency authorisation.~~

~~(2) The Regulator must, in accordance with any timetable prescribed by regulations, grant an authorisation (a **mandatory medical authorisation**) to persons who are equivalent to group A to carry out the medical activity in relation to persons who are equivalent to group B for that particular purpose.~~

~~(3) However, **subsection (2)** does not apply if the Regulator considers that granting the authorisation would result in an imminent risk of death, serious illness, or serious injury to people or serious damage to the environment.~~

(4) ~~The~~ Despite **subsection (2)**, the Regulator may impose any conditions on ~~a mandatory~~ an equivalent medical authorisation that the Regulator considers necessary or desirable.

(5) For the purposes of exercising its discretion under **subsection (4)**, the Regulator~~ must have particular regard to the conditions subject to which the recognised overseas authorities have granted the authorisations referred to in **subsection (1)**~~.

(a) must have particular regard to the conditions subject to which the recognised medical authorisations have been granted; and

(b) may consult any person as the Regulator considers necessary (including the Technical Advisory Committee).

~~(6) The Regulator must notify the Director-General of Health in writing as soon as is reasonably practicable if the Regulator proposes to grant a mandatory medical authorisation.~~

(6) The equivalent medical authorisation must authorise any of the following that the recognised medical authorisations authorise:

(a) 1 or more specified activities:

(b) a specified class of activities:

(c) all activities.

(6A) The equivalent medical authorisation must authorise the activities to be carried out in relation to any of the following that the recognised medical authorisations authorise:

(a) 1 or more specified regulated genetically modified organisms:

(b) a specified category of regulated genetically modified organisms.

(6B) The equivalent medical authorisation must authorise the activities to be carried out by any of the following that the recognised medical authorisations authorise:

(a) 1 or more specified persons:

(b) a specified class of persons:

(c) all persons.

(7) *See also* ~~also~~ **section 16** (authorisation of medical activities does not count as approval for other purposes).

(8) ~~A mandatory~~ An equivalent medical authorisation is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

51 Prerequisites for varying and revoking ~~mandatory~~ equivalent medical authorisation

(1AAA) If the Regulator decides to vary the conditions of an equivalent medical authorisation, the Regulator must have particular regard to the conditions subject to which the recognised medical authorisations have been granted.

(1) The Regulator may only revoke ~~a mandatory~~ an equivalent medical authorisation if ~~the Regulator considers that~~—

(a) the Regulator is no longer satisfied of a matter mentioned in **section 50(2)(a) and (b)**; or

(b) a recognised medical authorisation has been revoked.

~~(a) **section 50(2)** no longer applies in relation to the authorisation; or~~

~~(b) the 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.~~

(1A) If the Regulator decides to vary the conditions of, or revoke, an equivalent medical authorisation, the Regulator must, as soon as is reasonably practicable,—

(a) publish a notice on an internet site maintained by or on behalf of the Regulator; and

(b) notify the person who has been granted the equivalent medical authorisation, the Director-General of Health, and the recognised overseas authorities in writing.

Subpart 6—Emergency authorisations

52 Minister may grant emergency authorisation

(1) The Minister may grant an authorisation (an **emergency authorisation**) to a person to carry out an activity in relation to a ~~regulated organism~~ regulated genetically modified organism if—

(a) the Minister receives advice from a relevant Minister, and is satisfied, that—

(i) there is an actual or imminent threat to the health and safety of people or to the environment; and

(ii) the emergency authorisation is appropriate for the purposes of responding to that threat; and

(b) the Minister receives advice from the Regulator, and is satisfied, that the actual or imminent threat is likely to outweigh any relevant risks of the activity, having regard to—

(i) the nature of the threat and relevant risks; and

(ii) the likelihood of harm occurring as a result of the relevant threat and risks; and

(iii) the likely degree of harm if the threat or risks occur; and

(iv) the availability of mitigations (including the conditions that would apply under **section 55**).

(2) An actual or imminent threat to the health and safety of people or to the environment may include (without limitation) any of the following:

(a) a threat from a disease outbreak:

(b) a threat from a particular plant or animal, such as a pest or an invasive species:

(c) a threat from an industrial spillage.

(3) An emergency authorisation may be granted in respect of—

(a) 1 or more specified activities; or

(b) a specified class of activities; or

(c) all activities.

(4) An emergency authorisation may be for the activities to be carried out in relation to—

(a) 1 or more specified ~~regulated organisms~~ regulated genetically modified organisms; or

(b) a specified category of ~~regulated organisms~~ regulated genetically modified organisms.

(5) An emergency authorisation may be for the activities to be carried out by—

(a) 1 or more specified persons; or

(b) a specified class of persons; or

(c) all persons.

(6) An emergency authorisation must set out the reasons for the authorisation.

(7) An emergency authorisation is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Compare: Gene Technology Act 2000 s 72B (Aust)

53 Period of effect of emergency authorisation

(1) An emergency authorisation takes effect—

(a) on the day on which the emergency authorisation is granted; or

(b) on a later day that is specified in the emergency authorisation.

(2) If **subsection (1)(b)** applies, the Minister must give notice in the *Gazette* that the emergency authorisation is in effect on the day specified in that subsection.

(3) The authorisation ceases to have effect on the earlier of the following:

(a) at the end of the period of 6 months that starts when the emergency authorisation takes effect:

(b) at the end of the period specified in the emergency authorisation as the period during which the authorisation is in force.

(4) **Subsection (3)** is subject to **section 54**.

Compare: Gene Technology Act 2000 s 72C(1), (2) (Aust)

54 Extending effect of emergency authorisation

(1) The Minister may extend an emergency authorisation if—

(a) the Minister receives advice from a relevant Minister, and is satisfied, that the actual or imminent threat in response to which the emergency authorisation was made still exists; and

(b) the Minister and the relevant Minister are satisfied that the proposed extension is appropriate for the purposes of responding to that threat; and

(c) the Minister and the relevant Minister are satisfied the actual or imminent threat is likely to outweigh any relevant risks of the activity.

(2) The Minister may extend the period of effect of an emergency authorisation more than once, but each single extension must not exceed 6 months.

(3) An extension to the period of effect of an emergency authorisation takes effect at the time when the authorisation would have ceased to have effect but for the extension.

(4) The Minister must notify an extension to an emergency authorisation and the date on which it takes effect in the *Gazette* as soon as is reasonably practicable after ~~making~~ granting the extension.

(5) The Minister may seek advice from the Regulator in relation to extending an emergency authorisation under this section.

Compare: Gene Technology Act 2000 s 72C(3)–(7) (Aust)

55 Emergency authorisation may be subject to conditions

(1) The Minister may impose any conditions on an emergency authorisation that the Minister considers necessary or desirable.

(2) The Minister may seek advice from the Regulator in relation to the imposition of conditions under this section.

Compare: Gene Technology Act 2000 s 72D (Aust)

56 Variation, suspension, and revocation of emergency authorisation

(1) The Minister may, after consulting the relevant Minister who provided advice under **section 52**, vary or suspend an emergency authorisation.

(2) The Minister must revoke an emergency authorisation if—

(a) the Minister receives advice from the relevant Minister who provided advice under **section 52**, and is satisfied, that—

(i) there is no longer an actual or imminent threat to the health and safety of people or to the environment; or

(ii) the emergency authorisation is no longer appropriate for the purposes of responding to that threat; or

(b) the Minister receives advice from the Regulator, and is satisfied, that the actual or imminent threat is no longer likely to outweigh the relevant risks of the activity that is authorised, having regard to—

(i) the nature of the threat and relevant risks; and

(ii) the likelihood of harm occurring as a result of the threat and risks; and

(iii) the likely degree of harm if the threat or risks occur; and

(iv) the availability of mitigations (including the conditions that apply under **section 55**).

(3) The Minister must give notice in the *Gazette* of any variation, suspension, or revocation, the reasons for it, the date on which it takes effect, and (in the case of a suspension) the date on which it expires.

(4) A variation, suspension, or revocation takes effect—

(a) on the day on which it is notified under **subsection (3)**; or

(b) on a later day that is specified in the notice.

(5) The Minister may seek advice from the Regulator in relation to varying, suspending, or revoking an emergency authorisation under this section.

Compare: Gene Technology Act 2000 s 72E (Aust)

Subpart 7—Recognised overseas authorities

57 Recognised overseas authorities

(1) The Regulator may, by notice in the *Gazette* and on ~~the Regulator's internet site~~ an internet site maintained by or on behalf of the Regulator, declare that ~~a person~~ an authority in another jurisdiction is a recognised overseas authority for the purposes of 1 or more of the following provisions:

(a) **section 50** (~~mandatory~~ equivalent medical authorisations for certain activities approved by 2 or more recognised overseas authorities):

(b) **section 28(2)(b)** (public consultation not required in respect of certain activities approved by recognised overseas authorities):

(c) **section 153** (power to collaborate and share information with recognised overseas authorities for the purposes of assessing licence applications).

(2) The Regulator may only make a declaration in relation to ~~a person~~ an authority under **subsection (1)** if the Regulator is satisfied that—

(a) the ~~person~~ authority operates in a manner comparable to the Regulator in regulating gene technology and organisms or any category of gene technology and organisms; and

(b) the ~~person~~ authority operates under a legislative framework for regulating gene technology and organisms, or any category of gene technology and organisms, that is comparable to that of New Zealand; and

(c) the ~~person~~ authority is willing and able to provide information that is readily accessible by the Regulator.

(3) The Regulator must, by notice in the *Gazette* and on ~~the Regulator's internet site~~ an internet site maintained by or on behalf of the Regulator, revoke a declaration made in relation to ~~a person~~ an authority if the Regulator considers that the ~~person~~ authority no longer meets 1 or more of the criteria in **subsection (2)(a) to (c)**.

(4) Before declaring ~~a person~~ an authority to be a recognised overseas authority, the Regulator must—

(a) publish a notice on an internet site maintained by or on behalf of the Regulator that—

(i) states what the Regulator proposes to do; and

(ii) invites written submissions in relation to the proposal; and

~~(iii) specifies a reasonable time within which written submissions may be made; and~~

(iii) specifies the last day on which written submissions may be made, which must be no earlier than 30 working days after the day on which the notice is published; and

(b) consult any person that the Regulator considers appropriate; and

(c) have regard to any written submissions or advice received.

(5) Before revoking a declaration made under this section, the Regulator must—

(a) publish a notice on that internet site that states what the Regulator proposes to do; and

(b) consult any person that the Regulator considers appropriate; and

(c) have regard to any advice received.

(6) The Regulator may amend a declaration made under this section without complying with **subsection (4)** if it considers that the amendment is minor in effect or corrects a minor or technical error.

(7) In this section, **authority** includes any agency, body, or person.

Subpart 8—Register

58 Regulator to maintain register

(1) The Regulator must maintain a register with details of all—

(a) licence applications; and

(b) licences; and

(c) ~~mandatory~~ equivalent medical authorisations; and

(d) emergency authorisations; and

(e) non-notifiable activities; and

(f) notifiable activities; and

(g) pre-assessed activities; and

(h) recognised overseas authorities; and

(i) determinations made under **section 12**; and

(j) providers, manufacturers, and ~~third party~~ third-party vendors approved under **section 149**; and

(ja) introductions into the environment of an organism or a category of organisms registered under regulations referred to in **section 163A**; and

(k) ~~any~~ other matters relating to this Act that the Regulator thinks fit.

(2) The Regulator must—

(a) publish the register on an internet site maintained by or on behalf of the Regulator in a form that is readily accessible to the public at all reasonable times; and

(b) keep the register up to date.

~~(3) The register must include for each item in **subsection (1)(a) to (f)**—~~

~~(a) the name of any applicant; and~~

~~(b) a description of the activities and regulated organisms covered by the item; and~~

~~(c) a description of the status of the item (including, if applicable, whether it has been subject to any variation, surrender, suspension, cancellation, or transfer); and~~

~~(d) any written decision by the Regulator in relation to the item; and~~

~~(e) any draft risk assessment and risk management plan prepared in relation to the item, if not yet finalised; and~~

~~(f) any finalised risk assessment and risk management plan prepared in relation to the item; and~~

~~(g) any other documentation relating to relevant risks associated with the item; and~~

~~(h) a summary of any advice provided in connection with the item by the Technical Advisory Committee, the Māori Advisory Committee, or any other person; and~~

~~(i) a summary of any written submissions received in the course of public consultation under **section 28**.~~

(3) The register must include,—

(a) for each licence application, the name of the applicant; and

(b) for each licence, the name of the licence holder; and

(c) for each notifiable activity and non-notifiable activity,—

(i) the name of any person who notifies the Regulator that they are carrying out such an activity; and

(ii) a description of the activity and the regulated genetically modified organism in relation to which the activity is carried out; and

(iii) the date of the notification; and

(d) for each determination made under **section 12**, a description of the determination's status (including, if applicable, whether it has been subject to any amendment or revocation); and

(e) for each item in **subsection (1)(a) to (g)**,—

(i) the persons, activities, and regulated genetically modified organisms in relation to which the item is made, declared, or granted; and

(ii) a description of the status of the item (including, if applicable, whether it has been subject to any variation, surrender, suspension, cancellation, revocation, or transfer); and

(iii) any written decision by the Regulator in relation to the item; and

(iv) any draft risk assessment and risk management plan prepared in relation to the item, if not yet finalised; and

(v) any finalised risk assessment and risk management plan prepared in relation to the item; and

(vi) any other documentation relating to relevant risks associated with the item; and

(vii) a summary of any advice provided in connection with the item by the Technical Advisory Committee, the Māori Advisory Committee, and any other person; and

(viii) a summary of any written submissions received in the course of public consultation in connection with the item.

(4) The register must include, for each item in **subsection (1)**, any other details that may be required by the regulations.

Compare: Gene Technology Act 2000 s 77 (Aust)

Subpart 9—Information held by Regulator

59 Application of Official Information Act 1982

(1) For the purposes of the Official Information Act 1982, any information held by the Regulator, the Technical Advisory Committee, or the Māori Advisory Committee is held by the EPA.

(2) **Subsections (3) and (4)** apply if a person—

(a) supplies any information to the Regulator; and

(b) the information is likely to relate to—

(i) a licence application; or

(ii) an application for a determination under **section 12**; ~~and~~ or

(iii) an application for an approval under **section 149**; and

(c) the application has not yet been made.

(3) The Official Information Act 1982 does not apply to that information until the application is received by the Regulator.

(4) The information is to be held by the Regulator on behalf of the person who supplies it.

~~60 Withholding of information~~

~~(1) The section—~~

~~(a) applies in relation to any requirement or permission under this Act for the Regulator to publish information; but~~

~~(b) does not affect the operation of the Official Information Act 1982.~~

~~(2) The Regulator may withhold any information that the Regulator considers—~~

~~(a) could pose a risk to national safety and security; or~~

~~(b) is confidential information; or~~

~~(c) is personal information (as defined in section 7(1) of the Privacy Act 2020); or~~

~~(d) is likely to cause serious offence under tikanga Māori if published.~~

~~(2) The Regulator may withhold any information that the Regulator considers is likely to cause serious offence under tikanga Māori (Māori protocol and culture) if published.~~

~~(3) If the Regulator proposes to publish any information about a kaitiaki relationship under this Act, the Regulator must first consult the Māori Advisory Committee.~~

61 Confidential information

(1) Sections 23A to 23C of the Medicines Act 1981 apply (with the necessary modifications) to the Regulator, as if ~~it~~ the Regulator were the Minister of Health, in relation to confidential information received in respect of a ~~licence application~~ prospective authorisation if—

(a) the ~~regulated organism~~ regulated genetically modified organism to which the ~~application~~ prospective authorisation relates is or has been the subject of an innovative medicine application (as defined in section 23 of the Medicines Act 1987); and

(b) the confidential information is about that organism; and

(c) the Minister of Health is, at the time the Regulator wants to disclose or use the information, required under section 23B of the Medicines Act 1981 to protect information provided in, or in relation to, the innovative medicine application ~~(as defined in section 23 of the Medicines Act 1987)~~.

(2) Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997 applies (with the necessary modifications) to the Regulator, as if ~~it~~ the Regulator were the Director-General, in relation to confidential information received in respect of a ~~licence application~~ prospective authorisation if—

(a) the ~~regulated organism~~ regulated genetically modified organism to which the ~~application~~ prospective authorisation relates is or has been the subject of an innovative TNP application (as defined in section 72(1) of the Agricultural Compounds and Veterinary Medicines Act 1997); and

(b) the confidential information is about that organism; and

(c) the Director-General is, at the time the Regulator wants to disclose or use the information, required under Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997 to protect information provided in support of the innovative TNP application.

(3) Despite **subsections (1) and (2)**,—

(a) the Regulator must publish on an internet site maintained by or on behalf of the Regulator a summary of the relevant risks of the activities proposed to be authorised by the ~~licence application~~ prospective authorisation; and

(b) the Regulator may disclose confidential information to persons prescribed by the regulations.

~~(4) In this section, **innovative TNP application** has the meaning given in section 72(1) of the Agricultural Compounds and Veterinary Medicines Act 1997.~~

(4) In this section,—

prospective authorisation means—

(a) a licence application; or

(b) a prospective declaration of a non-notifiable activity; or

(c) a prospective declaration of a notifiable activity; or

(d) a prospective equivalent medical authorisation; or

(e) a prospective emergency authorisation.

Part 3
Inspection, enforcement, and ancillary powers

62 Interpretation

In this Part, unless the context otherwise requires,—

appointer means the holder of an office at the enforcement agency who is authorised to appoint enforcement officers under **section 64**

border information and **Ministry** have the meanings given in section 41A(1) of the Biosecurity Act~~; and~~ 1993

chief executive means the chief executive of the department of State that, under the authority of a warrant or with the authority of the Prime Minister, is responsible for the administration of the Biosecurity Act 1993

enforcement officer means a person appointed under **section 64**

issuing officer has the meaning given in section 3(1) of the Search and Surveillance Act 2012

Joint Border Management System or **JBMS** has the meaning given in section 302(4) of the Customs and Excise Act 2018.

legislative requirements means—

(a) the requirements of this Act; and

(b) the requirements of secondary legislation under this Act; and

(c) conditions imposed under this Act

organic material has the meaning given in section 2(1) of the Biosecurity Act 1993

place includes—

(a) a building, land, or structure; and

(b) a vehicle, vessel, aircraft, ship, or other mobile structure; and

(c) any waters and the bed of those waters; and~~ any installation on or under land, on the bed of, or under, or floating on any waters.~~

(d) any installation on or under land, on the bed of, or under, or floating on, any waters.

Subpart 1—General

63 Enforcement of this Act

(1) The enforcement agency is responsible for monitoring and enforcing compliance with the legislative requirements.

(2) For the purposes of this Act, the enforcement agency may appoint enforcement officers in accordance with **section 64**.

(3) In addition to the powers conferred by this Act, an enforcement officer may, in relation to a ~~regulated organism~~ regulated genetically modified organism, exercise the powers of inspectors under the Biosecurity Act 1993 that may be exercised in respect of an unwanted organism as identified in that Act.

(4) A person who may exercise powers under the Biosecurity Act 1993 in respect of an unwanted organism may also exercise those powers in respect of a ~~regulated organism~~ regulated genetically modified organism whether or not the person is appointed as an enforcement officer under this Act.

(5) The Biosecurity Act 1993, including the following sections, applies, with all necessary modifications, to the exercise of powers under **subsections (3) and (4)**:

(a) section 162A (compensation):

(b) section 163 (protection of inspectors and others):

(c) section 164 (liability for goods).

Compare: 1996 No 30 s 97A

64 Appointment of enforcement officers

(1) The enforcement agency may appoint an enforcement officer only if—

(a) the person is employed ~~or engaged~~ in the State services; and

(b) the appointer is satisfied that the person—

(i) has appropriate experience, technical competence, and qualifications to perform the functions and duties, and exercise the powers, specified in the officer's appointment document; and

(ii) meets any requirements specified in regulations.

(2) The enforcement officer's appointment document may—

(a) authorise the officer to perform all the functions and duties, and exercise all the powers, that this Act confers on enforcement officers; or

(b) specify the particular functions and duties that the officer may perform and the particular powers that the officer may exercise.

(3) The enforcement agency may impose written conditions on the appointment of an enforcement officer.

(4) In this section, **State services** has the meaning given in section 5 of the Public Service Act 2020.

Compare: 1996 No 30 s 100

65 Power to obtain information

(1) An enforcement officer may, by written notice, require a person to give the enforcement agency information about an activity, gene technology, an organism, a ~~regulated organism~~ regulated genetically modified organism, synthetic nucleic acid, or benchtop nucleic acid synthesis equipment.

(2) The enforcement officer must have reasonable grounds to believe that the information is necessary or desirable for performing the officer's or the enforcement agency's functions or duties, or exercising their powers under this Act.

(3) The information required may be any of the following:

(a) information that is in the person's possession or control:

(b) information to be obtained by the person (for example, a verification report):

(c) information that could be compiled from information referred to in **paragraph (a) or (b)** (for example, statistics).

(4) However, an enforcement officer may only require a person to give—

(a) information that is not already in the person's possession or control if the enforcement officer is satisfied on reasonable grounds that it is reasonable to require the person to compile or obtain the information; or

(b) personal information if the enforcement officer is satisfied on reasonable grounds that the information required by the enforcement agency could not reasonably be obtained unless the person disclosed that personal information.

(5) The notice—

(a) must set out the date by which it must be complied with (which must allow the person a reasonable time to comply); and

(b) may require the person to notify a specified person or class of persons of particular information.

~~(6) A person given a notice under this section must comply with it.~~

(7) This section does not affect section 60 of the Evidence Act 2006.

(8) In this section, **personal information** has the meaning given in section 7(1) of the Privacy Act 2020.

Compare: 1996 No 30 s 24

65A Power to obtain identity and other information

An enforcement officer who has reasonable grounds to suspect that an individual has committed an infringement offence (as defined in **section 90**) may require the individual to provide any of the following information:

(a) the person's name and date of birth:

(b) the person's residential address and contact details.

65B Declaration that organism not regulated genetically modified organism

An inspector may require a person importing any organism to make a statutory declaration that the organism is not a regulated genetically modified organism.

66 Border information supplied using JBMS must be supplied in approved form and manner

(1) This section applies to a requirement under this Act to supply border information to the Ministry.

(2) A person who uses a Joint Border Management System (**JBMS**) to comply with the requirement (including by supplying the information to Customs, or to an appointed agency, in accordance with section 41H of the Biosecurity Act 1993) must supply the information in a form and manner—

(a) for complying with the requirement by using the JBMS; and

(b) generally approved in writing by the chief executive.

(3) The chief executive—

(a) must notify the approved form and manner on an internet site that is, to the extent practicable, publicly available free of charge; and

(b) may set out the approved form and manner in rules under section 325 of the Customs and Excise Act 2018.

Compare: 1996 No 30 s 97AA

67 Duty to use JBMS to supply border information

(1) This section applies to a requirement under this Act to supply border information to the Ministry.

(2) The only ways in which a person can comply with the requirement are—

(a) by using a JBMS; or

(b) by using another means generally or specifically approved in writing by the enforcement agency.

Compare: 1996 No 30 s 97AB

68 Power to give directions

(1) ~~The enforcement agency or an~~ An enforcement officer may direct the owner or person in charge of a ~~regulated organism~~ regulated genetically modified organism, or the occupier of a place where a ~~regulated organism~~ regulated genetic-

ally modified organism is or may be present, to do 1 or more of the following within the time and in the manner specified in the direction:

(a) treat anything contaminated by the ~~regulated organism~~ regulated genetically modified organism:

(b) take steps to contain the ~~regulated organism~~ regulated genetically modified organism or prevent its spread:

(c) move the ~~regulated organism~~ regulated genetically modified organism to another place or dispose of it:

(d) if ~~there are~~ the enforcement officer has reasonable grounds to believe an organism, organic material, or thing contains a ~~regulated organism~~ regulated genetically modified organism,—

(i) move the organism, organic material, or thing to another place; or

(ii) dispose of it:

(e) monitor the place where the ~~regulated organism~~ regulated genetically modified organism is or may be present:

(f) report the presence or suspected presence of a ~~regulated organism~~ regulated genetically modified organism to the enforcement officer if the organism is identified through monitoring:

(g) something that the ~~enforcement agency or~~ enforcement officer believes on reasonable grounds is necessary or desirable to avoid, remedy, or mitigate the actual or likely adverse effects on the health and safety of people or the environment, or both, resulting from a breach of a specified legislative requirement.

(2) A direction may only be given if the ~~enforcement agency or an~~ enforcement officer believes on reasonable grounds that—

(a) the person's possession of~~,~~ or activities in relation to~~,~~ the ~~regulated organism~~ regulated genetically modified organism, organism, organic material, or thing are in breach of a specified legislative requirement; or

(b) the person is in possession of a ~~regulated organism~~ regulated genetically modified organism in respect of which an activity has been carried out in breach of a specified legislative requirement; or

(c) a ~~regulated organism~~ regulated genetically modified organism is required to be contained in a place and is present at another place.

(3) Costs associated with complying with a direction must be borne by the owner or person in charge of the ~~regulated organism~~ regulated genetically modified organism, or the occupier of any place where the ~~regulated organism~~ regulated genetically modified organism is or may be present.

(4) However, if the enforcement agency is satisfied that the owner, or person in charge of a regulated genetically modified organism, or occupier of a place where the ~~regulated organism~~ regulated genetically modified organism is or

may be present was not aware that it was a ~~regulated organism~~ regulated genetically modified organism, the enforcement agency, may, at the enforcement agency's discretion, bear any costs incurred, in whole or in part.

(5) In this section, **monitor** includes to take samples and carry out tests.

69 Powers of entry and inspection for regulatory purposes

(1) An enforcement officer may at a reasonable time enter and inspect a place for the purpose of—

(a) checking compliance with legislative requirements; or

(b) determining the nature of an organism that is or was in, on, or attached to the place.

(2) The enforcement officer must have reasonable grounds to believe it is a place where—

(a) an activity is being, or has been, carried out; or

(b) a ~~regulated organism~~ regulated genetically modified organism is or was present; or

(c) synthetic nucleic acid is or has been synthesised or distributed; or

(d) benchtop nucleic acid synthesis equipment is or has been manufactured or distributed; or

(e) devices, equipment, or information connected to activities regulated by ~~the~~ this Act or ~~regulated organisms~~ regulated genetically modified organisms are or were located.

(3) An enforcement officer may, for the purposes set out in **subsection (1)**, do 1 or more of the following:

(a) open, or direct a person to open, a thing:

(b) take a sample of organisms, tissues, parts of an organism, organic material, or any other goods or material, including for forensic or other scientific testing:

(c) carry out tests ~~and demonstrations~~:

(d) require a person present at the place to—

(i) produce a document or record within the person's control or possession that may be relevant to the inspection; or

(ii) provide an answer (including any explanation or information) to the officer~~, including any explanation or information~~ concerning~~,~~—

(A) an organism in, on, or attached to the place; or

(B) ~~a regulated~~ an activity; or

(C) the ~~provision~~ synthesis or distribution of synthetic nucleic acid; or

(D) the manufacture or distribution of benchtop nucleic acid synthesis equipment.

(4) Part 4 of the Search and Surveillance Act 2012 (other than subparts 2, 3, and 8 and sections 118 and 119) applies in respect of the powers conferred by this section.

(5) This section does not affect section 60 of the Evidence Act 2006.

(6) This section is subject to **sections 70 and 71**.

Compare: 1996 No 30 s 103

70 Search warrant to inspect dwellinghouse or marae for regulatory purposes

(1) An enforcement officer may only enter the following places under a search warrant or with the consent of the occupier:

(a) a dwellinghouse:

(b) a marae or a building associated with a marae.

(2) The enforcement officer—

(a) may apply for a search warrant only if ~~the~~ an enforcement ~~agency~~ officer is satisfied that the grounds for issuing a search warrant set out in **subsection (3)** exist; and

(b) must apply in accordance with subpart 3 of Part 4 of the Search and Surveillance Act 2012.

(3) An issuing officer may, on application by an enforcement officer, issue a search warrant if satisfied that there are reasonable grounds to believe that the place—

(a) is a place referred to in **section 69(2)**; or

(b) is the only practicable means by which an enforcement officer can enter a place referred to in **section 69(2)**.

(4) A warrant issued under this section authorises an enforcement officer to enter the places referred to in **subsection (1)** only for the purposes of exercising powers under **section 69**.

(5) Part 4 of the Search and Surveillance Act 2012 (other than ~~subparts 2 and~~ subpart 8 and sections 118 and 119) applies in respect of the powers conferred by this section.

71 Search warrant for law enforcement purposes

(1) An enforcement officer may apply for a search warrant in respect of any place if satisfied that the grounds for issuing a search warrant in **subsection (3)** exist.

(2) The enforcement officer must apply in the manner provided in subpart 3 of Part 4 of the Search and Surveillance Act 2012.

(3) An issuing officer may issue a search warrant in respect of the place if satisfied that there are reasonable grounds—

(a) to suspect that an offence has been, is being, or will be committed against this Act; and

(b) to believe that there is evidential material in the place.

(4) Part 4 of the Search and Surveillance Act 2012 (other than subparts 2 and 8 and sections 118 and 119) applies in respect of the powers conferred by this section.

(5) In this section, **evidential material** has the meaning given by section 3(1) of the Search and Surveillance Act 2012.

Subpart 2—Compliance orders

72 Issue and scope of compliance order

(1) An enforcement officer may make a compliance order against a person—

(a) requiring the person to stop doing something that the officer believes, on reasonable grounds, breaches, or is likely to breach, a specified legislative requirement; or

(b) requiring the person to do something that the officer believes, on reasonable grounds, is necessary or desirable to ensure that the person complies with a specified legislative requirement; or

(c) requiring the person to do something that the officer believes on reasonable grounds is necessary or desirable to avoid, remedy, or mitigate the actual or likely adverse effects on the health and safety of people or the environment, or both, resulting from a breach of a specified legislative requirement; or

(d) prohibiting the person from doing something (or having something done on the person's behalf) that the officer believes, on reasonable grounds, breaches or is likely to breach a specified legislative requirement.

(2) An enforcement officer may include conditions in the compliance order that the enforcement officer thinks are appropriate.

(3) The enforcement officer must send a copy of the compliance order to the Regulator within 3 working days of serving it in accordance with **section 186**.

Compare: 1996 No 30 s 104

73 Compliance

The person against whom a compliance order is made must—

(a) comply with the order within the period or from the date specified in it; and

(b) pay all the costs and expenses of complying with the order, unless the order states otherwise.

Compare: 1996 No 30 s 105

74 Content of compliance order

A compliance order must state—

(a) the name of the person against whom it is made; and

(b) the reasons why the enforcement officer made it; and

(c) the requirement or prohibition in **section 72(1)** ordered by the enforcement officer; and

(d) either,—

(i) for a requirement, the period, if any, within which the requirement must be achieved, which must start on the day on which the order is served and end after a time that is reasonable for the achievement of the requirement; or

(ii) for a prohibition, the time and date, if any, from which the prohibition is to take effect; and

(e) the conditions, if any, imposed by the enforcement officer; and

(f) the consequences of not complying with the order; and

(g) the person's right of appeal under **section 139**; and

(h) the name and address of the agency whose enforcement officer made the order.

Compare: 1996 No 30 s 106

75 Change to or cancellation of compliance order

~~(1) The appointer of the enforcement officer who made the compliance order may—~~

~~(a) confirm, change, or cancel the order under **subsection (2)**; or~~

~~(b) cancel the order under **subsection (3)**.~~

Application to appointer to change or cancel order

(2) If ~~the~~ an appointer receives a written application from the person against whom the compliance order was made to change or cancel the order, the appointer—

(a) must consider the application as soon as practicable, having regard to—

(i) the purpose for which the order was made; and

(ii) the effect of a change or cancellation on the purpose; and

(iii) any other matter the appointer thinks fit; and

(b) may confirm, change, or cancel the order; and

(c) must give the person against whom the order was made written notice of—

(i) the confirmation, change, or cancellation of the order; and

(ii) reasons for the confirmation, change, or cancellation.

Cancellation of order at appointer's initiative

(3) ~~The~~ An appointer—

(a) may cancel the compliance order if the appointer considers that the order is no longer required; and

(b) must give the person against whom the order was made written notice of the cancellation.

(4) The appointer must notify the Regulator as soon as is reasonably practicable of any change to, or cancellation of, a compliance order.

Compare: 1996 No 30 s 108

Subpart 3—Offences

76 Undertaking activity without authorisation

Offence involving knowledge or recklessness

(1) A person commits an offence if the person—

(a) carries out an activity in relation to a ~~regulated organism~~ regulated genetically modified organism in breach of **section 13** (authorisation required for activities with regulated genetically modified organisms); and

(b) knows that, or is reckless as to whether, the person has carried out an activity in relation to a ~~regulated organism~~ regulated genetically modified organism in breach of **section 13**.

(2) The person is liable on conviction,—

(a) in the case of an individual, to imprisonment for a term not exceeding 5 years or to a fine not exceeding $200,000, or both; or

(b) otherwise, to a fine not exceeding $1 million.

Strict liability offence

(3) A person commits an offence if the person carries out an activity in relation to a ~~regulated organism~~ regulated genetically modified organism in breach of **section 13** (authorisation required for activities with regulated genetically modified organisms).

(4) The person is liable on conviction,—

(a) in the case of an individual, to a fine not exceeding $100,000; or

(b) otherwise, to a fine not exceeding $500,000.

Compare: 1996 No 30 s 109

77 Breach of condition of non-notifiable or notifiable activity or ~~mandatory~~ equivalent medical authorisation

Offences involving knowledge or recklessness

(1) A person commits an offence if the person—

(a) breaches—

(i) **section 14(a)** (conditions related to a non-notifiable activity); or

(ii) **section 14(b)** (conditions related to a notifiable activity); or

(iii) **section 14(e)** (conditions related to ~~a mandatory~~ an equivalent medical authorisation)~~.~~; and

(b) knows that, or is reckless as to whether, the person has breached a condition related to a non-notifiable or notifiable activity or ~~mandatory~~ an equivalent medical authorisation.

(2) The person is liable on conviction, if the activity is a notifiable activity or an activity for which ~~a mandatory~~ an equivalent medical authorisation has been granted,—

(a) in the case of an individual, to a fine not exceeding $50,000; or

(b) otherwise, to a fine not exceeding $250,000.

(3) The person is liable on conviction, if the activity is a non-notifiable activity,—

(a) in the case of an individual, to a fine not exceeding $10,000; or

(b) otherwise, to a fine not exceeding $50,000.

Strict liability offences

(4) A person commits an offence if the person breaches **section 14(a), (b), or (e)**.

(5) The person is liable on conviction, if the activity is a notifiable activity or an activity for which ~~a mandatory~~ an equivalent medical authorisation has been granted,—

(a) in the case of an individual, to a fine not exceeding $20,000; or

(b) otherwise, to a fine not exceeding $100,000.

(6) The person is liable on conviction, if the activity is a non-notifiable activity,—

(a) in the case of an individual, to a fine not exceeding $5,000; or

(b) otherwise, to a fine not exceeding $25,000.

78 Breach of condition of pre-assessed activity, licence, emergency authorisation, or approval notice

Offence involving knowledge or recklessness

(1) A person commits an offence if the person—

(a) breaches—

(i) **section 14(c)** (conditions related to a pre-assessed activity); or

(ii) **section 14(d)** (conditions related to a licence); or

(iii) **section 14(f)** (conditions related to an emergency authorisation); or

(iv) ~~**section 149(5)(b)**~~**section 14(g)** (conditions related to approval of manufacturer~~, or~~ provider, or third-party vendor); and

(b) knows that, or is reckless as to whether, the person has breached a condition related to a pre-assessed activity, licence, emergency authorisation, or approval notice.

(2) The person is liable on conviction,—

(a) in the case of an individual, to imprisonment for a term not exceeding 5 years or to a fine not exceeding $200,000, or both; or

(b) otherwise, to a fine not exceeding $1 million.

Strict liability offence

(3) A person commits an offence if the person breaches **section 14(c), (d), (f), or (g)**.~~—~~

~~(a) **section 14(c), (d), or (f)**; or~~

~~(b) **section 149(5)(b)**.~~

(4) The person is liable on conviction,—

(a) in the case of an individual, to a fine not exceeding $100,000; or

(b) otherwise, to a fine not exceeding $500,000.

Compare: 1996 No 30 s 109

79 Failure to comply with requirement, direction, or compliance order

(1) A person commits an offence if the person fails to comply with—

(a) a notice under **section 65(1)** requiring the person to provide specified information~~)~~; or

~~(b) **section 66** (border information supplied using JBMS must be supplied in approved form and manner) or **section 67** (duty to use JBMS to supply border information); or~~

(b) a requirement to provide identity or other information under **section 65A**; or

(ba) a requirement to make a statutory declaration under **section 65B**; or

(c) a direction issued by an enforcement officer or the enforcement agency under **section 68**; or

(d) a compliance order issued under **section 72**.

(2) The person is liable on conviction,—

(a) in the case of an individual, to a fine not exceeding $100,000; or

(b) otherwise, to a fine not exceeding $500,000.

80 Offence to give false or misleading information

Offence involving knowledge or recklessness

(1) A person commits an offence if the person makes a statement or gives information for the purposes of this Act that the person knows is false or misleading in a material particular.

(2) The person is liable on conviction,—

(a) in the case of an individual, to imprisonment for a term not exceeding 5 years or to a fine not exceeding $200,000, or both; or

(b) otherwise, to a fine not exceeding $1 million.

(3) A person commits an offence if the person makes a statement or gives information for the purposes of this Act that is false or misleading in a material particular and the person is reckless as to whether the information is false or misleading in a material particular.

(4) The person is liable on conviction,—

(a) in the case of an individual, to a fine not exceeding $100,000; or

(b) otherwise, to a fine not exceeding $500,000.

Strict liability offence

(5) A person commits an offence if the person, makes a statement or gives information for the purposes of this Act that is false or misleading in a material particular.

(6) The person is liable on conviction,—

(a) in the case of an individual, to a fine not exceeding $50,000; or

(b) otherwise, to a fine not exceeding $250,000.

Compare: 1996 No 30 s 116

81 Impersonating enforcement officer

(1) A person commits an offence if the person, with intent to deceive, impersonates or pretends to be an enforcement officer.

(2) The person is liable on conviction to a fine not exceeding $100,000.

Compare: 1996 No 30 s 109

82 Obstruction of enforcement officers

(1) A person commits an offence if the person intentionally resists, obstructs, or delays an enforcement officer ~~either or both of the following persons~~ in performing a function or duty, or exercising a power ~~under this Act:~~, under this Act.

~~(a) an enforcement officer:~~

~~(b) the chief executive.~~

(2) The person is liable on conviction,—

(a) in the case of an individual, to a fine not exceeding $100,000; or

(b) otherwise, to a fine not exceeding $500,000.

Compare: 1996 No 30 s 109

83 Failure to comply with synthetic nucleic acid screening regime

(1) A person commits an offence if the person—

(a) breaches ~~**section 149(5)(a)** (Regulator approval required to provide synthetic nucleic acid or manufacture benchtop nucleic acid synthesis equipment)~~ **section 13A** (approval required for synthetic nucleic acid providers, manufacturers, and third-party vendors); and

(b) knows that the person has breached ~~**section 149(5)(a)**~~**section 13A** or is reckless as to whether the person has breached that section.

(2) A person commits an offence if the person does either of the following in breach of screening framework requirements, knowing that the person has breached the requirements, or being reckless as to whether they have been breached:

(a) ~~provides~~ synthesises or distributes synthetic nucleic acid:

(b) manufactures or distributes benchtop nucleic acid synthesis equipment.

(3) The person is liable on conviction for the offences in **subsections (1) and (2)**,—

(a) in the case of an individual, to imprisonment for a term not exceeding 5 years or to a fine not exceeding $200,000, or both; or

(b) otherwise, to a fine not exceeding $1 million.

(4) In this section, **screening framework requirements** means requirements set out in regulations referred to in **section 157**.

84 Strict liability and defences

(1) In a prosecution for an offence specified in **sections 76(3), 77(4), 78(3), 79(1), and 80(5)**, the prosecution is not required to prove that the defendant intended to commit the offence.

Defence: circumstances outside defendant's control

(2) The defendant has a defence if the defendant proves that—

(a) the action or event to which the prosecution relates was due to—

(i) the act or omission of another person (other than a director, employee, or agent of the defendant); or

(ii) an accident; or

(iii) some other cause or circumstance outside the defendant's control; and

(b) the defendant took all reasonable precautions and exercised due diligence to avoid—

(i) the commission of the particular offence; or

(ii) the commission of offences of the same kind.

Defence: action necessary for certain purposes

(3) The defendant also has a defence if the defendant proves that—

(a) the defendant's action was necessary to—

(i) save or protect life or the health or safety of people; or

(ii) prevent serious damage to property; or

(iii) avoid an actual or likely adverse effect on the health or safety of people or the environment; and

(b) the defendant's action was reasonable in all the circumstances; and

(c) the defendant took steps that were reasonable in all the circumstances to mitigate or remedy the effects of the action after it occurred.

Written notice of defences

(4) The defences in **subsections (2) and (3)** are available only if the defendant—

(a) prepares a written notice for the prosecutor that—

(i) states the defendant's intention to rely on the defence; and

(ii) includes the facts that support the defence; and

(b) gives the notice to the prosecutor—

(i) at least 15 working days before the hearing date; or

(ii) within another time that the court allows.

Compare: 1996 No 30 s 117

85 Other orders instead of or in addition to other sentencing options

(1) This section applies if a person is convicted of an offence against 1 or more of **sections 76 to 83**.

(2) If this section applies in relation to a person, the court may (in addition to or in substitution for any other sentence or order available under the Sentencing Act 2002) make 1 or more of the following orders:

(a) an order that the person mitigate or remedy 1 or more adverse effects referred to in **subsection (3)** that—

(i) have been or are being caused by or on behalf of the person:

(ii) relate to a place owned or occupied by the person:

(b) an order that the person pay the costs of mitigating or remedying the adverse effects referred to in **paragraph (a)**:

(c) an order that the person dispose of or arrange for the disposal of the ~~regulated organism~~ regulated genetically modified organism related to the person's conviction.

(3) The adverse effects relate to the following:

(a) the health or safety of people:

(b) property:

(c) the environment.

(4) All proceedings under **sections 76 to 83** (which relate to offences) must be heard—

(a) in the District Court; and

(b) except where otherwise directed by the Chief District Court Judge, by a District Court Judge who is also an Environment Judge.

(5) In deciding whether to make an order under this section, the court must have regard to all relevant matters, including—

(a) the nature and extent of the breach:

(b) the nature and extent of any commercial gain made or commercial loss avoided by the person because of the person's breach:

(c) the nature and extent of loss or damage caused to the health or safety of people, property, or the environment as a result of the breach:

(d) the circumstances in which the breach took place:

(e) whether or not the person has been found in previous proceedings under this Act to have engaged in similar conduct:

(f) the steps taken by the person to bring the breach to the attention of the appropriate authority:

(g) the steps taken by the person to avoid, remedy, or mitigate the effects of the breach.

86 Liability of principals and agents

(1) This section applies if an offence is committed against this Act by a person (**person A**) acting as the agent or employee of another (**person B**).

(2) Person B is liable for the offence as if person B had personally committed it, if it is proved that person B—

(a) authorised, permitted, or consented to the act or omission constituting the offence; or

(b) knew the offence was, or was to be, committed and failed to take all reasonable steps to prevent or stop it.

(3) This section does not limit the liability of person A.

Compare: 1996 No 30 s 115

87 Liability of director or manager of body corporate

If a body corporate is convicted of an offence against this Act, a director or manager of the body corporate is also guilty of the offence if it is proved that the director or manager—

(a) authorised, permitted, consented, or participated in the act or omission that constituted the offence; or

(b) knew, or could reasonably be expected to have known, that the offence was to be, or was being, committed and failed to take all practicable steps to prevent or stop it.

Compare: 1996 No 30 s 116

88 Time for filing charging document for certain offences

(1) Despite anything to the contrary in section 25 of the Criminal Procedure Act 2011, the limitation period in respect of a category 1 offence under this Act ends on the date that is 2 years after the date on which the matter giving rise to the charge first became known, or should have become known, to the enforcement agency.

(2) **Subsection (1)** does not affect the application of section 25 of the Criminal Procedure Act 2011 in relation to any offence not mentioned in that subsection.

(3) In this section, **category 1 offence** has the same meaning as in section 6(1) of the Criminal Procedure Act 2011.

(4) **Subsection (1)** is subject to **section 89**.

Compare: 1996 No 30 s 109A

89 Extension of time for filing charging document

(1) The District Court may, on application by a person, extend the time for the person to file a charging document under **section 88(1)**.

(2) The application must be made within the 2-year period that applies to the person under **section 88(1)**.

(3) The court must not grant an extension unless it is satisfied that—

(a) the person reasonably requires longer than the 2-year period to decide whether to file a charging document; and

(b) the reason for requiring the longer period is that—

(i) the investigation of the events and issues surrounding the alleged offence is complex or time-consuming; or

(ii) the effects of the alleged offending may not be known for some time; or

(iii) the scale of the effects of the alleged offending may not be known for some time; and

(c) it is in the public interest in the circumstances that a charging document can be filed after the 2-year period expires; and

(d) filing the charging document after the 2-year period expires will not unfairly prejudice the proposed defendant in defending the charge.

(4) The court must give the following persons an opportunity to be heard:

(a) the person seeking the extension:

(b) the proposed defendant.

Subpart 4—Infringement offences

90 Interpretation

In this Act,—

infringement fee, in relation to an infringement offence, means the infringement fee for the offence specified in regulations

infringement offence means an offence identified in regulations as being an infringement offence.

91 Infringement offences

(1) A person who is alleged to have committed an infringement offence may—

(a) be proceeded against by the filing of a charging document under section 14 of the Criminal Procedure Act 2011; or

(b) be issued with an infringement notice under **section 93**.

(2) Proceedings commenced in the way described in **subsection (1)(a)** do not require the leave of a District Court Judge or Registrar under section 21(1)(a) of the Summary Proceedings Act 1957.

(3) *See* section 21 of the Summary Proceedings Act 1957 for the procedure that applies if an infringement notice is issued.

92 Who may issue infringement notices

An enforcement officer or the enforcement agency may issue infringement notices under this Act.

93 When infringement notice may be issued

An enforcement officer or the enforcement agency may issue an infringement notice to a person if the enforcement officer or the enforcement agency believes on reasonable grounds that the person is committing, or has committed, an infringement offence.

94 Revocation of infringement notice before payment made

(1) An enforcement officer or the enforcement agency may revoke an infringement notice before—

(a) the infringement fee is paid; or

(b) an order for payment of a fine is made or deemed to be made by a court under section 21 of the Summary Proceedings Act 1957.

(2) The enforcement officer or the enforcement agency must take reasonable steps to ensure that the person to whom the notice was issued is made aware of the revocation of the notice.

(3) The revocation of an infringement notice before the infringement fee is paid is not a bar to any further action as described in **section 91(1)(a) or (b)** against the person to whom the notice was issued in respect of the same matter.

95 Notification to Regulator

An enforcement officer or the enforcement agency who issues or revokes an infringement notice under this subpart must notify the Regulator of the fact as soon as is reasonably practicable.

96 What infringement notice must contain

An infringement notice must be in the form prescribed in the regulations (if any) and must contain the following particulars:

(a) details of the alleged infringement offence that fairly inform a person of the time, place, and nature of the alleged offence:

(b) the amount of the infringement fee:

(c) the address of the enforcement agency:

(d) how the infringement fee may be paid:

(e) the time within which the infringement fee must be paid:

(f) a summary of the provisions of section 21(10) of the Summary Proceedings Act 1957:

(g) a statement that the person served with the notice has a right to request a hearing:

(h) a statement of what will happen if the person served with the notice neither pays the infringement fee nor requests a hearing:

(i) any other matters prescribed in regulations (if any).

97 How infringement notice may be served

(1) An infringement notice may be served on the person who the enforcement officer or the enforcement agency believes is committing or has committed the infringement offence by—

(a) delivering it to the person or, if the person refuses to accept it, bringing it to the person's notice; or

(b) leaving it for the person at the person's last known place of residence with another person who appears to be of or over the age of 14 years; or

(c) leaving it for the person at the person's place of business or work with another person; or

(d) sending it to the person by prepaid post addressed to the person's last known place of residence or place of business or work; or

(e) sending it to an electronic address of the person if the person does not have a known place of residence or business in New Zealand.

(2) Unless the contrary is shown,—

(a) an infringement notice (or a copy of it) sent by prepaid post to a person under **subsection (1)** is to be treated as having been served on that person on the fifth working day after the date on which it was posted; and

(b) an infringement notice sent to a valid electronic address is to be treated as having been served at the time the electronic communication first entered an information system that is outside the control of the enforcement agency.

98 Payment of infringement fees

All infringement fees paid for infringement offences must be paid into a Crown Bank Account.

99 Reminder notices

A reminder notice must be in the form prescribed in the regulations (if any) and must include the same particulars, or substantially the same particulars, as the infringement notice.

Subpart 5—Pecuniary penalties for breaches of this Act or secondary legislation

100 Pecuniary penalty order

(1) The enforcement agency may apply to the High Court for an order that a person (**A**) pays the Crown a pecuniary penalty under this Act.

Grounds for order

(2) The court may make the order if it is satisfied that A has breached 1 or more provisions listed in **subsection (3)** in the course of a business or an undertaking.

(3) The provisions are—

(a) **section 13** (authorisation required for activities with ~~regulated organisms~~ regulated genetically modified organisms):

(aa) **section 13A** (approval required for synthetic nucleic acid providers, manufacturers, and third-party vendors):

(b) **section 14** (person must not breach conditions ~~of authorisation~~):

~~(e) **section 149(5)(a)** (Regulator approval required to provide synthetic nucleic acid or manufacture benchtop nucleic acid synthesis equipment):~~

(d) the regulations referred to in **section 157** (relating to synthetic nucleic acid providers, manufacturers, and third-party vendors, and screening requirements).

Defences

(4) The court must not make the order if A satisfies the court—

(a) that the breach was necessary for the purpose of—

(i) saving or protecting life or the health or safety of people, preventing serious damage to property, or avoiding an actual or likely adverse effect on the health or safety of people or the environment; and

(ii) A's conduct was reasonable in all the circumstances; and

(iii) A took steps that were reasonable in all the circumstances to mitigate or remedy the effects of the breach after it occurred; or

(b) that the following apply:

(i) the breach was due to an event beyond A's control, including natural disaster, mechanical failure, or sabotage; and

(ii) A could not reasonably have foreseen the event; and

(iii) A could not reasonably have taken steps to prevent the event occurring; and

(iv) A took steps that were reasonable in all the circumstances to mitigate or remedy the effects of the breach after it occurred; or

(c) that A did not know, and could not reasonably have known, of the breach.

(5) In this section, **business or an undertaking** means a business, professional practice, or other undertaking carried on for gain or reward.

Compare: 1996 No 30 s 124B

101 Considerations for court in determining pecuniary penalty

(1) In determining an appropriate pecuniary penalty that a person (**A**) must pay, the court must have regard to all relevant matters, including—

(a) the nature and extent of A's breach:

(b) the nature and extent of any commercial gain made or commercial loss avoided by A because of A's breach:

(c) the nature and extent of loss or damage caused to the health or safety of people, property, or the environment as a result of A's breach:

(d) the circumstances in which A's breach took place:

(e) whether or not A has been found in previous proceedings under this Act to have engaged in similar conduct:

(f) the steps taken by A to bring A's breach to the attention of the appropriate authority:

(g) the steps taken by A to avoid, remedy, or mitigate the effects of A's breach.

Limits on amount court may order

(2) **Subsections (3) and (4)** state the limits on the amounts of pecuniary penalty that the court may order.

(3) For an individual, the limit is $500,000.

(4) In any other case,—

(a) if the court is satisfied the breach occurred in the course of producing a commercial gain that can be readily ascertained, the limit is the greater of—

(i) $10,000,000; and

(ii) 3 times the value of the commercial gain resulting from the breach:

(b) if the court is satisfied the breach occurred in the course of producing a commercial gain that cannot be readily ascertained, the limit is the greater of—

(i) $10,000,000; and

(ii) 10% of the turnover of the body corporate and all of its interconnected bodies corporate (if any) ~~(**interconnected** and **turnover** having the meanings given in section 2 of the Commerce Act 1986)~~:

(c) if the court is not satisfied that the breach occurred in the course of producing a commercial gain, the limit is $10,000,000.

(5) In this section, **interconnected** and **turnover** have the meanings given in section 2 of the Commerce Act 1986.

Compare: 1996 No 30 s 124C

102 Other orders instead of or in addition to pecuniary penalty

(1) In proceedings under **section 100**, the court may, instead of or in addition to making a pecuniary penalty order, make 1 or more of the following orders against a person (**A**):

(a) an order that ~~the person mitigate or remedy~~ A mitigate or remedy 1 or more adverse effects referred to in **subsection (2)** that—

(i) are caused by or on behalf of ~~the person~~ A:

(ii) relate to a place owned or occupied by ~~the person~~ A:

(b) an order that ~~the person pay~~ A pay the costs of mitigating or remedying the adverse effects referred to in **paragraph (a)**:

(c) an order that ~~the person dispose of or arrange~~ A dispose of or arrange for the disposal of the ~~regulated organism~~ regulated genetically modified organism related to ~~the person's~~ A's breach.

(2) The adverse effects relate to the following:

(a) the health or safety of people:

(b) property:

(c) the environment.

Compare: 1996 No 30 s 124D

103 Rules of civil procedure and civil standard of proof apply

A proceeding under this subpart is a civil proceeding and the usual rules of court and rules of evidence and procedure for civil proceedings apply (including the standard of proof).

Compare: 1996 No 30 s 124E

104 Relationship between concurrent proceedings for pecuniary penalty and criminal proceedings

(1) This section applies if the same act or omission, or substantially the same act or omission, could give rise to proceedings under **section 100** (**pecuniary penalty proceedings**) and proceedings under any of **sections 76 to 83** or the regulations (**criminal proceedings**).

(2) Criminal proceedings may be started whether or not pecuniary penalty proceedings have been started.

(3) If criminal proceedings are started when pecuniary penalty proceedings have been started but not completed, the pecuniary penalty proceedings are stayed.

(4) Criminal proceedings may not be started if pecuniary penalty proceedings have resulted in the making of a pecuniary penalty order that remains in place after all appeal rights either have not been exercised or have been exercised and abandoned or exhausted.

Compare: 1996 No 30 s 124F

105 Liability of principals and employers

(1) This section applies for the purposes of **sections 100 and 102**.

(2) **Subsections (3) and (4)** apply if the person who is liable under **section 100** (**person A**) was acting as the agent or employee of another person (**person B**) at the time of the breach.

(3) Person B is liable under **section 100** in the same manner and to the same extent as if person B had personally failed to comply, if it is proved—

(a) that the act or omission that constituted the breach took place with person B's actual or apparent authority, or express or implied permission, or consent; or

(b) that person B knew that the breach was occurring or was to occur and failed to take all reasonable steps to prevent or stop it.

(4) Person B's liability does not affect person A's liability.

(5) A court that makes an order under **section 100 or 102** against a body corporate may also make an order against a director or person concerned in the management of the body corporate if it is proved—

(a) that the act or omission that constituted the breach took place with the director or person's authority, permission, or consent; or

(b) that the director or person knew that the breach was occurring or was to occur and failed to take all reasonable steps to prevent or stop it.

Compare: 1996 No 30 s 124I

Part 4
Administration

Subpart 1—Minister

106 Functions of Minister

The Minister has the following functions:

(a) to appoint the Regulator under **section 108**:

(b) to appoint the members of the Technical Advisory Committee under **section 114**:

(c) to appoint the members of the Māori Advisory Committee under **section 121**:

(d) to give ~~general policy~~ directions to the Regulator to give effect to a Government policy under **section 106A** ~~(*see* **section 111(1)(b)**~~):

(e) to grant emergency authorisations under **section 52**:

(f) to perform any other functions and duties and exercise any other powers conferred or imposed on the Minister under this Act.

106A Power to direct Regulator to give effect to Government policy

(1) The Minister may direct the Regulator to give effect to a Government policy that—

(a) is consistent with the purpose of this Act; and

(b) relates to the Regulator's objective under **section 109**.

(2) However, the Minister may not direct the Regulator to—

(a) make a particular decision in relation to the performance of the Regulator's functions and duties or the exercise of the Regulator's powers under this Act, including in relation to—

(i) issuing a licence:

(ii) making a declaration that an activity is a pre-assessed, non-notifiable, or notifiable activity:

(iii) granting an equivalent medical authorisation:

(iv) imposing a condition:

(b) require the performance or non-performance of a particular act, or the bringing about of a particular result, in respect of a particular person or matter.

(3) Before giving a direction under **subsection (1)**, the Minister—

(a) must consult the Regulator; and

(b) may consult—

(i) the Technical Advisory Committee:

(ii) the Māori Advisory Committee (if the direction would relate to the functions of that committee):

(iii) any other Minister, agency, or group of persons that the Minister considers relevant in the circumstances.

(4) The Minister must publish the direction in the *Gazette* as soon as practicable after giving the direction.

107 Limits on Minister's powers of delegation

Despite anything in clause 5 of Schedule 6 of the Public Service Act 2020, the Minister must not delegate to any person—

(a) the power to appoint the Regulator under **section 108**:

(aa) the power to appoint an acting Regulator under **section 108B**:

(b) the power ~~to give general policy directions~~ to direct the Regulator to give effect to a Government policy under **section 106A** ~~(*see* **section 111(1)(b)**~~):

(c) the power to grant emergency authorisations under **section 52**.

Subpart 2—Regulator

108 Gene Technology Regulator

(1) There must be a Gene Technology Regulator.

(2) The Minister must appoint a person to be the Regulator on the recommendation of the EPA.

(3) The Minister must be satisfied that the person has the appropriate experience and expertise to perform the functions and duties and exercise the powers of the Regulator.

(4) The person appointed must be an employee of the EPA (or become employed as such for the purpose of taking up the appointment).

(5) The EPA must provide resources and administrative support for the Regulator.

108A Term of office, vacation of office, and suspension or removal from office

(1) The Minister must appoint the Regulator for a term of not more than 5 years, but may reappoint the Regulator.

(2) When the term for which a person has been appointed as Regulator expires, that person continues to hold office (unless sooner vacating or removed from office) until—

(a) the person is reappointed; or

(b) a successor to the person is appointed.

(3) A person appointed as Regulator may resign by notice in writing to the Minister.

(4) The Minister may at any time suspend or remove the Regulator from office for misconduct, inability to perform the functions of office, or neglect of duty.

(5) The suspension or removal must be made by written notice to the Regulator.

(6) The Minister must notify the suspension or removal in the *Gazette* as soon as practicable after giving the notice.

108B Acting Regulator

(1) The Minister may appoint a person, on the recommendation of the EPA, to act as the Regulator if—

(a) a person has not yet been appointed to be the Regulator under **section 108(1)**; or

(b) the office of the Regulator is vacant; or

(c) the Regulator is absent from duty (for whatever reason) and unable to perform the functions and duties and exercise the powers of the Regulator.

(2) The requirements in **section 108(3) to (5)** apply, with any necessary modifications, to the appointment of an acting Regulator under **subsection (1)**.

(3) The appointment of an acting Regulator under **subsection (1)(a)** ceases on the date on which the Regulator takes office.

(4) The appointment of an acting Regulator and acts done by the acting Regulator cannot be questioned in proceedings on either of the following grounds:

(a) there was no reason, or is no longer a reason, for the appointment:

(b) the acting Regulator was not appointed to the position of Regulator.

109 Objective of Regulator

The objective of the Regulator is to develop and maintain an independent, efficient, and transparent system to regulate the use of gene technologies and ~~regulated organisms~~ regulated genetically modified organisms to achieve the purpose of this Act.

110 Functions of Regulator

The Regulator has the following functions:

(a) to perform the functions and duties and exercise the powers conferred or imposed on the Regulator under this Act or any other legislation:

(b) to advise the Minister on any matter relating to the Regulator's functions under this Act:

(c) if requested by the Minister, to provide ~~technical~~ advice to the Government on any matter related to the Regulator's functions under this Act:

(d) to contribute to and co-operate with international forums related to the Regulator's functions under this Act:

(e) to facilitate New Zealand's compliance with its international obligations under the Convention on Biological Diversity and the Cartagena Protocol:

(f) to monitor international practice regarding the regulation of gene technologies:

(g) to provide information ~~and advice~~ to the public about the regulation of gene technologies and ~~regulated organisms~~ regulated genetically modified organisms.

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~~ a direction to give effect to a Government policy given by the Minister under **section 106A**.

~~(2) To avoid doubt, despite **subsection (1)(b)**, the Regulator is not subject to any direction requiring the performance or non-performance of a particular act, or the bringing about of a particular result, in respect of a particular person or matter.~~

(3) The Regulator is accountable to the Minister for the Regulator's performance of their functions and duties and exercise of their powers.

(3A) The Regulator is accountable to the EPA for the performance of the Regulator's obligations as an employee of the EPA.

(4) The Regulator must have arrangements in place to avoid or manage conflicts of interest relating to the performance of their functions and duties and exercise of their powers.

112 Delegation of functions and duties and powers of Regulator

(1) The Regulator may delegate to any suitably qualified and trained person any of their functions, duties, or powers, other than—

(a) this power of delegation; and

(b) the powers listed in **subsection (2)(a) to (e)**.

(2) The Regulator may delegate only to an employee of the EPA the power—

(a) to declare that an activity is a non-notifiable activity under **section 47**:

(b) to declare that an activity is a notifiable activity under **section 48**:

(c) to declare that an activity is a pre-assessed activity under **section 23**:

(d) to declare that ~~a person~~ an authority is a recognised overseas authority under **section 57**:

(e) to approve providers of synthetic nucleic acid and manufacturers of benchtop nucleic acid synthesis equipment under **section 149**.

(3) A delegation under this section—

(a) must be made in writing:

(b) may be made subject to any conditions that the Regulator thinks appropriate:

(c) may be made generally or in any particular case:

(d) does not affect or prevent the performance of any function or duty or the exercise of any power by the Regulator:

(e) does not affect the responsibility of the Regulator for the actions of any delegate acting under the delegation.

(4) The delegate may, unless the delegation provides otherwise, perform the function or duty or exercise the power in the same manner, subject to the same restrictions, and with the same effect as if the delegate were the Regulator.

(5) A person purporting to act as a delegate—

(a) is, in the absence of proof to the contrary, presumed to be acting in accordance with the terms of the delegation; and

(b) must produce evidence of their authority to do so, if reasonably requested to do so.

(6) A delegation under this section may be revoked at will by—

(a) written notice to the delegate; or

(b) any other method provided for in the delegation.

(7) A delegation made by a person who ceases to hold office as the Regulator continues to have effect as if it were made by the person who is the Regulator from time to time.

112A Annual report

(1) As soon as practicable after the end of each financial year, the Regulator must provide a report of the Regulator's operations during that year to the Minister.

(2) The report must contain information about the following:

(a) licences issued by the Regulator during the year; and

(b) declarations that an activity is a non-notifiable activity, a notifiable activity, or a pre-assessed activity made by the Regulator during the year; and

(c) equivalent medical authorisations granted by the Regulator during the year; and

(d) emergency authorisations granted by the Minister during the year; and

(e) a summary of any breach of conditions of a licence, declaration, equivalent medical authorisation, or emergency authorisation that has come to the Regulator's attention during the year, and any monitoring or enforcement action taken; and

(f) any other information that the Regulator considers necessary or desirable.

(3) As soon as practicable after receiving the report, the Minister must present a copy of it to the House of Representatives.

(4) As soon as practicable after a copy of the report is presented to the House of Representatives, the Regulator must publish the report on an internet site maintained by or on behalf of the Regulator.

112B Insurance for liability of Regulator

Despite section 123(b) of the Crown Entities Act 2004, the EPA may effect insurance cover for the Regulator in relation to the Regulator's acts or omissions, except for an act or omission that is—

(a) in bad faith; or

(b) not in the performance or intended performance of the Regulator's functions.

Subpart 3—Technical Advisory Committee

113 Technical Advisory Committee

(1) The Minister must establish a committee called the Technical Advisory Committee.

(2) The EPA must provide administrative support for the committee.

114 Appointment and membership of Technical Advisory Committee

(1) The Minister may, at any time,—

(a) appoint a person as a member of the Technical Advisory Committee; and

(b) remove a member from the committee and, if the Minister thinks fit, appoint another member in that member's place.

(2) The Minister must consult the Regulator before appointing or removing a person.

(3) 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) molecular biology:

(b) ecology:

(c) plant, microbial, animal, or human genetics:

(d) virology:

(e) entomology:

(f) agricultural or aquacultural systems:

(g) biosafety engineering:

(h) public health:

(i) occupational health and safety:

(j) risk assessment:

(k) clinical medicine:

(l) biochemistry:

(m) pharmacology:

(n) plant or animal pathology:

(o) botany:

(p) microbiology:

(q) animal biology:

(r) immunology:

(s) toxicology:

(sa) plant or animal breeding:

(sb) seed production:

(t) any other area recommended by the Regulator.

(4) In making an appointment, the Minister must also consider whether the proposed member has the skills, knowledge, or experience to participate effectively in the committee and to contribute to carrying out the functions of the committee.

(5) Each member of the committee is appointed on the terms and conditions that the Minister determines by written notice to the member.

(6) The Minister must notify the appointment in the *Gazette* as soon as practicable after making the appointment.

(7) A member of the committee—

(a) may at any time resign office by notice in writing to the Minister; and

(b) must inform the Regulator of their resignation.

115 Functions of Technical Advisory Committee

The functions of the Technical Advisory Committee are—

(a) to provide scientific and technical advice at the request of the Regulator 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~~ regulated genetically modified organisms and the identification and management of their risks; and

(b) to perform any other functions conferred or imposed on the committee under this Act.

116 Regulator must have regard to advice from Technical Advisory Committee

The Regulator must have regard to the advice given by the Technical Advisory Committee.

117 Procedure of Technical Advisory Committee

(1) The Technical Advisory Committee may, subject to any provision in this Act and any secondary legislation made under this Act, determine its own procedure.

(2) The committee must appoint—

(a) 1 of its members to be the chairperson of the committee; or

(b) 2 of its members to be co-chairpersons of the committee.

(3) The committee must have arrangements in place to avoid or manage conflicts of interest relating to the performance of its functions.

(4) The committee must—

(a) prepare and agree draft terms of reference for the committee; and

(b) submit the draft terms of reference to the Regulator for approval.

(5) The Regulator must—

(a) approve the terms of reference; or

(b) refer the draft terms of reference back to the committee for reconsideration, together with the Regulator's reasons for the referral.

(6) The committee must, on receiving a referral under **subsection (5)(b)**,—

(a) reconsider the draft terms of reference; and

(b) prepare and agree revised draft terms of reference and submit the revised draft terms to the Regulator under **subsection (4)(b)** for approval.

(7) Once the terms of reference have been approved, the Regulator must publish the approved terms of reference on an internet site maintained by or on behalf of the Regulator as soon as practicable after they are approved.

118 Remuneration of Technical Advisory Committee

The members of the Technical Advisory Committee are entitled, in accordance with the fees framework, to—

(a) receive remuneration for services as a member at a rate and of a kind determined by the Minister; and

(b) be reimbursed for actual and reasonable expenses incurred by them in undertaking the functions of the committee.

119 Reporting by Technical Advisory Committee

The Technical Advisory Committee must report to the Regulator on the matters referred to it by the Regulator.

Subpart 4—Māori Advisory Committee

120 Māori Advisory Committee

(1) The Minister must establish a committee called the Māori Advisory Committee.

(2) The EPA must provide administrative support for the committee.

121 Appointment and membership of Māori Advisory Committee

(1) The Minister may, at any time,—

(a) appoint a person as a member of the Māori Advisory Committee; and

(b) remove a member from the committee and, if the Minister thinks fit, appoint another member in that member's place.

(2) Before appointing or removing a person, the Minister must consult—

(a) the Regulator; and

(b) the Minister for Māori Development; and

(c) any other Minister that the Minister considers appropriate.

(2A) A person must not be appointed as a member of the committee unless, in the opinion of the Minister, the person is qualified for appointment, having regard

to that person's knowledge of mātauranga Māori (Māori traditional knowledge), tikanga Māori (Māori protocol and culture), te ao Māori (the Māori world), and taonga species.

(2B) In making an appointment, the Minister must also consider whether the proposed member has the standing in the Māori community, skills, knowledge, or experience to participate effectively in the committee and to contribute to carrying out the functions of the committee.

(3) Each member of the committee is appointed on the terms and conditions that the Minister determines by written notice to the member.

(4) The Minister must notify the appointment in the *Gazette* as soon as practicable after making the appointment.

(5) A member of the committee—

(a) may at any time resign office by notice in writing to the Minister; and

(b) must inform the Regulator of their resignation.

122 Functions of Māori Advisory Committee

The functions of the Māori Advisory Committee are to—

(a) provide advice to the Minister on ~~proposals to exempt~~ proposed regulations exempting certain organisms ~~or gene technologies~~ from the operation of ~~the~~ this Act under **section 163**, and any other proposed regulations, if the ~~proposal relates to an organism that uses an indigenous species as a host organism; and~~ regulations relate to a host organism that is—

(i) an indigenous species; or

(ii) a non-indigenous species of significance; and

(b) provide advice to the Regulator about whether material adverse effects on kaitiaki relationships may result from ~~an environmental risk~~ a risk to the environment posed by an activity, in relation to the matters referred to the committee under **section 126**, including by proposing conditions to mitigate those effects; and

(c) provide advice at the request of the Regulator about whether material adverse effects on kaitiaki relationships may result from ~~an environmental risk~~ a risk to the environment posed by an activity, including in relation to the following matters:

(i) suspending, cancelling, varying, transferring, or surrendering a licence in accordance with **sections 39, 41, 43 and 45**:

(ia) varying or revoking a declaration made under **section 23, 47, or 48**:

(ii) preparing a new or an amended risk assessment or risk management plan ~~prepared~~ in accordance with ~~**section 29**~~ **section 30**:

(iii) issuing standards and forms:

(iv) policies, processes, and decisions of the Regulator under this Act:

(v) imposing conditions to mitigate the effects; and

(d) issue engagement guidelines and provide advice to applicants for licences and to kaitiaki; and

(e) perform any other functions or duties conferred or imposed on the committee under this Act.

123 Advice given under section 122(b) and (c)

The Regulator must have regard to the advice given by the Māori Advisory Committee under **section 122(b) and (c)**.

124 Procedure of Māori Advisory Committee

(1) The Māori Advisory Committee may, subject to any provision in this Act and any secondary legislation made under this Act, determine its own procedure.

(2) The committee may conduct any investigations the committee considers appropriate to carry out its functions (including requesting further information from any person or convening hui).

(3) The committee must appoint—

(a) 1 of its members to be the chairperson of the committee; or

(b) 2 of its members to be co-chairpersons of the committee.

(4) The committee must have arrangements in place to avoid or manage conflicts of interest relating to the performance of its functions.

(5) The Committee must—

(a) prepare and agree draft terms of reference for the committee; and

(b) submit the draft terms of reference to the Regulator for approval.

(6) The Regulator must—

(a) approve the terms of reference; or

(b) refer the draft terms of reference back to the committee for reconsideration, together with the Regulator's reasons for the referral.

(7) The committee must, on receiving a referral under **subsection (6)(b)**,—

(a) reconsider the draft terms of reference; and

(b) prepare and agree revised draft terms of reference and submit the revised draft terms to the Regulator under **subsection (5)(b)** for approval.

(8) Once the terms of reference have been approved, the Regulator must publish the approved terms of reference on an internet site maintained by or on behalf of the Regulator as soon as practicable after they are approved.

125 Remuneration of Māori Advisory Committee

The members of the Māori Advisory Committee are entitled, in accordance with the fees framework, to—

(a) receive remuneration for services as a member at a rate and of a kind determined by the Minister; and

(b) be reimbursed for actual and reasonable expenses incurred by them in undertaking the functions of the committee.

126 Regulator to refer certain matters to Māori Advisory Committee

(1) This section applies to any of the licence applications or proposals to make a declaration set out in **subsection (2)** if the application, if issued, or the declaration, if made, would authorise an activity in relation to a ~~regulated organism~~ regulated genetically modified organism ~~that uses an indigenous species as~~ that is derived from a host organism that is—~~.~~

(a) an indigenous species; or

(b) a non-indigenous species of significance.

(2) The applications and proposals referred to in **subsection (1)** are the following:

(a) a licence application in which the Regulator is required to prepare a risk assessment and a risk management plan under ~~**section 25**~~ **section 26** in connection with the application:

(b) a proposal to make a declaration that an activity is—

(i) a non-notifiable activity under **section 47**:

(ii) a notifiable activity under **section 48**:

(iii) a pre-assessed activity under **section 23**.

(3) The Regulator must refer the application or proposal to the Māori Advisory Committee.

(4) When a licence application described in **subsection (2)(a)** is referred to the committee, the draft risk assessment and draft risk management plan prepared in relation to the application must also be referred to the committee.

(5) A failure to comply with this section does not affect the validity of a decision to issue a licence or make a declaration.

127 Māori Advisory Committee's functions in relation to matters referred to it under section 126

(1) The functions of the Māori Advisory Committee, in relation to an application or a proposal that is referred to it under **section 126**, are to assess whether—

(a) the activity that would be authorised would have material adverse effects on 1 or more kaitiaki relationships with the ~~indigenous~~ species ~~that would be~~ used as a host organism; and

(b) conditions could adequately mitigate those effects.

(2) In carrying out its functions, the committee must—

(a) assess any kaitiaki relationship that an iwi, a hapū, a Māori individual, or a Māori entity asserts that they have with the ~~indigenous~~ species, and the effect of the activity on that relationship, in the manner described in **sections 128 to 130**:

(b) if no kaitiaki relationship has been asserted, consider the nature of any kaitiaki relationships that Māori in general have with the ~~indigenous~~ species, and the effect of the activity on those relationships.

(3) The matters that the committee may take into account in carrying out its functions also include the effects of any activity already authorised in relation to the ~~indigenous~~ species.

128 Assessment if kaitiaki relationship asserted

In a case where an iwi, a hapū, a Māori individual, or a Māori entity ~~asserted~~ asserts that they have a kaitiaki relationship with ~~an indigenous~~ the species ~~that would be, or has been,~~ used as a host organism, the Māori Advisory Committee must also consider—

(a) whether that iwi, hapū, person, or other entity has demonstrated their kaitiaki relationship with the ~~indigenous~~ species:

(b) if a kaitiaki relationship has been demonstrated,—

(i) the kaitiaki's assessment of the effect of the activity on their relationship; and

(ii) any agreement to mitigate adverse effects reached between an applicant and the kaitiaki; and

(iii) whether there is any evidence that an applicant and the kaitiaki have not acted in good faith during their engagement (if any).

129 Process to be adopted by Māori Advisory Committee in relation to matters referred to it under section 126

The Māori Advisory Committee, in carrying out its functions in relation to the application or proposal referred to it under **section 126**, must,—

(a) if reasonably practicable, consider any submission (including any expert evidence given on a submitter's behalf) made by—

(i) any of the following who asserts that they have a kaitiaki relationship with ~~an indigenous~~ the species ~~that would be, or has been,~~ used as a host organism:

(A) the applicant:

(B) an iwi or a hapū:

(C) a Māori individual:

(D) a Māori entity; or

(ii) an organisation that the committee considers represents Māori generally or significant Māori interests; and

(b) comply with the requirements of natural justice; and

(c) act as soon as practicable in the circumstances; and

(d) provide written reasons in its report to the Regulator under **section 131** for every assessment and recommendation that it makes.

130 Proposed conditions to be considered when assessing adverse effects on kaitiaki relationship for licence applications

In assessing under **section 127(1)(a)** whether an activity that would be authorised by a licence would have material adverse effects on 1 or more kaitiaki relationships, the Māori Advisory Committee must consider whether the following can adequately mitigate the adverse or possible adverse effect:

(a) a proposed condition (if any) set out in a proposal by the applicant following discussion between the applicant and the committee:

(b) a proposed condition (if any) agreed by the applicant and the relevant ~~iwi, hapū, Māori individual, or Māori entity~~ kaitiaki.

131 Reporting by Māori Advisory Committee

(1) The Māori Advisory Committee must report to the Regulator on an application or a proposal referred to it by the Regulator under **section 126** relating to authorising an activity in relation to a ~~regulated organism~~ regulated genetically modified organism.

(2) The report must set out whether the committee is satisfied that—

(a) there is a kaitiaki relationship between—

(i) Māori in general and the ~~indigenous~~ species ~~that the regulated organism uses~~ used as a host organism; or

(ii) a particular ~~iwi, hapū, Māori individual, or Māori entity~~ kaitiaki and the ~~indigenous~~ species; and

(b) if it is ~~satisifed~~ satisfied that there is a kaitiaki relationship,—

(i) the kaitiaki relationship is unlikely to be materially affected by the activity that would be authorised; or

(ii) any adverse effect or likely adverse effect of the activity on the kaitiaki relationship would be adequately mitigated by 1 or more proposed conditions.

(3) If the committee is satisfied that there is a kaitiaki relationship but neither **subsection (2)(b)(i)** ~~**or**~~ **nor (ii)** applies, the committee must advise the Regulator not to proceed with the application or proposal.

(4) If the committee is satisfied that **subsection (2)(b)(ii)** applies, the committee must advise the Regulator to impose the proposed conditions.

Subpart 5—Subcommittees

132 Establishment of subcommittees

(1) The Regulator may establish subcommittees of the Technical Advisory Committee or the Māori Advisory Committee for the purpose of advising on specific matters or classes of matters.

(2) The Regulator may, at any time,—

(a) appoint a member of the Technical Advisory Committee, or any other person, to be a member of a subcommittee of the Technical Advisory Committee:

(b) appoint a member of the Māori Advisory Committee, or any other person, to be a member of a subcommittee of the Māori Advisory Committee:

(c) remove a member from a subcommittee, and, if the Regulator thinks fit, appoint another ~~member~~ person in that member's place:

(d) abolish a subcommittee.

(3) A member of a subcommittee—

(a) is appointed on the terms and conditions that the Regulator determines by written notice to the member:

(b) may resign office by notice in writing to the Regulator.

(4) The Regulator must notify the appointment of a member of a subcommittee on an internet site maintained by or on behalf of the Regulator as soon as practicable after making the appointment.

133 Reference to committee includes reference to subcommittee

Except where **section 132**, this section, or the context otherwise requires,—

(a) a reference in this Act or in any other legislation to the Technical Advisory Committee includes a reference to a subcommittee of the committee:

(b) a reference in this Act or in any other legislation to the Māori Advisory Committee includes a reference to a subcommittee of the committee.

Part 5
Miscellaneous

Subpart 1—Reviews

134 Request for review of Regulator's decision

(1) A person may request in writing to have a decision of the Regulator reviewed if—

(a) the decision is made under a provision listed in **Schedule 3**; and

(b) the person is identified in **Schedule 3** as a person who may apply for a review of that decision.

(2) The request must—

(a) be made to the Regulator—

(i) within 20 working days after notice of the decision is served on or given to (as applicable) the requester or at any later date permitted by the Regulator; and

(ii) in the form required by the Regulator; and

(b) contain any information required by the Regulator; and

(c) contain any information prescribed in regulations; and

(d) be accompanied by the fee (if any) prescribed in regulations; and

(e) state the reasons for making the request.

135 Procedure for review of decision by Regulator

(1) The reviewer of a decision described in **Schedule 3** is the Regulator.

(2) The Regulator must review the decision as soon as is reasonably practicable after the request is received.

(3) The Regulator may give the requester a notice in writing requiring the requester to supply information additional to that contained in the application, within a time specified by the Regulator.

136 Outcome of review

(1) The Regulator may confirm, modify, or reverse all or some of a decision or make a new decision.

(2) The Regulator must, as soon as practicable, give the applicant a notice in writing of—

(a) the decision on the review; and

(b) the reasons for the decision on the review; and

(c) the requester's right to appeal against the decision made on the review.

137 Effect of review

(1) The original decision described in **Schedule 3** is valid until the ~~reviewer~~ Regulator modifies~~,~~ or reverses it or makes a new decision.

(2) If the ~~reviewer confirms,~~ Regulator modifies, or reverses some of the original decision, ~~a decision that is confirmed or the parts of the decision that are not modified or reversed remain valid~~ the decision as modified or reversed replaces the earlier decision.

(3) If the Regulator undertakes a review, there is no further right to seek a review ~~on~~ of the decision made on the review.

(4) For the purposes of ~~any~~ exercising any right of appeal, the decision appealed against is—

(a) the decision made on the review, if the Regulator undertakes a review and modifies or reverses the original decision; and

(b) the original decision, if the Regulator does not undertake a review of that decision or confirms the original decision or review.

138 Regulator must enter outcomes of reviews in public register

The Regulator must enter the outcome of each review of a decision described in **Schedule 3** in the ~~licensed activities register or any other relevant public~~ register kept under **section 58**.

Subpart 2—Appeals

Appeals to District Court

139 Appeal to District Court

(1) The following persons may appeal to the District Court:

(a) the person against whom a compliance order is made under **section 72**:

(b) a person whose application under **section 75(2)** did not succeed:

(c) a person whose property has been seized under this Act or who has been required to dispose of any thing:

(2) The rules of procedure under the District Court Act 2016 and the District Court Rules 2014 apply to an appeal under this section.

(3) The appeal does not operate as a stay of the compliance order or a requirement to dispose of any thing until a stay is granted by the court under **section 140**.

(4) The District Court may confirm, change, or cancel the order appealed against.

140 Stay of compliance order or disposal requirement

(1) The person appealing against a compliance order or a requirement to dispose of any thing may apply for a stay of the compliance order or the disposal requirement pending the court's decision on the appeal.

(2) The rules of procedure under the District Court Act 2016 and the District Court Rules 2014 apply to an application for a stay.

(3) The court must consider the application for a stay as soon as practicable after the application is lodged.

(4) The court must consider—

(a) whether to hear from the following persons:

(i) the person appealing against the compliance order or the disposal requirement ~~to dispose of any thing~~:

(ii) the Regulator:

(iii) if applicable, the appointer of the enforcement officer whose compliance order is appealed against; and

(b) the likely effect of granting a stay on ~~human health or safety~~ the health and safety of people or the environment; and

(c) whether it is unreasonable for the person appealing against the compliance order or the disposal requirement ~~to dispose of any thing~~ to comply with it pending the decision on the appeal; and

(d) any other matters that the court thinks fit.

(5) The court may grant or refuse a stay and may impose any terms or conditions that the court thinks fit.

(6) The stay—

(a) has legal effect once a copy of it is served on the appointer of the enforcement officer whose compliance order is appealed against; and

(b) remains in force until the District Court order is lifted.

141 Appeal to High Court, Court of Appeal, or Supreme Court

(1) A party to an appeal under **section 139** may appeal to the High Court on a question of law.

(2) The High Court Rules 2016 and sections 126 to 130 of the District Court Act 2016 apply to an appeal under **subsection (1)**—

(a) as if it were an appeal under section 124 of the District Court Act 2016; and

(b) with all necessary modifications.

(3) A party to an appeal under **subsection (1)** may appeal to the Court of Appeal or the Supreme Court against a determination of the High Court on a question of law, with the leave of the court appealed to, and subject to section 75 of the Senior Courts Act 2016.

(4) The Court of Appeal or the Supreme Court hearing an appeal under this section has the same power to adjudicate on the appeal as the High Court had.

Appeals against Regulator's decisions directly to High Court on question of law

142 Appeals directly to High Court

(1) An eligible person may appeal to the High Court on a question of law against a decision that is able to be reviewed, and a decision of the Regulator made on review, on application by that person (whether or not the decision has been reviewed).

(2) An appeal must be lodged with the High Court within 20 working days of the date of—

(a) the decision (if the original decision); or

(b) the decision made on review (if the Regulator reviews the original decision).

(3) An appeal under this section must be made and determined in accordance with the Senior Courts Act 2016 and the High Court Rules 2016.

(4) In this section and **sections 143 and 144**, **eligible person** means ~~a person who is directly affected by a decision referred to in **subsection (1)**.~~—

(a) an applicant or licence holder affected by a decision that is able to be reviewed:

(b) a person who made a submission on a draft risk assessment or draft risk management plan (as defined in **section 12**) that relates to the decision:

(c) any other person or group who has asserted a kaitiaki relationship in relation to an indigenous species or a non-indigenous species of significance that was the subject of the decision.

143 Notice of appeal

Before or immediately after the filing and service of a notice of appeal, the appellant must serve a copy of the notice on—

(a) the Regulator; and

(b) every other party to the proceedings; and

(c) any other person who made a submission to the Regulator~~.~~; and

(d) any other eligible person.

144 Right to appeal and be heard on appeal

(1) A party to any proceedings or any other eligible person ~~who made submissions to the Regulator~~ who has been served with a notice under **section 143** who wishes to appear and be heard on an appeal to the High Court, must give notice of their intention to appear to—

(a) the appellant; and

(b) the Registrar of the High Court; and

(c) the Regulator.

(2) The notice of intention to appear under **subsection (1)** must be served within 10 working days after the party or the person is served with the notice of appeal.

145 Orders of High Court

(1) The High Court may, on application or on its own motion, make an order directing the Regulator to lodge with the Registrar of the High Court all or any of the following things:

(a) anything in the possession of the Regulator relating to the appeal; and

(b) a report recording, in respect of any matter or issue the court may specify, any of the findings of fact of the Regulator that are not set out in their decision or report and recommendation; and

(c) a report setting out, so far as is reasonably practicable and in respect of any issue or matter the order may specify, any reasons or considerations to which the Regulator had regard but that are not set out in their decision or report and recommendation.

(2) An application under **subsection (1)** must be made,—

(a) in the case of the appellant, within 20 working days after the date on which the notice of appeal is lodged; or

(b) in the case of any other party to the appeal, within 20 working days after the party or the person is served with the notice of appeal.

(3) The High Court may make an order under **subsection (1)**—

(a) only if it is satisfied that a proper determination of a point of law so requires; and

(b) subject to any conditions that the High Court thinks fit.

146 Additional appeals to High Court

If a party to an appeal, other than the appellant, wishes to contend that the decision is in error on any other point or points of law, that party may, within 20 working days after the party is served with notice of the decision, lodge a notice to that effect with the Registrar of the High Court.

147 Extension of time

On the application of a party to an appeal, the High Court may extend any period of time stated in **sections 142(2) and 144(2)**.

148 Appeals to Court of Appeal

Subpart 8 of Part 6 of the Criminal Procedure Act 2011 applies as far as applicable with the necessary modifications to a decision of the High Court on appeal under **section 142 or 144** as if the decision were made under section 304 of that Act.

Subpart 3—~~Notices and standards~~SNA notices

149 Notice specifying synthetic nucleic acid provider, manufacturer, and third-party vendor approval

(1) The Regulator may at any time issue a notice specifying that—

(a) 1 or more providers are approved for the purposes of this Act:

(b) 1 or more manufacturers are approved for the purposes of this Act:

(c) 1 or more third-party vendors are approved for the purposes of this Act.

(2) The notice must specify any conditions that apply in relation to those approvals.

(3) The Regulator may at any time amend, replace, or revoke a notice issued under **subsection (1)**.

(4) The Regulator must ensure that any notice issued under this section is— published on an internet site maintained by or on behalf of the Regulator.

~~(a) published on an internet site maintained by or on behalf of the Regulator; and~~

~~(b) maintained in a form that is accessible to the public.~~

~~(5) 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.~~

Subpart 3A—Standards

150 Regulator may issue or approve standards for ~~minimising~~ managing risks to health and safety of people and environment

(1) The Regulator may, after undertaking consultation in accordance with **subsection (1A)**, issue or approve standards for the purpose of ensuring that risks to the health and safety of people and the environment are ~~minimised~~ managed.

(1A) Before issuing or approving standards under **subsection (1)**, the Regulator—

(a) must consult persons or groups whom the Regulator considers to be representative of those with an interest in the proposed standard:

(b) may consult the Technical Advisory Committee or the Māori Advisory Committee, or both.

(2) Standards may be issued or approved under **subsection (1)** for— any or all of the following:

(a) ~~activities carried out in containment, activities carried out in the environment,~~ contained activities, environmental activities, medical activities, and any other kinds of activities:

(b) different kinds of authorised activities (for example, activities that are non-notifiable or notifiable, and activities that require a licence to carry out):

(c) activities related to a ~~regulated organism of~~ regulated genetically modified organism or a category of ~~regulated organisms~~ regulated genetically modified organisms or a subset of ~~those activities~~ that category (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, without limitation, 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~~ regulated genetically modified organism from containment.

(4) ~~The Regulator may approve~~ Standards approved under **subsection (1)** may include standards referred to in other Acts or regulations, or issued by any New Zealand agency other than the Regulator, or by a recognised overseas authority.

(5) The Regulator may, after undertaking public consultation and consultation in accordance with **subsection (1A)**, amend, revoke, or replace a decision on a standard under **subsection (1)**.

(6) Despite **subsection (5)**, the Regulator may amend their decision on a standard without public consultation if the purpose of the amendment is to correct a minor or technical error.

(7) Standards issued or approved under this section are secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Subpart 4—Information and sample sharing

151 Disclosure of information within New Zealand

(1) This section applies to—

(a) the information described in **subsection (2)**; and

(b) the agencies specified in **subsection (3)**.

(2) The information is—

(a) personal information as defined in the Privacy Act 2020 ~~that is supplied or obtained under or for the purposes of this Act; and~~; or

(b) information related to gene technology or ~~regulated organisms~~ regulated genetically modified organisms that is confidential information ~~or commercially sensitive information, or both~~.

(3) The agencies are those that perform functions or duties or exercise powers under, or administer, the whole or any part of this Act or the following Acts:

(a) the Agricultural Compounds and Veterinary Medicines Act 1997:

(b) the Animal Products Act 1999:

(c) the Animal Welfare Act 1999:

(d) the Biosecurity Act 1993:

(e) the Customs and Excise Act 2018:

(f) the Food Act 2014:

(g) the Imports and Exports (Restrictions) Act 1988:

(h) the Hazardous Substances and New Organisms Act 1996:

(i) the Health Act 1956:

(ia) the Health and Safety at Work Act 2015:

(j) the Human Assisted Reproductive Technology Act 2004:

(k) the Human Tissue Act 2008:

(l) the Medicines Act 1981:

(m) the Misuse of Drugs Act 1975:

(n) the Psychoactive Substances Act 2013~~.~~:

(o) any additional Act specified by Order in Council for the purposes of this subsection.

(4) An agency described in **subsection (3)** may disclose information to another agency described in that subsection if the agency reasonably believes that the disclosure relates only to information supplied or obtained—

(a) under or for the purposes of this Act that is necessary or desirable for the performance of functions or duties, or the exercise of powers, under this Act or other legislation referred to in **subsection (3)**; or

(b) under or for the purposes of legislation (other than this Act) referred to in **subsection (3)** that is necessary or desirable for the performance of functions or duties or the exercise of powers under this Act.

(4A) **Subsection (4)** provides grounds on which personal information may be disclosed or collected that are in addition to those permitted by information principles 2 and 11 as set out in section 22 of the Privacy Act 2020.

(5) An agency may impose conditions the agency ~~thinks fit~~ reasonably believes to be appropriate relating to the disclosure, including—

(a) the use and storage of information; and

(b) the copying, returning, or disposal of information; and

(c) the further disclosure of information.

(6) The agency that discloses the information must make and keep a record of—

(a) the information that was disclosed; and

(b) the agency to which it was disclosed; and

(c) any conditions subject to which it was disclosed.

152 Disclosure of information outside New Zealand

(1) This section applies to the disclosure of information described in **subsection (2)** outside New Zealand.

(2) The information is—

(a) personal information, as defined in the Privacy Act 2020~~, that is supplied or obtained under or for the purposes of this Act; and~~; or

(b) information related to gene technology or ~~regulated organisms~~ regulated genetically modified organisms that is confidential information ~~or commercially sensitive information, or both~~.

(3) The disclosure must not be made unless—

(a) **section 153** is satisfied; and

(b) the Regulator has regard to **section 61** (which relates to confidential information) if the information the Regulator intends to disclose is subject to that section; and

(c) if the information is about a kaitiaki relationship, the Regulator has sought advice on its disclosure from the Māori Advisory Committee.

(4) **Subsection (3)** provides grounds on which personal information may be disclosed that are in addition to those permitted by information privacy principle 11 as set out in section 22 of the Privacy Act 2020.

Compare: 1996 No 30 s 97B

153 Disclosure of information outside New Zealand must be under agreement

(1) The Regulator may disclose information under **section 152** under an agreement that is made between the Regulator and a recognised overseas authority (within the meaning of **section 57(1)**) to undertake joint assessments of licence applications under this Act ~~and the Hazardous Substances and New Organisms Act 1996~~.

(2) Before making an agreement, the Regulator—

(a) must consult the Privacy Commissioner; and

(b) must be satisfied that the agreement is necessary to—

(i) enable a joint assessment of a licence application under this Act ~~and the Hazardous Substances and New Organisms Act 1996~~ to take place; or

(ii) help monitor compliance, and investigate, prevent, identify, or respond to non-compliance, with this Act or a relevant law in the overseas country.

(3) The agreement—

(a) must be in writing; and

(b) must state the criteria for the disclosure of information under it to the overseas authority; and

(c) must state the use that the overseas authority may make of the information; and

(d) must state whether the overseas authority may disclose the information to any other person; and

(e) if the overseas authority may disclose any of the information to any other person, must state—

(i) the persons to whom the overseas authority may disclose it; and

(ii) the extent to which the overseas authority may disclose it; and

(iii) the conditions subject to which the overseas authority may disclose it; and

(f) may state—

(i) the form in which the information may be disclosed; and

(ii) the method by which the information may be disclosed.

153A Disclosure of information to Biosafety Clearing-House

(1) The Regulator may disclose information to the Biosafety Clearing-House operated under the Cartagena Protocol if the Regulator considers the disclosure is necessary to comply with New Zealand's obligations under the Protocol.

(2) Before disclosing information under **subsection (1)**, the Regulator must have regard to **section 61** (which relates to confidential information) if the information the Regulator intends to disclose is subject to that section.

(3) If the information is about a kaitiaki relationship, the Regulator must seek advice from the Māori Advisory Committee before releasing that information.

154 Exchange of samples

(1) This section applies to—

(a) a sample described in **subsection (2)**; and

(b) the agencies described in **section 151(3)**.

(2) The sample is a sample relating to a ~~regulated organism~~ regulated genetically modified organism or organic matter relating to a ~~regulated organism~~ regulated genetically modified organism.

(3) An agency described in **section 151(3)** may provide a sample to another agency described in that subsection if the agency reasonably believes the sample has been obtained or supplied—

(a) under this Act and provision of the sample is necessary or desirable for the performance of functions or duties or the exercise of powers under the other Acts described in **section 151(3)**; or

(b) under the Acts described in **section 151(3)** (other than this Act) and is necessary or desirable for the performance of functions or duties or the exercise of powers under this Act.

(4) The provision of a sample may be subject to any conditions the agency thinks fit.

Subpart 5—Regulations

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 163A, 164A,** and **165**:

(b) prescribing information to be provided with any application ~~for a licence relating to regulated organisms~~ under this Act:

(ba) prescribing other requirements relating to applications under this Act:

(c) prescribing requirements for enforcement officers appointed under **section 64** who perform functions relating to ~~regulated organisms~~ regulated genetically modified organisms:

(d) prescribing fees, charges, and levies, or a method of calculating any of those things, and providing for waivers ~~of~~ or exemptions from, and refunds of, any of those things, for the purposes of this Act, as provided in **section 164A**:

(e) prescribing matters relating to the Technical Advisory Committee and the Māori Advisory Committee:

(ea) specifying non-indigenous species of significance:

(eb) specifying additional circumstances or methods that constitute containment (as defined in **section 7(1)**):

(ec) providing for matters relating to the review of and appeals against decisions of the Regulator:

(f) providing for anything incidental that is necessary for carrying out, or giving full effect to, this Act.

(2) Any regulation made under this section is not invalid merely because it confers a discretion on, or allows a matter to be determined or approved by, any person.

(3) Regulations may not be made under this section except in compliance with **section 167**.

(4) Regulations under this section are secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

156 Regulations relating to joint applications

Regulations may be made under **section 155(1)(a)** prescribing how applications may be made jointly for approvals under this Act and the Hazardous Substances and New Organisms Act 1996.

157 Regulations relating to synthetic nucleic acid providers, manufacturers, third-party vendors, and ~~customer~~ screening requirements

(~~1~~) Regulations may be made under **section 155(1)(a)**—

(a) prescribing requirements that a provider of synthetic nucleic acid, including a third-party vendor, must meet to supply synthetic nucleic acid, relating to—

(i) screening ~~purchase requests~~ sequences to identify sequences of concern:

(ii) screening customers who make purchase requests:

(b) prescribing requirements that a manufacturer of benchtop nucleic acid synthesis equipment, including a third-party vendor, must meet to supply that equipment, relating to—

(i) screening customers who make purchase requests:

(ii) integrating into equipment the ability to screen ~~purchase requests~~ sequences for sequences of concern:

(c) setting out the steps that a provider or manufacturer, including a third-party vendor, must follow in relation to the supply of synthetic nucleic acid and benchtop nucleic acid synthesis equipment:

(d) prescribing criteria that must be satisfied in order for the Regulator to approve a person as a provider, manufacturer, or third-party vendor:

(e) providing for transfers and surrenders of approvals, and for the suspension or cancellation of those approvals, in circumstances specified in the regulations:

(ea) prescribing the duration of approvals:

(eb) specifying requirements relating to the auditing of manufacturers, providers, and third-party vendors in relation to synthetic nucleic acids and benchtop nucleic acid synthesis equipment:

(f) prescribing reporting, record-keeping, and data security requirements in relation to **paragraphs (a) to ~~(e)~~(eb)**.

~~(2) Regulations under this section may incorporate by reference standards set by the Regulator and recognised overseas authorities, in accordance with **subpart 6**.~~

158 Regulations relating to non-notifiable activities

Regulations may be made under **section 155(1)(a)** relating to non-notifiable activities—

(a) prescribing criteria that must be satisfied in order for an activity to be classified by the Regulator as a non-notifiable activity:

(b) prescribing ~~requirements~~ conditions for the purposes of **section 47(3)(b)** about where and how non-notifiable activity must be undertaken (for example, a requirement that a non-notifiable activity be undertaken in a containment facility that meets specified requirements including any relevant containment facility standards).

159 Regulations relating to notifiable activities

Regulations may be made under **section 155(1)(a)**—

(a) prescribing criteria that must be satisfied in order for an activity to be classified by the Regulator as a notifiable activity:

(b) prescribing ~~requirements~~ conditions, for the purposes of **section 48(3)(c)**, relating to notifiable activities, including, without limitation,—

(i) the timing of the notification:

(ii) the information to be supplied to the Regulator:

(c) prescribing requirements relating to the supervision and verification of specified notifiable activities:

(d) imposing requirements relating to the import, export, transportation, storage, and disposal of ~~regulated organisms~~ regulated genetically modified organisms in respect of which a notifiable activity takes place.

160 Regulations relating to timetables

(1) Regulations may be made under **section 155(1)(a)** setting timetables for the Regulator to process, consult, and decide on matters, and issue notifications, under this Act.

(2) The timetables referred to in **subsection (1)** include, without limitation, timetables for 1 or more of the following:

(a) the Regulator to make certain determinations about ~~regulated organisms~~ regulated genetically modified organisms and gene technology:

(b) the Regulator to prepare risk assessment and risk management plans under **section 26**:

(c) the Regulator to finalise risk assessment and risk management plans under **section 29**:

(d) the Regulator to make decisions on licence applications under **section 33**:

(e) giving notice under **section 40** of the Regulator's intention to suspend or cancel a licence:

(f) ~~advisory bodies~~ the Technical Advisory Committee to provide advice under **section 27** to the Regulator on matters relevant to the preparation of the risk assessment and risk management plans and the Māori Advisory Committee to provide advice to the Regulator under **section 131**:

(g) public consultation and the making of submissions ~~under **section 28**~~:

~~(h) the period of response for a licence holder under—~~

~~(i) **section 42(1)(b)**, which relates to surrender of licences:~~

~~(ii) **section 46(1)(b)**, which relates to the variation of licences:~~

(h) the Regulator to make decisions about matters relating to manufacturers, providers, and third-party vendors.

~~(i) the period—~~

~~(i) within which the Regulator must issue a notice in relation to non-notifiable activities under **section 47(1)**; or~~

~~(ii) within which written submissions may be received under **section 49(4)**.~~

(3) ~~Regulations made under **section 155(1)(a)** may provide~~ The Regulator may decide that ~~for~~ timetables set out in this Act or the regulations are to be extended or shortened, paused and reactivated, or replaced.

160A Timetables affected by specified international agreements

(1) If the relevant CPTPP or TPP provision applies to a matter to which **section 160(2)** applies, the Regulator must act under **section 160(3)** to extend (or further extend) any time limit set out in **Part 2** or referred to in **section 160(2)(g)**, as the Regulator considers appropriate, to give effect to the relevant CPTPP or TPP provision.

(2) An extension given for the purposes of making a submission applies for all submissions.

(3) In **subsection (1)**, **relevant CPTPP or TPP provision** means—

(a) Article 8.7.14 of the Trans-Pacific Partnership Agreement (done at Auckland on 4 February 2016) (technical barriers to trade: transparency: periods to comment on proposals):

(b) that provision as incorporated into the Comprehensive and Progressive Agreement for Trans-Pacific Partnership, done at Santiago, Chile, on 8 March 2018, by Article 1.1 of that agreement.

161 Regulations setting criteria ~~and conditions~~ for pre-assessed activities: relevant matters for ~~activities,~~ risk assessment and risk management plans~~, etc~~

Regulations may be made under **section 155(1)(a)** specifying—

(a) criteria to be taken into account when deciding whether to declare an activity to be a pre-assessed activity:

(b) matters to be taken into account by the Regulator in preparing and finalising risk assessment and risk management plans.

~~(a) prescribing criteria and conditions for all activities requiring a licence (including pre-assessed activities and different kinds of assessment for licences, medicines, and veterinary medicines):~~

~~(b) specifying matters to be taken into account by the Regulator in preparing and finalising risk assessment and risk management plans:~~

~~(c) prescribing conditions to manage risks.~~

162 Regulations relating to fit and proper persons

Regulations may be made under **section 155(1)(a)**—

(a) prescribing additional ~~criteria~~ matters that the Regulator must take into account under **section 35** in deciding whether a person is a fit and proper person:

(b) add or delete references to specified legislation for the purposes of the definition of relevant law in **section 35**.

162A Regulations relating to disclosure of confidential information

Regulations may be made under **section 155(1)(a)** prescribing persons or organisations, or classes of persons or organisations, to whom the Regulator may disclose confidential information (as defined in **section 7(1)**).

162AB Organisms, categories of organisms, and technologies not regulated by this Act

The organisms, categories of organisms, and technologies specified in **Schedule 3A** are not regulated by this Act.

162B Power to make declarations about status of entities, organisms, categories of organisms, and technologies

(1) Regulations may be made under **section 155(1)(a)** declaring that—

(a) specified entities are or are not organisms:

(b) specified organisms or categories of organisms are or are not regulated genetically modified organisms:

(c) specified technologies are or are not gene technologies.

(2) The Minister may not recommend the making of regulations referred to in **subsection (1)** unless the Minister has—

(a) received advice from the Regulator on the status of the entities, organisms or categories of organisms, or technologies; and

(b) the regulations are consistent with the advice received by the Minister from the Regulator.

163 Power to make ~~further~~ exemptions from operation of this Act ~~and non-regulated activities~~

(1) Regulations may be made under **section 155(1)(a)** exempting from the operation of this Act specified organisms or categories of organisms.—

~~(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 referred to in **subsection (1)** unless—

(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 that are not regulated under this Act or could be created ~~through conventional processes:~~ (irrespective of whether they have been created) through the use of technologies specified in **Schedule 3A** or technologies declared not to be gene technologies by regulations referred to in **section 162B**; and

~~(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.~~

(b) the Minister is satisfied that, in the absence of those regulations, the organisms or the category of organisms would be regulated genetically modified organisms.

~~(3) Regulations made under **section 155(1)(a)** may empower the Regulator to—~~

~~(a) impose conditions on any exemption:~~

~~(b) amend or revoke an exemption in any specified circumstances.~~

~~(4) 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).~~

163A Regulations requiring details of certain organisms or categories of organisms to be recorded on register

(1) Regulations may be made under **section 155(1)(a)**—

(a) requiring a person who first introduces into the environment an organism or a category of organisms to which an exemption under regulations referred to in **section 163** applies, to register that organism or category of organisms with the Regulator; and

(b) requiring the person undertaking the registration to provide to the Regulator—

(i) specified contact and other details of the person undertaking the registration; and

(ii) specified details of the organism or category of organisms.

(2) The regulations referred to in **subsection (1)** may apply only in relation to an organism, or a category of organisms, that—

(a) is the subject of an exemption made by regulations referred to in **section 163**; and

(b) is to be, or has been, introduced into the environment for the first time, either directly or from containment.

164 Regulations providing for transitional matters

(1) The Governor-General may, by Order in Council made on the recommendation of the Minister, make regulations—

(a) providing transitional and savings provisions concerning the coming into force of this Act that may be in addition to, or in place of, the transitional and savings provisions in **Schedule 1**:

(b) providing that, subject to any conditions specified in the regulations, during a specified transitional period,—

(i) specified provisions of this Act (including definitions) do not apply:

(ii) specified terms have the meaning given to them by the regulations:

(iii) specified provisions repealed, amended, or revoked by this Act continue to apply.

(2) No regulations under this section may be made, or continue in force, later than 2 years after the date of commencement of this section.

(3) Regulations under this section are secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

164A Regulations relating to fees, charges, and levies

Regulations may be made under **section 155(1)(d)**—

(a) imposing a levy on licence holders and any class of persons conducting an authorised activity under this Act for the purpose of recovering all or part of the reasonable direct and indirect costs of administering this Act:

(b) specifying the licence holders, or classes of licence holders, or other persons conducting an authorised activity under this Act, who are liable to pay the levy:

(c) specifying the levy, or how the levy or rates of levy are calculated:

(d) specifying when and how the levy is to be paid to the EPA:

(e) including in the levy, or providing for the inclusion in the levy, any shortfall in recovering the actual costs:

(f) to refund, or provide for refunds of, any over-recovery of the actual costs:

(g) requiring the payment to the EPA of fees and charges in connection with—

(i) an application or a request to the Minister or the Regulator to perform or exercise any function, duty, or power under this Act:

(ii) the performance or exercise of any other function, duty, or power under this Act:

(h) prescribing the amounts of the fees or charges referred to in **paragraph (g)** or the manner in which those fees are to be ascertained:

(i) providing for waivers, discounts, or refunds of the whole or any part of a fee, charge, or levy for any case or class of cases.

165 Regulations relating to offences

Regulations may be made under **section 155(1)(a)** prescribing—

(a) offences for breach of the regulations and maximum penalties for those offences, not exceeding $20,000:

(b) the offences in this Act that are infringement offences:

(c) breaches of the regulations that are infringement offences:

(d) infringement fees not exceeding $3,000 for infringement offences under this Act:

(e) fines not exceeding $6,000 that may be imposed by the court for infringement offences under this Act.

166 General provisions as to secondary legislation

Any regulations made under this Act may confer power to issue directions, orders, requirements, or notices for the purposes of this Act on all or any of the following:

(a) the Minister of a specified kind or description:

(b) the Regulator, or any specified chief executive or chief executives:

(c) all enforcement officers, or enforcement officers of a specified kind or description:

(d) all ~~authorised persons, or authorised~~ persons authorised under the regulations, to issue directions, orders, requirements, or notices for the purposes of this Act, or any such persons of a specified kind or description.

167 Procedure for making regulations

(1) Before the Minister may recommend the making of regulations under **section 155**, the Minister must—

(a) undertake public consultation on the proposed regulations; ~~or~~ and

(b) consult the Regulator on the proposed regulations; ~~or~~ and

(c) consult persons or representatives of persons who the Minister considers are likely to be affected by the proposed regulations.

(2) In undertaking consultation under **subsection (1)**, the ~~Regulator~~ Minister must allow the person or persons consulted at least 30 working days to comment on the proposed regulations.

(3) A failure to comply with this section does not invalidate regulations made in breach of this section.

Subpart 6—Incorporation by reference

168 Definitions for purposes of sections 169 to 172

In **sections 169 to 172**,—

gene technology documents means—

(a) regulations made under this Act:

(b) Orders in Council made under this Act:

(c) standards issued or approved under this Act:

(d) notices issued under this Act:

(e) instruments made under this Act

incorporated means incorporated by reference

~~**inspection site** means—~~

~~(a) the head office of the responsible person:~~

~~(b) any other place determined by the responsible person~~

material means~~;~~—

(a) all of the original material:

(b) part of the original material:

(c) the original material with modifications, additions, or variations:

(d) the original material with amendments incorporated:

(e) material that amends the original material:

(f) material that replaces the original material

original material means material as first published

responsible person means,—

(a) in the case of regulations, the chief executive of the department of State that, under the authority of a warrant or with the approval of the Prime Minister, is responsible for the administration of this Act; or

(b) in the case of a declaration, notice, standard, or other document issued by the Regulator, the Regulator.

169 Incorporation in documents

(1) The following written material may be incorporated in a gene technology document:

(a) frameworks, codes of practice, standards, requirements, or recommended practices of international or national organisations:

(b) frameworks, codes of practice, standards, requirements, or recommended practices prescribed in any country or jurisdiction:

(c) material that is from any other source, deals with technical matters, and is too large to include in, or print as part of, the gene technology document:

(d) material that is from any other source and deals with technical matters and that it would be impractical to include in, or print as part of, the gene technology document:

(e) the current edition of a work of reference that the responsible person considers is accepted internationally or by an industry as a standard one to refer to on its subject matter:

(f) a specific edition of a work of reference that the responsible person considers is accepted internationally or by an industry as a standard one to refer to on its subject matter:

(g) a register established by or under this Act.

(2) Material incorporated in a gene technology document has legal effect as part of the document.

170 Effect of amendments to, or replacement of, material incorporated

(1) Material that amends or replaces material incorporated in a gene technology document has legal effect as part of the document only if the responsible person publishes a notice under **subsection (2)**.

(2) The responsible person may publish a notice in the *Gazette* as soon as practicable after material is amended or replaced that—

(a) states that the amended or replacement material has legal effect as part of the document; and

(b) specifies the date on which the amended or replacement material has legal effect as part of the document.

(3) **Subsection (1)** does not apply if the gene technology document expressly says that it does not apply.

(4) **Subsection (1)** does not apply to the material described in any of **section 169(1)(e) to (g)**.

(5) The Regulator must ensure that the material published on the internet site managed by or on behalf of the Regulator is updated to reflect any changes made to material referred to in **subsection (2)** as soon as practicable after the notice is published in the *Gazette*.

171 Effect of expiry of material incorporated

(1) Material incorporated in a gene technology document that expires or that is revoked or that ceases to have effect, ceases to have legal effect as part of the document only if the responsible person publishes a notice under **subsection (2)**.

(2) The responsible person may publish a notice in the *Gazette* that—

(a) states that the material ceases to have legal effect as part of the document; and

(b) specifies the date on which the material ceases to have legal effect as part of the document.

(3) **Subsection (1)** does not apply if the gene technology document expressly says that it does not apply.

(4) The Regulator must ensure that the material published on an internet site managed by or on behalf of the Regulator is updated to reflect any changes made to material referred to in **subsection (2)** as soon as practicable after the notice is published in the *Gazette*.

172 Effect of other enactments

(1) Schedule 2 of the Legislation Act 2019 applies, except that references in that schedule to the chief executive of the administering agency must be read as references to the responsible person.

(2) However, section 66 of the Legislation Act 2019 does not apply.

(3) Sections 69 to 100 of the Legislation Act 2019 do not apply to material incorporated in a gene technology document.

(4) Subparts 1 and 2 of Part 5 of the Legislation Act 2019 apply to secondary legislation under this Act that incorporates material, but the requirement in section 114 of that Act does not apply to the material incorporated in the secondary legislation.

(5) Sections 29 to 32 of the Standards and Accreditation Act 2015 are not affected by **sections 168 to 171**.

Subpart 7—Fees, charges, levies, and cost recovery

173 Fees ~~and~~, charges, and levies payable

Any person making an application under this Act must pay the prescribed fees, ~~and~~ charges, and levies (if any) to the EPA, except as provided in **section 174**.

Compare: 2023 No 14 s 52

174 ~~Regulator~~ EPA must consider exemption, waiver, or refund of fees, charges, or levies

(1) The ~~Regulator~~ EPA must, on application, consider an exemption, a waiver, or a refund of fees, charges, or levies if the ~~Regulator~~ EPA is authorised to do so by regulations made under **section 155**.

(2) The ~~Regulator~~ EPA must comply with any regulations made under **section 155** that prescribe circumstances in which an exemption, a waiver, or a refund may be granted.

Compare: 2023 No 14 s 53

175 Costs to be recovered

(1) The relevant Minister must take all reasonable steps to ensure that the direct and indirect costs of administering this Act that are not funded by the Crown for that purpose are recovered by fees, charges, or levies.

(2) The enforcement agency's costs of enforcing this Act in respect of ~~regulated organisms~~ regulated genetically modified organisms are to be treated as if they were costs of administering the Biosecurity Act 1993, and may be—

(a) recovered in accordance with section 135 of that Act; and

(b) funded by a levy imposed under section 137 of that Act; and

(c) prescribed, in regulations made under section 165(12) of that Act, as costs that are recoverable.

Compare: 2023 No 14 s 69

176 Payments in advance

(1) The ~~Regulator~~ EPA may estimate the charge payable in respect of the exercise or performance of any function, power, or duty under this Act, and require that estimated charge or part of that estimated charge to be paid in full before the Regulator exercises or performs the function, power, or duty to which that charge relates.

(2) If the actual and reasonable costs of exercising or performing any function, power, or duty—

(a) exceed the amount paid in advance, the difference between the amount paid and the actual and reasonable costs are a debt:

(b) are less than the amount paid in advance, the ~~Regulator~~ EPA must refund the difference between the amount paid and the actual and reasonable costs.

177 Principles of cost recovery

In determining the most appropriate method of cost recovery, the relevant Minister ~~and the Regulator~~ must take into account, as far as is reasonably practicable, the following criteria:

(a) equity, in that funding for a particular function, power, or service (the **service**), or a particular class of service, should generally, and to the extent practicable, be sourced from the users or beneficiaries of the service at a level commensurate with their use of or benefit from the service:

(b) efficiency, in that costs should generally be allocated and recovered in order to ensure that maximum benefits are delivered at minimum cost:

(c) justifiability, in that costs should be collected only to meet the actual and reasonable costs (including indirect costs) of the provision or performance of the service:

(d) transparency, in that costs should be identified and allocated as closely as practicable in relation to tangible service provision for the recovery period in which the service is provided.

Compare: 2023 No 14 s 70

178 Further principles of cost recovery

A strict apportionment of costs to be recovered based on usage of a particular service is not required, and a fee or charge may be set at a level or in a way that—

(a) is determined by calculations that involve an averaging of costs or potential costs; and

(b) takes into account costs or potential costs of services that—

(i) are not directly to be provided to the person who pays the fee or charge, but that are an indirect or potential cost; and

(ii) arise from the delivery of the service to a class of persons or all persons who use the service.

179 Methods of cost recovery

The methods by which costs may be recovered are any 1 or more of the following:

(a) fixed fees or charges:

(b) fees or charges based on a scale or formula or at a rate determined on an hourly or other unit basis:

(c) use of a formula or other method of calculation for fixing fees and charges:

(d) the recovery by way of fee or charge of actual and reasonable costs expended in, or associated with, the performance of a service or function:

(e) estimated fees or charges, or fees or charges based on estimated costs, paid before the provision of the service or function, followed by reconciliation and an appropriate further payment or refund after provision of the service or function:

(f) refundable or non-refundable deposits paid before provision of the service or performance of the function:

(g) fees or charges imposed on users of services or third parties:

(h) levies.

Compare: 2023 No 14 s 71

180 Cost recovery ~~to relate to financial year~~

(1) Except as provided in **subsection (2)**, regulations that set a fee, charge, or levy ~~that applies in any financial year~~—

(a) may come into effect no less than 90 days after they are announced; but

(b) except as the regulations may otherwise provide, continue to apply until revoked or replaced.

(2) **Subsection (1)** does not prevent the alteration or setting ~~during any financial year~~ of a fee, charge, or levy payable ~~in that year~~ without waiting 90 days if—

(a) the fee, charge, or levy is reduced, removed, or restated without substantive alteration; or

(b) in the case of an increase or a new fee, charge, or levy,—

(i) appropriate consultation has been carried out with persons or representatives of persons substantially affected by the alteration or setting; and

(ii) the relevant Minister is satisfied that those persons, or their representatives, agree or do not substantially disagree with the alteration or setting.

(3) **Subsection (1)** does not prevent the amendment of a regulation that sets a fee, charge, or levy if a substantive alteration effected by the amendment is for the purpose of correcting an error.

(4) Recovery may be made in any financial year of a shortfall in cost recovery for any of the preceding 4 financial years, and allowance may be made for over-recovery of costs in those years (including an estimated shortfall or over-recovery for the immediately preceding financial year).

Compare: 2023 No 14 s 72

181 Three-yearly review of cost recovery

(1) The relevant Minister must review the levels and methods of cost recovery (including any exemptions) at least once in every 3-year period that occurs since the original setting of, or latest change to, the cost recovery levels and methods.

(2) In carrying out the review, the relevant Minister must—

(a) consult the persons (or representatives of the persons) they think are likely to be substantially affected by the levels and methods of cost recovery; and

(b) give those persons and opportunity to comment on the matters under review.

(3) A review may provide for recovery in any relevant financial year of any shortfall in cost recovery for any of the preceding 4 financial years, or allow for any over-recovery of costs in those years (including any estimated shortfall or over-recovery for the immediately preceding financial year).

Compare: 2023 No 14 s 73; 2023 No 37 s 349

Failure to pay

182 Fees, charges, and levies to constitute debt

(1) A fee, charge, or levy that has become payable to the Crown is EPA—

(a) is a debt due to the Regulator EPA; and

(b) is recoverable as a debt by the Regulator EPA in a court of competent jurisdiction.

(2) Until the fee, charge, or levy is paid in full, it remains a debt due to the Regulator EPA.

(3) The ~~Regulator~~ EPA must notify a person of the consequences of non-payment when it notifies the person of the fee, charge, or levy.

(4) In an action for recovery of the debt, the court may exercise any power of waiver contained in regulations made under this Act if the court is satisfied on the terms set out in those regulations.

Compare: 2023 No 14 s 74

183 Penalty on unpaid debt

(1) All or part of a fee, charge, or levy made under this Act or the regulations that remains unpaid after 20 working days since it was demanded in writing is deemed to have been increased by an amount calculated in accordance with **subsection (2)**.

(2) The amount by which the unpaid amount increases is the sum of—

(a) 10% of the debt (or of that part of the debt that remained unpaid after the expiry of the time provided for the debt's payment); and

(b) 10% of the debt or any part of it (including any deemed increase calculated under this subsection) that has remained unpaid for every complete period of 6 months after that expiry.

Compare: 2023 No 14 s 75

184 Dispute does not suspend obligation to pay fees, charges, levies, or penalties

A dispute between a person and the ~~Regulator~~ EPA about the person's liability to pay a fee, charge, levy, or penalty under this Part does not suspend—

(a) the obligation of the person to pay the fee, charge, levy, or penalty; or

(b) the right of the ~~Regulator~~ EPA to receive and recover the fee, charge, levy, or penalty.

Compare: 2023 No 14 s 76

185 Service to debtor may be withdrawn

(1) The ~~Regulator~~ EPA, if satisfied of the matters in **subsection (2)**, may give notice to the debtor that service of the kind to which the debt relates may be withdrawn or no longer provided to the person unless—

(a) the debt is paid within 20 working days; or

(b) the ~~Regulator~~ EPA agrees that the debt or part of the debt is not payable.

(2) The matters are—

(a) the debt has been correctly calculated; and

(b) the notified time for paying the debt has expired; and

(c) the debt has not been paid.

Compare: 2023 No 14 s 77

Subpart 8—Miscellaneous

Service of notices and other documents

186 Service of notices (other than those given to or by ~~the~~ the Regulator)

(1) Any notice or any other document required to be served on, or given to, any person under this Act or the regulations (other than a notice or other document given to or by the Regulator) is sufficiently served or given if the notice or document is—

(a) delivered personally or posted to the person at the person's address for service or last known place of residence or business; or

(b) sent by fax or electronic communication to the person's last known fax number or electronic address; or

(c) made available to the person in accordance with a prescribed electronic delivery method (if permitted under the regulations).

(1A) If a notice or other document is to be served on a body (whether incorporated or not) for the purposes of this Act, service on an officer of the body, or on the registered office of the body, in accordance with **subsection (1)**, is to be treated as service on the body.

(1B) If a notice or other document is to be served on a partnership for the purposes of this Act, service on any one of the partners in accordance with **subsections (1) and (1A)** is to be treated as service on the partnership.

(1C) However, in relation to any partnership that is a firm under the Partnership Law Act 2019, section 30 of that Act applies in relation to service of notices under this section.

(2) A notice or document that is sent to a person at a fax number or an electronic address must be treated as received by that person on the second working day after the date on which it is sent.

(3) A notice or document that is posted to a person must be treated as received by that person not later than 7 days after the date on which it is posted.

(4) However, a notice or document must not be treated as received if the person to whom it is posted or sent proves that it was not received, otherwise than through fault on the person's part.

(5) A notice or document that is made available to a person by the prescribed electronic delivery method must be treated as received by that person when specified by the regulations.

(6) This section does not apply to notices or other documents served, given, or filed in any proceeding in any court or to the extent that a different or particular delivery method is specified by this Act or the regulations.

Compare: 2013 No 68 s 233

Protection from civil and criminal liability

187 Protection from civil and criminal liability

(1) This section applies to the following persons:

(a) the Regulator:

(b) an employee or agent of the ~~Regulator~~ EPA:

(c) an enforcement officer:

(d) a member of the Technical Advisory Committee or the Māori Advisory Committee:

(e) a member of any subcommittee of those committees~~.~~:

(f) any other person exercising powers or performing duties or functions under this Act.

(2) The person is protected from civil and criminal liability, however it may arise, for any act that the person does or omits to do—

(a) under a requirement of this Act; or

(b) in the performance or purported performance of the person's functions or duties, or the exercise or purported exercise of the person's powers, under a requirement of this Act—

(i) in good faith; and

(ii) with reasonable cause; or

(c) in the performance or purported performance of the person's functions or duties, or the exercise or purported exercise of the person's powers, under this Act—

(i) in good faith; and

(ii) with reasonable cause.

(3) *See also* section 6 of the Crown Proceedings Act 1950.

Periodic review of operation of this Act, etc

187A Review of operation of this Act

(1) The Minister must, as soon as practicable after 4 years from the date this Act receives the Royal assent, commence a review of—

(a) the operation of the provisions of this Act:

(b) whether any amendments to this Act are necessary or desirable:

(c) the structure of the office of the Regulator.

(2) The Minister must consult the Regulator in the course of the review on the workability of the regime established by this Act.

(3) The Minister must, as soon as practicable after completion of the review, present a copy of it to the House of Representatives.

Revocations and consequentials

188 Revocations

The following regulations are revoked:

(a) Hazardous Substances and New Organisms (Genetically Modified Organisms—Information Requirements for Segregation and Tracing) Regulations 2008 (SR 2008/374):

(b) Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003 (SR 2003/152).

189 Consequential amendments

Amend the legislation specified in **Schedule 2** as set out in that schedule.

Part 6
Amendments to other legislation

Subpart 1—Amendments to Agricultural Compounds and Veterinary Medicines Act 1997

190 Principal Act

This subpart amends the Agricultural Compounds and Veterinary Medicines Act 1997.

191 Section 2 amended (Interpretation)

In section 2(1), insert in their appropriate alphabetical order:

Gene Technology Regulator means the Regulator as defined in **section 7(1)** of the Gene Technology Act **2024**

~~**regulated organism**~~**regulated genetically modified organism** has the same meaning as it has in **section 7(1)** of the Gene Technology Act **2024**

192 Section 4A amended (Scheme of Act)

In section 4A(5), after "Medicines Act 1981,", insert "the Gene Technology Act **2024**,".

193 Section 13 amended (Notification of application to Minister and departments)

After section 13(1)(b), insert:

(ba) the Gene Technology Regulator; and

194 Section 15 amended (Waiver of notification)

(1) After section 15(2)(b), insert:

(c) an emergency authorisation granted under **section 52** of the Gene Technology Act **2024**.

(2) In section 15(3)(a), after "1996)", insert "or a ~~regulated organism~~ regulated genetically modified organism".

195 Section 16 amended (Time limits and waivers)

(1) In section 16(2), after "organism", insert "or ~~regulated organism~~ regulated genetically modified organism".

(2) In section 16(3),—

(a) after "new organism", insert "or ~~regulated organism~~ regulated genetically modified organism for which a licence is required under the Gene Technology Act **2024**"; and

(b) replace "5" with "20"; and

(c) after "1996", insert "or the Gene Technology Act **2024**, whichever is later".

196 Section 21 amended (Decision on application)

After section 21(5), insert:

(6) The Director-General must not grant an application if—

(a) the trade name product to which it relates contains an agricultural compound that is also a ~~regulated organism~~ regulated genetically modified organism; and

(b) an activity using that organism is not authorised under the Gene Technology Act **2024**.

197 Section 27 amended (Decision on application for provisional registration)

After section 27(7), insert:

(8) The Director-General must not grant an application if—

(a) the trade name product to which it relates contains a ~~regulated organism~~ regulated genetically modified organism; and

(b) an activity using that organism is not authorised under the Gene Technology Act **2024**.

198 Section 79 amended (Relationship with other Acts)

After section 79(h), insert:

(i) Gene Technology Act **2024**.

Subpart 2—Amendments to Animal Products Act 1999

199 Principal Act

This subpart amends the Animal Products Act 1999.

200 Section 161 amended (Disclosure of information for purpose of ensuring product safety, etc)

(1) After section 161(5)(a)(viiib), insert:

(viiic) the Gene Technology Act **2024**:

(2) After section 161(5)(g), insert:

(h) the Regulator, as defined in **section 7(1)** of the Gene Technology Act **2024**.

Subpart 3—Amendments to Biosecurity Act 1993

201 Principal Act

This subpart amends the Biosecurity Act 1993.

202 Section 2 amended (Interpretation)

(1) In section 2(1), insert in their appropriate alphabetical order:

authorised regulated genetically modified organism means a regulated genetically modified organism that is ~~approved by the Gene Technology Regulator~~ authorised under the Gene Technology Act **2024** 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) authorised by a licence or an emergency authorisation, as those terms are defined in **section 7(1)** of the Gene Technology Act **2024**:

(c) ~~a mandatory~~ an activity related to an equivalent medical authorisation under **section 50** of the Gene Technology Act **2024**

Gene Technology Regulator means the Regulator, as defined in **section 7(1)** of the Gene Technology Act **2024**

~~**regulated organism**~~ **regulated genetically modified organism** has the same meaning as it has in **section 7(1)** of the Gene Technology Act **2024**

(2) In section 2(1), definition of **restricted organism**, after "and 258(3))", insert "or any ~~regulated organism~~ regulated genetically modified organism required to be held in a containment facility in accordance with the Gene Technology Act **2024**".

203 Section 28 amended (Restrictions on giving clearances)

After section 28(2), insert:

(3) An inspector must not give a biosecurity clearance for ~~goods that are or contain a regulated organism~~ a regulated genetically modified organism unless that organism ~~is an authorised regulated organism~~ is an authorised regulated genetically modified organism.

204 Section 28A amended (Dealing with suspected new organism)

(1) In the heading to section 28A, after "**organism**", insert "**or ~~regulated organism~~ regulated genetically modified organism**".

(2) In section 28A(1), after "new organism", insert "or a ~~regulated organism~~ regulated genetically modified organism".

(3) Replace section 28A(3) with:

(3) 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 and for a determination about any conditions as to its storage or release~~ as to whether or not the organism is a regulated genetically modified organism or the subject of an exemption under regulations referred to in **section 163** of that Act.

(4) In section 28A(6), after "new organism", insert "or a ~~regulated organism~~ regulated genetically modified organism ~~that the Gene Technology Regulator has not approved for release into the environment or for use in a containment facility~~".

205 Section 39 amended (Approval and cancellation of approval of transitional facilities and containment facilities)

Replace section 39(2A) with:

(2A) The Director-General may approve an application under subsection (2) for a place to be a containment facility for new organisms and regulated genetically modified organisms—

(a) if the application complies with the requirements of this Act; and

(b) if, in relation to the containment of new organisms, the place meets the relevant standards approved by the Authority in accordance with the Hazardous Substances and New Organisms Act 1996~~.~~; and

(c) if, in relation to the containment of regulated genetically modified organisms, the place meets the relevant standards issued or approved by the Gene Technology Regulator under the Gene Technology Act **2024**.

~~(2B) The Director-General may approve an application under subsection (2) for a place to be a containment facility for regulated organisms—~~

~~(a) if the application complies with the requirements of this Act; and~~

~~(b) if, in relation to the containment of regulated organisms, the place meets the relevant standards approved by the Gene Technology Regulator in accordance with the Gene Technology Act **2024**.~~

206 Section 40 amended (Approval and cancellation of approval of facility operators)

In section 40(3B)(b), after "1996,", insert "the Gene Technology Act **2024**,".

207 Section 41A amended (Definitions)

In section 41A(1), definition of **Ministry-related border management function**, after paragraph (c)(ii), insert:

(iia) the Gene Technology Act **2024**:

208 Section 44 amended (General duty to inform)

In section 44(2), after "Act 1996", insert "or ~~in accordance with an authorisation given under the Gene Technology Act **2024**~~ where it may be lawfully present under the Gene Technology Act **2024**".

209 Section 45 amended (Notifiable organisms)

After section 45(5), insert:

(5A) The responsible Minister must not recommend the making of an order under subsection (2) in respect of any organism that has been approved for ~~release in~~ introduction into New Zealand in accordance with the Gene Technology Act **2024** unless that Minister has first consulted the Gene Technology Regulator.

210 Section 126 amended (Inspection of and intervention in transitional facilities and containment facilities)

(1) Replace section 126(1) with:

(1) An inspector authorised in writing by the Director-General, and in accordance with section 112, may at any reasonable time enter a transitional facility or a containment facility for the purpose of confirming that any of the following apply:

(a) the facility complies with the standards set in accordance with section 39 of this Act or section 11(1)(fc) of the Hazardous Substances and New Organisms Act 1996:

(b) the operator is approved as the facility operator for that facility:

(c) the facility complies with the standards approved for a containment facility set in accordance with the Gene Technology Act **2024**~~:~~.

~~(d) the terms (including any conditions imposed by the Gene Technology Regulator) on which the regulated organism is contained are being complied with.~~

(2) After section 126(2)(c), insert:

~~(d) the transitional facility or containment facility does not comply with the standards approved by the Gene Technology Regulator under the Gene Technology Act **2024**; or~~

(ed) the terms (including any conditions imposed by the Gene Technology Regulator under the Gene Technology Act **2024**) upon which a ~~regulated organism~~ regulated genetically modified organism is contained in the facility are not being complied with.

(3) After section 126(3)(b)(ii), insert:

(iii) compliance with the terms (including any conditions imposed by the Gene Technology Regulator under the Gene Technology Act **2024**) on which a ~~regulated organism~~ regulated genetically modified organism is contained in the facility.

210A New section 166B inserted (Director-General may amend standards requiring change)

After section 166A, insert:

166B Director-General may amend standards requiring change

The Director-General may amend standards made or approved under Part 3 of this Act to make changes that they consider to be necessary or desirable in connection with the Gene Technology Act **2024**, or any subsequent legislation coming into force that affects those standards, without complying with any or all of the requirements for amending standards set out in this Act.

Subpart 4—Amendment to Environmental Protection Authority Act 2011

211 Principal Act

This subpart amends the Environmental Protection Authority Act 2011.

212 Section 5 amended (Interpretation)

In section 5, definition of **environmental Act**, after paragraph (ab), insert:

(ac) the Gene Technology Act **2024**:

Subpart 5—Amendments to Food Act 2014

213 Principal Act

This subpart amends the Food Act 2014.

214 Section 261 amended (Evidence of testing)

In section 261(1), after "Fisheries Act 1996,", insert "Gene Technology Act **2024**,".

215 Section 368 amended (Disclosing information inside New Zealand: application of section 369)

After section 368(3)(~~n~~xa), insert:

(~~na~~xb) the Gene Technology Act **2024**; or

Subpart 6—Amendments to Hazardous Substances and New Organisms Act 1996

216 Principal Act

This subpart amends the Hazardous Substances and New Organisms Act 1996.

217 Section 2 amended (Interpretation)

(1) In section 2(1), replace the definitions of **containment** and **containment facility** with:

containment means restricting an organism or substance to a secure location or facility to prevent escape

containment facility means a facility registered as a containment facility under the Biosecurity Act 1993

(2) In section 2(1), replace the definition of **develop** with:

develop,—

(a) in relation to new organisms other than incidentally imported new organisms, ~~means—~~

(i) means to regenerate a new organism from biological material of the organism that cannot, without human intervention, be used to reproduce the organism~~:~~; or

(ii) means to carry out large-scale fermentation using a micro-organism that is a new organism~~:~~; but

(iii) does not include field testing:

(b) in relation to incidentally imported new organisms,—

(i) means to carry out—

(A) the activities referred to in **paragraph (a)(i)**; and

(B) the deliberate isolation, aggregation, multiplication, or other use of the organism; but

(ii) does not include to carry out field testing

(3) In section 2(1), insert in its appropriate alphabetical order:

large-scale means 1 or more vessels with a total volume greater than 10 litres

(4) In section 2(1), repeal the definitions of **containment structure**, **genetic element**, **genetically modified organism**, **host organism**, and **human cells**.

218 Section 2A ~~amended~~ replaced (Meaning of term new organism)

Replace section 2A with:

2A Meaning of new organism

(1) A **new organism** is—

(a) an organism belonging to a species that was not present in New Zealand immediately before 29 July 1998:

(b) an organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, if that organism was not present in New Zealand at the time of promulgation of the relevant regulation:

(c) an organism for which a containment approval has been given under this Act:

(d) an organism for which a conditional release approval has been given:

(e) a qualifying organism approved for release with controls:

(f) an organism present in New Zealand before 29 July 1998, in contravention of the Animals Act 1967 or the Plants Act 1970:

(g) an organism that belongs to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand.

(2) A new organism does not cease to be a new organism because—

(a) it is subject to a conditional release approval; or

(b) it is a qualifying organism approved for release with controls; or

(c) it is an incidentally imported new organism.

(3) An organism is not a new organism if—

(a) an approval is granted under section 35, 38, or 38I to release an organism of the same taxonomic classification without controls; or

(b) an organism of the same taxonomic classification has been prescribed as not a new organism; or

(c) it was deemed to be a new organism under section 255, and other organisms of the same taxonomic classification were lawfully present in New Zealand before the commencement of that section, and it was in a place that was not registered as a circus or zoo under the Zoological Gardens Regulations 1977; or

(d) it is the organism known as rabbit haemorrhagic disease virus or rabbit calicivirus.

(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 organism~~ regulated genetically modified organism under the Gene Technology Act **2024**.

219 Section 19 amended (Delegation by Authority)

(1) In section 19(2)(a), delete "42, 42A, 42B".

(2) Repeal section 19(2)(bd).

220 Section 27A amended (Approvals at any taxonomic classification)

(1) In section 27A(2), delete "(that is not a genetically modified organism)".

(2) Repeal section 27A(3).

(3) In section 27A(4), replace "subsections (2) and (3)" with "subsection (2)".

221 Section 35 amended (Rapid assessment of risk for importation of new organisms)

In section 35(1), delete "that is not a genetically modified organism".

222 Section 38BA amended (Rapid assessment of risk for importation or release of new organisms with controls)

In section 38BA(1), delete "(other than a genetically modified organism)".

223 Section 40 amended (Application for containment approval for new organisms)

Replace section 40(2) with:

(2) Every application must be made in an approved form and must include—

(a) any prescribed information; and

(b) information on all occasions where the organism has been considered by the government of any prescribed State or country or by any prescribed organisation; and

(c) the results of those considerations; and

(d) information about the containment system for the organism.

224 Sections 41 to 42B repealed

Repeal sections 41 to 42B.

225 Section 42C amended (Rapid assessment of adverse effects for development in containment, etc, of certain new organisms)

(1) In section 42C(1), delete "(other than a genetically modified organism)".

(2) In section 42C(3)(a) and (b), delete "(other than a genetically modified organism)".

226 Section 43 ~~amended~~ replaced (Additional matters to be considered when application made for developing new organisms in containment)

Replace section 43 with:

43 Additional matters to be considered when application made for developing new organisms in containment

The Authority, when making a decision under section 45 in relation to an application made under section 40 to develop a new organism in containment, must have regard to the matters specified in section 37.

227 Section 44A repealed (Additional matters to be considered for certain developments and field tests)

Repeal section 44A.

228 Section 45 amended (Determination of application)

In section 45(1), delete "42, 42A, 42B, or".

229 Section 45A repealed (Controls required for certain developments and for all field tests)

Repeal section 45A.

230 Section 46 amended (Meaning of emergency)

After section 46(1)(c), insert:

(ca) a situation where an emergency authorisation has been granted under the Gene Technology Act **2024**:

231 Section 53 amended (Applications required to be publicly notified)

(1) Repeal section 53(1)(d).

(2) In section 53(2)(a), delete "(other than a genetically modified organism)".

(3) Repeal section 53(2)(b).

232 Section 59 amended (Time limits and waivers)

In section 59(1)(b), delete "42, 42A, 42B".

233 Section 62 amended (Grounds for reassessment of substance and organism)

In section 62(3), delete "42, 42A, 42B,".

234 Section 63 amended (Reassessment)

In section 63(2)(c), replace "42, 42A, 42B, 42C, or 45" with "42C or 45".

235 Section 123 repealed (Declaration that organism not genetically modified)

Repeal section 123.

236 Section 140 amended (Regulations)

Repeal section 140(1)(a) and (b).

237 Section 142 amended (Relationship to other Acts)

After section 142(1), insert:

(1A) Nothing in this Act affects the requirements of the Gene Technology Act **2024** in relation to any ~~regulated organism~~ regulated genetically modified organism (within the meaning of that Act).

237A New section 148A inserted (EPA may amend standards requiring change)

After section 148, insert:

148A EPA may amend standards requiring change

The Authority may amend standards for containment facilities approved under this Act to make changes that it considers necessary or desirable in connection with the Gene Technology Act **2024**, or any subsequent legislation coming into force that affects those standards, without complying with any or all of the requirements in this Act for amending standards set out in this Act.

238 Schedule 3 amended

(1) In Schedule 3, repeal Part 1.

(2) In Schedule 3, in the Part 2 heading, delete "**excluding genetically modified organisms**".

Subpart 7—Amendments to Medicines Act 1981

239 Principal Act

This subpart amends the Medicines Act 1981.

240 Section 2 amended (Interpretation)

In section 3(1), insert in its appropriate alphabetical order:

Regulator means the Regulator as defined in **section 7(1)** of the Gene Technology Act **2024**

241 New section 5AA inserted (Relationship with Gene Technology Act 2024)

After section 5, insert:

5AA Relationship with Gene Technology Act 2024

In relation to medicines or medical devices that are or contain ~~regulated organisms~~ regulated genetically modified organisms, the requirements of this Act are additional to the requirements of the Gene Technology Act **2024**.

242 Sections 24C to 24G replaced

Replace sections 24C to 24G with:

24C Interpretation

In sections 24C to 24K, unless the context otherwise requires,—

emergency authorisation has the same meaning as in **section 52** of the Gene Technology Act **2024**

hazardous substance has the same meaning as in section 2(1) of the Hazardous Substances and New Organism Act 1996

~~**regulated organism**~~ **regulated genetically modified organism** has the same meaning as in **section 7(1)** of the Gene Technology Act **2024**

responsible Minister means—

(a) the responsible Minister within the meaning of section 49A of the Hazardous Substances and New Organisms Act 1996:

(b) the Minister who issues an emergency authorisation under **section 52** of the Gene Technology Act **2024**

special emergency means—

(a) a special emergency, as defined in section 49A of the Hazardous Substances and New Organisms Act 1996; or

(b) a situation where the Minister has given an emergency authorisation under **section 52** of the Gene Technology Act **2024**.

24D Approval of medicines required for use in special emergency

(1) An application may be made to the Minister for approval to distribute, sell, or advertise during a special emergency a medicine or medical device that is or contains a hazardous substance, a new organism, or a ~~regulated organism~~ regulated genetically modified organism.

(2) The Minister may approve an application under **subsection (1)** with or without conditions, as long as the Minister is satisfied that—

(a) the special emergency has been declared or authorised (as the case requires) and has not come to an end; and

(b) the medicine or medical device is required for the special emergency; and

(c) the application complies with **subsection (3)**.

(3) An application under **subsection (1)** must—

(a) be accompanied by the prescribed application fee (if any); and

(b) be in a form approved by the Director-General; and

(c) be accompanied by any information that the Minister considers is necessary for determining whether to approve the application.

24E Notification or publication of approval

The approval of an application under **section 24D** must be notified in the *Gazette*.

24F Duration of approval

An approval of an application under **section 24D** takes effect on the day specified in the approval, and ends—

(a) on the earlier of the following:

(i) the date on which the special emergency ends, as specified by the responsible Minister (as the case requires) in—

(A) the declaration declaring the special emergency or the notice notifying the emergency authorisation; or

(B) a later declaration specifying that the special emergency has ended or notice that the emergency authorisation has been revoked:

(ii) the date of expiry (if any) specified by the responsible Minister in the approval, which must not be later than the date on which the special emergency ends; or

(b) if no date is specified as described in **paragraph (a) or (b)**, 2 years after the date on which the approval is granted.

24G Consequences of expiry of approval

On the expiry of an approval of an application under **section 24D**, the medicine or medical device to which the approval applies must not be distributed or used unless authorised by or under any other provision of this Act.

243 New section 109A inserted (Relationship with Gene Technology Act 2024)

After section 109, insert:

109A Relationship with Gene Technology Act 2024

(1) Nothing in this Act (other than **subsection (2)**) affects or limits the Gene Technology Act **2024**.

(2) In the event of any inconsistency between the provisions of the Gene Technology Act **2024** and the provisions of this Act, or between the provisions of any regulations made under that Act and the provisions of any regulations made under this Act, in the case of a medicine or medical device that is also a ~~regulated organism~~ regulated genetically modified organism, the provisions of this Act and of the regulations made under this Act prevail.

Subpart 8—Amendments to Ombudsmen Act 1975

244 Principal Act

This subpart amends the Ombudsmen Act 1975.

245 Schedule 1 amended

In Schedule 1, Part 2, insert in their appropriate alphabetical order:

Māori Advisory Committee within the meaning of **section 7(1)** of the Gene Technology Act **2024**

Technical Advisory Committee within the meaning of **section 7(1)** of the Gene Technology Act **2024**

Subpart 9—Amendments to Resource Management Act 1991

246 Principal Act

This subpart amends the Resource Management Act 1991.

247 Section 2 amended (Interpretation)

In section 2(1), insert in their appropriate alphabetical order:

genetically modified, in relation to any organism, means modified or constructed by gene technology (within the meaning of **section 7(1)** of the Gene Technology Act **2024**)

Regulator has the same meaning as in **section 7(1)** of the Gene Technology Act **2024**

248 Section 30 amended (Functions of regional councils under this Act)

After section 30(3), insert:

(3A) A regional council must not perform the functions specified in this section—

(a) for the purpose of treating an organism differently from another organism—

(i) depending on whether it is genetically modified; or

(ii) because it is genetically modified; or

(b) in a manner that distinguishes between an organism or organisms that are genetically modified and an organism or organisms that are not genetically modified.

249 Section 31 amended (Functions of territorial authorities under this Act)

After section 31(2), insert:

(3) A territorial authority must not perform its functions in this section—

(a) for the purpose of treating an organism differently from another organism—

(i) depending on whether it is genetically modified; or

(ii) because it is genetically modified; or

(b) in a manner that distinguishes between an organism or organisms that are genetically modified and an organism or organisms that are not genetically modified.

250 Section 66 amended (Matters to be considered by regional council (plans))

After section 66(3), insert:

(4) In preparing or changing any regional plan, a regional council must not do anything—

(a) for the purpose of treating an organism differently from another organism—

(i) depending on whether it is genetically modified; or

(ii) because it is genetically modified; or

(b) in a manner that distinguishes between an organism or organisms that are genetically modified and an organism or organisms that are not genetically modified.

(5) A regional plan that is or has been prepared or changed and is in contravention of **subsection (4)**—

(a) must, to the extent of the contravention, be treated on the commencement of this section as void:

(b) must be amended by the regional council as soon as practicable to comply with subsection (1), without following the process in Schedule 1.

251 Section 68 amended (Regional rules)

After section 68(11), insert:

(12) A regional council must not perform its functions in this section—

(a) for the purpose of treating an organism differently from another organism—

(i) depending on whether it is genetically modified; or

(ii) because it is genetically modified; or

(b) in a manner that distinguishes between an organism or organisms that are genetically modified and an organism or organisms that are not genetically modified.

252 Section 74 amended (Matters to be considered by territorial authority)

After section 74(3), insert:

(4) In preparing or changing any district plan, a territorial authority must not do anything—

(a) for the purpose of treating an organism differently from another organism—

(i) depending on whether it is genetically modified; or

(ii) because it is genetically modified; or

(b) in a manner that distinguishes between an organism or organisms that are genetically modified and an organism or organisms that are not genetically modified.

(5) A district plan that is or has been prepared or changed in contravention of **subsection (4)**—

(a) must, to the extent of the contravention, be treated on the commencement of this section as void:

(b) must be amended by the territorial authority as soon as practicable to comply with **subsection (4)**, without following the process in Schedule 1.

253 Section 76 amended (District rules)

After section 76(5), insert:

(6) A territorial authority must not perform its functions under this section—

(a) for the purpose of treating an organism differently from another organism—

(i) depending on whether it is genetically modified; or

(ii) because it is genetically modified; or

(b) in a manner that distinguishes between an organism or organisms that are genetically modified and an organism or organisms that are not genetically modified.

254 Schedule 12 amended

In Schedule 12,—

(a) insert the Part set out in **Schedule 4** of this Act as the last Part; and

(b) make all necessary consequential amendments.

Subpart 10—Amendments to Search and Surveillance Act 2012

255 Principal Act

This subpart amends the Search and Surveillance Act 2012.

256 Schedule amended

In the Schedule, insert in its appropriate alphabetical order:

Gene Technology Act **2024**	**69**	Enforcement officer may enter and inspect place to check compliance with requirements under the Gene	All (except subparts 2,3, and 8 and

	Technology Act **2024** and determine nature of organism in, on, or attached to place	sections 118 and 119)
70	Enforcement officer may enter and inspect home or marae under search warrant or with consent of occupier	All (except subparts ~~2 nad~~ 8 and sections 118 and 119)
71	Enforcement officer may obtain and execute search warrant to search for evidence of offence against Gene Technology Act **2024**	All (except subparts 2 and 8 and sections 118 and 119)

Schedule 1
Transitional, savings, and related provisions

s 9

Part 1
Provisions relating to this Act as enacted

1 Interpretation

In this Part,—

call in means to give a direction under section 68 of the HSNO Act

commencement means the day on which this schedule comes into force

HSNO Act means the Hazardous Substances and New Organisms Act 1996

Regulator means the Regulator within the meaning of **section 7(1)**.

withdrawal, in relation to an application or a request under the HSNO Act or this schedule by the applicant or requester,—

(a) means a withdrawal of an application or a request by an applicant or requester; and

(b) includes a deemed withdrawal under **clause 11**.

2 Pending applications for approvals under Part 5 of HSNO Act

(1) This clause applies if—

(a) an applicant has applied under Part 5 of the HSNO Act, before commencement, for an approval to import, develop, field test, release, or tranship a new organism that is also a regulated organism regulated genetically modified organism within the meaning of this Act; and

(b) any required fee [has been paid] was paid before commencement in order to lodge or determine that application; and

(c) that application has had not been determined by the EPA, as at commencement.

(2) The applicant may, at any time on or after commencement but before the application is determined by the EPA, notify the EPA that they elect—

(a) to continue to have the application determined under the HSNO Act; or

(b) to have the application treated as an application for a licence to be granted by the Regulator under this Act (in which case **clause 4** applies); or

(c) to withdraw the application.

(3) If the applicant fails to make an election before the application is determined by the EPA under **subclause (2)** or makes an election under **subclause (2)(c)**,—

(a) the application must be treated as withdrawn; and

(b) the EPA must notify the applicant of ~~this~~ that in writing.

(4) If the applicant makes an election under **subclause (2)(b) or ~~(2)~~(c)**, the fee that was paid is not recoverable by the applicant.

(5) If the applicant does not make an election under **subclause (2)(b) or (c)**, **clause 3** applies.

3 HSNO Act and regulations continue in unamended form for certain purposes

The HSNO Act and any regulations made under that Act continue in force, as that Act and those regulations read immediately before commencement, for the purposes of determining—

~~(a) an application that is the subject of an election under **clause 2**; and~~

(a) an application or a request—

(i) where the applicant does not make an election under **clause 2(2)(b) or (c)**; or

(ii) where the applicant does not make an election under **clause 5(2)(a) or (b)**; or

(iii) that is a request to which **clause 7A(5)** applies; or

(iv) that is an application to which **clause 8 or 9** applies; or

(b) any appeal in relation to a determination of ~~that application~~ any of those applications or requests.

4 ~~Application~~ What happens when application or request is transferred to ~~the~~ Regulator by EPA

If an applicant or a requester elects under **clause 2(2)(b)** or **5(2)(a) or 7(6) or 7A(2)(a)(ii)** to have the determination of their application or request transferred ~~from the EPA~~ to the Regulator,—

(a) the EPA must, as soon as is reasonably practicable, transfer the application or request and all supporting documentation to the Regulator; and

(b) the Regulator ~~may~~—

(i) may make any inquiries of the applicant or requester that the Regulator considers necessary to clarify the type of approval or decision that the applicant or requester is seeking or needs to obtain under this Act; and

(ii) may require the applicant or requester to supply any further information that the Regulator considers necessary to determine the application or request under this Act~~.~~; and

(iii) in the case of an application, must determine whether the application—

(A) is of a kind that would require a licence if the activity were authorised under this Act; or

(B) is for a determination under section 26 of the HSNO Act; and

(iv) in the case of a request under section 62 or 63 of the HSNO Act, must determine—

(A) whether there has been an election under **clause 7(6)** and, if so, whether an election was authorised under **clause 7(5)(b)**; or

(B) whether there has been an election under **clause 7A(2)(a)(ii)** and, if so, whether an election was authorised under **clause 7A(3)**; and

(v) must approve, decline, or otherwise determine the application or request (as the case requires).

~~**5 Pending applications under section 26 of HSNO Act**~~

~~An application under section 26 of the HSNO Act for a determination that has been lodged but not decided before commencement must, subject to **clauses 2 and 3**, continue to be determined in accordance with the HSNO Act and any regulations made under that Act and which for this purpose will be applied as they read immediately before commencement.~~

5 Pending applications for determinations under section 26 of HSNO Act

(1) This clause applies if the applicant has applied under section 26 of the HSNO Act, before commencement, for a determination and—

(a) any required fee was paid before commencement in order to lodge or determine that application; and

(b) that application had not been determined by the EPA, as at commencement.

(2) The applicant may, at any time on or after commencement but before the application is determined by the EPA, notify the EPA that they elect to—

(a) have the application treated as an application for a determination under this Act (in which case **clause 4** applies); or

(b) withdraw the application.

(3) If the applicant makes an election under **subclause (2)(b)**,—

(a) the application must be treated as withdrawn; and

(b) the EPA must notify the applicant of that in writing.

(4) If the applicant makes an election under **subclause (2)(a) or (b)**, the fee that was paid is not recoverable by the applicant.

6 ~~Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998 continue in force~~

~~The Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998 are deemed to have been made under this Act and continue in force until they are revoked or replaced under this Act.~~

7 Pending ~~application~~ request for determination whether there are grounds for reassessment under ~~the~~ HSNO Act

(1) This clause applies if—

~~(a) a person has requested, before commencement, under section 62 of the HSNO Act a decision on whether there are grounds for a reassessment; or~~

~~(b) a person has requested, before commencement, a reassessment under section 63 of the HSNO Act.~~

(a) a person has requested the EPA, before commencement, under section 62 of the HSNO Act, to decide whether there are grounds for a reassessment; and

(b) any required fee in order to lodge or determine the application was paid before commencement; and

(c) that request had not been withdrawn or determined by the EPA as at commencement.

~~(2) This clause does not apply unless any required fee in order to lodge or determine the application has been paid.~~

~~(3) Despite **subclause (1)**, the applicant may withdraw the application at any time until it is determined under section 26 of the HSNO Act.~~

~~(4) If the applicant withdraws the application under **subclause (3)**, the fee that was paid is not recoverable by the applicant.~~

~~(5) If a request referred to in **subclause (1)(a)** has not been determined before commencement, it lapses.~~

(5) A request referred to in **subclause (1)(a)** to which **subclause (1)** applies lapses on commencement unless the request—

(a) was made before commencement by an applicant and relates to a new organism in respect of which any activity would require a licence under **section 33** in order to be authorised under this Act; and

(b) the applicant would, if the request were granted under this Act, be the licence holder, and accordingly eligible to apply for a variation under **section 45**.

~~(6) If a request referred to in **subclause (1)(b)** has not been decided before commencement,—~~

~~(a) the request must be determined under the HSNO Act and any regulations made under that Act as they read immediately before commencement:~~

~~(b) the provisions of the HSNO Act relating to reviews and appeals continue in force, as they read immediately before commencement, in relation to the decisions to which the request relates.~~

(6) If **subclause (5)(b)** applies the requester may within 6 months of commencement elect, by notice to the EPA, to have the application considered as an application for a variation of a licence under **section 45**.

(7) If a request is subject to an election under **subclause (6)**, the request must be determined in accordance with **clause 4**.

7A Pending request for reassessment

(1) This clause applies if—

(a) a person requested, before commencement, a reassessment under section 63 of the HSNO Act; and

(b) any required fee in order to lodge or determine the request was paid before commencement; and

(c) that request had not been determined by the EPA, as at commencement.

(2) The applicant may, at any time before the request is determined by the EPA, notify the EPA that—

(a) they—

(i) believe they are eligible under **subclause (3)** to elect to have their request determined by the Regulator under this Act; and

(ii) elect to have their request determined by the Regulator under this Act, as if the request were a request under **section 45** for the variation of a licence; or

(b) they elect to withdraw the request.

(3) A request that is eligible for election under **subclause (2)(a)** is a request that satisfies the following criteria:

(a) the request under section 63 seeks an approval for an activity that would require a licence if it were to be authorised under this Act:

(b) the requester is an eligible person under **section 45** to request a variation to a licence.

(4) If the requester elects under **subclause (2)(a)(ii)** and the requester is eligible to make an election under **subclause (3)** to have the request dealt with by the Regulator under this Act, the request must be dealt with in accordance with **clause 4**.

(5) If the requester does not elect to have their request dealt with by the Regulator under this Act, within 3 months of commencement, it must be dealt with under **clause 3**.

(6) If the requester elects to withdraw their request under **subclause (2)(b)**, the fee that was paid by the requester is not refundable.

8 What happens if Minister calls in application before commencement

(1) This clause applies if, before commencement, the Minister for the time being responsible for the HSNO Act calls in, under section 68 of that Act, an application for an approval under that Act.

(2) The application continues to be determined under the HSNO Act in accordance with section 68 of that Act and the provisions of that Act, and any regulations made under that Act, continue in force, as they read immediately before commencement, in relation to the decisions to which the application relates, in accordance with **clause 3**.

9 Minister may call in certain applications after commencement

(1) This clause applies if, after commencement, any application referred to in any of **clauses 1 to 5 and 7A** is being determined under the HSNO Act and any regulations made under that Act in accordance with **clause 3**.

(2) The Minister for the time being responsible for the administration of the HSNO Act may call in~~, under section 68 of that Act,~~ an application referred to in any of **clauses 1 to 5 and 7**.

(3) If the Minister calls in an application ~~where~~ to which **subclause (2)** applies, the application continues to be determined ~~under the HSNO Act in accordance with section 68 of that Act and the provisions of that Act, and any regulations made under that Act, continue in force, as they read immediately before commencement, in relation to the decisions to which the application relates~~ in accordance with **clause 3**.

10 Withdrawal of application if clause 8 or 9 applies

(1) If **clause 8 or 9** applies, the applicant may withdraw an application by notice in writing to the EPA at any time before it is determined ~~in accordance with that clause~~.

(2) If the applicant withdraws the application under **subclause (1)**, the fee that was paid is not recoverable by the applicant.

11 Deemed withdrawal of application or request

(1) This clause applies if an applicant fails to provide information where an application or request referred to in ~~**clauses 1 to 7 and 8 and 9**~~ **clauses 2 to 9 and 13** is to be or is being determined in accordance ~~with the HSNO Act and any regulations made under that Act~~ with **clause 3** and the EPA requests the applicant or requester to provide further information, but—

(a) the applicant or requester ~~does~~ has not earlier ~~withdraw~~ withdrawn their application ~~or transfer it~~ or requested that it be transferred to the Regulator for the issue, or variation of, a licence under this Act; and

(b) the applicant or requester fails to provide the further information within ~~3~~ 6 months from the date of the request for information from the EPA.

(2) If this clause applies, the application or request must be treated for the purposes of any of **clauses 2 to 9 and 13** as having been withdrawn, and no determination is required in relation to the application or request.

12 Genetically modified organism-related decisions under HSNO Act continue in force

(1) This clause applies ~~if—~~

~~(a) the EPA has made, before commencement, a decision to approve an activity relating to a new organism that is genetically modified:~~

~~(b) the Minister has made a decision, before commencement, after calling in the matter under section 68 of the HSNO Act:~~

~~(c) decisions are made by the EPA or Minister, on or after commencement, in relation to applications or requests referred to in this schedule:~~

~~(d) the Regulator—~~

~~(i) revokes a decision; or~~

~~(ii) makes a replacement decision under the provisions of this Act.~~

(a) if—

(i) the EPA has made, before commencement, a decision to approve an activity relating to a new organism that is genetically modified; or

(ii) the Minister has made a decision, before commencement, after calling in the matter under section 68 of the HSNO Act; or

(iii) decisions are made by the EPA or Minister, on or after commencement, in relation to applications or requests referred to in this schedule; and

(b) if the decisions referred to in **paragraph (a)(i), (ii), and (iii)** have not lapsed or expired and remain in force.

(1A) If this clause applies, the Regulator may—

(a) revoke a decision; or

(b) make a replacement decision under the provisions of this Act.

(2) The Regulator may not revoke a decision under **subclause ~~(1)~~ (1A)** unless the Regulator is satisfied that the activity related to that decision will continue to remain lawful under this Act because—

(a) the genetically modified organism is not a ~~regulated organism~~ regulated genetically modified organism; or

(b) ~~the genetically modified organism is used for an activity~~ a decision to approve the activity would authorise an activity that is not regulated under this Act; or

(ba) the decision to authorise the activity would not require the issue of a licence under this Act; or

(c) the activity ~~to be undertaken using the genetically modified organism~~ satisfies the criteria for the grant of a licence under this Act~~.~~; or

(d) for any other reason, the approval granted as a consequence of the decision is no longer required.

(3) For the purposes of deciding under **subclause (2)(c)** whether the activity authorised by the decision satisfies the criteria for the ~~issue~~ grant of a licence, the Regulator—

(a) need not issue a risk assessment and risk management plan under this Act~~,~~ unless there are particular reasons to require a risk assessment and risk management plan (for example, ~~becoming aware~~ because of new information about risks)~~:~~; but

(b) may apply any conditions imposed by the decision under the HSNO Act to the licence issued under this Act.

(4) If any decision is revoked under **subclause ~~(1)(d)(i)~~ (1A)(a)**, it continues to apply in respect of any new organism to which it previously applied if that new organism is not ~~genetically modified~~ a regulated genetically modified organism or subject to gene technology.

13 Review of conditional release or qualifying organisms

(1) This clause applies if—

(a) the EPA ~~has~~ commenced a review before commencement,—

(i) under section 38G of the HSNO Act, of ~~the controls on~~ a conditional release approval ~~but has not completed it~~:

(ii) under section 38L of the HSNO Act, of the controls it has imposed on an approval under section 38I ~~of that Act but has not completed it~~; and

(b) any required fee ~~has been~~ was paid before commencement in order to lodge or determine that review; and

(c) the review ~~has not been~~ was not completed by the EPA ~~at~~ before commencement.

(2) If the review was initiated in response to an application by a user or the holder of an approval (as the case requires), the applicant may, at any time on or after commencement but before the review is complete, notify the EPA that they elect—

(a) to continue to have the application determined under the HSNO Act; or

(b) to have the application treated as an application for a licence to be granted by the Regulator under this Act, but that election may be made only if a licence would be required under this Act for the activity for which approval is sought to be authorised under this Act; or

(c) to withdraw the application.

(3) If the applicant makes an election under **subclause (2)(b) or ~~(2)~~(c)**, the fee that was paid is not recoverable by the applicant.

(4) If the review was initiated by the EPA,—

(a) the review must be transferred to the Regulator under this Act within 30 working days of commencement if it relates to an activity in respect of which the person conducting the activity would ~~be eligible to be granted a licence~~ be required to obtain a licence under this Act for the activity to be authorised under this Act; and

(b) in any other case, the EPA must cease the conduct of the review.

14 Consultation on various matters before commencement deemed to be carried out under this Act

(1) 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.

(2) Any consultation undertaken before the commencement of **sections 155 and 167** (procedure for making regulations) is deemed to have been undertaken on and after the commencement of that section.

15 Certain authorisations to remain in force

Any authority, approval to use any new organism, and any exemption from a requirement in or for the purposes of an emergency referred to in section 48 or 49F of the HSNO Act remain in force for—

(a) a period of 2 years after the authority or approval is issued; or

(b) any lesser period decided by the EPA.

16 Failure to seek advice does not invalidate certain declarations

The Regulator is not required to seek advice from the Māori Advisory Committee or the Technical Advisory Committee before the Regulator issues their first declaration under **section 23 or 48**.

17 Continuation of existing standards for containment facilities

Until standards are made or approved under **section 150(2)(d)**, standards made or approved under the HSNO Act or the Biosecurity Act 1993 in place at commencement continue in full effect for regulated genetically modified organisms—

(a) as if references to genetically modified organisms were references to regulated genetically modified organisms; and

(b) subject to any changes made to those standards by the Director-General under **section 166B** of the Biosecurity Act 1993; and

(c) subject to any changes made to those standards by the EPA under **section 148A** of the HSNO Act.

Schedule 2
Consequential amendments to other legislation

s 189

Imports and Exports (Living Modified Organisms) Prohibition Order 2005 (SR 2005/12)

In clause 3, ~~replace~~ repeal the definition of **Minister** ~~with:~~.

~~**Minister** has the same meaning as in **section 7(1)** of the Gene Technology Act **2024**~~

In clause 3, insert in its appropriate alphabetical order:

Regulator has the same meaning as in **section 7(1)** of the Gene Technology Act **2024**

In clause 6(1) and (2), replace "Minister" with "Regulator" in each place.

In clause 7(1), (2), and (3), replace "Minister" with "Regulator" in each place.

In clause 8(1), (2), and (3), replace "Minister" with "Regulator" in each place.

In clause 9, replace "Minister" with "Regulator".

Summary Proceedings Act 1957 (1957 No 87)

In section 2(1), definition of **infringement notice**, after paragraph (ca), insert:

(cb) **section 91** of the Gene Technology Act **2024**:

Schedule 3
Reviewable decisions

s 134

Section	Description	Who may apply for review
12(1)	~~Determination on regulated organism or gene technology~~Refusal of application for determination or different determination to that applied for	Applicant
33(1)	~~Decline or approval~~ Refusal of application for licence	Applicant
~~**33(3)**~~	~~Decision on licence for transhipment~~	~~Applicant~~
3637	Conditions imposed on licence~~ or in risk assessment and risk management plan~~	Licence holder
39	Suspension or cancellation of licence	Licence holder
43	~~Decline of request~~ Refusal of application to transfer licence	~~Licence holder and applicant~~ Applicants for transfer
45	~~Decline or approval of request~~ Refusal of application to vary licence ~~or conditions of licence~~ or decision to vary licence on Regulator's own initiative (except where variation is minor or technical)	Licence holder

Schedule 3A
Organisms that are not regulated genetically modified organisms and technologies that are not gene technologies

ss 162AB, 163(2)(a)

Part 1
Organisms that are not regulated genetically modified organisms

Item	Description
1	Organisms that result solely from selection or natural regeneration, hand pollination, or other managed, controlled pollination.
2	Organisms that result solely from artificial insemination, superovulation, embryo transfer, or embryo splitting.
3	Organisms resulting from spontaneous deletions, rearrangements, and amplifications within a single genome, including its extrachromosomal elements.
4	Organisms modified solely by— (a) the movement of nucleic acids using physiological processes, if the process does not include material modified or constructed by gene technology. Examples of physiological processes include conjugation, transduction, and transformation: (b) plasmid loss or spontaneous deletion.
5	Organisms that are regenerated from organs, tissues, or cell culture, including those produced through selection and propagation of somaclonal variants, embryo rescue, and cell fusion as described in this schedule (items 15 and 16).
6	A whole animal modified by the introduction of naked recombinant nucleic acid (such as a DNA vaccine) into its somatic cells.
7	An organism that is descended from a regulated 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.
8	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.
9	Organisms with epigenetic changes resulting from gene technology, but which lack inheritable genome sequence changes resulting from gene technology.
10	Eukaryotic organisms that have been treated with externally applied double-stranded (SiRNA) molecules to induce a small interfering (RNA) response.

Part 2
Technologies that are not gene technologies

Item	Description
11	Electromagnetic radiation-induced mutagenesis.
12	Particle radiation-induced mutagenesis.
13	Chemical-induced mutagenesis.
14	Either of the following transfers if the transfer does not involve material modified or constructed by gene technology: (a) nuclear transfer: (b) transfer of plastids or mitochondria.

Item	**Description**
15	Fusion of animal cells, or human cells if the fused cells are unable to form a viable whole animal or human.
16	Protoplast fusion, including fusion of plant protoplasts.
17	Embryo rescue.
18	In vitro fertilisation.
19	Zygote implantation.
20	A physiological process, if the process does not involve material modified or constructed by gene technology. **Examples**: Examples of physiological processes include conjugation, transduction, transformation and transposon mutagenesis.
21	Introduction of nucleic acid or nucleic acid analogue into an organism, if— (a) the introduction of the nucleic acid or nucleic acid analogue does not result in an alteration of the organism's genome sequence; and (b) the introduction of the nucleic acid or nucleic acid analogue cannot give rise to an infectious agent.

Schedule 4
New Part 8 inserted into Schedule 12 of Resource Management Act 1991

s 254

Part 8
Transitional, savings, and related provisions

48 Permitted activities may generally continue

(1) A rule or plan permitting activities relating to genetically modified organisms ceases to apply on and after the commencement of this clause.

(2) However, a person who carried out activities in reliance on that rule or plan may continue to carry out those activities without further authorisation unless—

(a) a licence is required to undertake those activities under the Gene Technology Act **2024**; or

(b) additional authorisation is required under other legislation to undertake those activities.

49 Surrender of resource consent no longer required

(1) If a person obtained a resource consent to carry out an activity because of a rule or plan that ceases to apply under **clause 48(1)**, that person may elect—

(a) to surrender that resource consent by giving written notice to the consent authority; or

(b) not to give notice of surrender of that resource consent.

(2) If the person elects not to give notice of surrender of the resource consent,—

(a) the resource consent continues in effect; and

(b) the rules or plans ceasing to have effect under **clause 48(1)** continue to apply to the person as if **clause 48(1)** does not apply.

50 Applications pending on commencement of clause 48

(1) This clause applies if, on the commencement of **clause 48**, a person has lodged an application because of a rule or plan referred to in **clause 48(1)** but that application has not been determined by a consent authority.

(2) The consent authority must notify the person in writing that—

(a) the resource consent or a specified part of the consent is no longer required; and

(b) the whole or part of the application will be treated as withdrawn unless, within 20 working days of the date of being notified, the person notifies the consent authority in writing that—

(i) they want the application to be determined; and

(ii) the determination should be made as if this Act had not been amended and the rule or plan referred to in **clause 48(1)** were still in force.

(3) If a person gives notice to the consent authority in accordance with **subclause (2)(b)**, the application must be determined as if—

(a) this Act had not been amended; and

(b) the rule or plan referred to in **clause 48(1)** were still in force.

Legislative history

10 December 2024	Introduction (Bill 110–1)
17 December 2024	First reading and referral to Health Committee

Wellington, New Zealand:

Published under the authority of the House of Representatives—2025