

Submission of Justice Watch New Zealand

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Submission on the Hazardous Substances and New Organisms Amendment Bill

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1. Introduction

Justice Watch New Zealand opposes the Hazardous Substances and New Organisms Amendment Bill.

The central issue raised by the Bill is not whether future biological interventions can be undertaken. The central issue is whether they are necessary.

The Bill establishes a framework intended to expedite approval pathways relating to genetically modified organisms and other biological interventions, including interventions capable of occurring on an industrial scale.

In the view of Justice Watch New Zealand, the Bill is principally concerned with how biological interventions may be approved rather than whether they should occur at all.

2. Necessity and Risk of Intervention

Justice Watch New Zealand submits that the first question for any approval process should be:

What is the necessity for the proposed genetic modification?

We submit that the threshold for answering that question should be exceptionally high.

The Bill is directed toward future interventions that do not yet exist and whose consequences cannot yet be known. Approval therefore necessarily occurs before outcome.

The beneficiaries of such a framework will ordinarily be commercial entities seeking approval for new organisms, products, and biological processes. While commercial activity is not improper, commercial interests are not synonymous with the public interest.

History demonstrates that commercial incentives do not always align with the public interest. Parliament should therefore be cautious about adopting a framework that may become heavily reliant upon information and representations supplied by those seeking approval.

Justice Watch New Zealand is concerned that New Zealand regulators are unlikely to possess the resources necessary to independently investigate every application to the depth required to fully assess long-term consequences. In practice, decision-makers may become reliant upon applicant-generated information and overseas assessments.

In those circumstances, the question of necessity becomes critical.

A biological intervention is intended to produce change. Before that change occurs, its consequences remain matters of prediction rather than established fact. The possibility of unintended consequences is therefore inherent in biological intervention itself.

2.1 Potential Risk to New Zealand

The principal risk is not the intended outcome of the intervention but the unintended outcome.

History provides many examples of human interference producing consequences not anticipated at the beginning. One example is the Chinese Four Pests Campaign commencing in 1958, where

the elimination of sparrows contributed to ecological imbalance and formed part of the chain of events associated with the Great Chinese Famine.

More recently, the possibility that SARS-CoV-2 may have escaped from a research environment has demonstrated the potentially profound consequences that may arise when biological containment fails. Regardless of competing views concerning the origin of the virus, the possibility of an escaping organism is now a recognised risk that cannot be ignored.

Parliament should therefore consider whether New Zealand's geographic isolation requires greater caution rather than less. If a biological intervention fails, the first consequences may be borne not by those promoting the intervention but by New Zealand people, agriculture, livestock, and the environment.

For that reason, Justice Watch New Zealand submits that uncertainty strengthens rather than weakens the case for caution. The greater the potential consequence of failure, the greater the necessity for restraint.

Accordingly, risk and necessity cannot be separated. The greater the uncertainty surrounding the outcome of a proposed biological intervention, the greater the burden upon the applicant to demonstrate why the intervention is necessary in the first place.

Accordingly, where the consequences of failure may extend to people, agriculture, livestock, and the environment, the primary question is not how the intervention may be undertaken, but why the intervention is necessary at all.

3. Human Consequences and Rights

Ultimately, biological interventions affect living systems, communities, and human beings.

Those consequences may be beneficial. They may also be harmful. The greater the scale of the intervention, the greater the potential scale of the consequences.

It follows that the question of necessity is not merely scientific. It is also a question of rights.

Justice Watch New Zealand notes that the explanatory material accompanying the Bill contains little discussion of the New Zealand Bill of Rights Act 1990 or the broader human rights implications of the proposed reforms.

Section 6 of the New Zealand Bill of Rights Act provides that wherever legislation can be given a meaning consistent with the rights and freedoms contained within the Act, that meaning is to be preferred.

The New Zealand Bill of Rights Act is directed toward the protection of the individual from the exercise of public power. Similar principles are reflected in international human rights instruments.

Where legislation seeks to expedite future biological interventions capable of affecting people, Parliament should proceed cautiously and place the public interest ahead of administrative efficiency or commercial opportunity.

Justice Watch New Zealand is concerned that the Bill contains extensive mechanisms directed toward approval and process, yet it is not readily apparent that it contains a corresponding requirement for applicants to demonstrate the necessity of the proposed intervention itself.

Justice Watch New Zealand is further concerned that, to the extent the Bill facilitates the accelerated approval of novel biological interventions capable of affecting people while reducing emphasis upon precautionary scrutiny, the resulting framework may be inconsistent with the rights and freedoms affirmed by the New Zealand Bill of Rights Act 1990.

4. Lessons from Recent Experience

Recent experience reinforces the importance of the necessity question.

During the COVID-19 pandemic, New Zealand participated in the deployment of a novel mRNA product developed and approved under accelerated international processes.

Subsequent experience gave rise to continuing questions concerning efficacy, transmission, adverse effects, and long-term consequences.

Nevertheless, hindsight permits a question that was not adequately asked at the beginning:

What was the necessity for the intervention?

That question remains relevant because the present Bill seeks to expedite the approval, development, manufacture, and deployment of future biological interventions whose consequences cannot yet be known with certainty.

The significance of that observation lies not in any particular product or technology, but in the reality that approval necessarily precedes outcome. At the point of approval, the anticipated consequences of a biological intervention remain matters of prediction rather than established fact.

Accordingly, Justice Watch New Zealand submits that commercial opportunity, scientific capability, and technological innovation do not themselves establish necessity.

5. A Recent New Zealand Example

Justice Watch New Zealand notes a recent New Zealand example that illustrates why precautionary assessment frameworks exist and why the concerns raised in this submission are not merely theoretical.

During the COVID-19 response, New Zealand participated in the deployment of a novel mRNA biological intervention under an alternative regulatory pathway. In practical terms, the intervention did not attract the level of scrutiny that precautionary legislation such as HSNO would ordinarily be expected to provide in relation to a novel biological technology intended for widespread use.

Questions concerning carcinogenicity testing, fetal and reproductive toxicity testing, biodistribution, and other long-term safety considerations either remained unresolved or had not been examined within particular populations before approval and deployment occurred. Nevertheless, the intervention was subsequently approved for widespread use, including within groups such as pregnant women.

Subsequent experience included millions of SARS-CoV-2 infections together with approximately 24,235 reports of serious adverse events and approximately 183 reported deaths following vaccination reported to Medsafe. Questions of individual causation remain matters for evidence and assessment. However, the circumstance demonstrates the practical consequences that may arise when novel biological interventions are deployed before all relevant risks have been fully identified and assessed.

Justice Watch New Zealand submits that the lesson from this experience is not that precautionary scrutiny should be reduced. Rather, it is that precautionary scrutiny should be strengthened. The purpose of precautionary legislation is to identify risk before harm occurs.

For that reason, the present Bill gives rise to concern. To the extent that it facilitates accelerated approval pathways for future biological interventions while reducing emphasis upon precautionary assessment, it may contribute to circumstances of the kind described above.

Where the State permits novel biological interventions capable of affecting people, those interventions necessarily engage the rights protected by the New Zealand Bill of Rights Act 1990.

Those rights would have little practical meaning if public authorities were free to expose people to avoidable and foreseeable risk without appropriate scrutiny.

Accordingly, this example reinforces the importance of ensuring that approval pathways for novel biological interventions remain subject to rigorous scrutiny and are not expanded at the expense of rights.

6. Commercial Interests and the Public Interest

The COVID-19 response demonstrated that biological interventions may generate extraordinary financial returns for developers and manufacturers.

Pfizer reported Comirnaty revenues of approximately US\$36.8 billion in 2021 and approximately US\$37.8 billion in 2022. BioNTech reported revenues of approximately €17.3 billion and net profits of approximately €9.4 billion in 2022.

Justice Watch New Zealand does not suggest that commercial success is improper. However, those figures illustrate why commercial incentives should not be confused with necessity.

Profit may explain why an intervention is attractive. It does not explain why it is necessary.

Where the consequences of intervention may ultimately be borne by the public, Parliament should be cautious not to allow commercial considerations to displace the prior question of necessity.

7. Conclusion

For the reasons set out above, Justice Watch New Zealand submits that the Bill is fundamentally deficient in its present form.

The Bill proceeds upon the premise that biological interventions should be more readily approved, developed, and deployed. In our view, the prior question of necessity has not been adequately addressed.

The fundamental question is not whether a biological intervention can be undertaken.

The fundamental question is whether it should be undertaken at all.

Before Parliament creates pathways designed to expedite the approval of future genetically modified organisms and other biological interventions, it should first require a compelling demonstration that the proposed intervention is necessary.

Accordingly, Justice Watch New Zealand submits that the Bill should not proceed in its present form and should instead be substantially redrafted to incorporate clear principles of necessity, precaution, public participation, and rights protection before pathways for future biological interventions are expanded.