

Gene Technology Bill

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Public submissions are now being called for the Gene Technology Bill

The closing date for submissions is 11.59 pm on Monday, 17 February 2025

The Health Committee is calling for submissions on the Gene Technology Bill 2024.

The purpose of the Bill is to enable the safe use of gene technology and regulated organisms in New Zealand. The intention is to establish a new regulatory regime for gene technology and genetically modified organisms (GMOs). The Bill seeks to provide for—

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

The Ministry of Business, Innovation & Employment have produced an overview of this legislation that can be found **here** (<https://www.mbie.govt.nz/science-and-technology/science-and-innovation/agencies-policies-and-budget-initiatives/gene-technology-regulation>).

This bill is available online from the 'Related links' panel.

What do you need to know?

- **Submissions are publicly released and published to the Parliament website.** Only your name or organisation's name is required on a submission. Please keep your contact details separate, as if they are included on the submission they will become publicly available when the submission is released.
- If you wish to include information of a private or personal nature in your submission you should discuss this with the clerk of the committee before submitting.
- If you wish to speak to your submission, please state this clearly.

Further guidance on making a submission can be found from the 'How to make a submission' link in the 'Related documents' panel.

If you have any questions about your submission or the submission process please contact the Committee Staff through the contact details provided on this page.

RELATED

-  **New Zealand Legislation** (<https://www.legislation.govt.nz/bill/government/2024/0110/7.0/LMS1009752.html>)
 -  **How to make a submission** (<https://www.parliament.nz/en/pb/sc/how-to-make-a-submission/>)
 -  **Bill page on Parliament website** (<https://bills.parliament.nz/v/6/22059628-b0cc-4931-5e07-08dd18a12bfb?Tab=history>)
 -  **Watch the first reading in the House** (<https://videos.parliament.nz/on-demand?id=8cf0459e-bc9d-4000-de2e-08dd1f7d1101>)
 -  **Read the departmental disclosure statement** (<https://disclosure.legislation.govt.nz/bill/government/2024/110>)
 -  **Read about gene technology regulation on MBIE website** (<https://www.mbie.govt.nz/science-and-technology/science-and-innovation/agencies-policies-and-budget-initiatives/gene-technology-regulation>)
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110—1

Explanatory note

General policy statement

Purpose of the Bill

The Gene Technology Bill 2024 (the **Bill**) is an omnibus Bill introduced in accordance with Standing Order 267(1)(a). The purpose of the Bill is to enable the safe use of gene technology and regulated organisms in New Zealand.

Objectives of the Bill

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

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

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

How the Bill will achieve its purpose and meet its objectives

The regime will replace parts of the Hazardous Substances and New Organisms Act 1996 (the **HSNO Act**) that regulate GMOs with a standalone regime that future-proofs the law. The Bill will—

- establish a Gene Technology Regulator (the **Regulator**) within the Environmental Protection Authority to be the independent decision-maker:
- establish a Technical Advisory Committee and a Māori Advisory Committee to provide the Regulator with expert advice:
- create an authorisation framework to regulate gene technologies and GMOs and manage any risks they pose to human health and safety and to the environment by imposing risk-proportionate conditions:
- create a process to enable the management of risks to Māori kaitiaki relationships with indigenous species:
- enable the Regulator to undertake joint assessments with overseas regulators and to draw on their expertise:

- include definitions of terms such as regulated organism and gene technology that can be clarified to account for potential future changes to gene technologies:
- enable some products of minimal risk gene editing to be exempted from regulation:
- establish offences and penalties for breaches of the regime:
- ensure a nationally consistent approach to regulation of gene technology by removing local authorities' ability to restrict its use:
- ensure New Zealand continues to be able to comply with its international legal obligations.

What will be regulated

The regulatory regime covers gene technology activities (for example, making, breeding, culturing, supplying, importing, or releasing a regulated organism) and regulated organisms (organisms—often referred to as GMOs—that have been modified or constructed by gene technology, but excluding human beings).

Risk tiers and authorisations

Activities will be categorised depending on the nature of the activity: medical, contained, or environmental. For each activity category, the Bill establishes risk tiers to enable proportionate management of risks to human health and safety and to the environment, and associated authorisations. The risk tier framework and risk management approach includes—

- *exempt activities*: minimal-risk products of gene editing, for example, products of editing techniques that result in organisms that cannot be distinguished from those produced by conventional processes:
- *non-notifiable activities*: very low-risk activities that do not require active monitoring by the Regulator, for example, gene therapies that are also regulated by Medsafe:
- *notifiable activities*: low-risk activities that require the Regulator to be notified, for example, laboratory research with mice:
- *licensed activities*: medium- and higher-risk, or uncertain-risk, activities that require a case-by-case assessment before they can be authorised to determine that all risks of the proposed activity can be managed.

In addition, the Bill enables 2 further types of authorisation in specific circumstances, namely—

- *mandatory medical activity authorisations*: for a human medicine that is or contains gene technology that has been approved by at least 2 recognised overseas Gene Technology Regulators:
- *emergency authorisations*: when there is an actual or imminent threat to the health and safety of people or to the environment, for example, threat from a disease outbreak or an industrial spillage. The Minister responsible for the Bill when enacted (the **Minister**) will have the power to grant an emergency authorisation.

Risk assessment and management

A key component of the Bill is to manage any risks gene technologies and GMOs pose to human health and safety and the environment. Any authorised activity may be subject to conditions to manage any risks the Regulator identifies. An example of a condition is that an activity must be carried out in a facility that complies with containment standards. Using conditions to manage risk will allow for an enabling, flexible, and risk-proportionate regulatory approach.

To identify risks, the Regulator will be required to prepare a risk assessment and risk management plan in relation to an application for a licensed activity. The plan will identify and detail any risks posed by the activity to human health and safety and to the environment and ways to manage those risks, which will be given effect to as conditions if the Regulator grants the licence.

The Bill empowers the Regulator to declare some activities to be non-notifiable, notifiable, or pre-assessed licensed activities. The Regulator will identify any risks and ways to manage the risks, which will be given effect to as conditions in the declaration.

Risk assessment will also be one of the mechanisms the Regulator uses to ensure New Zealand complies with its international obligations in respect of modified organisms and management of risks to the conservation and sustainable use of biodiversity arising from GMOs.

Decision-making, transparency, and public participation

In making its decisions on declarations, licences, and conditions, the Regulator will take expert advice from the Technical Advisory Committee and may seek advice from the Māori Advisory Committee where an activity may have a material adverse effect on Māori kaitiaki relationships with indigenous species. The Regulator may also seek and receive advice from other agencies.

The public will also be invited to participate in some processes. For example,—

- the Regulator will be required to publicly notify its proposals to declare activities to be non-notifiable, notifiable, or pre-assessed and seek input:
- the Regulator must consult on the draft risk assessment and draft risk management plan for a licensed activity unless there has been previous consultation about a similar activity and the Regulator is not aware of any significant new information.

The Bill sets expectations for transparency of the regime by requiring public notification of a range of matters including receipt of licence applications and notification of the Regulator’s final decisions and any changes to decisions.

Leveraging international expertise

The Bill provides the Regulator with the ability to recognise overseas Gene Technology Regulators that operate within a comparable legislative framework. The Regulator can develop an agreement with another regulator for the purposes of undertaking joint risk assessments to increase the efficiency of decision-making.

Streamlining interactions with domestic regulators

Where approval is required under both the Bill as enacted and the HSNO Act (for example, where a regulated organism may also be a new organism), the Bill enables joint applications and joint assessments to remove duplicative processes for the applicant.

The Bill enables the Regulator to issue a licence for a medicine or veterinary medicine that is, or contains, gene technology that the Regulator considers is low risk. A regulation-making power will provide for regulations to set a shorter time-frame for this assessment, thereby providing timely decisions for the applicant. The medicine or veterinary medicine cannot be used until it has approval under the Medicines Act 1981 or Agricultural Compounds and Veterinary Medicines Act 1997.

Changes to existing authorisations

The Regulator will be able to make changes to authorisations, such as varying licence conditions, transferring licences, and amending or preparing new risk assessments and risk management plans on the basis of significant new information about the relevant risks of the activities. Licence holders will be able to apply to vary or transfer a licence.

The Regulator will have the ability to suspend and cancel licences, and to amend and revoke the declarations of non-notifiable, notifiable, and pre-assessed licensed activities.

Reviews and appeals

Applicants and licence holders will have a right to request that the Regulator review certain licence decisions. This is a first opportunity for the Regulator to review the facts of the decision and make any changes, prior to a formal court process.

The Bill also provides a right of appeal direct to the High Court on matters of law for parties directly affected by a decision.

Compliance, monitoring, and enforcement

The Director-General of the Ministry for Primary Industries (MPI) will be responsible for compliance, monitoring, and enforcement of the regulatory regime, consistent with comparable enforcement responsibilities for other regimes, including for hazardous substances and new organisms. The Director-General of MPI will appoint enforcement officers who will monitor and enforce compliance.

The Bill includes offences for breaches of the regime. The Bill also establishes a pecuniary penalty regime to deter financially motivated offending.

Departmental disclosure statement

The Ministry of Business, Innovation, and Employment is required to prepare a disclosure statement to assist with the scrutiny of this Bill. The disclosure statement provides access to information about the policy development of the Bill and identifies any significant or unusual legislative features of the Bill.

A copy of the statement can be found at <http://legislation.govt.nz/disclosure.aspx?type=bill&subtype=government&year=2024&no=110>

Regulatory impact statement

The Ministry of Business, Innovation, and Employment produced a Regulatory impact statement on 31 July 2024 to help inform the main policy decisions taken by the Government relating to the contents of this Bill.

A copy of this Regulatory impact statement can be found at—

- <https://www.mbie.govt.nz/science-and-technology/science-and-innovation/agencies-policies-and-budget-initiatives/gene-technology-regulation>
- <https://www.regulation.govt.nz/mfr-what-we-do/regulatory-impact-analysis-ria/regulatory-impact-statements-riss>
- <https://treasury.govt.nz/publications/informationreleases/ris>

Clause by clause analysis

Clause 1 is the Title clause.

Clause 2 is the commencement clause. It provides that the Bill comes into force on the day after Royal Assent. 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 come into force on 1 or more dates set by Order in Council or 2 years after Royal assent (if not brought into force earlier by Order in Council).

Part 1

Preliminary provisions

Clause 3 sets out the purpose of the Bill. It is to enable the safe use of gene technologies and regulated organisms by managing their risks to the health and safety of people and the environment.

Clause 4 describes how this Bill recognises and respects the Crown's obligations under the principles of the Treaty of Waitangi.

Clause 5 requires decision makers to have regard to the convention on biological diversity and the Cartagena Protocol.

Clause 6 is an outline provision, which provides a guide to the general scheme and effect of the Bill.

Clause 7 defines various terms used in the Bill, including activity, contained activity, gene technology, organism, and regulated organism.

Clause 8 defines medical activity.

Clause 9 indicates that the transitional, savings, and related provisions are set out in *Schedule 1*.

Clause 10 provides that the Act will bind the Crown.

Part 2

Regulation of gene technology

Clause 11 defines terms used in *Part 2*.

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

Clause 12 enables the Regulator to determine whether any organism is a regulated organism, or any technique is a gene technology, or any organism or technique is exempt from the operation of the Bill. *Clause 12* also provides that—

- a determination may be made on application by any person or on the Regulator's own initiative;
- the Regulator must have regard to specified information before making a determination, including any previous determinations made under this clause;
- if a Regulator does not approve an application, the Regulator must provide the applicant with the reasons for that decision and inform the applicant of the right to a review of the decision under *clause 134* and the right to appeal the decision under *clause 142*;
- the Regulator must publish any determination on its internet site and apply this Bill in accordance with it.

Subpart 2—General provisions

Clause 13 provides that activities relating to regulated organisms are prohibited unless the activities are non-notifiable, notifiable, or have been authorised by a licence, a mandatory medical authorisation, or an emergency authorisation.

Clause 14 provides that a person must not breach any conditions that apply to the person under an authorisation, a declaration, or a licence.

Clause 15 provides that a power to impose conditions in relation to an activity under *Part 2* includes a power to impose conditions relating to various matters, such as the scope of the activity authorised, disposal requirements, and of auditing and reporting.

Clause 16 provides that the authorisation of a medical activity involving a medicine, medical device, or veterinary medicine is not an approval to use that medicine or device until it has been approved for use under the Medicines Act 1981 or the Agricultural Compounds and Veterinary Medicines Act 1997, as applicable.

Clause 17 provides requirements for applications made under *Part 2*, including that they must be in writing, contain any information required by the Regulator or prescribed in regulations, and be accompanied by any fee prescribed in regulations.

Clause 18 provides that the Regulator may commission research or expert advice and consult any person for the purposes of exercising its functions.

Subpart 3—Licences

Licence applications

Clauses 19 to 24 establish a licensing system to enable a person to apply to the Regulator for authorisation to carry out an activity in relation to regulated organisms, as follows:

- *clause 19* provides that licence applications may seek authorisation for specified persons or all persons to carry out specified activities or all activities in relation to specified regulated organisms:
- *clause 20* provides that a person may make a joint application to the Regulator and the Environmental Protection Authority (the **EPA**) that contains an application for a licence under *clause 19* and an application under specified provisions of the Hazardous Substances and New Organisms Act 1996 in respect of the same person, activity, or regulated organism. It also provides that the Regulator and the Environmental Protection Authority must collaborate for the purposes of assessing the application:
- *clause 21* requires certain licence applications to contain additional information about kaitiaki relationships:
- *clause 22* provides that the applicant may withdraw a licence application at any time before the licence is issued:
- *clause 23* provides that the Regulator may make a declaration (as secondary legislation) that an activity is a pre-assessed activity for the purposes of any licence applications in respect of that activity if certain requirements are met. The effect of this is that there is no further requirement to prepare a risk assessment or risk management plan for licence applications in respect of the activity or to provide additional information about kaitiaki relationships in the applications:
- *clause 24* sets out consultation and notification requirements that must be met when revoking a declaration of a pre-assessed activity.

Risk assessments and risk management plans

Clauses 25 to 32 provide for the preparation of risk assessments and risk management plans (**risk documents**) by the Regulator. In particular, they provide that the Regulator—

- must notify an applicant in writing if the Regulator proposes to prepare risk documents as part of the licence application assessment and give the applicant 30 working days to provide further information and to request the Regulator to reconsider the proposal (*clause 25*):
- must prepare risk documents if the Regulator is assessing a licence application in respect of an activity that is not a pre-assessed activity, transshipment activity, or low-risk medical activity, or if the Regulator is proposing to declare that an activity is a pre-assessed activity (*clause 26*):
- must seek and have regard to advice from the Technical Advisory Committee when preparing risk documents (*clause 27*):
- must release draft risk documents for public consultation unless certain conditions are met (in which case the Regulator is not required to release the drafts, but still has the discretion to do so) and the Regulator must have regard to any written submissions (*clause 28*):
- must finalise any draft risk documents after complying with the preceding requirements (*clause 29*):
- must prepare new or amended risk documents if the Regulator becomes aware of significant new information about the relevant risks of an activity, and considers that the new information means that the risk documents are no longer materially accurate (*clause 30*):

- may temporarily restrict any activity in relation to a regulated organism in specified circumstances, including if the Regulator has decided to prepare new or amended risk documents (*clause 31*);
- may amend risk documents to correct minor errors (*clause 32*).

Licensing decisions

Clause 33 sets out the criteria for the issue of a licence, including that,—

- for a pre-assessed activity, the Regulator is satisfied that the applicant is a fit and proper person, and is willing and able to meet any conditions; and
- for a transshipment activity, the Regulator is satisfied that the regulated organism that is to be transhipped can be adequately contained to prevent exposure to the environment and that the applicant is willing and able to meet any conditions; and
- for a low-risk medical activity, the Regulator is satisfied that it is in fact a low-risk medical activity and that the applicant is a fit and proper person, and is willing and able to meet any conditions; and
- for any other activity, the Regulator is satisfied that the relevant risks of the activity can be reasonably managed and controlled having regard to various factors, and that the applicant is fit and proper, and willing and able to meet any conditions.

Clause 34 sets out notification requirements for the Regulator’s licensing decisions.

Clause 35 sets out the matters that the Regulator must have regard to when determining whether a person is a fit and proper person to hold a licence, including any relevant convictions of the person and any suspension or revocation of any authority the person holds or has held under a relevant law.

Contents and conditions of licences

Clause 36 provides that a licence must contain certain information, including the conditions of the licence, the period for which it is in force, and the activities, regulated organisms, and persons to which it relates.

Clause 37 provides that a licence under this Bill is subject to the conditions specified in that clause, and any other conditions that the Regulator considers necessary. However, if the licence is for a pre-assessed activity, the Regulator may only impose conditions relating to auditing, reporting, supervision, and monitoring.

Clause 38 provides that a licence continues in force until the end of the period specified in the licence (if any) or until it is cancelled or surrendered, and that a licence is not in force while suspended.

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

Clauses 39 to 46 provide for the ability to suspend, cancel, surrender, vary, or transfer licences if certain requirements are met and include notification requirements for the Regulator.

Clause 39 provides that the Regulator may suspend or cancel a licence if the Regulator believes that—

- a condition of the licence has been breached by the licence holder or a person authorised by the licence to carry out the activity:
- the licence holder or an authorised person has committed an offence against this Bill:
- the licence was obtained on the basis of false or misleading information:
- there are relevant risks associated with the continuation of the activity authorised by the licence and the Regulator is satisfied that the licence holder is not in a position to manage those risks:
- the licence holder is no longer a fit and proper person to hold the licence (where this is a requirement):
- the persons who are authorised to carry out activities under the licence are authorised to carry out those activities under another type of authorisation:
- there is no prospect that the persons who are authorised to carry out the activities under the licence will carry out those activities.

Clause 40 sets out notification requirements that the Regulator must comply with if it intends or decides to suspend or cancel a licence.

Clause 41 enables a licence holder to apply to the Regulator to surrender their licence. The Regulator must consent to the surrender of the licence if the licence holder has—

- complied with all the application requirements:
- provided any additional information requested by the Regulator:
- complied with any conditions imposed by the Regulator.

Clause 42 sets out notification requirements that the Regulator must comply with if they do not intend to consent to the surrender of a licence and when they make a decision.

Clause 43 (which relates to the transfer of a licence from a licence holder to another person) and *clause 45* (which relates to the variation of a licence) provide that the Regulator may only consent to the transfer of a licence if satisfied that the relevant criteria for granting the licence in *clause 33* will continue to be met, and may only consent to the variation of a licence if satisfied that the applicant is willing and able to meet the conditions attached to the licence. .

Clauses 44 and 46 set out notification requirements that the Regulator must comply with when considering and deciding whether to vary or transfer licences.

Subpart 4—Non-notifiable and notifiable activities

Clauses 47 and 48 provide that the Regulator may, if certain criteria are met, declare that an activity in relation to a regulated organism is—

- a non-notifiable activity under *clause 47*, and therefore able to be carried out by any person without a licence and without notifying the Regulator; or
- a notifiable activity under *clause 48*, and therefore able to be carried out by any person who notifies the Regulator that they are carrying out the activity.

A declaration under either of these sections is secondary legislation and is subject to statutory conditions, including that if the activity is a contained activity in relation to a regulated organism, any person carrying out the activity must not introduce the regulated organism into the environment and must notify the Regulator of any such introduction as soon as is reasonably practicable. The Regulator may also impose any conditions that it considers necessary.

Clause 49 provides that, unless certain exceptions apply, the Regulator must seek and have regard to advice from the Technical Advisory Committee before making, varying, or revoking a declaration under *clause 47 or 48* and must publish what it proposes to do on its internet site and have regard to any written submissions.

Subpart 5—Mandatory medical authorisations

Clause 50 requires the Regulator to grant a mandatory medical authorisation in respect of certain medical activities that the Regulator is aware have been approved by 2 or more recognised overseas authorities in equivalent circumstances. This requirement does not apply if the Regulator considers that it would result in an imminent risk of death, serious illness, or serious injury to people or serious damage to the environment. The Regulator may impose conditions on the authorisation and, in exercising this discretion, must have regard to the conditions that the overseas regulators have imposed. The Regulator must notify the Director-General of Health in writing as soon as is reasonably practicable if they propose to grant a mandatory medical authorisation, and the authorisation is secondary legislation.

Clause 51 provides that the Regulator may revoke a mandatory medical authorisation only if they consider that the relevant criteria for granting the authorisation in *clause 50* no longer apply or that the revocation is necessary in order to avoid an imminent risk of death, serious illness, or serious injury to people or serious damage to the environment.

Subpart 6—Emergency authorisations

Clause 52 enables the Minister to grant an emergency authorisation for specified persons or all persons to carry out specified activities or all activities in relation to specified regulated organisms if the Minister is satisfied,—

- on receiving advice from a relevant Minister, that there is a threat to the health and safety of people or the environment (for example, a threat from a disease outbreak) and an emergency authorisation is appropriate for responding to that threat; and
- on receiving advice from the Regulator, that the threat is likely to outweigh any relevant risks of the activity, having regard to certain factors.

An emergency authorisation is secondary legislation.

Clause 53 provides that an emergency authorisation takes effect on the day it is made or on a specified later date and ends on the earlier of 6 months after it has taken effect or at the end of the period specified in the emergency authorisation.

Clause 54 provides that the Minister may extend the period of effect of an emergency authorisation if the Minister is satisfied that the threat still exists and the proposed extension is appropriate for the purposes of responding to the threat.

Clause 55 provides that the Minister may impose conditions on the emergency authorisation and seek advice from the Regulator for that purpose.

Clause 56 provides that the Minister may vary, or suspend an emergency authorisation on advice from the relevant Minister who provided advice under *clause 52* or the Regulator. The Minister must revoke an emergency authorisation in certain circumstances specified in the clause.

Subpart 7—Recognised overseas authorities

Clause 57 provides that the Regulator may declare that a person in another jurisdiction is a recognised overseas authority for the purposes of specified provisions of this Bill, if the Regulator is satisfied that the person meets criteria about operating in a comparable manner to the Regulator and under a comparable legislative framework, and that the person is willing and able to provide information that is readily accessible by the Regulator. The Regulator must revoke a declaration if the person no longer meets any of the criteria.

Subpart 8—The register

Clause 58 provides that the Regulator must maintain a register of information related to the administration of this Bill, including details of licences, mandatory medical authorisations, emergency authorisations, notifiable, non-notifiable, and pre-assessed activities, and recognised overseas authorities.

Subpart 9—Information held by Regulator

Clause 59 provides that information held by the Regulator, the Technical Advisory Committee, or the Māori Advisory Committee is held by the EPA for the purposes of the Official Information Act 1982. It also provides that the Official Information Act 1982 does not apply to information provided to the Regulator that is likely to relate to a licence or determination application until the application is actually received.

Clause 60 specifies reasons why the Regulator may withhold any information that they would ordinarily be required to publish under this Bill if certain criteria are met, including if the Regulator considers that the information could pose a national security risk or cause serious offence to tikanga Māori. The Regulator must also consult the Māori Advisory Committee if they propose to publish information about a kaitiaki relationship. This provision does not affect the operation of the Official Information Act 1982.

Clause 61 applies certain provisions about the protection of information to the Regulator. The provisions apply to confidential information received in respect of a licence application if the regulated organism to which the application relates is or has been the subject of—

- an innovative medicine application (under the Medicines Act 1981, in which case sections 23A to 23C of the Medicines Act 1981 apply to the Regulator as if the Regulator were the Minister under that Act); or
- an innovative Trade Name Product application (under the Agricultural Compounds and Veterinary Medicines Act 1997, in which case, Part 6 of that Act applies to the Regulator as if the Regulator were the Director-General under that Act).

However, the Regulator must still publish a summary of relevant risks of any activities proposed to be authorised by the licence application and may disclose confidential information to persons prescribed by regulations.

Part 3

Inspection, enforcement, and ancillary powers

Clause 62 defines various terms used in this Part.

Subpart 1—General

Clause 63 states that the chief executive of the Ministry for Primary Industries and any organisation delegated powers under this Part (the **enforcement agency**) are responsible for monitoring and enforcing compliance with this Bill. This clause also provides that—

- the enforcement agency may appoint enforcement officers; and
- persons who have powers under the Biosecurity Act 1993 in respect of an unwanted organism (for example, inspectors) may exercise those same powers in respect of a regulated organism; and
- enforcement officers may also exercise those powers; and
- certain provisions of the Biosecurity Act 1993 (for example, about compensation) apply to the exercise of those powers.

Clause 64 allows the enforcement agency to appoint an enforcement officer if that person is employed or engaged in the State services and has the appropriate experience, technical competence, and qualifications (including any qualifications stated in regulations made under this Act) for the role. The enforcement agency may impose written conditions on the appointment of an enforcement officer.

Clause 65 enables an enforcement officer to obtain, by written notice, information from a person about an organism, a regulated organism, gene technology, or an activity regulated by the Act. An enforcement officer may require information that the person possesses or controls, or that could be compiled from information the person possesses or controls, or that the person is able to obtain. An enforcement officer may only require a person to give personal information (information about an identifiable individual) or information that is not in that person's control or possession under specified circumstances.

Clauses 66 and 67 apply to a requirement under the Bill to supply border information (as defined in the Biosecurity Act 1993) to the Ministry. *Clause 66* relates to the approved form and manner requirements relating to border information supplied to the Ministry by using the Joint Border Management System (**JBMS**). *Clause 67* imposes a duty to use the JBMS or another means approved by the enforcement agency to supply border information to the Ministry.

Under *clause 68*, the enforcement agency or an enforcement officer may give directions to an owner or a person in charge of a regulated organism or the occupier of a place where a regulated organism is or may be present. Those directions may relate to the treatment, containment, movement, disposal, monitoring, and reporting of a regulated organism (or associated organisms, organic material, or things) as specified in *clause 68(1)*.

Under *clause 69*, an enforcement officer may enter and inspect a place to check compliance with requirements of this Act, or secondary legislation made under this Act, or conditions imposed under this Act (**legislative requirements**) or to determine the nature of an organism. This clause also specifies what are reasonable grounds for entry and inspection and what an enforcement officer may do during the course of an inspection, for example, taking samples or requiring a person present at the place to answer certain questions. The clause also provides that the privilege against self-incrimination in the Evidence Act 2006 is not affected.

Under *clause 70*, an enforcement officer may enter a dwellinghouse or a marae (or building associated with a marae) only under a search warrant. An enforcement officer may apply for a search warrant only if satisfied that the grounds set out in *subsection (3)* exist, that is, there are reasonable grounds to believe the place is a place referred to in *section 69(2)* or is the only practicable means by which a person can enter such a place. A Judge or person authorised to act as an issuing officer (an **issuing officer**) may issue a search warrant if satisfied of the grounds in *subsection (3)*. The warrant authorises the enforcement officer to exercise the powers in *section 69*.

Under *clause 71*, an enforcement officer may apply for, and an issuing officer may issue, a search warrant in respect of a place if there are reasonable grounds to suspect that an offence against the Act has been, is being, or will be committed and there is evidential material in the place.

Subpart 2—Compliance orders

Clauses 72 to 75 relate to compliance orders—

- *clause 72* empowers an enforcement officer to make a compliance order against a person as follows:
 - require the person to stop doing something that breaches or is likely to breach a specified legislative requirement; or
 - require the person to do something that is necessary or desirable to ensure that the person complies with a specified legislative requirement; or
 - require the person to do something that is necessary or desirable to avoid, remedy, or mitigate certain adverse effects arising from a breach of a specified legislative requirement; or
 - prohibit the person from doing something that breaches or is likely to breach a legislative requirement:
- *clause 73* requires a person to comply with a compliance order:
- *clause 74* sets out the required content of a compliance order:
- *clause 75* allows the appointer of the enforcement officer who made a compliance order to confirm, change, or cancel that compliance order.

Subpart 3—Offences

Clauses 76 to 83 set out the following offences:

- undertaking an activity regulated by the Act without a licence or a mandatory medical authorisation, or an emergency authorisation, unless the activity has been declared by the Regulator to be a low-risk activity (**notifiable activity**) or

very low-risk activity (**non-notifiable activity**) (*clause 76*):

- breaching a condition that relates to a non-notifiable or a notifiable activity, or a mandatory medical authorisation (*clause 77*);
- breaching a condition of a pre-assessed activity, a licence, an emergency authorisation or an approval related to synthetic nucleic acid (*clause 78*);
- failing to comply with a requirement, direction, or compliance order (*clause 79*);
- giving false or misleading information in connection with the purposes of the Act (*clause 80*);
- impersonating an enforcement officer (*clause 81*);
- obstructing an enforcement officer or the chief executive (*clause 82*);
- providing synthetic nucleic acid or manufacturing benchtop nucleic acid synthesis equipment without being approved by the Regulator or failing to comply with requirements in regulations relating to nucleic acid synthesis and benchtop nucleic acid synthetic equipment (*clause 83*).

Clauses 84 provides that a defendant being prosecuted for an offence under this Bill has a defence if the defendant proves that

- the offence was committed in a circumstance that was outside of the defendant's control and that the defendant took all reasonable precautions to avoid committing it; or
- the defendant's actions were necessary to avoid harm and reasonable in all the circumstances and that the defendant took reasonable steps to mitigate or remedy the effects of the action after it occurred.

Clause 85 allows the court to order a person convicted of an offence against *clauses 76 to 83* to do 1 or more of the following:

- mitigate or remedy the adverse effects caused by the offending action;
- pay the costs of mitigating or remedying the adverse effects caused by the offending action;
- dispose of the regulated organism related to the person's conviction.

The court may make an order instead of, or in addition to, imposing other sentences or orders available under the Sentencing Act 2002. The court must have regard to all relevant matters when deciding to make an order under this clause.

Clauses 86 and 87 provide for when an agent's principal, or director, or manager of a body corporate that is liable for an offence under this Bill.

Clauses 88 and 89 provide for the time in which a person may file a charging document. Under *clause 88*, the limitation period for offences not generally punishable by a term of imprisonment under this Bill (a **category 1 offence**) ends 2 years from the date the matter relating to the charge first became known, or should have become known, to the enforcement agency. However, the District Court may extend the limitation period in specified circumstances if a person applies for an extension within the relevant 2-year period.

Subpart 4—Infringement offences

Clauses 90 to 93 provides for an enforcement officer or the enforcement agency to issue an infringement notice to a person if the enforcement officer or the enforcement agency believes on reasonable grounds that a person is committing, or has committed, an infringement offence.

Infringement fees and infringement offences under this Bill will be specified in regulations made under *clause 155(1)(a)* (see also *clause 165*).

Clauses 94 and 95 provide for revoking an infringement notice. An enforcement officer or the enforcement agency may revoke an infringement notice before the infringement fee is paid. An enforcement officer or the enforcement agency must notify the Regulator of a revocation as soon as reasonably practicable.

Clauses 96 to 99 set out the content of an infringement notice, how an infringement notice may be served, that infringement fees must be paid into a Crown Bank Account, and the form of reminder notices.

Subpart 5—Pecuniary penalties of Act or secondary legislation

Clause 100 provides that—

- the High Court may make a pecuniary penalty order if a person breaches certain provisions of the Act and does so in the course of a business; and
- the High Court may not make a pecuniary penalty order if the person satisfies the court the breach was necessary for specified purposes and the person took reasonable steps to mitigate or remedy the effects of the breach.

Clause 101 sets out some of the relevant matters a court must consider when determining the amount of a pecuniary penalty.

The clause also sets out the monetary limits for pecuniary penalties. The pecuniary penalty limit for an individual is \$500,000.

The limit in any other case, for example, a body corporate, is \$10,000,000 or the greater of one of the following depending on whether the court is satisfied that the breach took place in the course of producing a commercial gain and whether the commercial gain can be readily ascertained:

- 3 times the value of the commercial gain resulting from the breach:
- 10% of the turnover of the body corporate and all of its interconnected bodies corporate.

Under *clause 102*, instead of or in addition to a pecuniary penalty order, the High Court may order the person to do 1 or more of the following:

- mitigate or remedy any adverse effects from the person's breach:
- pay the cost of mitigating or remedying the adverse effects from the person's breach:
- dispose of the regulated organism related to the person's breach.

Clause 103 covers the standard of proof and procedural matters. The civil standard of proof, rules of evidence, and procedure for civil proceedings apply.

Clause 104 provides for the following if the same conduct results in both pecuniary penalty proceedings and criminal proceedings being brought:

- if criminal proceedings are started and pecuniary penalty proceedings are incomplete, the pecuniary penalty proceedings are stayed:
- if pecuniary penalty proceedings have resulted in the making of a pecuniary penalty order and appeal rights have expired or been exhausted, criminal proceedings may not be started.

Clause 105 provides for when an agent's principal or an employee's employer is liable for an offence under this Bill.

Part 4 Administration

Subpart 1—Minister

Subpart 1 (clauses 106 and 107) outlines the functions of the Minister and imposes limits on the Minister's power of delegation.

Subpart 2—Regulator

Clause 108 establishes the Gene Technology Regulator and *clauses 109 and 110* set out the objective and functions of the Regulator, which include advising the Minister, facilitating New Zealand's compliance with international obligations, monitoring international practice, and providing information and advice to the public.

Clause 111 sets out how the Regulator must perform their functions and their exercise powers, and *clause 112* gives the Regulator the ability to delegate any of the Regulator's functions or powers with the following exceptions:

- the power of delegation itself; and
- powers that can only be delegated to an employee of the EPA (*see clause 112(2)*).

Subpart 3—Technical Advisory Committee

Under *clause 113*, the Minister must establish the Technical Advisory Committee. The Minister is also responsible for appointing committee members and must only appoint members to the committee that have relevant subject-matter expertise (*see clause 114(3)*).

The committee's functions are described in *clause 115* and include providing scientific and technical advice to the Regulator and performing other statutory functions. The Regulator must have regard to the committee's advice but is not bound by it (*clause 116*). *Clauses 117 and 118* are administrative provisions that cover the committee's procedures and remuneration.

Clause 108 requires the committee to report back to the Regulator.

Subpart 4—Māori Advisory Committee

Under *clauses 120 and 121*, the Minister must establish the Māori Advisory Committee. The Minister is also responsible for appointing committee members and must first consult with the Regulator and the Minister for Māori Development before appointing or removing a member from the committee (*clause 121*).

The committee's functions are described in *clause 122* and include providing advice to the Minister and the Regulator, issuing engagement guidelines, and performing other statutory functions. The Regulator must have regard to the committee's advice

but is not bound by it (*clause 123*). *Clauses 124 and 125* are administrative provisions that cover the committee's procedures and remuneration.

Clause 126 requires the Regulator to refer to the Māori Advisory Committee specified licence applications and proposals to make a declaration about an activity that would use an indigenous species as a host organism. *Clause 127* outlines the role of the committee when reviewing matters referred to it under *clause 126*, which is that the committee must assess whether the activity would materially impact 1 or more kaitiaki relationships with an indigenous species that would be used as a host organism.

Clauses 128 to 130 outline what the committee is to take into account when assessing a kaitiaki relationship with an indigenous species, the process to follow when carrying out its functions under *clause 115*, and the proposed conditions the committee should consider when assessing adverse effects on a kaitiaki relationship.

Clause 131 provides for reporting requirements in relation to *clause 126*.

Subpart 5—Subcommittees

Subpart 5 (clauses 132 and 133) allows the Regulator to establish subcommittees of the Technical Advisory Committee or the Māori Advisory Committee for the purposes of advising on specific matters or classes of matters.

Part 5 Miscellaneous

Subpart 1—Reviews

Clauses 134 to 138 provide for the review of certain decisions made by the Regulator. In particular, these clauses provide—

- that a person may request the review of a decision of the Regulator if the decision is made under a provision listed in *Schedule 3* and the person is identified in *Schedule 3* as a person who may apply for that review (*clause 134*);
- for the procedure for the review carried out by the Regulator (*clause 135*);
- that the Regulator may confirm, modify, or reverse all or part of the decision, or make a new decision (*clause 136*);
- that the original decision remains valid until the Regulator modifies, reverses, or replaces it (*clause 137*);
- that there is no further right to seek a review of the decision made on the review (*clause 137*);
- that the Regulator must enter the outcome of the review of a decision in the licensed activities register (*clause 138*).

Subpart 2—Appeals

Appeals to District Court

Clauses 139 to 141 provide for appeals to the District Court in relation to compliance orders and for a person whose property has been seized under this Bill (or who was required to dispose of any thing). The filing of an appeal does not amount to a stay of the compliance order, but a party may apply for a stay under *clause 140*. Further, a decision of the District Court may be appealed to the High Court on a question of law, and to the Court of Appeal or Supreme Court on questions of law with the leave of that court.

Appeals against Regulator's decision directly to the High Court

Clauses 142 to 148 provide for appeals directly to the High Court on a point of law. In particular, these clauses provide that—

- a reviewable decision may be appealed to the High Court by a person directly affected by the decision within 20 working days (*clause 142*);
- a notice of appeal must be served on specified persons (*clause 143*);
- a party to proceedings or a person who made submissions to the Regulator and wishes to be heard on an appeal must give notice of that intention to specified persons (*clause 144*);
- the High Court may order, upon application or on its own motion, that the Regulator must lodge certain documents relating to the appeal. An application that such an order be made may be filed by the appellant or other party to the appeal (*clause 145*);
- *clause 146* makes provision for other parties to the appeal to appeal on different points of law;
- the High Court may extend the period of time relating to the filing of a notice of appeal and the giving of notice for a party that wishes to be heard on an appeal (*clause 147*);
- the procedure that applies for any appeal to the Court of Appeal from a decision of the high Court is that set out in the Criminal Procedure Act 2011 (*clause 148*).

Subpart 3—Notices and standards

Clause 149 permits the Regulator to issue a notice approving for the purposes of the Bill, providers, manufacturers, and third-party vendors and distributors of synthetic nucleic acids, including any conditions applying to those approvals. The notices must be published on an internet site.

Clause 150 permits the Regulator to issue or approve standards for the purpose of ensuring risks to health and safety of people and the environment are minimised.

Subpart 4—Information and samples sharing

Clauses 151 to 153 permit the disclosure of information by the Regulator in order to perform their functions and duties. Specifically,—

- specified agencies may share information to another agency provided the disclosure is necessary or desirable for the performance of functions or duties under this Bill or under other specified legislation. Disclosure is also permitted for the purpose of the Regulator and the EPA collaborating for the purposes of assessing any combined licence application (*clause 151*);
- the Regulator may disclose information to a recognised overseas authority under information sharing agreements between the two regulators. Such agreements must be in writing and the Regulator must consult with the Privacy Commissioner before entering into an agreement to share information (*clauses 152 and 153*);
- the agencies listed in *clause 151* may provide to other specified agencies a sample or organic matter relating to a regulated organism for the purpose of performing functions or duties under this Bill (*clause 154*).

Subpart 5—Regulations

Clauses 155 to 163 and *clauses 155 and 156* contain the regulation-making powers for this Bill. Regulations may be made that—

- prescribe that things and processes are not organisms or regulated gene technologies for the purpose of this Bill (*clause 155*);
- prescribe fees, charges and forms (*clause 155*);
- prescribe matters relating to the Technical Advisory Committee and Māori Advisory Committee (*clause 155*);
- prescribe how applications may be made jointly for approvals under this Bill, (*clause 156*);
- prescribe requirements relating to synthetic nucleic acid providers, manufacturers, and third party vendors and distributors, including customer screening requirements (*clause 157*);
- relate to non-notifiable activities (*clause 158*);
- relate to notifiable activities (*clause 159*);
- set timetables for the Regulator to process, consult, and decide on matters (*clause 160*);
- prescribe criteria and conditions for activities, risk assessment and risk management plans (*clause 161*);
- prescribe additional criteria that the Regulator must take into account in deciding whether a person is a fit and proper person under *clause 35* (*clause 162*);
- exempt from the operation of the Bill organisms or gene technologies, including any conditions to that exemption (*clause 164*);
- provide for transitional and savings provisions concerning the coming into force of this Bill, and provide for specified provisions to not apply during that transitional period (*clause 164*);
- prescribe offences as infringement offences against this Bill, including prescribing infringement fees up to \$3,000 or \$6,000 if imposed by the court (*clause 165*).

Clause 166 provides that regulations made under this Bill may require the Minister, Regulator, enforcement officers and authorised persons to issue directions, orders, requirements and notices.

Clause 167 sets out the procedure the Minister must undertake prior to recommending the making of regulations under this Bill.

Subpart 6—Incorporation by reference

Clauses 168 to 172 set out the rules for incorporation of material by reference in gene technology documents, including clauses that—

- define terms used in this subpart, including gene technology documents and responsible persons (*clause 168*);
- specify the types of written material that may be incorporated in a gene technology document (*clause 169*);

- provide that a responsible person may, by notice in the *Gazette*, amend or replace material incorporated in a gene technology document (*clause 170*):
- provide that a responsible person may, by notice in the *Gazette*, state that expired or revoked material incorporated in a gene technology document no longer has legal effect (*clause 171*):
- apply certain provisions of the Legislation Act 2019 but exempt material incorporated in a gene technology document from specified provisions of the Legislation Act 2019 (*clause 172*).

Subpart 7—Fees, charge, and cost recovery provisions

Clauses 173 to 182 set out provisions relating to the charging of fees and cost recovery by the Regulator and other bodies, including clauses that—

- require any person making an application under the Bill to pay the prescribed fees and charges (*clause 173*):
- require the Regulator to must consider granting an exemption, waiver or refund of fees, charges or levies if authorised to do so by regulations made under this Bill (*clause 173*):
- require the costs of administering the Bill to be recovered by fees, charges, and levies where it is not covered by Crown funding, while the costs of enforcing this Bill by the enforcement agency is managed under provisions of the Biosecurity Act 1993 (*clause 174*):
- permit the Regulator to estimate a charge payable for the performance of a function, power, or duty, and require that estimate to be paid in advance (*clause 175*):
- set out the principles to be taken into account by the Minister and Regulator when determining the most appropriate method of cost recovery (*clauses 177 and 178*):
- set out the various methods by which cost recovery may occur (*clause 181*).

Clause 174 requires the Minister to review costs charged under this Bill at least every 3 years.

Failure to pay

Clauses 182 to 185 set out provisions relating to unpaid debts under the Bill, including clauses that—

- provide that a fee, charge or levy that has become payable to the Crown is a debt due to the Regulator and recoverable by the Regulator (*clause 182*):
- provide for a 10% penalty to be charged for any debt that remains unpaid 20 working days after it was demanded in writing to be paid (*clause 183*):
- specify that a dispute over a person's liability to pay a fee, charge, levy or penalty does not suspend the obligation to pay (*clause 184*):
- provide for the Regulator to withdraw service under this Bill to the debtor unless the debt is paid (*clause 185*).

Subpart 8—Miscellaneous

Service of notices and other documents

Clause 186 provides what constitutes the service of notices under this Bill or the regulations.

Protection from civil and criminal liability

Clause 187 protects certain persons from civil and criminal liability for any act that the person does or omits to do in the performance of their functions or duties under this Bill.

Revocations and consequential

Clause 188 revokes the following secondary legislation:

- Hazardous Substances and New Organisms (Genetically Modified Organisms—Information Requirements for Segregation and Tracing) Regulations 2008:
- Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003.

Clauses 189 and *Schedule 2* consequentially amend other legislation.

Part 6

Amendments to other legislation

Part 6 of this Bill makes amendments to other legislation.

Subpart 1—Amendments to Agricultural Compounds and Veterinary Medicines Act 1997

Clauses 190 to 198 amend the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM). In particular, these clauses—

- define regulated organism and Gene Technology Regulator (*clause 191*);
- provide the subject matter of ACVM may interact with the subject matter regulated under this Bill (*clause 192*);
- requires the Director-General of Primary Industries to notify the Regulator when it receives an application to register a trade name product that contains an agricultural compound (*clause 193*);
- waives the requirement to notify under *clause 194* if the agricultural compound has an emergency authorisation under the Bill (*clause 195*);
- amends ACVM to require public notification of a decision regarding the registration of a trade name product that contains a regulated organism within 20 working days of a decision under the Hazardous Substances and New Organisms Act 1996 or this Bill (*clause 196*);
- prohibit the Director-General from granting an application for registration or provisional registration of a trade name product if that product contains or is a regulated organisms that is not authorised under this Bill (*clauses 196 and 197*);
- adds this Bill to the list of Acts whose requirements are not affected by the ACVM (*clause 198*).

Subpart 2—Amendments to Animal Products Act 1999

Clauses 199 and 200 amends the Animal Products Act 1999 to add this Bill and the Regulator to the list of Acts and entities between which information sharing can occur under the Animal Products Act.

Subpart 3—Amendments to Biosecurity Act 1993

Clauses 201 to 210 amend the Biosecurity Act 1993. In particular, these clauses—

- define authorised regulated organism, regulated organism, and Gene Technology Regulator and amends the definition of restricted organism (*clause 202*);
- prohibit inspectors from giving biosecurity clearance for goods that are or contain a regulated organism unless that organism is an authorised regulated organism or is going to a containment facility that meets the relevant standards under this Bill (*clause 203*);
- permit the holding of organisms by the Director-General of Primary Industries while the Regulator determines if the organism is an authorised regulated organism (*clause 204*);
- permit the Director-General to approve a containment facility for regulated organisms if it complies with requirements under this Bill and the Biosecurity Act (*clause 205*);
- permit the Director-General to consider any conviction under this Bill when considering an application to approve or cancel an approval as an operator of a transitional or containment facility (*clause 206*);
- define any function of the Ministry for Primary Industries under this Bill as a Ministry-related border management function (*clause 207*);
- exclude from the duty on every person to inform the Ministry of the presence of any organism not normally seen or detected in New Zealand any regulated organism that is lawfully present in accordance with an approval given under this Bill (*clause 208*);
- prevent a regulated organism being declared a notifiable organism under the Biosecurity Act unless the Minister has consulted with the Regulator (*clause 209*);
- permit an inspector to enter a transitional facility or containment facility to assess if it complies with the standards set under this Bill or any conditions set by the Regulator (*clause 210*).

Subpart 4—Amendment to Environmental Protection Authority Act 2011

Clauses 211 and 212 provides that this Bill is an environmental Act under the Environmental Protection Act 2011, and under which the Environmental Protection Authority has functions.

Subpart 5—Amendments to Food Act 2014

Clauses 213 to 215 amend the Food Act 2014. In particular, these clauses—

- provide for a test conducted under this Bill to be used in relation to a prosecution under the Food Act in certain circumstances (*clause 214*);

- add this Bill to the list of Acts under which agencies perform functions and can share information relating to the administration of the Food Act (*clause 215*).

Subpart 6—Amendments to Hazardous Substances and New Organisms Act 1996

Clauses 216 to 238 amend the Hazardous Substances and New Organisms Act 1996 (**HSNO**). In particular, these clauses—

- amend the definitions of containment, development, and organism, define large scale, and repeal a number other definitions (*clause 217*):
- replace the definition of new organism (*clause 218*):
- amend the delegation powers of the EPA to align with the policy in this Bill (*clause 219*):
- amend HSNO to remove references to genetically modified organisms where applications, risk assessments, conditions of containment, field trials or release, and public notification are now regulated by this Bill:
- amend the information required to be included in an application for containment approval for new organisms (*clause 223*):
- amend the definition of emergency to refer include a situation where an emergency authorisation has been granted under this Bill (*clause 230*):
- repeal the power of an inspector to require any person importing any organism to make a statutory declaration that an organism is not a genetically modified organism (*clause 235*):
- repeal the regulation making powers relating to regulations prescribing an organism to be, or not to be, a genetically modified organism (*clause 236*):
- provide that nothing in HSNO affects the requirements under this Bill in relation to any regulated organism (*clause 237*):
- amend Schedule 3 to repeal Part 1 and amend the heading of Part 2 to reflect that regulated organisms are regulated under this Bill (*clause 238*).

Subpart 7—Amendments to Medicines Act 1981

Clauses 239 to 243 amend the Medicines Act 1981. In particular, these clauses—

- define Regulator as the Regulator under this bill (*clause 240*):
- provide that for medicines or medical devices that are or contain regulated organisms, the Medicines Act requirements are in addition to the requirements of this Bill (*clause 241*):
- replace sections 24C to 24G of the Medicines Act 1981, which provide for approvals of medicines in special emergencies to incorporate the provisions of this Bill for medicines that are or contain a regulated organism (*clause 242*):
- provide that nothing in the Medicines Act affects the requirements under this Bill in relation to any regulated organism, but for any inconsistency between that provision or any regulation made under that Act, the Medicines Act prevail over this Bill (or any regulation made under this Bill) (*clause 243*).

Subpart 8—Amendments to Ombudsmen Act 1975

Clauses 244 and 245 amends the Ombudsmen Act 1975 to include the Māori Advisory Committee and the Technical Advisory Committee, as defined in this Bill, as organisations in Part 2 of Schedule 1 of that Act to which the function of the Ombudsman apply.

Subpart 9—Amendments to Resource Management Act 1991

Clauses 246 to 254 amend the Resource Management Act 1991 (**RMA**). In particular, these clauses—

- define genetically modified and Regulator (*clause 247*):
- prohibit a regional council or territorial authority from performing its functions under sections 30 and 31 of the RMA in a manner that treats genetically modified organisms differently from other organisms, including in regional plans, district plans and regional rules (*clauses 248 to 253*):
- insert a new *Part 8* into Schedule 4 of the RMA, providing transitional, savings and related provisions (*clause 254*).

Subpart 10—Amendments to Search and Surveillance Act 2012

Clause 255 and 256 amends the Schedule in the Search and Surveillance Act 2012 to include powers under this Bill. That Schedule sets out the powers in other enactments to which all or part of Part 4 of Search and Surveillance Act applies.

Schedule 1: Transitional, savings, and related provisions

Schedule 1 contains transitional, savings, and related provisions. These provisions relate to applications, decisions, reviews or consultation under the Hazardous Substances and New Organisms Act 1996 (the **HSNO Act**). This is because parts of that Act are being replaced by the new regulatory regime under this Bill.

Schedule 1 outlines the processes for pending applications that meet the specifications in the schedule and that have been submitted, but not determined, under the HSNO Act. Depending on the circumstances, these applications may be determined under the new regime or the old regime or withdrawn. The schedule also outlines actions that applicants must take in relation to their pending applications.

Schedule 1 provides for decisions made, under the HSNO Act, by the EPA or the Minister responsible for that Act, before the commencement of the Bill or in relation to applications referred to in the schedule. *Schedule 1* also provides for any reviews or consultation undertaken before the commencement of the Bill.

Schedule 2: Consequential amendments to other legislation

Schedule 2 provides for a consequential amendment to the Imports, and Exports (Living Modified Organisms) Prohibition Order 2005. The amendment replaces the definition of Minister in that order to align with the definition in the Bill.

Schedule 3: Reviewable decisions

Schedule 3 lists the decisions, made by the Regulator under specified provisions, that a person may request a review for. The schedule identifies who may apply for a review for each decision listed. On application, the decisions are reviewed by the Regulator. *Subpart 1 of Part 5* outlines the requirements for a review application and the process of a review.

Schedule 4: New Part 8 inserted into Schedule 12

Schedule 4 inserts *new Part 8* into Schedule 12 of the Resource Management Act 1991. *New Part 8* provides for transitional, savings, and related provisions related to the Bill. In summary, *new Part 8* ceases the application of any rule or plan that permits activities relating to genetically modified organisms, but allows for the following circumstances:

- a person may continue to carry out activities, that were previously permitted under those rules or plans if those activities do not require a licence under the Bill or additional authorisation under any other legislation:
- if a person has obtained a resource consent because of those rules or plans, they have the option to surrender or not surrender that resource consent:
- if a person has lodged an application for a consent that has not yet been determined because of those rules or plans, they may elect for the application to be determined as if the rules or plans still apply.

Hon Judith Collins

Gene Technology Bill

Government Bill
110—1

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- 209 Section 45 amended (Notifiable organisms)
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Schedule 1
Transitional, savings, and related provisions
Schedule 2
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New Part 8 inserted into Schedule 12

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.
- (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 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, the identification of any material adverse effect on a kaitiaki relationship that may result from an environmental risk posed by an activity.

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

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

- (a) the Convention on Biological Diversity ; and
- (b) the Cartagena Protocol.

6 Outline of 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 as to 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:
 - (iii) establishing a licensing regime to permit persons to carry out activities in relation to regulated organisms, and providing for combined licence applications to be made jointly to the Environmental Protection Authority and the Regulator:
 - (iv) requiring a risk assessment or risk management plan to be prepared for all authorisations except emergency authorisations, and in response to significant new information received:
 - (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 medical authorisations in certain circumstances:
 - (ix) permitting the Minister to grant emergency authorisations to carry out activities in relation to a regulated organism 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, 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, 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:
- (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, 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:
 - (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:
 - (v) detailing how information and samples obtained under this Act may be shared or disclosed 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:
 - (iv) **Schedule 4** inserts additional provisions to 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 organism, means—

- (a) making, developing, fermenting, regenerating, producing, breeding, propagating, manufacturing, growing, raising, or culturing the regulated organism:
- (b) modifying an regulated existing organism (other than a human being):
- (c) supplying, importing, exporting, storing, or transporting the regulated 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:
- (e) releasing the regulated organism into the environment:
- (f) disposing of the regulated organism:
- (g) possessing the regulated 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)

containment facility, in relation to a regulated organism, means a facility registered 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, means making the regulated 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

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

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
 - (ii) any other technology specified in the regulations for the purposes of this paragraph

host organism means an organism that is the subject of a gene technology

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

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, 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 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 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-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 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 total genetic structure of an entity); but
- (b) includes an entity declared to be an organism by the regulations; and
- (c) does not include an entity declared not to be an organism by the regulations

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 and distributes synthetic nucleic acids in trade or for reward; and
- (b) includes a third-party vendor

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 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
- (b) does not include—
 - (i) an organism or a category of organisms declared by regulations not to be regulated organisms; 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—

- (a) means molecules, of any sequence length, that have been constructed outside living cells by joining nucleic acid molecules; and
- (b) includes—
 - (i) DNA and RNA, whether single- or double-stranded; and
 - (ii) whole-organism genomes (for example, viruses or bacteria)

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 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 where a person is a body of persons that is unincorporated, the successor includes a body of persons that is incorporated and composed of substantially the same members.

8 What is medical activity

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

- (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 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 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

transshipment activity, in relation to a regulated organism, means the importation into New Zealand of the regulated 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 or gene technology

12 Regulator may determine what constitutes regulated organism or gene technology

(1) The Regulator may, on its own initiative or on application by any person, determine whether or not—

- (a) any organism is a regulated organism; or
- (b) any technique is a gene technology; or
- (c) any organism or technique falls within an exemption made by **section 163(4)**.

(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 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)**, 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

A person must not carry out an activity in relation to a regulated organism unless—

- (a) the activity is a non-notifiable activity; or
- (b) the activity is 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 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)

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 medical authorisation; or
- (f) an emergency authorisation.

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 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, including details of the studies to be conducted:
- (g) auditing and reporting:
- (h) in the case of the release of a regulated organism from containment, actions to be taken :
- (i) the 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 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

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.

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.

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.
- (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; or
 - (b) a specified category of regulated 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; and
 - (b) an application under 1 or more of the following provisions of the Hazardous Substances and New Organisms Act 1996 that is made in respect of the same person, activity, and regulated organism:
 - (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 (transshipment 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 and 153* regarding sharing information 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 that uses an indigenous species as a host organism; and
 - (b) is not any of the following:
 - (i) a pre-assessed activity;
 - (ii) a transshipment 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; 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; or
 - (b) a specified category of regulated organisms.
 - (5) A declaration under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

24 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.
- (2) The Regulator must have regard to any written submissions received in the course of public consultation under **subsection (1)**.
- (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.

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;
 - (b) release drafts of the risk assessment and the risk management plan for public consultation under **section 28**.
- (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.

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 transshipment 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.

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.
- (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 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 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.

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.
- (3) However, if the 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.
- (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, the Regulator must give notice to the licence holder in writing, with reasons; and
 - (b) in relation to a pre-assessed activity, the Regulator must—
 - (i) give notice in the *Gazette* and on the Regulator's internet site with reasons; and
 - (ii) give notice to each person who holds a licence in respect of 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, prohibit or restrict any activity in relation to a regulated organism if—
 - (a) the Regulator has decided to prepare a new or an amended risk assessment and 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

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

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.
- (3) The Regulator may only issue a licence for a transshipment activity if the Regulator is satisfied that—
 - (a) the regulated organism that is to be transhipped can be adequately contained so as to protect 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.
- (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:
 - (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 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:
- (a) any conviction of the person 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 under a relevant law;
 - (c) if the person 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 in relation to the authority;
 - (iii) any disqualification from holding the authority;
 - (iv)

any contravention by the person of the authority or a provision of a relevant law that applied to the person as the holder of the authority:

- (d) whether there are other reasonable grounds to believe that the person is likely to contravene a provision of this Act:
 - (e) whether the person 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 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)**.

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 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.

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 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 transshipment 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 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, the person —
 - (i) must not release the regulated organism into the environment; and
 - (ii) must notify the Regulator and the enforcement agency in writing of any introduction of the regulated organism into the environment as soon as is reasonably practicable and 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 that the Regulator considers necessary 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 transshipment 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 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 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 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; 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; 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 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; and
 - (b) impose conditions 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; 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 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 transshipment activity if the Regulator is satisfied that—
 - (a) the regulated 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; 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 transshipment activity if the Regulator is satisfied that—
 - (a) the regulated 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.
- (2) If the Regulator decides to vary a licence, 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; and
 - (b) specify in the notice the day on which the variation 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**.
- (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 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—
- (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, a person carrying out the activity—
 - (i) must not release the regulated organism into the environment in the course of the activity; and
 - (ii) must notify the Regulator in writing of any introduction of the regulated organism into the environment as soon as reasonably practicable and 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.
- (4) A declaration 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; or
 - (b) a specified class of regulated organisms.
- (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 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 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, any person carrying out the activity—
 - (i) must not introduce the regulated organism into the environment in the course of the activity; and
 - (ii) must notify the Regulator in writing of any introduction of the regulated organism into the environment as soon as reasonably practicable and 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.
- (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; or
 - (b) a specified category of regulated organisms.
- (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.

- (4) After complying with any requirements under **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,—
 - (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.
- (7) *See* **section 126** about engagement with the Māori Advisory Committee in relation to declarations made under **section 47 or 48**.

Subpart 5—Mandatory medical authorisations

50 Regulator must grant mandatory medical authorisation

- (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 Regulator may impose any conditions on a mandatory 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)**.
- (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.
- (7) *See* also **section 16** (authorisation of medical activities does not count as approval for other purposes).
- (8) A mandatory medical authorisation is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

51 Prerequisites for revoking mandatory medical authorisation

The Regulator may only revoke a mandatory medical authorisation if the Regulator considers that—

- (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.

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 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 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; or
 - (b) a specified category of regulated 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 the extension.

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, declare that a person in another jurisdiction is a recognised overseas authority for the purposes of 1 or more of the following provisions:
 - (a) **section 50** (mandatory 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 under **subsection (1)** if the Regulator is satisfied that—
 - (a) the person operates in a manner comparable to the Regulator in regulating gene technology; and
 - (b) the person operates under a legislative framework for regulating gene technology that is comparable to that of New Zealand; and
 - (c) the person 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, revoke a declaration made in relation to a person if the Regulator considers that the person no longer meets 1 or more of the criteria in **subsection (2)(a) to (c)**.
- (4) Before declaring a person 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
 - (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.

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 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 vendors approved under **section 149**; 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**.
- (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
 - (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.
- (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 were the Minister of Health, in relation to confidential information received in respect of a licence application if—
- (a) the regulated organism to which the application relates is or has been the subject of an innovative medicine application; 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 were the Director-General, in relation to confidential information received in respect of a licence application if—
- (a) the regulated organism to which the application relates is or has been the subject of an innovative TNP application; 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; 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.

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

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 any installation on or under land, on the bed of, or under, or floating on any waters.

Subpart 1—General

63 Enforcement of 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, 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 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, 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

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 enforcement officer may direct the owner or person in charge of a regulated organism, or the occupier of a place where a regulated 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:
 - (b) take steps to contain the regulated organism or prevent its spread:
 - (c) move the regulated organism to another place or dispose of it:
 - (d) if there are reasonable grounds to believe an organism, organic material, or thing contains a regulated 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 is or may be present:
 - (f) report the presence or suspected presence of a regulated 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, organism, organic material, or thing are in breach of a specified legislative requirement; or
 - (b) the person is in possession of a regulated organism in respect of which an activity has been carried out in breach of a specified legislative requirement; or
 - (c) a regulated 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, or the occupier of any place where the regulated organism is or may be present.
- (4) However, if the enforcement agency is satisfied that the occupier of a place where the regulated organism is or may be present was not aware that it was a regulated 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 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 is present; or
 - (c) synthetic nucleic acid is synthesised or distributed; or
 - (d) benchtop nucleic acid synthesis equipment is manufactured; or
 - (e) devices, equipment, or information connected to activities regulated by the Act or regulated organisms are 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 concerning,—
 - (A) an organism in, on, or attached to the place; or
 - (B) a regulated activity; or
 - (C) the provision of synthetic nucleic acid; or
 - (D) the manufacture 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:
- (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 enforcement agency 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 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)**.
- (2) If the 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.
- (3) The 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 in breach of **section 13**; and
 - (b) knows that, or is reckless as to whether, the person has carried out an activity in relation to a regulated 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 in breach of **section 13**.
- (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 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 medical authorisation).
 - (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 medical authorisation.
- (2) The person is liable on conviction, if the activity is a notifiable activity or an activity for which a mandatory 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 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)** (conditions related to approval of manufacturer or provider); 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—
 - (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
 - (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 either or both of the following persons in performing a function or duty, or exercising a power 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); and
- (b) knows that the person has breached **section 149(5)(a)** 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 synthetic nucleic acid;
- (b) manufactures benchtop nucleic acid synthesis equipment.

- (3) The person is liable on conviction for the offences in **subsection (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 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 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 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.

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 and must include the same particulars, or substantially the same particulars, as the infringement notice.

Subpart 5—Pecuniary penalties for breaches of 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):
 - (b) **section 14** (person must not breach conditions of authorisation):
 - (c) **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**.

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.

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) an order that the person mitigate or remedy 1 or more adverse effects referred to in **subsection (2)** that—
 - (i) are 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 related to the person'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 (*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.

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**;
- (b) the power to give general policy directions to the Regulator (*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.
- (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.
- (5) The EPA must provide administrative support for the 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 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.

111 Performance of functions, duties, and exercise of powers

- (1) In performing their functions and duties and in exercising their powers, the Regulator—
 - (a) must act independently of the EPA and the Minister; but
 - (b) is subject to general policy directions given by the Minister.
- (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.
- (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 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.

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:
 - (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 and the 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.
- (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 certain organisms or gene technologies from the operation of the Act under **section 163** if the proposal relates to an organism that uses an indigenous species as a host organism; and
- (b) provide advice to the Regulator about whether material adverse effects on kaitiaki relationships may result from an environmental risk 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 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**;
- (ii) preparing a new or amended risk assessment or risk management plan prepared in accordance with **section 29**;
- (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 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 that uses an indigenous species as a host organism.
- (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** 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.

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 that they have a kaitiaki relationship with an indigenous 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 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 to the Regulator for every assessment and recommendation that it makes.

130 Proposed conditions to be considered when assessing adverse effects on kaitiaki relationship

In assessing under **section 127(1)(a)** whether an activity 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.

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.
- (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 as a host organism; or
 - (ii) a particular iwi, hapū, Māori individual, or Māori entity and the indigenous species; and
 - (b) if it is 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 (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 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 review.

137 Effect of review

- (1) The original decision described in **Schedule 3** is valid until the reviewer modifies or reverses it or makes a new decision.
- (2) If the reviewer confirms, 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.
- (3) If the Regulator undertakes a review, there is no further right to seek a review on the decision made on the review.
- (4) For the purposes of any appeal, the decision appealed against is—
 - (a) the decision made on the review, if the Regulator undertakes a review; and
 - (b) the original decision, if the Regulator does not undertake a review of that decision.

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.

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

- (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 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 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 or the environment; and
 - (c) whether it is unreasonable for the person appealing against the compliance order or the 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, **eligible person** means a person who is directly affected by a decision referred to in **subsection (1)**.

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.

144 Right to appeal and be heard on appeal

- (1) A party to any proceedings or any person who made submissions to the Regulator 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 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

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—
 - (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.

150 Regulator may issue or approve standards for minimising risks to health and safety

- (1) The Regulator may issue or approve standards for the purpose of ensuring that risks to the health and safety of people and the environment are minimised.
- (2) Standards may be issued or approved under **subsection (1)** for—
 - (a) activities carried out in containment, activities carried out in the environment, and any other kinds of activities;
 - (b) different kinds of authorised activities (for example, activities that are notifiable and activities that require a licence to carry out);
 - (c) activities related to a regulated organism of a category of regulated organisms or a subset of those activities (for example, an activity relating to a micro-organism or the disposal of micro-organisms);
 - (d) containment facilities that have been developed by another agency.
- (3) Standards issued or approved under **subsection (1)** may include—
 - (a) requirements for record keeping and reporting;
 - (b) the conduct of internal audits or requirements relating to supervision, monitoring, or verification;
 - (c) requirements for the collection of data and samples, and the conduct and details of studies to be undertaken;
 - (d) actions to be taken in case of the release of a regulated organism from containment.
- (4) The Regulator may approve standards referred to in other 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, amend, revoke, or replace a decision under **subsection (1)**.
- (6) Despite **subsection (5)**, the Regulator may amend their decision 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—
- the information described in **subsection (2)**; and
 - the agencies specified in **subsection (3)**.
- (2) The information is—
- personal information as defined in the Privacy Act 2020 that is supplied or obtained under or for the purposes of this Act; and
 - information related to gene technology or regulated 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:
- the Agricultural Compounds and Veterinary Medicines Act 1997:
 - the Animal Products Act 1999:
 - the Animal Welfare Act 1999:
 - the Biosecurity Act 1993:
 - the Customs and Excise Act 2018:
 - the Food Act 2014:
 - the Imports and Exports (Restrictions) Act 1988:
 - the Hazardous Substances and New Organisms Act 1996:
 - the Health Act 1956:
 - the Human Assisted Reproductive Technology Act 2004:
 - the Human Tissue Act 2008:
 - the Medicines Act 1981:
 - the Misuse of Drugs Act 1975:
 - the Psychoactive Substances Act 2013.
- (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—
- 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 other legislation referred to in **subsection (3)**; or
 - 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.
- (5) An agency may impose conditions the agency thinks fit relating to the disclosure, including—
- the use and storage of information; and
 - the copying, returning, or disposal of information; and
 - the further disclosure of information.
- (6) The agency that discloses the information must make and keep a record of—
- the information that was disclosed; and
 - the agency to which it was disclosed; and
 - 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
 - (b) information related to gene technology or regulated 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.

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 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 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.

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 or organic matter relating to a regulated 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 163** and **165**:
 - (b) prescribing information to be provided with any application for a licence relating to regulated organisms:
 - (c) prescribing requirements for enforcement officers appointed under **section 64** who perform functions relating to regulated organisms:
 - (d) prescribing fees, charges, and levies, or a method of calculating any of those things, and providing for waivers of exemptions from, and refunds of, any of those things, for the purposes of this Act:
 - (e) prescribing matters relating to the Technical Advisory Committee and the Māori Advisory Committee:
 - (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 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 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 the suspension or cancellation of those approvals in circumstances specified in the regulations:
 - (f) prescribing reporting, record-keeping, and data security requirements in relation to **paragraphs (a) to (e)**.
- (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 about where and how non-notifiable activity must be undertaken (for example, a requirement that a 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 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 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 under this Act.
- (2) The timetables referred to in **subsection (1)** include, without limitation, timetables for the following:
 - (a) the Regulator to make certain determinations about regulated 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 to provide advice under **section 27** to the Regulator on matters relevant to the preparation of the risk assessment and risk management plans:
 - (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:
 - (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 for timetables set out in this Act to be extended or shortened, paused and reactivated, or replaced.

161 Regulations setting criteria and conditions for activities, risk assessment and risk management plans, etc

Regulations may be made under **section 155(1)(a)**—

- (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 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**.

163 Power to make further exemptions from operation of Act and non-regulated activities

- (1) Regulations may be made under **section 155(1)(a)** exempting from the operation of this Act—
 - (a) organisms or categories of organisms specified in the regulations:
 - (b) gene-editing techniques or gene technology specified in the regulations.
- (2) The Minister must not recommend the making of regulations—
 - (a) referred to **subsection (1)(a)**, in the case of an organism or a category or organisms, unless the organism or category of organisms cannot be distinguished from organisms or categories of organisms created through conventional processes:
 - (b) referred to **subsection (1)(b)** unless the Minister is satisfied that the gene-editing technique or gene technology in question creates no more than a minimal level of risk to the health and safety of people or the environment.
- (3) Regulations made under **section 155(1)(a)** 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).

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).

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 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
 - (b) consult the Regulator on the proposed regulations; or
 - (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 must allow the person or persons consulted at least 30 working days to comment on the proposed regulations.

Subpart 6—Incorporation by reference

168 Definitions for 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* that—
 - (a) states that the material has legal effect as part of the document; and
 - (b) specifies the date on which the 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)**.

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.

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, and cost recovery

173 Fees and charges payable

Any person making an application under this Act must pay the prescribed fees and charges (if any) except as provided in **section 174**.

Compare: 2023 No 14 s 52

174 Regulator must consider exemption, waiver, or refund of fees

- (1) The Regulator must, on application, consider an exemption, a waiver, or a refund of fees, charges, or levies if the Regulator is authorised to do so by regulations made under **section 155**.
- (2)

The Regulator 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 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 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 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 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 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—
 - (a) a debt due to the Regulator; and
 - (b) recoverable as a debt by the Regulator 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.
- (3)

The Regulator 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—
- 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
 - 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 about the person's liability to pay a fee, charge, levy, or penalty under this Part does not suspend—

- the obligation of the person to pay the fee, charge, levy, or penalty; or
- the right of the Regulator 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, 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—
- the debt is paid within 20 working days; or
 - the Regulator agrees that the debt or part of the debt is not payable.
- (2) The matters are—
- the debt has been correctly calculated; and
 - the notified time for paying the debt has expired; and
 - 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 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—
- delivered personally or posted to the person at the person's address for service or last known place of residence or business; or
 - sent by fax or electronic communication to the person's last known fax number or electronic address; or
 - made available to the person in accordance with a prescribed electronic delivery method (if permitted under the regulations).
- (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:
 - (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.
- (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.

Revocations and consequential

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 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”.

195 Section 16 amended (Time limits and waivers)

(1) In section 16(2), after “organism”, insert “or regulated organism”.

(2) In section 16(3),—

- (a) after “new organism”, insert “or regulated 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; 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; 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)(viii**b**), insert:

(viii**c**) 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 organism means a regulated organism that is approved by the Gene Technology Regulator for use in an activity that is—

- (a) a notifiable activity or a non-notifiable activity, as those terms are defined in **section 7(1)** of the Gene Technology Act **2024**;
- (b) 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 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 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 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 unless that organism is an authorised regulated organism.

204 Section 28A amended (Dealing with suspected new organism)

- (1) In the heading to section 28A, after “**organism**”, insert “**or regulated organism**”.
- (2) In section 28A(1), after “new organism”, insert “or a regulated 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.

- (4) In section 28A(6), after “new organism”, insert “or a regulated 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—
- (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.
- (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**”.

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 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
- (e) the terms (including any conditions imposed by the Gene Technology Regulator under the Gene Technology Act **2024**) upon which a regulated 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 is contained in the facility.

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), insert:

(na) 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) to regenerate a new organism from biological material of the organism that cannot, without human intervention, be used to reproduce the organism;
 - (ii) to carry out large-scale fermentation using a micro-organism that is a new organism;
- (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 (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 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 (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 (within the meaning of that 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, 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 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.
- (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, 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 Technology Act 2024 and determine nature of organism in, on, or attached to place	All (except subparts 2,3, and 8 and sections 118 and 119)
	70	Enforcement officer may enter and inspect home or marae under search warrant	All (except subparts 2 and 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,—

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)**.

2 Pending applications 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 within the meaning of this Act; and
- (b) any required fee has been paid in order to lodge or determine that application; and

- (c) that application has not been determined by the EPA, as at commencement.
- (2) The applicant may, at any time 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; 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 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.

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
- (b) any appeal in relation to a determination of that application.

4 **Application transferred to the Regulator by EPA**

If an applicant elects under **clause 2(2)(b)** to have the determination of their application transferred from the EPA to the Regulator,—

- (a) the EPA must, as soon as is reasonably practicable, transfer the application and all supporting documentation to the Regulator; and
- (b) the Regulator may—
 - (i) make any inquiries of the applicant that the Regulator considers necessary to clarify the type of approval that the applicant is seeking or needs to obtain under this Act; and
 - (ii) require the applicant to supply any further information that the Regulator considers necessary to determine the application under this Act.

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.

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 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.
- (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.
- (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.

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.

9 Minister may call in certain applications after commencement

- (1) This clause applies if, after commencement, any application referred to in **clauses 1 to 5 and 7** is being determined under the HSNO Act and any regulations made under that Act.
- (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 **clauses 1 to 5 and 7**.
- (3) If the Minister calls in an application where **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.

10 Withdrawal of application if clause 8 or 9 applies

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.

11 Deemed withdrawal of application

- (1) This clause applies if an applicant fails to provide information where an application referred to in **clauses 1 to 7 and 8 and 9** is to be or is being determined in accordance with the HSNO Act and any regulations made under that Act and the EPA requests the applicant to provide further information, but—
 - (a) the applicant does not earlier withdraw their application or transfer it to the Regulator for the issue of a licence under this Act; and
 - (b) the applicant fails to provide the further information within 3 months from the date of the request.
- (2) If this clause applies, the application must be treated as having been withdrawn.

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.
- (2) The Regulator may not revoke a decision under **subclause (1)** unless the Regulator is satisfied that the activity related to that decision will continue to remain lawful because—
 - (a) the genetically modified organism is not a regulated organism; or

- (b) the genetically modified organism is used for an activity that is not regulated 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.
- (3) For the purposes of deciding whether the activity authorised by the decision satisfies the criteria for the issue 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 of new information about risks);
 - (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)**, it continues to apply in respect of any new organism to which it previously applied if that new organism is not genetically modified.

13 Review of conditional release or qualifying organisms

- (1) This clause applies if—
- (a) the EPA has commenced a review,—
 - (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 paid in order to lodge or determine that review; and
 - (c) the review has not been completed by the EPA at 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 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; 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 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 **section 155** (procedure for making regulations) is deemed to have been undertaken on and after the commencement of that section.

Schedule 2

Consequential amendment to other legislation

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Imports and Exports (Living Modified Organisms) Prohibition Order 2005 (SR 2005/12)

In clause 3, replace the definition of **Minister** with:

Minister has the same meaning as in **section 7(1)** of the Gene Technology Act **2024**

Schedule 3

Reviewable decisions

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Section	Description	Who may apply for review
12(1)	Determination on regulated organism or gene technology	Applicant
33(1)	Decline or approval of application for licence	Applicant
33(3)	Decision on licence for transshipment	Applicant
36	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 to transfer licence	Licence holder and applicant for transfer
45	Decline or approval of request to vary licence or conditions of licence	Licence holder

Schedule 4

New Part 8 inserted into Schedule 12

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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.