PSGRNZ

Physicians & Scientists for Global Responsibility Charitable Trust

June 3, 2026

Submission

Hazardous Substances and New Organisms Amendment Bill (304-1)

Submitted to the:

Primary Production Committee

Address

PO Box 16164
Bethlehem
Tauranga 3147
New Zealand

Email

info@psgr.org.nz

Website

www.psgr.org.nz

Phone

Ph+64 27 505 0808

PSGRNZ would welcome an opportunity to speak to this submission.

Physicians and Scientists for Global Responsibility Charitable Trust (PSGRNZ) works to educate the public on issues of science, medicine, technology (SMT). PSGRNZ work to encourage scientists and physicians to engage in debate on issues of SMT, particularly involving genetics and public and environmental health.

The Hazardous Substances and New Organisms Amendment Bill (304-1): This assessment provides evidence that it will likely frustrate the legislative intent of the HSNO Act.

Call on the Primary Production Committee. *PSGRNZ opposes this Bill and calls on members of Parliament to reject this Bill in its entirety. PSGRNZ request that the Primary Production Committee pause proceedings and return the Bill for fundamental revision, following genuine consultation extending well beyond the narrowly selected groups engaged to date.*

Sections [4-7] highlight specific failings which PSGRNZ explicitly rejects.

PSGRNZ opposes the specific mechanisms this Bill uses to achieve efficiency, because they systematically reduce the scientific rigour, public participation, and independent oversight that the HSNO Act was designed to provide; and submit that the Regulatory Impact Statement (RIS) is unfit, and that the Bill is premature and fundamentally misconceived for the following reasons:

1. The underpinning policy prioritised industry concerns about process speed, with human and environmental health protection treated as secondary considerations throughout.
2. The Bill has a deficient basis, as it 'copies' and 'pastes' the policy foundation from the Ministry for Regulations' Agricultural and Horticultural Products Regulatory Review (2025).
3. The Review and RIS directly contradicted the *Parliamentary Commissioner for the Environment*, by claiming that the current systems are effective for managing risks.
4. The targeted stakeholder engagement for Bill policy was dominated by organisations with direct commercial interests in its outcomes; human and environmental health considerations not discussed. No independent toxicologists, public health bodies, environmental advocates, or affected communities were included.
5. The process is upside down. To be 'risk proportionate', the risk assessment analysis & review should have been developed prior to the Bill, to then inform development of the Bill.
6. The process is being shunted through at the same time that the Ministry for the Environment is being disestablished. Participating officials and Ministers would know this.
7. The process is being shunted through just prior to a new NZEPA CEO commences giving that new CEO to take part in design and scope of any regulatory amendments.
8. The risk assessment framework, universally acknowledged to be outdated and unfit for purpose, is currently directed for redesign by a consultancy with commercial conflicts of interest, and a preference for maximizing efficiency in navigating regulatory systems.
9. Faults: The Bill's text, taken as a whole, risks undermining the principles and purposes of the HSNO Act, the very framework it purports to improve.
10. The Bill invents new terms (denewed), creates new meanings for language (vagrant), and fails to define key terms (low-risk, risk-species, recognised international regulator, significant public interest and risk proportionate).
11. Faults: The Bill creates a fast-track approval pathway requiring sign-off from just two overseas regulators. The NZEPA has no mechanism to ask whether those two decisions rest on recent high-quality reviews. Two jurisdictions can both trace back to a single unreviewed assessment and New Zealand can view that as sufficient.
12. Faults: The Bill may contradict a 2014 High Court finding. It permits the NZEPA to declare a genetically modified organism - an apparently invented term - a 'denewed' organism.

Contents

INTRODUCTION

The Hazardous Substances and New Organisms (HSNO) Amendment Bill (304-1), introduced to Parliament on 11 May 2026 by Hon Nicola Grigg, proposes the most significant restructuring of New Zealand's chemical and new organism regulatory system since the HSNO Act came into force 30 years ago. The Bill is being considered by the Primary Production Committee (submissions closing 11.59pm Monday 15 June 2026) rather than an Environment Committee

This likely follows the disestablishment of the Ministry for the Environment, notwithstanding that the vast majority of submissions to that select committee had opposed that Bill.

The Bill makes 150-plus amendments to the HSNO Act 1996. Its stated purpose is to streamline approval pathways, reduce processing times, and make greater use of overseas regulator assessments. PSGRNZ does not oppose efficiency in regulation. We oppose the specific mechanisms this Bill uses to achieve efficiency, because they systematically reduce the scientific rigour, public participation, and independent oversight that the HSNO Act was designed to provide.

The companion Agricultural Compounds and Veterinary Medicines Amendment Bill (305-1), introduced on the same day by Hon Andrew Hoggard, is before the same committee and raises parallel concerns.

To ensure public trust in the regulatory system, there must be a scientifically robust response to finding that risk assessment models are not fit for purpose in order to update them before expanding the approvals that depend on them.

In the May 2025 RIS, proportionate is used repeatedly as a positive regulatory objective. The term is associated with reducing regulatory burden, streamlining approvals, aligning assessment effort with perceived risk, accelerating innovation, and avoiding unnecessary scrutiny. The underlying assumption appears to be that existing regulatory requirements are, in some circumstances, disproportionate to the risks presented.

The difficulty is that the RIS appears to devote considerably more attention to the administrative consequences of proportionality than to the scientific determination of proportionality. The document explains why approvals should be faster, more efficient, and more closely aligned with risk.

This is a recurring issue throughout contemporary regulatory reform. ‘Risk proportionate’ regulation is often treated as though it were synonymous with reduced regulation. Yet these are not necessarily the same thing. A proportionate response to uncertainty may, in some circumstances, require more extensive assessment, additional monitoring, broader consultation, stronger containment measures, or post-market surveillance. Proportionality depends upon the nature of the risk being managed, not upon a prior preference for regulatory simplification.

Risk-proportionate regulation is the outcome of a methodology. Unless the scientific assessment process is demonstrably systematic, transparent, and reproducible - which is widely recognised not to be the case - claims that a regulatory response is risk-proportionate remain assertions rather than verifiable conclusions.

However, despite finding that risk assessment models are not fit for purpose and first updating them before expanding the approvals that depend on them, the Bill takes an opposite approach. It further transfers (and/or delegates) market entry reliance on overseas assessments, while simultaneously removing the methodology requirement that would at minimum have required the Authority to articulate what standard it was applying when making those decisions. It delegates authority to two foreign jurisdictions without specifying the rigour with which those jurisdictions must undertake risk assessment.

The RIS and Bill provides much less discussion of the methodology by which risk itself is identified, characterised, and evaluated, particularly in circumstances involving uncertainty, cumulative effects, environmental persistence, self-replicating organisms, ecosystem interactions, or long-term consequences. As a result, key policy questions that might traditionally be resolved through primary legislation are instead deferred to secondary instruments and regulatory practice.

The importance of the scientific process to ensure that decision-making follows robust procedures and is trustworthy and can stand the test of time, has not been a priority of the underlying policies, nor is it emphasised in the text of the Bill. In contrast, the language that is inserted in the Bill, reflects a shift away from accountability and transparency, despite claiming to achieve such effects.

At the same time, the Bill shifts greater discretionary powers to decision-makers. Yet if this was to work – there should have been a greater the obligation for the scientific process informing those decisions to be systematic, transparent, and reproducible. This did not occur.

This distinction is particularly important in the stewardship of hazardous substances and genetically modified organisms because the regulatory challenge is fundamentally different from many conventional administrative activities. The purpose of the system is not simply to process applications efficiently. It is to evaluate technologies and substances whose risks may be uncertain, delayed, cumulative, difficult to reverse, or not fully observable at the time decisions are made. In such circumstances, proportionality cannot be reduced to a question of how much regulatory effort is applied. It must also encompass the adequacy of the scientific inquiry itself.

Quite clearly, terms such as ‘risk-proportionate’, ‘denewed’, ‘low risk’, ‘vagrant’, and ‘significant public interest’ do substantial regulatory work yet are either undefined or dependent upon future administrative interpretation. This may reduce legal certainty, increase regulatory discretion, and make it more difficult for affected parties to anticipate how statutory powers will be exercised.

The RIS invents a new word ‘denewed’ that is then incorporated in the Bill. The Bill assigns an ecological term (vagrant) as a legal term yet neither the RIS nor the Bill clarifies this altered use approach.

It is unclear whether ‘vagrant’ is confined to naturally occurring organisms or whether it may also apply to genetically modified, gene-edited, volunteer, feral, or descendant organisms arising from escaped heritable material. Given that the designation carries substantive regulatory consequences, greater clarity is required regarding the intended scope of the category and the criteria governing its application.

For genetically modified, gene-edited, or self-propagating organisms, that becomes particularly important because 'low risk' today may depend heavily on assumptions about persistence, dispersal, heritability, and ecological interaction that can only be tested over time.

Therefore, the Bill appears to establish a series of broad enabling concepts while leaving much of their substantive content to future NZEPA notices, regulations, guidance, classifications, and administrative determinations.

This is not a response to inadequate risk assessment. It is a legislative instruction to proceed despite it, with an expansion of risk to the public and the environment because of built-in regulatory blindspots.

A Constitutional Question: If Parliament is increasing the terminology and expanding regulatory powers, what corresponding safeguards, regulatory frameworks, constraints, review mechanisms, transparency requirements, evidential standards, and accountability measures are being strengthened at the same time?

[1] REGULATORY REVIEW WHITEWASHES RISK

New Zealand's regulatory system for hazardous substances exists for one purpose: to protect the health and safety of people and communities, and the environment, from the adverse effects of hazardous substances and new organisms. That purpose is not served by a Bill built on an admitted scientific foundation failure, explicitly designed to prioritise industry interests, and timed to limit the capacity of independent voices, scientific, public, Māori, and institutional, to be heard before it becomes law.

The narrow framing and poor underpinning of the current Bill which takes its purpose from the findings of the Ministry of Regulation's Agricultural and Horticultural Products Regulatory Review (February 2025)[1] is itself a legacy of the faulty terms of reference that had then set up that review.

The *May 2025 Regulatory Impact Statement (RIS)*[2] highlighted that the 16 changes recommended by the review revolved around improving efficiency, transparency and certainty. The Government accepted the recommendations and approved that the related legislative amendments would occur via an Omnibus Bill. The RIS stated

> '*if no changes are made, inefficiencies and delays will persist, harming competitiveness and innovation.*' The core policy issue is to make the '*regulatory approval path for new organism and chemical substance products in New Zealand more efficient, timely, transparent and certain, while maintaining effective risk management.*' The policy objective is to '*create a regulatory system … that balances fostering innovation, productivity and competitiveness with effective risk management*'.

[1] Ministry for Regulation (February 2025). Agricultural and Horticultural Products Regulatory Review Report. Ministry for Regulation. IBSN 978-0-473-73833-4. https://www.regulation.govt.nz/assets/Publication-Documents/Agricultural-Horticultural-Products-Regulatory-Review-full-report.pdf

[2] Ministry for the Environment (23 May 2025). Regulatory Impact Statement: Omnibus Changes to the HSNO Act 1996. https://www.regulation.govt.nz/assets/RIS-Documents/RIS-Omnibus-changes-to-the-Hazardous-Substances-and-New-Organisms-Act-1996.pdf

The Regulatory Review contradicts itself in its treatment of risk. It stated:

> '*We consider that the systems are effective in managing risks as there is no evidence to indicate regulators are overlooking risks during assessment processes (page 59)*', however then it went on to state that '*The EPA's risk assessment models are outdated and no longer fit for purpose page 70*).'

WAYLAID: PARLIAMENTARY COMMISSIONER FOR THE ENVIRONMENT CONCERNS

However, the Review was not in a position to claim that the current systems were effective in managing risks. In fact, the Ministry for Regulation (MfR) directly contradicted information from the Parliamentary Commissioner for the Environment (PCE). The MfR's '*no evidence'* claim lacked substance. For there to be evidence, the review would need to more broadly evaluate regional systems for bioaccumulation, and consider for example, logged reports with ACC for workplace harm from agrichemical use. This was not undertaken. Instead, the comments above suggest that the Ministry of Regulation deliberately misconstrued and indeed, set aside the Parliamentary Commissioner for the Environment's September 2024 findings and concerns that the PCE had considered were directly 'relevant to this review'. These include:

- We do not have the information to appropriately manage the risks of chemicals used in our environment
- New Zealand lacks a cohesive framework to understand and prioritise chemicals' risk
- Many chemicals in use have not been properly assessed
- We do not appropriately manage the environmental risks of substances equally
- The EPA does not have the tools nor the resources to adequately manage the risk of chemicals, including AgHort chemicals, used in New Zealand

The Parliamentary Commissioner for the Environment (PCE) reaffirmed the findings of his 2022 report directly to the Ministry for Regulation during the agricultural and horticultural products regulatory review that produced this Bill, specifically requesting that environmental and public health interests be given equal weight to industry.[3] [4] This did not occur.

The PCE had emphasised that the Reviews':

> '*Terms of Reference overplays industry as a stakeholder and underplays stakeholders with other concerns such as public health and the environment'*.

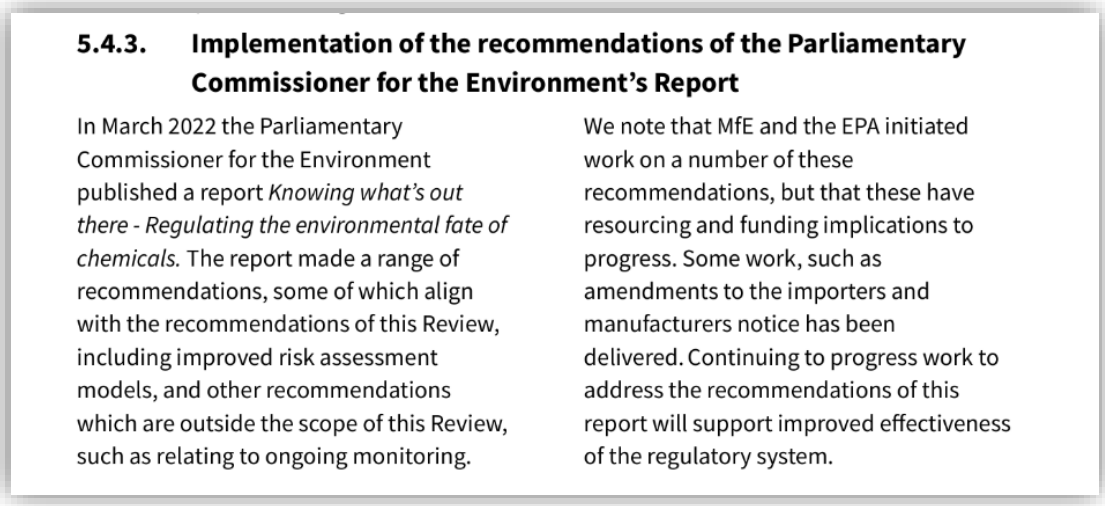
The PCE's concerns were misconstrued and miscommunicated in the Review paper and then largely not reflected in the MfR's Review's sixteen recommendations (pages 8-9), none of which required independent toxicological or public health scrutiny of the substances being approved.

The downplaying by the Ministry for Regulation of the PCE's concerns, is most clearly depicted on page 97 of the Agricultural and Horticultural Products Regulatory Review (February 2025). Is a disturbing example of regulatory reasoning. The Ministry for Regulation's treatment of the PCE's

[3] Parliamentary Commissioner for the Environment. (2022). Knowing what's out there: Regulating the environmental fate of chemicals. Wellington: Parliamentary Commissioner for the Environment. 978-0-947517-31-1

[4] Parliamentary Commissioner for the Environment. (Sept 6, 2024). Submission on the Agricultural and Horticultural products regulatory review.

concerns shows the surface level acknowledgement: the report is cited by name, a minor administrative action claimed as delivery, the substantive recommendations deferred on resource grounds, and the Bill proceeded to design faster approval pathways around risk assessment models the same review found to be outdated and unfit for purpose. However, the deeper concerns of the PCE appear to have been brushed aside across the body of the document.



5.4.3. Implementation of the recommendations of the Parliamentary Commissioner for the Environment's Report

In March 2022 the Parliamentary Commissioner for the Environment published a report *Knowing what's out there - Regulating the environmental fate of chemicals.* The report made a range of recommendations, some of which align with the recommendations of this Review, including improved risk assessment models, and other recommendations which are outside the scope of this Review, such as relating to ongoing monitoring.

We note that MfE and the EPA initiated work on a number of these recommendations, but that these have resourcing and funding implications to progress. Some work, such as amendments to the importers and manufacturers notice has been delivered. Continuing to progress work to address the recommendations of this report will support improved effectiveness of the regulatory system.

Agricultural and Horticultural Products Regulatory Review (February 2025). Page 97.

A statutory officer of Parliament, the Parliamentary Commissioner for the Environment (PCE), produced an independent, evidence-based assessment finding that New Zealand's chemical regulatory system is fundamentally inadequate: that the models are outdated, that environmental fate cannot be tracked, that endocrine disruptors are unmanaged, and that the system is disjointed and patchy.

The appropriate public law response to such a finding should have been to treat the PCE's advice as a material consideration requiring substantive engagement before further legislative action is taken. Instead, the Ministry for Regulation selectively extracted the recommendations compatible with the velocity-focused priorities of a reference group drawn entirely from approval-seeking sectors, for whom process speed was the organising concern and independent risk scrutiny was not within their professional frame of reference.

FAULTY POLICY PROCESS

The Regulatory Review's 16 recommendations relegated to concerns about New Zealand's unfit risk assessment framework to a single point. The quality of risk assessment is critical if hazardous substances and new organisms (genetically modified organisms including newer gene edited organisms) are to be stewarded safely.

This Bill should have been established after the core concerns in point 10 were addressed. Instead, government officials have in haste, rushed to produce a Bill that effectively renders the PCE's core concerns out of scope. No responsible regulatory system designs new approval pathways before the models those pathways will rely upon have been validated. The correct sequence, fix the models, then legislate, was not merely ignored; it was inverted.

Recommendations

The efficiency of the approval path must be improved to enable more timely access to agricultural and horticultural products (and uses of products) while still maintaining effective management of products risks. To achieve this, we have made 16 recommendations:

Issue: Lack of strategic direction

1. Establish a Sector Leaders Forum that brings together policy and regulatory agencies and stakeholders at a senior level to improve transparency and facilitate strategic discussions for the whole approval path.
2. Responsible Ministers use their available levers to prioritise prompt implementation of the Review's recommendations and consider issues raised by the Sector Leaders Forum on an ongoing basis.

Issue: Long application queues and assessment time

3. Minister for the Environment and Minister for Food Safety request specific and ambitious targets to reduce HSNO and ACVM applications queues and accelerate assessment process.

Issue: Complexity of the approval path across the two regulatory systems

4. Make the two regulatory systems easier to navigate by better coordination between the two regulators, for example offering combined guidance, sharing industry knowledge and technical expertise, and supporting alignment of workable controls.

Issue: Disproportionate and inefficient regulation

5. Increase the use of HSNO rapid pathways and group standards, ACVM registration exemptions and self-assessments for appropriate product and application types.
6. Reduce ACVM efficacy requirements for inhibitors to the minimum required to manage risks.
7. The EPA and NZFS further use international regulators' assessments to save time and resources.
8. The EPA and NZFS prioritise engagement at the international level to support harmonisation of requirements.
9. NZFS and the EPA explore a strategic pathway for priority products to mitigate the impacts of waiting time in the current queues.

Issue: Concerns about regulators' resources, tools, and engagement

10. Update the EPA's outdated risk assessment models and considering how to keep them up to date for the future.
11. Review HSNO cost recovery provisions.
12. Strengthen the framework overseeing ACVM independent data assessors.
13. The EPA and NZFS improve their performance reporting, and the Ministry for the Environment and Ministry for Primary Industries review statutory timeframes.
14. The EPA and NZFS prioritise the provision of up-to-date guidance, pre-application support, and transparency on application processing.
15. Extend existing NZFS and EPA stakeholder engagement forums to operate across both regulatory systems for agricultural and horticultural products.
16. Review HSNO emergency provisions to better enable products to be approved for biosecurity responses.

The New Zealand Environmental Protection Authority (NZEPA) than 'found' $3.16 million to enable the risk assessment framework to be rebuilt under a contract held by a firm with commercial relationships to the regulated industry, with no outputs published and no independent validation framework in place.

The contract to evaluate and rebuild the risk assessment models, the foundational analytical infrastructure on which every HSNO approval rests, was awarded on 30 January 2026, after Cabinet had agreed all sixteen recommendations in February 2025, after the targeted stakeholder engagement had concluded in March 2025, and after the Bill's policy architecture was effectively settled.

The Government then instructed the drafting of the Bill even while the outdated models remain, by the government's own acknowledgement, unfit for purpose.

The contract to rebuild those models was awarded after the Bill's policy was already settled. This is not implementation. It is the appearance of implementation deployed to forestall the criticism that none was occurring.

At the same time, Parliament is being asked to entrench in statute an accelerated approval regime whose evidentiary foundation does not yet exist.

NZEPA CONTRACTOR: COMMERCIAL RELATIONSHIPS IN REGULATED SECTOR

The Government's response to the recognised out-dated and not fit for purpose nature of the NZEPAs risk assessment framework, including its methodology, was for the NZEPA to contract a firm for the following specified project[5]:

> *The Hazardous Substances Models Modernisation project is to deliver to the EPA modern, fit for purpose models and supporting data, to usefully strengthen our risk assessment processes. To be fully fit for purpose the EPA requires updates to a range of ecotoxicology, toxicology, and environmental fate models, data requirements, and environmental assessment factors.*
>
> *The project outputs must be aligned with international best practices and account for the use and impact of hazardous substances specific to New Zealand conditions.*
>
> *We are seeking a comprehensive update of our toxicology, ecotoxicology, and environmental fate models that underpin our risk assessment approach for hazardous substances. We are also seeking to obtain a range of data to support modelling that accounts for Aotearoa New Zealand-specific conditions.*
>
> *We are looking for an implementation partner with the relevant knowledge, qualifications, experience, and access to the relevant networks to deliver the requirements of this project*

The NZEPA subsequently contracted ERM (Environmental Resources Management), a London-headquartered global consultancy majority-owned by private equity firm KKR, at a cost of NZ$3.16

[5] MBIE. Ecotoxicology and Toxicology Models Modernisation. RFx ID:32645989. Stephen McCloskey https://www.gets.govt.nz/EPA/ExternalTenderDetails.htm?id=32645989. Award Date: Friday, 30 January 2026

million to modernise its hazardous substances risk assessment models (RFP 2992, awarded 30 January 2026).

ERM's paying clients include the chemical industry, for whom it provides product stewardship and regulatory compliance services including preparing dossiers for chemical approvals. No outputs from this contract have been published. ERM's own published case studies confirm a named, multi-year client relationship with Syngenta, one of the world's largest agrochemical companies, whose pesticides and herbicides are approved for use in New Zealand, for whom ERM has conducted global compliance audits across Syngenta's worldwide operations. ERM also actively recruits ecotoxicologists specifically to help agrochemical and biocide sector clients prepare risk assessment dossiers and navigate regulatory approval processes. ERM is, in other words, simultaneously being paid by the NZ EPA to design the models that will assess chemical risk in New Zealand, and operating a commercial practice that helps chemical companies navigate exactly those kinds of regulatory systems.

No outputs have been published. No conflict-of-interest framework for the contract has been made public. No independent peer review of the outputs has been announced. And the HSNO Amendment Bill creates new approval pathways, clause 33 temporary approvals and clause 31 expanded rapid pathway, that will rely on those models before they have been completed, published, or independently scrutinised.

[2] INCOMING NZEPA CEO MUST HAVE THE OPPORTUNITY TO ASSESS THE UNDERPINNING POLICY AND BILL CONTENT BEFORE IT PROCEEDS

The NZEPA is the statutory body responsible for implementing the HSNO Act. Its incoming Chief Executive, Lian Butcher, takes office after the submission deadline of 15 June 2026.

The submission deadline of 15 June 2026 falls before the incoming EPA Chief Executive, Lian Butcher, takes office. While Ms Butcher has an environmental biology background, she lacks a background in chemicals regulation or the specialised regulatory interface at the core of the HSNO Act's operation.

The truncated submission window means that the Bill's architecture will be substantially fixed before the officer statutorily responsible for implementing it has had any opportunity to assess its implications, contribute technical EPA expertise to the select committee process, or exercise independent regulatory judgment.

A new CEO arriving to a Bill already through select committee, with no expertise in regulatory systems, faced with a Bill with methodology requirements removed, public notification discretionary, and secondary legislation powers already delegated, inherits a framework she had no opportunity to scrutinise or contest.

Butcher will also be faced with a report from Syngenta contractor ERM, where the 'devil will be in the details', and where the regulatory risk context will be shaped by that contractor, and by legacy approaches within the NZEPA. This means that historical problems relating to persistence, bioaccumulation and toxicity by class, by formulation, and from mixture (cocktail) effects, where

the issues are unpalatable to industry toxicologists (and contested) but observed in the scientific literature, will risk being downplayed.

Few regulatory agencies have comprehensively incorporated these issues into routine risk-assessment practice, although European agencies have generally progressed further than many other jurisdictions.[6] [7] [8] [9] [10] [11] [12] [13] [14] [15] [16] [17]

First, the single-substance linear modelling in the 2020 HSNO methodology is not merely outdated, it has been explicitly identified by the Riedo/Rillig group and others as a fundamental methodological failure that systematically underestimates real-world risk, because the real world presents organisms with five to ten or more pesticides simultaneously, not one at a time.

Second, persistence means that regulatory decisions made on the basis of outdated science produce contamination that outlasts the assessment by decades, DDT in 31% of European soils in 2022 is the evidence.

Third, trophic amplification means that risks assessed at the point of application do not reflect risks at the point of ecological impact, contamination increases downstream and up the food chain, precisely the dynamic that New Zealand's freshwater and coastal ecosystems are most exposed to and that the HSNO methodology has no framework to assess.

Fourth, conventional risk assessment assumes a linear dose-response with a safe threshold below which no harm occurs, but endocrine-disrupting chemicals violate this assumption entirely, producing their most significant biological effects at the lowest doses, at developmental windows whose consequences may not appear for decades, and in combination with other substances

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[6] Gee, D. (Ed.), Grandjean, P. (Ed.), Hansen, S. F., van denHove, S. (Ed.), MacGarvin, M. (Ed.), Martin, J. (Ed.), Nielsen, G. (Ed.), Quist, D. (Ed.), & Stanners, D. (Ed.) (2013). Late lessons from early warnings: science, precaution, innovation. European Environment Agency. EEA Report Vol. 2013 No. 1 https://doi.org/10.2800/70069

[7] Persson L et al. (2022) Outside the Safe Operating Space of the Planetary Boundary for Novel Entities. Environmental Science & Technology 56 (3), 1510-1521 DOI: 10.1021/acs.est.1c04158

[8] Vandenberg LN, Pierce EJ and Arsenault RM (2025) Pesticides, an urgent challenge to global environmental health and planetary boundaries. Front. Toxicol. 7:1656297. doi: 10.3389/ftox.2025.1656297

[9] González Combarros R, González-García M, Blanco-Díaz GD, Segovia Bravo K, Reino Moya JL, López-Sánchez JI. Risk Assessment of Chemical Mixtures in Foods: A Comprehensive Methodological and Regulatory Review. Foods. 2026 Jan 9;15(2):244. doi: 10.3390/foods15020244.

[10] Trasande L, Sargis RM. Endocrine-disrupting chemicals: Mainstream recognition of health effects and implications for the practicing internist. J Intern Med. 2024;295:259–274.

[11] Meidl P, Lehmann A, Bi M, Breitenreiter C, Benkrama J, Li E, Riedo J, Rillig MC. Combined application of up to ten pesticides decreases key soil processes. Environ Sci Pollut Res Int. 2024 Feb;31(8):11995-12004. doi: 10.1007/s11356-024-31836-x.

[12] Riedo J, Rillig MC, Walder F. Beyond Dosage: The Need for More Realistic Research Scenarios to Understand Pesticide Impacts on Agricultural Soils. J Agric Food Chem. 2025 Apr 30;73(17):10093-10100. doi: 10.1021/acs.jafc.4c12818.

[13] Walder F, Schmid MW, Riedo J. et al (2022). Soil microbiome signatures are associated with pesticide residues in arable landscapes. Soil Biology and Biochemistry 174:108830, https://doi.org/10.1016/j.soilbio.2022.108830

[14] Preprint. Dr. Fabian Balk, Dr. Eva Lauber, Dr. Benoît J.D. Ferrari, et al. Current mixture toxicity assessments on soil organisms and applied risk assessments. ChemRxiv. 21 November 2025. DOI:10.26434/chemrxiv-2025-3kvxt

[15] Hou L, Xiong W, Xu J et al (2025). Pesticide Pollution Reduces the Functional Diversity of Macroinvertebrates in Urban Aquatic Ecosystems Environ. Sci. Technol. 2025, 59, 17, 8568–8577. https://doi.org/10.1021/acs.est.5c01093

[16] Qin Y, Cao H, Cheng C et al (2025). Occurrence and ecological risk of typical pesticides in a river–lake system. Water Science and Engineering, 18: 4:422-430. https://doi.org/10.1016/j.wse.2025.09.003

[17] Sefali, S., Ruby, R., Dimple, D. et al. Toxicological implications of emerging pollutants on aquatic organisms. Discov Environ 4, 43 (2026). https://doi.org/10.1007/s44274-026-00557-y

acting on the same hormonal pathway. The HSNO 2020 methodology's linear modelling instruments cannot detect this category of harm

The New Zealand science system does not fund this work, and the NZEPA are neither funded, nor required to undertake the work to understand broader human and environmental systems toxicology, based on the state of science in 2026.

The Chief Executive of the NZEPA has both the authority and the responsibility to revise current approaches and assess legislative proposals that fundamentally reshape the agency's core functions, its decision-making powers, its risk assessment obligations, and its relationship with the public it serves.

NO, NOT A SHORTAGE OF TOXICOLOGISTS

The Regulatory Impact Statement identifies a shortage of toxicologists as a constraint on the EPA's capacity to conduct independent risk assessment, and uses this constraint as partial justification for increased reliance on overseas regulatory decisions. The factual record suggests a more precise characterisation is warranted.

In late 2024, the NZEPA proposed disestablishing one in five positions across the agency as a direct consequence of central government funding reductions. Budget 2024 imposed targeted reductions of $9.6 million to environmental evidence and data funding by 2028, with those savings redirected to RMA reform. The agency's capacity to employ and retain specialist toxicologists is therefore, at least in part, a function of resourcing decisions made at central government level rather than solely a reflection of available workforce supply.

The distinction matters for the purposes of this submission. A workforce scarcity framing locates the constraint outside the regulatory system, as a labour market condition beyond government control. A resourcing framing locates it within the system, as a consequence of funding choices that are, in principle, reversible. If the EPA's reduced assessment capacity reflects the latter rather than the former, then the Bill's proposed solution, accelerating approvals and increasing reliance on overseas regulators, addresses a symptom while leaving the cause unexamined.

The appropriate policy response to an underfunded regulator is adequate funding, not a reduction in the standard of assessment the regulator is required to perform. The submission respectfully invites the Committee to consider whether the RIS has correctly identified the nature of the constraint it relies upon to justify the Bill's central design choices.

The NZEPA's decision to contract an external consultancy for $3.16 million to rebuild the risk assessment methodology, rather than investing equivalent resourcing in internal capability, warrants scrutiny in this context. An internal process, drawing on recruited specialist staff, would have built institutional knowledge, identified constraints from within the system, and left the NZEPA with enhanced capacity after completion.

[3] STAKEHOLDER COI's UNDERMINE BILL 304-1 CONSULTATION

The pre-Bill consultation comprised fourteen days in March 2025 and involved eleven organisations, the majority of which were industry bodies or Crown Research Institutes with direct

commercial interests in faster approvals. No independent public health organisations, no medical associations, no toxicologists from outside the regulated sector, no environmental NGOs, no consumer organisations, no organic sector representatives, no communities with direct exposure to agrichemicals, and no national Māori body were included. A single Māori entity, Te Rūnanga o Ngāi Tahu HSNO Komiti, was the only voice representing Treaty interests for the entire country.

The Sector Reference Group that informed the Ministry for Regulation (MfR) Agricultural and Horticultural Products Regulatory Review (February 2025) providing much of the information that resulted in the 16 recommendations included representatives from (formerly Agcarm) Animal and Plant Health New Zealand (APHANZ), Dairy Companies Association New Zealand, Federated Farmers of New Zealand, Foundation for Arable Research, Horticulture New Zealand, Veterinary Council of New Zealand, and New Zealand Wine Growers.

The consultation that underpinned Ministry for the Environment decision-making for the HSNO Amendment Bill primarily involved a similarly select group:

> **What consultation has been undertaken?** From the 11 to 24 March 2025, MfE officials undertook a series of meetings with targeted stakeholders, with meetings geared towards either hazardous substances, new organisms or both. The participating stakeholders received a slide deck outlining the proposals.

Former AGCARM and agrichemical lobbyist APHANZ was included in the seven organisations involved in targeted engagement on Hazardous Substances, while over half of the organisations invited to the New Organisms (genetically modified organisms) are active investors in GMO and biotech development, therefore they have a direct financial interest in GMO and other biotech approvals. Whilst government intention for this Bill may be to enable those sectors, it is not acceptable to prioritise only those interests in consulting and development of the Bill.

NEW ORGANISMS CONSULTATION

Of the seven organisations present at the new organisms consultation, the conflicts of interest are concentrated and can be demonstrated. The participating organisations were AgResearch, Manaaki Whenua Landcare Research, Plant and Food Research, Scion, New Zealand Plant Producers Incorporated, AgriZeroNZ, and Te Rūnanga o Ngāi Tahu HSNO Komiti.

No environmental health organisation, no independent scientists or toxicologists, no consumer group, and no public health body appears on the list. Te Rūnanga o Ngāi Tahu HSNO Komiti was the sole voice with a mandate to represent interests other than research, industry, or production. A consultation conducted over two weeks, among eleven organisations, the majority of whom have active financial stakes in the outcome, cannot credibly be characterised as the evidence base for legislation that will govern the release of genetically modified organisms into New Zealand's environment.

Four of the seven have merged into an institute dedicated to advancing biotechnologies. AgResearch, Plant and Food Research, Manaaki Whenua – Landcare Research and Scion are Crown Research Institutes that merged in July 2025 into the New Zealand Institute for Bioeconomy Science, a body explicitly focused on accelerating bioeconomy-related science and advanced biotechnologies. All three carried, and the merged institute carries, active GMO and gene editing

research programmes whose commercial deployment depends directly on the regulatory pathway the Bill creates. Their institutional interest in a more permissive new organisms approval regime directly relates to their research commercialisation prospects and future financial gain.

Again, while acknowledging government intention for this Bill may be to enable those sectors, it is not acceptable to prioritise only those interests in consulting and development of the Bill.

Manaaki Whenua Landcare Research's new organism work primarily involves importing biocontrol agents into containment for weed and pest management research. Manaaki Whenua is a member of GBIRd, the Genetic Biocontrol of Invasive Rodents partnership, which received funding from DARPA, the US military's advanced research agency, identified as the world's largest funder of gene drive research, committing approximately $100 million to the technology. Documents showed that New Zealand islands were considered for field trials of gene drive technology, with GBIRd members in contact with the Department of Conservation about suitable sites. Staff at Manaaki Whenua have been involved in New Zealand funded research modelling the capacity for CRISPR gene drive systems to eliminate rodents on New Zealand islands.

Gene drives, self-propagating genetic modifications designed to spread through and potentially suppress or eliminate a wild population, represent perhaps the most consequential and irreversible application of new organism technology contemplated for environmental release. Manaaki Whenua's research interest in gene drives for conservation purposes is framed in environmental rather than commercial terms, but it gives the organisation an institutional stake in the emergency and biosecurity provisions of the Bill, and in lower thresholds for development of organisms in containment, that was not disclosed at the consultation.

The framing of invasive species management as a conservation imperative 'the war on pests' provides a politically sympathetic pathway for introducing gene drive organisms into the regulatory framework, one that is structurally easier to defend publicly than the commercial GMO approvals sought by AgResearch or AgriZeroNZ, but whose environmental consequences, once a gene drive organism is released, are no less permanent.

AgriZeroNZ is a public-private joint venture with $191 million committed to developing biotech emissions reduction tools, including engineered organisms. Its CEO has publicly stated that the pathway for future engineered products will be dependent on the outcome of the Gene Technology Bill. The government retains 50 percent ownership through the Ministry for Primary Industries, meaning the Crown is simultaneously a co-owner of an entity with a direct financial interest in the regulatory outcome, and the author of the legislation designed to create it.

New Zealand Plant Producers Incorporated represents nursery operators and plant propagators with legitimate biosecurity and plant health interests in the new organisms regime. Its conflict of interest is the least acute of the group, it is a downstream user rather than a developer of new organisms, but its regulatory preferences, particularly around faster pathways for biocontrol agents and approved plant material, align with the reform's direction.

Te Rūnanga o Ngāi Tahu HSNO Komiti was the sole participant with a mandate grounded in Treaty obligations, kaitiakitanga, and community wellbeing rather than research or commercial interest. A single iwi body, however expert and engaged, cannot structurally counterbalance six

organisations whose institutional interests are aligned, to varying degrees and for varying reasons, with a more permissive new organisms approval regime.

The consultation was not a balanced evidence-gathering exercise. It was, in its new organisms composition, a conversation dominated by institutions that develop, fund, or depend upon the commercial deployment of new organisms, with one iwi body as the sole voice oriented toward protection rather than permissiveness.

HAZARDOUS SUBSTANCES CONSULTATION

Of the six organisations invited to the targeted hazardous substances engagement, the conflict of interest profile is as follows.

APHANZ is, as documented throughout this article, the lobby group for multinational agrochemical manufacturers, Syngenta, Bayer, BASF, Corteva, Nufarm, FMC, and UPL, whose products are the hazardous substances whose approval pathway the Bill directly advances. Its presence is not a conflict of interest to be noted; it is the originating cause of the review itself, confirmed in the RIS's own language. APHANZ was formerly known as Agcarm, however the name was changed in 2022, '*after the Animal Remedy and Plant Protectant Association joined the fold and to better reflect a $1 billion industry*.'

Federated Farmers is the national lobby group for farming businesses. It has no institutional conflict of interest in the sense of financial stakes in agrichemical approvals, but its policy positions on regulatory reform have consistently aligned with industry calls for faster approvals and reduced compliance costs. It co-signed letters with APHANZ calling for bold action on approval backlogs. It represents users of agrichemicals, not a neutral public interest.

Horticulture New Zealand is a growers' advocacy body whose corporate membership of the New Zealand Plant Protection Society places it in the same institutional body as Bayer Crop Science, Corteva, Syngenta, Nufarm, and UPL. Its regulatory interests — faster access to crop protection products — structurally align with those of the manufacturers funding the same sector bodies.

A Lighter Touch, has Corteva Agriscience, a core APHANZ member and one of the world's four dominant agrichemical multinationals, as a foundation crop protection partner. It cannot be characterised as an independent horticultural voice in a consultation about hazardous substance approvals where Corteva's products are directly at issue.

AgriZeroNZ is a public-private joint venture with $191 million committed to developing biotech emissions reduction tools, with the government holding 50 percent through MPI. Several of its portfolio investments involve engineered organisms and agrichemical-adjacent products whose regulatory pathway sits within the HSNO framework. It has a direct financial interest in the outcome.

Te Rūnanga o Ngāi Tahu HSNO Komiti is the sole participant with a mandate grounded in Treaty obligations, environmental kaitiakitanga, and community wellbeing rather than commercial interest. Its presence is necessary and appropriate; it is also, structurally, a single voice against five organisations whose interests are commercially aligned with the reform's direction of travel.

[4] RISK: BILL TEXT MAY UNDERMINE HSNO PRINCIPLES AND PURPOSE

The Amendment Bill does not repeal sections 4 to 7 of the 1996 Act, the purpose, principles, precautionary approach, and matters including public health, ecosystem integrity, and Māori relationships with taonga, and the government will point to this throughout the select committee process.

Precautionary principle undermined by rapid assessment and light touch pathways

However, the legal question is not whether those provisions survive on paper; it is whether the operational architecture of the Bill is compatible with them in practice.

The precautionary principle in section 7 requires that decision-makers '*take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty*.' Courts have interpreted this as requiring that the uncertainty itself be identified and weighed, the Act has been described as *'risk averse but not 'no risk*.'' That duty falls on the person exercising the function.

But the Bill shifts this interpretation to propose that applications be assessed through expanded '*rapid assessment'* and '*light-touch'* pathways, with greater deference to prior decisions of overseas regulators. These regulators would have conducted their assessments under different legislative mandates, with no obligation to apply the precautionary standard of section 7, and no regard for the specific requirements of section 6 around public health, ecosystem intrinsic value, or Māori relationships with their taonga.

Reliance on assessments undertaken by the US EPA, EFSA, or other overseas regulators does not, of itself, discharge New Zealand's statutory obligations under sections 5, 6, and 7; it simply substitutes a foreign cost-benefit analysis for a domestic one.

An additional problem concerns the shift in procedure: under the Bill, public notification would occur only where the NZEPA considers there to be 'significant public interest', replacing the current presumption of notification with a gatekeeping discretion held by the same regulator being asked to process applications faster.

It must be clear to the Select Committee that there is significant and broad public interest in matters relating to gene technology having social license that should not be obscured or subverted by discretionary decision-making for technical re-definitions or notifications. For example, New Zealand is not a party to the Aarhus convention whilst European environmental governance has been significantly shaped by the Aarhus Convention, which places strong emphasis on access to information, public participation, and access to justice. As a result, European regulatory systems often embed extensive consultation and transparency mechanisms within environmental decision-making processes.[18] Many European frameworks tend to specify assessment methodologies, uncertainty frameworks, consultation requirements, evidential standards and review procedures in considerably greater detail than appears in parts of the HSNO Amendment Bill.

[18] Statement on Entry into Force of the GMO Amendment to the Aarhus Convention. https://www.cbd.int/article/aarhus-convention-gmo-amendment-2025

Section 6(c) requires that public health be taken into account; the public, including health professionals and iwi, are the primary bearers of the risks that sections 4 to 7 are designed to manage. A process that systematically reduces their standing to participate does not formally contradict those sections, but it removes the mechanism by which they could ever be enforced.

No capacity to weigh uncertainty and hence cost-benefit

Of significant concern is that the precautionary duty in section 7 presupposes a regulator with the scientific capacity to identify and weigh uncertainty. Currently, as the PCE has highlighted, the NZEPA does not currently have that capacity, and the Amendment Bill does nothing to change or improve this situation. The NZEPA itself has acknowledged that funding constraints and a shortage of specialist ecotoxicologists have been a recurring theme of its ministerial briefings for several years, and that the complexity of applications has increased over the same period, requiring more extensive assessments.

The NZEPA faces a problem well known to global regulators, i.e., systemic underfunding that expressly limits the regulator's ability to perform its functions. A 2023 government briefing confirmed the EPA faced a projected $65 million shortfall over four years, with minimal capacity for post-approval monitoring and enforcement. Meanwhile, the Parliamentary Commissioner for the Environment (PCE) found in 2022 that New Zealand operates a '*disjointed and patchy system for asking, and answering, questions about the environmental fate and impact of chemicals'*, and that the country has long operated on the basis of '*what you don't know can't hurt you'*.

This signals that targeted amendments to the HSNO Act like this Bill, will fail to meet the purpose and objectives without proper time and attention taken in their development. The failure extends into the future when the EPA is without capacity, funding and operational systems to be informed.

Experts reviewing the PCE's report noted that New Zealand relies on international literature for guidance on the toxicity of chemical contaminants, with no adequate local data collection. This means that compounds cannot be systematically prioritised for research and emerging risks go undetected. New Zealand remains the only OECD country without a pollutants release and transfer register, meaning there is no systematic national record of what chemicals are used, in what volumes, or where they end up, in groundwater, in soil, in the bodies of the farmers and rural workers applying them and in food.

Despite this recognised void, the Amendment Bill proposes to accelerate approvals and reduce public participation. There is no register or systematic national record, but there needs to be. An agency that lacks the ecotoxicological staff to independently evaluate overseas risk assessments, that cannot track what is already in the environment, and whose risk models are being rebuilt by a commercial consultancy with industry clients, is not equipped to exercise the precautionary judgment that sections 5, 6 and 7 require. The Bill speeds up a system whose protective underpinnings are already compromised; it does not repair them.

[5] HSNO AMENDMENT BILL SPECIFIC FAILINGS

(a) INCREASING AMBIGUITY OF LANGUAGE

Of substantial concern is the increasing reliance on broad and discretionary regulatory concepts, both in the Regulatory Impact Statement and the Bill itself, in place of clearly defined statutory tests, assessment frameworks, and decision-making criteria.

A number of concepts central to decision-making, including *low risk*, *risk species*, *vagrant*, *significant public interest*, and *recognised international regulator*, either lack clear definition or derive their substantive meaning from future regulations, NZEPA notices, or administrative determinations. As a consequence, the legislation often establishes a framework without specifying the evidential thresholds, criteria, or methodologies that will govern how these concepts are applied in practice. This can make it difficult for applicants, affected parties, and the public to understand in advance how decisions will be reached or to scrutinise whether those decisions are being made consistently.

A related issue is the increasing delegation of substantive policy decisions from primary legislation to secondary instruments. Matters that go to the heart of regulatory oversight, such as what constitutes a *low-risk* organism, the criteria for streamlined approvals, or the designation of *risk species*, are increasingly capable of being determined through EPA notices or administrative processes rather than through Parliament. While delegated powers can improve flexibility and responsiveness, they also reduce the level of parliamentary scrutiny applied to decisions that may have significant environmental, economic, and public policy implications. The cumulative effect is that important policy choices may be made outside the legislative process itself.

The Bill also introduces or elevates a number of regulatory categories that are not established scientific classifications. Terms such as *denewed organism*, *risk species*, and *vagrant organism* are not biological or taxonomic concepts but administrative constructs created for regulatory purposes. Their legal significance therefore depends entirely upon how they are interpreted and applied by the regulator. This creates a risk that categories which appear objective or scientific may in practice operate as discretionary policy tools, particularly where the legislation provides little guidance on the evidential standards or decision-making criteria that apply.

The proposed use of the term *vagrant* as a new regulatory category (a threshold concept), is particularly notable. While the term has an established meaning in ecology, where it generally refers to a naturally bred (non-GMO) organism occurring outside its normal range on an occasional or transient basis. It does not appear to be an established term used within GMO, gene-editing, or biotechnology regulation internationally. The Bill appears to repurpose an ecological descriptor into a legal category that carries regulatory consequences, yet provides limited guidance as to the threshold between a vagrant occurrence, a recurring population, a feral population, or an established population. In the context of self-replicating organisms, including genetically modified organisms, such distinctions may be highly consequential.

The repeated use of terms such as *low risk* and *risk-proportionate* also raises questions of legal certainty. These expressions can create an appearance of scientific precision, yet they are ultimately policy conclusions rather than scientific facts. Determining whether an activity is low

risk requires judgments about hazard, exposure, uncertainty, reversibility, timeframes, and acceptable levels of harm. Unless the methodology and decision criteria are clearly specified, different decision-makers may reasonably reach different conclusions while using the same terminology. The Bill therefore risks embedding significant discretion behind language that appears more objective and determinate than it may be in practice.

Taken together, these features suggest a shift from a legislative model in which Parliament defines the substantive criteria governing approvals and regulatory oversight, toward one in which Parliament establishes broad enabling powers and regulatory categories, with much of the operational meaning subsequently developed through notices, guidance, and administrative decision-making. From a rule-of-law and regulatory-governance perspective, the key question is whether the legislation provides sufficient certainty, transparency, and accountability regarding how those powers will be exercised, particularly where decisions concern novel technologies, self-propagating organisms, and areas characterised by scientific uncertainty.

Clause 7 removes the requirement for a publicly established methodology, the foundational quality-assurance mechanism of the entire HSNO Act, for a new class of approvals that will last up to four years in commercial use.

Clause 33 creates "temporary hazardous substance approvals" (**new sections 29A–29AC**) allowing substances to enter the New Zealand market for up to four years on the basis of approval by just two overseas regulators, without full assessment, without public notification, and without any requirement that those overseas approvals used current, independent, or formulation-level risk assessment.

The '*lawfully authorised by at least 2 international regulators'* criterion in **new section 29A** contains no requirement that those overseas assessments covered the formulated product. A substance approved by two overseas regulators based on single active ingredient assessment, using models equivalent to or older than NZ's own outdated tools, would qualify for temporary New Zealand market entry without any of these considerations being examined.

When New Zealand's EPA officially 'recognises' an overseas regulator, it only checks whether that regulator's general system is broadly comparable to our own, it never looks at the quality of any individual decision that regulator has made. This means it cannot tell whether a specific approval is based on recent science, independent research, or industry-supplied data. The proposed Amendment Bill makes this worse by allowing a substance to be fast-tracked into New Zealand if just two overseas regulators have approved it.

However, two regulators can easily both be relying on the same original assessment, often one conducted by an international panel with no public accountability and heavily dependent on data provided by the very industry seeking approval. Counting two jurisdictions is not the same as having two independent scientific opinions. The law as it stands, and as proposed, confuses trusting a regulator's general processes with trusting any particular decision that regulator has made, and provides no mechanism to ask how old that decision is, who paid for the underlying science, or whether the originating country had a commercial interest in the outcome.

Clause 31 narrows the '*significant effects test*' that governs the rapid assessment pathway (section 28A), making it easier to rely on overseas assessments as substitutes for New Zealand-specific analysis.

(b) PUBLIC NOTIFICATION COLLAPSE

Clause 85 replaces the existing public notification regime with one in which the Authority notifies applications only 'if the Authority considers that there is likely to be significant public interest'. This converts public participation from a right to a discretion exercised by the regulator itself. It is possible that regulatory creep could phase out the right for public participation altogether.

Clause 12 simultaneously delegates hearing and decision-making powers for non-publicly-notified applications to the EPA chief executive (new section 19(2)(cb)). The practical consequence: the same person determines whether public interest is significant, and if not, makes the approval decision. There is no independent check or balance at either stage. This does not provide an independent check on the regulatory assessment.

The temporary approvals created by clause 33 are expressly excluded from public notification (new section 53(6)). This means a substance can enter the New Zealand market for up to four years, exposing workers, communities, animals, waterways, and ecosystems, without any public awareness that an application was made or decided.

For Māori, the consequences are specific and serious. The HSNO Act section 8 obligation to take Treaty principles into account has historically been given substance through public notification, which provides the mechanism for iwi and hapū to identify effects on taonga species, mahinga kai, and waterways. The Bill creates no new Māori participation mechanism to replace what it removes. The pre-Bill consultation (fourteen days in March 2025) involved a single Māori entity for the entire country.

(c) OVERSIGHT ARCHITECTURE: CONCENTRATED POWER, PUBLIC SCRUTINY CLOUDED

The Bill systematically removes transparency around consequential regulatory decisions by shifting them from primary legislation and public processes into secondary instruments and administrative determinations.:

Clause 114 (new Part 5A, sections 73E–73J) allows the Authority, or the chief executive by delegation, to prescribe organisms as 'not new organisms' by NZEPA notice, permanently removing them from HSNO Act coverage. These exclusions and definitions are well evidenced as a matter of public concern but from which the public are to be excluded. No parliamentary approval is required. Consultation is conditional on the Authority what significant effects would result. How could they possibly know all of the effects, if the organisms have not been released in New Zealand before?

Clause 42 (new section 34B) creates a pathway for conditionally released new organisms, including GMOs, to transition to release without controls, based on criteria set entirely by EPA notice. Parliament sets no floor. The environmental consequences of unconditional organism release are irreversible and have potential to be devastating financially and ecologically devastating.

Clauses 147–151 move statutory assessment timeframes into regulations. Once enacted, timeframes are removed from broader public scrutiny and can be extended or compressed by regulation without parliamentary debate.

Clause 68–70 replaces 'emergency' with 'adverse event' as the trigger for accelerated approvals, broadening the pathway to include any biosecurity incursion managed under the Biosecurity Act, without requiring a formal emergency declaration that would create public visibility and ministerial accountability.

The Regulations Review Committee, cited in the Regulatory Impact Statement as adequate scrutiny for secondary legislation, reviews delegated legislation for technical compliance with its enabling Act. It does not conduct substantive risk assessment or science-quality review.

(d) UNDERSTANDING REGULATORY CONCEPTS: WHERE ARE THE DECISION-MAKING CRITERIA LOCATED?

A comparison of New Zealand and European regulatory systems is a valuable exercise as it focuses attention on the regulatory architecture rather than the merits of any particular technology.

Whether the subject matter is a hazardous substance, genetically modified organism, gene-edited organism, synthetic biology product, or another emerging technology, the fundamental question is how decisions are made under conditions of scientific uncertainty.

European frameworks generally seek to make this process visible by separating scientific assessment, risk-assessment methodology, and policy decision-making, and by anchoring key regulatory concepts within published methodologies, statutory criteria, uncertainty frameworks, and consultation requirements. This provides transparency regarding the evidence considered, the assumptions adopted, the treatment of uncertainty, and the basis upon which risks are judged acceptable or unacceptable. From a governance perspective, the issue is therefore not whether a particular technology should be approved, but whether the legislative framework provides sufficient certainty, accountability, and transparency regarding how approval decisions are reached and how regulatory discretion is exercised.

A notable feature of many European regulatory systems is that broad regulatory concepts are rarely left to operate as standalone legal categories. Instead, terms that carry significant regulatory consequences are generally embedded within a broader framework comprising statutory criteria, published methodologies, technical guidance, implementing measures, consultation requirements, evidential standards, and uncertainty-analysis frameworks. As a result, the practical meaning of key concepts is typically derived not from the words themselves, but from the transparent assessment processes and decision-making methodologies that sit beneath them.

(i) Low Risk

In New Zealand's HSNO Act the phrase 'low risk' appears only in limited contexts. For example the '*Rapid assessment of projects for low-risk genetic modification*' (s 42A) appears in the table of contents. There is no general definition of 'low-risk' in the interpretation section of the Act. The Act does not set out a risk gradient in order to define whether a substance or organism presents a low,

negligible, acceptable or insignificant risk. Historically, the detail has been supplied through regulations and NZEPA processes rather than through a statutory definition. Therefore the term 'low-risk' functions more as a gateway category than a legislatively defined risk concept.

Within European chemicals, food, biotechnology, and pesticide regulation, low risk is generally treated as the outcome of a structured assessment rather than a self-defining category. Regulatory conclusions are typically supported by hazard identification, exposure assessment, risk characterisation, uncertainty analysis, and defined decision criteria. For example, where European legislation establishes special pathways for lower-risk substances or activities, those pathways are ordinarily linked to specified statutory criteria and exclusion criteria rather than a broad discretionary judgement that an activity is simply considered to be low risk. The assessment framework therefore remains visible and capable of independent scrutiny.

(ii) Vagrant

The term 'vagrant' does not exist in the HSNO Act. In ecology and biogeography, a vagrant species is a recognised term referring to an organism occurring outside its normal range, often arriving accidentally through dispersal events. However, what is striking here is that the Bill appears to use 'vagrant' as a regulatory category without inserting a definition into the interpretation provisions. The explanatory note repeatedly refers to organisms in Schedule 2 'that the Authority considers to be a vagrant' and creates a special pathway for their development in containment. The explanatory note states that:

> *development of a new organism specified in Schedule 2 that the Authority considers to be a vagrant may be permitted in accordance with an approval granted under section 45*.

The Bill then creates a distinct assessment pathway and additional considerations regarding offspring, progeny, descendants, and containment. However, while the consequences of being classified as a vagrant are described, the process for determining whether an organism is a vagrant is largely not.

Neither the Bill nor the accompanying explanatory material appears to specify the evidential threshold by which an organism becomes, remains, or ceases to be a 'vagrant'. In particular, the material does not appear to address how the concept applies to recurring occurrences, reproducing populations, volunteer organisms arising from escaped heritable material, or descendants of genetically modified organisms. While the designation carries significant regulatory consequences, the criteria governing its application do not appear to be clearly articulated. This may create uncertainty regarding both the scope of the category and the consistency with which it may be applied.

No directly equivalent concept appears to exist within European biotechnology, GMO, NGT, or gene-editing regulation. Instead, European frameworks tend to rely on established ecological and regulatory concepts such as volunteer plants, feral populations, adventitious presence, naturalised species, invasive alien species, or established populations. These terms are supported by extensive scientific literature and generally have recognised meanings within their respective disciplines. Where distinctions between transient and established populations are important, those distinctions are usually addressed through biological criteria, ecological

assessment, or defined regulatory classifications rather than through a broad discretionary determination.

(iii) Risk Species

Section 2 of the HSNO Act defines risk species:

> *'risk species means any species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species under section 140'*

Section 140 then provides the power to prescribe a risk species:

> *a species may be prescribed as a risk species where it "may have adverse effects on the health and safety of people or the environment".*

The HSNO Act does not describe:

- A threshold of adverse effect;
- A definition of risk;
- An evidential standard;
- A methodology;
- An uncertainty framework.

The Act therefore explains when the power may be exercised, but does not establish a detailed framework for determining when a species should become a risk species.

European regulation generally avoids broad classifications such as risk species in favour of more specific legal categories tied to defined criteria. Examples include quarantine pests, regulated non-quarantine pests, invasive alien species, protected species, and species of Union concern. In each case, the category is supported by statutory definitions, assessment criteria, and procedural requirements governing designation and review. The regulatory focus is therefore placed on the conditions under which a species is classified rather than on an open-ended determination that a species presents a risk.

(iv) Recognised International Regulator

European regulatory systems frequently rely upon international science and foreign regulatory assessments. However, this reliance is usually structured through formal concepts such as equivalence, mutual recognition, international standards, OECD test guidelines, or specific third-country recognition arrangements. The relevant legislation or guidance typically specifies the criteria by which external assessments may be relied upon and the conditions under which they are considered comparable. The emphasis is therefore not simply on whether a regulator is recognised, but on whether the underlying scientific standards, legal frameworks, evidential requirements, and procedural safeguards are sufficiently equivalent.

(v) Significant Public Interest

The term 'significant public interest' appears as a trigger for discretion, but seems to lack any general statutory definition. There is a significant difference between the *public interest* (a well-developed legal concept), and *significant public interest* (usually a discretionary policy phrase).

The Ombudsman has stated that 'public interest' is not defined and must be assessed in context. Factors include accountability, participation in decision-making, public health, environmental protection, expenditure of public money, and matters affecting large numbers of people.

Regulatory Impact Statements and Cabinet papers often using 'significant public interest' as a reason for consultation, ministerial involvement, or enhanced scrutiny but the threshold is usually left undefined.

The concept of 'significant public interest' should not be determined solely by the level of public attention, political interest, or stakeholder advocacy associated with a proposal. In areas involving hazardous substances, genetically modified organisms, gene-edited organisms, and other emerging technologies, public interest is often inseparable from scientific uncertainty, the potential scale of consequences, the distribution of risks and benefits, and the degree to which important questions remain unresolved.

The phrase does not appear to be a defined concept in the current HSNO Act. The closest provision is the Ministerial call-in power. Section 68 is titled:

> *'Minister's power to call in applications with significant effects'*

Scientific evidence therefore plays a critical role in informing whether a matter warrants heightened scrutiny. However, for science to legitimately support public-interest determinations, the assessment process itself must be demonstrably robust, transparent, and procedurally fair. This requires systematic consideration of the full body of relevant evidence, including evidence of hazard, exposure, uncertainty, vulnerability, cumulative effects, and knowledge gaps. Equally important, it requires that evidence selection criteria, methodologies, assumptions, and limitations be visible and capable of independent scrutiny.

Scientific advice that is selective, non-systematic, or reliant upon unpublished judgements risks undermining confidence in the decision-making process itself. In this sense, significant public interest is not simply a question of scientific findings, but of scientific process. Where the scientific assessment concerns matters with potentially wide-ranging environmental, health, cultural, economic, or intergenerational consequences, the public interest is served not merely by obtaining expert advice, but by ensuring that the process by which that advice is generated is transparent, methodologically rigorous, reviewable, and capable of withstanding independent examination.

European environmental governance is strongly influenced by principles of transparency and participation, particularly through the Aarhus Convention framework (which New Zealand is not a signatory to). Public participation rights are therefore often built directly into regulatory processes rather than being triggered only when a regulator determines that significant public interest exists. While concepts such as public interest remain relevant, the system generally places greater emphasis on procedural rights, public consultation, access to information, and participation mechanisms that operate independently of a prior determination regarding the level of public interest.

(vi) Risk-Proportionate

The term risk-proportionate does not appear in the HSNO Act 1996. Rather, it has emerged as a contemporary regulatory policy concept frequently used in Cabinet papers, Regulatory Impact Statements, reform programmes, and departmental policy documents. Despite its increasing prominence, the term does not currently have a statutory definition, prescribed methodology, or established legal test within the HSNO framework.

At a practical level, a risk-proportionate approach is not inherently problematic. Regulatory effort should ordinarily bear some relationship to the magnitude, likelihood, and consequences of potential harm. However, the phrase increasingly functions as a policy objective rather than an operational standard. It communicates an intention to align regulatory scrutiny with risk, but often without specifying how risk is to be identified, measured, characterised, or weighed against uncertainty.

Proportionality cannot be determined independently of methodology. Before a regulator can conclude that a regulatory response is proportionate, there must first be a transparent process for evaluating the evidence, identifying hazards, assessing exposure pathways, characterising uncertainty, and determining what level of risk is considered acceptable. Without such a framework, proportionality becomes a conclusion rather than an assessment. The term may therefore create an appearance of scientific precision while masking substantial discretion regarding how evidence is selected, interpreted, and weighted.

This issue is becoming increasingly significant at the interface between science and regulation. Across a range of policy domains, including hazardous substances, biotechnology, gene editing, environmental health, and emerging technologies, regulators and policymakers frequently invoke risk-proportionate regulation as a justification for streamlined approvals, reduced assessment requirements, or reliance on overseas decisions. PSGRNZ observed this in the Ministry of Business, Innovation, and Employment's policy and in the draft text of the Gene Technology Bill.[19]

Yet in many cases the underlying scientific assessment processes remain insufficiently visible. There is often limited evidence that the full body of relevant literature has been systematically identified, evaluated, and synthesised through a published methodology. Instead, conclusions may rely upon selected expert advice, existing institutional assumptions, targeted literature reviews, or regulatory precedent, without providing transparency regarding what evidence was included, excluded, or considered uncertain.

From a scientific perspective, the credibility of a risk-proportionate framework depends not merely on the expertise of decision-makers but on the procedural integrity of the assessment process itself. A conclusion that a regulatory response is proportionate can only be meaningfully evaluated if the methodology used to reach that conclusion is visible and reproducible. This ordinarily requires clear evidence-selection criteria, systematic literature review methods, documented treatment of conflicting findings, explicit consideration of uncertainty, and transparent explanation of how scientific evidence informs regulatory judgement. Without these elements, it becomes

[19] PSGR (2025) When powerful agencies hijack democratic systems. Part I: The case of gene technology regulatory reform. Bruning, J.R., Dommisse, E.. Physicians & Scientists for Global Responsibility New Zealand. ISBN 978-1-0670678-0-9

difficult to distinguish between a conclusion that is genuinely evidence-based and one that primarily reflects institutional preference, policy objectives, or administrative convenience.

European institutions frequently refer to proportionality, but proportionality is generally treated as a legal principle rather than as a substitute for risk assessment. The principle operates within a broader framework requiring that regulatory measures be suitable, necessary, and proportionate to the objectives being pursued. Importantly, proportionality is ordinarily applied after the relevant scientific assessment has been conducted. In practice, proportionality sits alongside precaution, uncertainty analysis, evidence evaluation, and statutory objectives. It does not replace those processes.

(vii) A 'denewed' organism.

The term '*denewed organism*' appears nowhere in international regulatory, scientific, or biosafety law. No comparable jurisdiction, not the European Union under Directive 2001/18/EC, not the United States under the Coordinated Framework for Biotechnology Regulation, not Australia under the Gene Technology Act 2000, not Canada, and not the Cartagena Protocol on Biosafety framework, has resolved the definitional challenge posed by gene-edited organisms by creating an administrative power to declare that an organism previously subject to regulatory oversight is no longer so by notice. Each of those jurisdictions has addressed the question through transparent legislative amendment to the definition of a regulated organism, a process subject to parliamentary scrutiny and disallowance.

The Bill instead invents a term without scientific foundation, without international legal precedent, and without equivalent in any comparative biosafety framework, and vests in an administrative officer the power to apply it by notice, converting what is properly a question of biological fact and legislative definition into a matter of administrative declaration. The absence of this term from the entire body of international regulatory law is not incidental: it reflects the globally recognised principle, most recently affirmed in the European Court of Justice in Case C-528/16 Confédération paysanne, that the regulatory status of a genetically modified organism is determined by what it is, not by what a regulator elects to call it.

The Deeper Governance Difference

The principal distinction is not that European systems avoid broad regulatory concepts. They do not. Rather, they generally seek to anchor those concepts within visible and reviewable assessment frameworks. Broad terms derive their meaning from published methodologies, guidance documents, evidential standards, uncertainty frameworks, consultation requirements, and statutory criteria that explain how conclusions are reached and how discretion is intended to be exercised.

Viewed through a regulatory-governance lens, modern European systems tend to separate three related but distinct layers of decision-making.

- ***First, scientific assessment:*** What is known? What is uncertain? What hazards may exist? What are the plausible exposure pathways and consequences?

- ***Second, risk-assessment methodology:*** How should evidence be evaluated? How should hazard, exposure, uncertainty, persistence, reversibility, and consequence be weighed? What criteria determine whether a risk is acceptable, negligible, low, or unacceptable?
- ***Third, policy decision-making:*** What level of risk is acceptable to society? What controls are proportionate? What precautionary measures are justified? What level of public participation is required?

The concern raised by the HSNO Amendment Bill is not the use of broad regulatory concepts themselves, but the extent to which important terms such as low risk, risk-proportionate, vagrant, risk species, and recognised international regulator may derive much of their practical meaning from future notices, guidance, classifications, and administrative determinations rather than from methodologies and criteria established directly in legislation.

As a result, the legislation increasingly relies upon open-textured statutory concepts whose substantive content may emerge through regulatory implementation rather than being fully articulated by Parliament itself. From a legal certainty and administrative law perspective, the key question is whether sufficient statutory guidance exists to ensure that the exercise of discretion remains transparent, predictable, reviewable, and consistent with legislative intent.

[6] HSNO AMENDMENT BILL: NEW ORGANISMS

The concerns about the Bill's effects on new organism regulation, including GMOs, are well-founded on a close reading of the Bill's text. The parent Act's protective framework for new organisms remains formally in place, but the Bill introduces a series of operational mechanisms that, taken together, create meaningful pathways to faster approvals, reduced public oversight, and downward definitional pressure on what constitutes a "new organism" at all. Each concern maps to specific clauses as follows.

(a) ALTERED DEFINITIONS

Clause 4 amends key definitions throughout the Act, including the definitions of '*develop'*, *'release'*, and *'qualifying organism'*, with the qualifying organism category expanded to cover medical devices containing new organisms.

Clause 27 gives the Authority a new power to '*determine any one or more taxonomic classifications for an organism or a group of organisms*'. Under the existing Act, any such determination had to be issued by notice in the Gazette, creating a public record and an implicit accountability mechanism. Under the Bill, it need only be published on a website maintained by or on behalf of the Authority. The practical risk is that categorical reclassification, shifting an organism into or out of a regulated category, becomes an administrative act rather than a formal legislative one, with the only check being the Authority's own website.

(b) NZEPA MAY DECLARE A NEW ORGANISM 'NOT A NEW ORGANISM

This is the most significant new organism provision in the Bill. New **Part 5A** (inserted by Clause 114, new sections 73E to 73J) creates a formal mechanism for the Authority to prescribe, by notice, a form of secondary legislation, that an organism is 'not a new organism' for the purposes

of the HSNO Act. Essentially, new organisms are no longer new organisms, because the definition of a new organism has been changed.

The effects of such a prescription are far-reaching: organisms sharing the same taxonomic classification (and, in the case of genetically modified organisms, the same genetic modification) as the prescribed organism are automatically excluded from the new organism approval regime. The prohibition in Schedule 2, which applies to the most restricted organisms, also ceases to apply to the prescribed organism.

The Bill further permits the Authority to delegate this prescribing power to its own chief executive or to a committee appointed under the Crown Entities Act. This means a decision to remove an organism, including a genetically modified organism, from the new organism category could ultimately be made by a single official or a sub-committee, below the level of the full Authority. The Bill introduces some procedural requirements: the Department of Conservation and affected agencies must be notified, and consultation with directly affected persons is required if significant effects are likely. But the threshold for consultation is discretionary and the decision ultimately rests with the authorised maker. This is a structural shift from the existing model, under which prescribing an organism as not a new organism required regulations, a higher-order legislative instrument subject to Cabinet oversight and the Legislation Act 2019's disallowance regime.

(c) NEW CONCEPT: THE 'VAGRANT' PATHWAY

Schedule 2 of the HSNO Act contains organisms subject to the strictest controls, those that cannot be imported, developed, or released without approval, and where development was previously prohibited outright.

The Bill introduces a new concept: the Authority may now determine that a Schedule 2 organism present in New Zealand is a '*vagrant*', and if it does so, development of that organism in containment may be approved under section 45.

This is a material lowering of the threshold. Previously, the development of a Schedule 2 organism was prohibited. Under the Bill, if the Authority makes a vagrant determination, which is a matter of the Authority's own judgment, not a separate approval process, development becomes permissible. The process outlined is therefore essentially entirely subjective.

This exposes a new vulnerability while opening up a pathway for the development of prohibited organisms, including prohibited GMOs that have arrived in New Zealand without authorisation, provided the Authority considers them vagrant rather than deliberately introduced. The criteria for a 'vagrant' determination are not defined on the face of the Bill, meaning the operative standard will be set by regulation or EPA notice, secondary legislation made by the regulated authority itself.

(d) MULTIPLE EXTENSIONS OF TIME FOR RELEASE APPROVALS – PERMANENT DEFERMENTS?

Under the existing Act, a new organism release approval could be extended by up to five years on one occasion only. **New section 38AAB** allows extension by up to five years at a time on up to three occasions, a total potential extension of 15 years beyond the original approval period. The same provision applies to conditional release approvals (**Clause 52**). An organism can therefore remain in conditional or extended release status for an extended period before a full unrestricted release assessment is required, if one is ever triggered.

(e) SIMPLIFIED PATHWAY: FROM CONDITIONAL TO UNCONDITIONAL RELEASE

New **section 34B** creates a new pathway under which a person may apply to the Authority for approval to release, without controls, a new organism that is currently subject to a conditional release approval. The Authority may grant that application if satisfied that criteria prescribed by an EPA notice are met. If granted, the conditional approval expires immediately, and the organism may be released without controls.

The critical feature is that the criteria for transitioning from conditional to unconditional release are set by NZEPA notice, secondary legislation made by the Authority itself, without the parliamentary process that would attend primary legislation. The public engagement necessary for the EPA to be confident of social license is removed. This means the standard for removing controls on a conditionally released GMO can be set and changed by the Authority without a democratic process and parliamentary vote.

(f) LOWERED THRESHOLD FOR ADVERSE/EMERGENCY RELEASE OF NEW ORGANISMS

The Bill replaces the term ‘emergency’ throughout with ‘adverse event’, and the new definition of adverse event is broader, it now explicitly covers "*the arrival or establishment in New Zealand of an unwanted organism*."

This is significant because it means that a biosecurity incursion can activate the adverse event approval pathway, allowing a hazardous substance or new organism to be imported and approved for release under an expedited process.

The Bill also removes the existing requirement that release or use occur only after an emergency has been declared under the HSNO Act or another Act. Under new section 48(2), release or use in response to an adverse event no longer requires a formal declaration, it requires only that the adverse event and the release be foreseeable, and (for biosecurity incursions specifically) that the Director-General of MPI give notice in the Gazette. This is a meaningful reduction in the safeguards that currently gate the emergency release of new organisms.

(g) SIGNIFICANT PUBLIC INTEREST – DISCRETIONARY

Under the existing Act, certain applications, including applications for new organism release approvals, were required to be publicly notified as a matter of course, regardless of whether the Authority considered there to be public interest. The Bill replaces this with a single discretionary test: the Authority is required to publicly notify an application only if it considers there is likely to be ‘significant public interest’. For applications that do not meet that threshold, consultation is replaced by ‘targeted consultation with affected persons’ under new section 53A, which applies only where the Authority considers significant effects are likely.

The combined effect is to move from a default of public participation to a default of administrative determination, with public participation reserved for cases the Authority itself selects. In the context of new organism releases, where affected communities may not know to request participation and where the effects of release are irreversible, this is a materially weaker protective mechanism. Notably, the right to appeal is removed from non-submitters, who will be marginalised as non-submitters by any covert, non-notified approval.

Powers to delegate hearing and decision applications to CEO or an assigned delegate.

Clause 12 amends section 19 to allow the Authority to delegate to its chief executive, or the chief executive's delegate, the power to hear and decide applications under Part 5 that are not publicly notified. For new organism applications that fall below the 'significant public interest' threshold under **new section 53**, and therefore are not publicly notified, the decision can be made by the chief executive or a delegate, not the full Authority. This removes the collegial, multi-member deliberation that the existing model requires for new organism decisions.

[7] NEW ORGANISMS: STATUTE CANNOT UNDERMINE LEGAL PRECEDENT

The drafters of the Bill appear to have invented a word without legal precedent.

> *25(c) In this section, denewed organism mean an organism that is prescribed as not a new organism in regulations made under section 140(1)(c) or a notice made under Part 5A.*

The legal foundation for treating gene-edited organisms as GMOs under the HSNO Act is not merely a policy position, but one that has been settled by the courts, in New Zealand and in Europe. In May 2014, the High Court of New Zealand (Wellington Registry) rendered what was the first judicial opinion in the world on the legal classification of gene-editing techniques, in *Sustainability Council of New Zealand Trust v Environmental Protection Authority* [2014] NZHC 1067.

The court ruled that ZFN-1 and TALE techniques constitute techniques of genetic modification and therefore fall within the HSNO Act's regulatory regime governing genetically modified organisms. Neither party appealed the High Court's ruling, making the judgment final, controlling, and precedential within the New Zealand legal system.

The court also found that only Cabinet or Parliament, not the NZEPA, has the authority to determine which techniques are exempt from the GMO regime: the NZEPA had overstepped its powers by purporting to add gene-editing techniques to the exemption list administratively.

In *Confédération paysanne and Others v Premier ministre* (Case C-528/16, 25 July 2018), the Grand Chamber of the CJEU held that organisms obtained by directed mutagenesis techniques, the category that encompasses modern gene-editing tools including CRISPR, are GMOs within the meaning of EU GMO Directive 2001/18/EC and are subject to its full regulatory obligations, grounding that finding expressly in the precautionary principle.

Both courts thus converged on the same position: the precautionary principle requires that gene-edited organisms be regulated as GMOs, and the power to exempt techniques from that regime rests with the legislature, not the regulator. The courts' decision for regulation of gene edited organisms also aligns with the public interest and expectations of transparency that has been identified across markets in consumer surveys.

The Amendment Bill's new Part 5A, which allows the EPA to prescribe, by notice, that an organism is 'not a new organism', with that power delegable to the Authority's own chief executive, inverts precisely the constitutional logic that the New Zealand High Court confirmed in 2014. It restores to the regulator the exempting power that the court held it did not have, and it does so not by Act of

Parliament but by a provision that authorises secondary legislation below the parliamentary threshold.

[8] INCREASED EXECUTIVE AUTHORITY WITHOUT CORRESPONDING GUARDRAILS

Under traditional environmental and public-health regulatory models, the system is designed on the assumption that no individual, regardless of experience or expertise, can personally understand all relevant dimensions of a complex decision. The decision-maker therefore relies upon a structured process comprising specialist expertise, published methodologies, risk assessment frameworks, uncertainty analyses, public submissions, peer review, consultation obligations, and transparent reasoning requirements. The legitimacy of the decision derives not solely from the decision-maker, but from the robustness of the framework through which the decision is reached.

The concern arising from the Bill is therefore not simply that additional powers may be vested in the Chief Executive. Rather, it is whether sufficient statutory and procedural guardrails exist to support the exercise of those powers. Hazardous substances, genetically modified organisms, gene-edited organisms, synthetic biology products, and other emerging technologies frequently involve questions that span multiple disciplines including molecular biology, ecology, toxicology, environmental fate, exposure science, epidemiology, risk assessment, systems biology, economics, mātauranga Māori, ethics, and public policy. No Chief Executive, however capable, can reasonably be expected to possess expertise across all such domains.

This is precisely why mature regulatory systems generally rely on assessment frameworks rather than individual judgement alone. Where statutory criteria, published methodologies, uncertainty frameworks, and evidential standards are clearly articulated, the role of the decision-maker becomes one of applying a transparent process. Where such frameworks are absent, incomplete, or highly discretionary, a greater proportion of the decision necessarily rests upon personal judgement, institutional culture, and administrative interpretation. The result is that the quality of regulatory outcomes may become increasingly dependent upon who occupies the office rather than upon the consistency of the system itself.

From a public law perspective, this raises an important rule-of-law question. Good regulatory design generally assumes that decision-makers will change over time, expertise will vary, institutional priorities will evolve, and scientific understanding will develop. The purpose of legislation is therefore not merely to confer powers, but to constrain and guide their exercise through clear criteria, procedural safeguards, transparency obligations, and review mechanisms. The stronger the delegated authority, the greater the need for an equally robust framework governing how that authority is exercised.

A useful way of framing the issue is that regulatory systems should not be designed around the assumption of an exceptionally knowledgeable or benevolent decision-maker. Rather, they should be designed so that a competent decision can be reached even when decision-makers have incomplete knowledge, face competing pressures, or operate under conditions of scientific

uncertainty. The resilience of the system therefore depends less on the qualities of the individual Chief Executive than on the quality of the assessment architecture surrounding them.

This becomes particularly significant where the Bill simultaneously expands administrative discretion while relying upon open-textured concepts such as *low risk*, *risk-proportionate*, *risk species*, *vagrant*, and *recognised international regulator*. If the methodologies by which these concepts are interpreted are not fully specified in legislation or supporting frameworks, the practical meaning of the law may increasingly depend upon the judgement of individual officeholders. In that circumstance, the question is not whether the Chief Executive is competent. The question is whether the legislative framework provides sufficient structure to ensure that different Chief Executives, acting in different circumstances and at different points in time, would be likely to reach decisions through a transparent, consistent, and reviewable process.

That is ultimately a governance issue rather than a biotechnology issue. It goes to the design of the regulatory system itself and whether Parliament has provided adequate safeguards to ensure that significant environmental, health, and technological decisions remain anchored to a durable and transparent decision-making framework rather than to the discretion of any particular individual.

[9] NZEPA'S RISK ASSESSMENT MODELS ARE NO LONGER FIT FOR PURPOSE

What the Government's Own Review Found, and What It Failed to Examine

The Agricultural and Horticultural Products Regulatory Review (Ministry for Regulation, February 2025), the review that generated this Bill made an unambiguous finding: "*The EPA's toxicological, ecotoxicological, and environmental fate models are outdated and no longer fit for purpose.*" This is not a critic's characterisation. It is the government's own commissioned finding.

- The EPA's 2022 Risk Assessment Methodology document confirms the problem in detail. Among the models currently underpinning chemical risk decisions in New Zealand:
- Groundwater: Sci-Grow, a US EPA model from 2003, now only available on a US EPA archive page because it was superseded and retired by the originating agency in 2016.
- Aquatic screening: GENEEC2, a US surface water model from 2001, calibrated to a hypothetical American farm pond with no relationship to New Zealand waterway geometry or hydrology.
- Spray drift: AgDRIFT, based on empirical field trials conducted on flat US farmland in the 1990s; the Australian modifications New Zealand uses were themselves flagged by APVMA as in need of update.
- Operator exposure: BBA CRD model, built on field measurement data from the 1970s and 1980s, using assumptions about equipment from that era.
- Soil organisms: FOCUS 1997 equations, a framework now 28 years old.
- Non-target invertebrates: ESCORT2, a 25-year-old workshop report acknowledged in the EPA's own methodology document as the only approach ever considered for this receptor group.

The EPA's own methodology document describes reviewing several of these and notes they will be reconsidered 'in due course'.

The Bill amendments add new vulnerabilities to a system that is not fit for purpose.

The MfR review's finding that the models are outdated is serious. However the MfR Review did not examine (because its terms of reference did not permit it) that the current risk assessment approach is not merely using old tools, but is strategically incapable of detecting the kinds of harm that the scientific literature now identifies as the primary risks of chemical exposure in modern agricultural environments and risks indicated from human exposure to new organisms.[20]

The EPA's current approach favours reassessments over formal risk assessment, and relies primarily on industry-supplied data. Under the existing methodology, the primary responsibility for constructing the risk assessment rests with the applicant. The EPA evaluates what is submitted. There is no statutory obligation to conduct an independent literature search, no requirement to resolve conflicts between industry dossier data and peer-reviewed independent science, and no mechanism for the EPA to commission its own toxicological testing. The consequence is a system in which the regulator's knowledge of a substance is bounded by what the manufacturer chooses to provide.

There are no feedback loops connecting environmental monitoring data to regulatory decisions, and hence claims that current risk assessment is safe lacks foundation. The NZEPA has no systematic programme for monitoring the fate and persistence of approved chemicals in New Zealand's environment, in soils, groundwater, surface water, or biota, and no requirement that such data, when generated by third parties, be integrated into regulatory decision-making.

Yet this is fundamental to the capacity of the Regulator to uphold its obligations in law. Without this capacity it means that the regulatory system cannot learn from what is actually happening in the environment. Approvals made on the basis of modelled predictions are never checked against observed outcomes. Controls found to be inadequate in field conditions cannot trigger reassessment unless someone brings a formal application, and the EPA's own work plan, as amended by clause 19 of the Bill, expressly removes temporary approvals from the highest-priority reassessment category.

New Zealand has been falling behind in effective regulations, with chemicals persisting in its environment that have been heavily regulated or banned in Europe for years. It is a documented consequence of a reassessment programme that has completed fewer than three reassessments per year on average since 2001, for a regulatory inventory of approximately 30,000 approved chemicals.

Substances that EFSA and ECHA have restricted or withdrawn on grounds of endocrine disruption, persistence, bioaccumulation, or unacceptable aquatic toxicity remain approved for use in New Zealand because no reassessment has been initiated or completed. The EPA has neither the models to assess persistence and bioaccumulation by region, nor the monitoring data to know what is accumulating where, nor the institutional obligation under the current framework to seek that information.

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[20] Abrams SA, Albin JL, Landrigan PL, COMMITTEE ON NUTRITION, COUNCIL ON ENVIRONMENTAL HEALTH AND CLIMATE CHANGE; Use of Genetically Modified Organism (GMO)-Containing Food Products in Children. Pediatrics January 2024; 153 (1): e2023064774. 10.1542/peds.2023-064774

This is the scientific context within which the Bill's new approval pathways must be assessed. The temporary approval pathway (**clause 33**) allows substances onto the NZ market for up to four years on the basis of two overseas approvals, approvals that were almost certainly conducted using single-substance, active-ingredient-only assessment, in overseas environmental conditions, with no class-level cumulative toxicity assessment, and with no NZ-specific environmental fate data.

The rapid pathway (**clause 31**) narrows the test that would otherwise require a more thorough NZ-specific assessment. And the methodology exemption (clause 7) removes the requirement that any principled framework govern the decision at all.

The government found the scientific foundation inadequate. It recommended the models be updated. It then legislated to expand the approvals those models support, removed the methodology requirement that would at minimum have required the Authority to acknowledge the inadequacy, and opened a five-week submission window to manage public response, before the models have been updated, before a regional environmental fate programme has been established, before class-level cumulative toxicity has been addressed in legislation, and before the incoming CEO of the EPA has taken office.

ABSENT POLICY FOUNDATIONS

The extraordinary and extensive deficiencies in the NZEPA's risk assessment framework extend beyond outdated models and the absence of regional environmental fate data. There are entire domains of contemporary chemical risk science for which the EPA has produced no policy guidance whatsoever, leaving decision-makers without the analytical foundations necessary for precautionary or evidence-based action. This failure increases vulnerability of the New Zealand environment, public health and the economy.

Chemical Classes – cumulative loading unrecognised. Chemical classes can be approved as a class, yet there is no capacity to recognise the cumulative toxicity of a class and regulate when cumulative levels extend beyond recognised safe levels for any chemical in that class. This is one of the most significant scientific failures in the existing framework, and it is not addressed at all by the Bill.

Long-term research in New Zealand, including the work of Murray Close and colleagues at ESR, has documented the accumulation of pesticide mixtures in groundwater, including the detection of multiple chemicals from the same chemical being present in the same body of water.

The triazine herbicide group is a well documented example: individual triazine compounds may each fall below regulatory thresholds in groundwater near forestry regions, but multiple triazines from the same class can be present simultaneously, and their combined effect on aquatic ecosystems, drinking water quality, and human health is not being assessed by any current NZ regulatory mechanism.

The Bill text itself implicitly acknowledges the class-based structure of chemical approvals and provisions for group standards and class-based approvals appear throughout. But there is no provision anywhere in the Bill, or in the existing HSNO Act, that requires or even permits the Authority to assess the cumulative toxicity of various substances from a chemical class as a

distinct risk. Each substance is only assessed in isolation. Each reassessment is simply conducted one substance at a time. The aggregate chemical load from a class, whether triazines in forestry catchments, organophosphates in horticulture regions, or neonicotinoids across pollinator habitats, is invisible to the regulatory system.

Scientific uncertainty and a precautionary approach. More broadly, the NZEPA has failed to produce policy documents that would guide decision-makers on how to handle scientific uncertainty and apply the precautionary principle in the context of chemical approvals and reassessments. These are documents that best-practice regulators regard as foundational, and whose absence in New Zealand means that uncertainty about harm is routinely resolved in favour of approval rather than caution.

Systemic Failure. These are not peripheral gaps, but represent the systematic failure of a regulatory body to keep pace with the science it is obliged to apply, and they compound every other deficiency identified in this briefing.

Endocrine disrupting compounds. The NZEPA has no policy document addressing non-linear dose-response relationships in endocrine-disrupting chemicals, a scientifically established anomaly in which hormonally active substances cause harm at low doses that would be predicted as safe under conventional linear toxicology, and in which the standard regulatory assumption that "the dose makes the poison" demonstrably does not hold.

Endocrine-disrupting pesticides, herbicides, and industrial chemicals are approved and in use in New Zealand; the regulatory framework contains no mechanism for assessing their effects at environmentally relevant low-dose exposures, no requirement for endocrine disruption screening, and no policy acknowledging that standard NOAEL-derived risk quotients are structurally inadequate for this class of harm.

Fluoride releases into the environment. The NZEPA has produced no policy document addressing the release of fluoride into the environment through the discharge of fluoridated municipal water into waterways, soils, and coastal receiving environments. This is a documented pathway that affects aquatic invertebrates, soil organisms, and plant health, and that implicates the HSNO Act's environmental protection obligations, yet has received no systematic regulatory attention.[21] [22] [23]

For example, New Zealand's thoroughbred and standardbred industries are significant agricultural sectors. The benchmark level of fluoride consumption for when harm occurs is not known. Horses are among the most fluoride-sensitive large mammals documented in the veterinary literature, they consume large volumes of water daily, they accumulate fluoride in bone at rates dependent on water concentration and exposure duration, and the skeletal pathology fluoride produces is mechanistically identical to the conditions that end racing careers and destroy the economic

[21] Zhang J, Pu Y, Ye J, Hu X, Feng C. Water Quality Criteria and Ecological Risk Assessment of Fluoride for the Protection of Water Organisms in Surface Water. Toxics. 2026 Jan 22;14(1):106. doi: 10.3390/toxics14010106.
[22] Bai Z, Zhang D, Zhang S (2025) Integrating multi-omics and biomarkers to reveal the stress mechanisms of high fluoride on earthworms. Journal of Hazardous Materials, 494:138706, https://doi.org/10.1016/j.jhazmat.2025.138706
[23] Pramanik, K., Sen, A., Dutta, S. et al. Microbial populations under fluoride stress: a metagenomic exploration from Indian soil. World J Microbiol Biotechnol 41, 221 (2025). https://doi.org/10.1007/s11274-025-04408-5

value of high-value animals.[24] [25] [26] The skeletal fluorosis/ankylosing spondylitis connection is well established in the medical literature and directly applicable to horses. Periosteal bone formation and calcification occur at ligamentous and tendinous insertions in both the axial and appendicular skeleton in skeletal fluorosis, mimicking the enthesopathy of ankylosing spondylitis and diffuse idiopathic skeletal hyperostosis, with bony excrescences developing especially in key structural areas and the interosseous membranes ossifying in variable degree.

The absence of any New Zealand research on fluoride levels in racing stables' water supplies, bone fluoride concentrations in retired or injured horses, or correlation between fluoridated supply zones and musculoskeletal injury rates is a specific, documentable, and economically salient scientific gap.

Ignorant on Regional Variation. The NZEPA has no knowledge of persistence and degradation on a regional basis, and current regulatory practices do not require that such information be integrated into decision-making. New Zealand's highly variable rainfall, temperatures, sunshine hours, humidity, soil diversity, topography, and land use patterns mean that the fate and transport of agrichemicals in NZ environments can differ substantially from the overseas conditions used to parametrise the models.

A substance with a soil half-life of 30 days in a free-draining, low-rainfall European scenario may persist for months in the anaerobic, high-rainfall soils of NZ's West Coast or Southland. The EPA's 2022 methodology document uses a single default soil type for all of New Zealand.

This demonstrates a striking lack of knowledge of the wide range of soil types that exist. There is no regional parametrisation which can ensure that the NZEPA is accurately informed on the environmental fate of the pesticides that it stewards. There is no requirement for applicants to provide NZ-specific environmental fate data. And there is no monitoring programme that would reveal whether approved chemicals are accumulating in NZ groundwater, sediment, or soil at levels the models did not predict, because the models were never calibrated to NZ conditions in the first place.

Formulation toxicity predominantly ignored. Neither the Bill nor the Regulatory Impact Statement that underpins it contains any reference to:

Formulation toxicology: the well-documented scientific finding that the toxicity of a hazardous substance as formulated and sold can differ substantially from the toxicity of its active ingredient alone. Adjuvants, surfactants, and co-formulants can be independently toxic and can potentiate active ingredient effects. International regulatory failures to assess formulated products have been extensively documented by the European Environment Agency (Late Lessons from Early Warnings, 2013) and have been central to public health controversies including glyphosate/POEA surfactant toxicity.

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[24] Choubisa SL. A Brief and Critical Review of Skeletal Fluorosis in Domestic Animals and its Adverse Economic Consequences. Dairy and Vet Sci J. 2024; 16(4): 555942..DOI: 10.19080/JDVS.2024.15.555942

[25] Kelly LH, Uzal FA, Poppenga RH, Kinde H, Hill AE, Wilson WD, Webb BT. Equine dental and skeletal fluorosis induced by well water consumption. J Vet Diagn Invest. 2020 Nov;32(6):942-947. doi: 10.1177/1040638720962746.

[26] Sauerheber R (2013). Racehorse breakdowns and artificially fluoridated water in Los Angeles. Guest editorial Fluoride 46(4)170–179.

Mixture effects and cumulative exposure: the reality is that New Zealand farmers, workers, and ecological receptors are not exposed to single chemicals at any one time, but rather to complex mixtures across time and landscape. EFSA has required cumulative risk assessment for organophosphates, triazoles, and pyrethroids since 2019. No equivalent obligation exists in New Zealand.

Planetary boundary exceedance: Persson et al. (2022, Environmental Science & Technology 56(3): 1510–1521) demonstrated using global data that aggregate chemical pollution has already transgressed the planetary boundary for novel entities, meaning that regulatory frameworks assessing individual substances against individual thresholds are insufficient to prevent systemic harm.

CONCLUSION: AN INDEPENDENT SCIENTIFIC REVIEW MUST PRECEDE FURTHER PROGRESS

PSGRNZ calls on members of Parliament to reject this Bill, and on the Primary Production Committee to reject the Bill and return it for fundamental revision, on the following grounds.

The Bill is premature. The underpinning policy and rationale reflect a reform process that was only briefly and narrowly consulted on. In addition, it was conducted over a two-week targeted engagement period in March 2025 with eleven organisations, the majority of whom have demonstrable conflicts of interest in the outcome.

The government's own commissioned review found that the EPA's risk assessment models are ‘outdated and no longer fit for purpose’. This finding alone, before any consideration of the Bill's specific provisions, establishes that the scientific foundation on which the Bill's new approval pathways will operate is not adequate for its purpose.

No review or assessment has followed this, and simply preceding to legislative drafting, without review of global practice to assess how New Zealand might reflect best practice approaches, in alignment with protection of human and environmental health, is neither scientifically nor legally appropriate.

The NZEPA effectively handballed this consultation to a global consultancy with demonstrable conflicts of interest. The consultancy serves the pesticide industry.

The Bills ‘targeted stakeholder’ consultation was so narrowly formulated, and the principal participants so uniformly aligned with the commercial and institutional interests that future faster approvals would serve, that it cannot credibly constitute the evidence base for legislation of this scope and consequence.

The text of the Bill risks undermining the principles and purposes of the HSNO Act, in particular with respect to the precautionary principle in section 7, the public health and ecosystem obligations in section 6, and the protective purpose in section 4, not by repealing those provisions, but by reconfiguring the operational architecture through which they are given effect, in ways that make them more difficult to operationalise in the public interest.

Before Parliament legislates to expand, accelerate, and reduce the oversight of chemical and new organism approvals, an independent review must be conducted by a committee with known expertise in:

1. Human and environmental health risk assessment methodology, including formulated product assessment and mixture toxicology;
2. Formulation toxicology, mixture effects, and cumulative exposure science, areas currently absent from the EPA's existing risk assessment framework and excluded from the ERM modelling contract's published scope;
3. Ecotoxicology and environmental fate modelling relevant to New Zealand's unique ecosystems, endemic species, soils, and freshwater and marine systems, recognising that New Zealand remains the only OECD country without a pollutants release and transfer register, and that the Parliamentary Commissioner for the Environment found in 2022 that the country operates a disjointed and inadequate system for identifying and prioritising chemical risks;
4. International best practice in chemical regulation, including the EU's REACH framework, EFSA's pesticide peer review methodology, and ECHA's mixture assessment factor approach. These frameworks specifically designed to address the cumulative and combinatorial exposures that single-substance assessments cannot capture;
5. A 2022 report by the Parliamentary Commissioner for the Environment, *Knowing What's Out There* constitutes the most authoritative independent assessment of the regulatory monitoring baseline. The report established that New Zealand cannot adequately track what chemicals are in use, where, or what harm they are causing. The Commissioner himself reaffirmed those findings directly to the Ministry for Regulation during the review that produced this Bill, and they were not addressed. A Bill that accelerates approvals and reduces scrutiny of an already demonstrably degraded baseline is not a reform, it is an acceleration of the problem the PCE identified.
6. Legal expertise in the application of the precautionary principle in environmental and regulatory law, including the relationship between sections 5, 6 and 7 of the HSNO Act and the Bill's proposed approval architecture, expertise of the kind held by legal experts such as Professor Catherine Iorns Magallanes; and
7. The Treaty of Waitangi/Te Tiriti o Waitangi obligations in the context of environmental health regulation, including the Crown's duty to protect Māori relationships with taonga species, ancestral waterways, and wāhi tapu from the adverse effects of hazardous substances. Obligations in section 6(d) of the HSNO Act require it to be taken into account, and that a regulatory reform conducted without national Māori representation is not acceptable.

This review must be genuinely independent. It cannot be conducted by the Ministry for the Environment, the EPA, or any entity whose primary mandate is regulatory efficiency rather than the protection of human and environmental health. It must include scientists from New Zealand universities with no commercial relationship to the agrochemical or biotechnology industries; independent public health and toxicology experts; Māori science and mātauranga perspectives

with national representation; appropriate legal expertise; and international peer review by regulators or scientists from jurisdictions operating under precautionary frameworks comparable to New Zealand's stated obligations.

Its terms of reference must be broad enough to examine not only whether existing risk assessment models should be updated, but also what a fit-for-purpose New Zealand chemical risk assessment framework should look like. This would include whether formulated products, mixture toxicology, cumulative environmental exposure, and post-approval monitoring must be assessed as standard risks to be evaluated, rather than as exceptions.

The Hazardous Substances Models Modernisation project currently contracted to ERM is a necessary but wholly insufficient component of what this review must cover. As ERM is a global corporation that contracts to agrichemical corporations, its outputs must be subject to public scrutiny and independent scientific peer review before they are incorporated into any approval pathway.

The current approaches to regulatory governance by the government Ministers, and by the NZEPA is not adequate. A revised Bill should be presented to Parliament, but only after:

- ✓ The completion and public release of findings from the independent scientific review described above;
- ✓ Public and independent scientific review of the contracted work by ERM, with explicit assessment of whether the updated risk models meet current international standards for mixture toxicology, cumulative exposure, and environmental fate modelling in New Zealand conditions;
- ✓ The development and validation of a new methodology updated to current international standards, before any new approval pathways, including rapid, temporary, or overseas-recognition pathways, are activated;
- ✓ Restoration of public notification as a statutory right, not a discretion, for applications involving: new active ingredients not previously approved in New Zealand; new organisms including gene-edited organisms; substances with potential effects on fresh and marine water systems (including their sediments), soils, or taonga species; and any application where a community, iwi, or health body requests notification;
- ✓ A full Treaty impact analysis conducted with national Māori representation, examining the Bill's effects on the Crown's obligations under section 6(d) of the HSNO Act and the principles of the Treaty as they apply to environmental health regulation;
- ✓ The establishment of minimum methodology quality standards for overseas regulator assessments used under any rapid or temporary approval pathway — including explicit requirements that overseas assessments have considered mixture toxicology, cumulative exposure, and environmental fate in conditions comparable to New Zealand; and
- ✓ Removal of the delegation to the chief executive of the power to prescribe organisms as outside the coverage of the HSNO Act by administrative notice, a power that the New Zealand High Court confirmed in Sustainability Council of New Zealand Trust v

Environmental Protection Authority [2014] NZHC 1067 belongs to Cabinet or Parliament, not to a regulatory official, and whose restoration to the administrative level by the Bill inverts the constitutional logic of that judgment.

The increasing use of the term risk-proportionate raises a broader governance question. If proportionality is to function as a central organising principle of modern regulation, should legislation or supporting regulatory frameworks also specify the assessment methodologies by which proportionality is determined? \Put differently, how can Parliament, affected parties, and the public evaluate whether a regulatory response is genuinely proportionate if the evidential pathway leading to that conclusion is not itself transparent, systematic, and capable of independent scrutiny?

References and Further Reading

Hazardous Substances and New Organisms Amendment Bill (304-1), introduced 11 May 2026: https://www.legislation.govt.nz/bill/government/2026/304/en/latest/

Regulatory Impact Statement: Omnibus Changes to the HSNO Act 1996 (MfE, 23 May 2025): https://www.regulation.govt.nz/assets/RIS-Documents/RIS-Omnibus-changes-to-the-Hazardous-Substances-and-New-Organisms-Act-1996.pdf

Agricultural and Horticultural Products Regulatory Review — Full Report (MfR, February 2025): https://www.regulation.govt.nz/assets/Publication-Documents/Agricultural-Horticultural-Products-Regulatory-Review-full-report.pdf

NZ EPA Risk Assessment Methodology for Hazardous Substances (December 2022, Version 1.1): https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/Risk-Assessment-methodology/

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European Environment Agency (2013). Late Lessons from Early Warnings: Science, Precaution, Innovation. Vol. 2, Chapter 13. Copenhagen: EEA.

Parliamentary Commissioner for the Environment (2021). Submission on the Hazardous Substances and New Organisms (Hazardous Substances Assessments) Amendment Bill: https://pce.parliament.nz/publications/submission-on-the-hazardous-substances-and-new-organisms-hazardous-substances-assessments-amendment-bill/

Physicians and Scientists for Global Responsibility New Zealand (PSGR) is an independent scientific and medical organisation committed to evidence-based public interest advocacy. This briefing is based on analysis of the enrolled bill text, the Regulatory Impact Statement, the MfR Review full report, and the EPA's 2022 Risk Assessment Methodology document. All cited documents are publicly available at the URLs listed above.