Submission on the Gene Technology Bill

TO: Health Select Committee

FROM: Grasslanz Technology Limited

Contact; Dr John Caradus, CEO

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Grasslanz Technology Limited

Grasslanz Technology Limited, a subsidiary of AgResearch, is a plant and microbial technology provider that focuses on providing proprietary technologies for farmers. The company works with international investors and research organizations to develop innovative new products and establish partnerships with companies for commercialisation. The vision is to expand its forage and microbial technologies while embracing biotechnology opportunities. The company has several subsidiaries and joint ventures, including Grasslands Innovation Limited, MI8 Optics Limited, AgResearch USA Ltd, Grasslanz Technology Australia Pty Ltd, and Endophyte Innovation. Employees have expertise in plant breeding, nucleus seed production, research project management, intellectual property management, contract management, product development management, and customer relationship management.

Submission

In principle Grasslanz Technology Limited supports the intent of the Bill with the following comments.

We support:

1. The purpose of the Bill to enable the safe use of gene technologies by managing their risks to the health and safety of people and the environment.

2. The intent of establishing a new regulatory regime for gene technology and genetically modified organisms (GMOs) with a more enabling and modern system.

3. The objectives of the Bill which seek 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.

4. The objective of having a "*nationally consistent approach to regulation of gene technology by removing local authorities' ability to restrict its use*". We must work avoid regulatory variations

across the country. We therefore support the removal of the ability for territorial authorities to restrict the use of gene technologies which have been approved by the regulator.

5. The formation of an independent single decision maker acknowledging that it:
    - Has worked well in Australia for 20 years.
    - Increases efficiency and reduces process time.
    - Provides for clear accountability.
    - Reduces the risk that process will be politicised.

6. The housing of the Regulator in the Environmental Protection Authority. However, the appointment of the Regulator should not be restricted to employees of the EPA, but we agree that the Regulator should become an employee of the EPA.

7. The establishment of a Technical Advisory Committee (subject to comments made below) and Māori Advisory Committee and that these committees do not have decision making powers.

8. The removal of assessment criteria about the benefits of an activity because:
    - The Regulator is not well placed to make such assessments which are subjective and moves the Regulator away from evidence-based decision making.
    - Balancing risk and benefit can often result in lowering the risk threshold.
    - MFAT advises (p8 RIS) that the international trade environment is unpredictable, and assurance processes can be complex. Leaving trade market decisions to producers is in line with government policy.

9. The exclusion of explicit references to the "Precautionary Principle" because:
    - The Precautionary Principle is unhelpful in this context as it can be applied to both not approving an activity or approving it.
    - Interpretation of the meaning of the Precautionary Principle can be variable.
    - Science-based risk assessment includes the requirement for caution where there is uncertainty, thus the Bill is consistent with international agreements such as the Cartagena Protocol in this respect.

10. The exclusion of supply chain segregation and identity preservation regulations. These are better managed by the market. The organics industry already has segregation and identity preservation practices in place so much of the costs are already occurring. We agree with the Regulatory Impact Statement (para 505) that "*additional costs to obtain [a GE-Free] premium should be borne by those seeking to obtain value from it*". Besides which, countries such as Australia and the USA who are benefitting from genetic technologies in their agriculture production systems and who also have productive organic industries rely on market mechanisms.

<u>Some considerations:</u>

1. We are aware that the legislation is only designed to enable the Regulations to be set by the Regulator and appear in the Secondary Legislation/Regulations. But the result is that the Bill

lacks a significant amount of detail and some confusing logic particularly with regard to the decision-making activities (Clauses 47, 48 and 49). We would suggest that Clause 49 comes before clauses 47 and 48 and better definitions of the criteria to be used for deciding what might be 'notifiable' and 'non-notifiable' activities is described.

2. The establishment and membership of the Technical Advisory Committee will be critical for the delivery of practical outcomes that result in improved environmental, economic and social outcomes for New Zealand. In Clause 114 (3) there is a list of skills, knowledge, or experience required on the Technical Advisory Committee. We believe the capability of *plant breeding* (and animal breeding for that matter) should be added to the list. This is different to plant genetics – it is more applied and more likely to have a delivery of a technology than someone working as a plant geneticist. Plant breeders also understand the interaction between genetics and environment.

3. The regulatory regime covers gene technology activities (for example, making, breeding, culturing, supplying, importing, or releasing a regulated organism) and genetically modified organisms (except humans) that have been modified or constructed by gene technology. So, this is then a mix of regulations based on process used and product outcome. We believe a better more holistic system is to simply regulate on the risk of the product outcome – this would then ensure that any changes in methods of genetic modification in the future are covered because it is the risk associated of the product rather than the process that is used to decide how it should be regulated.

4. The Bill has a 4-stage risk tier framework – these categories are "*exempt activities*", "*non-notifiable activities*", "*notifiable activities*" and "*licensed activities*". It is unclear at what stage, and what processes are to be used to categorise gene related activities into these 4 categories. It seems that a lot rests on the Technical Advisory Committee to advise the Regulator, which is appropriate but the Regulations that follow this Bill need to clearly define the limits of the 4 stages of risk. For example, how do "*exempt activities*" differ from "*non-notifiable activities*"?

5. In many places in the Bill the apparent need for legal boundaries makes it difficult for the reader to clearly understand the intent. We need the Bill to be written so that it is clearly understood.

6. We support the stated definitions of organism, regulated organism, conventional processes and environment. The definition of *Environment* which is appropriately limited to "*ecosystems and their constituent parts, natural and physical resources, and the qualities and characteristics of locations, places, and areas*" will enable the Regulator to make decisions in an objective and evidence-based manner.

   However, some definitions are concerning:

   - The meaning of *Gene Technology* which is critical for understanding the definition of a regulated organism is defined as "*means any technology used to modify or construct genes or other genetic material*". We question suitability of the use of "*modify or construct genes or other genetic material*." We do not believe the proposed definition aligns with one of the stated objectives of the bill to "*include definitions of terms such as regulated organism and gene technology that can be clarified to account for potential future*

changes to gene technologies". We suggest this is changed to simply using *modifying heritable genetic material*.

- There is no definition for what constitutes a "*very low*" or "*low"* risk activity and yet a stated objective is to "*enable some products of minimal risk gene editing to be exempted from regulation*". So, what guidance does the Regulator have in deciding which technologies or outcomes can be listed as *very low* or *low* risk? This is pertinent because under Section 47, the Regulator can declare that the activity is non-notifiable, but first (as per Section 49) they must seek advice from the Technical Advisory Committee. Once they have done that, they then have to publish notice of their intention to make an activity 'non-notifiable' and invite public submission. Same process for declaring activities notifiable. So, with no definition for what constitutes a *very low* or *low* risk activity how can non-notifiable activities be fairly and consistently determined?

7. What are the criteria for a "*non-notifiable activity"* and when, who and how is that decided? Clause 58 (1) (e) – indicates that a register of non-notifiable activities is to be maintained. But if they are non-notifiable how can a list be assembled? The issue probably is in defining clearly what is meant by a "*non-notifiable activity"*.

8. Economic concerns/market risk are not part of the considerations of this Bill, and one might assume of the regulations. How can we ensure that the removal of trade as an assessment criterion does not create tension with primary sector exporting entities? Effective engagement with these entities during the establishment of the regulations will be critical. Having said that, it is acknowledged that the direction indicated by the Bill to exempt organisms which could have been produced using conventional processes brings us into line with our trading partners.

9. Engagement with Recognised Overseas Authority (section 153), particularly in regard to declaring pre-assessed activities, needs a better description of the standards required to control the information to be shared. Levels and requirements of confidentiality need to be better described, so at the very least they contain conditions which are no less onerous than those imposed on the Regulator with respect to the confidential information provided.

10. Public consultation – section 28. The Regulator should be given more leniency here in the need to engage. Therefore, consultation should be based on whether there is a reasonable public interest and adopt similar wording as used in section 95B of the RMA.

11. What is the proposed interpretation of the licensing? It isn't clear whether a company granted a license (under Section 19(4)), would have background checks done on all employees? When selling GM forages/crops, who would need the license – the wholesaler or the retailer, and every employee of those companies?

12. Exemptions under section 163 are confusing, particularly with regard to clause 163(2) which suggests that a conventional organism with the same genetic structure already exists. We suggest either deleting or rewording to indicate that they could be created through conventional means.