PSGRNZ

Physicians & Scientists for Global Responsibility Charitable Trust

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Submission

Natural Health Products Regulation, Ministry of Health Consultation

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

Natural Health Products Regulation Consultation

- Consultation on Natural Health Products. Consultation closes: November 2, 2026.
- Consultation document: Purpose, principles and elements of a natural health products regulatory system, October 2026. Cabinet Paper, September 22, 2026.

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1. Summary

Physicians and Scientists for Global Responsibility New Zealand (PSGRNZ) supports the development of a coherent, transparent and scientifically defensible regulatory framework for natural health products (NHPs). We welcome this initial consultation as an opportunity to establish the scientific and legal principles necessary for effective reform.

However, PSGRNZ considers that the Ministry of Health is not yet sufficiently prepared to proceed directly to drafting a regulatory impact statement or legislation. New Zealand's longstanding underinvestment in nutritional science has left significant gaps in institutional expertise and publicly disclosed methodologies for evaluating nutrients, supplements and other natural health products.

Officials strive to produce a proportionate response to a problem. Yet the problem definition has not been clearly articulated, and this is an essential starting point for regulatory reform. The problems arising from New Zealand's existing natural health products framework are interconnected, with consequences that differ across affected groups.

Two underlying problems require particular attention: (1) historical over-regulation of nutrients, subjecting them to medicine-like classifications and restrictions without sufficient consideration of their distinct nutritional functions, biological risk profiles and dose-dependent effects; and (2) chronic underinvestment in independent nutritional science and risk assessment, contributing to a regulatory culture in which restrictive classification can substitute for proportionate, evidence-based evaluation.

The consequences extend across different communities and professional groups. Restrictive nutrient classifications can constrain the clinical judgement of medical practitioners and other qualified health practitioners, particularly those with specialist expertise in nutritional interventions. Medical doctors with limited training in nutritional science may also be hesitant to prescribe medicine-classified nutrients, particularly where the classification creates an impression of pharmaceutical-level risk without a corresponding product-specific assessment.

The public may consequently face prescription requirements, additional consultation costs and barriers to access, disproportionately disadvantaging low-income communities where nutritional interventions are not publicly funded through Pharmac. Smaller domestic manufacturers and suppliers also face compliance costs that may render low-volume products commercially unviable, further restricting affordability, availability and consumer choice.

The limited evaluation preceding this consultation has been constrained by existing policy directions, an absence of systematic assessment of the costs of the current regime, and historical under-resourcing of its scientific foundations.

Consequently, the October 2026 consultation presents an outline of approaches for preliminary engagement without a clearly articulated central problem definition. Its options are remarkably rudimentary in their treatment of biological risk, scientific evidence, regulatory independence and the potential for improving existing legislation. (We are concerned that any future regulatory

impact assessment might also fail to identify these broader challenges while stepping into the implementation of some already preferred model that might not sufficiently resolve them.)

The October options concentrate on administrative mechanisms, including ingredient lists, business licensing, product notification, manufacturing standards, health claims and regulatory oversight. Although these are legitimate matters for consultation, the document does not explain the scientific criteria that would underpin ingredient classification, risk-tiering, dose restrictions or the distinction between evidence of therapeutic benefit and biological safety. Nor does it identify how independent scientific assessment and periodic reassessment would be supported.

Importantly, reform of the existing legislative framework is not presented as a developed alternative. The consultation therefore risks directing public attention towards the design of a new regulatory structure before the necessity, scientific foundations and relative merits of that structure have been adequately established. It is not adequately equipped to address the underlying problems of historical over-regulation and inadequate scientific capacity, and risks reproducing these deficiencies within a new regulatory regime.

Against a backdrop of increasing chronic metabolic and mental illness, continued underinvestment by the Ministries responsible for Health and Science in nutritional monitoring, research and independent scientific assessment raises broader questions about public-health priorities. It is also important to recognise that in the four decades since the current regime was established, an extraordinary expansion of digital research tools has reduced many practical barriers to scientific investigation, creating greater opportunities for regulators, medical doctors, patients and natural health practitioners to access, critically evaluate and update nutritional evidence.

The Ministry of Health can harness these advances to strengthen its own scientific assessment capacity, develop more adaptable regulatory frameworks and respond flexibly to emerging evidence in a rapidly evolving informational landscape. Such a shift could transform and future-proof regulation, ensuring that classifications, safeguards and regulatory decisions reflect present and evolving nutritional knowledge and can evolve alongside scientific shifts, technological innovation and changing public-health needs.

Natural health products reform presents an opportunity to examine these systemic deficiencies within a wider public-interest framework, rather than treating regulation as an isolated administrative exercise.

Three evaluations could reasonably have been provided even at this early stage:

1. **An assessment of the existing regulatory framework,** identifying demonstrated deficiencies and distinguishing biological safety concerns from administrative, classification and commercial barriers. This should examine who bears the costs of existing restrictions, including practitioners, consumers, low-income communities and smaller suppliers, and whether those restrictions are justified by evidence of biological risk.
2. **A comparative evaluation of regulatory reform options,** examining the potential benefits, costs and limitations of improving existing legislation against establishing a new regime. This should consider not only administrative efficiency and industry development, but also

the distribution of compliance costs, effects on product affordability and availability, practitioner autonomy, consumer choice and equitable access to nutritional and therapeutic interventions.

3. **An evaluation of the scientific foundations of regulation,** establishing the principles and institutional capacity required for ingredient classification, risk-tiering, health claims and periodic reassessment. This should consider whether existing restrictions are supported by contemporary evidence of biological risk, including dose, exposure and individual susceptibility, and whether sufficient independent scientific expertise and funding exist to prevent precautionary restrictions becoming entrenched in the absence of systematic reassessment.

An important consideration throughout these evaluations is who bears the costs of regulatory decisions, and whether those costs are justified by demonstrated biological risks or arise from deficiencies in scientific evidence, classification processes and regulatory administration. Requirements that impose relatively modest costs on large manufacturers and financially secure consumers may create substantial barriers for smaller domestic suppliers, practitioners and people with limited financial resources.

Any assessment of reform must therefore consider not only product safety and administrative efficiency, but also the cumulative effects of regulation on affordability, professional practice, consumer choice and equitable access to nutritional and therapeutic interventions.

Unlike medicines, essential nutrients must be assessed in the context of their normal biological functions and the consequences of both inadequate and excessive intake. Assessments should consider dietary requirements, nutritional adequacy, relevant cofactors and interactions, tolerable upper intake levels, and differences associated with age, sex, life stage and physiological status.

New Zealand lacks a clearly established, continuously resourced public programme for reviewing these questions as scientific knowledge develops. Regulatory decisions may consequently depend on occasional commissioned reviews, without the benefit of consistent, enduring scientific assessment processes.

The Ministry's recent vitamin D classification review illustrates this problem. Although the report considered extensive scientific literature, it did not disclose a systematic search strategy, formal evidence-quality appraisal, structured nutrient risk assessment or explicit decision rule explaining the proposed classification threshold. Our concern is not necessarily the competence of the expert, but the institutional resources, methodological requirements and oversight governing such evaluations.

As the Hardys Daily Essential Nutrients (DEN) case illustrates, the cost of restricted access is itself a regulatory outcome, extending beyond legal requirements to influence clinical perceptions of risk and prescribing decisions. Suppliers have reported that some medical doctors declined to prescribe DEN because its classification as a medicine led them to anticipate a pharmaceutical-like adverse-effect profile, rather than considering its specific ingredients, doses and available safety evidence. These issues highlight the need for Government to evaluate not only the biological risks of allowing products onto the market, but also the public-health and financial consequences

of making potentially beneficial nutritional interventions inaccessible or unaffordable, particularly for those least able to bear the costs. We examine these cases in Section 3.

Our concern is that regulatory powers may be established before the scientific framework necessary to exercise them consistently, proportionately and transparently has been developed.

This is all the more relevant as the proposed natural health products framework is being developed alongside reforms to medicines regulation. The October 2026 consultation excludes products intended to fall within the proposed Medical Products Bill. If the definition of a medicine or therapeutic purpose is settled separately, the NHP framework may inherit classification boundaries that have not been examined as part of the present consultation.

The result could be a nominally risk-proportionate NHP system that excludes certain nutrients because of claims or classifications established under another statute.

Invest in Nutrition for the Future

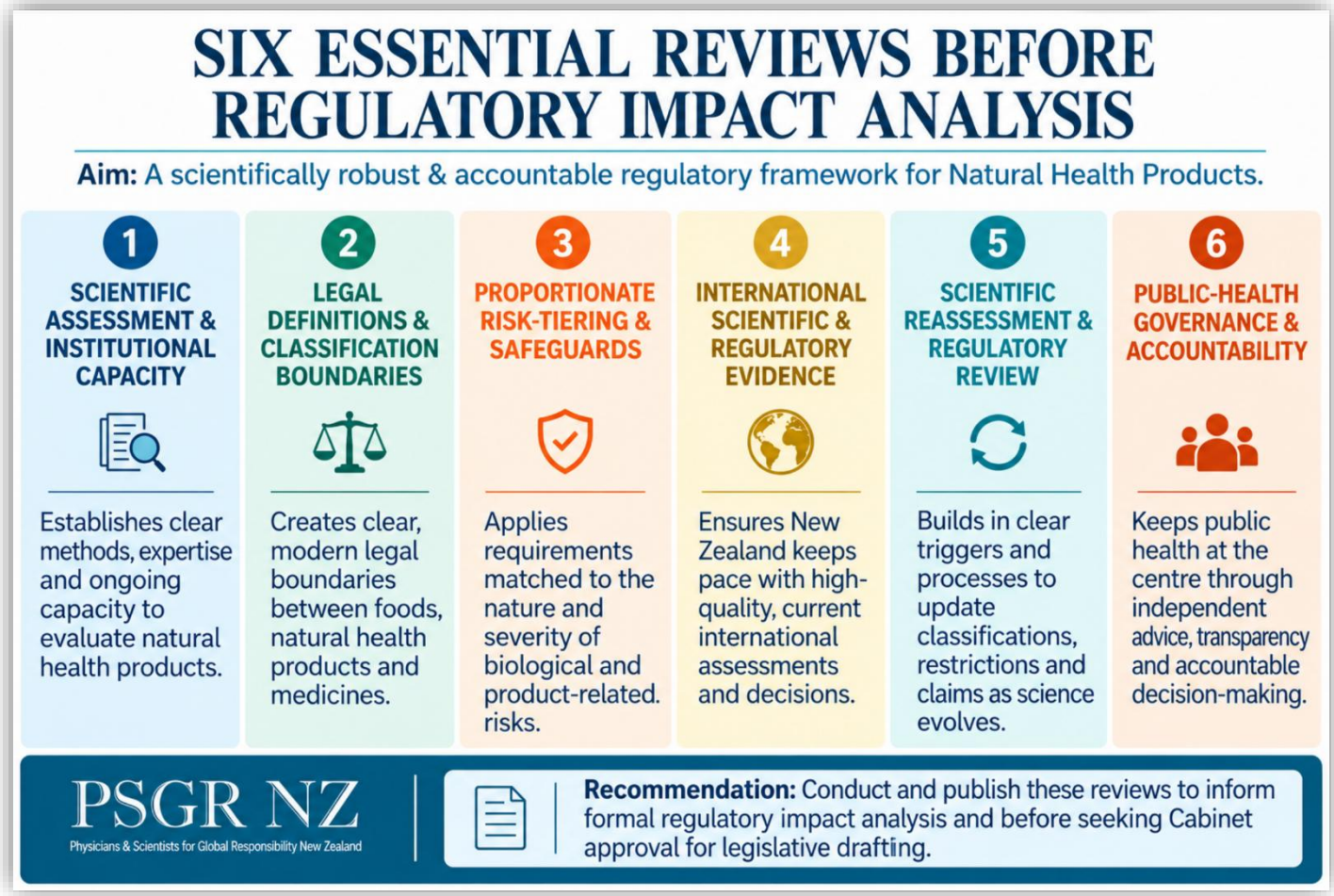
Rather than seeing scientific capacity as a regulatory cost, Government can recognise it as a long-term, public-good investment, delivering health, research, industry and export benefits.

New Zealand has an opportunity to transform natural health products regulation from a predominantly restrictive administrative exercise into a forward-looking investment in public health, scientific excellence and economic innovation.

International markets for personalised nutrition, functional foods, dietary supplements and healthy-ageing products are expanding rapidly, with forecast annual growth ranging from approximately 7% to 15%, while the broader biohacking sector is projected to grow even faster. These emerging markets reflect growing consumer interest in metabolic health, brain health, healthy ageing, personalised nutrition and interventions intended to prevent or reverse chronic illness.

A knowledgeable, scientifically adept Ministry and governance system could position New Zealand to participate in these developments, supporting domestic researchers, qualified health practitioners and innovative businesses to develop high-quality, evidence-based products for international markets. Investment in independent nutritional science, clinical research, biological risk assessment and transparent regulatory pathways could create competitive advantages through scientific credibility, product quality and demonstrable benefits.

The opportunity is not simply to regulate an expanding industry, but to build the scientific capability that enables it to flourish responsibly. A proportionate regulatory system should protect consumers from demonstrated harm while enabling innovation, supporting smaller domestic enterprises and ensuring that New Zealanders themselves benefit from advances in nutritional science.



PSGRNZ Recommends: Strategic Consultation on Six Major Themes

PSGRNZ therefore recommends that six major strategic themes are consulted upon, and that the outcomes of the reviews be published, together with proposed scientific and legal frameworks, to inform formal regulatory impact analysis prior to seeking Cabinet approval for legislative drafting.

1. Scientific Assessment and Institutional Capacity

Review and consult on the scientific principles, methodologies and institutional expertise required to evaluate natural health products and support proportionate regulatory decisions.

a. Include international assessment frameworks, particularly EFSA's nutrient risk-assessment principles, addressing biological hazards, dose–response, total exposure, susceptible populations and uncertainty.
b. Distinguish biological risk, nutritional adequacy, physiological benefit and therapeutic efficacy, with evidence requirements proportionate to potential harm.
c. Establish how New Zealand will maintain the independent scientific expertise and resources necessary to assess both product safety and the consequences of restricting access, particularly for consumers and qualified health practitioners.

2. Legal Definitions and Classification Boundaries

Review and consult on revised legal boundaries between foods, dietary supplements, natural health products and medicines, including the consequences of classification decisions for consumers, qualified health practitioners and suppliers.

The Medicines Act's therapeutic-purpose provisions are outdated and poorly aligned with contemporary nutritional science. Essential nutrients inherently exert physiological, metabolic and immunological effects as part of normal biological function. Such effects should not, in themselves, provide grounds for classification as medicines. The framework can:

a. Establish scientifically defensible boundaries based on the nature and magnitude of biological effects, dose, exposure, intended use and demonstrable risk, while distinguishing product safety from the substantiation of therapeutic claims. It should clarify when higher-dose products require professional supervision, which authority resolves classification disputes, and how decisions can be independently reviewed.
b. Ensure classification decisions account for their practical consequences, including prescription and consultation costs, barriers to practitioner-led care, access for low-income communities and the commercial viability of smaller domestic suppliers.

3. Proportionate Risk-Tiering and Safeguards

Review and consult on regulatory tiers reflecting the nature and severity of biological and product-related risks, while ensuring that regulatory burdens are proportionate to the risks being managed.

a. The framework can distinguish intrinsic toxicity from contamination, manufacturing defects, interactions, inappropriate use and individual susceptibility.
b. Establish when quality assurance, labelling, dose restrictions or professional supervision are justified, and when medicines-level controls are necessary.
c. Risk-tiering can recognise the importance of comparative risk assessment, including the relative risks and potential benefits of nutritional interventions and conventional medical treatments for comparable health conditions.
d. Regulatory decisions can consider the risks of both intervention and restricted access, including their wider public-health consequences. Compliance requirements can be assessed for their differential impacts on large and small suppliers, qualified health practitioners and consumers, particularly where additional costs may reduce product availability, affordability or equitable access without commensurate safety benefits.

4. International Scientific and Regulatory Evidence

Review and consult on criteria for evaluating the scientific quality of international guidelines, overseas assessments and regulatory decisions.

New Zealand agencies and industry applicants are likely to rely on international evidence and regulatory precedents, but decision-makers should have the skills and guidance to critically evaluate the quality of foreign regulatory approaches.

a. The framework can establish transparent criteria for evaluating the breadth, depth, scientific rigour and recency of overseas assessments, including their underlying

methodologies, the independence and expertise of contributing specialists, and the disclosure and management of conflicts of interest.

b. New Zealand can keep pace with international scientific developments, giving appropriate weight to the most recent and comprehensive assessments while retaining responsibility for decisions appropriate to domestic circumstances.
c. Recognition of overseas evidence can assist to avoid unnecessary duplication of assessments and associated compliance costs, without compromising scientific scrutiny or consumer protection.

5. Scientific Reassessment and Regulatory Review

Review and consult on triggers for revising classifications, restrictions and permitted claims, including evidence that existing requirements impose disproportionate costs or barriers to access.

a. Triggers can include significant new evidence of benefit or harm, changes in exposure, emerging adverse events, international scientific developments and evidence that existing restrictions are disproportionate.
b. Reassessment can permit both stronger safeguards and reduced restrictions, supported by transparent decisions, independent review and ongoing scientific monitoring.
c. Reassessment can provide accessible pathways for qualified health practitioners, consumers and smaller suppliers to seek reconsideration of classifications where new evidence or demonstrated access barriers warrant review.

6. Public-Health Governance and Accountability

Review and consult on the statutory responsibilities, scientific independence and public accountability of the regulatory system, including its obligations to assess the distribution of regulatory costs and benefits.

a. The Government can recognise its responsibility to protect and promote public health as distinct from its objectives of supporting industry growth and exports, and demonstrate that restrictions deliver public-health benefits proportionate to their scientific justification and social and economic consequences.
b. Scientific expertise in diet and nutrition can be supported by enduring institutional capacity and sufficient independent funding to enable officials to critically evaluate emerging evidence, including findings that challenge established scientific consensus or longstanding regulatory positions. This requires capacity beyond occasional, narrowly commissioned reviews.
c. The framework can require transparent expert appointments, disclosure and management of conflicts of interest, publication of scientific advice and decision criteria, and meaningful opportunities for independent scrutiny and review.
d. Regulatory accountability can extend to evaluating who bears the costs of regulatory decisions, including their effects on practitioner autonomy, consumer access, affordability for disadvantaged communities and the viability of smaller domestic suppliers.

The Economic Case for the Six Reviews:

A vibrant scientific environment that encourages independent inquiry, open debate and new ideas, while upholding rigorous standards of evidence, quality and best practice, provides fertile ground for creativity and innovation.

These synergies can nurture new products and approaches that improve domestic health while creating international export opportunities, strengthening New Zealand's reputation for natural products underpinned by scientific excellence.

Conversely, when regulatory and academic institutions are inadequately resourced, scientific conservatism can become entrenched. Smaller innovators and start-ups may face disproportionate barriers to developing and bringing products to market, particularly where emerging scientific concepts or approaches fall outside established regulatory assumptions or are not yet recognised as legitimate by the State.

PSGRNZ Recommends: Deepen the Purpose and Principles

Two purposes:

i. Public health, scientific integrity and informed choice

To protect and promote public health through scientifically justified, transparent, adaptable and proportionate regulation of the safety, quality and claimed benefits of natural health products; recognising established and emerging scientific knowledge, supporting informed consumer choice and appropriate professional judgement, and enabling affordable and timely access to products suitable for their intended use.

ii. Responsible innovation and scientific excellence

To support a responsible, innovative and scientifically informed natural health products sector, including domestic research, product development and exports, through a regulatory framework that encourages independent scientific inquiry, accommodates advances in knowledge and technology, and maintains public confidence through transparent decision-making, independent scientific scrutiny and accountability.

Principles

PSGRNZ proposes that the current principles are too narrow.

1. **Evidence of benefit and informed choice:** Regulation recognises established histories of safe use and credible evidence of nutritional, physiological and therapeutic benefits, with evidential requirements proportionate to the nature and significance of claims. Consumers and health practitioners have access to clear, accurate information concerning benefits, harms and uncertainties.
2. **Proportionality to biological risk:** Regulation is proportionate to demonstrated or reasonably foreseeable biological risks from under-dosing as well as over-dosing at relevant exposures, considering dose, chemical form, duration, cumulative exposure, nutrient synergies, medical interactions and susceptible populations. Regulatory controls are no more restrictive than reasonably necessary to manage identified risks.

3. **Distinction between scientific uncertainty and identified risk:** Regulation can distinguish between uncertainty about therapeutic benefit, uncertainty about biological safety and scientifically identified risks of harm. That insufficient evidence of benefit may justify limitations on particular claims, but does not itself establish biological harm. Uncertainty about safety can prompt investigation proportionate to the plausibility and potential severity of adverse effects, the extent of relevant exposure and the significance of the evidence gaps. Where warranted, precautionary safeguards are targeted and proportionate, without an automatic presumption of harm. Decisions are transparent, independently reviewable and responsive to emerging scientific evidence.
4. **Distinction between classification and risk:** Product classifications distinguish established nutritional and physiological functions, evidence of therapeutic benefit and biological risk. Recognition of a physiological, immunological or metabolic effect, or therapeutic benefit, does not, by itself, trigger classification as a pharmaceutical medicine. Evidential requirements for claims are distinguished from controls necessary to manage biological risk.
5. **Timely access and appropriate safeguards:** Regulation supports affordable and timely access to natural health products, with appropriate safeguards, including dose restrictions, warnings, monitoring and clinician supervision where scientifically justified. The potential public-health consequences of unnecessarily restricting access are taken into account.
6. **Scientific integrity, responsiveness and accountability:** Regulatory decisions are grounded in the best available scientific evidence, using transparent and independently reviewable methods. Classifications, permitted claims and restrictions are subject to periodic and evidence-triggered reassessment, informed by relevant clinical and practitioner experience, independent scientific research and expert evaluation. Regulatory oversight is supported by accessible review mechanisms, feedback information from clinicians and practitioners, independent scientific scrutiny and public reporting.
7. **Efficient administration and international alignment:** Administrative and compliance requirements are efficient, proportionate and affordable, without unnecessarily disadvantaging consumers, qualified health practitioners, researchers or small businesses. International standards and practices are adopted only where scientifically justified and relevant to New Zealand's circumstances.
8. **Distributed scientific expertise and practitioner autonomy:** Regulators and regulation recognise that scientific knowledge and evidence-informed judgement develop across a continuum, from qualified clinicians and practitioners working directly with patients, through professional and independent scientific communities, to national regulatory authorities. The framework supports appropriate professional autonomy, access to emerging scientific evidence, systematic clinical observation and reporting, and mechanisms through which practitioner experience and independent research can inform regulatory review. Responsibilities for evaluating evidence, making binding regulatory decisions and maintaining public accountability are clearly defined, with safeguards proportionate to biological risk.

2. The Current Natural Health Products Regime: Limited Official Assessment

The Food-Medicines Regulatory Landscape

New Zealand's existing natural health products framework operates across the Food Act 2014, the Dietary Supplements Regulations 1985, the Medicines Act 1981 and the Medicines Regulations 1984. These instruments perform different regulatory functions, with responsibilities divided principally between the Ministry for Primary Industries and the Ministry of Health/Medsafe.

How NHPs are regulated in New Zealand

Legislation / Regulation	Administering Agency
Dietary Supplements Regulations 1985 and other legislation under the Food Act 2014	Medsafe, Ministry for Primary Industries, local councils
Medicines Act 1981 and Medicines Regulations 1984	Medsafe
Cosmetic Products Group Standard 2020 (under the Hazardous Substances and New Organisms Act 1996)	Environmental Protection Authority
Animal Products Act 1999	Ministry for Primary Industries
Consumer Guarantees Act 1993 and Fair Trading Act 1986	Ministry of Business, Innovation and Employment

Figure 1 Ministry of Health. Accessed November 1, 2026.

This division creates tensions and scientific contradictions that should reasonably be addressed with any revision of natural health products regulation. Dietary supplements are subject to ingredient, composition and dose requirements under food legislation, while products intended for therapeutic purposes may fall within medicines legislation. Consequently, a nutritional formulation can become subject to substantially different regulatory controls because of its composition, dose or intended use, without the classification decision necessarily establishing that the formulation presents an unacceptable biological risk.

PSGRNZ's examination (below) of the Hardys Daily Essential Nutrients case illustrates this difficulty. The regulatory treatment of a multinutrient formulation involved statutory limits for particular nutrients, medicines classifications and the therapeutic purposes for which the product was intended. However, the key public-health questions concern the biological safety of the formulation at relevant exposures, the evidence of biological benefit, appropriate conditions of use and the consequences of restricting access were not addressed by the Ministry.

The problem is not necessarily that the Food Act and Medicines Act are legally inconsistent. Rather, their intersection may leave important scientific and public-health questions insufficiently examined. Food-safety regulation does not necessarily address therapeutic nutritional requirements, while medicines classification does not, by itself, establish whether a particular nutrient dose is harmful or beneficial.

This raises a spectrum of challenges across any proposed reform: should New Zealand first modernise the definitions, dose restrictions, therapeutic-claims provisions and classification

procedures within existing legislation, or is a standalone statute necessary to resolve these difficulties?

PSGRNZ recommends that the Ministry undertake a comparative assessment of these legislative options, informed by the six essential reviews proposed in this submission. These reviews would establish the scientific, legal and governance foundations for proportionate regulation, including transparent criteria for nutritional adequacy, therapeutic benefit, biological risk, dose–response, susceptible populations and periodic reassessment. They would also clarify institutional responsibilities for maintaining the scientific evidence base and reviewing restrictions as knowledge develops.

Without these foundations, new legislation risks reproducing the same classification tensions within a different administrative structure.

Officials have identified targeted amendments to the existing framework but it is difficult to identify a comprehensive evaluation of the existing regime against the costs, benefits and feasibility of any alternative reforms.

Officials have not produced a report evaluating the challenges of operating within the current regime, such as overly restrictive guideline limits, health and safety complaints, and impediments to New Zealand industries and consumer access. Nor have they evaluated the barriers that arise when a nutrient is classified as a medicine because of a claimed physiological, immunological or metabolic effect (often a recognised biological pathway of that nutrient), or the resulting challenges for public access.[1]

- February 2024 – Sapere Regulatory Scan: International approaches to Natural Health Product regulations
- February 2025 -H2025061418: Targeted improvements for regulating natural health products
- April 2025 - H2025065159: Update on the impacts of changes to the regulation of dietary supplements
- May 2025 - H2025066272: Evaluating regulatory pathways to enable dietary supplement exports
- September 2026 - Cabinet paper: Natural health products regulation – approval to engage

PSGRNZ observes that any assessment of alternatives has been limited by the existing policy direction and the limited content in these related policy papers. The February 2025 Ministry of Health briefing rejected targeted amendments partly because they might divert resources from developing standalone legislation. Consequently, the potential for improving the existing framework was not assessed through a comprehensive, comparative evaluation of regulatory outcomes.

The costs and benefits of reform remain insufficiently quantified. Although officials identified legislative fragmentation, export barriers and classification difficulties, the documents do not

[1] See for example a 2026 Ministry of Health Consultation on proposed changes to the classification of Vitamin D. https://consult.health.govt.nz/medsafe/vitamin-d-classification/supporting_documents/vitamin-d-consultation-2026-information-questionspdf

establish the extent of existing consumer safety failures or the anticipated improvements from a new regime. Nor do they adequately evaluate the potential consequences of additional regulation for affordability, consumer access, small suppliers and practitioner autonomy, alongside the benefits of stronger safeguards.

The scientific foundations of regulation remain underexamined. The documents discuss ingredient permissions, composition limits, medicine classification and health claims without demonstrating a systematic evaluation of the scientific criteria and processes underpinning these decisions. New legislation will not, by itself, provide the scientific expertise, research capacity, exposure data, dose–response assessments or independent reassessment mechanisms necessary for proportionate, evidence-based regulation.

The current six-page Appendix One presents a preliminary range of approaches to defining natural health products, permitted ingredients, pre-market requirements, health claims, manufacturing, labelling, exemptions and regulatory oversight. As an initial engagement document, it is understandably broad. However, the options are largely administrative, concentrating on ingredient lists, licensing, notification, compliance and enforcement, without adequately articulating the scientific and public-interest criteria that would govern these mechanisms.

In particular, the proposed approaches do not explain how biological risk would be assessed, how higher- and lower-risk products would be distinguished, or how decisions concerning ingredient restrictions, dose limits and therapeutic claims would be independently reviewed as evidence develops. Nor is systematic improvement of the existing legislative framework presented as a developed alternative, notwithstanding the Ministry's earlier identification of opportunities for targeted reform.

The concern is therefore not that the consultation lacks detailed legislative proposals, but that it invites public preferences on regulatory structures before establishing the scientific foundations, demonstrated deficiencies and comparative costs and benefits necessary to inform those preferences. An initial consultation should establish the scope of the problem and the principles governing its resolution, rather than risk narrowing public consideration to a selection of administrative mechanisms.

Without this foundation, consultation responses may identify preferences for particular regulatory arrangements without providing a reliable basis for determining whether those arrangements are necessary, proportionate or capable of improving public-health outcomes.

3. Regulatory Classification in Practice: Two Case Studies

3.1 Case Study of the 2025 Vitamin D Evaluation

The Ministry commissioned an independent expert report, Classification of Vitamin D: Review of Classifications for Dietary Supplements (October 2025), which surveys an extensive body of literature on vitamin D requirements, physiological functions, clinical benefits and potential

adverse effects. The report considered randomised controlled trials, observational studies, systematic reviews and Mendelian randomisation research.[2]

A systematic scientific assessment would integrate hazard, dose-response, total dietary and supplemental exposure, susceptible populations and uncertainty. However, a reproducible methodology for identifying, selecting, appraising or integrating the evidence in the paper was not disclosed and no systematic literature-search strategy, database selection, search dates, eligibility criteria, study-exclusion records or formal risk-of-bias assessment are presented.

The report did not identify an established methodological framework, such as PRISMA for systematic-review reporting, GRADE for assessing certainty in intervention effects, or the European Food Safety Authority's (EFSA) structured approach to assessing tolerable upper intake levels for nutrients. These frameworks serve different purposes and need not all be applied to a classification review. However, their absence highlights the lack of an explicit, fit-for-purpose assessment methodology.

Unresolved dose-response and safety questions

The report stated that supplementation with 2,000 IU daily can achieve serum 25-hydroxyvitamin D concentrations above 75 nmol/L in more than 90% of adults. However, the cited reference, Cui et al. (2023)[3], is a pooled analysis of worldwide vitamin D deficiency prevalence, rather than a dose-response study establishing this population-wide estimate. Although the estimate also appears in Pludowski et al. (2024)[4], the report did not identify the underlying trials, model response distributions or assumptions necessary to independently verify it.

The review acknowledged substantial individual variation in vitamin D requirements, including differences associated with baseline status, age, body weight, skin pigmentation and geographical location. Nevertheless, it did not present a population-specific analysis demonstrating the proportion of New Zealand adults expected to achieve particular serum concentrations at 1,000, 2,000 or 3,000 IU daily, and it did not establish an independently reproducible decision rule explaining why 2,000 IU daily is acceptable for general sale while 3,000 IU is not.

The report discussed relevant hazards, including hypercalcaemia, hypercalciuria, kidney stones and possible adverse effects associated with higher or prolonged supplementation. This is particularly relevant as a tolerable upper intake level, a recommended intake and a legal general-sale limit are scientifically and legally distinct concepts. A tolerable upper intake level is not automatically the appropriate threshold for restricting access to a nutrient.

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[2] Ministry of Health (October 2025). Expert Report. Classification of Vitamin D. Review of Classifications for Dietary Supplements. https://consult.health.govt.nz/medsafe/vitamin-d-classification/supporting_documents/vitamin-d-consultation-2026-expert-reportpdf

[3] Cui A, Zhang T, Xiao P, Fan Z, Wang H, Zhuang Y. Global and regional prevalence of vitamin D deficiency in population based studies from 2000 to 2022: A pooled analysis of 7.9 million participants. Front Nutr. 2023 Mar 17;10:1070808.

[4] Pludowski P, Grant WB, Karras SN, Zittermann A, Pilz S. Vitamin D Supplementation: A Review of the Evidence Arguing for a Daily Dose of 2000 International Units (50 µg) of Vitamin D for Adults in the General Population. Nutrients. 2024 Jan 29;16(3):391.

3.2 Case Study: Hardys DEN Nutrients

Hardy's Daily Essential Nutrients (DEN), a broad-spectrum formulation of nutrients with long histories of safe use and well-characterised risk profiles, was recently classified as a medicine. The trigger for medicines classification was technical and based on the legislative trigger. Despite a substantial body of research on DEN, officials did not evaluate its safety nor compare the adverse-effect profile with those of psychiatric medicines conventionally prescribed for related conditions (and the potential benefits that the public may have from changing to DEN).[5 6 7 8 9]

In an October 2024 Official Information Act response (H2024052860), Medsafe confirmed that it held no information on DEN's risk profile, no published literature on its safety or efficacy, and no records of consultation or advice sought to reclassify the product.[10] Instead, the classification arose from statutory ingredient, dose and therapeutic-purpose provisions. A subsequent Ministry briefing confirmed that even revising the relevant nutrient dose limits would not remove the medicines classification arising from the product's therapeutic purpose.[11]

Medsafe's classification captured lithium orotate (a naturally present component of another ingredient in one of the Hardy's products) within prescription-medicine controls, despite the substantial difference between trace or low-dose lithium exposure and the pharmacological doses used in psychiatric treatment. Professor Julia Rucklidge's subsequent application to reclassify lithium at environmentally relevant levels was declined in 2025.[12] The case highlighted the need for regulatory assessments that distinguish chemical form, dose, exposure and demonstrated biological risk. Such assessments must recognise the substantial differences between low-dose exposure and pharmacological treatment.

The Hardys case suggests that officials were reluctant to challenge the Medicines Act 1981 by considering the proportionality of the risks that could be experienced by people diagnosed with

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[5] Rucklidge JJ, Johnstone JM, Villagomez A, Ranjbar N, Kaplan BJ (2023) Broad Spectrum Micronutrients and Mental Health. Chapter 9. In Nutritional psychiatry: A primer for clinicians, pages 152-171. Edited by Ted Dinan. Cambridge University Press. DOI: 10.1017/978100929986

[6] Chand, A., Darling, K. & Rucklidge, J.J. Duration effects of micronutrients in children with ADHD: Randomised controlled trial vs. Open-Label extension. Eur Child Adolesc Psychiatry 35, 463–475 (2026). https://doi.org/10.1007/s00787-025-02841-3

[7] Mitchell, M., Bradley, H., Blampied, N.M., Mulder, R.T., Rucklidge, J.J. (2025). Protective effect of micronutrients used to treat antenatal depression on rates of postnatal depression at six months: A secondary analysis of NUTRIMUM. Journal of Affective Disorders 388 (2025) 119560. DOI: 10.1016/j.jad.2025.119560

[8] Rucklidge JJ, Usman Azfali M, Kaplan BJ et al (2021). Massacre, Earthquake, Flood: Translational science evidence that the use of micronutrients post-disaster reduces the risk of post-traumatic stress in survivors of disasters. International Perspectives in Psychology 10(1):39–54. DOI: 10.1027/2157-3891/a000003.

[9] Blampied M, Tylianakis JM, Bell C, et al. Efficacy and safety of a vitamin-mineral intervention for symptoms of anxiety and depression in adults: A randomised placebo-controlled trial "NoMAD". J Affect Disord 2023; 339: 954-964. DOI: 10.1016/j.jad.2023.05.077.

[10] Ministry of Health (October 30, 2024). Official Information Act request: Hardys Daily Essential Nutrients. H2024052860 https://fyi.org.nz/request/28602/response/111282/attach/7/H2024052860%20Response.pdf

[11] Ministry of Health (April 9, 2025) Aide-Mémoire Meeting with Minister Hoggard and Professor Julia Rucklidge to discuss 'Daily Essential Nutrients'. H2025064312. https://www.health.govt.nz/system/files/2025-11/H2025064312-Aide-Memoire-Meeting-with-Minister-Hoggard-and-Julia-Rucklidge-to%20discuss-Daily-Essential-Nutrients.pdf

[12] Medsafe. Minutes for the 74th meeting of the Medicines Classification Committee held at 133 Molesworth Street, Wellington on 23 July 2025. 5.4 Lithium (Prof Julia Rucklidge). https://www.medsafe.govt.nz/profs/class/Minutes/2021-2025/74mccMin23July2025.htm

related psychiatric conditions, and consider not just the potential benefits, but the relative safety compared with conventional treatment options.

The Hardy's case demonstrates the need to distinguish nutritional interventions from pharmaceutical treatments and to assess their relative risks, potential benefits and available treatment alternatives. Recognising this distinction is central to ensuring that regulatory restrictions are proportionate to scientifically established risks.

The challenge for a new regime is to ensure that restrictions on nutritional interventions are justified by transparent, product-specific assessments of biological risk at relevant exposures.

3.3 Scientific Rigour Requires Biological Context and Classification Must Follow Risk

The vitamin D and Hardys DEN cases illustrate how medicines classification can be driven by therapeutic purpose, ingredient restrictions or uncertainty about clinical benefit, without a sufficiently transparent assessment of biological risk at relevant exposures.

In the vitamin D case, the review placed considerable emphasis on therapeutic uses and the circumstances requiring professional supervision. However, whether a nutrient has sufficient evidence to support a particular disease-treatment claim is a separate question from whether it presents an unacceptable biological risk at a specified dose.

Similarly, Hardys DEN was captured by medicines classification provisions despite Medsafe acknowledging that it held no product-specific risk assessment or published safety and efficacy literature. The presence of lithium orotate also highlighted uncertainty about whether regulatory decisions could adequately distinguish low-dose exposure from the substantially higher doses used in psychiatric treatment, and the disproportionate impact on low-socioeconomic groups.

These cases demonstrate the need to separate biological risk assessment, evidence of benefit, claims substantiation and legal classification. Where nutritional interventions are proposed for conditions conventionally treated with medicines, their potential benefits and adverse effects should also be considered in the context of available treatment alternatives.

Nutritional risk assessment presents particular methodological challenges because essential nutrients have physiological functions, and both inadequate and excessive intakes may produce adverse health consequences. Biological effects depend on dose, chemical form, duration, total exposure, nutrient interactions and individual susceptibility.

For vitamin D, baseline serum 25-hydroxyvitamin D concentrations, adiposity, age, sunlight exposure, gastrointestinal absorption, relevant medical conditions and concurrent medications may influence supplementation responses. For Hardys DEN, the presence of multiple interacting micronutrients, including low-dose lithium in the original formulation, similarly requires assessment of the actual formulation, exposure levels and potential adverse effects rather than reliance on classification by ingredient or therapeutic purpose alone.

The European Food Safety Authority's (EFSA) 2024 Guidance for establishing and applying tolerable upper intake levels for vitamins and essential minerals provides an established approach

to nutrient safety assessment.[13] It incorporates hazard identification, hazard characterisation, intake assessment and risk characterisation, including dose-response relationships, total exposure, susceptible populations and scientific uncertainty.

Where particular risks are identified, screening, product labelling, dose restrictions or healthcare supervision may provide more proportionate safeguards than restrictions applied indiscriminately to the general population.

A tolerable upper intake level is a health-based reference value for assessing risk from total chronic exposure; it is neither a recommended intake nor automatically an appropriate legal general-sale limit. Equally, the presence of a nutrient in a medicine-classified formulation does not establish that every dose or exposure presents equivalent risk.

Any future Natural Health Products regime must be supported by the capacity to conduct scientifically reproducible assessments of the nature, probability and severity of biological harm at relevant exposures, alongside consideration of nutritional benefits, available alternatives and proportionate safeguards.

4. Establish Scientific Principles Before Legislation

The Ministry proposes that regulation should be proportionate to the risks and benefits associated with natural health products, support consumer choice and timely access, impose fair compliance costs, and align with international standards where appropriate.

However, the current approach is not sufficiently developed to guide legislative drafting.

The consultation repeatedly refers to higher-, medium- and lower-risk products without identifying the scientific criteria by which those categories would be determined. It also proposes different approaches to permitted ingredients, product notification, health claims, manufacturing standards and regulatory oversight without explaining how those requirements would be linked to biological risk.

This creates the possibility that the Government will adopt an administratively tiered system without establishing a scientifically defensible methodology for risk classification.

PSGRNZ recommends that the Ministry first distinguish a. *product classification*, b. *biological risk assessment* and the c. *substantiation of health claims* as separate regulatory questions.

The proposed tiers must not conflate biological safety with the evidence required to substantiate nutritional, physiological or therapeutic claims. A product with an established low-risk safety profile may require additional evidence to support a particular therapeutic claim. An unsupported claim should ordinarily be addressed through claims regulation; it does not, by itself, establish that a product presents a higher biological risk.

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[13] EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), Turck, D., Bohn, T., Cámara, M., Castenmiller, J., de Henauw, S., Hirsch-Ernst, K.-I., Jos, A., Maciuk, A., Mangelsdorf, I., McNulty, B., Pentieva, K., Siani, A., Thies, F., Aggett, P., Crous-Bou, M., Cubadda, F., Dopter, A., Fairweather-Tait, S.,… Naska, A. (2024). Guidance for establishing and applying tolerable upper intake levels for vitamins and essential minerals. EFSA Journal, 22(11), e9052. https://doi.org/10.2903/j.efsa.2024.9052

Administrative proportionality is not necessarily biological proportionality.

- A product may be classified as higher risk because it makes a particular therapeutic claim, contains an unfamiliar ingredient, or falls outside an established regulatory category.
- Conversely, products containing familiar ingredients may present significant risks through excessive dosing, interactions, contamination or use by susceptible populations.
- Over-regulation may also lead to under-dosing: low doses may prevent overt deficiency but fail to meet higher needs arising from poor absorption or illness.

European regulatory practice provides a useful distinction between these questions. EU food supplement legislation recognises ingredients with nutritional or physiological effects, while separate rules govern the scientific substantiation of health claims, the safety assessment of novel ingredients and the classification of medicinal products.

The European Food Safety Authority's revised 2024 guidance for assessing the tolerable upper intake levels of vitamins and minerals establishes a step-wise approach encompassing hazard identification, hazard characterisation, intake assessment and risk characterisation. It explicitly recognises the distinctive physiological functions and homeostatic mechanisms of essential nutrients.[14]

> ***Guidance for establishing and applying tolerable upper intake levels for vitamins and essential minerals (EFSA 2024)***
>
> *However, specific to nutrients are their biochemical and physiological roles and the specific and selective mechanisms that maintain the systemic homeostasis and regulate the accumulation of the nutrient over a range of intakes. Nutritional requirements also need to be considered, i.e. there is a level of intake below which the risk of deficiency or sub-optimal function arises (EFSA NDA Panel, **2010**).*

European medicinal-product definitions retain broad therapeutic-purpose and functional criteria, demonstrating why international regulatory models should be evaluated critically rather than adopted wholesale.

4.1 Consider the Public-Health Costs of Restriction

The proposed regulatory framework must consider the consequences of both regulatory action and inaction. A regulatory impact assessment that considers only the costs of permitting unsafe products will provide an incomplete account of public-health consequences.

Potential costs of unnecessary restrictions include:

- Reduced access to beneficial nutritional interventions.
- Higher consumer prices and reduced affordability.
- Reduced availability of specialised formulations.
- Barriers to independent nutritional research.
- Disincentives to investigate non-patentable substances.

[14] EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), (2024). Guidance for establishing and applying tolerable upper intake levels for vitamins and essential minerals. EFSA Journal, 22(11), e9052.

- Constraints on truthful communication about established nutritional benefits.
- Greater reliance on interventions that may be more expensive or carry different risks.

These considerations do not establish that every proposed nutritional intervention is effective.

They establish that the consequences of regulatory restrictions should be assessed alongside the risks those restrictions are intended to prevent.

The public-health evaluation should be especially attentive to groups experiencing nutritional insufficiency, chronic disease and financial disadvantage.

PSGRNZ's *Reclaiming Health* report identifies substantial gaps in New Zealand's capacity to investigate nutritional status and translate emerging nutritional research into clinical practice.[15]

These institutional limitations are relevant to regulatory design. For example, where independent research capacity is limited, a system relying exclusively on commercially sponsored applications may systematically under-evaluate low-cost, non-patentable nutrients.

The framework should therefore provide practical pathways for academic and public-interest scientific applications.

5. Reform Classification Before Introducing Risk Tiers

5.1 The problem with therapeutic-purpose definitions

The Medicines Act 1981 establishes a broad framework for identifying products that may be regulated as medicines, including by reference to therapeutic purpose. The interaction between therapeutic-purpose definitions and the regulation of nutrients has created longstanding difficulties. The existence of a therapeutic benefit does not confirm a pharmaceutical level of biological risk.

Essential nutrients participate in biochemical pathways that are fundamental to human physiology. Their biological effects are not incidental; they are the reason those nutrients are required for life and health. Vitamins and minerals may influence neurological function, mitochondrial activity, glucose metabolism, immune responses, hormone synthesis and numerous other physiological processes.

Recognition of these effects should not, in itself, establish that a nutrient is a pharmaceutical medicine. Nor should the emergence of evidence demonstrating that a nutrient can alleviate a deficiency-related disorder or improve a clinically relevant outcome automatically require that it be regulated under the same framework as a novel pharmaceutical drug.

PSGRNZ considers that a regulatory system which does not adequately distinguish these concepts may discourage scientific research, constrain truthful communication about nutritional benefits, and restrict access to interventions that have favourable benefit–risk profiles.

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[15] PSGRNZ (2026) Reclaiming Health: Reversal, Remission & Rewiring. Understanding & Addressing the Primary Drivers of New Zealand's Metabolic & Mental Health Crisis. Bruning, J.R., Physicians & Scientists for Global Responsibility New Zealand. ISBN 978-1-0670678-2-3. https://psgr.org.nz/component/jdownloads/send/1-root/206-reclaiming-health2026

Australia's model illustrates the problem

The Sapere international regulatory review identifies Australia's three principal complementary-medicine pathways:

- Listed medicines (AUST L).
- Assessed listed medicines (AUST L(A)).
- Registered medicines (AUST R).

These pathways provide different levels of regulatory scrutiny.

However, Australia's *Therapeutic Goods Act 1989* defines therapeutic use broadly enough to include influencing, inhibiting or modifying a physiological process.

Consequently, the Australian model provides an example of proportionate regulation within a therapeutic goods framework, but it does not necessarily resolve the prior question of whether a nutrient should be classified as a medicine.

Certain physiological and health claims can also be made under Australia's food regulatory framework, subject to applicable requirements. Nevertheless, the boundary between foods and therapeutic goods remains an important determinant of regulatory treatment.

New Zealand should therefore distinguish the legal classification of a product from the biological risks associated with its ingredients, formulation and intended use. Australia's tiered regulatory system offers useful administrative models, but its broad therapeutic-purpose definition does not resolve whether an established nutrient should be regulated as a medicine. International approaches should be assessed for their scientific foundations and suitability for New Zealand before adoption.

5.2 Recommended classification principles

PSGRNZ recommends that classification decisions consider:

1. Whether the ingredient is an essential nutrient, a conventional dietary constituent, a traditionally used substance, a novel substance or a pharmacologically active compound;
2. The ingredient's established physiological role and history of human exposure;
3. The chemical form, bioavailability and proposed dose;
4. Whether the product is intended to maintain nutritional adequacy, correct insufficiency, support physiological function or treat a diagnosed condition;
5. The nature, quality, consistency and strength of the scientific evidence supporting the proposed use; and
6. Whether the proposed use introduces risks requiring additional safeguards or clinical supervision.

These considerations should be evaluated together.

Point 5 above warrants a comment. Evidence may include relevant clinical trials, observational studies, established nutritional and physiological knowledge, mechanistic research and documented histories of safe use, assessed according to their relevance to the scientific question instead of automatically applying rigid hierarchies of evidence.

Having established the appropriate legal boundaries, the next matter concerns how regulatory oversight should be proportionate to the risks associated with products within those boundaries.

6. Establish Scientifically Defensible Risk Tiers

PSGRNZ supports risk-proportionate regulation, but the proposed tiers must be based on transparent scientific criteria. PSGRNZ recommends that the Ministry develop an integrated scientific framework incorporating established nutrient risk-assessment methodologies alongside appropriate pathways for novel ingredients and formulations.

The evidential requirements should reflect the nature and significance of the uncertainty, the potential consequences of harm and the proposed conditions of use and reflect the current state of scientific knowledge. The framework must remain responsive to scientific developments and permit classifications to change as evidence evolves.

Intensive regulatory controls should not automatically require pharmaceutical classification. Where the evidence establishes that medicines regulation is necessary, the regulator should provide a documented scientific and legal justification explaining why the identified risks cannot be adequately managed within the natural health products framework.

6.1 Established and Novel Ingredients and Formulations

The scientific methodology must accommodate both established nutrients with extensive histories of human consumption and newer ingredients, chemical forms, botanical extracts and formulations for which the available evidence may be more limited.

EFSA's 2024 guidance provides an established methodology for evaluating the risks of excess intake of vitamins and essential minerals.[16] Importantly, it recognises that new chemical forms of established nutrients may require separate assessment of safety and bioavailability, including whether existing tolerable upper intake levels remain applicable.

EFSA explicitly recognises that some susceptible populations are better protected through screening, healthcare providers, product labelling or other individualised measures, rather than lowering the general population's upper intake level. It also distinguishes medically supervised nutrient use from general-population upper intake levels.[17]

For novel substances and formulations, the assessment should additionally consider chemical identity, composition, manufacturing processes, absorption, distribution, metabolism, excretion, potential toxicity, interactions and relevant human exposure.

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[16] Note: this guidance is not a complete methodology for botanicals or other novel substances

[17] EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), (2024). Guidance for establishing and applying tolerable upper intake levels for vitamins and essential minerals. EFSA Journal, 22(11), e9052. Page 6.

Gaps in the evidence should trigger targeted investigation and safeguards proportionate to the plausibility and severity of potential harm. Novelty alone does not establish greater biological risk. Conversely, an established history of safe use should not automatically exempt a substantially altered formulation from further assessment.

This would allow scientific innovation without compromising public-health protection, while ensuring that established nutrients are not subjected unnecessarily to the same evidential requirements as substances with substantially different or poorly characterised biological properties.

A suitable framework would distinguish at least three broad categories of regulatory oversight, with flexibility for products whose risks do not fit neatly within a single category.

6.2 Permitted ingredient lists: the risks of regulatory exclusion

Key challenges concern whether:

- the regulator has the scientific capacity, legal flexibility and public-interest obligations necessary to make and continually revise proportionate decisions.
- such products can remain accessible under proportionate food or natural health product regulation without being unnecessarily drawn into medicines classification.

If New Zealand established a closed permitted-ingredient list, the regulator must decide which botanical species, plant parts, extracts, chemical forms and preparations qualify for inclusion. Such complexity can create confusion, over-regulation, regulatory hesitancy and absurdities in law. A listing for a plant species alone may be scientifically inadequate.

A tea, tincture, essential oil and concentrated extract can differ considerably in composition and exposure. Requiring every traditional preparation to undergo an expensive, individual authorisation process could be equally inappropriate. In an effort to be ‘safe’ the regulator could expose suppliers and the public to unnecessary over-regulation.

Peer-reviewed research has identified fragmented national ingredient requirements, inconsistent food–medicine classification, inflexible authorisation procedures and substantial compliance costs affecting botanical products and traditional preparations. These barriers can disproportionately disadvantage small producers, traditional practitioners and manufacturers of low-volume formulations.[18] [19][20]

Bilia and Costa (2021) provide concrete examples involving St John's wort, valerian, ginkgo, ginseng and green tea. Their review found that similar botanical products could occupy different

[18] Singh A. The Fragmented Regulatory Puzzle of so-called Botanicals in the EU between Food and Medicine. European Journal of Risk Regulation. 2026;17(3):971-983. doi:10.1017/err.2026.10081

[19] Warda, R., Purnhagen, K. & Molitorisová, M. Has Mutual Recognition in the EU Failed?—A Legal-Empirical Analysis on the Example of Food Supplements Containing Botanicals and Other Bioactive Substances. J Consum Policy 47, 425–443 (2024). https://doi.org/10.1007/s10603-024-09571-0

[20] Hermann M (2009). The impact of the European Novel Food Regulation on trade and food innovation based on traditional plant foods from developing countries. Food Policy, 34:6;499-507. DOI: 10.1016/j.foodpol.2009.08.005

regulatory categories across European markets, influencing authorisation costs, product development and permissible claims.

A herbal preparation may have established physiological effects without necessarily presenting the same risks as a concentrated pharmaceutical preparation. Conversely, a product sold as a food supplement may have significant toxicity or interaction risks. [21]

For example, St John's wort can interact with prescription medicines through effects on drug-metabolising enzymes and transporters. Concentrated green tea extracts have also raised concerns about liver injury. Such examples demonstrate why neither natural origin nor historical familiarity can substitute for exposure-specific assessment.

European experience demonstrates that ingredient regulation can create significant barriers to market access without necessarily resolving the underlying questions of biological safety. The EU Traditional Herbal Medicinal Products Directive (2004/24/EC) applies to herbal preparations classified as medicinal products, rather than ordinary food-based herbal products. Its simplified registration pathway therefore does not resolve the regulatory difficulties faced by traditional foods, herbal tonics and other botanical preparations marketed outside the medicines framework.

The European Union's revised Novel Food Regulation (EU) 2015/2283 provides a useful precedent for recognising traditional knowledge as relevant scientific evidence. Traditional foods from countries outside the EU may qualify for a simplified notification procedure where at least 25 years of safe dietary use can be reliably demonstrated.[22] This framework may also be relevant to ingredients used in nutritional supplements, although the simplified traditional-food pathway has narrower eligibility requirements and does not replace the separate regulatory provisions governing vitamins, minerals and food supplements.

The European Union's Novel Food Regulation (EU) 2015/2283 provides a useful precedent for recognising traditional dietary knowledge as relevant scientific evidence. Qualifying traditional foods from countries outside the EU may follow a simplified notification procedure where at least 25 years of safe food use can be reliably demonstrated.

EFSA's updated 2024 guidance provides for the assessment of historical consumption, composition, preparation methods and dietary exposure, although applicants must still submit an adequate dossier and substantiated safety objections may require further assessment.[23]

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[21] Bilia AR and do Céu Costa M. (2021). Medicinal plants and their preparations in the European market: Why has the harmonization failed? The cases of St. John's wort, valerian, ginkgo, ginseng, and green tea. Phytomedicine, 81:153421, DOI: 10.1016/j.phymed.2020.153421

[22] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (Text with EEA relevance)

[23] EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), Turck, D., Bohn, T., Castenmiller, J., De Henauw, S., Engel, K.-h., Hirsch-Ernst, K. I., Kearney, J., Knutsen, H. K., Maciuk, A., Mangelsdorf, I., McArdle, H. J., Naska, A., Pentieva, K., Siani, A., Thies, F., Tsabouri, S., Vinceti, M., Peláez, C., … Turla, E. (2024). Guidance on the scientific requirements for a notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283. EFSA Journal, 22(9), e8966. https://doi.org/10.2903/j.efsa.2024.8966

The regulation can also apply to novel ingredients intended for food supplements, although the simplified traditional-food pathway is subject to specific eligibility requirements. Importantly, the framework recognises that established histories of safe consumption outside Europe can contribute to scientific assessment rather than being disregarded because they do not conform to conventional clinical trial or toxicological evidence frameworks.

Traditional knowledge may encompass generations of observations concerning preparation methods, quantities, contraindications, seasonal variation, individual susceptibility and combinations of ingredients. Such knowledge can provide valuable evidence concerning exposure, tolerability and potential benefits, although historical use alone may not reliably identify rare adverse effects, long-latency harms or interactions with modern medicines.

A proportionate and scientifically defensible framework should therefore evaluate traditional knowledge critically, without either dismissing it or treating it as conclusive evidence of safety or therapeutic efficacy.

This is particularly relevant to rongoā Māori and other traditional health practices in New Zealand, where knowledge may be held collectively and transmitted through practitioners and communities rather than commercial research institutions.

Regulation should recognise this expertise, respect the authority of knowledge holders and provide accessible assessment pathways without assuming that traditional practices must be converted into commercially registered products.

The consequences of poor- or over-regulation extend beyond administrative inconvenience. Where scientific evidence requirements and regulatory costs exceed the resources of smaller producers, potentially beneficial products may be withdrawn, never developed or rendered commercially unviable. Regulatory systems may consequently favour well-capitalised enterprises capable of financing formal authorisation and claims substantiation, irrespective of whether their products offer superior safety or therapeutic benefit.

PSGRNZ is particularly concerned that closed permitted-ingredient lists could reproduce these structural disadvantages in New Zealand. Ingredients with established histories of use may be excluded not because relevant exposure assessments demonstrate unacceptable biological risk, but because no applicant has the resources or commercial incentive to secure regulatory recognition. This is especially problematic for non-patentable substances, traditional preparations and small-scale cottage industries.

A scientifically defensible framework must therefore distinguish an absence of regulatory authorisation from evidence of biological harm. It should provide accessible pathways for recognising established ingredients, evaluating traditional knowledge, conducting independent assessments and reconsidering restrictions. Where restrictions are necessary, the regulator should transparently identify the evidence of harm or material uncertainty, the relevant conditions of exposure and why less restrictive safeguards would be insufficient.

Regulation should not inadvertently confer commercial advantage through the exclusion of traditional or non-patentable products where proportionate safeguards could adequately protect public health and ensure local access to treatments with a long history of safe use.

6.3 Proposed Risk-Proportionate Regulatory Framework

PSGRNZ supports a tiered regulatory framework, provided that classification is grounded in biological risk at relevant exposures, with therapeutic claims, ingredient novelty and existing regulatory categories assessed separately.

The framework should distinguish between established safety, scientific uncertainty and identified risks requiring additional controls. It should accommodate both well-characterised nutrients and newer ingredients or formulations, with assessment requirements proportionate to their particular characteristics.

Tier 1: Established Low-Risk Products

This category would include essential nutrients and other well-characterised ingredients supplied in forms, doses and conditions of use for which relevant scientific evidence supports a low risk of harm. These are products with a documented history of safe human consumption. Recognised nutritional and safety assessments, and evidence concerning safe intake ranges should inform classification, taking account of chemical form, bioavailability, physiological function and susceptible populations.

Regulatory requirements should focus on ingredient identity and purity, manufacturing quality, accurate labelling, traceability and proportionate post-market surveillance.

Routine product-by-product pre-market approval should not be required where established scientific assessments adequately support the safety of the ingredient, formulation and proposed exposure.

Tier 2: Products Requiring Targeted Assessment

This category would accommodate products for which additional scientific assessment is warranted because of their exposure characteristics, formulation, intended population or material uncertainties in the available safety evidence. Novelty or incomplete evidence should trigger proportionate investigation, not an automatic presumption of high biological risk.

For example, EFSA requires consideration of differences in the absorption, distribution, metabolism and excretion of different chemical forms; it also explains that new forms may require separate assessment of safety and bioavailability, including whether an existing upper intake level remains applicable.[24]

Examples may include:

- Higher nutrient doses or prolonged exposure beyond established conditions of use.

[24] EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), (2024). Guidance for establishing and applying tolerable upper intake levels for vitamins and essential minerals. EFSA Journal, 22(11), e9052. Pages 7-8.

- Novel ingredients, chemical forms or formulations for which safety or bioavailability has not been adequately characterised.
- Products with materially altered absorption, metabolism or systemic exposure.
- Ingredients or combinations with potentially significant interactions.
- Products intended for populations with particular susceptibilities.
- Products for which existing safety assessments cannot reliably be extrapolated to the proposed conditions of use.

Additional assessment should address the specific evidence gaps or potential harms identified, with requirements proportionate to their plausibility, severity and the proposed exposure.

Frameworks must be suitably flexible and responsive to change in evidence. Where additional assessment establishes a favourable safety profile, the product should be eligible for lower-tier classification. Where significant risks are identified, additional safeguards or higher-tier classification may be warranted. Targeted controls could include dose restrictions, warnings, additional quality specifications, exposure monitoring or clinician supervision where justified.

Tier 3: Products Requiring Intensive Controls

This category would include products for which scientific assessment identifies significant biological risks at intended or reasonably foreseeable exposures, or where material uncertainties concerning potentially serious harm cannot adequately be managed through less restrictive measures.

Frameworks should be designed to maximise transparency and disclosure of how uncertainty, plausibility, exposure and severity are weighted. Relevant considerations may include:

- A narrow margin between beneficial and harmful exposures.
- Evidence of clinically significant toxicity.
- Serious or potentially irreversible adverse effects.
- Significant interactions with medicines or other substances.
- Risks requiring individualised monitoring or clinical supervision.
- Formulations or exposure conditions for which ordinary consumer safeguards are insufficient.

Such products may require pre-market safety assessment, enhanced manufacturing and quality requirements, restrictions on dose or supply, post-market monitoring or clinician supervision.

Assess each element of a natural health product separately.

Each regulatory tier should distinguish four assessment dimensions: biological safety, evidence of nutritional or therapeutic benefit, manufacturing and product quality, and conditions of supply and use.

1. **Biological safety:** Hazard, dose-response, relevant exposure, bioavailability, interactions and susceptible populations.
2. **Evidence of benefit:** The quality and relevance of evidence supporting nutritional, physiological and therapeutic claims.

3. **Manufacturing and product quality:** Ingredient identity, purity, consistency, contamination risks and traceability.
4. **Conditions of supply and use:** Appropriate labelling, restrictions, monitoring and circumstances requiring clinician supervision.

Biological risk should determine the level of safety oversight, while evidence supporting product claims should be evaluated through a separate, proportionate process. Manufacturing requirements and conditions of supply should reflect the risks associated with the product and its intended use. These assessments should inform an integrated regulatory decision without being conflated.

The credibility of these tiers ultimately depends on the scientific methods used to identify and characterise biological risk. Those methods must therefore be established before the proposed tiers can be meaningfully evaluated.

7. Evaluating Biological Risk

7.1 Avoid Inappropriate Evidence Hierarchies

PSGRNZ cautions against importing clinical evidence hierarchies into natural health products regulation without first establishing their suitability for the scientific questions being assessed.

Randomised controlled trials (RCTs) are important for evaluating many intervention effects, but observational, mechanistic, toxicological and established physiological evidence may be equally relevant, or more appropriate, for particular questions concerning nutrient requirements, long-term exposure and biological safety.

The GRADE framework is influential in determining which evidence is considered sufficiently certain to support clinical and public-health recommendations. Its conventional approach generally assigns higher initial certainty to RCTs than to observational studies. This can systematically disadvantage nutritional and physiological research, particularly where long-term randomised trials are difficult, expensive or impracticable.

This approach is increasingly recognised as overly rigid.[25] [26] [27] The United Kingdom's Scientific Advisory Committee on Nutrition identified limitations in applying GRADE to nutritional evidence, including the difficulty of blinding dietary interventions, the initial downgrading of prospective cohort evidence and limited opportunities to upgrade evidence of potentially important population-level effects. Published criticisms of the United Kingdom's Scientific Advisory Committee on Nutrition (SACN) subsequently identified deficiencies in the systematic evaluation

[25] Concato J. Observational versus experimental studies: what's the evidence for a hierarchy? NeuroRx. 2004 Jul;1(3):341-7. doi: 10.1602/neurorx.1.3.341. PMID: 15717036; PMCID: PMC534936.
[26] Tobias DK, Wittenbecher C, Hu FB. Grading nutrition evidence: where to go from here? Am J Clin Nutr. 2021 Jun 1;113(6):1385-1387. doi: 10.1093/ajcn/nqab124.
[27] Neale EP, Tapsell LC. Perspective: The Evidence-Based Framework in Nutrition and Dietetics: Implementation, Challenges, and Future Directions. Adv Nutr. 2019 Jan 1;10(1):1-8. doi: 10.1093/advances/nmy113.

of mechanistic evidence and the exclusion of relevant clinical-practice and observational research from particular reviews. [28]

A later SACN (2025) methodological paper acknowledged that conventional GRADE approaches may undervalue prospective cohort evidence, particularly where long-term randomised dietary trials are impracticable and observed effects do not meet conventional thresholds for upgrading certainty. [29]

Comparative research challenges the assumption that observational evidence necessarily produces less reliable estimates of intervention effects. A 2024 Cochrane methodological review encompassing 47 reviews and overviews 'found no difference or a very small difference between effect estimates from RCTs and observational studies', and recognised that while differences in confounding, bias and applicability remained central to understanding the effect of an intervention, its findings were largely consistent with recently published research.[30] More recent research published in 2026 found that:

> '*Both randomized controlled trials (RCTs) and cohort studies provide valuable evidence to understand diet-disease relationships and inform dietary guidelines*.'[31]

Many groups, such as the UK Academy of Nutrition Sciences show evidence of robust debate and ongoing conversations that can provide context and information in a rapidly shifting environment.[32]

These findings demonstrate that regulatory decisions should not be determined primarily by study design without examining the quality, relevance and consistency of the available evidence.

The regulatory implications are significant. What evidence is considered legitimate has historically influenced which interventions obtain recognition, which research attracts investment and whether established, inexpensive nutritional approaches remain accessible. Where pharmaceutical-style trial requirements are imposed without regard to biological risk, scientific feasibility or the nature of the proposed claim, regulation may inadvertently privilege commercially funded interventions over lower-cost nutritional approaches.

Any regulatory system must have the sophistication and flexibility to account for different routes of exposure, ingredient characteristics, intended uses and biological risks across age, sex and health

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[28] Singh M, Elsom R, Cullum A, de Souza RJ, Greenwood DC, Mela DJ, Ong KK, Young IS, Lovegrove JA; Scientific Advisory Committee on Nutrition (SACN). Updating the Scientific Advisory Committee on Nutrition's Framework for the evaluation of evidence. Br J Nutr. 2025 Aug 14;134(3):257-262. doi: 10.1017/S0007114525104054. Epub 2025 Jul 31. Erratum in: Br J Nutr. 2025 Aug 28;134(4):343. doi: 10.1017/S0007114525105060.

[29] Singh M, Elsom R, Cullum A, et al. Updating the Scientific Advisory Committee on Nutrition's Framework for the evaluation of evidence. British Journal of Nutrition. 2025;134(3):257-262. doi:10.1017/S0007114525104054

[30] Toews I, Anglemyer A, Nyirenda JLZ, Alsaid D, Balduzzi S, Grummich K, Schwingshackl L, Bero L. Healthcare outcomes assessed with observational study designs compared with those assessed in randomized trials: a meta-epidemiological study. Cochrane Database of Systematic Reviews 2024, Issue 1. Art. No.: MR000034. DOI: 10.1002/14651858.MR000034.pub3.

[31] Stadelmaier J, Bantle G, Cuello-Garcia C ...
Integrating evidence from randomized trials and prospective observational studies: an application of GRADE Guidance 44 to nutrition evidence syntheses
Journal of Clinical Epidemiology, 2026; 197

[32] U.K. Academy of Nutrition Sciences. The importance of transparent frameworks for the assessment of evidence https://www.academynutritionsciences.org.uk/outputs-and-activities/the-importance-of-transparent-frameworks-for-the-assessment-of-evidence

status. Many vitamins, minerals and herbs have long histories of use, established mechanistic understanding, characterised risk profiles and scientifically documented biological interactions.

Qualified health practitioners with appropriate nutritional training understand the importance of nutrient interdependence. Nutrients do not act in isolation: synergistic nutrient interactions and metabolic cofactor relationships mean that increasing the intake of one nutrient may alter the absorption, utilisation, metabolism or requirements of others. These interdependencies are relevant when assessing biological risk, determining appropriate doses and establishing proportionate safeguards, particularly where practitioners are managing individual nutritional requirements.

Similarly, medical doctors routinely consult the medical literature to evaluate the potential benefits and risks of pharmaceutical medicines, including drug–drug interactions. Natural health products also have a substantial and expanding scientific literature, including research into nutrient metabolism, physiological effects, interactions, clinical applications and safety. The depth of nutritional expertise varies across medical and other qualified health practitioners, and regulatory frameworks should recognise this gradient of knowledge rather than presume that expertise resides exclusively within one professional category.

Twenty years ago, comprehensive literature retrieval and evidence synthesis often depended on specialised research infrastructure, substantial library resources and labour-intensive processes. Today, searchable scientific databases, reference-management systems, automated screening and AI-assisted research tools make it possible to undertake much of this work from an ordinary office. These developments have substantially increased the capacity of motivated clinicians and practitioners to investigate unfamiliar interventions, critically evaluate emerging evidence and update their knowledge in response to individual patient needs.

This changing knowledge environment has implications for professional autonomy and regulatory design. Qualified practitioners should have appropriate flexibility to exercise evidence-informed judgement when evaluating nutritional interventions for individual patients, taking account of their clinical circumstances, nutritional status, metabolic function, absorption, concurrent treatments and potential interactions. Such flexibility should be supported by clearly defined competencies, access to reliable scientific information, appropriate monitoring and proportionate safeguards, rather than unnecessarily restrictive product classifications.

We emphasise that the evidence required to substantiate a general commercial therapeutic claim need not be identical to the evidence a qualified practitioner may reasonably consider when assessing an intervention for an individual patient. Regulatory frameworks should distinguish these functions, recognising that individualised clinical care involves integrating published research, established biological mechanisms, clinical experience, patient circumstances and monitored responses. Practitioner autonomy should not displace requirements for product safety or informed consent, but neither should regulatory classifications unnecessarily prevent qualified practitioners from applying emerging scientific knowledge.

These issues are part of a broader rationale, as to why separate, fit-for-purpose methodologies that can flexibly address biological safety, nutritional and physiological functions, therapeutic claims and post-market surveillance are required.

These methodologies can recognise the role of qualified clinician and practitioner autonomy in evaluating evidence, exercising professional judgement and contributing to the evidence base through systematic observation, outcome monitoring and the reporting of benefits, adverse effects and interactions.

Furthermore, modern digital research capabilities create opportunities to support this work through accessible evidence resources, clinical guidance and structured reporting systems.

Evidence should be evaluated according to its relevance, methodological quality, consistency and capacity to answer the regulatory question, recognising the strengths and limitations of different study designs. This can be undertaken not only by Ministry officials, but by clinicians and qualified health practitioners in their day-to-day role.

The Ministry should explicitly demonstrate how cohort studies, case-control studies, mechanistic research, clinical case series and other relevant evidence will be considered, and how regulatory decisions will avoid confusing the absence of randomised trials with evidence of ineffectiveness.

7.2 Establish Relevant Exposures

The mere capacity of a substance to influence a physiological pathway does not establish toxicity. Risk assessment must distinguish the identification of a potential hazard from the likelihood and severity of harm at relevant human exposures. Likewise, a substance that occurs naturally or is essential to human health may nevertheless present risks that vary with dose, chemical form, duration of exposure and individual physiology.

PSGRNZ recommends that ingredient and product assessments consider the following.

Dose and dose-response

Assessment should identify the relationship between exposure and relevant biological outcomes, including:

- Nutritional adequacy and deficiency.
- Physiological benefit.
- Potential therapeutic benefit.
- Adverse effects and toxicity.
- Uncertainty in the available evidence.

Where suitable data exist, the assessment should identify the exposure ranges associated with benefit, potential harm and relevant uncertainty.

Chemical form and bioavailability

Different chemical forms of the same nutrient may have different absorption, distribution, metabolism and elimination characteristics and these differences can affect both efficacy and

safety. Regulatory decisions should therefore avoid treating all forms of a nutrient as equivalent where the scientific evidence indicates otherwise.

Total and cumulative exposure

Risk assessment should consider reasonably foreseeable exposure from all relevant sources, including:

- Ordinary dietary intake.
- Fortified foods.
- Dietary supplements.
- Multiple products containing the same ingredient.
- Relevant medicinal sources.

For nutrients, the relevant question is often total exposure rather than the contribution of an individual product considered in isolation.

Where reliable exposure data are unavailable, that limitation should be explicitly acknowledged.

Susceptible populations

Assessment should consider whether risk differs according to:

- Age and developmental stage.
- Pregnancy and lactation.
- Renal or hepatic function.
- Nutritional status.
- Relevant genetic or metabolic characteristics.
- Existing medical conditions.
- Concurrent medication use.

A single population-wide threshold may not adequately characterise risk for all groups.

Uncertainty concerning one susceptible group should not automatically justify restrictions on the entire population where narrower safeguards can adequately manage the identified concern.

Interactions and cumulative effects

The assessment should consider clinically relevant nutrient–nutrient and nutrient–medicine interactions. This is particularly important for products containing multiple ingredients and for people taking several medications.

The regulatory response should target the particular combinations or circumstances responsible for the identified risks. Advances in machine learning, metabolic-network modelling and systems pharmacology offer new opportunities to investigate complex nutrient–drug interactions, integrating information on biochemical pathways, absorption, metabolism and individual susceptibility.[33] These approaches could strengthen regulatory horizon scanning and identify

[33] Marzouk, N.H., Selim, S., Elattar, M. et al. A comprehensive landscape of AI applications in broad-spectrum drug interaction prediction: a systematic review. J Cheminform 17, 141 (2025). https://doi.org/10.1186/s13321-025-01093-2

priorities for targeted research, provided computational predictions are independently validated and interpreted within their biological context.

8. Evaluating Nutritional and Therapeutic Benefits

The proposed framework must provide credible pathways for recognising beneficial effects. Safety and efficacy are distinct questions, but both are relevant to informed choice and proportionate regulation.

Claims concerning established nutrient functions should be assessed against relevant physiological, biochemical and nutritional evidence. A claim describing a well-established role in normal human biology should not necessarily require the same evidential process as a claim that a product treats a diagnosed disease.

8.1 Claims concerning correction of insufficiency & therapeutic claims

Where evidence supports the correction of nutritional insufficiency or deficiency, the framework should provide a practical pathway for communicating that benefit. This may include consideration of relevant biomarkers, clinical outcomes and evidence from susceptible populations.

Established nutritional and physiological functions may be supported by biochemical, mechanistic and nutritional evidence, while claims concerning disease prevention, treatment or remission require stronger evidence of clinically meaningful benefit.

Documented histories of traditional use can provide valuable evidence of human exposure, tolerability and potential physiological benefits. Assessments should recognise that nutritional interventions may support biological repair, restoration of function and longer-term health, with outcomes influenced by baseline nutritional status, dose, duration and individual circumstances. Evidence requirements should reflect the proposed benefit, including biological repair, restoration of function and longer-term health outcomes.

Evidence may include randomised controlled trials, systematic reviews, clinical studies and other relevant scientific information. Mechanistic studies, observational evidence, clinical audits and traditional use may contribute to assessment, but their evidential limitations should be recognised.

Distinguish claims-related risks from biological risks

Importantly, the regulation of health claims must also recognise that risks can arise from how products are represented and used, independently of their intrinsic biological safety. Unsupported or misleading therapeutic claims may encourage inappropriate substitution for effective treatment, delay diagnosis or discourage necessary clinical supervision, particularly among vulnerable populations.

These risks warrant proportionate safeguards, including transparent evidence requirements, accurate labelling, appropriate warnings and restrictions on claims where scientifically justified.

However, the existence of a claims-related risk should not automatically establish that the product itself presents an unacceptable biological risk or requires classification as a pharmaceutical medicine. Regulatory responses should distinguish the risks arising from the product, its intended use and the claims made about it, applying controls appropriate to each.

The framework should not require pharmaceutical-style evidence indiscriminately for every physiological claim. Equally, it should not permit unsupported disease-treatment claims merely because the ingredient is natural.

8.2 Evidence should be independently reviewable

Informed choice requires access to reliable evidence, not simply access to products. PSGRNZ recommends that the regulator publish accessible scientific assessments explaining:

- The evidence considered.
- The methods used to evaluate its quality.
- The benefits and harms identified.
- Important uncertainties and limitations.
- The reasons for accepting or rejecting particular claims.
- Any conditions attached to approval.

Where evidence permits, information should include absolute measures of benefit and harm, accompanied by appropriate context for interpreting relative changes.

This is particularly important when products are promoted to people experiencing chronic illness, psychiatric conditions or other circumstances in which consumers may be vulnerable to overstated claims.

9. Establish Appropriate Restrictions and Safeguards

Having separately assessed biological risk and evidence of benefit, the regulator must determine which safeguards are necessary, scientifically justified and proportionate to the circumstances of use. This requires distinguishing scientific reference values from enforceable legal limits, recognising when individualised clinical supervision is appropriate, and ensuring that manufacturing and quality-assurance requirements reflect actual product-related risks.

A proportionate system should adopt the least restrictive measures reasonably capable of managing identified or reasonably foreseeable risks, while preserving access to beneficial nutritional interventions and avoiding unnecessary compliance burdens.

Depending on the evidence, these safeguards may include:

- Ingredient and purity specifications.
- Manufacturing and contamination controls.
- Dose recommendations and maximum permitted exposures.
- Warnings concerning pregnancy, age or particular medical conditions.
- Information on clinically significant interactions.
- Limits on unsupported claims.
- Product traceability and adverse-event reporting.

- Restrictions on particular formulations or supply circumstances.
- Clinician supervision where justified.

Regulatory restrictions should be justified by identified risks or material gaps in safety evidence, supported by transparent reasoning and reassessed as new evidence emerges. Restrictions should not be maintained indefinitely merely because they have historically existed.

Where targeted warnings, dose restrictions or clinician supervision can adequately manage the identified risks, the regulator should explain why broader restrictions or prohibitions are necessary.

9.1 Distinguish Nutritional Reference Values From Legal Limits

PSGRNZ considers that particular care is required when translating scientific nutrient reference values into regulatory restrictions. Recommended dietary intakes, adequate intakes, tolerable upper intake levels and therapeutic doses serve different purposes and cannot be treated as interchangeable.

A recommended dietary intake is generally intended to describe an intake sufficient to meet the nutritional requirements of most healthy individuals within a defined population group.

A tolerable upper intake level is generally intended to identify a level of habitual total intake unlikely to pose appreciable risk of adverse effects in the population for which it was established.

Neither necessarily establishes an optimal intake for every individual or an appropriate upper limit for clinically supervised therapeutic use.

A tolerable upper intake level is a scientific risk benchmark, not automatically a justified legal limit for every product or clinical circumstance.

Where the Government proposes to adopt a maximum permitted product dose, it should explain:

a. Which scientific assessment supports the threshold.
b. Whether it concerns total daily intake or intake from supplements alone.
c. Which population and exposure assumptions were used.
d. Whether the threshold applies to the specific chemical form.
e. How background dietary exposure was considered.
f. Whether evidence supports different limits for supervised and unsupervised use.
g. How uncertainty was addressed.

PSGRNZ also recommends reviewing the terminology used in the Dietary Supplements Regulations 1985, clearly distinguishing recommended daily intakes, tolerable upper intake levels and maximum permitted product doses. Relevant international terminology and assessment methods, including those developed by EFSA, should be considered according to their scientific rigour, currency and relevance to New Zealand.

9.2 Define When Clinician Supervision Is Necessary

PSGRNZ recommends that the proposed framework explicitly recognise a category of nutritional products or uses that may be appropriate under clinical supervision without necessarily requiring full pharmaceutical regulation. This would allow regulation to reflect differences in exposure and clinical circumstances. This could include circumstances involving:

- Higher doses or defined dosing periods to correct a documented deficiency.
- Nutrients with a narrow margin between beneficial and harmful exposure.
- Products requiring biochemical monitoring.
- Clinically significant interactions with prescribed medicines.
- Treatment of patients with renal, hepatic or other relevant conditions.
- Uses in pregnancy or other circumstances requiring individualised assessment.

Guidance should identify circumstances where clinical supervision may be necessary to manage demonstrated or reasonably foreseeable risks. For example, higher-dose vitamin D may warrant monitoring of calcium status and renal function in susceptible patients; iron supplementation may require assessment of iron status and underlying conditions; and particular nutrients may require additional caution during pregnancy or where clinically significant medication interactions exist. These circumstances should be distinguished from minor, transient effects, such as mild gastrointestinal discomfort, which may be managed through appropriate labelling or dose adjustment.

Clinical guidance should support, rather than unduly constrain, professional judgement. Decisions concerning dose, duration, monitoring and supervision must accommodate individual patient history, nutritional status, multimorbidity, concurrent medications, treatment response and patient capacity and preferences. Guidance should remain responsive to emerging evidence and developing clinical expertise, allowing qualified health practitioners appropriate discretion to individualise care. Where supervision is justified, the regulatory framework should clarify which practitioners may provide it and whether lower-dose formulations can remain available without supervision.

9.3 Affordable, Risk-Proportionate Quality Assurance

PSGRNZ recommends an affordable quality-assurance pathway for manufacturers of established, low-risk nutritional products, recognising existing scientific assessments, internationally accepted ingredient specifications, accredited laboratories and verified supplier documentation.

Requirements should distinguish ingredient safety from finished-product quality. Testing and certification should be proportionate to identified risks, including ingredient identity, purity, potency, contamination, manufacturing consistency and traceability. Independent testing should remain available or required where justified by product characteristics, supplier history or credible safety concerns.

The Ministry should investigate shared testing arrangements, recognition of accredited overseas laboratories and a publicly accessible register of accepted ingredient specifications and analytical

methods. These measures could reduce unnecessary duplication and compliance costs, particularly for smaller manufacturers, without compromising consumer protection.

This would support consumer safety, market competition and affordable access while preserving the regulator's ability to impose more stringent requirements where scientifically justified.

10. Require Periodic Scientific Reassessment & International Precedent

Scientific knowledge changes and regulatory decisions should therefore be capable of revision when new evidence becomes available. A scheduled review cycle should be supplemented by evidence-triggered reassessment. Relevant triggers could include new systematic reviews, major clinical trials, updated international scientific assessments, credible safety signals or evidence of previously unrecognised benefits. Emerging machine learning and AI technologies have changed the landscape for scientific review, lowering many of the cost barriers.

Classification must remain reviewable and products initially requiring enhanced assessment because of uncertainty should be eligible for reclassification when sufficient evidence establishes their safety under defined conditions of use. Similarly, products previously considered low risk should be reassessed where new evidence identifies clinically significant hazards, interactions or susceptible populations.

The regulator should publish the scientific reasoning for maintaining, amending or withdrawing classifications and restrictions, with accessible mechanisms for independent review.

There should also be a transparent process through which researchers, qualified health practitioners, consumers and public-interest organisations can request reconsideration.

Learn Selectively From International Systems

The Sapere (2024) review identifies useful features of overseas regulatory systems. However, international alignment should not mean automatic adoption. New Zealand must consider differences in scientific assessment methods, dietary patterns, environmental exposures and population nutritional status, while retaining responsibility for decisions appropriate to domestic circumstances.

11. Strengthen Scientific Independence and Oversight

The consultation identifies possible regulatory functions, including product classification, post-market surveillance, advisory committees, enforcement and appeals.

These functions are necessary but insufficient without clear scientific governance arrangements.

PSGRNZ recommends that the framework specify:

1. The scientific competencies required for ingredient and product assessment, including nutritional science, toxicology, pharmacology, clinical medicine and exposure assessment.
2. Procedures for managing conflicts of interest.
3. Requirements to publish the evidence and reasoning supporting significant decisions.
4. Independent scientific review where substantial uncertainty or disagreement exists.

5. Accessible mechanisms for challenging classifications and restrictions.
6. Public-interest pathways for initiating reviews.
7. Reporting on adverse events, emerging evidence and regulatory responses.

The regulator should not be dependent solely on industry applications to identify when existing restrictions require reconsideration.

Scientific stewardship includes responsibility for examining evidence that may support relaxing restrictions as well as evidence that may justify strengthening them.

12. Public Consultation Must Address Practitioner Expertise & Scientific Foundations

The Cabinet paper proposes targeted engagement with industry, consumers, qualified health practitioners and health representatives.

However, the foundational questions raised by this reform extend beyond administrative arrangements and sector compliance. They concern the legal boundaries of nutritional and therapeutic products, the scientific basis of regulatory decisions, the gradient of expertise held by medical doctors and nutritionally trained health practitioners, and the circumstances in which the state may restrict access to substances that play established roles in human physiology.

These matters warrant broad public scrutiny.

There is considerable variation in nutritional knowledge and experience across health professions. Medical practitioners may have limited formal training in nutritional therapeutics, while other qualified practitioners may possess substantial expertise in nutrient biochemistry, therapeutic dosing, interactions and individualised nutritional care.

Equally, some medical doctors have developed considerable expertise in nutritional interventions through clinical practice, research and continuing professional development. Professional qualifications alone do not establish the depth or currency of an individual's knowledge in this field.

Importantly, the means by which practitioners acquire and update scientific knowledge are changing. By 2026, access to online scientific literature, systematic reviews, international risk assessments, clinical research databases and emerging AI-assisted research tools enables motivated practitioners to investigate unfamiliar nutritional interventions and rapidly deepen their understanding, particularly when seeking solutions to an individual patient's clinical problem.

This creates greater flexibility in how scientific knowledge is acquired and applied, although access to information does not itself establish competence, and the quality of evidence and its interpretation remain essential.

Regulatory frameworks can flexibly recognise this changing knowledge environment rather than presume that expertise resides exclusively within particular professional categories. Where nutritional interventions require clinical supervision, the necessary competencies, monitoring requirements and biological risks should be clearly identified, allowing appropriately qualified practitioners to exercise informed professional judgement.

The objective should be to support evidence-informed clinical decision-making, rather than allow regulatory classification to become a substitute for understanding the actual biological risks and potential benefits of an intervention.

PSGRNZ recommends that the Ministry publish a substantive scientific discussion paper addressing classification and risk assessment before proceeding to legislative drafting.

The paper should provide worked examples illustrating how the proposed system would regulate different ingredients, doses, formulations and claims.

At a minimum, these examples can include:

- Vitamin D at conventional and higher supplemental doses.
- Vitamin B6 at different exposure levels.
- Selenium and iodine, where both insufficiency and excess may be relevant.
- Low-dose lithium-containing formulations.
- Broad-spectrum multinutrient products.
- Traditional herbal preparations with differing evidence and risk profiles.

For each example, the Ministry should explain the proposed classification, evidence requirements, risk assessment, permitted claims, restrictions and circumstances requiring clinical supervision. Such examples would allow stakeholders to evaluate whether the proposed system is genuinely proportionate. Without them, the consultation risks inviting support for abstract principles without disclosing their practical regulatory consequences.

13. Recommendations & Conclusion

PSGRNZ recommends that the Government:

1. **Establish classification boundaries before risk-tiering.** Review the legal distinctions between foods, dietary supplements, natural health products and medicines, coordinated with medicines reform, before determining the regulatory controls applicable to each category.
2. **Reform therapeutic-purpose classification.** Ensure that established nutritional, physiological, metabolic or immunological effects, or evidence of therapeutic benefit, do not automatically trigger medicines classification without consideration of biological risk and appropriate regulatory safeguards.
3. **Publish fit-for-purpose scientific methodologies.** Establish transparent, reproducible methods for evaluating biological safety, nutritional adequacy, therapeutic benefits and scientific uncertainty, supported by enduring institutional expertise and independent funding. Recognise the transformation in research capacity through digital scientific databases, systematic-review tools, computational modelling and AI-assisted evidence synthesis, which increasingly enable comprehensive scientific investigation within ordinary research and clinical settings.
4. **Distinguish biological risk from claims substantiation.** Apply evidential standards appropriate to nutritional, physiological and therapeutic claims, without treating insufficient evidence for a claim as proof of biological harm.

5. **Establish scientifically justified risk tiers.** Link regulatory requirements to the nature, probability and severity of harm at relevant exposures, distinguishing established low-risk ingredients from novel formulations and products requiring additional assessment.
6. **Distinguish nutrient reference values from legal limits.** Require explicit scientific justification when recommended intakes or tolerable upper intake levels are translated into maximum permitted doses or restrictions on supply.
7. **Recognise appropriate therapeutic uses of nutrients.** Provide proportionate pathways for evidence-based nutritional interventions, including higher-dose formulations and professionally supervised applications where justified. Recognise the gradient of nutritional expertise across medical practitioners and other qualified health practitioners, ensuring that supervision requirements reflect demonstrated competencies, relevant biological risks and monitoring needs rather than professional classifications alone.
8. **Apply targeted, affordable safeguards.** Use proportionate manufacturing standards, quality assurance, labelling, warnings, dose restrictions, monitoring and professional supervision, avoiding unnecessary compliance burdens on smaller manufacturers and innovators.
9. **Require ongoing scientific reassessment.** Establish scheduled and evidence-triggered reviews of classifications, permitted claims and restrictions, with accessible pathways for researchers, practitioners and the public to request reconsideration. Modern digital research capabilities should support more timely, systematic and affordable reassessment, reducing reliance on occasional commissioned reviews and preventing outdated restrictions from persisting unnecessarily.
10. **Establish independent scientific governance.** Provide enduring expertise in nutrition, safety assessment and relevant clinical disciplines, recognising that specialist nutritional knowledge is distributed across professional groups and can develop through research, clinical experience and continuing education. Require transparent expert appointments, conflict-of-interest safeguards, published scientific reasoning, independent review mechanisms and sufficient institutional capacity to critically evaluate emerging evidence.
11. **Evaluate international evidence critically.** Establish criteria for assessing the scientific rigour, comprehensiveness, timeliness, independence and relevance of overseas assessments and regulatory decisions, rather than automatically adopting foreign classifications.
12. **Assess comparative risks and regulatory consequences.** Evaluate the benefits and harms of nutritional interventions alongside relevant conventional treatment alternatives, and account for the public-health, equity, affordability, research and innovation consequences of unnecessary restrictions.
13. **Publish worked regulatory case studies.** Demonstrate how proposed classification rules, risk tiers, evidence requirements and safeguards would apply to vitamin D, broad-spectrum micronutrients, low-dose lithium and other representative products.
14. **Complete foundational reviews before legislative decisions.** Publish the six proposed scientific, legal and governance reviews, together with draft assessment methodologies and regulatory principles, for further public consultation before formal regulatory impact analysis and Cabinet approval for legislative drafting.

Conclusion: Getting the Scientific Foundations Right

New Zealand has an opportunity to establish a scientifically credible, proportionate and transparent natural health products regulatory system. However, reform must address the two major problems that characterise the current framework: the historical over-regulation of nutrients through medicine-like classifications that insufficiently distinguish nutritional function and biological risk; and chronic underinvestment in independent nutritional science and risk assessment, which has allowed restrictive classifications to persist without systematic, evidence-based reassessment.

A failure to address these deficiencies will result in different consequences for affected groups:

- For expert health practitioners: restrictions on professional judgement and access to nutritional interventions;
- For medical doctors: Confusion and hesitancy in recognising safety profiles and evaluating cost-benefits in comparison to conventional clinical approaches;
- For consumers: Unnecessary prescription requirements, consultation costs and barriers to access;
- For disadvantaged communities: Additional financial burdens where nutritional interventions are not publicly funded;
- For smaller domestic suppliers: Disproportionately onerous compliance costs that hold potential to undermine commercial confidence, commercial viability and consumer choice.

The costs of restricted access are themselves regulatory outcomes that must be evaluated alongside the risks of allowing products onto the market.

This opportunity for reform will be undermined if administrative requirements are prioritised without first resolving the scientific and legal foundations of classification, biological risk assessment and evidence of benefit. These foundations cannot simply be imported from overseas regulatory systems without critical scientific evaluation and consideration of New Zealand's circumstances.

Nor can regulation be genuinely risk-proportionate if established nutritional or physiological benefits become grounds for medicines classification without adequate consideration of biological risk.

The current framework has contributed to disproportionate restrictions on certain nutrients, particularly where evidence of therapeutic benefit triggers medicines classification without a corresponding assessment of biological risk. A nutrient does not become inherently more hazardous because science demonstrates that it has a therapeutic benefit.

Biological safety, evidence of benefit and claims substantiation require distinct, appropriate scientific assessments. Identified risks should attract proportionate safeguards, while uncertainty should be transparently characterised rather than automatically treated as evidence of harm. Regulatory decisions must also remain open to reassessment as scientific knowledge develops.

PSGRNZ therefore urges the Ministry to undertake and publish the six foundational reviews to inform formal regulatory impact analysis, followed by further public consultation before seeking Cabinet approval for legislative drafting.

The objective is scientifically justified and proportionate regulation that protects public health, respects informed choice and professional judgement, enables equitable access to beneficial nutritional interventions, and ensures that regulatory restrictions and compliance costs are commensurate with demonstrated biological risks and public-health benefits.

Appendix: Response to October 2026 Consultation Questions

Q5. Dedicated regulatory system

PSGRNZ supports a coherent, scientifically defensible regulatory framework, but does not consider that the problem definition is adequate and that the need for standalone legislation has been demonstrated. The Ministry should first undertake a genuine comparative evaluation of improving existing legislation against establishing a new regime, considering scientific capacity, consumer protection, practitioner autonomy, equitable access, industry costs and the consequences of existing medicine classifications.

As such, we recommend six foundational reviews to provide a robust scientific and legal basis for subsequent regulatory reform.

Supporting sections: Summary (pp. 3–6); Strategic Consultation on Six Major Themes (pp. 7–9); Section 2, Limited Official Assessment (pp. 12–14); Section 5, Reform Classification Before Introducing Risk Tiers (pp. 20–22).

Q6. Proposed objectives

PSGRNZ broadly recommends strengthening their public-health and scientific foundations. The objectives should explicitly recognise the protection and promotion of public health, affordable and timely access to beneficial nutritional interventions, informed choice and responsible domestic innovation, while maintaining independent scientific oversight of product safety, quality and claimed benefits.

Expand the purposes:

i. Public health, scientific integrity and informed choice

To protect and promote public health through scientifically justified, transparent, adaptable and proportionate regulation of the safety, quality and claimed benefits of natural health products; recognising established and emerging scientific knowledge, supporting informed consumer choice and appropriate professional judgement, and enabling affordable and timely access to products suitable for their intended use.

ii. Responsible innovation and scientific excellence

To support a responsible, innovative and scientifically informed natural health products sector, including domestic research, product development and exports, through a regulatory framework that encourages independent scientific inquiry, accommodates advances in knowledge and

technology, and maintains public confidence through transparent decision-making, independent scientific scrutiny and accountability.

Supporting sections: Invest in Nutrition for the Future (p. 6); Deepen the Purpose and Principles (pp. 10–11); Section 4.1, Public-Health Costs of Restriction (pp. 19–20).

Q7. Proposed principles

PSGRNZ supports the general direction but considers the proposed principles insufficiently developed to guide legislation. Proportionality must be established through scientific assessment of biological risk at relevant exposures, while distinguishing nutritional adequacy, therapeutic benefit, claims substantiation and uncertainty. Regulatory decisions must also account for the health, financial and distributional consequences of unnecessary restrictions.

PSGRNZ proposes that the current principles are too narrow.

1. **Evidence of benefit and informed choice:** Regulation recognises established histories of safe use and credible evidence of nutritional, physiological and therapeutic benefits, with evidential requirements proportionate to the nature and significance of claims. Consumers and health practitioners have access to clear, accurate information concerning benefits, harms and uncertainties.
2. **Proportionality to biological risk:** Regulation is proportionate to demonstrated or reasonably foreseeable biological risks from under-dosing as well as over-dosing at relevant exposures, considering dose, chemical form, duration, cumulative exposure, nutrient synergies, medical interactions and susceptible populations. Regulatory controls are no more restrictive than reasonably necessary to manage identified risks.
3. **Distinction between scientific uncertainty and identified risk:** Regulation can distinguish between uncertainty about therapeutic benefit, uncertainty about biological safety and scientifically identified risks of harm. That insufficient evidence of benefit may justify limitations on particular claims, but does not itself establish biological harm. Uncertainty about safety can prompt investigation proportionate to the plausibility and potential severity of adverse effects, the extent of relevant exposure and the significance of the evidence gaps. Where warranted, precautionary safeguards are targeted and proportionate, without an automatic presumption of harm. Decisions are transparent, independently reviewable and responsive to emerging scientific evidence.
4. **Distinction between classification and risk:** Product classifications distinguish established nutritional and physiological functions, evidence of therapeutic benefit and biological risk. Recognition of a physiological, immunological or metabolic effect, or therapeutic benefit, does not, by itself, trigger classification as a pharmaceutical medicine. Evidential requirements for claims are distinguished from controls necessary to manage biological risk.
5. **Timely access and appropriate safeguards:** Regulation supports affordable and timely access to natural health products, with appropriate safeguards, including dose restrictions, warnings, monitoring and clinician supervision where scientifically justified. The potential public-health consequences of unnecessarily restricting access are taken into account.

6. **Scientific integrity, responsiveness and accountability:** Regulatory decisions are grounded in the best available scientific evidence, using transparent and independently reviewable methods. Classifications, permitted claims and restrictions are subject to periodic and evidence-triggered reassessment, informed by relevant clinical and practitioner experience, independent scientific research and expert evaluation. Regulatory oversight is supported by accessible review mechanisms, feedback information from clinicians and practitioners, independent scientific scrutiny and public reporting.
7. **Efficient administration and international alignment:** Administrative and compliance requirements are efficient, proportionate and affordable, without unnecessarily disadvantaging consumers, qualified health practitioners, researchers or small businesses. International standards and practices are adopted only where scientifically justified and relevant to New Zealand's circumstances.
8. **Distributed scientific expertise and practitioner autonomy:** Regulators and regulation recognise that scientific knowledge and evidence-informed judgement develop across a continuum, from qualified clinicians and practitioners working directly with patients, through professional and independent scientific communities, to national regulatory authorities. The framework supports appropriate professional autonomy, access to emerging scientific evidence, systematic clinical observation and reporting, and mechanisms through which practitioner experience and independent research can inform regulatory review. Responsibilities for evaluating evidence, making binding regulatory decisions and maintaining public accountability are clearly defined, with safeguards proportionate to biological risk.

Supporting sections: Deepen the Purpose and Principles (pp. 10–11); Section 4, Establish Scientific Principles Before Legislation (pp. 18–20); Section 6, Establish Scientifically Defensible Risk Tiers (pp. 22–28).

Q8. Additional principles

See above (question 7). PSGRNZ recommends explicit principles of scientific independence, transparent and reproducible assessment, proportionate biological safeguards, equitable access, professional judgement and periodic reassessment. The framework should distinguish uncertainty about benefit from identified biological harm, recognise the changing scientific knowledge and expertise available to practitioners, and ensure that restrictions and compliance costs are no greater than reasonably necessary.

Supporting sections: Strategic Consultation on Six Major Themes (pp. 7–9); Deepen the Purpose and Principles (pp. 10–11); Section 10, Scientific Reassessment and International Precedent (p. 37); Section 12, Practitioner Expertise and Scientific Foundations (pp. 38–39).

Q9. Edible and inedible products

PSGRNZ is particularly concerned that the Ministry of Health's current institutional knowledge base and scientific assessment capacity may be insufficiently developed to navigate the considerable diversity and complexity of natural health products – particularly locally, naturally made edible and inedible products. Without specialist expertise in nutritional science, traditional

preparations, botanical toxicology, relevant exposure pathways and the practical circumstances of small-scale production, regulators may default to standardised, overly precautionary controls rather than exercising the scientific discernment necessary to distinguish genuine biological hazards from established, low-risk practices.

This creates a risk of regulatory overcorrection, where the administrative preference for uniformity outweighs consideration of demonstrated safety, potential health benefits, practitioner expertise and the social and economic value of local cottage industries. A scientifically under-resourced regulator may inadvertently suppress beneficial, low-risk activities precisely because it lacks the expertise necessary to regulate them proportionately. The framework must therefore be supported by enduring specialist scientific capacity and explicit provisions enabling proportionate requirements, appropriate exemptions and simplified compliance pathways for traditional and small-scale producers.

Therefore, PSGRNZ hesitantly supports including edible and inedible natural health products within a coherent regulatory framework, provided that any future resourcing and regulation recognises their different routes of exposure, ingredient characteristics, intended uses, histories of safe use and biological risk profiles and is sufficiently equipped to do such work.

Consequently, a future framework should be sufficiently sophisticated and flexible to distinguish traditional preparations and small-scale production from novel, highly concentrated or substantially modified formulations, without imposing pharmaceutical-style requirements where these are not scientifically justified.

Many traditional herbal balms, topical preparations and tonics have long histories of human use and may present relatively low risks when prepared and used appropriately. Small-scale producers, herbalists and local practitioners may manufacture these products in limited quantities, using established ingredients and traditional methods. Disproportionate requirements for product registration, testing, manufacturing certification or compliance could make such production economically unviable, even where the risks could be adequately managed through proportionate quality assurance, hygiene, accurate labelling and traceability.

The consequences extend beyond individual businesses. Excessive regulation may restrict community access to familiar and affordable health products, undermine traditional knowledge and practitioner expertise, and discourage the development of local cottage industries and small enterprises. These costs should be explicitly considered alongside the demonstrated or reasonably foreseeable risks that regulation seeks to prevent.

At the same time, a history of traditional use should inform, but not replace, scientific assessment. Safeguards must account for differences in oral, topical and other exposure routes, ingredient concentration, contamination, interactions, duration of use and susceptibility associated with age, sex, pregnancy and health status. Regulation should also respect informed consumer choice, appropriate practitioner autonomy and the capacity for individualised clinical judgement.

A health-related or therapeutic claim should not automatically determine medicines classification or the level of biological safety oversight. Claims substantiation, product safety and legal

classification should be assessed as distinct but related questions, with the boundaries between natural health products and medicines resolved coherently alongside medicines reform.

Supporting sections: Strategic Theme 2, Legal Definitions and Classification Boundaries (pp. 7–8); Section 5.1, Therapeutic-Purpose Definitions (pp. 20–21); Section 5.2, Recommended Classification Principles (pp. 21–22).

Q10. Which approach do you think would work best for identifying permitted ingredients in natural health products?

PSGRNZ recommends an alternative approach: an open, scientifically informed recognised-ingredients register, complemented by evidence-based restrictions and accessible, risk-proportionate assessment pathways. The register must not become a prerequisite for lawful market access.

PSGRNZ opposes the introduction of a closed permitted-ingredients list. New Zealand's longstanding underinvestment in independent nutritional science, botanical toxicology and regulatory assessment has left the Ministry without a demonstrably adequate scientific framework or enduring institutional capacity to ensure that ingredient restrictions are necessary, proportionate and responsive to emerging evidence. In these circumstances, establishing a new permission-based regime risks institutionalising historical over-regulation: ingredients and traditional preparations could be excluded not because they present demonstrated biological risks, but because the Ministry has not undertaken the scientific work necessary to evaluate them.

The burden of this institutional deficiency should not be transferred to consumers, practitioners and small domestic producers through prohibitions, costly applications or restricted access. Until the Ministry can demonstrate that it has the expertise, funding, transparent assessment methods and independent review mechanisms required to administer such a system fairly, there is no adequate justification for introducing a new closed-list regime. Regulatory intervention should instead focus on scientifically justified, proportionate safeguards addressing identifiable risks, while preserving access to established products and traditional preparations.

Neither a closed list of permitted ingredients nor a prohibited-ingredients list alone provides an adequate regulatory solution. A closed positive list risks excluding ingredients simply because they have not undergone formal assessment, while a negative list alone may not adequately communicate conditions of safe use. The framework should therefore combine the following six elements.

1. An open recognised-ingredients register, not a closed gate

The register should identify established ingredients and preparations, including relevant chemical forms, preparation methods, histories of human consumption, recognised conditions of use, exposure ranges and scientifically justified restrictions.

Recognition should draw on independent scientific assessments, relevant international evaluations, established nutritional knowledge, documented histories of safe use and credible evidence held by qualified practitioners and traditional knowledge holders.

Absence from the register should not, in itself, make an ingredient unlawful, require prior authorisation or establish that it is unsafe. The register should function as an accessible scientific resource rather than a prerequisite for market access. Additional assessment should be required where there are identifiable grounds for concern, including materially novel ingredients, substantially altered preparations, potentially hazardous exposures or credible evidence of harm. Evidential requirements should be proportionate to the nature and significance of those concerns.

2. Scientifically justified prohibitions and restrictions

Prohibitions should be reserved for ingredients or uses where credible scientific evidence identifies risks that cannot reasonably be managed through less restrictive safeguards. Where serious or potentially irreversible harm is scientifically plausible but material uncertainties remain, temporary precautionary restrictions may be justified, provided they are proportionate, supported by a documented scientific rationale and subject to defined review requirements. Scientific uncertainty alone should not constitute sufficient grounds for indefinite exclusion.

Every prohibition or restriction should identify its scientific and legal basis, including the relevant hazard, dose–response evidence where available, anticipated exposure, susceptible populations, uncertainty and the reasons why alternative controls would be insufficient.

The framework should distinguish an ingredient that is hazardous under its intended conditions of use from one that presents risks only at particular doses, in concentrated forms, through particular preparation methods or for susceptible populations.

Where risks can be adequately managed through dose limits, purity standards, warnings, quality controls, restricted conditions of sale or professional supervision, these measures should be considered before imposing a general prohibition.

3. Differentiated pathways for traditional and small-scale producers

Established traditional preparations and other products with well-characterised, low-risk exposure profiles should remain accessible without unnecessary pre-market authorisation. Where notification or additional compliance requirements are scientifically justified, simplified and affordable pathways should be available, with safeguards proportionate to the nature of the product, its preparation, intended use and foreseeable exposures.

Assessment should recognise documented histories of safe use, including knowledge concerning preparation, quantities, contraindications, combinations of ingredients and populations for whom particular products may be unsuitable. Traditional knowledge should be critically evaluated as relevant evidence, without being treated as either scientifically irrelevant or conclusive proof of safety.

This is particularly important for rongoā Māori and other traditional health practices. The regulatory framework should respect the authority of traditional knowledge holders and distinguish community-based traditional practice from the commercial manufacture and marketing of products. Recognition of traditional knowledge should not depend on converting traditional practices into commercially registered products.

Compliance requirements should reflect actual manufacturing and biological risks. Small-scale producers should not automatically face the same fixed costs, dossier requirements or testing obligations as large manufacturers of novel, highly concentrated or substantially modified formulations. Appropriate safeguards for ingredient identity, contamination, quality and traceability should nevertheless be maintained.

4. Independent, publicly supported scientific assessment

Ingredient recognition should not depend exclusively on the financial capacity of commercial applicants to commission scientific assessments.

An applicant-funded model risks favouring established, well-capitalised businesses while disadvantaging non-patentable nutrients, traditional botanical preparations, independent researchers and small domestic producers. This can create regulatory exclusion through the cost of generating evidence rather than through a demonstrated biological risk.

The Government should maintain independent scientific assessment capacity, supported by enduring public funding, to evaluate ingredients of potential public-health significance, review international evidence and investigate important safety uncertainties.

Qualified researchers, clinicians, practitioners and traditional knowledge holders should have accessible routes for submitting evidence, requesting assessment and challenging existing classifications. Publicly funded evaluations should be independently reviewable, with their methodologies, findings and regulatory implications published.

5. Periodic reassessment and scientific autonomy

Ingredient recognition, restrictions and prohibitions should be responsive to scientific developments rather than becoming permanent administrative classifications.

The framework should establish periodic reviews and evidence-based triggers for reassessment, including new findings concerning safety or benefit, changes in exposure, adverse-event reports, improved analytical methods and evidence that existing restrictions impose disproportionate costs.

Reassessment must operate in both directions: strengthening safeguards where credible risks emerge and reducing restrictions where contemporary evidence no longer supports them.

Overseas regulatory decisions should inform, but not determine, New Zealand classifications. Before adopting foreign permitted or prohibited lists, the regulator should examine their scientific foundations, legal definitions, evidential requirements and relevance to New Zealand circumstances.

An overseas refusal of authorisation, omission from a permitted-ingredients list or unresolved application should not, without examination of the underlying reasons and evidence, be treated as proof that an ingredient is biologically unsafe. Administrative decisions, evidential deficiencies and scientifically demonstrated hazards must be distinguished.

Independent researchers, qualified practitioners and affected producers should have accessible mechanisms for initiating reassessment, without being required to finance extensive commercial applications merely to bring relevant scientific evidence before the regulator.

6. An explicit assessment of regulatory exclusion

Before introducing any legally binding ingredient restrictions, mandatory registration requirements or overseas-derived permitted or prohibited lists, the Ministry should assess the likely consequences for existing products, traditional preparations, domestic manufacturers, practitioners and consumers.

This assessment should identify which ingredients or products would become unlawful, require reformulation, face additional approval costs or become commercially unviable. It should establish whether these outcomes are justified by evidence of biological risk, whether less restrictive safeguards are available and which groups would bear the resulting costs.

Particular attention should be given to small domestic enterprises, traditional knowledge holders, non-patentable ingredients, specialist formulations and consumers who may lose access to affordable products.

The Ministry should also consider whether regulatory costs and evidence requirements could unintentionally favour large commercial enterprises, reduce market diversity, discourage independent scientific investigation or concentrate market access among businesses with the resources to finance regulatory approval.

The assessment should be published before regulatory decisions are finalised, enabling affected communities, practitioners, researchers and businesses to scrutinise the evidence and proposed consequences.

Governing principle

Restrictions on ingredients and preparations must be justified by transparent scientific assessment of biological risk at relevant exposures, rather than by an ingredient's absence from an administrative list, the financial capacity of an applicant or its classification in another jurisdiction. The burden of demonstrating the necessity and proportionality of a restriction should rest with the regulator.

A recognised-ingredients register should function as a publicly accessible scientific resource, not a prerequisite for lawful supply. It should support informed decision-making, responsible innovation and consumer protection while preserving access to established products and traditional preparations.

The purpose of regulation should be to manage credible risks through effective, proportionate safeguards, rather than create unnecessary barriers to products and practices where restrictions have not been scientifically justified. Where genuine safety uncertainties warrant further investigation, the regulatory response should be targeted, transparent and subject to independent reassessment, rather than defaulting to indefinite exclusion.

Supporting sections: Section 5.2, Recommended Classification Principles (pp. 21–22); Section 6.1, Established and Novel Ingredients (pp. 22–23); Section 6.2, Risks of Regulatory Exclusion (pp. 23–26); Section 7, Evaluating Biological Risk (pp. 28–33); Section 10, Scientific Reassessment and International Precedent (p. 37).

Q11. Pre-market oversight

Preferred option: Another approach — proportionate business registration with targeted, scientifically justified product oversight.

PSGRNZ supports a regulatory framework that establishes accountability for commercial suppliers without imposing routine product-by-product notification, registration or pre-market approval on established low-risk natural health products.

Business registration may provide a proportionate mechanism for identifying responsible commercial operators, supporting traceability, facilitating product recalls and enabling post-market surveillance. However, registration requirements should be simple, affordable and appropriate to the scale and nature of the business, with particular consideration given to small domestic producers and traditional practitioners. Registration should not operate as a discretionary licensing barrier to market entry.

Products with established histories of safe use, well-characterised ingredients and low-risk exposure profiles should not require routine pre-market notification or approval. Consumer protection should instead be supported through proportionate quality requirements, accurate labelling, traceability, adverse-event reporting and effective post-market enforcement.

Additional product-level oversight should be triggered by identifiable scientific concerns, rather than by the mere absence of an ingredient or formulation from an administrative register. These concerns may include materially altered bioavailability, exposure beyond established safe-use conditions, significant interactions, particular population susceptibilities or credible evidence of potentially serious harm. Where additional assessment is justified, the regulator should identify the specific scientific questions requiring resolution and apply the least burdensome effective safeguards.

Products presenting significant biological risks, or material uncertainties concerning potentially serious harm that cannot adequately be managed through ordinary safeguards, may warrant pre-market safety assessment, enhanced quality requirements, restricted conditions of supply or professional supervision. Such decisions must be scientifically justified, transparent, proportionate and independently reviewable.

The Ministry and regulator should be broadly required to demonstrate that it possesses the scientific expertise, institutional resources and assessment methodologies necessary to distinguish these categories reliably before introducing new mandatory pre-market requirements. Otherwise, notification and registration systems risk becoming administrative barriers that exclude products without establishing that their exclusion delivers corresponding public-health benefits.

The governing principle should be that pre-market obligations increase with scientifically substantiated risk, not merely with administrative classification, product novelty or the financial capacity of suppliers to meet regulatory requirements.

Supporting sections: Section 6.1, Established and Novel Ingredients and Formulations (pp. 22–23); Section 6.2, Permitted Ingredient Lists: The Risks of Regulatory Exclusion (pp. 23–26); Section 6.3, Proposed Risk-Proportionate Regulatory Framework (pp. 26–28); Section 9.3, Affordable, Risk-Proportionate Quality Assurance (p. 36).

Q12. Health claims

Insufficient evidence to substantiate a therapeutic claim should ordinarily be addressed through claims regulation; it should not automatically establish biological harm or require medicines classification where the product's safety profile does not justify that response.

Preferred option: Allow businesses to substantiate claims using accepted scientific or traditional evidence, subject to transparent, proportionate and independently reviewable standards.

PSGRNZ supports a flexible, evidence-based approach that enables truthful communication about the nutritional, physiological and therapeutic benefits of natural health products, while protecting consumers from misleading or unsupported claims.

The requirements for information and evidence should reflect the nature and significance of the claim:

Established nutritional and physiological functions: Claims concerning recognised nutrient functions, maintenance of health and correction of nutritional insufficiency should be supported by relevant nutritional, biochemical, physiological and clinical evidence. Such claims should not routinely require pharmaceutical-style clinical trials.

Claims concerning therapeutic benefit: Claims relating to disease prevention, treatment, remission or clinically significant improvement should require stronger evidence of meaningful benefit. Relevant evidence may include controlled trials, systematic reviews, clinical studies, observational research and other scientifically appropriate sources, evaluated according to the claim being made.

Traditional-use claims: Documented histories of traditional use, including practitioner knowledge and established preparation methods, should be recognised as relevant evidence. However, claims should distinguish traditional use from scientifically established clinical efficacy, particularly where serious diseases are concerned.

A closed list of pre-approved claims should not be introduced. Such a system risks entrenching outdated scientific assumptions, restricting truthful communication and excluding emerging evidence of nutritional and therapeutic benefits. Overseas-approved claims may provide useful precedents but should not be adopted automatically without examining their scientific basis and relevance to New Zealand.

The framework should enable businesses, qualified practitioners and independent researchers to substantiate claims using publicly accessible evidence without requiring costly pre-market

approval of every claim. General consumer protection law should remain an important safeguard, supplemented where necessary by clear evidential standards, appropriate warnings and targeted enforcement against misleading representations.

Importantly, claims-related risks must be distinguished from biological risks. Unsupported therapeutic claims may encourage inappropriate substitution for effective treatment, delayed diagnosis or avoidance of necessary clinical supervision. These risks warrant proportionate controls on the claims themselves. However, insufficient evidence for a particular therapeutic claim does not establish that the underlying product is biologically unsafe or automatically justify its classification as a medicine.

The regulator should publish transparent assessment criteria, explain the reasons for accepting or rejecting contested claims and provide accessible mechanisms for independent scientific review. Standards must remain responsive to new evidence and should not favour businesses with the resources to finance proprietary clinical research over established, non-patentable nutrients and traditional preparations.

The governing principle should be that truthful health information is enabled, the strength of claims reflects the strength of evidence, and restrictions on communication are no greater than necessary to protect consumers from material harm or deception.

Supporting sections: Section 4, Establish Scientific Principles Before Legislation (pp. 18–20); Section 7.1, Avoid Inappropriate Evidence Hierarchies (pp. 28–31); Section 8, Evaluating Nutritional and Therapeutic Benefits (pp. 33–34), particularly Sections 8.1–8.2.

Q13. Manufacturing requirements

Manufacturing requirements should ensure ingredient identity, purity, consistency, contamination control and traceability, with standards proportionate to the nature and severity of product-related risks.

Uniform pharmaceutical-level requirements should not be imposed where lighter quality-assurance arrangements provide adequate protection, particularly where additional compliance costs could make low-volume products commercially unviable and disadvantage smaller New Zealand manufacturers.

Supporting sections: Section 6.3, Proposed Risk-Proportionate Regulatory Framework (pp. 26–28); Section 9, Establish Appropriate Restrictions and Safeguards (pp. 34–37), particularly Section 9.3, Affordable, Risk-Proportionate Quality Assurance (pp. 36–37).

Q14. Labelling requirements

Labels should provide accurate, accessible information about ingredients, doses, intended uses, relevant warnings, interactions and circumstances requiring professional supervision. Requirements should be proportionate to demonstrated biological risks and relevant uncertainties, supporting informed consumer choice without imposing unnecessary administrative burdens or restricting truthful communication about established nutritional and physiological benefits.

Supporting sections: Deepen the Purpose and Principles (pp. 10–11); Section 6.3, Proposed Risk-Proportionate Regulatory Framework (pp. 26–28); Section 9, Establish Appropriate Restrictions and Safeguards (pp. 34–37).

Q15. Exemptions

PSGRNZ recommends broad, clearly defined exemptions from unnecessary pre-market authorisation, product notification, licensing and intensive compliance requirements, where these obligations are not justified by the nature and magnitude of identifiable biological or product-related risks.

Exemptions should be an integral feature of proportionate regulation, not discretionary concessions granted only after expensive applications. New Zealand's limited institutional capacity for independent nutritional and botanical risk assessment makes this particularly important. Without appropriate exemptions, regulatory uncertainty and administrative requirements may become barriers to lawful supply, even where there is no credible evidence of unacceptable biological risk.

European experience demonstrates the importance of distinguishing regulatory simplification from genuine accessibility. Requirements for scientific dossiers, product registration and manufacturing compliance can impose substantial fixed costs on smaller enterprises, while established histories of traditional use may not fit conventional evidential frameworks. New Zealand should avoid reproducing arrangements that unnecessarily disadvantage traditional preparations, small domestic producers and non-patentable ingredients.

Exemptions or substantially simplified requirements should be available for:

Established nutrients and conventional dietary ingredients with well-characterised safety profiles at relevant exposures, including established formulations and preparations.

Traditional botanical and food-based preparations, where documented histories of use, preparation methods and exposure conditions provide reasonable evidence of tolerability, subject to consideration of credible safety concerns.

Small-scale and low-volume domestic producers, where manufacturing methods and foreseeable exposures justify simplified compliance, without compromising essential product-quality safeguards.

Traditional practitioners and community-based practices, including rongoā Māori, with appropriate recognition of the authority of knowledge holders and the distinction between traditional practice and commercial product marketing.

Products supplied under appropriate professional supervision, where practitioner expertise, individual assessment and monitoring can adequately manage risks that might otherwise justify more restrictive general-sale requirements.

Established products affected by regulatory transition, ensuring that the introduction of a new regime does not automatically make previously lawful preparations unavailable before their risks and the consequences of exclusion have been properly assessed.

Exemptions should not depend on proving the complete absence of risk, an evidential standard that is scientifically unrealistic. Instead, the regulator should consider established exposure, available evidence of safety, the plausibility and severity of potential harm, susceptible populations and whether ordinary quality controls or targeted safeguards are sufficient.

Equally, exemptions should not remove fundamental obligations concerning ingredient identity, contamination, accurate information, traceability where appropriate, or the management of credible biological risks. Novel concentrations, materially altered preparations, significant interactions or emerging evidence of serious harm may justify additional assessment.

The burden of demonstrating why more restrictive requirements are necessary should rest with the regulator. Exemptions should be transparent, predictable and available by operation of clear statutory criteria wherever possible, rather than dependent on discretionary approvals, costly applications or the financial capacity of suppliers.

Before removing existing exemptions or narrowing eligibility, the Ministry should evaluate the likely consequences for consumer access, traditional practices, small domestic enterprises, practitioner autonomy and product affordability. Such decisions should be independently reviewable and responsive to new scientific evidence.

The governing principle should be that regulation addresses identifiable risks without unnecessarily restricting established products, traditional knowledge, professional practice or small-scale production. Where the Ministry cannot demonstrate that an additional regulatory obligation delivers a proportionate public-health benefit, that obligation should not be imposed.

We recognise that the proposed exemptions would need to be expressly provided for in the new legislation and coordinated with the Food Act and medicines legislation. An exemption under natural health products legislation would not automatically prevent an ingredient or product being captured by another statute.

Supporting sections: Section 4.1, Public-Health Costs of Restriction (pp. 19–20); Section 6.2, Permitted Ingredient Lists: The Risks of Regulatory Exclusion (pp. 23–26); Section 6.3, Proposed Risk-Proportionate Regulatory Framework (pp. 26–28); Section 9.2, Clinician Supervision (p. 36); Section 9.3, Affordable, Risk-Proportionate Quality Assurance (pp. 36–37).

Q16. What considerations should apply in determining the form and functions of a regulator?

The form and functions of the regulator should be determined by the scientific expertise, institutional independence and public accountability necessary to protect and promote public health, rather than primarily by administrative efficiency or industry development objectives.

The regulator must possess enduring, independently supported expertise in nutritional science, toxicology, biological risk assessment, clinical nutrition and relevant medical disciplines. It should recognise that specialist nutritional knowledge and evidence-informed judgement are distributed across qualified clinicians, health practitioners, independent researchers and traditional knowledge holders, rather than residing exclusively within regulatory institutions.

Scientific assessment and regulatory decision-making should be transparent, distinguishable and independently reviewable. Governance arrangements should provide for:

Scientific independence: Transparent expert appointments, disclosure and management of conflicts of interest, and safeguards against undue commercial, institutional or political influence.

Enduring scientific capacity: Adequate public funding and expertise to undertake systematic evidence reviews, evaluate dose–response and exposure, investigate emerging risks and benefits, and reassess established classifications and restrictions.

Distributed expertise and participation: Accessible mechanisms through which independent researchers, qualified practitioners, traditional knowledge holders and affected communities can contribute evidence, identify regulatory deficiencies and request reassessment.

Transparent and accountable decisions: Publication of scientific methodologies, evidence considered, uncertainties, decision criteria and reasons for imposing or retaining restrictions, with accessible avenues for independent challenge and review.

Responsive regulatory oversight: The capacity to use contemporary scientific research tools, international assessments, clinical observations and post-market information to update decisions as knowledge develops, including removing restrictions that are no longer scientifically justified.

The regulator should also be required to assess the wider public-health and economic consequences of its decisions, including whether restrictions disproportionately affect smaller domestic producers, practitioner autonomy, affordability and access to potentially beneficial nutritional interventions.

Importantly, scientific uncertainty should not become a justification for indefinite administrative restriction. Where material uncertainties warrant precautionary safeguards, the regulator should identify the scientific questions requiring resolution, establish proportionate controls and provide clear mechanisms for reassessment.

Whether these functions are located within an existing agency or a new statutory body is secondary to ensuring that the regulator has the scientific competence, operational independence, adequate funding and enforceable public-interest obligations necessary to exercise its powers responsibly.

Supporting sections: Strategic Theme 1, Scientific Assessment and Institutional Capacity (p. 7); Strategic Theme 6, Public-Health Governance and Accountability (p. 9); Section 11, Scientific Independence and Oversight (pp. 37–38); Section 12, Practitioner Expertise and Scientific Foundations (pp. 38–39).

Q17. What roles, if any, should a regulator have in relation to natural health products (eg, post-market safety actions, compliance and enforcement, export certificates)? How should this be funded?

Routine administration, compliance and export certification can reasonably involve proportionate cost recovery from regulated businesses. Independent scientific assessment, population surveillance, investigator-initiated research, horizon scanning and reassessment of established

regulatory positions are public-good functions and should be supported principally through dedicated parliamentary appropriations, rather than relying on industry fees or commercial applications.

Regulatory functions cannot be separated from scientific capacity and its funding. New Zealand's historical underinvestment in independent nutritional science, population nutritional surveillance and biological risk assessment has left significant gaps in the evidence and expertise required to support effective regulation. This has left institutional weaknesses that cannot be resolved through routine cost recovery, business registration fees or commercially funded product assessments.

PSGRNZ supports a regulator whose functions are clearly defined, scientifically justified and proportionate to identifiable product-related risks. These should include:

a. **Post-market safety surveillance:** Monitoring adverse events, emerging scientific evidence, product contamination, interactions and risks to susceptible populations, with the capacity to investigate safety signals and undertake targeted reassessments.
b. **Compliance and enforcement: Ensuring** ingredient identity, product quality, accurate labelling and substantiated claims, with proportionate powers to require corrective action, issue warnings, restrict supply or recall products where justified by evidence.
c. **Scientific classification and reassessment:** Publishing transparent assessments of ingredients, formulations, exposure levels and regulatory restrictions, with mechanisms for independent review and reconsideration as evidence develops.
d. **Proportionate pre-market oversight:** Applying additional assessment requirements where credible biological risks or material uncertainties justify them, without imposing routine product-by-product authorisation on established low-risk products.
e. **Export certification:** Providing timely, affordable and internationally credible export certificates, while ensuring that export requirements do not unnecessarily determine domestic product classification or market access.
f. **Public information and accountability:** Maintaining accessible information on regulatory decisions, identified risks, relevant uncertainties, compliance actions and the scientific reasoning supporting restrictions.

New Zealand's historical underinvestment in independent nutritional science, population nutritional surveillance and biological risk assessment has left significant gaps in the scientific capability required for effective regulation. These deficiencies cannot be resolved through business registration fees, commercial applications or narrowly commissioned product assessments.

A regulator must possess the enduring expertise and resources to investigate emerging evidence, distinguish biological risks from unsupported claims, evaluate relevant exposures and susceptible populations, and determine whether existing restrictions remain scientifically justified. Without this capacity, additional regulatory powers risk institutionalising historical knowledge gaps and imposing unnecessary costs on consumers, practitioners and domestic producers.

PSGRNZ therefore recommends a separate, ring-fenced appropriation within Vote Health to establish and sustain an independent, public-good nutritional science capability that extends beyond the regulator's immediate administrative responsibilities. This should support population nutritional surveillance, longitudinal research, systematic evidence reviews, biological risk assessment, investigator-initiated research and the periodic reassessment of regulatory decisions. The resulting evidence should inform natural health products regulation, wider public-health policy, clinical guidance and, where appropriate, the assessment of publicly funded nutritional interventions.

Such funding should address the longstanding disadvantage of non-patentable nutrients and nutritional interventions, where commercial incentives to undertake research or seek regulatory reassessment may be limited. It should also support investigation of nutritional requirements beyond the prevention of overt deficiency, including the needs of susceptible populations and people experiencing chronic illness or metabolic dysfunction.

The regulator's responsibilities should extend beyond enforcing established rules to identifying when those rules require scientific reconsideration. Public funding must be sufficient to ensure that scientific uncertainty is investigated rather than simply converted into indefinite regulatory restrictions.

Rationale:

An enduring Vote Health appropriation should establish the capacity for scientifically autonomous, investigator-initiated research and regulatory review, rather than limiting experts to narrowly commissioned assessments or immediate government policy priorities.

Qualified experts should have the institutional independence, resources and authority to investigate emerging evidence, reassess established classifications and restrictions, evaluate the safety and therapeutic potential of nutritional interventions, and publish findings and recommendations without inappropriate political, administrative or commercial influence.

This should include the capacity to generate and critically evaluate scientific evidence concerning the clinical use of nutritional interventions, and to submit evidence-based recommendations for consideration through Pharmac’s established assessment and funding decision-making processes.

Such an arrangement would preserve institutional knowledge across successive governments, provide continuity for specialist scientific careers and long-term research programmes, and establish an enduring public-good research capability capable of identifying emerging nutritional risks and benefits. It would also address the structural disadvantage faced by non-patentable nutrients and interventions for which commercial incentives to undertake research or seek regulatory reconsideration are limited.

The objective is to establish nutritional science as a permanent public-health responsibility, rather than an intermittently funded activity dependent upon short-term policy priorities, commercial applications or discretionary commissioning.

Scientific capacity, clinical discretion and health equity

The importance of enduring public investment extends beyond the production of scientific evidence. It concerns the capacity of government agencies, clinicians and other qualified health practitioners to exercise informed scientific judgement, respond to emerging knowledge and make proportionate decisions that protect and promote health.

When public institutions lack sufficient expertise, research capacity and continuity, regulatory decisions may become overly dependent on established classifications, conservative interpretations of existing guidance and narrowly commissioned assessments. Such institutional conservatism can impede the recognition of emerging nutritional evidence and constrain the professional discretion of practitioners working directly with patients, who must consider individual nutritional status, clinical circumstances, treatment responses and the potential consequences of inadequate intervention.

These limitations can generate or reinforce health inequities. People with sufficient financial resources may obtain specialist advice, privately funded investigations and alternative nutritional interventions, while those in deprived communities remain more dependent on publicly funded services and standardised regulatory pathways. Where scientific capacity is insufficient to distinguish between genuine biological risk and potentially beneficial nutritional interventions, restrictions may disproportionately disadvantage those least able to navigate or afford alternatives. This may be the case currently, with increasing metabolic and brain-related illness.

Although established nutritional reference frameworks address dietary adequacy, deficiency, and in some cases chronic disease risks and upper intake levels, they do not comprehensively establish optimal nutritional requirements across different clinical conditions, metabolic states and developmental circumstances. Important uncertainties remain concerning nutritional needs during pregnancy, early childhood and adolescence, and among people experiencing chronic illness, metabolic dysfunction or altered nutrient requirements. These gaps warrant sustained independent investigation rather than an assumption that existing population reference values adequately resolve questions of individualised nutritional care. Where regulatory restrictions limit access to potentially beneficial interventions without sufficient scientific justification, the consequences may fall disproportionately on people with fewer resources to obtain specialist assessment or alternative care.

An enduring, independently resourced nutritional science capability would enable the Ministry to investigate these distinctions, critically evaluate changing evidence, support informed clinical discretion and identify where existing regulatory restrictions or public funding arrangements may be contributing to avoidable health inequities.

The public-health responsibility is therefore not simply to prevent harm from nutritional products, but to ensure that deficiencies in institutional scientific knowledge do not themselves become barriers to appropriate care, nutritional adequacy and better health outcomes.

Supporting sections: Strategic Themes 1, 5 and 6 (pp. 7–9); Section 4.1, Public-Health Costs of Restriction (pp. 19–20); Section 6.3, Proposed Risk-Proportionate Regulatory Framework (pp. 26–

28); Section 10, Scientific Reassessment and International Precedent (p. 37); Section 11, Scientific Independence and Oversight (pp. 37–38).

Q18. Further comments

PSGRNZ urges the Ministry to undertake and publish the six foundational scientific, legal and governance reviews, followed by further public consultation, to inform formal regulatory impact analysis before legislative drafting.

New Zealand should recognise the opportunity to invest in nutritional science as a public good, establishing a knowledgeable, adaptable regulatory system that protects public health, enables equitable access and professional judgement, and supports domestic innovation in rapidly expanding international markets for personalised nutrition, metabolic health and healthy ageing.

It is important to recognise that in the four decades since the current regime was established, an extraordinary expansion of digital research tools has reduced many practical barriers to scientific investigation, creating greater opportunities for regulators, medical doctors, patients and natural health practitioners to access, critically evaluate and update nutritional evidence.

A knowledgeable, scientifically adept Ministry and governance system could position New Zealand to participate in these developments, supporting domestic researchers, qualified health practitioners and innovative businesses to develop high-quality, evidence-based products for international markets. Investment in independent nutritional science, clinical research, biological risk assessment and transparent regulatory pathways could create competitive advantages through scientific credibility, product quality and demonstrable benefits.

The opportunity is not simply to regulate an expanding industry, but to build the scientific capability that enables it to flourish responsibly. A proportionate regulatory system should protect consumers from demonstrated harm while enabling innovation, supporting smaller domestic enterprises and ensuring that New Zealanders themselves benefit from advances in nutritional science.

Supporting sections: Summary (pp. 3–6), including Invest in Nutrition for the Future; Strategic Consultation on Six Major Themes (pp. 7–9); Section 13, Recommendations and Conclusion (pp. 39–41).