PSGR
Physicians & Scientists for Global Responsibility

Email: info@PSGR.org.nz
Social: @PSGRNZ
Website: PSGR.org.nz

May 29, 2025.

Dear Rosie,

Re: Ombudsman Case: 024150

Thank you for your letter dated May 15, 2025, stating that the Ombudsman intends to reject our complaint regarding the Ministry of Business, Innovation and Employment (MBIE) on the basis of a technical matter, namely 'insufficient personal interest' under section 17(1)(e).

Our complaint to the Ombudsman concerns an issue of structural integrity, which historically has been the Ombudsman's main activity, or 'bread and butter'. Prior to the enactment of the Official Information Act (OIA), work investigating poor administrative processes formed the core of the Ombudsman's duties. The Ombudsman should not rely on a technicality to set aside this complaint. This would require the Ombudsman to provide proof that under section 17(1)(e), PSGR members will not be personally affected, particularly when the broader substantive issues also overlap with potential risks and resulting harm, to human, environmental and economic health.

MBIE is not above the rule of law. Our complaint suggests that with respect to gene technology reform, there are many significant points of departure from established conventions and good process. These are not discrete, minor exceptions, these departures are so extensive that they may amount to an abuse of discretionary powers.

The Ombudsman has made no effort to adequately address the substance of the larger complaint. PSGR emphasized the fundamental importance of public trust in governing institutions, which, as the Ombudsman's office must recognise, is inherently tied to adherence to administrative and constitutional law principles. The Ombudsman is a key lynchpin in New Zealand's democratic 'checks and balances', with responsibility to ensure that agencies and officials are transparent and accountable in their undertaking of public duties. The public trust that when policies and laws are developed, that agencies follow good procedure, undertake due diligence and adhere to democratic conventions.

We do not ask the Ombudsman to review the development or content of legislation, but to consider the processes or lack thereof, that led to the Bill in question being fast-tracked into policy. It is our understanding that the Ombudsman regularly carries out such work.

You are correct in that PSGR has a strong interest in the matters raised and that the interest is one that is shared by the general public. As a registered charity, PSGR has an obligation to serve the public interest. This complaint is entirely consistent with that mandate.

PSGR had acknowledged that 'personal interest' could be grounds for rejection. We had noted this in our letter dated 30 April. PSGR's objectives as a charity directly relate to the substance of this discussion.

However, we suggest that the substance of the larger complaint not only carries sufficient weight as to *override* the uncertainties of any potential personal impact, but also reveals that there are manifold uncertainties in claiming that our members have no personal interest. Ironically, the uncertainties are themselves a function of the *failure* by officials to apply good regulatory processes in the first place.

In our April 30 letter, PSGR noted that the Gene Technology Bill as it stands, will result in unregulated and hence unquantified releases of gene editing techniques and organisms on the market which would likely *'impact exporters, Māori Rongoa, food practitioners and the public (consumers)' – as bodies of persons* under section 13(1).

The Regulatory Impact Statement, as we discuss below, acknowledged that risk was unquantifiable.

1. PSGR'S PERSONAL INTEREST & THE CARTEGENA BIOSAFETY CONVENTION

PSGR is a body of living persons in New Zealand who have a demonstrably personal interest in this proposed legislation that is greater than that of the public generally. Four of our objectives, as per our charitable purpose include:

a. To educate the public concerning the risks of the release into the environment of genetically engineered organisms and to promote scientific research and analysis of those risks, and to educate the public on relevant matters of science and medicine.
b. To educate physicians and scientists about issues of science, medicine and technology, particularly those involving genetics.
c. To provide scientific and medical information and analysis in the service of the public's right to be independently informed on issues concerning genetics, including genetic engineering and biotechnology, and other relevant matters of science and technology.
d. To encourage scientists and physicians to engage in public debate on issues of science, medicine and technology, particularly those involving genetics.

Genetically modified organisms present risks. New Zealand is a signatory to the Cartagena Protocol on Biosafety, the objective of which is:

> '... is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.'

Article 2, Point 2 of the Protocol states:

> 2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

2. LEGISLATION CANNOT ASSUAGE RISK IF RISK ASSESSMENT IS ABANDONED

The legislation can only be 'risk-proportionate' if scientifically valid risk assessment is undertaken. Any policy producing legislation, needs to be reasonable, unbiased, and fairly produced. Claims based on 'risk' require judgement of scientific information. Yet MBIE have omitted to demonstrate procedure-based risk assessment practices to underpin their claims relating to 'safe' use of GMOs and therefore 'risk'.

The Ombudsman can simply query whether risk assessment has been undertaken, and require that this be proven. This would ensure that MBIE's claims in the Regulatory Impact Statement and Gene Technology Bill are reasonable and valid so as to sustain public trust. That scientific enquiry has been undertaken according to convention. As an example, Article 15 of the Convention, states:

> 'Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.'

The Conference of the Parties serving as the Meeting of the Parties to the Protocol (COP-MOP) continues to establish Ad Hoc Technical Expert Groups (AHTEGs) under the Cartagena Protocol on Biosafety. The AHTEGs continue to emphasize the need for risk assessment to remain an essential scientific criterion. Such risk assessments involve transboundary and long-term ecological risks and the need for experts to comprise scientists in ecology, molecular biology, and biosafety, regulatory officials, indigenous peoples' representatives, non-government organisations, civil society, and sometimes industry observers. The AHTEGs, like the European Union, continue to support precaution.

Fundamentally, PSGR believes that MBIE has discarded the convention of risk assessment, and failed to bring in [groups of] experts that would mirror the rigor of practices used by the Convention to ensure that any legislation produced in New Zealand would be fit for purpose.

The personal interest of PSGR is tangible. PSGR's charitable purposes include *'to educate the public, to promote scientific research and analysis of those risks'*. They involve serving the public's right to be '*independently informed on issues concerning genetics, including genetic engineering and biotechnology.*'

In our previous letter we drew attention to the public interest nature of our request. This is because once GMOs are released into the environment they cannot, like the proverbial genie released from the bottle, be contained. It will be impossible to reverse the course of action. Any admission by MBIE that they 'got it wrong' will be of no comfort. The damage will already have been done.

PSGR's complaint concerns evidence that the policy formulation was demonstrably poor, the consultation demonstrably biased and that the policy formulation process failed to include any independent scientific experts who could estimate whether the subsequent legislation would actually fulfil the poorly drafted purpose. We noted that Emeritus Professor Jane Kelsey had also drawn attention to the deficiency of process.

3. BROADER PERSONAL INTEREST

We draw attention to the wider public interest nature of this where the 'personal interest' reasons affect many in the wider community:

a. Personal interest of a wide portion of New Zealanders is indicated by the 15,000 submissions to the Bill.

b. Personal interest can be confirmed by the fact that the legislative framework would place some GMOs in a risk tier exempt outside regulatory purview, i.e, the Gene Bill would structure GMOs outside the regulation. Such risk-tiers have been politically enabled by way of a pseudo-scientific, unfounded claim that a certain class of GMO is not GMO. However, no scientifically robust, methods-based assessment was undertaken to provide even plausible support for this claim.

c. Personal interest arises from the absence of risk assessment and from the fact that the policy and the Bill have not considered safety. The pseudo-scientific claims as to safety are meritless. Demonstrable scientific process as a convention is reflective of administrative law principles. As it stands, the Bill cannot and does not prove safety.

d. Personal interest arises from the public needing to be able to make informed choices, and from the fact that this legislation would prevent tracking, tracing and the obligation that GMO foods are currently required to be labelled. The Australia and New Zealand Food Standards legislation Object (3(c)) ensures that people have sufficient knowledge in order to make informed choices. PSGR's submission emphasized (page 14) that people in China, Russia, Vietnam, Japan, France will pay a premium for GMO free food – such is the desire for people to avoid consuming genetically modified and edited food. This Bill removes choice for people. For example, up to 94% of GMO plants could avoid oversight and not have to be declared if the Bill were passed. These issues, consumer preference, and the extent of organisms which would avoid regulation was never considered.

e. Personal interest also arises, most concerningly, as a consequence of the unprecedented inclusion of *mandatory medical authorisations* for gene edited and biologic medicines. This Subpart 5 was integrated into the legislation without any prior consultation. It circumvents existing statutes, including the Health Act 1956 obligation to protect health, and the Medicines Act 1981 and it ignores broad obligations to consult with Treaty partners.

f. Personal interest is triggered as the inclusion of a mandatory medical authorisation represents a direct threat to public health if that medicine is released without the full measure of safety testing which include long-term randomised control trials, including for particular vulnerable sub-groups such as immunocompromised people and pregnant women. The direct threat to public health triggers a personal interest as legislation must require that all batches are tested for contamination, due to the evidence that biologic/gene edited medicines mandated during COVID-19 represent a DNA and RNA contamination threat which is far more extensive than was considered during the 2021 approval process.

4. FAIR-MINDED LAY OBSERVER – WAS GOOD PROCESS FOLLOWED?

Our complaint reflects what we believe is extensive evidence appended in our initial complaints, that the policy formulation was demonstrably poor. This includes the intention of setting aside principles by claiming they were 'out of date'. No evidence was provided to back up this claim and it prevented the consulted parties from considering whether the existing Hazardous Substances and New Organisms (HSNO) Act could be amended with minimal cost. We emphasise that the policy formulation process failed to include any independent scientific body that could estimate whether the future overarching Act and any subsequent (secondary) legislation would enable officials working under the Act to fulfil the purpose.

We raise the issue of apparent bias, where MBIE has pre-existing relationships with the parties to the consultation, due to its control over science funding. MBIE had directed funding to many of the individuals invited as experts to the consultation, or to scientists working directly with the organisations that were invited to consult. These parties would therefore have a prejudice towards a particular policy direction.

We are simply asking what a fair-minded lay observer might think, having been fully informed of the facts. Would they possibly suspect that the decision-maker was biased towards a particular outcome?

MBIE's departure from good administrative practices, including the 2021 Legislation Design and Advisory Committee Legislation Guidelines (consultation with people or bodies likely to be affected), Good Regulatory Practice (2017) (making genuine effort to undertake cost and benefit analyses) constitutes serious procedural deficiency. The delegation of safety assessments to offshore jurisdictions with unknown standards further compounds these concerns.

The Ombudsman's function extends to the power to investigate a recommendation to a Minister of the Crown. The Regulatory Impact Statement outlines that the Hon Judith Collins directed officials to depart from conventions and explicitly exclude options for reforming the existing HSNO Act (page 3) and not consult with the public on the reforms (page 13). The fiscal costs of reforming the existing HSNO Act in comparison to establishing an entirely new regulatory framework were never considered.

The benefits and costs of the reform remain unquantified (page 6-7 and 9) and 'due to the timeframes for developing the proposal, MBIE did not publicly consult on the proposed regulatory changes or engage broadly with Māori (page 7). Consultation, as we have explained, predominantly involved individuals and organisations who had received funding from MBIE for, and/or financial interests in, scientific research for the development of gene edited organisms. These groups would stand to gain direct financial benefit from a weaker regulatory jurisdiction. We understand that courts have consistently maintained that even the appearance of bias is enough to vitiate a decision. This has been referred to as the 'reasonable apprehension of bias' standard.

The late inclusion of a *mandatory medical authorisation,* was procedurally improper and may violate constitutional norms. Delegating regulatory control to foreign entities without consultation is a profound breach of domestic legislative conventions. Does the rule of law not apply to MBIE?

We will continue to urge the Ombudsman to investigate this matter, as it is of wide public concern.

5. RISK OF JUDICIAL REVIEW

We are aware that declining our complaint on the basis of a technicality may expose the Ombudsman to the risk of judicial review under the New Zealand Bill of Rights Act 1990. The Bill of Rights Act s 27 guarantees the rights to natural justice and judicial review of determinations affecting personal interests:

> 27 Right to justice
> (1) Every person has the right to the observance of the principles of natural justice by any tribunal or other public authority which has the power to make a determination in respect of that person's rights, obligations, or interests protected or recognised by law.
> (2) Every person whose rights, obligations, or interests protected or recognised by law have been affected by a determination of any tribunal or other public authority has the right to apply, in accordance with law, for judicial review of that determination.

We would like to reiterate our point that the Minister has a responsible role in explaining departmental failings. The Minister took a particularly active role in explicitly directing officials not to consult with the general public and to remove

any question of maintaining the existing HSNO legislation from consultation. The Ombudsman must surely be aware that if something goes wrong the minister is responsible, although not personally culpable.

The decision to exclusively draw attention to a legislative technicality as the sole reason for declining the complaint is concerning because it may expose such a decision to judicial review.

We personally and collectively object to the inadequacy of risk assessment, lack of coherence with existing legislation to protect native flora and fauna and the flagrant disregard for the people of New Zealand and all future generations, who will inevitably bear the consequences of deregulation due to the heritability potential of gene edited technologies and organisms, which can include reagents used by scientists and non-target organisms.

Our complaint is neither trivial nor vexatious and has been made with the knowledge evidential data and principles. We therefore maintain that rejection of our complaint by the Ombudsman would be totally unreasonable.

We ask that the Ombudsman have the courage to investigate this complaint - to ask whether MBIE has acted fairly, transparently, and with integrity, consistently over time, and in accordance with principles of public law.

This is clearly a case of the greater public interest at stake and the Ombudsman should be seeking to ensure that the correct process has been followed, if not for this extremely important issue, then for what?

Yours faithfully,

Jodie Bruning

On behalf of the trustees of the
Physicians and Scientists for Global Responsibility Charitable Trust New Zealand.

PSGR

New Zealand Charitable Trust