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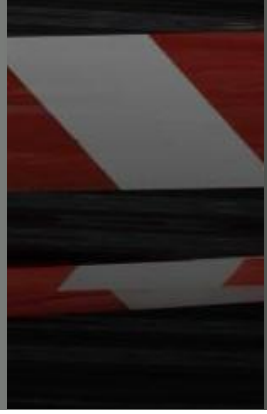
MNZH MAKE NEW ZEALAND HEALTHY

Remove Pharmac/Medsafe Barriers to Recognised Safe Nutrients. In Brief.



THE PROBLEM: New Zealand's regulatory system does not adequately recognise the biological necessity of nutrients and lacks effective mechanisms to signal their foundational role in human physiology. Its alignment with pharmaceutical toxicokinetic frameworks renders it relatively insensitive to nutrients as endogenous, biologically essential substances, resulting in regulatory settings that do not reflect their functional importance.

The health system operates under the Health Act 1956, which places a clear duty on the Crown to protect and promote public health. However, current regulatory frameworks are overly restrictive and insufficiently adaptive, limiting the capacity of officials to respond to contemporary scientific evidence on risk, safety, and biological function.

Decision-making is constrained by legacy classifications and historic regulatory protocols, with a tendency to defer to established thresholds and historical interpretations, not actively engage with evolving evidence. This results in regulatory hesitancy, where absence of precedent becomes a barrier to action, even where the scientific literature is substantive. Updating legislation and regulatory settings is essential not only to support public health, but to enable officials to exercise informed, evidence-based judgement consistent with the statutory purpose of protecting health.

A central issue concerns the overly broad 'therapeutic purpose' trigger in the Medicines Act 1981. Section 4 automatically categorises a nutrient formulation as a medicine if marketing and consumer information describes that formulation as influencing physiological processes, irrespective of dose or intrinsic risk. This blurs the line between the body's normal biology and drug treatment, bringing low-risk nutrients under medicine-style controls when they would be better managed through food and public health systems.

Current governance frameworks assess nutrients through models derived from deficiency prevention and chemical-style risk assessment. This approach does not adequately distinguish between adaptive physiological responses, nutrient interactions, and clinically meaningful toxicity. As a result, lower-order or context-dependent biological effects may be interpreted as safety risks, while the systemic roles of nutrients in metabolism, immune function, neurobiology, and long-term health are under-recognised.

While different types of evidence - mechanistic, clinical, and observational, may be looked at, there's no clear process to bring them together into a coherent picture of how the biology actually works. In practice, this contributes to decision-making that is cautious, fragmented, and reactive.

Outdated nutrient reference value dietary guideline frameworks remain anchored in legacy methodologies which priories preventing deficiency and avoiding harm, rather than supporting functional sufficiency across the life course. This leaves practitioners without a clear basis to evaluate biological relevance, dose-response, or therapeutic potential, and contributing to overly conservative guidance that does not reflect contemporary science.

In this context, precaution can result in officials holding onto outdated regulatory positions, even where evidence of harm is absent and biological plausibility is strong. By contrast, other regulatory models demonstrate that a more proportionate, evidence-based approach is feasible. These systems maintain a clear, tiered structure that distinguishes:

i. Nutrients (food/supplement pathway)
ii. Intermediate or higher-dose or novel substances (enhanced assessment pathway)
iii. Medicines (high-risk, pharmacological)

This enables controlled access to low-risk substances while reserving medicines regulation for genuinely pharmacological interventions, and supports case-by-case assessment grounded in dose, exposure, and biological effect.

THE SOLUTION: Reform nutrient regulation so that biologically essential, low-risk nutrients are assessed through a proportionate, biologically informed framework grounded in dose, exposure context, and demonstrated risk. This requires:

1. A tiered regulatory system distinguishing nutrients, intermediate low-dose or novel substances, and medicines, ensuring regulatory burden scales with risk.
2. Removal of automatic medicines classification based on physiological function, with classification anchored to pharmacological effect at relevant dose.
3. Use of upper intake levels as scientific benchmarks, not regulatory triggers.
4. Case-by-case assessment incorporating dose, form, cumulative exposure, and population context, explicitly distinguishing nutritional and pharmacological exposure regimes.
5. A strengthened evidential framework. Regulatory assessments must incorporate:
    - mechanistic biology
    - clinical trials
    - observational and cohort data
    - case reports and real-world use
    - biomarker and physiological data
6. Statutory support for proportionate decision-making under uncertainty, recognising absence of harm as distinct from evidence of risk.
7. Establishment of a dedicated nutrient assessment pathway independent of pharmaceutical approval models.
8. Embedding an adequacy and function standard, moving beyond a deficiency–toxicity paradigm.
9. Restoration of independent, evidence-led standard setting, ensuring external benchmarks are adopted only where scientifically justified.

These reforms aim to align regulation with biological reality, enable proportionate governance, and restore access to recognised safe nutrients into a coherent public health framework.