agresearch
āta mātai, mātai whetū

Submission on the Gene Technology Bill

Introduction

AgResearch is one of seven Crown Research Institutes in Aotearoa New Zealand. Its purpose is to use science to enhance the value, productivity and profitability of New Zealand's pastoral, agri-food and agri-technology sector value chains to contribute to economic growth and beneficial environmental and social outcomes for New Zealand. AgResearch has science capability in plants, animals and microbes, including in the use of gene technology to improve productivity and value from the organisms involved in New Zealand's pastoral systems.

Research programmes currently running within AgResearch that utilise gene technology include:

- *High Metabolisable Energy (HME) Ryegrass.* Increased levels of plant oils compared to non-modified ryegrass increase the amount of metabolisable energy available to livestock, potentially increasing productivity. Researchers have also demonstrated that HME Ryegrass reduces methane emissions from livestock.
- *High-Condensed Tannin White Clover.* Condensed tannins produced in flower petals can also be produced in the leaves of clover. This is expected to result in a similar level of methane reduction as HME Ryegrass, as well as reducing nitrogen losses and increasing animal health.
- *Gene-Edited Endophytes.* Epichloë endophytes are fungi which have a symbiotic relationship with plants such as pasture grass to protect the plants from insect pests, improving pasture yields and persistence. However, endophytes can also produce compounds that are harmful for livestock. Gene editing endophytes aims to prevent production of compounds affecting livestock, but maintaining or improving those that provide protection from pests.

General comments on the Bill

AgResearch supports the development of the Gene Technology Bill and its application of up-to-date scientific knowledge to categorise activities according to the real-world risks of gene technologies on human health and the environment. We see the Bill as providing the opportunity to align New Zealand's activities and regulations with those of our major trading partners (e.g. the USA, Australia, China, potentially the EU). Regulations of gene technologies within multiple overseas jurisdictions has enabled New Zealand to review how they have operated alongside a range of adjunct regulations then develop the Gene Technology Bill based on best practice.

As a user of gene technology in research, AgResearch's work has been impacted by the current regulatory regime through the Hazardous Substances and New Organisms Act. We envisage that the Gene Technology Bill will enhance research with potential for improved human health, export revenue, reduced environmental impact, and so on. We anticipate a reduction in the number of time and resource-intensive processes set by regulations that are not aligned with risk and providing a clear pathway for regulatory approval of a new modified crop/organism/etc. As part of the enabling process we are relying on the new Regulator to be suitably resourced to manage the expected workload. This will be particularly important for the first 2-3 years as the regulations become embedded within the organisations using gene technology and a potential surge in requests for licences.

Application of gene technologies

We support that there are no assessment criteria about the benefits of an Activity. We also support the real-world use of any organism developed through the application of gene technology is expected to be driven by the actual benefits to the users, rather than the benefits predicted during the research and development phases. Benefits and Costs, as well as business risks, are best

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assessed by the users, and the management of production and processes to differentiate value-added products is already managed within supply chains.

We wish to note that gene technologies raise the possibility of cross-industry effects. For example, if pollen from a genetically modified pine tree was found on an organically-grown apple, would current limits set by NZ's organics industry body mean that the apple would fail to meet the industry's standards? Liability issues relating to marketing, trade, or other matters can be addressed in the courts via civil actions. However, if the Gene Technology Regulations and relevant industry standards could be suitably aligned before the Bill is passed, then a significant number of claims could be avoided. We believe that prior to the expected date of the Final Reading work should be resourced and undertaken to achieve alignment across the various production, processing, and exporting systems within agriculture, horticulture, forestry, and so on.

The widespread use of modified crops in countries with a flourishing organics industry (e.g. Australia, the USA) shows that a combination of on-farm strategies, regulations, and management of supply chains and product streams allows multiple farming systems to carry out their core business without disrupting neighbouring producers. New Zealand doesn't have the large-scale monocultures associated with many of the modified crops (e.g. maize, soy, canola) where separation strategies would have a smaller impact as a proportion of the total crop area. However, there is nothing to indicate that controls required for all industries to thrive cannot be successfully developed and implemented in NZ. This would include how to delegate costs associated with co-existence (e.g. testing for non-gm status not currently required because NZ has no gm crops).

Review of selected clauses

3 - Purpose

Align cross-industry production, processing and exportation systems

The Bill does not seek to deal with issues related to the commercial application of gene technologies. Liability issues relating to marketing, trade, or other matters may be addressed in the courts via civil actions, but unless the Gene Technology Regulations and relevant industry standards are suitably aligned there is the risk that a significant number of avoidable claims will be filed with the courts in the first 1-2 years following the passing of the Bill. **We recommend** that, prior to the expected date of the Final Reading, government should resource work to achieve alignment across the various production, processing, and exporting systems within agriculture, horticulture, forestry, and so on.

6 - Outline of Act

Clarification of terms used in the Bill

Clause 6 could usefully be replaced or augmented with text which contains information which is similar to the Risk tiers and authorisations part of the Explanatory Note to the Bill, or a table similar to the table in paragraph 19 of the *Regulation of gene technologies – policy* decisions Cabinet paper which was publicly released by MBIE. One of the issues we have found with interpreting the Bill is that the levels of activities and the types of authorisation are not readily understood without having these terms in one place. **We think this is a risk for the Act** once it is passed unless there is some concise information explaining these terms. As it is, clause 6 seems to summarise the Contents and isn't overly useful.

7 - Interpretation

Containment

Recognise that biological characteristics create limitations

The examples used for '*containment*' are all physical structures, whereas biological characteristics may limit (i.e. contain) an organism to specific environments (e.g. the absolute need for specific nutrients or growing conditions). **We recommend** that regulated organisms, or those at specific growth stages, with highly restrictive growth and/or reproductive requirements be included in lists of Exempt, Non-Notifiable, and Notifiable Activities, together with risk-appropriate containment levels. For example, pine trees reach maturity at 6-12 years old and cones take >12 months to mature, therefore modified pines could be maintained at a low level of containment up to two years prior to expected sexual maturity.

Conventional processes

Pathway for non-regulated processes

We support section (b) of this interpretation because it provides a path to consider currently undefined processes as non-regulated in the future.

Environment

Include human working environments

We recommend that this definition is expanded to explicitly include the human-created-and-occupied environment, in addition to the natural environment. Managing risk to the environment is one of the key purposes of the Bill, and in that context we believe this should include the likes of the on-farm environment, amongst other human environments. While the definition isn't a limiting definition, we believe it should be more definitive in including the human environment.

Gene technology—

Include heritability

We recommend that clause 7(1)(a) is simplified to: "*any technology used to modify or construct* **heritable** *genetic material.*"

Indigenous species

Clarify indigenous species

History suggests that it will be extremely difficult to define *indigenous species* to a standard that does not cause ongoing litigation. For example, how might the following cases be defined:

- A species that is sourced from another country but capable of crossbreeding with local varieties.
- Organisms associated with non-indigenous species (e.g. microbes that inhabit the rumen of sheep grazing in New Zealand; organisms inhabiting the roots or leaves of pine trees).

We recommend that this definition is clarified.

Regulated organism

Simplify regulated organism wording

We recommend that clause 7(1) *regulated organism*(a)(ii) be modified to remove brackets: "*an organism that has inherited from a host organism genes or genetic material that occurred in the host organism because of gene technology.*"

12 - Regulator may determine what constitutes regulated organism or gene technology

Enabling external input into determinations

We support clause 12(3)(c) that allows for external expertise to have input into the determination. It is an improvement on the corresponding section in the HSNO Act, which only allowed the EPA to make determinations on whether an organism was a new organism if someone submitted a successful application. Given rapidly evolving technology, the Regulator being able to make determinations about whether a particular technique is gene technology, whether an organism or technique falls within exemptions, and to do this on their own initiative, are all positive improvements that will enable more rapid and responsive classifications to be made.

15 - Conditions that may be imposed in relation to authorisation

Ensure science-based balance is carried through to Licensed Activities

While, "*The current regulatory regime.. inhibits the development and use of safe gene technologies and products"* (Cabinet Paper, 10Dec24; [CP]), **it is difficult to see how the Bill will change activities** that may encompass small-scale research projects (e.g. field trials). We find this particularly relevant following recent experience in developing plans and drafting an Application to undertake a Field Test (EPA0324). **We recommend** that the Regulations are designed to ensure that the systems for managing the application of innovative gene technologies achieve a science-based balance between the Purpose of the Bill and a solution to the 'missed opportunity' as outlined in the Problem Definition of the Regulatory Impact Statement.

21 - Certain licence applications must contain additional information about kaitiaki relationships

Encoding unique traits of indigenous species

This clause only relates to an indigenous species as a host. **We recommend** that this section also includes the use of DNA sequences encoding unique traits of an indigenous species.

24 - Revocation of declaration of pre-assessed activity

Clarify revocation

We recommend that this section is clarified because there are no details on how to manage work being undertaken under the Pre-Assessed Activity prior to revocation. Revocation could result in significant negative impacts on an organisation, such as loss of potential return on costs already invested. As part of due diligence preceding an investment in research, we need more information to give more certainty over outcomes.

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

Technical advisory group input

We support input from the Technical Advisory Committee as being critical for an Authorisation, as well as the information supporting any decisions around an Authorisation, which may be used to inform future Authorisations.

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

Strong governance of Licensed Activities

We support clause 28(2) in that there are higher risks associated with Licensed Activities. We note that this is not a requirement if sufficient information is already available, or if the activity is contained.

49 - Prerequisites for making, varying, or revoking declarations under section 47 or 48

Clarify application of 'minor in effect'

Experience with the current process has shown that amendments to an Approval that may have been minor in effect (e.g. the addition of a host species) have not been permitted and have required a new Application to be submitted. This apparently arose because sequential requests for a Variation would not have been minor in effect in their totality if they had been added to the Approval (e.g. extending activities beyond the original Purpose). While the term 'minor in effect' does allow the Regulator to apply their expertise effectively, **we wish to note** that this step can be unintentionally redirected, and that a mechanism in the Regulations for scheduled review of the Variation process would be beneficial.

58 - Regulator to maintain register

Clarify focus of the register of Activities

Clause 58(1)(e-g) requires clarification in that the register must contain details on what constitutes these Activities, rather than a register of the application of these Activities. As it currently reads it could appear that any development considered to be one of the activities, including individual laboratory experiments, would have to be recorded in the register.

Clarify stage at which items enter the register

As it may be difficult to define the exact stage at which a draft would enter the register, and as an early-stage draft may contain little valuable information, **we recommend** that 58(3)(e) should either be removed or modified to read:

> *(e) any draft risk assessment and risk management plan prepared in relation to the item**, and released for public consultation**~~, if not yet finalised~~; and*

80 - Offence to give false or misleading information

Reconsider strict liability offence

We question whether clause 80 should appropriately be categorised as having a strict liability option. If a person knows information is false or makes no effort to check it, they will be caught by the offences in subclauses (1) or (3). We believe the strict liability offence may catch people who have a genuine honest belief that information is correct, even if that is not the case. They may not have the defences listed in clause 84 available to them in the circumstances if they have not relied on another person. If a strict liability offence is still desired, consideration should be given to articulating a defence of honest belief, or the availability of the more general absence of fault defence.

112 - Delegation of functions and duties and powers of Regulator

Simplify delegations

Subclause (1) currently excludes delegation of the powers listed in subsection (2), but those powers can be delegated under that subsection. **We recommend** that phrasing of subclause (1) is changed to:

> *(1) Subject to subsection (2), the Regulator may delegate to any suitably qualified and trained person any of their functions, duties, or powers, other than this power of delegation.*

113 - Technical Advisory Committee

Support Technical Advisory Committee

We support clause 113(1) because the Regulator as an individual can't be expected to be sufficiently expert in all fields necessary to have an informed view on all types of decisions needing to be made by the Regulator.

120 - Māori Advisory Committee

Decision-making Māori Advisory Committee

We support the establishment of a Māori Advisory Committee because the Regulator cannot be expected to be expert in tikanga concerning indigenous species and kaitiaki relationships, but it is very important that these are considered carefully in the application of the Act. Through our experiences with the Kaupapa Kura Taiao team within the EPA we see that a Māori Advisory Committee could provide applicants with excellent guidance on considering how Activities may impact Māori. **We support** adopting the Plant Variety Rights Act model for the committee, and **we recommend** that the committee is a decision-making body for organisms where direct kaitiaki relationships exist.

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

Effective management of health and safety risk

We note that the terms '*minimising*' and '*minimised*' set a very high bar and are likely to have the same inhibitory effect on the development of new technologies important to human health, the environment, and productivity, as the current legislation. **We recommend** that these two terms are modified to '*effectively managing*' and '*effectively managed*', respectively.