

SUBMISSION

to the

HEALTH COMMITTEE

on the

Gene Technology Bill

CONTACT:

BioTech New Zealand E: info@biotechnz.org.nz BioTech New Zealand (BioTechNZ) welcomes the opportunity to make the submission to the Health Committee on the Gene Technology Bill and celebrates the modernising of gene technology laws to bring New Zealand into the 21st Century.

Working with a government that genuinely listened to the sector has been refreshing and the next step is to create a regulatory framework that ensures New Zealand farmers, health practitioners, researchers, and the broader public have access to all the tools and products needed to support New Zealand wellbeing and prosperity.

ABOUT BIOTECH NEW ZEALAND

BioTechNZ is a membership-funded organisation. A diverse range of members share a desire to maximise the ways that biotechnology can address many of New Zealand's (and the World's) agricultural, environmental, industrial and health problems.

In 2018, BioTechNZ joined the NZTech Alliance. NZTech Alliance is Aotearoa New Zealand's united voice for technology. We're supercharging the growth and uptake of technology in service of a better tomorrow for all New Zealanders. BioTechNZ furthermore connects innovators, investors, regulators, researchers, social entrepreneurs and interested public. We also help raise awareness and increase understanding of biotechnology to enable our nation to embrace the best opportunities biotech offers to us daily, helping us live better, healthier and more productive lives.

BioTechNZ is the voice for the biotechnology ecosystem. We take a practical, but information and evidence-based approach, focusing on harnessing the opportunities and addressing the issues. We draw on the active contributions of all members (Appendix One).

INTRODUCTION

In 2003 the New Zealand Government created three taskforces. The Biotechnology Taskforce was established to develop a strategy for the biotechnology sector. The taskforce's report, released in September 2003, outlined several key recommendations to grow the sector and remove barriers to its development.

The Science Minister Pete Hodgson 6 May, 2003 said "biotechnology would be critical to maintaining the competitiveness of the nation's agricultural sector, it doesn't stop with farming, forestry and fishing. Biotechnology applications also have significant benefits for health care, forensics, and biosecurity."

January 2025, we have just had the announcement marking the start of the most significant reset of New Zealand's science, innovation and technology system in over 30 years. The first move the Government has confirmed is the refocusing the Crown Research Institutes (CRI) in areas of New Zealand's seven existing CRIs will be refocused around the areas of:

- Bioeconomy
- Earth sciences
- Health and forensic science services
- A fourth, new advanced technology around advanced technologies such as artificial intelligence, synthetic biology, and quantum.

Biotechnology in some form again underpins all four of these focused areas. It is an exciting time for New Zealand biotechnology sector.

"We made a choice not to invest in biotechnology 30 years ago; now it appears that choice will be reversed, allowing New Zealand to seek advantage in its biological economy from scientific advances." quote in the Science System Advisory Group report.

New Zealand's tech sector has a bright future. The technology adoption process moves from innovators to fast followers, early adopters, the vast majority, late majority, and laggards. The latter are the last to adopt changes, showing little opinion leadership and resistance to change.

New Zealand has pockets of greatness and world leading with the use of traditional biotechnology technology, and modern technology with CAR-T in humans in New Zealand. Imagine where Zealand could sit on the innovation scale with the access to these modern biotech technologies like the rest of the world has had.

What we do know is there is over 30 years of data with regards to gene technologies, which we can use to inform our primary and secondary legislation with the reduction in risk, which will enable New Zealand companies and researchers to remain internationally competitive, be those opinion leaders which New Zealand needs, while creating a sustainable and prosperous New Zealand.

POSITION

BioTechNZ is fully supportive of the purpose and objectives of the bill as this is a critical step forward in the regulation of gene technology in New Zealand. It is an opportunity to modernise its approach to biotechnology and embrace a framework that aligns with international best practices and foster innovation.

COLLABORATION

BioTechNZ members are diverse with over 100 companies, many of whom will be putting in submissions. We have worked closely with other industry bodies and companies/research institutes and BioTechNZ will not duplicate details in their submissions out of respect for the select committee's valuable time reading all submissions.

BioTechNZ collaborations:

- Medicines New Zealand (MedicinesNZ)
- Malaghan Institute
- Life Sciences Network (LSN)
- Seeds Industry NZ
- Prevar
- T&G
- Agresearch
- Scion
- Plant and Food Research
- Animal and Plant Health New Zealand
- CropLife Australia and their associated member companies.

These organisation and views in their submission are supported by BioTechNZ as we are all in favour of updating the current outdated regulation.

Life Sciences Network's submission is very comprehensive due to the expertise and connection within the ecosystem, and with over 20 years of experience, BioTechNZ is supportive of the detailed suggestions in their submission.

BioTechNZ is proud to be CropLife Trans-Tasman Industry Partner due to their expertise, experience and have a long history of working with a diverse group of New Zealand stakeholders and BioTechNZ is supportive of the detailed suggestions in their submission.

RECOMMENDATIONS

We would like to highlight to stakeholders the following overarching recommendations to improve the operation of the framework:

Framework:

BioTechNZ is aware that this primary legislation is creating the framework for the secondary legislation and the bill's operational detail will be in the subordinate Gene Technology Regulations (the Regulations), which are yet to be released. Without the release of the proposed secondary regulations or guidance on their content, stakeholders are unable to provide a complete evaluation of the Bill

Therefore, once released, aspects of the Bill may need revisiting, and this must remain an option.

Definitions:

Amendments to the definitions of "gene technology" and "regulated organisms" is too broad and will capture many low-risk gene technologies, it should be made to ensure technologies that result in organisms and products indistinguishable from conventional breeding are exempt.

Gene technology is one of the most rapidly moving fields and therefore a framework that ensures opportunities for innovation while maintaining health and safety is needed. There needs to be flexibility of these changes in regulations.

Regulator:

Duplication of risk assessment between domestic regulatory schemes should be minimised. The Bill should be strengthened to ensure the independence of the new regulator. Ensure the regulator is properly staffed to ensure competitive timelines. Cost recovery must be realistic and not stifle innovation.

• Synthetic Nucleic Acids:

The Bill specifically regulates "synthetic nucleic acid", with no minimum size threshold. This has been discussed in more detail within other submission, but restrictive provisions on the import and use of synthetic nucleic acids should be removed from the Bill.

APPENDIX ONE

BioTechNZ Membership

AbacusBio Ltd

AcademyEX

Acclime New Zealand

AgResearch

AgriZeroNZ

Algavive Limited

Amazon Web Services New Zealand Limited (AWS)

Amerging Technologies Limited

Ampersand Technologies

Aroa Biosurgery Ltd

Arotec Diagnostics

AsureQuality New Zealand

ASX (Australian Securities Exchange)

Auckland Institute of Studies (AIS)

Auckland University of Technology (AUT)

Avasa Limited

BioCatalyst Ltd

BioCell Corporation

BioFab

Bio-Logic Solutions Ltd

BioOra Limited

BioPacific Partners Limited

Bio-Rad Laboratories

BioSouth

Biostart Limited

BioValeo Limited

BioViros Limited

BLIS Technologies Ltd

Blue Penguin IP

BNZ

Brandon Capital Partners

Bridgewest Ventures NZ

Butler Techsense Ltd

Callaghan Innovation

Capsugel Australia Pty Ltd T/A Lonza

Catalyst Intellectual Property

Cetogenix

ChristchurchNZ (CDC)

Daisy Lab

Elastomer Products Limited T/A PolyNatural

EpiVets Limited

ESP Medical

Estendart Research Ltd

Even Capital GP Limited

FB Rice (NZ) Limited

Futurity

Gillies McIndoe Research Institute

Global Life Sciences Solutions New Zealand (Cytiva)

Gordon Waldron

Harvest Integrated Research Organization New Zealand

Limited (HiRO)

Henry Hughes IP

HGM Legal

Illumina

Index Scientific & Technical Recruitment

Insitugen

IPPC

James & Wells

Keraplast Manufacturing

Kimer Med

Kode Biotech Group

LanzaTech

Lifescience ANZ

Lincoln Agritech

Malaghan Institute of Medical Research

Mandal-Johnson Ltd

Manuka Bioscience Limited

Marken NZ

McCabe & Company

Merck Life Science Pty Ltd

Microsoft

Mint Innovation

MinterEllisonRuddWatts

Miruku Limited

MJ Biosciences Ltd T/A Azora Biosciences

MQB Partners Ltd

Nanophage Technologies Limited

NEB New Zealand Ltd

New Wayz Consulting Ltd

New Zealand Ministry of Foreign Affairs & Trade (MFAT)

New Zealand Trade & Enterprise (NZTE)

NewFish

NZ Native Honey Products Ltd

NZCR Group Holdings Ltd T/A Optimal Clinical Trials and

NZCR

NZeno Limited

Orbis Diagnostics

Pacific Channel

Pacific Clinical Research Network Ltd

Pacific Edge Ltd

Pacific Stride Limited

Pictor Limited

Plant and Food Research

Precision Chromatography Limited

Prevar

Rock Stack Innovation

Ruminant Biotech

SAPRO Consulting & CRO

Sartorius

Scion Research

Smartways Logistics

Souson Technologies Limited

South Pacific Sera Ltd

SR Intellectual Property

Tātaki Auckland Unlimited

The cGP Lab Ltd

The University of Auckland

TheiaNova Limited

Thermofisher Scientific

Trinity Bioactives

Trust Tairawhiti Ltd

University of Otago

University of Waikato

Venture Taranaki Trust

Vetter Pharma International GmbH

Victoria University of Wellington

West Pharmaceutical Services

XR Pharmaceuticals Ltd